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PUBLIC VERSION

**COMMISSION DECISION**

**of 18.4.2012**

**addressed to:  
Johnson & Jonson**

**declaring a concentration to be compatible with the internal market and the EEA  
agreement**

**Case No COMP/M.6266 – Johnson & Johnson/Synthes**

(Text with EEA relevance)

(Only the English version is authentic)

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**Case No COMP/M.6266 - Johnson & Johnson/Synthes**

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to the Agreement on the European Economic Area, and in particular Article 57 thereof,

Having regard to Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings<sup>1</sup>, and in particular Article 8(2) thereof,

Having regard to the Commission's decision of 3 November 2011 to initiate proceedings in this case,

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission on 13 February 2012,

Having regard to the opinion of the Advisory Committee on Concentrations<sup>2</sup>,

Having regard to the final report of the Hearing Officer in this case<sup>3</sup>,

Whereas:

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<sup>1</sup> OJ L 24, 29.1.2004, p. 1. With effect from 1 December 2009, the Treaty on the Functioning of the European Union ("TFEU") has introduced certain changes, such as the replacement of "Community" by "Union" and "common market" by "internal market". The terminology of the TFEU will be used throughout this Decision.

<sup>2</sup> OJ C .....200. , p....

<sup>3</sup> OJ C .....200. , p....

- (1) On 27 September 2011, the European Commission received the notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings<sup>4</sup> (the "Merger Regulation") by which Johnson & Johnson ("the Notifying Party") acquires within the meaning of Article 3(1)(b) of that Regulation control of the whole of Synthes, Inc. ("Synthes", USA), by way of purchase of shares.

## **1. THE PARTIES**

- (2) Johnson & Johnson ("J&J") is the ultimate parent company of a global group of companies whose activities are divided into three business segments: (i) Consumer, (ii) Pharmaceutical, and (iii) Medical Devices and Diagnostics. Within the segment of Medical Devices and Diagnostics J&J is active in the field of orthopaedic medical devices<sup>5</sup> through its subsidiary De Puy Orthopaedics, Inc. ("DePuy") and in cranio-maxillofacial ("CMF") devices and power tools through its subsidiary Codman and Shurtleff, Inc. ("Codman").
- (3) Synthes is a global medical device group of companies active in the supply of a wide range of medical devices, instruments, implants and biomaterials used for the surgical fixation, correction and regeneration of the human skeleton and its soft tissues.
- (4) According to the Notifying Party, Synthes is currently controlled by the chairman of Synthes' board, Hansjörg Wyss, who, together with trusts controlled by him, currently holds 39.22% of Synthes' shares and exercises de facto control over Synthes.<sup>6</sup>

## **2. THE OPERATION AND THE CONCENTRATION**

- (5) On 26 April 2011 J&J, Samson Acquisition Corp. ("Samson") and Synthes entered into the Agreement and Plan of Merger (the "Merger Agreement"). According to the Merger Agreement, J&J intends to acquire de jure sole control through the acquisition of all voting securities in Synthes. The acquisition will be effected by way of a statutory merger under Delaware law, whereby Samson (a wholly-owned subsidiary of J&J set up for this purpose), will be merged with and into Synthes, with Synthes surviving as a wholly-owned subsidiary of J&J. As a result of the merger, each share of issued and outstanding common stock in Synthes will be converted into the right to receive approximately 35% cash and 65% J&J common stock. No public tender offer will take place.

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<sup>4</sup> OJ L 24, 29.1.2004, p. 1.

<sup>5</sup> Specifically, trauma, spine and shoulder implants.

<sup>6</sup> No other shareholder has more than a 5% holding in Synthes and none of Synthes' shareholders currently exercises de jure (joint or sole) rights. The parties submit that Mr Hansjörg Wyss exercises de facto sole control over Synthes in light of (i) the high percentage of shares concentrated in one person, Mr Hansjörg Wyss, (ii) [...] and (iii) the fact that he is the chairman of the Synthes board.

- (6) The proposed transaction therefore constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

### **3. UNION DIMENSION**

- (7) The proposed transaction has a Union dimension as it meets the thresholds of Article 1(2) of the Merger Regulation. The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million<sup>7</sup> (J&J: EUR 50 500 million, Synthes: EUR 2 800 million. Each of them has an Union-wide turnover in excess of EUR 250 million (J&J: EUR [...]\*\* million, Synthes: EUR [...]\*\* million), but they do not achieve more than two-thirds of their aggregate Union-wide turnover within one and the same Member State.

### **4. THE PROCEDURE**

- (8) After examination of the notification and a market investigation, the Commission concluded that the operation falls within the scope of the Merger Regulation and raises serious doubts as to its compatibility with the internal market and with the EEA Agreement. During a meeting held on 17 October 2011, the Notifying Party was informed of the substance of the serious doubts raised by the proposed transaction. The Notifying Party did not submit commitments during the first phase procedure. The Commission adopted a decision to initiate proceedings pursuant to Article 6(1)(c) of the Merger Regulation ("the Article 6(1)(c) decision") on 3 November 2011.
- (9) The parties jointly submitted their written comments to the Article 6(1)(c) decision in several parts, respectively on 11 November (Spine – Competitors), 16 November (Trauma – External fixation, Spine – Vertebral Compression Fractures, Spine - UK), 17 November (Spine – Coordinated Effects), 21 November (AO Foundation, Spine – Interbody Devices), 22 November (Trauma - Product range), 23 November (Trauma - Bulgaria, Trauma – Ancillary devices, Trauma – Cannulated screws, Spine - Sweden), 24 November (Market entry, Trauma - Compression hip screws, Trauma – IM Hip screws, Spine - Product range, Spine – Corpectomy Cages, Spine – Thoracolumbar posterior fixation), 25 November (Conglomerate effects, Key Documents, Trauma - IM nails, Trauma - plating systems, Spine – Austria, Spine - Cervical Fixation) and 30 November 2011 (shoulder implants). Further information was submitted, partly based on requests by the Commission, in a number of further submissions.

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<sup>7</sup> Turnover calculated in accordance with Article 5(1) of the Merger Regulation and the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (OJ C95, 16. 4.2008, p. 1).

\* Parts of this text have been edited to ensure that confidential information is not disclosed; those parts are enclosed in square brackets and marked with an asterisk.



- (10) Following a request by the Notifying Party, non-confidential versions of certain key submissions of third parties collected during the first phase investigation were provided to the parties on 18 and 30 November 2011.
- (11) While the Article 6(1)(c) decision identified serious doubts in various sub-segments of all five broad areas (namely trauma devices, spine devices, shoulder implants, cranial custom-made fixation devices, and certain power tools), the second phase market investigation pointed to competition concerns only with respect to various markets in the first two broad segments, namely, spine and trauma devices.
- (12) On 25 January 2012 the Commission adopted a Statement of Objections ("SO") pursuant to Article 18 of the Merger Regulation. The Notifying Party replied to the SO on 8 February 2012. At the Notifying Party's request, an Oral Hearing took place on 13 February 2012. No third parties attended the Oral Hearing.
- (13) On 15 February 2012, Spinal Kinetics, Inc. ("Spinal Kinetics") submitted a formal request to be heard as a third party and was granted this status the same day. On 28 February 2012 Spinal Kinetics received a non-confidential summary of the SO. Spinal Kinetics submitted written observations on 2 March 2012.
- (14) A state of play meeting with the parties took place on 17 February 2012. In order to address competition concerns identified in the SO in the field of trauma devices, the Notifying Party submitted commitments on 21 February 2012. The Commission launched a market test of those commitments on 23 February 2012. Following the results of the market test, the Notifying Party submitted modified commitments on 13 March 2012.

## **5. MARKET DEFINITION**

### **5.1. Relevant product markets**

- (15) The proposed transaction has an impact on a number of markets or groups of markets in the area of orthopaedic medical devices, more particularly (i) Trauma devices, which are used to treat bone fractures throughout the upper and lower extremities of the body and pelvis; (ii) Spine devices, which are used to correct various conditions of the spine caused by degenerative disorders, trauma, tumours and deformities; (iii) Shoulder replacement devices, which are used to reconstruct shoulder joints; (iv) CMF devices, which are used for the treatment of facial and skull fractures; and (v) Power tools, which are surgical tools such as drill systems, drill bits, reamers and saws. The Commission has not examined the orthopaedic medical devices affected by the proposed transaction in prior merger cases.
- (16) The Commission used the above five broad categories of devices as a starting point for its investigation. Within each category the Commission has investigated

whether the different types of devices belong to separate product markets and whether devices for different anatomies constitute separate product markets.<sup>8</sup>

### 5.1.1. Trauma

#### 5.1.1.1. Overview

- (17) Trauma devices are used to treat bone fractures throughout the appendicular skeleton, i.e. the upper extremities (including hand and wrist), the lower extremities (including foot and ankle), the shoulder girdle and the pelvic girdle. Their main purpose is to keep the bone in place and support it during the healing process. The treatment method for bone fractures depends primarily on the fracture's nature and severity. In particular in case of multiple or non-aligned fractures, surgeons apply internal and external fixation devices, which are hereafter referred to as "trauma devices".
- (18) Internal fixation is the surgical application of devices/implants that physically hold a broken bone together. The range of internal fixation devices is broad. Industry reports<sup>9</sup> covering internal fixation devices generally identify the following product categories: (i) plating systems (plates and screws), (ii) Intra-medullary<sup>10</sup> ("IM") nails, (iii) cannulated screws<sup>11</sup>, (iv) compression hip screws, (v) IM hip screws, and (vi) ancillary devices (such as pins, wires and cables). External fixation devices are minimally invasive appliances used for a wide range of treatments, including fracture fixation, limb lengthening and osteotomy.
- (19) The parties claim that the relevant product markets are at least as wide as those product categories. The reasons given are the purchasing patterns of the hospitals and that the suppliers offer a broad range of trauma devices or are at least able to expand their product range.
- (20) During the market investigation, 90% of the competitors have submitted that they do not consider that a manufacturer of a particular type of trauma device (for example, plates and screws) can, in principle, and without significant investment start supplying another type of trauma device (such as, for example, IM nails) without any previous experience in supplying that other type of device.<sup>12</sup> It would take two to three years to enter a new market segment.<sup>13</sup> Consequently, not all

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<sup>8</sup> The Commission concludes, based on the results of the market investigation that the markets for orthopaedic devices are heterogeneous and differentiated. The treatment of certain pathologies might be possible with different devices and to some extent depends on the preference of the operating surgeon. In such heterogeneous product markets, the exact market definition can become less meaningful and where markets are narrowly defined, the competitive assessment accordingly examines the possible continuum of substitution, such as competition from neighbouring markets and the possibility of entry from these markets to the extent this was raised by the parties.

<sup>9</sup> See, for example, the report of Millenium Research Group "European markets for trauma devices 2010", published June 2010.

<sup>10</sup> Intramedullary is a medical term meaning the soft, fatty, vascular tissue filling the cavities of bones.

<sup>11</sup> Cannulated screws have a hollow central shaft as opposed to normal screws which are not hollow.

<sup>12</sup> See replies to question 16 of Q17 - questionnaire to competitors (Trauma).

<sup>13</sup> See replies to question 18 of Q17 - questionnaire to competitors (Trauma): 9 out of 17 respondents stated that it would take more than two or even more than three years.

suppliers offer a wide range of devices but tend rather to specialise in some segments (often, specific plating systems) whilst disregarding other parts of the market such as IM nails or IM hip screws.

- (21) The situation is different when introducing a new product within a product segment (such as plates or IM nails) where a supplier is already active. In this case, the majority of competitors submit that it would take them two years or less (including all regulatory steps).<sup>14</sup> Products which are additions to or incremental developments of an existing product (as for example the length of a screw) take an even shorter time to demonstrate compliance with the essential requirements under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices<sup>15</sup> (“MDD”). The majority of competitors submit that it would take them less than a year to start marketing such product variations.<sup>16</sup> According to the parties<sup>17</sup>, this could be done within [1-12 months]\*. In addition, such products can benefit from a shorter time to demonstrate compliance with the essential requirements under the MDD. For example, a locking plate would be considered as a new product based on an existing product, namely the respective non-locking plate.
- (22) The flexibility on the supply side to switch production is not high enough to define wider markets due to supply side substitution as competitors cannot switch production in the short term and without significant investment.<sup>18</sup> The possibility to switch production would thus rather have to be considered as potential competition. Switching production within a sufficiently short time is only possible for small modifications of existing products, so that only those product variations would have to be considered as being part of the relevant product market.
- (23) Despite limited demand and supply side substitution, broader markets could also be considered if most customers, in practice, purchased bundles of products which not mutually substitutable (assortment markets).<sup>19</sup> This could be the case in Belgium, Denmark, Germany, Ireland, Luxembourg, and Slovakia, where none of the answering hospitals submitted that they carry out requests for quota (tenders or price inquiries) on the basis of narrower trauma categories (for example plating systems for a given anatomy or even at particular product level).<sup>20</sup> However, the number of hospitals answering this question in the respective countries (between

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<sup>14</sup> See replies to question 19 of Q17 - questionnaire to competitors (Trauma): 15 out of 21 respondents.

<sup>15</sup> OJ L 169, 12.7.1993, p. 1.

<sup>16</sup> See replies to question 20 of Q17 questionnaire to competitors (Trauma): 12 out of 21 respondents stated that it would take not more than 12 months. Only 1 respondent submitted that it would take longer than two years.

<sup>17</sup> Submission of the parties of 16.11.2011, response to question 13.

<sup>18</sup> See paragraphs 20 and 24 of the Commission Notice on the definition of the relevant market for the purposes of Community competition law, (“Notice on Market Definition”), OJ C 372, 9.12.1997, p. 5.

<sup>19</sup> See paragraph 41 of the Notice on Market Definition.

<sup>20</sup> See replies to question 27 of Q18 - questionnaire to customers (hospitals), asking for typical lots when tendering or inquiring prices.

two and four replies per country) is not high enough to confirm the presence of assortment markets in those countries. The market will, therefore, be defined based on the general principles of demand and supply side substitutability.

- (24) In fact, the market is to be defined as comprising products which are regarded as interchangeable or substitutable by a customer by reason of the products' characteristics, price and intended use<sup>21</sup>. The majority of customers and key opinion leaders consider that the different categories of trauma devices are not, or only to a certain degree, mutually substitutable by reasons of product characteristics and their intended use. Although several trauma devices seem to be capable of treating fractures of a specific anatomy<sup>22</sup>, the degree of substitutability between these trauma devices is generally limited. It varies from anatomy to anatomy, and depends on the kind of fracture. As a result, the trauma market does not seem to form one product market only, but needs to be subdivided.<sup>23</sup> The significant price differences between trauma devices also support this view<sup>24</sup>. Furthermore, the results of the market investigation also suggest that most of those categories should be further sub-segmented following the devices' anatomic use.

#### 5.1.1.2. Plating Systems

- (25) Plating systems account for about half of internal fixation trauma devices sales. They include a variety of metal plates of different sizes. Plates can be either (i) straight/non-anatomic plates (about a quarter of all plate sales) which have not been designed for a specific anatomy (type of bone) but rather for a specific bone size or (ii) anatomically pre-contoured plates (about three quarters of all plate sales), which are designed for use in a specific anatomy such as the humerus, femur and tibia. Moreover, anatomically contoured plates are rather specialized even within a particular anatomy, for example, different plating systems exist for the proximal humerus (the shoulder area) and the distal humerus (the elbow area). In addition to these characteristics, plating systems are differentiated in many other ways, namely they can be locking and non-locking (according to the way a broken bone is held together) or according to the materials used for their production (titanium or various alloys of stainless steel). Most of the sales within the anatomic plating systems concern the wrist (28%) and the knee (26%).
- (26) The results of the market investigation showed that the plating system market is to be further divided into at least two sub-segments: (i) standard (straight) plating systems (of different sizes) and (ii) anatomically shaped plating systems (meant for the clavicle, the shoulder (the proximal humerus), the elbow (including the distal humerus, the proximal radius and the olecranon), the wrist (including the distal radius and the distal ulna), the hand (including the carpals, the Metacarpals and the phalanges), the proximal femur (excluding compression hip screws), the

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<sup>21</sup> See paragraph 7 of the Notice on Market Definition.

<sup>22</sup> Throughout the decision the term "anatomy" refers to a particular bone or body part.

<sup>23</sup> This necessarily also holds true regarding a potential overall market for orthopaedic devices comprising spine, trauma and prosthetics.

<sup>24</sup> Source: Form CO.

knee (including distal femur and proximal tibia), the ankle (including the distal tibia and the distal fibula) and the foot (including the tarsals, metatarsals and the phalanges)). Within anatomical plating systems, it is clear that anatomically designed plates are not substitutable for different anatomies as a given anatomically shaped plate (for example an ankle plate) can never be substituted by an anatomically shaped plate designed for a different anatomy (for example, the wrist). Also from the supply side it takes more than one or two years to start marketing a new anatomically shaped plate. They thus belong to different product markets.

- (27) Various standard (straight) and anatomically shaped plates cannot or can only to a certain degree be substituted for each other. Non-anatomic plates can be substituted by a specific anatomic plate. An anatomically shaped plate could only partially be substituted by a straight plate as it would never fit as well as an anatomically shaped plate, resulting in a sub-optimal result. However, anatomically shaped plates do not exist for all fractures, with the result that only non-anatomic plates are available for use. Moreover, the market investigation showed that there is a trend towards devices with specific anatomic applications (in other words, formed to fit a certain anatomy) which are expected to become standard and are considered as the "state-of-the-art" products.<sup>25</sup>
- (28) Therefore the non-anatomic and the different anatomically shaped plates do not belong to the same market, but to neighbouring markets with a certain degree of marginal substitution. The competitive pressure is limited.
- (29) Non anatomic plating systems are only a marginal substitute for anatomically shaped plating systems - the majority of the customers replied that, because of their characteristics and intended use they are not, or only to a certain degree, mutually substitutable.<sup>26</sup>
- (30) Other characteristics of plating systems such as the alloys used or the particular design of the screw insertion and fixation (such as locking, non-locking, hybrid or multi-axial), although important, might not constitute in themselves an adequate basis for further market segmentation. However, they still play a role in product differentiation.

#### 5.1.1.3. IM nails

- (31) IM nails account for about 15% of total internal fixation trauma device sales in the European Economic Area (EEA). They are long solid or hollow nails made from stainless steel or titanium inserted into the medullary canal of the treated

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<sup>25</sup> See replies to question 32 of Q18 - questionnaire to customers (hospitals). A vast majority of the respondents were of this opinion whilst only a few doubt that they will become attractive for the mass market. This is reflected in the fact that anatomically shaped plates already today count for about three quarter of all plating system sales.

<sup>26</sup> See answers to question 19 of Q18 - Questionnaire to customers (hospitals): Out of the respondents 2 stated that the products are entirely substitutable, 17 that they are widely substitutable, 30 that they are substitutable to a certain degree and 14 denied any substitutability. The rest said not to know.

bone. They are primarily used to treat long bone fractures, for example fractures of the upper leg (femur), of the lower leg (tibia), and of the upper arm (humerus). Most of the sales for IM nails are in the tibia (32%) and the femur (30%) area.

- (32) IM nails for different anatomies are normally not mutually substitutable. Furthermore, the range of products offered by competitors in the market varies. While most of the competitors market IM nails for femur and tibia fractures, only some of them also offer IM nails for ulna or radius fractures. Therefore, there it can be argued that the market can in principle be divided according to anatomy, namely IM nails for the humerus, the clavicle, the ulna, the radius, the femur, the tibia and the ankle. However, since the proposed transaction does not raise competition concerns under the alternative market definitions, the exact market definition can be left open for the purposes of this Decision.

#### 5.1.1.4. Compression hip screws

- (33) A compression hip screw is a specialised form of plating system, designed for the treatment of hip fractures. It includes a screw barrel that penetrates the femoral neck and a plate to which it connects, which stabilizes the fracture. Compression hip screws account for about 3% of all internal fixation trauma device sales.

#### 5.1.1.5. IM hip screws

- (34) IM hip screws are also designed for the treatment of hip fractures. They consist of a compression screw which penetrates the femoral neck and an IM nail to which it connects, being inserted into the femur. Unlike compression hip screws, rather than being anchored by a plate external to the shaft of the bone, they are anchored in an IM nail which is inside the medullary cavity. IM hip screws do not, therefore, combine aspects of a compression screw with a plate but rather with an IM nail stabilizing the fracture. IM hip screws account for about 16% of all internal fixation trauma device sales.

#### 5.1.1.6. Cannulated screws

- (35) Cannulated screws have a hollowed central shaft enabling them to be inserted over a guide wire or guide pin. The diameter of the guide pin is much smaller than the screw itself and it can be placed more accurately using fluoroscopy in the operating room. In addition, given its small diameter, the guide pin can be reinserted several times if necessary for accurate placement without excessive damage to the bone. Cannulated screws come in various sizes and are used in the fixation of a variety of fractures. They account for about 7% of all internal fixation trauma devices sales.
- (36) The market investigation showed that cannulated screws should further be subdivided into the following subsegments: (i) cortical screws and (ii) cancellous screws. Both types of screws serve quite different purposes and, therefore, cannot

normally be substituted for each other.<sup>27</sup> However, the market could eventually be defined at the level of (all) cannulated screws on the basis of supply side considerations because suppliers could switch production in the relatively short term without incurring significant additional costs or risks in response to small and permanent changes in relative prices<sup>28</sup>. Most producers offer both cortical and cancellous cannulated screws in various lengths. Moreover, competitors confirm that they would be able to switch production in less than one year and that the time necessary is mainly due to regulatory approval (if the changes were considered as a variation of an existing product it would only take them about three months).

- (37) Given that the Commission concludes that the proposed transaction, even under the broader market definition, creates a significant impediment to effective competition, the exact market definition can be left open.

#### 5.1.1.7. Ancillaries

- (38) The category of ancillary devices includes different types of products which are frequently used in conjunction with other trauma implants – often on a temporary basis during the procedure to stabilise the fracture while the main trauma implant is being inserted – or on a stand-alone basis. This category includes pins, wires, cables (thicker than wires), screws which can be used on a stand-alone basis, and staples. They account together for about 7% of all internal fixation trauma device sales.
- (39) As regards ancillary devices, the market investigation results were not fully conclusive. A case can be made for a wider market definition as these devices are normally used with various procedures. The anatomies more commonly treated with ancillary devices on a stand-alone basis are smaller bones that require less device strength in order to obtain stable fixation. Since alternative fixation devices (including plates and screws, IM nails, and cannulated screws) can provide stronger fixation than ancillary trauma devices, surgeons tend to prefer these devices for primary fixation in more complex fractures and for weight-bearing bones, such as the femur and the tibia. Ancillary devices are therefore more commonly used for secondary fixation in conjunction with other trauma devices.
- (40) However, on the demand side, they serve rather different purposes. Pins are flexible and ductile. They can be used independently or in conjunction with other internal fixation devices, including plates and screw systems and IM nails. They can also be used to secure external fixation devices. Surgeons commonly use pins to fix small bone fractures on a stand-alone basis. Wires have similar properties to pins, such as flexibility and ductility, which makes them suitable for suturing or tension band wiring. Often wires are used to treat periprosthetic fractures

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<sup>27</sup> See answers to question 17 of Q18 - Questionnaire to customers (hospitals): Only about a quarter of the respondents were of the opinion that cortical and cancellous screws could in principle be substituted by each other whilst more than half of the respondents denied this.

<sup>28</sup> See paragraphs 20-21 of the Notice on Market Definition.

(fractures involving bones with implants), where a part of the intramedullary canal inside the long bones is occupied by a prosthetic device (hip/knee replacement) making the use of screws in that part difficult or even impossible. Cables are generally used in cerclage wiring, providing an alternative and less invasive means to secure an internal fixation device, particularly in cases where poor bone quality may impede the efficiency of screw usage or to treat periprosthetic fractures. Staples are used for the fixation of fractured bones, in particular when the use of a screw is not possible, for example in small bones in the hand or the foot. In addition, staples can be used for soft tissue fixation in the case of a tear.

- (41) It follows that ancillaries' characteristics differ both on the demand side and –to a varying extent – also as regards the production process. Only a limited number of suppliers offer all kinds of ancillary devices. In particular, staples are provided by less than half of the competitors which responded to the Commission's market investigation. Therefore it is unlikely that all ancillary devices together can be defined as a relevant market. Due to the intended use and their presumably similar production, cables and wires could, in principle, belong to one product market. General screws and possibly also pins could belong to another market and also staples could constitute a separate market. Alternatively, each of the five categories could constitute a separate product market. However, since the proposed transaction does not raise competition concerns under these alternative market definitions, the market definition can be left open for the purposes of this decision.

#### 5.1.1.8. External fixation

- (42) External fixation devices are minimally invasive appliances used for a wide range of indications, including fracture fixation, limb lengthening and osteotomy. An external fixator consists of a series of rods, rings, or clamps that form an appliance fixed to the bone by a series of pins that penetrate the skin. A general distinction can be made between unilateral fixators (located externally on only one side of the limb), circular fixators (ring shaped and surrounding the limb) and hybrid fixators which combine the features of the other two external fixation systems. Specialized external fixation systems also exist such as distal radius, ring system and limb lengthening fixation systems. The market investigation showed that some devices belonging to these categories have very specific applications, such as in paediatric fractures or periprosthetic fractures.
- (43) As regards external fixation devices, the market investigation confirmed that universal and specialized external fixation devices cannot be substituted or can only be substituted to a certain degree. Some respondents also indicated that a further sub-division of these categories is possible although this cannot be confirmed with the results available. However, in the absence of competition concerns, the market definition can be left open.



## 5.1.2. Spine

### 5.1.2.1. Overview

- (44) The spine is a complex structure that is made of many components. A disruption of the integrity and position of these parts can cause spine pathologies. The main symptom of spine pathologies is pain. Spinal implants and instruments of the type made by the parties are designed to assist in the treatment of degenerative disorders, trauma, tumour and deformity. There are essentially three types of spine products, notably (i) fusion devices, (ii) non-fusion (or motion) devices and (iii) Vertebral Compression Fractures ("VCF") systems.
- (45) Fusion devices are implants used to permanently fuse together two or more vertebrae to immobilize and stabilize the spine and prevent painful movement in the affected region. Fusion devices fall into several broad categories: (i) pedicle screw/rod based fixation devices, (ii) plating systems, (iii) interbody cages (for the replacement of intervertebral disks), and (iv) corpectomy cages (for the replacement of whole vertebral bodies and the adjacent intervertebral discs). Specific device types are manufactured in a wide variety of forms to allow for a different surgical 'approach' (for example, anterior, posterior, transforaminal, lateral), or to fit a different region of the spine (for example, thoracolumbar or cervical).
- (46) Non-fusion devices are generally used to treat similar pathologies to fusion devices, but, unlike fusion devices, they seek to preserve the natural motion of the spine. The two main segments of non-fusion implants are (i) dynamic stabilization systems (pedicle-screw-based posterior dynamic stabilisation systems and interspinous stabilisation devices and (ii) artificial discs for lumbar and cervical spine. In addition, there are a number of other non-fusion implants and technologies (for example, facet arthroplasty, annulus repair, nucleus replacement), most of which are still in development.
- (47) VCF devices are used in the (minimally invasive) non-surgical treatment of vertebral compression fractures. Such fractures are caused by a sudden collapse of vertebrae which are significantly weakened (most commonly by osteoporosis, but also by tumours), causing significant pain to the patient. The two main types of VCF devices are vertebroplasty and vertebral augmentation (VA) products (with VA products including the most common technique currently, kyphoplasty), both involving the injection of cement into the site of the fracture.
- (48) According to the parties, the product market is at least as wide as the main product categories mentioned, namely, fusion (comprising cervical fixation, thoracolumbar fixation, and interbody devices), non-fusion and VCF devices, and may be as wide as spine devices as a whole. The reasons given are the purchasing patterns of the hospitals and that suppliers offer a broad range of spine devices and are likely to supply a range of different products within one of the major categories (fusion/non-fusion/VCF). Furthermore, where a supplier does not supply a specific product (for example, a Lateral Lumbar Interbody Fusion ("LLIF") cage or kyphoplasty), it often competes with another product from its portfolio as a valid alternative for a particular treatment.

- (49) In line with the Relevant Market Notice, the markets are to be defined as comprising products which are regarded as interchangeable or substitutable by the customer by reason of the products' characteristics, price and intended use. Despite limited demand and supply side substitution, one could also consider broader markets if most of the customers actually purchased bundles of products which are not mutually substitutable (assortment markets).<sup>29</sup> Although the competitors of the parties confirm that competition among key players typically takes place at the level of major spine product categories and certain hospitals procure for all spine devices or major categories thereof, this does not mean that they consider the purchased products as being interchangeable or substitutable. Not all players offer complete lines of spine devices (for example, a number of companies have limited or no non-fusion product lines) and many hospitals multisource different categories of spine devices from different suppliers and they even do so within the major spine product categories proposed by the parties.<sup>30</sup> There are also niche players that offer specific products.
- (50) Similarly, the fact that the same pathology can be treated by several devices does not mean that the products are regarded by surgeons as substitutable by virtue of their product characteristics.<sup>31</sup> For example, although degenerative disc disease can be treated by a variety of devices (fixation devices and interbody cages or artificial discs), these products present different technical product characteristics and/or required surgical approaches.
- (51) The vast majority of respondents to the market investigation confirmed the view that fusion, non-fusion and VCF devices are in general not substitutable as regards their product characteristics and intended uses.<sup>32</sup> However, the responses in relation to the interaction between certain fusion and non-fusion devices were mixed.
- (52) The first product category includes fusion interbody cages (for either the lumbar or the cervical spine) and non-fusion artificial discs (for either the lumbar or the cervical spine), which can be used in degenerative cases. According to the Notifying Party and industry reports, traditional interbody fusion cages face increasing competition from motion preserving implants, such as artificial discs.

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<sup>29</sup> Paragraph 41 of the Notice on Market Definition.

<sup>30</sup> In most group 1 countries, the answering hospitals submitted that they purchase specific spine products or group of several spine products separately rather than purchase all spine devices as part of overall spine contract. Only in a few countries (Latvia, Luxembourg, Sweden) the market investigation has shown that specific products are more often purchased under overall spine contracts. However, the number of hospitals answering to this question in the respective countries is not high enough to reliably find the presence of assortment markets in those countries (see replies to questions 33, 45, 57, 66, 87, 98, 128 of Q28 - Questionnaire to hospitals). Replies to question 44 of Q18 - Questionnaire to customers (hospitals) also show that hospitals often tend to design lots (in tenders or price enquiries) not necessarily for all spine devices, but also for narrower product categories.

<sup>31</sup> For example both pedicle screw/rod based dynamic stabilization system and lumbar artificial discs can be used to treat lumbar degenerative disorders.

<sup>32</sup> Replies to questions 1 and 2 of Q1 – Questionnaire to Competitors- Competitors Spine (and respective questions of Q9, Q11 and Q12).

The majority of respondents to the Commission's market investigation did not support a wider market encompassing artificial discs and interbody cages, but the replies were divided.<sup>33</sup> Respondents indicated that competitive constraints between discs and cages are limited due to different patient needs or indications and surgeon preferences (advanced pathologies are most often treated only with fusion devices), significant price differences (artificial discs are typically more expensive), and differences in reimbursement. The fact that competitors do not typically price interbody cages against artificial discs supports the view that these products do not closely compete in the same product market.<sup>34</sup> In the absence of competition concerns under any market definition, for the purposes of this Decision, the question as to whether artificial discs and interbody cages compete in the same product market can be left open.<sup>35</sup>

- (53) Similarly, the market investigation did not support a wider market encompassing traditional pedicle screw/rod fixation systems (fusion devices) and posterior dynamic stabilisation ("PDS") systems (non-fusion devices), which, for example, can be used as an adjunct to fusion in the treatment of degenerative cases. Although, according to the Notifying Party and industry reports traditional fusion systems face increasing competition from motion-preserving technologies, the replies of respondents to the market investigation were divided.<sup>36</sup> Respondents indicated that competitive constraints between PDS and traditional pedicle screw fixation are limited due to different patient needs (typically only younger patients are treated with motion devices) and surgeon preferences, significant price differences, and differences in indications. However, in the absence of competition concerns under any market definition, for the purposes of this Decision, the question as to whether PDS and traditional thoracolumbar pedicle screw/rod fixation systems compete in the same product market can be left open.<sup>37</sup>

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<sup>33</sup> 5 competitors stated that artificial discs face significant competition from interbody devices whilst 7 did not think so. Only one competitor stated to price its artificial discs against interbody devices whilst 7 did not.

<sup>34</sup> See replies to questions 65 and 67 of Q30 – Phase II questionnaire to competitors (spine).

<sup>35</sup> For the sake of completeness, it should also be noted that in addition to artificial discs there are other types of novel non-fusion devices designed to replace a specific part of the disc. According to the Notifying Party, nucleus replacement devices replace only the centre of the discs (nucleus pulposus) and therefore can be used as an alternative to artificial discs and traditional cages as a treatment of disc degenerative disease in certain indications (for example in cases of an early intervention). Annulus repair devices are used to repair the defective annulus after a partial removal of the disc and can also be seen as an alternative to artificial discs and/or traditional cages in certain clinical circumstances. In the absence of competition concerns, for the purposes of this Decision it can be left open whether such devices belong to the same product market as artificial discs and/or traditional cages, given that none of the parties is currently active in these segments or has advanced pipelines to be launched in the EEA.

<sup>36</sup> 6 competitors stated that PDS face significant competition from traditional pedicle screw fixation devices whilst 6 did not think so (see replies to questions 43 of Q30 – Phase II questionnaire to competitors (spine)). Only two competitors stated to price their posterior dynamic stabilisation systems against traditional thoracolumbar pedicle screw systems (or vice versa), whilst 8 do not (see replies to questions 43-48 of Q30 – Phase II questionnaire to competitors (spine)).

<sup>37</sup> For the sake of completeness, it should also be noted that in addition to PDS there are a few other novel non-fusion devices that can be used as an adjunct to fusion fixation. For example,

- (54) As to the exact segmentation of fusion devices, the participants in the market investigation broadly supported the view that even further segmentation would be appropriate taking into account the part of the spine (cervical and thoracolumbar devices typically cannot be substituted), the type of device, and the surgical approach, resulting in the following subcategorisation:<sup>38</sup> (i) thoracolumbar pedicle screw/rod based fixation systems, (ii) thoracolumbar plating systems, (iii) cervical pedicle screw/rod based fixation systems, (iv) cervical plating systems, (v) thoracolumbar interbody cages, designed for either anterior, posterior, transforaminal or lateral surgical approaches, (vi) cervical interbody cages (typically anterior), (vii) thoracolumbar corpectomy cages (trimmable mesh, expandable, stackable/monoblocks), (viii) cervical corpectomy cages (trimmable mesh, expandable, stackable/monoblocks). However, in the absence of competition concerns it can be left open for the purposes of this Decision whether such fusion devices constitute separate product markets or belong to broader markets comprising several or all of the above categories.
- (55) The Notice on Market Definition<sup>39</sup> provides that supply side substitutability may also be taken into account when defining markets, where suppliers are able to switch production to relevant products and start marketing them in the short term without incurring significant additional costs. These situations typically arise when companies market a wide range of qualities of product, even if for a given customer the different qualities are not substitutable, the different qualities will be grouped in one market, provided that most of the suppliers are able to offer and sell various qualities immediately and without significant increase in costs. Supply-side arguments cannot be applied to spine devices, especially given the significant time required to develop and obtain clinical evidence for a new surgical device, the additional cost and lead times required for regulatory approvals, for the training of sales forces and for convincing surgeons about the benefits of a given surgical device and to train them on how to use it. The respondents to the market investigation estimated that this can take up to two years if a manufacturer is active in a neighbouring product market or even longer in the case of a complex or a completely new product.<sup>40</sup>

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interspinous spacers ("ISS") can be inserted between the spinous processes at the back of the spine in order to restore normal height and reduce pressure on neural elements. Facet arthroplasty devices replace the facet joints to address the discomfort due to pain or lumbar stenosis. However, in the absence of competition concerns under any market definition, for the purposes of this Decision it can be left open whether such devices belong to the same product market as traditional thoracolumbar fusion devices.

<sup>38</sup> Replies to question 2 of Q1 – Questionnaire to Competitors-Competitors Spine

<sup>39</sup> See paragraph 20 of the Notice on Market Definition.

<sup>40</sup> For example, if a manufacturer marketing cervical corpectomy cages decides to enter with an equivalent thoracolumbar corpectomy device (see replies to question 74.1 of Q30 – Phase II questionnaire to competitors (spine) for three fourths of respondents it would take 1-2 years or more. See also minutes with a third party dated 22 December 2011, explaining that if a specific product needs to be developed the timeline could be 18 months or more. Additional time could be needed to wait for tendering opportunities, convince and train the surgeons for the use of new products.

### 5.1.2.2. Fusion devices

#### Thoracolumbar pedicle screw/rod based fixation systems and thoracolumbar plating systems

- (56) Pedicle screw, rod-based systems and plating systems are the main fixation implants dedicated to the thoracolumbar spine. Pedicle screw-based systems are typically inserted through a posterior approach, while plating systems are generally inserted through an anterior approach.<sup>41</sup>
- (57) The second phase market investigation has broadly confirmed that pedicle screw/rod fixation systems are typically not constrained by plating systems for thoracolumbar spine.<sup>42</sup> According to respondents, the systems differ in philosophy and approach. Pedicle screw/rod fixation systems are used for the posterior surgeries of the spine, while plates are used in anterior or lateral surgical procedures. According to respondents, surgeons generally follow an approach based on the clinical case, and therefore would not be typically switching between plate and pedicle screw systems. Furthermore, there are fewer spine indications that can be treated with plates. The fact that competitors do not price plating systems against pedicle screw systems also confirms that these products do not generally compete in the same product market.<sup>43</sup>
- (58) However, in the absence of competition concerns under any market definition, for the purposes of this Decision the question as to whether thoracolumbar pedicle screw/rod fixation systems and plating systems for thoracolumbar spine belong to the same product market can be left open, as the parties do not overlap (or overlap only to a negligible extent) in plating systems, which represent only a negligible portion of the overall demand for thoracolumbar fixation devices in a given country. The inclusion of plating systems would in any event have only a minimal impact on the parties' market shares and the competitive assessment. The parties also acknowledge that thoracolumbar plating systems are nowadays rarely used.

#### Cervical pedicle screw/rod based fixation systems and cervical plating systems

- (59) As is the case with thoracolumbar spine systems, cervical pedicle screws and rod-based systems together with plating systems are the main fixation implants for the cervical area. Pedicle screw-based systems are typically inserted through a

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<sup>41</sup> Plates can be either rigid (do not permit movement) or non-rigid (permit movement in line with spine).

<sup>42</sup> See replies to questions 16 and 17 of Q30 – Phase II questionnaire to competitors (spine). 2 respondents answered "Yes, to a significant extent", 6 "Yes, to some extent", and 7 "No, thoracolumbar pedicle screw/rod based systems do not compete with plating systems" whilst 25 did not answer this question. One respondent indicated 2 options in the reply. Furthermore, no competitor indicated pricing thoracolumbar pedicle screw/rod based fixation systems against thoracolumbar plating systems.

<sup>43</sup> See replies to question 16 of Q30 – Phase II questionnaire to competitors (spine), where 7/14 respondents considered that pedicle screw system do not compete with plating systems and 13/13 competitors acknowledged that pedicle screw systems are not priced against plating systems.

posterior approach, while plating systems are generally inserted through an anterior approach.<sup>44</sup>

- (60) The second phase market investigation largely confirmed that cervical pedicle screw/rod fixation systems are typically not constrained by plating systems for cervical spine.<sup>45</sup> According to respondents, cervical plating systems are, in principle, for a different indication than cervical pedicle screw/rod fixation systems. Pedicle screw/rod fixation systems are used for the posterior surgeries of the spine, while plates are used in anterior procedures. Surgeons generally follow an approach based on the clinical case, and therefore would not be typically switching between plate and pedicle screw systems. The fact that competitors do not price plating systems against pedicle screw systems also confirms that these products do not generally compete in the same product market.<sup>46</sup>
- (61) However, in the absence of competition concerns under any market definition, for the purposes of this Decision, the question as to whether cervical pedicle screw/rod based fixation systems and cervical plating systems belong to separate product markets can be left open.
- (62) In addition to traditional cervical plating systems, Synthes offers one hybrid product, Zero-P, which combines a plate and a cervical cage in a single device. Based on the results of the market investigation and [...]\*,<sup>47</sup> this device does not directly compete with traditional cervical plating devices, but rather with other hybrid products, such as stand-alone cervical interbody cages with inherent fixation (examples include LDR ROI-C, SurgiCraft Stalif-C, and Globus Coalition) or cervical plate and cage devices (examples include Alphatec PCB and [...]\*). However, for the purposes of this Decision it can also be left open whether cages with inherent fixation and plate and cage devices, such as Zero-P, belong to the same product market as traditional cervical plating systems and/or traditional cervical cages (ACIFs), given that the competitive assessment on a broader market comprising all such devices would not change materially, especially given that only Synthes is active in plate-and-cages and stand-alone cages. Given the closeness of these product markets to traditional cervical fixation systems, the competitive assessment should nevertheless take into account, as appropriate, any competition constraint stemming from cages with inherent fixation or plate and cage devices.

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<sup>44</sup> Plates can be either rigid (do not permit movement) or non-rigid (permit movement in line with spine).

<sup>45</sup> See replies to questions 28 and 29 of Q30 – Phase II questionnaire to competitors (spine). No competitor answered "Yes, to a significant extent", 5 answered "Yes, to some extent", and 7 competitors ticked "No, pedicle screw/rod based systems do not compete with plating systems", 27 did not answer this question. Furthermore, no competitor indicated pricing cervical pedicle screw/rod based fixation systems against cervical plating systems.

<sup>46</sup> See replies to question 29 of Q30.

<sup>47</sup> See replies to question 32 of Q30 – Phase II questionnaire to competitors (spine) and [...]\*.

## Interbody cages

- (63) Interbody cages are meant to replace the intervertebral discs and are intended to restore the normal height of the spine and to allow for vertebral fusion.<sup>48</sup> Interbody cages are specifically designed for each anatomy, namely either cervical or thoracolumbar spine regions, and approved for the respective surgical procedures (which are not equivalent for cervical and lumbar spine). Thoracolumbar interbody cages also differ depending on the surgical approach by which they are inserted (anterior or ALIF, posterior or PLIF, transforaminal or TLIF, lateral or LLIF). Cervical cages (ACIFs) and thoracolumbar cages are typically not substitutable, as they are designed for different spine parts.
- (64) For thoracolumbar cages, the market delineation is not clear-cut, and the replies of the respondents were divided. However, a significant portion of respondents considered that there is a limited substitutability among the various cages for lumbar spine (ALIF, TLIF, PLIF, LLIF) and that switching of usage among these devices is rather uncommon. This is due to different indications and training for the surgeons for a particular surgical approach.<sup>49</sup> This is [...] by the parties' internal documents, which [...]\*. However, in the absence of concerns under any market definition it can be left open whether different types of thoracolumbar interbody cages belong to separate product markets.
- (65) In addition to traditional interbody cages, there is a trend towards stand-alone ALIF devices (such as Synthes' SynFix LR device) and cervical interbodies with inherent fixation, making a combination of interbody cages with supplementary fixation no longer necessary. As explained above, there are also hybrid cervical devices (such as Synthes' Zero-P) combining a plate and a cervical cage in a single device. However, in the absence of competition concerns under any market definition, for the purpose of this Decision it can be left open whether cages with inherent fixation and/or plate and cage devices constitute separate product markets or rather belong to a broader product market, as the parties do not overlap with respect to such stand-alone devices. Where relevant, this distinction between self-fixation and traditional cages should nevertheless be taken into account in the competitive assessment and in particular as regards the closeness of substitution among various interbody cages.

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<sup>48</sup> They are generally filled with bone graft and have a porous nature to allow for natural bone growth through the device to achieve a stronger fusion.

<sup>49</sup> See reply to questions 49 of Q30 – Phase II questionnaire to competitors (spine). Although half of the competitors indicated that various interbody cages are interchangeable, the same number of respondents stated the contrary. More specifically, the respondents explained that although the intended use is similar (i.e. replacement of an intervertebral disc), the indication and surgical approaches for various interbody cages are different; therefore switching between different approaches is not common. In particular, reference is made to the reply of Medtronic [ID 4743]\*, explaining that customers rather look for a device suited for a particular surgical approach, rather than switch among the cages for different surgical procedures. See also minutes with a third party dated 22 December 2011.

## Corpectomy cages

- (66) Corpectomy cages are intended for Vertebral Body Replacement procedures; they can be of three main types: (i) trimmable mesh, (ii) stackable/monoblocks and (iii) expandable cages. Corpectomy cages are also specifically designed for either cervical or thoracolumbar spine regions and are almost exclusively used for trauma and tumour cases.
- (67) The market investigation has shown that there are important differences between the various types of corpectomy devices. In particular the devices for thoracolumbar and cervical spine are typically developed individually and require a separate approval process (regulatory approval is granted based on clinical indications, which are not equivalent for cervical and lumbar spine). The main indications for cervical corpectomy cages are multi-discectomy, or severe trauma to vertebra or tumour, which are relatively uncommon procedures. The number of procedures for thoracolumbar corpectomy is higher (for example thoracolumbar corpectomy devices are used for treating fractures, which do not often occur in cervical spine fractures). However, in the absence of competition concerns under any market definition, for the purposes of this decision it can be left open whether thoracolumbar and cervical corpectomy devices constitute separate product markets.
- (68) As regards the distinction between trimmable mesh, stackable and expandable devices, the market delineation is less clear-cut. On the one hand, all corpectomy devices are indicated for the same surgical procedure – vertebral body replacement and they all serve the same clinical purpose. On the other hand, there are material price differences between the oldest generation of trimmable mesh devices and newer products, such as stackable and expandable devices.<sup>50</sup> There are also some differences in their product characteristics. Trimmable mesh devices are the oldest and most basic type of corpectomy implant (and therefore the cheapest type). Stackable cages are stacked together to fill the space left by the removal of a vertebral body or bodies. Expandable cages are inserted and then expanded to fill the space. Unlike expandable cages, mesh and stackable cages enable greater use of bone graft, which some surgeons believe can create a faster and stronger fusion. Expandable cages allow for smaller incision and reduce surgical procedure time (for mesh and stackable cages time is needed for cutting or stacking). This reduces relative procedure costs and partly compensates for price differences. The internal documents of the parties [...]\*.<sup>51</sup> The three types of devices therefore offer different degrees of ease of use.
- (69) For the purposes of this Decision, it can be left open whether thoracolumbar and cervical corpectomy devices constitute separate product markets.

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<sup>50</sup> As acknowledged by the parties (see paper "Competition in corpectomy cages in Europe" dated 24 November 2011).

<sup>51</sup> See for example, Synthes internal document [...]\*



### 5.1.2.3. Non-fusion devices

- (70) As to non-fusion devices, the majority of respondents in the first phase market investigation supported the view that a distinction should be made between PDS, interspinous devices and artificial discs, and, within artificial discs, between lumbar and cervical artificial discs.
- (71) For the purposes of this Decision it can be left open whether non-fusion devices belong to the same relevant product market or whether they should be further sub-segmented as concerns do not arise under any market definition.

### 5.1.2.4. Vertebral Compression Fractures ("VCF")

- (72) Before the introduction of percutaneous vertebroplasty, VCF patients were mostly treated with traditional methods (including painkillers, physical therapy, back braces) or even remained undiagnosed. Despite minimally invasive VCF treatments gaining ground, the majority of the patient base is still treated with traditional methods or is undiagnosed. For example, according to an internal document of the Notifying Party, only [...] % of osteoporotic VCF patients have undergone a VCF procedure in the United Kingdom<sup>52</sup>.
- (73) The parties argue that all VCF procedures belong to the same relevant product market. In addition to the general arguments in Recital (48), the parties argue that both procedures treat the same problem (VCF) and kyphoplasty is only a "variation" of vertebroplasty. Finally, the parties argue that manufacturers of only one product (for example, vertebroplasty or kyphoplasty) try to market aggressively their product as an alternative to all VCF treatments (not only the same type of treatment). Whilst this was confirmed by the market investigation, this in itself is not an indication of a separate market. The relevant factor to consider would be the effect and success of such marketing, namely, to what extent customers view these products as interchangeable as a result of cross-marketing. As explained in Recitals (74) - (79) of this Section, the market investigation revealed that such demand-side substitutability is presently not sufficiently extensive to clearly place these products in the same relevant product market. This is despite a degree of migration from vertebroplasty users to kyphoplasty and a degree of (especially future) convergence in prices and in the marketing of VCF procedures.
- (74) The phase 1 market investigation pointed to the existence of separate vertebroplasty and kyphoplasty markets. The phase 2 market investigation provided further evidence that there was a distinct demand for vertebroplasty procedures in the EEA notwithstanding that both vertebroplasty and kyphoplasty and other vertebral augmentation ("VA") techniques target the same general condition and share the same patient base.

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<sup>52</sup> See J&J internal document No 581 submitted in response to Question 5a of the Commission's Article 11 request ("RFI") of 17 November 2011).

- (75) Firstly, a kyphoplasty/VA procedure is more complex, necessitates the use of an additional device and requires specific additional skills and techniques to perform.<sup>53</sup>
- (76) Secondly, the phase 2 market investigation confirmed that kyphoplasty/vertebral augmentation is significantly more expensive than standard vertebroplasty<sup>54</sup>. This is also clear from the iData 2011 report, which shows that the average selling price of vertebroplasty products was less than 20%<sup>55</sup> of the average selling price of VA products in 2010. Whilst prices of kyphoplasty /VA products are expected to fall due to new entry and product launches<sup>56</sup>, the 2011 iData report indicates that vertebral augmentation will continue to have a premium price as compared to vertebroplasty<sup>57</sup>. This was confirmed by the market investigation.<sup>58</sup>
- (77) The price difference seems to have a particular importance for demand especially in Member States where the reimbursement for kyphoplasty procedures is not generous. This includes for example Central and Eastern European Member States. This notwithstanding, the market investigation indicated that in countries where kyphoplasty benefits from a generous reimbursement (for example Germany), there may be significantly more competitive constraints from kyphoplasty<sup>59</sup>. In particular, the motivation to perform kyphoplasty may be higher due to its stronger reimbursement. Whilst kyphoplasty would not constrain the prices of vertebroplasty in these countries either<sup>60</sup>, the immediate demand for these products (physicians/hospitals) would not be particularly price sensitive due to generous reimbursement schemes.
- (78) Thirdly, the differentiation within the customer base (type of doctors) also points to significant differences between vertebroplasty and kyphoplasty/VA. In particular, a significant part of demand for VCF procedures does not come from the "regular" customers of spine companies (orthopaedic and neurosurgeons) but from interventionist radiologists (IRs) and interventionist neuroradiologists (INRs). This is because VCF procedures require X-ray technology to perform (for the precise placement of the needle) and vertebroplasty was therefore marketed

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<sup>53</sup> During a basic vertebroplasty procedure bone cement is injected via a needle to the site of the fracture. Vertebroplasty therefore only necessitates the use of bone cement and a needle. During kyphoplasty, an additional device is inserted in the vertebral body which is used to create a cavity before the injection of the cement.

<sup>54</sup> See replies to question 101.3 of Q30 - Phase II Questionnaire to competitors (Spine) and Question 4.3 of Q31 Phase II- Questionnaire to competitors (VCF treatments).

<sup>55</sup> EUR 2301 for vertebral augmentation products vs EUR 398 for vertebroplasty.

<sup>56</sup> See reply of Stryker to question 105.1 of Q30 - Phase II- Questionnaire to competitors (Spine).

<sup>57</sup> European Markets for Spinal Implants and VCF, iData Research, 2011 - Figure 12-2.

<sup>58</sup> See agreed non-confidential minutes of a call with Medtronic dated 14 December 2011..

<sup>59</sup> See agreed non-confidential minutes of a call with CareFusion dated 21 December 2011 [ID6090]\*. *"The retail price of kyphoplasty is significantly higher than vertebroplasty []\*. This notwithstanding, in some EEA countries, for example Germany and Belgium, hospitals may have a financial incentive to use kyphoplasty due to a generous reimbursement regime (the reimbursement of kyphoplasty is significantly higher so hospitals have a preference to use it). In these countries kyphoplasty exerts a competitive constraint on vertebroplasty."*

<sup>60</sup> The state or insurers would eventually still pay for (at least) a large part of it even if hospitals do not need to.

historically to IRs and INRs primarily. The market investigation showed a pronounced difference in the preferences towards and familiarity with vertebroplasty and kyphoplasty/VA according to the specialty of the physician. In particular, a majority of vertebroplasty procedures still seem to be performed by IRs and INRs<sup>61</sup>. The Millenium Research Group ("MRG") also forecasts that, due to the simplicity of vertebroplasty procedures, there is a tendency to target other types of non-surgeon physicians (for example pain management specialists, anesthesiologists), which will contribute to growing vertebroplasty procedure volumes, [...] <sup>62</sup>. By contrast, kyphoplasty was originally marketed to surgeons<sup>63</sup> and the market investigation showed that surgeons, in general, seem to be more open to kyphoplasty and VA than IRs and INRs and still perform the majority of kyphoplasty/VA procedures<sup>64</sup>. Kyphoplasty/VA suppliers (including the parties) are therefore increasingly targeting the non-surgeon customer base (traditionally more loyal to vertebroplasty) as well.<sup>65</sup> However, in countries, where the market is more surgeon-driven (for example Germany, Austria), the competitive constraints from kyphoplasty will be stronger.

- (79) Overall, due to the factors outlined in Recitals (75) - (78), the introduction of kyphoplasty does not seem to have halted the growth of vertebroplasty<sup>66</sup> so that kyphoplasty cannot simply be considered as a new generation of vertebroplasty that has or would in the foreseeable future replace traditional vertebroplasty. Vertebroplasty still seems to account for over half of the procedures performed and is expected to grow, albeit at a lower rate than kyphoplasty, in the coming years.<sup>67</sup> This is also confirmed by qualitative evidence from the Phase 2 market investigation. In particular, [...] <sup>68</sup> and industry reports<sup>69</sup> suggest that a significant proportion of physicians are not convinced about the additional

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<sup>61</sup> This is the case for example in the United Kingdom, Italy and France- See Millenium Research Group report "Global markets for minimally invasive VCFs" – May 2011, p.82. See also agreed non-confidential minutes of the conference call with Medtronic on 14 December 2011 *"Due to the history of the introduction and marketing of vertebroplasty and kyphoplasty, interventionist radiologists perform more vertebroplasty whilst kyphoplasty is more performed by surgeons."*

<sup>62</sup> [...]\*

<sup>63</sup> See agreed non-confidential minutes of the conference call with Medtronic on 14 December 2012.

<sup>64</sup> "Global markets for minimally invasive VCFs" Report by the Millenium Research Group, May 2011, p.82-83. See also agreed non-confidential minutes of the conference call with Medtronic on 14 December 2011 –*"Due to the history of the introduction and marketing of vertebroplasty and kyphoplasty, interventionist radiologists perform more vertebroplasty whilst kyphoplasty is more performed by surgeons."*

<sup>65</sup> Millenium Research Group report "Global markets for minimally invasive VCFs" – May 2011, p.46.

<sup>66</sup> In fact, both segments have been growing and are expected to grow due to, inter alia, an aging population (enlarging patient base) and a very significant part of the patient base currently not being surgically treated. Whilst a study published by the New England Medical Journal in 2009 called into question the efficiency of vertebroplasty vis-a-vis non-surgical methods and resulted in a decreased growth rate for vertebroplasty, it did not halt the market growth of vertebroplasty – Section 12.4.2 of the 2011 iData report on European Markets for Spinal Implants and VCF.

<sup>67</sup> See European Markets for Spinal Implants and VCF, iData Research, 2011 – Figure 12-1.

<sup>68</sup> [...]\*

<sup>69</sup> Section 12.4.1. p. 427: *"Many surgeons also prefer vertebroplasty due to the lower price of the procedure"*. Millenium Research Group report "Global markets for minimally invasive VCFs" – May 2011, p.100.

benefits of kyphoplasty over vertebroplasty and accordingly they do not see a perceived benefit which would justify the higher price. This could explain why vertebroplasty is still widely used in the market almost a decade after the introduction of kyphoplasty.

- (80) This notwithstanding, there are indications of increasing overlaps in the use of these products and more convergence in the future. As mentioned in Recital (78), IRs and INRs increasingly use kypohoplasty/VA. Furthermore, price convergence may also come from the expected decrease in prices for kyphoplasty and the introduction of more innovative, higher priced products in vertebroplasty (Confidence). These more innovative vertebroplasty products are focussed on increased safety either for the patient (cement leakage) or for the physician (exposure to radiation)<sup>70</sup>. As safety is also a key selling point of kyphoplasty (along with the claim of height restoration), such innovative vertebroplasty products would share one of the two key selling points of kyphoplasty.
- (81) Whilst complete kyphoplasty kits (or procedures) do not seem to be viewed as substitutes by at least a significant part of VCF users, the information from the parties and the market investigation shows that supply-side substitutability may technically be possible. In particular, kyphoplasty kits contain the components necessary to perform a vertebroplasty procedure (namely, cement and a needle) and may also be sold "*à la carte*". It follows that hospitals could therefore buy only the components needed for vertebroplasty without having to buy the additional kyphoplasty device. The parties argue, in the case of Medtronic Inc. ("Medtronic") for example, that by offering its kyphoplasty cement and delivery device separately from its balloon device, Medtronic in fact offers vertebroplasty products despite being "*primarily*" a kyphoplasty competitor. It can therefore be argued that there is a one-way supply-side substitutability between kyphoplasty and vertebroplasty products: kyphoplasty suppliers could easily start supplying vertebroplasty products as they have all the components needed to perform a vertebroplasty procedure. Notwithstanding that supply-side substitutability may technically be possible, there are however no apparent commercial incentives, due to the very significant price difference between these segments, in support of such substitutability becoming a reality. In other words, a 10% price increase in the vertebroplasty segment is unlikely to prompt kyphoplasty suppliers to enter this segment given that they can currently charge as much as five times the price of vertebroplasty products for their kyphoplasty product.
- (82) In conclusion, whilst it is true that all VCF treatments have the same patient base (people suffering from VCF), there are significant differentiating factors between the use of these products, including in particular the devices and required skill-set and the price, which, together with physician loyalty, significantly limit the demand-side substitution of vertebroplasty with kyphoplasty. The evidence, as

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<sup>70</sup> See agreed non-confidential minutes of the conference call with Medtronic on 14 December 2012: "*Vertebroplasty is not growing very fast due to safety concerns. Kyphoplasty has an increased safety profile as compared to vertebroplasty. There are new vertebroplasty products on the market offering more safety [ ]\**" and Section 2.3.1 of the Millenium Research Group report "Global markets for minimally invasive VCFs" – May 2011.

outlined in Recitals (75) - (79), points to a distinct demand for vertebroplasty products. In addition, there are no apparent commercial incentives to support an argument for wide-spread supply-side substitutability that would justify the delineation of a wider market. (The question whether Medtronic can be considered as a vertebroplasty supplier is therefore a specific issue relating to its activities in these markets and will therefore be examined under Section 6.4.4.) Notwithstanding a distinct demand for vertebroplasty, there appears to be a certain overlap in the use and a degree of competition between these products, which appears to vary from one country to another. Further convergence is expected in terms of price, marketing and product characteristics (in particular relating to safety as a key selling point).

- (83) Whether there is a distinct market for vertebroplasty on the one hand and kyphoplasty/VA on the other or whether VCF treatments belong to the same relevant market can be left open as the transaction does not raise competition concerns on the basis of either the narrower or the wider market definition.

### 5.1.3. *Shoulders*

#### 5.1.3.1. Overview

- (84) The shoulder is a complex ball-and-socket joint that permits the greatest range of motion of any joint in the body. In the shoulder, the rounded end of the upper arm bone (head of the humerus) glides against a small dish-like socket (glenoid) in the shoulder blade (scapula) in order to form a sliding joint (the glenohumeral joint). The rotator cuff or rotor cuff (medical terminology) is the group of muscles and their tendons that act to stabilize the shoulder. The rotator cuff muscles are important in shoulder movements and in maintaining shoulder joint stability.
- (85) Shoulder replacement by an implant (total or partial) may be indicated as a result of (i) either complex shoulder fractures or (ii) degenerative conditions.
- (86) Shoulder implants consist of three components: a humeral stem, a humeral head, and a glenoid cup. The humeral stem is inserted into the medullary canal of the humerus (also referred to as the humeral shaft) and an artificial humeral head is attached to the stem to form the ball component of the shoulder joint.
- (87) Shoulder implants can be classified by pathology. Firstly, shoulder replacement may be required in case of complex shoulder fractures which cannot heal naturally (fracture shoulder replacement). Secondly, shoulder replacement surgery is also used to address degenerative conditions of the shoulder, such as arthritis, arthropathy or osteonecrosis (degenerative shoulder replacement). Finally, there is a procedure whereby the socket and the metal ball are switched (reversed) compared to the standard shoulder prosthesis, which is almost exclusively used in case of large rotator cuff tear (reverse shoulder replacement).
- (88) Shoulder implants can also be classified by the particularities and extent of the patient's pathology and needs. In this respect, depending on the extent of the patient's needs, the surgeon has the choice to proceed to (i) a total shoulder implant, (ii) a stemless shoulder replacement where a long stem is not present,

(iii) a partial shoulder replacement where only the humeral stem and the head are replaced, (iv) a resurfacing shoulder implant which is a less invasive alternative, or (v) a revision shoulder implant, namely a subsequent operation years after the first one.

#### 5.1.3.2. Market definitions

- (89) The Notifying Party submitted that as far as the surgical aspects of shoulder replacements are concerned, there is no differentiation on the basis of the pathology (degenerative, fracture, reverse) or the level of intervention (total, stemless, partial, resurfacing or revision) regarding the necessary training qualifications of the shoulder (or upper extremity) surgeons. Moreover, since trauma departments often perform shoulder surgeries, trauma surgeons can deal with all types of indications related to fractures of the shoulder and are aware of the different alternatives available from different suppliers.
- (90) The Notifying Party also argues that the different manufacturers' products are designed to function as a system, so mixing components from different suppliers cannot be done due to incompatibility issues and because such use would be off-label and outside the products' CE approval licenses.
- (91) Finally, some major suppliers (J&J, Biomet Orthopedics, LLC ("Biomet"), Tornier, Inc ("Tornier") and Zimmer, Inc ("Zimmer") offer shoulder prostheses which are specifically dedicated to each of those pathologies, whereas others (Synthes, Limacorporate S.p.a. ("Lima"), Arthrex, Inc. ("Arthrex")) offer products that can be used for both fractures and degenerative conditions.
- (92) For these reasons, the Notifying Party argues that the product market definition should cover all shoulder implants. It nonetheless states that the competition analysis does not hinge on market definition and that regardless of how the market is defined the transaction would not give rise to a significant impediment to effective competition. It thus provided market share data for an overall market encompassing all shoulder implants and also for degenerative, fracture and reverse pathologies.
- (93) The market investigation did not support the Notifying Party's assertion for one overall market encompassing all shoulder implants disregarding the pathology. An overwhelming majority of respondents were of the opinion that competition does indeed take place at the level of the three different pathologies (i.e. degenerative, fracture, revision)<sup>71</sup>.
- (94) The market investigation confirmed however that, as indicated by the Notifying Party, further sub-segmentations according to the level of the intervention (total,

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<sup>71</sup> See answers to questions 6, 29 and 39 of Q4 - Questionnaire to Competitors- Competitors Shoulder, Q6 - Questionnaire to Competitors- Competitors Trauma-Shoulder, Q11- Questionnaire to Competitors- Trauma-Spine-CMF-SH-PT & Q12 –Questionnaire to Competitors- Trauma-Spine-CMF-SH respectively: An overwhelming majority of the respondents were of the opinion that competition does indeed take place at the individual pathology level.

stemless, partial, resurfacing, revision) inside each of these three categories by pathology are not plausible<sup>72</sup>. This is mainly because shoulder replacement products (inside each pathology category) are viewed as one class of products for tender and contract purposes and also because all major suppliers are likely to offer various types of shoulder replacement devices across each of these major categories.

- (95) As the proposed transaction does not give rise to a significant impediment of effective competition either in an overall market encompassing all shoulder implants or in the narrower markets for each of the three pathologies. Therefore there is no need to further analyse the divergence between the Notifying Party's opinion and the results of the market investigation in this respect as the market definition can be left open.
- (96) Consequently, for the purposes of this Decision the Commission considers the overall market for shoulder implants as well as the markets for degenerative, fracture and reverse shoulder implants.

#### 5.1.4. *CMF*

- (97) CMF devices are used for a specialised branch of oral and maxillofacial surgery treating the entire cranio-maxillofacial complex: the anatomical area of the mouth, jaws, face and skull, as well as associated structures. Cases include trauma-related fractures, facial and skull reconstructions due to tumours or congenital deformities, or neurosurgery where access to the brain is required. CMF surgery requires small implants for fastening together delicate facial bones, as well as pieces of skull bone.
- (98) CMF devices include the following types of products: (i) CMF fixation devices, including plates and screws, which can be used in either the facial, cranial or intermaxillary facial regions, and cranial flaps, which are used to secure the removed section of the skull during a cranial surgery to the surrounding skull once the surgical intervention is completed; (ii) CMF distraction devices, which are used as a bone stabilising and lengthening device or as a bone transport device; (iii) temporomandibular joint (“TMJ”) replacement devices, which consist of implants to replace the natural temporomandibular joint; and (iv) dental and thorax fixation devices, which are used in other parts of the anatomy, including in the dental and thorax area..
- (99) CMF fixation devices are usually sold as kits consisting of a variety of plates, screws and flaps of different sizes and shapes suited for cranial, midface or mandibular surgery, generally including the related instrumentation (for example forceps to handle the implants, cutters to modify them, screw drivers). Certain

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<sup>72</sup> See answers to questions 5, 28 and 38 of Q4 - Questionnaire to Competitors - Competitors Shoulder, Q6 - Questionnaire to Competitors- Competitors Trauma-Shoulder, Q11- Questionnaire to Competitors - Trauma-Spine- CMF-SH-PT & Q12- Questionnaire to Competitors - Trauma-spine-CMF-SH respectively: An overwhelming majority of the respondents were of the opinion that competition does indeed take place at the major individual pathology level.

kits include plates, screws and flaps for all regions (or more than one region) of the skull, while other kits contain CMF products dedicated to specific CMF regions. There are differences between maxillofacial and cranial kits. The kits for the maxillofacial region are generally larger and contain several different pieces of varying sizes to provide the surgeon with the required range of options, since the surgeon cannot predict exactly what shapes and sizes will be needed in surgery. The kits contain fixation devices for the mandible, midface, and the two regions combined. Cranial kits have fewer pieces because cranial fixation procedures are relatively standard. Kits can also be customised for hospitals or surgeons. They are chosen by the hospitals/surgeons themselves, who decide which components should be included in the kit.

- (100) Although the vast majority of CMF fixation devices are stock products delivered in kits and kept at the hospital, there are also custom-made implants. Custom-made implants are mainly used in cranioplasty surgeries where the reconstruction of large and complex cranial defects is required. Custom-made devices are produced for an individual patient using measurements derived from computed tomography scans of the patient's skull. This information is then processed to create an anatomically correct skull model and an implant model. These custom-made implants can be made of different materials, including titanium and other biocompatible materials. Their advantages include reduced operating time and a more satisfactory aesthetic outcome for the patient. However, stock plates and screws account for the vast majority of CMF procedures.
- (101) Plates and screws for the maxillofacial region are used mainly by maxillofacial surgeons ("MF surgeons") and to a limited extent by plastic surgeons, for facial reconstruction. Plates and screws and flap fixators for the cranial region are used mainly by neurosurgeons in craniotomies to re-affix the cranial flap. Because plate reconstruction in the maxillofacial area requires more technical expertise, surgeons exhibit stronger preferences when selecting maxillofacial products. For this reason, MF surgeons tend to have greater influence in hospital purchasing decisions for maxillofacial devices than neurosurgeons for cranial devices. Neurosurgeons view cranial fixation products as secondary devices, and focus more on the devices used during the actual brain surgery. As a result, neurosurgeons will typically not have a strong preference as to which brand they use to close up the cranium.
- (102) The number of devices used in a CMF procedure can vary from one to more than five. In neurosurgery it is common to use three small two hole plates and six screws or three flap fixators. In maxillofacial surgery there is the potential for a larger number of plates and screws to be used depending on the location and complexity of the case.
- (103) Plates, screws and flaps are made of metal (titanium) or resorbable materials, with metal devices being used in the vast majority of procedures in 2010 in the EEA. Resorbable implants are mostly useful in paediatric surgery because a stiff metal implant can interfere with normal craniofacial growth.
- (104) Fixation devices for the cranial region (with the exception of custom-made devices) tend to be more commoditised products, with lower prices. The price of



these basic Neuro-kits is considerably lower than the equivalent plates and screws used in a maxillofacial procedure. Custom-made implants are significantly more expensive than cranial or maxillofacial stock implants and take longer to be delivered (10 to 14 days on average). Given that each implant is specifically produced and unique, a market price does not exist for custom-made implants.

- (105) CMF fixation devices suppliers also provide professional training and education to surgeons. Suppliers offer training both at international level and within each country or region. As cranial fixation devices have become increasingly commoditised, training tends to be confined to devices for the maxillofacial region. Codman does not offer any CMF training. Generally, more training is needed for maxillofacial and plastic surgeons than for neurosurgeons. In neurosurgery, the fixation of the skull will typically take only a few minutes at the end of the procedure, and is not a priority or concern for the surgeon as this is typically a simple step. A neurosurgeon will thus rarely require training in this regard.
- (106) CMF distraction devices are typically used in distraction osteogenesis procedures, which are surgical procedures for reconstructing skeletal deformities through the controlled displacement of surgically created fractures (osteotomies).
- (107) J&J [...]\*. Through its subsidiary Codman it acts as the [...] distributor for Bioplate Inc's cranial fixation and maxillofacial<sup>73</sup> products. Codman is also the [...] distributor in the EEA of custom-made cranial reconstruction implants manufactured by Fin-Ceramica Faenza S.p.A. Codman does not sell CMF distraction devices, TMJ replacement devices and dental or thorax fixation devices in the EEA.
- (108) Synthes is active in the development, production and sale of fixation devices and distraction devices across most CMF areas (i.e. cranium, face or midface and jaw), except for TMJ. Synthes also has [...] sales of dental and thorax fixation products.
- (109) The market investigation showed that cranial stock fixation implants and custom-made implants have to be considered as two separate markets due to the purchasing patterns of hospitals, the different product characteristics and price levels, the different types of surgeons using the implants and the different suppliers.<sup>74</sup> On this basis, the Commission concludes that the two relevant product markets for the present case are (i) cranial stock fixation implants and (ii) custom-made implants.

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<sup>73</sup> In 2010, only sales of EUR [...] of maxillofacial devices were made in [...] countries of the EEA [...]. Only the [...] market is affected at the national level and the increment post-merger is only [0-5] %.

<sup>74</sup> See replies to questions 18 and 19 of Q 15 - questionnaire to competitors (CMF) and replies to questions 3, 4, 75 and 76 of Q18 - questionnaire to customers (hospitals).

#### 5.1.5. *Power Tools*

- (110) Power tools are used by surgeons in a variety of surgical procedures, including trauma, spine, CMF, neurosurgery as well as orthopaedic joint reconstruction. There are essentially three types of power tools: large bone, small bone and high-speed.
- (111) Large bone power tools are used primarily in orthopaedic joint reconstruction and trauma surgery. Small bone power tools are used in a variety of surgical applications like orthopaedic hand and foot surgery, shoulder reconstruction, oral, maxillofacial, ENT (ear, nose and throat), spine and low impact trauma surgery. High-speed power tools are drills used in neurosurgery, spine surgery, ENT surgery and, to a lesser extent, maxillofacial surgery. High-speed typically means that the drill operates above 60 000 revolutions per minute.
- (112) The Notifying Party notes that within each type of power tool, a distinction could also be made between the power tools themselves ("the capital equipment") and their consumable accessories ("consumables"), which are mounted on the tool to perform a surgical task and can either be single-use or re-usable (though even re-usable consumables need to be replaced after a certain number of uses). The relative value of the capital equipment and the relevant consumables varies between categories of power tool.
- (113) The Notifying Party submits that each of the three types of power tools (namely large bone, small bone and high-speed power tools) can be considered as a product market in itself, because each is used in a different kind of operations, requiring different characteristics, speed, power and size, which also results in differences in complexity and price. In addition, within the high speed power tools two different segments can be differentiated, (i) high speed power tools (capital equipment and consumables with the exclusion of cranial perforators) and (ii) cranial perforators, which are used for the cutting of circular sections of the cranium. .
- (114) Synthes sells all three types of power tools and their consumables. J&J (through its subsidiary Codman) sells only high-speed power tools and their consumables. In view of this, for the purposes of the present case, only high speed power tools and their consumables are of relevance.
- (115) Consumables for high-speed power tools consist largely of specialized burrs, cutters, drill bits, micro saw blades and cranial perforators. In general, they are provided together with the power tools themselves, as part of a proprietary system. According to the Notifying Party, the only exception to this are cranial perforators. These are consumables used with high-speed power tools to open the cranium (part of the skull). In general, these perforators have a "universal" end fitting (the "Hudson Brace") and therefore they can be used with any high-speed drill supporting this universal fitting, i.e. they are typically not part of a proprietary system, such as other consumable parts.
- (116) It has, however, to be noted that Synthes' proprietary cranial perforator does not have a Hudson end and can only be connected to a Synthes high speed drill.

Therefore it does not compete with J&J and other manufacturers whose cranial perforators can be used with any competitor's drill.

- (117) The market investigation supported the view that the three types of devices are indeed used for different types of operations and cannot be substituted, confirming therefore the segmentation into three product categories. Furthermore, inside high speed power tools, it also supported the further segmentation into two categories, (i) one for high speed power tools (capital equipment and consumables with the exclusion of cranial perforators) and (ii) another one for cranial perforators<sup>75</sup>. As mentioned, this is due to the fact that in general high speed power tools are provided together with their respective consumables, as part of a proprietary system, with the exception of cranial perforators. Finally, there is no need to further sub-segment per type of consumable (burrs, cutters, drills etc.)

## 5.2. Relevant Geographical Markets

- (118) In previous cases concerning medical devices<sup>76</sup>, the Commission has considered the markets for medical devices as national.
- (119) The Notifying Party argues that from a demand-side perspective there are some industry characteristics suggesting that the relevant geographic markets for the medical devices affected by the proposed transaction are national, in particular due to (i) national reimbursement regimes; (ii) national scale of purchasing patterns by hospitals; (iii) national sales organisations of competitors and national price level differences. At the same time, according to the Notifying Party, from a supply-side perspective there are several factors indicating that the relevant geographic market could also be EEA-wide in particular due to (i) low regulatory barriers (CE Mark); (ii) pan-European (or worldwide) production and R&D and low transport costs; and (iii) the scope of public tenders not being limited to national suppliers. The Notifying Party concludes that, even if the relevant geographic market is assumed to be national, these industry characteristics establish the absence of any significant barriers to entry, expansion or repositioning across the EEA.
- (120) The market investigation broadly confirmed the points mentioned by the parties. The Commission has found that market shares of the major players in this sector vary from country to country. Also the market structure varies from country to country. There are regional players which are active in one or some countries but not EEA wide (only 4 out of 19 competitors in trauma devices indicated that they

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<sup>75</sup> See answers to questions 1, 4 and 10 of Q5 - Questionnaire to Competitors – Competitors PT, Q9 – Questionnaire to Competitors – CMF-PT-Trauma-Spine, and Q11 – Questionnaire to Competitors – Trauma-Spine-CMF-SH.

<sup>76</sup> See for example Commission decision of 27 May 2003 in Case No COMP/M.3146 Smith & Nephew/Centerpulse; Commission decision of 28 October 1998 in Case No COMP/M.1286 Johnson & Johnson/DePuy; Commission decision of 25 August 2005 in Case No COMP/M.3687 Johnson & Johnson/Guidant.

were active in more than 20 EEA countries)<sup>77</sup>. Furthermore, similar to other medical sectors, the presence of public reimbursement systems in a large number of Member States has partitioned off the markets at national level. The reimbursement schemes vary from country to country resulting in significant price differences between the Member States.<sup>78</sup> Hospitals' purchasing behaviour differs from one country to another (individually vs. purchasing groups; tender procedures vs. informal requests)<sup>79</sup>. On a national scale the importance of a local/national sales force is stressed.<sup>80</sup> Service (training and assistance from the suppliers; quick delivery; presence of sales force) is regarded as essential by hospitals when choosing their suppliers.<sup>81</sup>

- (121) In view of the above, the product markets considered in this Decision are analysed on a national level.

## 6. COMPETITIVE ASSESSMENT

### 6.1. Introduction

#### 6.1.1. *Legal test*

- (122) Under Article 2(2) and (3) of the Merger Regulation, the Commission must assess whether a proposed transaction would significantly impede effective competition in the internal market or in a substantial part of it, in particular as a result of the creation or strengthening of a dominant position. That assessment is based on a prospective analysis of how the proposed transaction may alter the factors that determine the state of competition in a given market, to establish whether the proposed transaction will give rise to a significant impediment to effective competition.

- (123) Paragraph 22 of the Commission Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings<sup>82</sup> ("Horizontal Guidelines") provides that, apart from situations where a merger will lead to the creation or strengthening of a dominant position,

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<sup>77</sup> See replies to question 8 of Q17 – questionnaire to competitors (Trauma).

<sup>78</sup> As an example the same plate is sold by Synthes in [...] at a price which is about five times higher than in [...]. Source: Form CO, p. 165 (table 65). See also J&J internal documents provided as response to the RFI of 17 November 2011, Doc No 197 "[...] is the 2<sup>nd</sup> highest priced market in Europe. Pricing is [10-20]\*% higher than average European market prices", Price developments of Synthes' products, submitted by email on 21 December 2011; Minutes of the meeting with Mr Schaefer (Head of Purchasing at Einkaufsgemeinschaft Kommunalen Krankenhäuser) on 30 November 2011 [ID 5830]\*.

<sup>79</sup> See replies to question 3 of Q18 - questionnaire to customers (hospitals).

<sup>80</sup> See replies to question 17.6 of Q17 - questionnaire to competitors (Trauma): 5 perceived this as being no significant or just a moderate barrier to entry whilst 13 considered it as being a considerable or crucial barrier.

<sup>81</sup> See replies to questions 31.5 (95 out of 119 statements) and 48.5 (85 out of 107 statements) of Q18 - questionnaire to customers (hospitals): The vast majority of responding hospitals submits that the service provided is a very important if not crucial criterion for their supplier selection.

<sup>82</sup> OJ C31, 5.2.2004, p.5.

one can also distinguish between two main ways in which mergers between actual or potential competitors on the same relevant market may significantly impede effective competition, namely non-coordinated effects and coordinated effects.<sup>83</sup> The Commission also assessed the likelihood of conglomerate effects according to the Commission guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings<sup>84</sup> ("Non-Horizontal Guidelines"),

#### 6.1.1.1. Non-coordinated effects

- (124) Non-coordinated effects may significantly impede effective competition by eliminating important competitive constraints on one or more firms, which consequently would have increased market power, without resorting to coordinated behaviour.<sup>85</sup> The reduction in competitive constraint between the merging firms may lead to significant price increases. Nonetheless, price is not the only criterion that needs to be examined since the implementation of the proposed transaction may also affect available capacity, choice, quality of service and innovation.<sup>86</sup>
- (125) The Horizontal Guidelines list a number of factors which may influence whether or not significant non-coordinated effects are likely to result from a merger, such as the large market shares of the merging firms, the fact that the merging firms are close competitors, the limited possibilities for customers to switch suppliers, or the fact that the merger would eliminate an important competitive force. This list of factors is however not exhaustive<sup>87</sup>. Furthermore, not all of these factors need to be present in order for significant horizontal effects to be likely.<sup>88</sup>
- (126) The Horizontal Guidelines also recognize that some firms, despite having a relatively small market share, may be an important competitive force. A merger involving such a firm may change the competitive dynamics in a significant, anti-competitive way, in particular where the market is already concentrated.<sup>89</sup>
- (127) Finally, according to the Horizontal Guidelines, in assessing the competitive effects of a merger, the Commission compares the competitive conditions that would result from the notified merger with the conditions that would have prevailed without the merger.<sup>90</sup> In order to determine whether the merger would cause a significant change in market conditions, the Commission is therefore required to conduct a prospective analysis, in which it has to compare the respective prospects for competition in the presence and in the absence of the merger.

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<sup>83</sup> There are no vertically affected markets. Neither party produces or sells a product that is vertically upstream or downstream from products supplied by the other party.

<sup>84</sup> OJ C265, 18.10.2008, p.6.

<sup>85</sup> Horizontal Guidelines, paragraph 24.

<sup>86</sup> T-342/07 *Ryanair Holdings v Commission*, judgment of 6 July 2010, not yet published, para.250.

<sup>87</sup> Horizontal Guidelines, paragraph 26.

<sup>88</sup> Horizontal Guidelines, paragraph 26.

<sup>89</sup> Horizontal Guidelines, paragraph 37.

<sup>90</sup> Horizontal Guidelines, paragraph 9.

- (128) Taking into account these factors and for the reasons explained in Section 6.3, the Commission concludes that for a number of markets in the trauma areas the proposed transaction will result in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the merged entity.
- (129) In the respective product markets in the field of trauma devices in Austria, Belgium, the Czech Republic, Denmark, Estonia, France, Germany, Latvia, Luxembourg, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom, the proposed transaction would eliminate the constraint exerted by J&J on Synthes strengthens Synthes' leading position but in some instances also vice versa (namely in some instances the proposed transaction would eliminate the constraint exerted by Synthes on J&J thereby strengthening J&J's position)<sup>91</sup>. The merged entity would consequently have increased market power and the ability to increase prices. In the markets where the market shares to date are already very high and where the increment brought by J&J is either significant or small but leading to a creation of a market structure close to a monopoly, the transaction would result in a significant change in the market structure that would bring the merged entity into a position to act independently of competitors and would enable it to increase prices.

#### 6.1.1.2. Coordinated effects

- (130) A merger in a concentrated market may significantly impede effective competition through the creation or a strengthening of a collective dominant position because it increases the likelihood that firms are able to coordinate their behaviour in this way and raise prices, even without entering into an agreement or resorting to a concerted practice within the meaning of Article 101 of the Treaty ("coordinated effects").<sup>92</sup>
- (131) According to the Horizontal Guidelines, coordination is more likely to emerge in markets where it is relatively simple to reach a common understanding on the terms of coordination.<sup>93</sup> In addition, three conditions are necessary for coordination to be sustainable. First, the coordinating firms must be able to monitor to a sufficient degree whether the terms of coordination are being adhered to. Second, discipline requires that there is some form of deterrent mechanism that can be activated if deviation is detected. Third, reactions of outsiders, such as current and future competitors not participating in coordination as well as customers, could not be able to jeopardise the results expected from coordination
- (132) As will be discussed in Section 6.4.5 in more detail, the risk of coordinated effects resulting from the proposed transaction can be excluded.

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<sup>91</sup> This holds for six markets, being anatomic wrist plates in Norway, Portugal and the United Kingdom and (cancellous) cannulated screws in Greece, Slovakia and the United Kingdom.

<sup>92</sup> Horizontal merger guidelines, paragraph 39.

<sup>93</sup> Non-horizontal merger guidelines, paragraph 41.

### 6.1.1.3. Conglomerate effects

(133) Conglomerate effects may significantly impede effective competition, where a merger could result in foreclosure so that actual or potential rivals' access to markets is hampered and where the combination of products may confer on the merged entity the ability and incentive to leverage a strong market position from one market to another by means of tying and bundling or other exclusionary practices.<sup>94</sup> As will be discussed in Section 6.3.4 and 6.4.6 in more detail, the risk of conglomerate effects resulting from the proposed transaction can be excluded.

### 6.1.2. Market reconstruction in Phase 2

(134) The Notifying Party provided sales volumes and market share data for relatively broad market segmentations for the period 2008 - 2010. This information was established on the basis of actual sales of the parties, market reports (available only for a limited number of countries and products) and the parties' estimates.

(135) Estimates were in particular necessary for areas for which market reports and data were not available, as for some product categories or certain countries<sup>95</sup>. The parties submit that for such cases they had to rely on their experience and make various assumptions based on internal best estimates. These assumptions may have an "averaging" effect, thereby underestimating high and overestimating low market shares in countries/product categories which are not covered by the market reports. The parties were also not able to provide market share data on the level of various sub-segments which in some cases could constitute the relevant product markets.

(136) Due to the weaknesses in the provided market data the Commission decided to reconstruct market shares in the product segments of trauma devices, spine, shoulder and CMF devices (more than 50 product markets in 30 countries) in order to have market data on narrower segments and to verify the accuracy of the parties' estimates as the market data provided by the parties did not seem reliable in some instances<sup>96</sup>.

(137) The market reconstruction was conducted on the basis of standard template sheets (one per category: Spine, Trauma, Shoulder, CMF) collecting the net retail sales of the parties and of competitors (manufacturers and distributors) in all 30 Contracting Parties to the EEA Agreement and in all relevant product sub-

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<sup>94</sup> Non-horizontal merger guidelines, paragraph 93.

<sup>95</sup> Market reports are published by Eucomed, iData, MRG. In addition to market share data the reports provide a comprehensive description of the markets and a significant amount of qualitative information. The reports provide market share data only for a limited number of EEA countries (about 60%) and product categories (about 70%) and do not cover all major market players. In particular, it does not cover the competitors which have significant market shares in some niche markets.

<sup>96</sup> For example, the Notifying Party has attributed sales to a certain competitor in a certain product category in a certain Member State for which that competitor claims actually not to generate sales or a competitor has declared not to possess of a whole product category for which the Notifying Party has indicated that competitor as one of the main competitors in a number of Member States.

categories (32 in Spine, 28 in Trauma, 3 in Shoulders and 3 in CMF) for the year 2010. In order to collect the net retail sales the Commission sent standard template sheets to the parties and to competitors. About 90 competitors replied to the Commission's request. These replies include all companies mentioned by the parties as their main competitors in the EEA.

- (138) Following the issue of the SO, the Commission decided to widen the time period for the market reconstruction in the area of spine as there were indications of recent entrants. In these more innovative product markets it was important to assess whether and to what extent these companies were able to gain market shares and to see whether the position of the parties had been affected. Consequently the market was reconstructed not only for the year prior to the notification but also for the preceding year, 2009, and the subsequent year, 2011 for those spine markets for which the Commission concluded in the SO on a preliminary basis that the proposed transaction would significantly impede effective competition. Since the parties with the exception of the markets for spine devices, did not claim that recent entrants have been changing the competitive landscape in the other segments, and the market shares of 2010 can thus be considered as providing a sufficiently reliable picture of the competitive situation in these other segments, and in order not to put an unnecessary burden on the market players, a reconstruction of market shares for 2009 and 2011 was not carried out for trauma, shoulder implants and CMF.

#### 6.1.3. *Classification of markets*

- (139) In line with a recent medical device case<sup>97</sup>, the affected markets were grouped in three categories. These groupings are:
- Group 1: The parties' joint market share exceeds 35% and the increment exceeds 1%.
  - Group 2: The parties' joint market share exceeds 35% but the increment is less than 1%.
  - Group 3: The parties' joint market share is between 15% and 35%.
- (140) *Prima facie*, competition concerns would be more apparent in group 1 markets than in the other two categories. Also, the market investigation has not revealed any indications pointing at possible competition concerns in group 2 or 3 markets. The Commission has therefore focused its investigation (and its assessment in this decision) in particular on affected markets falling into group 1 ("group 1 markets").

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<sup>97</sup> Commission decision of 18 August in Case No COMP/M.6293 –Thermo Fisher/Phadia.



## 6.2. General characteristics of the markets

### 6.2.1. Overview

- (141) The products concerned by this decision are orthopaedic medical devices intended to, for example, heal trauma-related fractures, correct spine deformities or treat tumour-related diseases. Many of the devices are implantable and are designed to remain in the patients' body after surgery. Some are innovative and need complex implantation techniques. This requires the clinicians handling the devices to undergo specific training in order to become familiar with the devices' characteristics and learn the specific surgical technique.
- (142) Following the phase II investigation, the Commission has concluded that the different markets, such as spine, shoulder, CMF and trauma have different characteristics and that the parties' and their competitors' position also differ. This will be discussed in Sections 6.3, 6.4, 6.5, 6.6 and 6.7.
- (143) Compared to the spine market, the trauma market overall is more consolidated and mature. More specifically the trauma and spine markets differ in terms of innovation, market structure, new entries and the role of the AO (Arbeitsgemeinschaft für Osteosynthesefragen) Foundation ("AOF"). Unlike in the spine area, the prestige and camaraderie between trauma surgeons and the AOF creates a strong preference for the AOF-certified Synthes' products.
- (144) In the field of trauma, the level of innovation is lower than in the field of spine as regards many product segments. The markets are relatively mature as the main categories of trauma devices (namely, plating systems, IM nails, compression hip screws, pins and wires) were already available 50 years ago. Since then, trauma companies have mainly focused on improving existing devices. Most of the innovations in trauma markets in the last decade relate to anatomic plating systems. Other products, such as IM nails have become less popular for certain fractures due to the use of anatomic plates. Non-anatomic plating systems and ancillaries such as pins and wires are quite mature products and often commoditised.
- (145) There have been fewer and significantly less meaningful entries by new companies in trauma than in spine markets. In spine, there has been a strong entry in the last few years. New competitors such as K2M, Inc ("K2M") or Nuvasive, Inc ("Nuvasive") have achieved in some markets from [5-10]\*%<sup>98</sup> to [10-20]\*% market share after one or two years. Contrary to that, no significant entry took place in trauma in the same period. Consequently, market shares are in general quite stable in trauma markets.

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<sup>98</sup> This Decision only states ranges of market shares suitable for protecting business secrets as laid down in the Commission's best practice guidelines, see [http://ec.europa.eu/competition/mergers/legislation/market\\_share\\_ranges.pdf](http://ec.europa.eu/competition/mergers/legislation/market_share_ranges.pdf)

### 6.2.2. Importance of sale forces

- (146) The market investigation has confirmed the importance of having a dedicated sales force comprised of sales representatives or specialized distributors in the respective country<sup>99</sup>. Even though hospitals (or hospital purchasing groups) are a well-defined, homogenous customer group and their needs in orthopaedic devices are driven by continuous restocking, a strong sales force is important: Orthopaedic devices are highly specialized products. The need for training is greatest for new products, but also for incremental changes of existing product lines, surgeons and hospital staff need introduction or training. Sales representatives visit the hospitals frequently (sometimes on a weekly basis) and maintain a very close relationship with the staff.<sup>100</sup> Important sales-related services are the advice to surgeons on the choice of the devices to be used and assistance during surgeries. In smaller countries, the manufacturers tend to rely on specialized distributors.<sup>101</sup> The importance of a strong sales force is also confirmed by the Profit & Loss accounts of Synthes<sup>102</sup>: The major cost block is linked to sales and sales related services (about [...]\*)%. The access to an effective (direct) sales force appears to be a key element of success in this business. Synthes and J&J (as well as many other competitors) mainly base their sales efforts on a direct and highly qualified own sales force or distributors (those mostly in smaller countries), which have direct contact with the surgeons.<sup>103</sup>
- (147) The necessity of qualified sales representatives, be it an own sales force or a qualified distributor, is of high importance in particular for expansion into new Member States. The parties submit that geographical expansion works first through distributors. This is confirmed by the market investigation.
- (148) Nonetheless, less than one third of the responding distributors said that there are many qualified distributors available in the market, while the rest states that the available distributors are not very qualified or that it will take considerable time to train the distributors' sales force on the devices of the new supplier.<sup>104</sup> For trauma products a significant majority of the competitors submits that there are considerable difficulties in finding a qualified new distributor for a new country.<sup>105</sup> The distributors need relevant expertise which is highly specialized, a proven financial record and have to comply with regulatory guidelines regarding

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<sup>99</sup> See replies to question 17.6 of Q17- Questionnaire to competitors (Trauma) 5 respondents indicated that this constitutes no significant or just a moderate barrier to entry whilst 13 perceived it as being an important or crucial barrier to entry.

<sup>100</sup> Minutes of the telephone interview with Mr Rupinder [ID 5215]\*.

<sup>101</sup> See replies to question 26 of Q17 - questionnaire to competitors (Trauma).

<sup>102</sup> Profit and loss analysis carried out on the basis of Synthes audited accounts which are publicly available on Synthes' website.

<sup>103</sup> Based on the information provided in the Form CO (table 148, at p. 291), both J&J and Synthes are directly present in [...]\*. J&J is also directly present in [...]\*. Synthes has a direct sales force in [...]\*. In other countries the parties are present via distributors, i.e. Synthes in [...]\* and J&J in [...]\*.

<sup>104</sup> See replies to question 19 of Q25 – Questionnaire to distributors.

<sup>105</sup> See replies to question 29 of Q17 – questionnaire to competitors (trauma): 10 confirming replies, 5 disagreeing.

the distribution of medical devices. Therefore, new geographical entries without their own sales personnel might be more difficult than has been presented by the parties. Although the market investigation has confirmed that the entry of new competitors, in particular in the spine device market, is possible, be it through established distributors or (in particular in larger countries) through cross-hiring of sales representatives<sup>106</sup>, in the trauma device market such entries take place on a limited scale.

- (149) In sum, having a strong sales force or being able to rely on specialized distributors is a competitive advantage.

### 6.2.3. *Hospital purchasing patterns*

- (150) The medical devices of concerned by this Decision are sourced by hospitals and not by the patient as the "ultimate end user". Within the hospitals the purchasing departments buy the devices and the surgeons often have considerable influence which devices are bought. The vast majority of the responding hospitals source their supplies through open tenders or informal tenders/price inquiries, and typically award framework contracts to their chosen suppliers.<sup>107</sup> Price is only one of several criteria for the purchase decision or award of the contract. Service, training, the support provided by the suppliers' sales personnel, quality and surgeons' preference, are taken into account<sup>108</sup>. The relevance of these criteria differs depending on the products concerned. For example, while a surgeon's preference and loyalty seems to play a more important role, in particular for trauma devices<sup>109</sup>, for CMF devices the preference of surgeons seems of little importance and these devices are mostly sourced by the hospital purchasing department without further input from surgeons.<sup>110</sup>
- (151) While in general hospitals source the majority of their supply through framework contracts, they still purchase specific products from other suppliers and the award of a framework contract does not guarantee a certain volume of sales. This was confirmed by the market investigation as the clear majority of responding hospitals source their devices from several suppliers, mostly from two to five for a particular area such as trauma, spine or shoulder.<sup>111</sup> This is due to the fact that: (1) many suppliers do not offer a full product range, (2) the specifications or quality of products differ within the suppliers' portfolios, (3) different operating surgeons within one hospital have different preferences, (4) hospitals do not want

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<sup>106</sup> Minutes of meeting with Mr. Schaefer (Head of Purchasing at Einkaufsgemeinschaft Kommunaler Krankenhäuser) on 30 November 2011 [ID 5830]\*.

<sup>107</sup> See replies to question 3 column 3 of Q18 - questionnaire to customers (Hospitals).

<sup>108</sup> See replies to question 3.6 of Q18 - questionnaire to customers (Hospitals).

<sup>109</sup> See replies to question 3 column 6 of Q18- questionnaire to customers (hospitals), replies to question 4 of Q23 – Questionnaire to Key Opinion Leaders - Trauma, Minutes of the meeting with Mr Schaefer (Head of Purchasing at Einkaufsgemeinschaft Kommunaler Krankenhäuser) on 30 November 2011 [ID 5830]\*, Minutes of the telephone interview with Mr Rupinder (Portfolio Manager of Joint Procurement Services, Guy and St. Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust) on 9 December 2011, [ID 5215]\*.

<sup>110</sup> See replies to question 3, 4 and 75 of Q18 – Questionnaire to customers (Hospitals).

<sup>111</sup> See replies to question 4 column 2 and question 23 of Q18 - questionnaire to customers (hospitals).

to rely on only one firm to ensure continuous supply, and (5) hospitals seek to get more competitive offers from the suppliers.<sup>112</sup>

- (152) Although the majority of responding hospitals considered that they are able to exert some buying power over the prices and/or services offered by the suppliers<sup>113</sup> and although most hospitals confirmed that they would be able to change supplier<sup>114</sup>, switching of suppliers does not actually appear to happen frequently and easily.<sup>115</sup> As regards the reasons why they would not switch (even in response to a 10% price increase), hospitals mentioned the need to retrain staff, surgeons' preferences or reluctance to switch, and the service provided by the manufacturer.<sup>116</sup>
- (153) In some countries (for example Austria, Germany, Italy, Portugal, Sweden and the United Kingdom) some hospitals source their supplies through purchasing groups.<sup>117</sup> The size of the purchasing groups differs widely from country to country and can comprise around 4 to 10 hospitals, often in one region of a Member State. Sometimes purchasing groups can represent 80 to 100 hospitals<sup>118</sup> and even up to 400 hospitals (for example, the NHS supply chain in the United Kingdom)<sup>119</sup>. The purchasing groups negotiate framework contracts with different suppliers. In their own view and the view of suppliers they are able to influence prices and other important conditions of supply.<sup>120</sup> However, since purchasing groups often negotiate framework contracts with a host of suppliers and the individual hospitals still choose the products, the role of surgeons in the procurement process remains very important. In addition, since the framework contracts generally do not contain a volume commitment, hospitals do not necessarily receive the best prices compared to contracts or tender in which they commit to a certain volume or to exclusivity with a certain supplier.

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<sup>112</sup> See replies to question 4 column 5 of Q18 - questionnaire to customers (hospitals).

<sup>113</sup> See replies to question 5 column 2 of Q18 - questionnaire to customers (hospitals).

<sup>114</sup> See replies to question 5 column 3 of Q18 - questionnaire to customers (hospitals).

<sup>115</sup> See replies to question 4 to Q18 - questionnaire to customers (hospitals) on supply structure – switching of suppliers in the last three years; replies to questions 13, 17, 43, 54, 85, 111, 132 of Q28 - Phase II questionnaire to customers (hospitals).

<sup>116</sup> See replies to questions 4, 39, 51, 63, 81 of Q 28 - Phase II questionnaire to customers.

<sup>117</sup> See replies to question 5 column 1 of Q18 - questionnaire to customers (hospitals). In other countries, such as the Netherlands, this seems less common, see for example the Sector Study Medical Devices carried out by ECORYS on behalf of the Netherlands Competition authority and the Dutch Ministry of Health, Welfare and Sports, 1 December 2011.

<sup>118</sup> In Germany and Austria for example the EKK (Einkaufsgemeinschaft Kommunaler Krankenhäuser) which represents around 80 hospitals, see minutes of meeting with Mr Schaefer (Head of Purchasing at Einkaufsgemeinschaft Kommunaler Krankenhäuser) on 30 November 2011 [ID 5830]\*.

<sup>119</sup> Minutes of the telephone interview with Mr Fairlamb (NHS Supply Chain Manager) of 8 December 2011 [ID 5931]\*,

<sup>120</sup> See replies to question 30 of Q17 – questionnaire to competitors (Trauma): 9 replies state that purchasing groups have significant influence whilst 7 state that they have not. Minutes of the meeting with Mr Schaefer (Head of Purchasing at Einkaufsgemeinschaft Kommunaler Krankenhäuser) on 30 November 2011 [ID 5830]\*, Minutes of the telephone interview with Mr Fairlamb (NHS Supply Chain Manager) of 8 December 2011 [ID 5931]\*, replies to question 5 of Q24 - Questionnaire to purchasing groups.

- (154) As a result, in spite of the fact that hospitals' purchasing departments and hospitals' purchasing groups have the ability to influence prices during the negotiation processes, such influence is limited in cases where they cannot react to price increases by changing supplier in a sufficiently short time due to surgeons' preferences and their reluctance to switch to the devices of a different manufacturer.

#### 6.2.4. *Role of regulatory approvals and reimbursement systems*

- (155) In order to be sold on the EEA territory orthopaedic medical devices must be manufactured according to the ISO 13485<sup>121</sup> and ISO 9001<sup>122</sup> standards (referring to medical devices, quality management systems and requirements for regulatory purposes). Furthermore, they have to obtain a CE marking<sup>123</sup> which provides a presumption that the device complies with the essential requirements of the MDD and enables it to freely circulate within the EEA territory.
- (156) The timelines for complying with these requirements depend on the medical device (its risk level, its complexity and whether it is a completely new product or rather an enhancement to an existing product). According to the parties' reply to the SO it takes on average [1-12]\* months to obtain regulatory approval for spine devices. While this may be the average duration for the regulatory approval process only, the replies to the market investigation indicated that in the case of innovative or complex surgical devices this might take longer.<sup>124</sup> More specifically, the replies indicated the following timeline: mechanical testing takes about two to three months, clinical trials and consultation can take from three to up to 24 months in the case of new devices, the design validation and elaborating the technical files takes another two months and finally the CE approval itself takes about one month. Adding these time periods together it can take up to 30 months before a new product can be sold in the EEA.
- (157) Therefore, the need for regulatory approval is only a barrier for a competitor entering the EEA with a new product, which does not yet have the CE marking. Once a product has obtained the CE marking, it can circulate freely in the EEA territory.
- (158) Unlike in pharmaceutical markets, reimbursement requirements do not pose a significant barrier to entry due to prevalent "payment-per-case" reimbursement systems (also referred to as Diagnosis Related Groups system). Under these

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<sup>121</sup> ISO 13485 is an ISO standard, published in 2003, that represents the requirements for a comprehensive management system for the design and manufacture of medical devices.

<sup>122</sup> ISO 9001 belongs to the ISO 9000-family of standards related to quality management systems and designed to help organizations ensure that they meet the needs of customers and other stakeholders. It deals with the requirements that organizations wishing to meet the standard have to fulfil.

<sup>123</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD) specifies general requirements that the product has to meet in order for the manufacturer to affix the CE marking. These are the so-called Essential Requirements that are listed in Annex I to the MDD. Compliance with the essential requirements must be demonstrated by a clinical evaluation in accordance with Annex X to Directive 93/42/EEC.

<sup>124</sup> See replies to question 14 of Q17 – questionnaire to competitors (Trauma).

systems hospitals receive a lump sum payment per admission according to a tariff based on the category of diagnosis, and suppliers do not typically need to apply separately for reimbursement status. The only exceptions are Belgium, the Czech Republic, and France, where suppliers are required to apply for reimbursement status where the additional cost and delays for this have to be taken into account when bringing a new device to the market.

#### 6.2.5. *Full product range*

- (159) The market investigation showed that the ability to offer a full range of products is an advantage but not a significant barrier to entry or expansion as customers in general have a preference to buy the full product line due to ease of handling, restocking and the availability of range discounts.<sup>125</sup> In trauma devices, the transaction would slightly strengthen the already very strong portfolio of Synthes, but other companies, such as S&N and Stryker Orthopaedics ("Stryker") also have a broad range of products. In spine devices, the combination of the portfolio of Synthes and J&J would clearly strengthen the merged entity and would allow it to compete more effectively on the market. However, in some areas of spine devices such as fusion cages, VCF and non-fusion devices, there is also strong evidence that companies are successful in the market without having a full-product range.

### **6.3. Trauma - compatibility with the internal market**

#### 6.3.1. *The parties' view*

- (160) The Notifying Party submits that J&J is not a close competitor of Synthes and, consequently, that the proposed transaction will not remove an important competitive constraint as Synthes' closest competitors are in particular Smith & Nephew plc ("Smith & Nephew"), Stryker and Zimmer.
- (161) Furthermore, the Notifying Party submits that there are numerous players such as Acumed LLC ("Acumed"), Aesculap Inc ("Aesculap"), Biomet Orthopedics, LLC ("Biomet"), Königsee Implantate und Instrumente zur Osteosynthese GmbH ("Königsee") and Orthofix Holdings Inc ("Orthofix") which aggressively compete with Synthes and J&J. The Notifying Party claims that, besides there being enough competition, the trauma area is not characterised by barriers to entry, expansion and repositioning. Therefore, the ability of rivals to pursue competitive opportunities that they perceive in any trauma market will not diminish as a result of this transaction.

#### 6.3.2. *Market characteristics specific to trauma*

##### 6.3.2.1. General observations

- (162) The trauma area overall appears to be more consolidated and mature than the spine area (See Section 6.2). As confirmed by the parties, there have been fewer

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<sup>125</sup> See replies to question 31.1 of Q18 - questionnaire to customers (hospitals).

new entrants in recent times and the level of innovation is lower in most product segments. Accordingly market shares are more informative for the purposes of carrying out the competitive assessment of the proposed transaction in the area of trauma than in the area of spine.

- (163) On the basis of the market reconstruction there are 112 group 1 markets in trauma (on the basis that markets within the different segments are defined according to anatomies, for example plating systems for the ankle, plating systems for the wrist, plating systems for the elbow, etc.). These 112 group 1 markets are spread over 23 countries.

#### 6.3.2.2. Market Structure and competitors

- (164) The markets are highly concentrated. Synthes is very strong in the markets for trauma devices with market shares in the different sub-segments of up to [80-90]\*%. Its market share for plating systems (where most critical markets arise) is on an aggregate EEA-wide basis around [50-60]\*%. Synthes also has the largest product portfolio and the widest geographical footprint. J&J is one of several competitors (on an aggregate EEA-wide basis number four or five in the market) and has in many instances moderate market shares (in most countries and segments below 5%). However, in some product segments (such as distal radius plating systems and cannulated screws) and in some countries such as the United Kingdom, Spain and Portugal the increment added by J&J is in general higher.
- (165) Apart from J&J there are four competitors which have a similar product portfolio and geographic reach with comparable market shares overall, ranging from [0-5]\*% to [40-50]\*% in individual segments. These are Stryker, Smith & Nephew, Zimmer and Königsee
- (166) Stryker is the second biggest competitor in the European trauma device market.<sup>126</sup> The company was a pioneer in the IM nail segment and in IM hip nails and is still the number one provider of IM nails and IM hip nails in most of the EEA countries. The company holds a particularly strong position in the French and German IM nail markets due to its Grosse & Kempf IM nails, which have an established history in these markets. In plating systems, Stryker is the number two in most EEA countries and number three in compression hip screws and in cannulated screws.
- (167) Smith & Nephew<sup>127</sup> is among the five leading trauma companies in the EEA. It is particularly strong in IM nails, IM hip screws, compression hip screws and external fixation where it is among the top 3 in the market. Smith & Nephew is based in the United Kingdom and has a relatively strong position there – it is the second leading competitor in the overall UK trauma device market. Its product range covers the Peri-Loc plating system (designed for both the upper and lower extremities) and the Trigen IM nail. Smith & Nephew provides medical education through KLEOS, a global platform for knowledge sharing among orthopaedic

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<sup>126</sup> Millenium Research Group "European markets for trauma devices 2010", p. 35.

<sup>127</sup> Millenium Research Group "European markets for trauma devices 2010", p. 34.

health care professionals which offers educational courses and services structured around topics in orthopaedic surgery. The company also recently launched its training academy, partnered with the Academy for Medical Training and Simulation in Lucerne, Switzerland.

- (168) Zimmer's position in the European market for trauma devices is comparable to J&J's, particularly due to its plate and screw segment.<sup>128</sup> The company's product portfolio covers the periarticular, precontoured plates and the Versa Fix II plating system, which is available in several sizes, tube/plate angles, and screw hole configurations. The company earns only moderate revenues in IM nail and cannulated screws. However, its presence in all internal fixation device segments demonstrates the company's focus on maintaining a broad product portfolio. In 2010, the company further expanded its product offering in the IM nail segment by announcing the launch of a new IM Nail System.<sup>129</sup>
- (169) Königsee is the smallest of the set of comparable competitors. Its market share is on an aggregate level lower than the market shares of the abovementioned four competitors. The overall price level of its products is lower. Furthermore, Königsee, though offering a broad product range, focuses on plating systems, where it achieves a market share of around 5% on an EEA-wide basis, making it the third supplier after Synthes and Stryker.
- (170) In addition to these larger companies there are smaller regional players which focus on certain Member States or groups of Member States, for example ChM Sp. z o.o. ("ChM") and Medgal ("Medgal") focusing on Poland; Sanatmetal Ltd ("Sanatmetal"), Medimetal Kft ("Medimetal") and Medin a.s. ("Medin") focusing on Hungary, Slovakia and Czech Republic; Orthofix, Hofer GmbH & Co KG ("Hofer"), Axomed GmbH ("Axomed") and I.T.S. GmbH ("ITS") focusing on Germany and Austria; Small Bone Innovation Inc. ("Small Bone Innovation") in France and Lima/Hitmedica and Gruppo Impianti s.r.l. ("Bioimpianti") focusing on Italy. In addition to the regional players there are smaller 'niche' players which focus on particular segments, such as Medartis AG ("Medartis") or Litos GmbH ("Litos") focusing on anatomic plating systems for particular anatomies. The Commission concludes, based on the results of the market investigation, that these competitors can exercise sufficient competitive constraint on the parties in their region or for their product segment and that hospitals have them as their main or secondary supplier<sup>130</sup>. However, in the markets where the proposed transaction leads to a significant impediment to effective competition these other competitors are either not present or achieve very limited sales.
- (171) As regards closeness of competition the Commission concludes, based on the results of the market investigation, that in general the parties are not seen as each

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<sup>128</sup> Millenium Research Group "European markets for trauma devices 2010", p. 36.

<sup>129</sup> The so-called Natural Nail Cephalomedullary Nail System which features an anatomically contoured nail, providing fixation to help restore the shape and function of the femur.

<sup>130</sup> See replies to question 23 of Q18 – Questionnaire to customers (hospitals) and questions 147.1, 147.2, 151.1, 151.2, 155, 156, 160.1, 160.2, 164.1, 164.2 of Q28 – Phase II questionnaire to customers (Hospitals).



other's closest competitor and that Stryker is seen as the closest competitor to Synthes, while J&J, Smith & Nephew, or Zimmer are seen as close competitors, but not the closest.<sup>131</sup> However, in some countries, such as Portugal, Spain and the United Kingdom, where J&J maintains a strong sales force or, where J&J maintains a strong sales force or in the United Kingdom, has a historically strong foothold, J&J was more often mentioned as the closest competitor to Synthes and as exercising a high competitive constraint on Synthes.<sup>132</sup>

### 6.3.2.3. Barriers to entry/expansion

#### High degree of surgeon's loyalty due to training and education

- (172) The Commission concludes, based on the results of the market investigation that significant barriers to entry exist in the trauma area. The main barriers to entry and/ or expansion are the reputation of the brand, and the need to continuously provide training and education to the surgeons<sup>133</sup>, which leads to a high degree of loyalty of surgeons in relation to a certain supplier.<sup>134</sup> There is a significant tendency for surgeons to develop a preference for the devices of a given manufacturer and to remain loyal to the same supplier. Specifically, as surgeons seek to decrease the risks involved in a procedure, they prefer to use the devices they know well rather than switching to new and unfamiliar devices Surgeons typically receive training with implants early on in their careers, and often remain loyal to the same supplier. Any switching to a different supplier thus involves retraining of surgeons and other medical staff in the specific new devices.
- (173) Therefore, the need for manufacturers to offer training and continuous education of surgeons in their devices is a specific feature of medical device markets. Training and education capabilities of the manufacturers are key assets to access the market, given that they are crucial to overcome surgeon's reluctance to switch to a new device, and to maintain surgeon's loyalty to the products of a given manufacturer. Training may be provided in different ways: at specialised academies set up by manufacturers for this purpose, at workshops run by scientific organisations or by the manufacturers themselves, through training organisations contracted by the manufacturers and at scientific congresses and symposia by independent organisations where manufacturers may present their

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<sup>131</sup> See replies to question 33 and 34 of Q18 - questionnaire to customers (hospitals), asking for the closest competitor to J&J and Synthes respectively. Parameters for the assessment of closeness of competition were amongst others price, quality, scope and service.

<sup>132</sup> See replies to question 33 and 34 of Q18 - questionnaire to customers (hospitals), asking for the closest competitor to J&J and Synthes respectively. Parameters for the assessment of closeness of competition were amongst price, quality and service; reply of Stryker to question 8.1 to Q27 – Phase II questionnaire to competitors (trauma) [ID 3683]\*.

<sup>133</sup> See for example replies of Zimmer, Smith & Nephew and Orthofix to question 17.8 in Q17 - questionnaire to competitors (trauma) [ID 1521, 1770, 1498]\*. Bernstein Research "JNJ, Synthes, what could Synthes' relationship with the AO foundation bring to Johnson & Johnson?"

<sup>134</sup> See replies to question 17.3 (9 stated that reputation is an insignificant or moderate barriers whilst 12 considered them being considerable or even crucial) and 17.4 (9 stated that brand loyalty is an insignificant or moderate barrier whilst 9 considered them being considerable or even crucial) of Q17 – questionnaire to competitors (trauma).

latest developments. Training is also provided through demonstrations provided by medical sales representatives as part of the visits to hospitals.

- (174) Changing to a new device may imply some switching costs for the surgeons or their employers in terms of the time needed to get familiar with a new device and fees for training. Therefore, there may be substantial economies of scale for surgeons in using the same product or products of the same product range, although this needs to be balanced against the need for surgeons to offer the best clinical care which may involve switching to alternative devices that offer certain advantages for example, devices that are less invasive or offer better quality of life for the patient. Training costs may also be borne by the manufacturers (for example on-the-job training of surgeons by sales representatives or through sponsoring participation of surgeons in medical congresses or training courses offered by organisations that specialize in research and development and the continuous training and education of orthopaedic surgeons). To the extent that the cost of training is borne by suppliers of medical devices this can be considered as a barrier to entry.
- (175) Synthes is particularly strong in the training of surgeons in the trauma area due to its long-standing relationship with the AOF.<sup>135</sup> The AOF is a primarily surgeon-led, not-for-profit organization based in Switzerland that is formally independent from any commercial company. It was set up in 1958 for the development of implants and instruments for trauma fixation and the teaching of osteosynthesis techniques. The founding principles of the AOF include research and development in products and techniques and continuous education and training of surgeons in new surgical procedures in the fields of trauma, spine, cranio-maxillo-facial devices and veterinary.<sup>136</sup> The AOF fosters an extensive network of surgeons, operating room personnel and scientists. The AOF attracts key opinion leaders, membership in the AOF and participation in the seminars organised by it is viewed as very prestigious by surgeons.<sup>137</sup> The prestige and camaraderie

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<sup>135</sup> See replies from both competitors and customers: For example, replies to question 38 of Q17 – questionnaire to competitors (Trauma): 19 replies emphasised the AOF's role in training and education, 12 its role in R&D, 17 its prestige among surgeons, 15 its platform function for sharing professional experiences whilst the statement "it has a somewhat important role though it should not be overestimated" was only ticked 3 times. No competitor thought that the AOF does not play an important role in trauma. Regarding hospitals see replies to question 40 of Q24 – questionnaire to purchasing groups, replies to question 40 of Q18 – questionnaire to customers (hospitals): Out of 122 replies which did not choose "I do not know", the relative majority of 53 respondents thought this would best describe the role of the AOF, 18 answered that the AOF contributes greatly to research and innovation, 9 answered that it is viewed as being a very prestigious institution, to which every self-respecting trauma surgeon wants to belong, and 18 answered that it organizes events serving as a basis for sharing professional experiences. Only 6 answered that the AOF has a somewhat important role which should, however not be overestimated whilst no customer stated that the AOF does not play an important role in trauma. Replies to question 10 of Q23 - questionnaire to KOLs; see also minutes of the conference call with representative of Aesculap (Dr. van Lackum, Mr Schelkle, Mr Güttler) on 4 November 2011 [ID 2447]\*.

<sup>136</sup> Bernstein Research, "JNJ, Synthes, what could Synthes' relationship with the AO foundation bring to Johnson & Johnson?"

<sup>137</sup> See AO Foundation, submission of 20.1.2011.

associated with the AOF further creates a strong preference for the AOF-certified Synthes' products.

- (176) The AOF emphasizes that the training it provides is different from similar organisations because the main emphasis is given to the clinical needs of surgeons. The AOF decides autonomously which courses it offers and their curriculum. During the training sessions, different techniques and devices of different manufacturers are explained and presented. However, during the practical sessions only Synthes' devices are used.<sup>138</sup> The AOF cooperates closely with Synthes on the basis of a cooperation agreement on the basis of a cooperation agreement<sup>139</sup> and the AOF is funded by Synthes to a [...]\*.<sup>140</sup>
- (177) Synthes itself recognizes that "much of the success of our company [Synthes]\* would not be possible without the relationship we have with the AO Foundation, our partner in education for surgeons and operating room personnel."<sup>141</sup>
- (178) In the field of trauma, the AOF has the largest training capacity in the market. In 2011 108 courses took place in 25 EEA countries which were attended by more than [5500-6500]\* persons.<sup>142</sup> In addition there were [1000-2000]\* surgeons trained by Synthes itself (apart from the training through the AOF).<sup>143</sup> The market investigation showed that with respect to trauma, AOF-trained surgeons have a strong preference for working with Synthes products.<sup>144</sup> Synthes and the AOF's training capacities compare to [500-1500]\* surgeons trained by J&J at a European level, approximately [1100 to 1300]\*<sup>145</sup> trauma surgeons across the EEA trained by Smith & Nephew and approximately [1000 to 2000]\* trauma surgeons trained by Stryker in 2011. Other trauma associations are, for example, the Orthopaedic Trauma Association (OTA) whose mission is to promote excellence in care for the injured patient, through provision of scientific forums and support of musculoskeletal research and education of orthopaedic surgeons and the public or the American Association for the Surgery of Trauma (AAST) dedicated to the advancement of knowledge in treating and preventing traumatic injuries. Those entities are, however rather targeting the US. Aside from that there is the UK- based International Society for Fracture Repair (I.S.F.R.) which is an organisation dedicated to the advancement and interchange of science of fracture repair and its application to improvement of patient care. The Society

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<sup>138</sup> See minutes of the meeting with representative of the AO Foundation, [...] on 1 December 2011 [ID 5932]\*.

<sup>139</sup> [...]\*

<sup>140</sup> [...]\*

<sup>141</sup> See Synthes' Annual Reports 2010, Letter to shareholders, [ID 7494]\*.

<sup>142</sup> See email of [...] of 20 January 2012 [ID 6446 and 6445]\*.

<sup>143</sup> Figures on a country level were not available as according to the Notifying Party [...] Trauma suppliers offer several kinds of trainings. Whilst some assigned trainers to specific countries, others rely on a pool of trainers or KOLs who provide training as requested. Finally, there are suppliers who have established own training academies or who outsourced their training to independent formation centres. Some combine different forms of training, others rely on one or two of them. See replies to question 15 of Q27- Phase II questionnaire to competitors (trauma).

<sup>144</sup> Replies to question 39 of Q17 - questionnaire to competitors (trauma).

<sup>145</sup> The numbers are stated in brackets due to confidentiality.

was founded in 1987 and today comprises some 200 members. The Society holds a number of different meeting activities (the I.S.F.R Conferences, the I.S.F.R Symposia and the I.S.F.R Workshops) for the interchange and advancement of science related to its mission. None of those bodies have exclusive relations with a trauma competitor as Synthes does with the AOF.

- (179) Some other competitors such as for example Zimmer, Aesculap or Smith & Nephew established their own training centres, for example, the Aesculap Academy. While some competitors try to replicate the link with a scientific organisation (e.g. Smith & Nephew provides medical education through KLEOS, a platform for knowledge sharing among orthopaedic health care professionals, which offers also courses, online literature, clinical and lecture videos, and has launched its training academy, partnered with the Academy for Medical Training and Simulation in Lucerne, Switzerland in 2010), the scale and reach of those organisations is much smaller than the AOF and since they are not independent from manufacturers they are not able to offer accredited/certified medical education courses.<sup>146</sup> In addition, their training, for example in the case of Smith & Nephew, is more focused on product specific training and less on general techniques. In the field of trauma the AOF is unique. Its scientific reputation has been maintained and unmatched since the late 1950s, as it is the organisation which "invented" plating systems for the treatment of fractures.
- (180) In addition to the large training capacity, surgeon loyalty to Synthes' products can also be explained by the fact that these products have been developed through the AOF and Synthes with the support of key opinion leaders with clinical needs in mind, and the fact that they have been carefully checked for usability and are reliable.<sup>147</sup> Regarding Research and Development, the AOF serves as a platform for new product development which satisfies the clinical needs of surgeons. In particular, the AOF has its own quality certification system ("TK system") which is exclusive to Synthes products.<sup>148</sup> In essence, AOF-affiliated surgeons decide which R&D will be carried out based on clinical needs, but Synthes also has a right to propose areas of clinical needs and ideas for product development and it has done so on a regular basis. [...]\*.<sup>149</sup> The AOF provides Synthes with clinical studies and evidence in both product development and marketing stages.<sup>150</sup> As part of the quality certification system all of the product developments then have to be tested and approved by a technical commission. The Commission regards Synthes' agreement with the AOF on product development as a substantial

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<sup>146</sup> In some countries, such as the United Kingdom, for a surgeon to attend a Continued Medical Education ("CME") event, i.e. if it has CME points, often the employer will allow them to attend as part of their study leave. If the course is not accredited and therefore doesn't have CME points, the surgeon is still able to attend, but may have to take the time off as part of his vacation time. Also if the course is not being 100% sponsored by the company he would have to pay any cost him/herself which might otherwise have been borne by the employer.

<sup>147</sup> See for example Bernstein Research: "JNJ, Synthes: What Could Synthes' Relationship With the AO Foundation Bring to Johnson & Johnson?".

<sup>148</sup> [...]\*

<sup>149</sup> [...]\*

<sup>150</sup> See minutes of the meeting with representative of the AO Foundation, [...]\* on 1 December 2011 [ID 5932]\*.

competitive advantage as it involves input from specialized expert groups comprised of highly reputed surgeons from all over the world. In the words of an industry report: "*The TK quality certification stands for high end efficacy and safety testing making that surgeons trust in Synthes spine and trauma products*".<sup>151</sup>

- (181) The proposed transaction reinforces the training capabilities of Synthes, which are already unmatched in terms of prestige in terms of training and product development through its relationship with the AOF. The Commission concludes that this is likely to make the entry and expansion of competitors even more difficult, thus constituting a barrier to entry or to expansion.
- (182) As mentioned in Section 6.2.2. the market investigation has confirmed the importance of having a dedicated own sales force or specialized distributors in the respective country<sup>152</sup>, since they perform to a large extent the on-the-job training for surgeons and theatre staff in case of the introduction of new products or changes to existing products and devices. They advise surgeons in the choice of devices to be used and "assist" during surgeries.

#### Role of surgeons in the procurement process

- (183) The loyalty of surgeons is a crucial barrier to entry or expansion in the trauma area also because surgeons play an important role in the procurement process and in general choose together with (or sometimes against) the purchasing department the suppliers of the medical devices. Across all countries the majority of hospitals consider the surgeons' preference for a particular trauma supplier an important, very important or sometimes the most important criterion in purchase decisions.<sup>153</sup> It appears that the procurement departments in hospitals are rarely able to decide against the will of the surgeons. Instead, in most cases surgeons are involved to some extent and a change of supplier without the backing of the surgeons appears difficult.<sup>154</sup> The prestige and camaraderie associated with the AOF which creates a strong preference for Synthes' products as explained in Recitals (175) and (177) presents an additional hurdle to switch from Synthes' products to the products of another manufacturer.

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<sup>151</sup> See Bernstein Research: "JNJ, Synthes: What Could Synthes' Relationship With the AO Foundation Bring to Johnson & Johnson?".

<sup>152</sup> See replies to question 17.6 of Q17 - questionnaire to competitors (Trauma) 5 respondents indicated that this constitutes no significant or just a moderate barrier to entry whilst 13 perceived it as being an important or crucial barrier to entry.

<sup>153</sup> See replies to question 3.7 of Q18 - questionnaire to customers (hospitals). This is also supported by other evidence such as Sector Study Medical Devices carried out by ECORYS on behalf of the Netherlands Competition authority and the Dutch Ministry of Health, Welfare and Sports, 1 December 2011.

<sup>154</sup> See for example replies to question 3, columns 5 and 6 of Q18 – questionnaire to customers (hospitals), Minutes of telephone interview with Mr Rupinder (Portfolio Manager of Joint Procurement Services, Guy and St. Thomas' NHS Foundation Trust and King's College Hospital NHS Foundation Trust) on 9 December 2011 [ID 5215]\*.

- (184) On the basis of the market investigation it is possible to conclude that the role of surgeons in the procurement for individual countries differs to some extent as regards the sourcing of trauma devices. For example in Italy and Poland the preference of surgeons plays a relatively small role in the selection compared to other countries like Austria, the Benelux countries, the Czech Republic, Sweden, or the United Kingdom. When asked to specify the importance of surgeons' preferences when selecting a trauma supplier for their hospital, in Poland the majority of hospitals answered that a strong surgeon preference for some devices would not prevent the hospital from delisting the supplier if overall other suppliers provide better offers.<sup>155</sup> In other countries, such as Austria<sup>156</sup>, the Czech Republic<sup>157</sup>, Sweden<sup>158</sup>, and the United Kingdom<sup>159</sup>, none or only very few hospitals would decide against a strong surgeon preference, instead they replied that the strong surgeons' preference for some devices would strongly influence the selection of the supplier for the whole category or would influence the selection for the devices concerned while other suppliers remain tier 2 suppliers.<sup>160</sup>
- (185) In sum, the loyalty of surgeons to a particular supplier with whom they have trained and their reluctance to switch is a considerable barrier to entry and limits expansion by alternative suppliers.

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<sup>155</sup> See replies to question 38 of Q18 - questionnaire to customers (hospitals): 6 out of 11 hospitals in Poland answered that the surgeon preference would not prevent them from delisting a trauma supplier, while five replied that it would influence the selection of the supplier, but other suppliers would remain Tier 2 suppliers. Replies to question 3.5 of Q18 - questionnaire to customers (hospitals) also point in this direction. In Poland this is in line with the evidence that a high proportion of supplies is tendered, see replies to question 3.2 of Q18 - questionnaire to customers (hospitals).

<sup>156</sup> See replies to question 38 of Q18 - questionnaire to customers (hospitals): in Austria out of 10 responses one hospital replied that it would strongly influence the selection of the supplier for the whole category seven hospitals replied that the strong preference for some devices would influence the selection of the devices concerned and only 2 would consider a delisting despite a strong preference.

<sup>157</sup> See replies to question 38 of Q18 - questionnaire to customers (hospitals): In the Czech Republic, 4 hospitals replied that a strong preference would influence the choice of the supplier for the devices concerned, 1 hospital replied that it would strongly influence the selection of the supplier for the whole category, while none would consider a delisting. Two hospitals did not know.

<sup>158</sup> See replies to question 38 of Q18 - questionnaire to customers (hospitals): In Sweden, 5 hospitals replied that a strong preference would influence the choice of the supplier for the devices concerned, 1 hospital replied that it would strongly influence the selection of the supplier for the whole category, while none would consider a delisting. Two hospitals did not know.

<sup>159</sup> See replies to question 38 of Q18 questionnaire to customers (hospitals): In the United Kingdom, out of 13 responding hospitals only 2 would consider a delisting while 4 replied that the strong preference for some devices would influence the selection of the devices concerned and another four replied that it would strongly influence the selection of the supplier for the whole category. Three hospitals did not know.

<sup>160</sup> In a number of countries, such as Spain, Denmark, Germany and France the number of responding hospitals was too small number of answers to give a valid answer and based on the answers given it is not possible to detect any particular tendency. For example in Germany and France out of three replies every option (strong preference influences the supply of the whole category, strong preference influences the choice of devices concerned, strong influence would not prevent delisting) was ticked once.

#### 6.3.2.4. Competitive advantages of the parties

##### Research and development – Synthes' link to the AOF

- (186) An additional factor which was considered by market participants as a barrier to entry is the need for significant R&D investments. Although R&D in the industry is in general done on a worldwide basis and therefore does not constitute a barrier to entry to a particular national market, it is still an entry barrier for companies not yet active in a particular product segment. Synthes enjoys a competitive advantage as regards R&D due to its link with the AOF.
- (187) As explained in Recital (180), the AOF carries out research on the basis of suggestions of AOF-affiliated surgeons, but Synthes also has the right to propose areas of clinical needs and ideas for product development. The AOF focuses on the development of concepts, methods and techniques of treatments. [...] Accordingly, Synthes can base itself on a significant body of R&D when developing the concepts, methods and techniques of treatments into new products which can shorten its own product development times. Although the subsequent TK certification process (see above Recital (180)) might take some time until the product comes to the market, the link to the AOF still gives Synthes a competitive advantage in relation to R&D.
- (188) In addition, [...]\*.<sup>161</sup> It should be noted that IP rights play a less important role in the medical devices concerned by the proposed transaction than in other industries, such as for example pharmaceuticals: While certain inventions, such as the arrangement of holes in a plate or an angle of a pre-drilled hole can be patented, other competitors can normally find a way to "design around" these patents and develop similar solutions. Nevertheless, the ownership of IP rights makes it more difficult for competitors to bring a similar device to the market and therefore delays market entry.
- (189) Furthermore, Synthes benefits from its relationship with the AOF as regards the regulatory approval as the AOF also supports it with clinical trials and studies which can be used in the process of obtaining regulatory approval.<sup>162</sup>
- (190) In sum, R&D constitutes a moderate barrier to entry and expansion in the trauma industry. When a manufacturer is already active in a neighbouring product segment it has an advantage due to the know-how stemming from other products. If a manufacturer is not yet active in a neighbouring product segment, R&D constitutes a moderate barrier to entry/expansion.

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<sup>161</sup> See minutes of the meeting with representative of the AO Foundation, [...] on 1 December 2011 [ID 5932]\*.

<sup>162</sup> See minutes of the meeting with representative of the AO Foundation, [...] on 1 December 2011 [ID 5932]\*.

### 6.3.2.5. Limited potential competition

- (191) As discussed above in Recitals (20) and (21) potential competition arises to some extent from competitors which are already active in neighbouring product market segments. The vast majority stated that a manufacturer of particular trauma devices (for example plating systems) could not in principle and without significant investment start supplying other types of trauma devices (for example IM nails) if it has not been active in this market<sup>163</sup>, but that it would rather take two or three years to enter a new market segment.<sup>164</sup> As regards potential competition by competitors active in a neighbouring country the market investigation showed that there is some degree of potential competition, in particular from Germany and France into neighbouring countries. Amongst the respondents who said it depended on the countries, the Benelux countries were explicitly considered to be a good example for a possible expansion.<sup>165</sup>
- (192) [...]trauma markets are, unlike spine markets, not characterised by a large number of recent entrants and those who have entered are less price aggressive and do not gain market shares as rapidly as they do in the spine segment. [...]also acknowledge that the markets are more mature and less innovative.<sup>166</sup>
- (193) The lower level of entry is related to the barriers to entry as explained in Section 6.3.2.3 and to the fact that trauma is a more mature segment, with less innovation taking place. To the extent that innovation is happening, it takes the form rather of incremental innovation consisting in the improvement of existing devices. It is in this context of a much lower level of innovation (compared to the spine segment) that the other characteristics of the trauma markets (strong surgeons' loyalty and their influence on purchasing, important role of AOF in training and education, high reputation of Synthes, strong sales force) need to be viewed. In an environment where the innovativeness of products practically ceases to apply as an argument to incentivise surgeons to switch to other suppliers, and in particular to potential new entrants, these characteristics gain added weight, and make switching more difficult and unlikely. Therefore, even though some entrants have been on the market for several years they often achieve market shares of less than 5% in the markets where they are active and do not manage to capture a significant share of the market possibly due to the natural reluctance of surgeons to switch. To the extent that entry takes place, it focuses (understandably) on the market segments with a higher volume.<sup>167</sup>

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<sup>163</sup> See replies to question 16 of Q17 - questionnaire to competitors (trauma): only 1 out of 19 respondents indicated the contrary.

<sup>164</sup> See replies to question 18 of Q17 - questionnaire to competitors (trauma): 10 out of 18 respondents stated that it would take more than 2 or even more than 3 years.

<sup>165</sup> See replies to question 5 of Q27 – questionnaire to competitors (trauma).

<sup>166</sup> See submission of [...] of 24 February 2012 on the historical development of the trauma area.

<sup>167</sup> Such as distal radius plating systems as fractures of the wrist are the most common type of fractures, see Minutes of the meeting with Mr Schäfer (Head of Purchasing at Einkaufsgemeinschaft Kommunalen Krankenhäuser) on 30 November 2011 [ID 5830]\*.



### 6.3.3. *Competitive assessment of individual markets*

- (194) The market investigation confirmed that in a large number of group 1 trauma markets a number of competitors which can exercise a sufficient competitive constraint on the parties remain post- transaction and that the changes to the market structure resulting from the merger can be considered limited in most cases. In particular, the Commission was able to conclude that the proposed transaction would not raise competition concerns in a number of trauma markets where post-merger at least two other competitors remain both of which have a market share comparable to the smaller of the parties or which have a significant market share. For this assessment the Commission took into account the actual market shares of the parties and competitors resulting from the market reconstruction. However, this Decision only states ranges of market shares suitable for protecting business secrets as laid down in the Commission's best practice guidelines.<sup>168</sup>
- (195) However, in a number of markets not only are the market shares high, but also the increment added by J&J is significant. In product terms this applies to a number of countries in particular for cancellous cannulated screws and distal radius plating systems. In geographical terms (over several product markets) this applies in particular to Portugal, Spain and the United Kingdom. In these three countries, in addition to the higher increment, there are more group 1 markets for trauma devices than in other countries showing the overall strength of the parties in terms of sales force, reputation and services.<sup>169</sup> For example, [...] while in other countries its own sales force sells [...] or it sells via a distributor.
- (196) In addition, in Portugal, Spain and the United Kingdom, according to the parties' own estimates, both parties have gained market share in the years 2008 to 2010 in the overall market for plating systems, the product segment where there are most markets with a significant impediment of effective competition and which is revenue wise the most important segment of the parties. According to its own estimates J&J increased its market share in Spain from [5-10]% to [5-10]%, in Portugal from [5-10]% to [5-10]%, and in in the United Kingdom from [10-20]% to [10-20]%, while Synthes increased its share from [50-60]% to [60-70]% in Portugal, from [50-60]% to [60-70]% in Spain and from [40-50]% to [40-50]% in the United Kingdom. Since the market share estimates for the three countries were based on industry reports<sup>170</sup> and since the market reconstruction also confirmed the market share estimates for 2010 for Spain and the United Kingdom (in Portugal the parties underestimated Synthes' position),

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<sup>168</sup> See [http://ec.europa.eu/competition/mergers/legislation/market\\_share\\_ranges.pdf](http://ec.europa.eu/competition/mergers/legislation/market_share_ranges.pdf).

<sup>169</sup> There are 11 group 1 markets in the United Kingdom, 14 in Portugal and 8 in Spain: In the United Kingdom the increment added by J&J is across most product segments higher than in other countries, while in turn the market share of Synthes is smaller. The transaction would in many group 1 markets combine the strongest player with the number 2 or 3. This is consistent with the results of the market investigation that the parties are each other's closest competitors, see footnote 132 above.

<sup>170</sup> It was based on MRG for all three countries, for United Kingdom in addition on iData.

the estimates for these countries reliably show as a trend that the parties' position is getting stronger.

- (197) In other markets, given Synthes' extremely high market share (up to [90-100%]\*), it is sufficient for competition concerns to arise that the transaction would remove the competitive constraint exerted by J&J on Synthes, despite J&J adding only a relatively small increment. This holds in particular where only a few of the main competitors achieve small sales and where the transaction would thus result in a quasi-monopoly situation.
- (198) Taking all this into account the remainder of Section 6.3.3 sets out the markets where the Commission has concluded that the notified transaction would significantly impede effective competition.

#### 6.3.3.1. Plating systems

- (199) The proposed transaction results in 79 affected markets, out of which 49 belong to group 1. The group 1 markets are in Austria, Belgium, Bulgaria, Czech Republic, Denmark, France, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

Table 1: Plating systems – affected markets in 2010

Plates	Affected markets	Group 1 markets
Non anatomic plates	21	13
Anatomic foot plates	7	1
Anatomic ankle plates	8	6
Anatomic knee plates	10	5
Anatomic shoulder plates	10	8
Anatomic elbow plates	4	2
Anatomic wrist plates	19	14
Sum	79	49

Source: Market reconstruction

- (200) These markets will be assessed more in detail in the next sections.

#### Non-anatomic plating systems

- (201) The parties would have high or very high combined market shares in non-anatomic plating systems across most Member States with J&J contributing in general modest increments. There are 13 group 1 markets with combined market shares of the parties ranging from [50-60]\*% to [90-100]\*%.

Table 2: Group 1 markets in non-anatomic plating systems (shares 2010, in %)

	J&J	Synthes	Comb.	Stryker	S&N	Zimmer	Königsee	Others
<b>SI</b>	[0-5]*	[90-100]*	[90-100]*			[0-5]*		
<b>SE</b>	[5-10]*	[80-90]*	[90-100]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	Litos [0-5]*
<b>NO</b>	[5-10]*	[80-90]*	[90-100]*		[5-10]*		[0-5]*	
<b>DK</b>	[0-5]*	[80-90]*	[80-90]*	[0-5]*	[5-10]*		[0-5]*	Litos, Marquardt together [0-5]*
<b>BE</b>	[0-5]*	[80-90]*	[80-90]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	Surgival [0-5]*
<b>PT</b>	[0-5]*	[80-90]*	[80-90]*	[5-10]*			[0-5]*	Surgival, Sanatmetal, AAP, Marquadt together [0-5]*
<b>IT</b>	[0-5]*	[70-80]*	[80-90]*	[0-5]*	[0-5]*	[5-10]*	[0-5]*	Bioimpianti [5-10]*, Sanatmetal, Marquardt together [0-5]*
<b>UK</b>	[10-20]*	[70-80]*	[80-90]*	[5-10]*	[5-10]*	[0-5]*		Litos, Marquardt together [0-5]*
<b>ES</b>	[5-10]*	[70-80]*	[70-80]*	[5-10]*	[0-5]*	[10-20]*		Surgival, AAP, ITS, Sanatmetal, Bioimpianti, Litos, Marquardt together [0-5]*
<b>FR</b>	[0-5]*	[60-70]*	[60-70]*	[10-20]*	[0-5]*	[10-20]*	[0-5]*	Sanatmetal [0-5]*
<b>DE</b>	[0-5]*	[60-70]	[60-70]*	[0-5]*	[0-5]*	[0-5]*	[20-30]*	Litos, AAP together [0-5]*
<b>EL</b>	[0-5]*	[50-60]*	[50-60]*	[10-20]*	[10-20]*	[5-10]*	[0-5]*	Sanatmetal, Litos, Marquardt together [5-10]*
<b>BG</b>	[5-10]*	[50-60]*	[50-60]*	[0-5]*		[0-5]*	[10-20]*	Sanatmetal [10-20]*, Marquardt [5-10]*, Medin [0-5]*

Source: Market reconstruction

- (202) The main products of the parties include on the part of J&J the Anatomic Locking Plating Systems ("A.L.P.S.") product line. This product line covers both anatomically pre-contured plates but also straight plates for large and small fragments. Other non-anatomic plates of J&J are F3, SS (Mini, Small, Large), and ACE (Small Frag, Large Frag). Synthes offers a wide range of non-anatomic plates, such as the VA Hand Modules, MiniSet 1.5/2.0/2.7, LCP, DC (SF), LCP Generic Plates, DC Plates and Special Implants, Polypin 2.0, LCP 1/3 Tubular Plates, LCP Metaphyseal Plate (LF), LCP Hook Plate 3.5mm, and the Locking Attachment Plate. Stryker offers the SPS basic and small fragment plates. Zimmer offers FreeLock, Trofix, Universal, ZPS, and Astrid as non-anatomic plate product lines. S&N's non anatomic plates are mainly the TC-100. This list of Synthes' products shows the breadth and depth of its portfolio, while product ranges of competitors are significantly smaller. Nevertheless, within the A.L.P.S.

system J&J has a focus on small and mini plates used for example in hand surgeries, where it competes with Synthes' products.

- (203) The main areas of concern lie in Slovenia, Sweden, Norway, Denmark and the United Kingdom.
- (204) In Sweden and Norway not only is the starting point extremely high as Synthes holds a market share of [80-90]\*% but also the increment brought by J&J with a market share of [5-10]\*% is not small but rather moderate. In Sweden the transaction would eliminate the strongest competitor of Synthes and only Smith & Nephew would be left with a market presence which is not insignificant. The four other remaining competitors have only insignificant sales. In Norway, Smith & Nephew is currently somewhat stronger than J&J, but apart from Smith & Nephew only Königsee would remain whose sales are insignificant. In Slovenia, whilst the increment added by J&J is smaller than in Norway or Sweden, the transaction would remove the only competitor with a not insignificant market share. Zimmer would be the only remaining competitor and has much fewer sales compared to J&J. Given these very high combined market shares and the market characteristics such as the surgeons' reluctance to switch and the role of the AOF (as described above in Recitals (175) - (181) the Commission concludes that the proposed transaction would result in a significant impediment of effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for non-anatomic plating systems in Norway, Sweden and Slovenia.
- (205) Also in Denmark Synthes has a very strong position with a market share of [80-90]\*%. There are currently only two competitors with not insignificant market shares - J&J [0-5]\*% and Smith & Nephew [5-10]\* - whilst the market shares of Stryker, Königsee, Litos and Dieter Marquardt Medizintechnik GmbH ("Marquardt") are together smaller than those of J&J. Post-merger there would thus remain only one competitor with not insignificant market presence (Smith & Nephew) and the proposed transaction would reinforce the asymmetry in the market, resulting in a big difference in market shares between the merged entity and the second largest competitor. On this basis and taking into account the market characteristics such as the surgeons' reluctance to switch and the role of the AOF (as described above in Recitals (175) - (181) the Commission concludes that the proposed transaction would result in a significant impediment of effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for non-anatomic plating systems in Denmark.
- (206) Furthermore, concerns arise in the United Kingdom. Here, J&J is the strongest competitor of Synthes [10-20]\*%. But not only are there significant increments but also a number of hospitals responding to the Commission's market investigation pointed out that both parties supply them with plating systems<sup>171</sup>, and hence that the transaction would be liable to eliminate a direct competitor to

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<sup>171</sup> Replies to question 23 of Q18 - questionnaire to customers (hospitals).

Synthes. Moreover, [...] based on industry reports, J&J has been the fastest growing company of the three main competitors between 2008 and 2010<sup>172</sup>. In view of the foregoing and taking into account the general market characteristics as well as the fact that J&J has a very strong sales force in the United Kingdom[...] (see Recital (195) above) the Commission concludes that the proposed transaction would result in a significant impediment of effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for non-anatomic plating systems in the United Kingdom.

- (207) J&J's position in the Spanish market is not insignificant [5-10]%. However, the merger would not change the competitive pressure on the market leader (Synthes) significantly as Stryker [5-10]% and Zimmer [10-20]% are stronger than J&J [5-10]%. Moreover, Smith & Nephew [5-10]%, and the low cost supplier Sanatmetal [5-10]% are, although with fewer sales than J&J, present in Spain, exerting all together sufficient competitive pressure on the market leader. Therefore the transaction is not likely to significantly impede effective competition in Spain.
- (208) In Bulgaria, the combined market share is high [50-60]% but not as high as in the other group 1 markets. The market position of J&J, [5-10]% is significantly stronger compared to Stryker and Zimmer which are usually Synthes' competitors. Smith & Nephew is not present in Bulgaria. However, in addition to Stryker and Zimmer there are two low cost suppliers Königsee [10-20]% and Sanatmetal [10-20]% present which have a good reputation in the country and achieve market shares significantly higher than those of J&J, Stryker and Zimmer all together. Moreover, in this price-sensitive market<sup>173</sup> the market share of both Synthes and J&J has [...] decreased in the last years<sup>174</sup>. Against these dynamics in the market, the proposed transaction is not likely to significantly impede effective competition in Bulgaria.
- (209) In Belgium, the increment brought by J&J is almost insignificant [0-5]%. Synthes faces competition from Stryker [0-5]%, Smith & Nephew [0-5]%, and Zimmer [5-10]%. Stryker and Smith & Nephew achieve sales which are about twice as high as those of J&J. Zimmer is the strongest competitor in Belgium with a significantly better market presence than Stryker, Smith & Nephew and J&J. Therefore the proposed transaction is not likely to significantly impede effective competition in Belgium.

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<sup>172</sup> See Form CO, [...]

<sup>173</sup> The National Health Insurance Fund generally does not reimburse the costs of trauma devices. As a result, patients must in principle support the entire cost of such devices, many of them by obtaining loan funding from banks, whilst this becomes less and less affordable due to the financial crises. [...] hospitals therefore source increasingly from price aggressive rivals that have entered the Bulgarian market over the past years and which seem to offer a sufficient quality.

<sup>174</sup> In 2011 the sales of the parties, in particular those of Synthes, have plunged by at least [40-50%][...] in every trauma segment, reinforcing the negative sales trend since 2009.

- (210) In Italy, the increment brought by J&J is almost insignificant [0-5]\*%. Synthes faces competition from Stryker [0-5]\*%, Smith & Nephew [0-5]\*%, and Zimmer [5-10]\*%, which are all present in the country. Their market share is more than six times higher than that of J&J. Furthermore, there is with Gruppo Bioimpianti [5-10]\*% a regional player with a good reputation, which is currently number three in the market. Therefore the proposed transaction is not likely to significantly impede effective competition in Italy.
- (211) Also in Portugal, the increment brought by J&J is almost insignificant [0-5]\*%. The main competitor of Synthes in the market is Stryker but Marquardt also achieves sales which are significantly higher than those of J&J. The competitive pressure on Synthes is therefore unlikely to change significantly post-merger.
- (212) In France, Synthes already currently has about [60-70%]\* of the market. The increment brought by J&J is small, also in comparison to Synthes' main competitors in this market, Zimmer and Stryker. Low cost suppliers such as Königsee and Sanatmetal also achieve sales in France. Therefore in France the competitive pressure on Synthes is not likely to be significantly reduced by the proposed transaction.
- (213) Synthes also currently already has about [60-70%]\*...]\* of the market in Germany. As in France, the increment brought by J&J is small. The strongest competitor to Synthes in this mature market with little possibility of product differentiation is the low cost supplier Königsee, which achieves about a quarter of the respective sales. Zimmer also has sales which are about twice as high as J&J, and with Smith & Nephew, Stryker and two regional players (Litos and AAP Implantate AG ("AAP Implante")) there remain enough competitors which are as strong as or stronger than J&J. Therefore, a significant impediment of effective competition is not likely to be brought by the proposed transaction in Germany.
- (214) In Greece, the combined market share is high but not as high as in most of the other group 1 markets. Furthermore, the increment brought by J&J is smaller than the market share of the five other remaining competitors, two of which achieve market shares of above 10% (Stryker and Smith & Nephew). It is likely that the constraint imposed especially by these larger competitors would not be changed substantially as a result of the merger. Thus, no significant impediment to effective competition is likely to arise due to the proposed transaction.
- (215) As described in the Section 5.1.1.2., anatomic and non-anatomic plating systems do not belong to the same market, but to neighbouring product markets with a certain degree of substitution at the margin. However, as anatomic plates are considerably higher priced than non-anatomic plates, the competitive constraint is not likely to countervail the identified substantial impediment to effective competition. Furthermore, in Norway, Sweden and the United Kingdom the Commission has also found competition concerns regarding certain anatomically shaped plates. The fact that there is a certain degree of substitution at the margins would thus not alter the respective conclusions for any of those markets for non-anatomic plating system.

- (216) In view of the foregoing and taking into account the market characteristics as described in Sections 6.2 and 6.3.2, the Commission concludes that the proposed transaction would result in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for non-anatomic plating systems in Norway, Denmark, Slovenia, Sweden, and the United Kingdom.

Anatomic plating systems – wrist (distal radius)

- (217) The parties would have very high combined market shares in distal radius (wrist) plating systems across most Member States, with J&J accounting for an increment above 10% in seven out of 14 group 1 markets (Bulgaria, Norway, Portugal, Slovenia, Spain, Sweden, and the United Kingdom), while in the rest of the countries (Belgium, Czech Republic, Ireland, Italy, Luxembourg, the Netherlands and Slovakia) the increment is moderate.

Table 3: Group 1 markets in distal radius plates (shares 2010, in %)

	J&J	Synthes	Comb.	Stryker	S&N	Med-artis	Acumed	Others
<b>NO</b>	[40-50]*	[40-50]*	[80-90]*	[5-10]*	[0-5]*			
<b>LU</b>	[5-10]*	[60-70]*	[70-80]*	[0-5]*				Marquardt [10-20]*, Zimmer [0-5]*
<b>PT</b>	[30-40]*	[30-40]*	[70-80]*	[10-20]*	[0-5]*			Marquardt, Medimetal together [0-5]*
<b>ES</b>	[30-40]*	[40-50]*	[70-80]*	[10-20]*	[0-5]*	[0-5]*	[5-10]*	Small Bone Innovations ("SBI"), Marquardt, Zimmer, Litos, Sanatmetal, together [0-5]*
<b>NE</b>	[0-5]*	[60-70]*	[60-70]*	[30-40]*	[0-5]*			ITS, Zimmer, Small Bone Innovations, together [0-5]*
<b>SE</b>	[10-20]*	[40-50]*	[60-70]*	[10-20]*	[5-10]*		[0-5]*	Königsee [5-10]*
<b>SK</b>	[0-5]*	[60-70]*	[60-70]*	[20-30]*				Medin [5-10]* Sanatmetal [0-5]* Medimetal [0-5]*
<b>UK</b>	[40-50]*	[20-30]*	[60-70]*	[10-20]*	[0-5]*	[5-10]*	[5-10]*	Zimmer, SBI, ITS, Litos, Orthofix, Marquardt, Königsee, Medimetal together [0-5]*
<b>BE</b>	[0-5]*	[40-50]*	[50-60]*	[30-40]*	[0-5]*	[5-10]*	[0-5]*	Zimmer, Königsee together [0-5]*
<b>IT</b>	[5-10]*	[40-50]*	[50-60]*	[0-5]*	[0-5]*	[20-30]*	[5-10]*	Zimmer, Königsee, Orthofix, SBI, Sanatmetal together [0-5]*
<b>CZ</b>	[5-10]*	[40-50]*	[40-50]*			[40-50]*		Königsee [5-10]* Medin, Medimetal together [0-5]*
<b>BG</b>	[10-20]*	[20-30]*	[40-50]*	[30-40]*				Königsee [5-10]*, Marquardt [5-10]*, Medin, Sanatmetal, together [0-5]*
<b>SI</b>	[10-20]*	[30-40]*	[40-50]*			[50-60]*		ITS [0-5]*
<b>IR</b>	[0-5]*	[30-40]*	[30-40]*	[40-50]*	[0-5]*		[0-5]*	Marquardt [5-10]*, Zimmer[0-5]*

Source: Market reconstruction

- (218) In the market for distal radius plating systems, J&J and Synthes can be considered as close competitors. J&J's distal radius volar plate (DVR) is [...]\*. It accounts for about [...]\* of J&J's EEA-wide revenue of trauma devices and for



almost [...] of J&J's EEA-wide revenue for plating systems. Synthes' product is the LCP Distal Radius Plates 2.4. [...] <sup>175</sup> On the customer side, hospitals considered these companies as first and/or second alternative should the established main supplier become uncompetitive. <sup>176</sup> In the market investigation both competitors and customers indicated that the parties would have particular strengths as regards specific anatomic plating systems, in particular for the hand and wrist area. <sup>177</sup>

- (219) Given the high combined market shares, the disappearance of one very close competitor to the market leader (Synthes) raises competition concerns, in particular in those countries where the market position of the smaller of the two parties is already today stronger than the position of any other competitor. This is the case in Norway, Portugal, Spain and the United Kingdom.
- (220) In Norway, the proposed transaction would combine the two strongest players in the market, with Synthes and J&J each having a market share of [40-50]\*%. The transaction would result in a significant change of the market structure and would eliminate the closest competitor of J&J. The remaining two competitors (Stryker and Smith & Nephew) would have market shares far below those of the merged entity. Given the very high combined market share, the significant change in the market structure and the market characteristics as described in Recital (172) - (181), in particular the inertia in the market and the loyalty of surgeons to certain products, the Commission concludes that the proposed transaction would result in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for wrist plating systems in Norway.
- (221) In Portugal and Spain, the transaction would combine the two strongest players in the market resulting in a very high combined market share of [70-80]\*%. In Portugal, Synthes and J&J each have a market share close to 40%. In both countries the proposed transaction would eliminate the parties' closest competitor <sup>178</sup>. Post-merger Stryker would be number 2 in these markets with market shares much smaller than those of the merged entity. In both countries, the merged entity would have by far the largest sales force. Given the reluctance of surgeons to switch away from products they are used to, it cannot be expected that the remaining competitors would be able to grow their sales in a sufficiently strong and timely manner to counteract an attempt to raise prices by the merged entity. It can be concluded that the proposed transaction would result in a significant impediment to effective competition by creating a dominant position

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<sup>175</sup> See for example J&J's internal documents No. [...]\*

<sup>176</sup> See replies to question 151.1 of Q28 – Phase II - questionnaire to customers (Hospitals).

<sup>177</sup> See replies to question 8.1 of Q27 – Phase II - questionnaire to competitors (Trauma) - for example replies of Smith & Nephew, Biomet.

<sup>178</sup> See replies to question 33 and 34 of Q18 - questionnaire to customers (hospitals), asking for the closest competitor to J&J and Synthes respectively. Parameters for the assessment of closeness of competition were amongst others price, quality, scope and service. Reply of Stryker to question 8.1 to Q27 – Phase II - questionnaire to competitors (trauma) [ID 3683]\*.

or further strengthening the dominant position of the parties in the market for wrist plating systems in Spain and Portugal.

- (222) In the United Kingdom, the transaction would significantly strengthen the market position of J&J which is currently the market leader with a market share of [40-50]\*% as Synthes, currently number 2 in the market, would add a high increment of [20-30]\*%. As explained in Recital (196) the market share development in the overall market for plating systems over the last three years shows that the parties have steadily increased their market share at the expense of the remaining competitors. [...]\*. Other competitors are Stryker with a significant market share and Acumed and Medartis with moderate market shares. In the United Kingdom, the transaction would again eliminate the parties' closest competitor.<sup>179</sup> Despite the prevalence of tenders in the United Kingdom, it is a country with relatively high prices<sup>180</sup>, which shows the ability of the parties to set prices relatively independently. In addition, the relative strength of J&J in the United Kingdom also results from the fact that [...]\*. In other countries [...]\*. On this basis the Commission concludes that the proposed transaction would significantly strengthen the already strong position of J&J, thus leading to a significant impediment of effective competition by creating a dominant position or further strengthening the dominant position of the parties.
- (223) In Luxembourg, J&J adds a moderate increment to the high market share of Synthes, resulting in a high combined market share of [70-80]\*%. Post-merger three competitors would remain, Marquardt with a significantly higher market share than J&J ([10-20]\*%) in addition to Stryker with a smaller market share than J&J of [0-5]\*%. Zimmer is also present with a very small market share. The total market value is small (below EUR 120,000) and the award of a single tender to another supplier can strongly influence the market shares so that these are not necessarily indicative of market power. Given the fact that three remaining competitors remain post-merger and could start selling their products immediately in case of an attempted price increase, the proposed transaction does not lead to a significant impediment of effective competition.
- (224) In Sweden, the increment added by J&J with a [10-20]\*% market share substantially strengthens the already strong position of Synthes, and the parties would have a high combined market share of [60-70]\*%. Only one competitor (Stryker) with a similar market share as J&J would remain, while the other competitors (Acumed, Königsee, and Smith & Nephew) together do not achieve J&J's market share. Given the reluctance of surgeons to switch away from products they are used to and bearing in mind that Stryker, and to an even greater extent the remaining smaller competitors, would be competing at a long distance from the merged entity, it cannot be expected that the competitors remaining post-merger would be in a position to sufficiently constrain the merger entity.

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<sup>179</sup> See replies to questions 33 and 34 of Q18 - questionnaire to customers (hospitals), asking for the closest competitor to J&J and Synthes respectively. Parameters for the assessment of closeness of competition were amongst others price, quality, scope and service.

<sup>180</sup> See Form CO, p. 165.

Therefore, the proposed transaction results in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for wrist plating systems in Sweden.

- (225) In the Netherlands, J&J would add a small increment to the strong position of Synthes. Three international competitors, Smith & Nephew, Zimmer and Stryker are present. Stryker in particular has a considerable presence with [30-40]\*% market share. In addition, ITS is present with a small market share. It is likely that Stryker with its significant presence would be able to constrain the merged entity post-merger.
- (226) In Bulgaria, there is a strong dynamic in the market which led to a [...] decrease of the parties' sales, [...]\*.<sup>181</sup> On the basis of 2010 figures the combined market share of the parties would be below 50%. Stryker has a larger market share than either of the parties and other companies such as Marquardt and Königsee also have a sizeable presence. It is likely that the presence of Stryker would be sufficient to constrain the parties post-merger.
- (227) In Ireland, the combined market share is below 40% and the increment added by J&J is negligible so that the market structure would not change significantly as a result of the merger. Stryker has a larger market share than the merged entity and Acumed, Smith & Nephew and Marquardt have a higher market share than the increment added by J&J. It can be expected that they would continue to constrain the merged entity.
- (228) In Slovakia the increment added by J&J is negligible so that the market structure would not change significantly as a result of the merger. In addition, several competitors remain post-merger, in particular Stryker, but also regional players such as Sanatmetal, Medimetal and Medin, have a higher market share than the increment added by J&J. It is likely that these competitors would be in a position to constrain the merged entity.
- (229) In Belgium, the increment added by J&J is small. Three competitors, Stryker, Medartis and Smith & Nephew, have a stronger or similar market position than J&J. It is likely that these competitors, in particular Stryker, would be in a position to sufficiently constrain the merged entity.
- (230) In the Czech Republic, the combined market share of the parties is below 50% with J&J adding an increment of [5-10]\*%. Medartis with a market share of [40-50]\*% is as big as the parties. In addition, the low cost supplier Königsee [5-10]\*% has a similar size to J&J. It is likely that Medartis in particular would continue to exert sufficient competitive pressure on the merged entity.
- (231) In Slovenia, the transaction does not raise concerns due to the strong position of Medartis with a market share of [50-60]\*%. Although, there would be only one

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<sup>181</sup> The parties provide with their submission of 23.11.2011 [...] three factors to explain the [...] erosion of the parties sales: [...]\*.

competitor left after the transaction, this competitor (Medartis) is well recognized in the market and has a higher market share than the parties' combined market share. Therefore it is likely that it would exert sufficient competitive pressure on the merged entity.

- (232) Given that in the other affected markets (Austria, Denmark, France, Germany and Greece) the combined market shares are below 35%, with J&J often contributing only a small increment, the market structure is such that a number of competitors with a comparable or better market position than J&J would remain and that no competition concerns arise for these other markets. Also there were no complaints from customers in these markets which may have led to an in-depth investigation.
- (233) In view of the foregoing and taking into account the market characteristics as described in Sections 6.2 and 6.3.2, the Commission concludes that the proposed transaction would result in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for anatomic wrist plating systems in Norway, Portugal, Spain, Sweden and the United Kingdom.

#### Anatomic plating systems – shoulder

- (234) The parties would have very high combined market shares in anatomic shoulder plating systems across most Member States. However, in eight countries, the increment brought by the proposed transaction is slightly higher than 1% (group 1 markets). In Portugal, Sweden, and the United Kingdom, there are increments of about 10% or more and the combined market shares of the parties account for more than 70% of the market.

Table 4: Group 1 markets in shoulder plating systems (shares 2010, in %)

	J&J	Synthes	Comb.	Zimmer	S&N	Köni gsee	Acu- med	Arth- rex	Others
<b>UK</b>	[10-20]*	[60-70]*	[70-80]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	Marquardt, Medimetal, Litos, Königsee, Lima, and Stryker together [0-5]*
<b>PT</b>	[5-10]*	[60-70]*	[70-80]*	[0-5]*	[0-5]*		[5-10]*		Stryker [5-10]*; Lima, Marquardt, and Medimetal together [0-5]*
<b>SE</b>	[10-20]*	[60-70]*	[70-80]*	[0-5]*	[5-10]*	[0-5]*	[5-10]*		Litos, Integra, together [0-5]*
<b>BE</b>	[0-5]*	[60-70]*	[60-70]*	[20-30]*	[5-10]*	[0-5]*	[0-5]*		Stryker[0-5]*
<b>CZ</b>	[5-10]*	[70-80]*	[80-90]*	[5-10]*		[5-10]*			Medin, Medimetal together [0-5]*
<b>FR</b>	[0-5]*	[50-60]*	[50-60]*	[5-10]*		[0-5]*		[5-10]*	Tornier [10-20]* Integra, Sanatmetal, Königsee, ITS, Stryker together [0-5]*
<b>IT</b>	[0-5]*	[60-70]*	[60-70]*	[10-20]*	[0-5]*	[0-5]*	[0-5]*	[5-10]*	Lima, Tornier, Acumed, Königsee, Sanatmetal, Stryker together [0-5]*
<b>ES</b>	[5-10]*	[40-50]*	[50-60]*	[10-20]*	[5-10]*		[10-20]*	[0-5]*	Tornier, Litos, Lima, Marquardt, Stryker, Sanatmetal together [0-5]*

Source: market reconstruction

- (235) In the market for shoulder plating systems J&J and Synthes can in general not be considered as each other's closest competitors in terms of the product offering. Synthes sells various types of shoulder plates (namely Periarticular Proximal Humerus Plates, Humerus Block + Button Fix, and PHILOS), whereas J&J is present with one single product (its S3 plates). Competitors such as Zimmer (PAP, PLP, and NCB shoulder plates), Königsee (different proximal humerus plates, AC-Gelenkshakenplatte) and Axomed (WINSTA-PH) achieve much higher sales than J&J on an EEA-wide level. Moreover, there are companies which have a firm presence in shoulder replacement (protheses) markets such as Arthrex (Suture Plate) and Tornier (Aequalis Humeral Plate S19) and which are quite successful in certain countries.
- (236) However, there are a few countries where these competitors are not present or achieve only limited sales and where the transaction results in very high combined market shares (above 70%) and increments of between [5-10]\*% and [10-20]\*% in the United Kingdom, Portugal and Sweden. In addition, in Portugal

and the United Kingdom the parties can be considered closer competitors on the basis of other parameters than product offering, such as price, quality, product offering and service<sup>182</sup>.

- (237) In the United Kingdom, the merger would remove the strongest competitive constraint to Synthes. The market share of Synthes is already very high [60-70]\*% and the increment added by J&J is also substantial [10-20]\*%. Post-merger the merged entity would be by far the market leader. The competitors remaining achieve only small to moderate sales. In addition, J&J increased its market share in recent years in the overall market for plating systems as the market investigation showed, J&J and Synthes are often seen as close competitors. Furthermore the proposed transaction would combine the parties' strong sales forces and training capabilities in the United Kingdom [...]\*. On this basis the Commission concludes that the proposed transaction would result in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in the UK market for anatomic shoulder plating systems.
- (238) In Portugal J&J would add a moderate increment to the already high market share of Synthes, leading to a very high combined market share of [70- 80]\*%. The largest competitors remaining post-merger would be Acumed and Stryker, both with market shares of [5-10]\*%. Thus the transaction increases the already high level of concentration in the market, as well as the distance between the leading player and the remaining competitors. Therefore, it is likely that it would result in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for shoulder plating systems in Portugal.
- (239) In Sweden, the proposed transaction would remove the strongest competitive constraint to Synthes. The market shares of Synthes are already now high [60-70]\*% and well protected by the AOF and the inherent reluctance of surgeons to switch supplier. In view of the high increment of [10-20]\*% added by J&J and the very high combined market share the Commission concludes that the proposed transaction would result in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for anatomic shoulder plating systems in Sweden.
- (240) In Belgium, J&J adds a small increment to the overall high market share of Synthes. However, two competitors with significantly higher market shares than J&J (Zimmer and Smith & Nephew), would remain together with Königsee which has a similar market share to J&J. Therefore, it can be concluded that the transaction does not create a significant impediment to effective competition in the market for shoulder plating systems in Belgium.

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See replies to question 33 and 34 of Q18 – questionnaire to customers (hospital).

- (241) In the Czech Republic the transaction would lead to very high combined market shares with J&J adding a moderate increment. However, bearing in mind that two competitors remain post-merger with a market share higher than J&J's (Zimmer and the low cost supplier Königsee) in addition to two established regional players (Medin and Medimetal) it can be concluded that the transaction does not create a significant impediment to effective competition in the market for shoulder plating systems in the Czech Republic.
- (242) In France and Italy J&J contributes a negligible increment to Synthes' high market share. In France, Stryker, Zimmer, Königsee and Integra are all larger than J&J. For Italy this holds true for Stryker, Zimmer, Smith & Nephew and Lima. Therefore, it is likely that the impact of the merger on the competitive structure is limited and that there would be a sufficient number of competitors remaining post-merger, which would be able to sufficiently constrain the merger entity. Thus the proposed transaction would not result in a significant impediment to effective competition in these markets.
- (243) In Spain, the parties have post-merger a strong combined market position [50-60]\*% with J&J adding a moderate increment. However, two large international competitors (Zimmer, and Acumed) are well established in this market with market shares of between [10-20]\*%, i.e. larger than J&J's. Smith & Nephew is also present with a moderate market share [5-10%]\*, together with a number of smaller players. It is likely that these competitors would be in a position to sufficiently constrain the merged entity post-merger. Thus the proposed transaction would not result in a significant impediment to effective competition in this market.
- (244) In view of the foregoing and against the background of the market characteristics as described in Sections 6.2 and 6.3.2, the Commission concludes that the proposed transaction would result in a significant impediment to effective competition in the market for anatomic shoulder plating systems in Sweden, Portugal and the United Kingdom.

#### Anatomic plating systems – ankle

- (245) Across most of the EEA, Synthes has very high market shares and in some cases even a monopolistic position in anatomic ankle plating systems. J&J only has sales in six Member States, namely France, Germany, Italy, Portugal, Spain and the United Kingdom.

Table 5: Group 1 markets in ankle plating systems (shares 2010, in %)

	J&J	Synthes	Combined	Stryker	Zimmer	S&N	Others
<b>FR</b>	[0-5]*	[90-100]*	[90-100]*			[0-5]*	
<b>DE</b>	[0-5]*	[90-100]*	[90-100]*	[0-5]*		[0-5]*	
<b>PT</b>	[10-20]*	[80-90]*	[90-100]*			[0-5]*	Medimetal [0-5]*
<b>UK</b>	[10-20]*	[40-50]*	[50-60]*	[0-5]*	[0-5]*	[20-30]*	Ortho [5-10]*; Biomet, Medimetal together [0-5]*
<b>ES</b>	[5-10]*	[40-50]*	[50-60]*	[0-5]*	[0-5]*	[30-40]*	Arthrex, Biomet, Sanatmetal together [0-5]*
<b>IT</b>	[0-5]*	[40-50]*	[40-50]*		[30-40]*	[20-30]*	Sanatmetal [0-5]*

Source: Market reconstruction

- (246) As regards France and Germany, since the proposed transaction would lead to a quasi-monopoly in these countries, even a small increment significantly worsens the competitive structure. In Germany, J&J is the only competitor with a not wholly insignificant market share (Stryker and S&N together achieve only about [...]\*), and in France, although the increment is small, the transaction would remove the only competitor whose market share is not entirely negligible. Furthermore, in France a potential entrant would face an additional regulatory hurdle as it would have to apply for the reimbursement status of its device which requires the submission of a medical-technical dossier to a national evaluation body which will assess the device under several criteria and set the tariff for reimbursement or a fixed price. In the market investigation, when asked about geographic expansion and possible country specificities, France was mentioned as a particularly difficult country to enter.<sup>183</sup> As a result, it can be concluded that the proposed transaction would lead to a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in these markets.
- (247) In Portugal, the increment added by J&J is significant [10-20]\*% and the transaction would result in very high combined market shares [90-100]\*%. As such the transaction significantly worsens the competitive situation in this market where the merged entity would face competition only from one remaining supplier with a market share of [0-5]\*%. As a result, it can be concluded that the proposed transaction would lead to a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in this market.

<sup>183</sup> Reply of Litos to question 5.3 of Q27- Phase II - questionnaire to competitors (Trauma), [ID 3946]\*.



- (248) In the United Kingdom, the increment added by J&J is above 10%. The transaction would therefore further strengthen the market leader position of Synthes [40-50]\*% and it would result in high combined market shares [50-60]\*%. Out of three competitors (Stryker, Zimmer and Smith & Nephew) present in this market only Smith & Nephew has a significant market share [20-30]\*%. As discussed in Recitals (195) - (196), J&J [...] and the market share development over the last three years in the overall segment of plating systems shows that J&J was the fastest growing competitor. More precisely J&J's market share grew from around [10-20]\*% to [10-20]\*% while Stryker, Zimmer and Smith & Nephew all lost market sales. In this context, it can be held that pre-merger J&J exerted a significant constraint on Synthes that cannot be replicated by the remaining competitors with declining sales. Thus the proposed transaction would lead to a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in this market.
- (249) In Spain, J&J adds a moderate increment. Despite a rather high combined market share of [50-60]\*% no concerns arise as the international competitor Smith & Nephew has a strong presence with a market share of [30-40]\*%. In addition to Smith & Nephew other international competitors, such as Stryker, Zimmer and Arthrex are present. Thus it is likely that the proposed transaction would not result in a significant impediment to effective competition in this market.
- (250) In Italy, no concerns arise as the combined market share is lower than in other countries and the increment is small. International competitors such as Zimmer and Smith & Nephew have a strong presence in the market with a market share of more than 20% and 30% respectively. Therefore it is likely that the proposed transaction would not result in a significant impediment to effective competition in this market.
- (251) In view of the foregoing and taking into account the market characteristics as described in Sections 6.2 and 6.3.2, the Commission concludes that the proposed transaction would result in a significant impediment to effective competition in the market for anatomic ankle plating systems in France, Germany, Portugal and the United Kingdom.

#### Anatomic plating systems – knee

- (252) Across most of the EEA, Synthes has very high market shares and in some cases even a monopolistic position in anatomic knee plating systems. J&J had sales in [...] countries, half of them qualifying as group 1 markets, namely the Czech Republic, Portugal, Slovenia, Spain and the United Kingdom.

Table 6: Group 1 markets in knee plating systems (shares 2010, in %)

	<b>J&amp;J</b>	<b>Synthes</b>	<b>Comb.</b>	<b>Stryker</b>	<b>S&amp;N</b>	<b>Zimmer</b>	<b>Others</b>
<b>CZ</b>	[0-5]*	[90-100]*	[90-100]*			[0-5]*	Medin, Medimetal together [0-5]*
<b>SI</b>	[0-5]*	[80-90]*	[90-100]*			[5-10]*	
<b>PT</b>	[0-5]*	[80-90]*	[80-90]*	[10-20]*	[0-5]*		Medimetal [0-5]*
<b>ES</b>	[0-5]*	[70-80]*	[70-80]*	[5-10]*	[10-20]*	[0-5]*	Litos, Sanatmetal together [0-5]*
<b>UK</b>	[0-5]*	[60-70]*	[70-80]*	[10-20]*	[5-10]*	[0-5]*	Litos, Medimetal together [0-5]*

Source: Market reconstruction

- (253) The market position of Synthes is particularly strong in the Czech Republic, Slovenia and Portugal, so that even the small increment provided by J&J would lead to a significant change in the market structure such that only one non-insignificant competitor would remain in the market.
- (254) In the United Kingdom and Spain Synthes' market shares are significantly lower and post-merger there would be at least two competitors with a market presence bigger than J&J.
- (255) In view of the foregoing and taking into account the market characteristics as described in Sections 6.2 and 6.3.2 the Commission concludes that the proposed transaction would result in a significant impediment to effective competition in the market for anatomic knee plating systems by creating a dominant position or further strengthening the dominant position of the parties in the Czech Republic, Slovenia, and Portugal.

Anatomic plating systems – elbow

- (256) Regarding anatomic elbow plating systems, the position of Synthes across the EEA is quite differing. Whilst in some countries it achieves no sales at all, there are others where Synthes appears to be in a monopolistic position as the only supplier achieving sales. J&J achieves sales in [...] countries out of which two are group 1 markets, namely Germany and Portugal.

Table 7: Group 1 markets in anatomic elbow plating systems (shares 2010, in %).

	<b>J&amp;J</b>	<b>Synthes</b>	<b>Comb.</b>	<b>Stryker</b>	<b>S&amp;N</b>	<b>Zimmer</b>	<b>Acumed</b>	<b>Others</b>
<b>PT</b>	[5-10]*	[80-90]*	[80-90]*	[0-5]*	[0-5]*		[5-10]*	Medimetal [0-5]*
<b>DE</b>	[0-5]*	[70-80]*	[70-80]*	[10-20]*	[0-5]*	[0-5]*	[0-5]*	Medartis [5-10]*; AAP, Litos, Königsee together [0-5]*

Source: Market reconstruction

- (257) Germany just qualifies as group 1 market as the overlap is insignificant (<2%). Also present are Stryker, Smith & Nephew, Zimmer, Medartis, and AAP Implantate, five competitors that are stronger than J&J. It is likely that the proposed transaction would not result in a significant impediment of effective competition in this market.
- (258) Synthes' position in Portugal is very strong as reflected by its market share of [80-90]\*% and the increment brought by J&J [5-10]\*% is moderate. Considering Synthes' strength in the market this leads to a situation that post-merger there would be only one competitor with a non-insignificant presence left. The competitive pressure on the market leader would thus significantly decrease in the Portuguese market for anatomic elbow plating systems. Therefore the Commission concludes that the proposed transaction would result in a significant impediment of effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for anatomic elbow plating systems in Portugal.

#### 6.3.3.2. IM nails

- (259) As set out in Section 5.1.1.3, the market definition for IM nails can be left open as the proposed transaction does not result in a significant impediment to effective competition under any market definition. In particular, it can be left open whether the relevant product market has to be segmented according to anatomies or whether the relevant market is an overall IM nail market on the basis of supply side substitution.
- (260) On the basis of an overall market for IM nails, the proposed transaction would result in 17 affected national markets, five of which would be group 1 (Austria, Belgium, Germany, Luxembourg, Portugal and the United Kingdom).
- (261) Under the alternative market definition, on the basis of anatomies the proposed transaction would result in
- five group 1 markets in the segment of IM nails femur (Belgium, Luxembourg, Netherlands, Portugal, and the United Kingdom ),
  - six group 1 markets in the segment of IM nails tibia (Belgium, France, Lithuania, Luxembourg, Portugal and the United Kingdom)
  - six group 1 markets in the segment of IM nails ankle (Bulgaria, Greece, Luxembourg, Portugal, Spain and the United Kingdom) and
  - three group 1 markets in the segment IM nails humerus (Austria, Bulgaria and Portugal).
- (262) In the other anatomies (ulna, clavicle, radius) the transaction would not result in any group 1 markets.

(263) The market structure for the overall IM nails market and the anatomic sub-segments is as follows:

Table 8: Group 1 markets for IM nails overall

	J&J	Synthes	Comb.	S&N	Stryker	Aescu-lap	Biomet	Zimmer	Others
<b>LU</b>	[0-5]*	[80-90]*	[90-100]*		[5-10]*			[0-5]*	
<b>AT</b>	[0-5]*	[50-60]*	[50-60]*	[0-5]*	[30-40]*	[0-5]*		[0-5]*	AAP, Integra ITS, Königsee together [0-5]*
<b>PT</b>	[0-5]*	[30-40]*	[40-50]*	[5-10]*	[30-40]*	[0-5]*	[0-5]*	[0-5]*	Laffit [5-10]*, ITS, Integra, Lima, Medimetal, Surgival, Sanatmetal, together [0-5]*
<b>BE</b>	[0-5]*	[30-40]*	[30-40]*	[20-30]*	[20-30]*	[0-5]*	[0-5]*	[0-5]*	Integra, ITS, Acumed together [0-5]*
<b>UK</b>	[5-10]*	[20-30]*	[30-40]*	[20-30]*	[20-30]*	[0-5]*	[0-5]*	[0-5]*	Medimetal, Ortho, Orthofix, Acumed together [0-5]*

Source: market reconstruction

Table 9: Group 1 markets in IM nails femur (upper leg)

	J&J	Synthes	Comb.	Stryker	S&N	Bio-met	Others
<b>LU</b>	[0-5]*	[90-100]*	[90-100]*	[0-5]*	[0-5]*		Zimmer [0-5]*
<b>BE</b>	[0-5]*	[60-70]*	[70-80]*	[5-10]*	[10-20]*	[0-5]*	Aesculap, Zimmer [0-5]*
<b>UK</b>	[10-20]*	[30-40]*	[50-60]*	[10-20]*	[20-30]*	[0-5]*	Aesculap, Ortho, Orthofix, Zimmer, Medimetal together [5-10]*
<b>PT</b>	[5-10]*	[30-40]*	[40-50]*	[20-30]*	[5-10]*	[0-5]*	Laffit [10-20]* Medimetal, Sanatmetal, Surgival, Aesculap, Lima together [0-5]*
<b>NE</b>	[0-5]*	[40-50]*	[40-50]*	[40-50]*	[5-10]*	[5-10]*	Orthofix, Zimmer together [0-5]*

Source: market reconstruction

Table 10: Group 1 markets in IM nails tibia (lower leg)

	J&J	Synthes	Comb.	Stryker	S&N	Zimmer	Ortho-fix	Others
<b>LU</b>	[0-5]*	[80-90]*	[80-90]*	[10-20]*	[0-5]*	[0-5]*		
<b>BE</b>	[0-5]*	[40-50]*	[50-60]*	[30-40]*	[10-20]*	[0-5]*		
<b>FR</b>	[0-5]*	[30-40]*	[40-50]*	[20-30]*	[10-20]*	[0-5]*	[10-20]*	
<b>PT</b>	[0-5]*	[30-40]*	[40-50]*	[50-60]*	[5-10]*			Medimetal [0-5]*
<b>LT</b>	[10-20]*	[20-30]*	[30-40]*	[0-5]*				ChM [50-60]*
<b>UK</b>	[5-10]*	[20-30]*	[30-40]*	[30-40]*	[20-30]*	[0-5]*	[0-5]*	Ortho, Medimetal together [0-5]*

Source: market reconstruction

Table 11: Group 1 markets IM nails ankle

	J&J	Synthes	Comb.	Stryker	S&N	Acumed	Others
<b>LU</b>	[5-10]*	[60-70]*	[70-80]*	[20-30]*			
<b>BG</b>	[20-30]*	[20-30]*	[40-50]*	[50-60]*			
<b>UK</b>	[30-40]*	[10-20]*	[40-50]*	[20-30]*	[20-30]*	[0-5]*	
<b>ES</b>	[10-20]*	[20-30]*	[40-50]*	[30-40]*	[10-20]*	[0-5]*	
<b>PT</b>	[10-20]*	[20-30]*	[30-40]*	[50-60]*	[0-5]*		Integra, Surgival together [0-5]*
<b>GR</b>	[5-10]*	[30-40]*	[30-40]*	[50-60]*	[5-10]*		

Source: market reconstruction

Table 12: Group 1 markets IM nails humerus (upper arm)

	J&J	Synthes	Comb.	Stryker	S&N	Sanat-metal	Aesculap	Others
<b>AT</b>	[0-5]*	[40-50]*	[40-50]*	[30-40]*	[0-5]*		[10-20]*	ITS [5-10]*, Zimmer, Biomet together [0-5]*
<b>BG</b>	[10-20]*	[20-30]*	[40-50]*			[10-20]*		Medin [20-30]*, Königsee [5-10]*, Zimmer [0-5]*
<b>PT</b>	[0-5]*	[30-40]*	[40-50]*	[40-50]*	[0-5]*	[0-5]*		Biomet [5-10]*, ITS, Medimetal, and Zimmer together [0-5]*

Source: market reconstruction

## IM nails overall

- (264) Stryker and Smith & Nephew are particularly strong in IM nails. Stryker was a pioneer in the development of IM nails and is the number one in most countries, having a market share of more than 30% on a (hypothetical) EEA-wide market for IM nails. Aesculap is a further competitor which is present in more than 20

Member States and is particularly strong in IM nails, having a market share of more than 10% on an EEA-wide aggregate basis. Smith & Nephew is equally strong as Aesculap. As regards the parties, Synthes has a strong position in many countries, while J&J's market share is often negligible (EEA-wide around [0-5]\*%). In most countries, there would be a number of competitors remaining post-merger, often with a significantly higher market share than the increment added by J&J.

- (265) The only exception to this overall picture is Luxembourg, where Synthes is clearly the market leader. Depending on the overall market or sub-segments J&J's market share is small or insignificant. Stryker is present, but has a smaller market position than in other countries, but its market shares under the different market definitions and sub-segments are still larger than the increment added by J&J. Nevertheless, despite the very high combined market share of the parties in Luxembourg in the overall market for IM nails and in sub-segments, the transaction does not significantly impede effective competition. The market volume of the sub-segments is small (in one instance below EUR 10 000, in the other below or around EUR 100 000). The number of hospitals is small and the award of a single tender to another company can strongly influence the market shares so that these are not necessarily indicative of market power. Other competitors with brand recognition for IM nails, such as Stryker, Smith & Nephew and Aesculap are present with a sales force in Luxembourg itself or in the Benelux countries (in case they have set up their sales forces in regional clusters) and could start selling their products immediately in case of an attempted price increase.

#### IM nails femur

- (266) Regarding IM nails for the femur, in Belgium, Luxembourg and the Netherlands the increment added by J&J is insignificant or small. In Belgium and the Netherlands both Stryker and Smith & Nephew are established suppliers of IM nails and have a much stronger position in the market than J&J does. Further competitors such as Aesculap and Biomet are also present. As regards Luxembourg, Stryker, Smith & Nephew and Zimmer are present, albeit with a smaller market share than J&J. However, given the small market value of less than EUR 100 000 the market shares are not necessarily indicative of the strength in the market. Zimmer announced in 2010 the launch of a new IM nail system, which features an anatomically contoured nail in particular for the femur and which is not yet reflected in the sales figures. In Portugal and the United Kingdom, where the increment is higher, Synthes' market share is smaller in turn. In both countries, Stryker and Smith & Nephew, and in Portugal, Laffit SA ("Laffit") are also present with a higher market share than the increment added by the smaller party. On this basis, it can be concluded that the proposed transaction would not significantly impede effective competition in these markets.

#### IM nails tibia

- (267) Regarding IM nails for the tibia, in Portugal and the United Kingdom, Stryker would remain the strongest player also after the transaction, while the parties have a combined market share of [50-60]\*% and [30-40]\*% respectively. In

Lithuania, the Polish company ChM would remain the number 1 player with a market share of [50-60]\*%, while the parties' combined market share is below 40%. In France and Belgium, the increment added by J&J is small and Stryker, Smith & Nephew and in the case of France, Orthofix are significantly stronger than J&J. In Luxembourg, the increment added by J&J is insignificant and both Stryker and Smith & Nephew have higher market shares than the increment. Despite the overall very high combined market share, the transaction would not significantly change the market structure and Stryker and Smith & Nephew would continue to exert a similar competitive pressure on the merged entity as they did before on Synthes. Therefore, the proposed transaction would not significantly impede competition in these markets.

#### IM nails ankle

- (268) Regarding IM nails for the ankle, in Bulgaria, Greece and Portugal, Stryker would post-merger still remain the market leader with a market share of [50-60]\*% and also Smith & Nephew would continue to compete in these countries except Bulgaria where it is not present. However, in Bulgaria the market reconstruction data showed only a very small market volume (well below EUR 5 000), so that it seems possible that the market reconstruction did not capture all suppliers.<sup>184</sup> In the other group 1 markets for IM nails ankle (Luxembourg, Spain and the United Kingdom) Stryker has a higher market share than the increment added by the smaller party. In the United Kingdom, this is also the case for Smith & Nephew. In Spain, Smith & Nephew is smaller than the increment, but it still has a substantial market share (above 10%). In Luxembourg, Stryker remains an established competitor with a strong market share of [20-30]\*%. Therefore, the proposed transaction would not significantly impede effective competition in these markets.

#### IM nails humerus

- (269) Regarding IM nails for the humerus, the transaction would result in three group 1 markets (Austria, Bulgaria and Portugal). In these countries, the combined market share would remain below 50%, with J&J adding an insignificant or small increment in Austria and Portugal and a higher increment in Bulgaria. In all countries at least two competitors with a substantially higher market share than the increment would remain present post-merger. Therefore, the proposed transaction would not significantly impede effective competition in these markets.
- (270) In sum, the proposed transaction would not significantly impede effective competition either in the overall IM nail markets or in the various sub-segments.

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<sup>184</sup> The market investigation indicated that Asian suppliers had recently entered the market, however they are not captured in the market reconstruction.

### 6.3.3.3. Compression Hip Screws

(271) As regards compression hip screws the position of Synthes across the EEA differs. It achieves moderate market shares in some countries, whilst in others it appears to be in a monopolistic position. The proposed transaction would result in eight group 1 markets, namely Belgium, France, Greece, Germany, Italy, Luxembourg, Portugal, and the United Kingdom. In one market (Greece) J&J is significantly stronger than Synthes. Compression hip screws are one of the most mature markets in the area of trauma and the product has seen only very limited changes over the last 40 years<sup>185</sup>.

Table 13: Group 1 markets in compression hip screws (shares 2010, in %).

	J&J	Synthes	Comb.	Stryker	S&N	Zimmer	Aesculap	Others
<b>LU</b>	[5-10]*	[90-100]*	[90-100]*		[0-5]*	[0-5]*		
<b>PT</b>	[0-5]*	[70-80]*	[80-90]*	[0-5]*	[0-5]*		[10-20]*	Laffit, Surgival together [0-5]*
<b>DE</b>	[0-5]*	[60-70]*	[70-80]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	Orthofix [10-20]*, Königsee, Acumed together [0-5]*
<b>BE</b>	[0-5]*	[50-60]*	[60-70]*	[0-5]*	[30-40]*	[5-10]*		Lima [0-5]*
<b>UK</b>	[5-10]*	[50-60]*	[50-60]*	[10-20]*	[20-30]*	[0-5]*	[0-5]*	Ortho [0-5]*
<b>FR</b>	[0-5]*	[40-50]*	[50-60]*	[10-20]*	[5-10]*	[10-20]*	[0-5]*	Integra, Orthofix together [0-5]*
<b>IT</b>	[5-10]*	[40-50]*	[40-50]*	[0-5]*	[5-10]*	[10-20]*		Orthofix [20-30]* Lima [0-5]*

Source: market reconstruction

(272) In Luxembourg, the proposed transaction reinforces the very strong position of Synthes with a moderate increment. Two international competitors (Smith & Nephew and Zimmer) would remain present post-merger albeit with negligible or small market shares. However, the market volume is below EUR 50 000 and the award of a single tender to another company can strongly influence the market shares so that these are not necessarily indicative of market power. Other competitors such as Stryker, Smith & Nephew and Aesculap are present with a sales force in Luxembourg itself or in the Benelux countries (in case they have set up their sales forces in regional clusters) and could start selling their products immediately in case of an attempted price increase. This holds true, in particular, for Smith & Nephew which has a market share of [30-40]\*% in Belgium. On this

<sup>185</sup>

See submission of the Notifying Party of 24 February 2012.



basis the Commission concludes that the proposed transaction would not result in a significant impediment to effective competition in Luxembourg.

- (273) In France, Belgium and Germany the increment added by J&J is insignificant. Although the combined market is between [50-60]\*% and [70-80]\*% there would be, depending on the countries, between three to five competitors remaining, each of them having a higher market share than the increment added by J&J. It is likely that the remaining competitors, which are all established players in the respective country, continue to exert a similar competitive pressure on the merged entity as they did on Synthes pre-merger. Therefore the transaction does not significantly change the market structure and accordingly it can be concluded that the proposed transaction would not significantly impede effective competition in these markets.
- (274) In Portugal, the increment added by J&J is small. Despite the overall combined high market share of [80-90]\*% of the parties a number of competitors remain post-merger: Aesculap with a significantly higher market share than J&J and Stryker, Smith & Nephew and regional player Laffit with a comparable market position to that of J&J. In view of these remaining competitors, the proposed transaction would not significantly impede effective competition in this market.
- (275) In the United Kingdom, the increment added by J&J is moderate, leading to a combined market share of [50-60]\*%. Apart from a number of smaller competitors, Stryker and Smith & Nephew both have a three to four times higher market share than J&J. It is likely that these competitors would be sufficient to constrain the merged entity from increasing prices. Therefore, the proposed transaction would not significantly impede effective competition in this market.
- (276) In Italy, the combined market share post-merger would be below 50%. Although the increment added by J&J is moderate, Zimmer and Orthofix have substantially higher market shares than J&J while Smith & Nephew and Stryker have slightly higher or comparable market shares than J&J. In view of these remaining competitors the proposed transaction would not significantly impede effective competition in this market.

#### 6.3.3.4. IM Hip Screws

- (277) Across the EEA, the market position of Synthes differs depending on the countries concerned. While in some countries it has a market share close to a monopoly, in others its market share is only [10-20]\*%. J&J has sales in a few countries only and in most cases these sales are insignificant. The only exception is Bulgaria, where J&J's market share is [20-30]\*%. While the transaction would result in a small number of affected markets, Bulgaria is the only group 1 market.

Table 14: Group 1 market in IM Hip screws.

	J&J	Synthes	Comb.	Zimmer	Königsee	Medin
BG	[20-30]*	[50-60]*	[80-90]*	[10-20]*	[0-5]*	[0-5]*

Source: market reconstruction

(278) In Bulgaria, the combined market share of the parties would be very high with J&J adding a significant increment of [20-30]\*%. The remaining competitors are Zimmer with a significant market share of [10-20]\*% and low cost providers Königsee and Medin with small market shares. However, in Bulgaria, there is a strong dynamic in the market which has led to a [...] decrease of the parties' sales, which further decreased in 2011.<sup>186</sup> The market investigation confirmed that customers are price sensitive, as patients have to pay for implants themselves and the costs are generally not reimbursed by health insurers. In addition, because of the relatively small market volume of less than EUR [...]\*, the market shares are not necessarily indicative of market power, as the award of a single tender to another supplier can already change the overall picture. Accordingly, it can be concluded that the proposed transaction does not significantly impede effective competition in the market for IM hip screws in Bulgaria.

#### 6.3.3.5. (Cancellous) cannulated screws

(279) In phase I, competitors were asked to submit their sales figures for all cannulated screws. As Synthes does not offer any cortical cannulated screws and as it is likely that cancellous cannulated screws belong to a different market, a more comprehensive market reconstruction in phase II was done for cancellous cannulated screws only.

(280) Regarding cancellous cannulated screws, the market reconstruction identified 18 group 1 markets, namely in Austria, Belgium, Estonia, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, and the United Kingdom.

(281) The comparison of the firms' sales in cancellous cannulated screws in relation to their overall sales of cannulated screws shows that cancellous cannulated screws account for most of the market. This is to be expected as cannulated screws are usually used to drill into the softer medullary part of the bone, and a cancellous thread is better suited to the needs than a cortical thread which rather sticks to the hard part of the bones. The average ratio of cancellous cannulated screws compared to all cannulated screws of the three biggest competitors is [80-90]\*%. J&J generates more than [...] of its EEA wide turnover of cannulated screws with cancellous cannulated screws. The overall market volume is thus not likely to encompass more than 120% of the reconstructed volume for cancellous cannulated screws. The parties' market shares would therefore not decrease by more than about 20% in case of an overall cannulated screws market<sup>187</sup>; under such a scenario Italy, Greece, and possibly Lithuania would no longer qualify as group 1 markets. For J&J's trauma segment cannulated screws are, [...]\*. On an aggregated (EEA level) J&J achieved around [...] of its total trauma sales

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<sup>186</sup> The parties provide with their submission of 23.11.2011 provide three factors to explain the [...] erosion of the parties' sales: (i) a very unfavourable economic environment, public and private sources of funding for trauma devices have dried up; (ii) hospitals increasingly source trauma devices from price-aggressive rivals to ensure patients can afford treatment; and (iii) the entry and expansion of rivals that compete aggressively on price]\*.

<sup>187</sup> Not to be confused with a decrease by 20 percentage points.

with cannulated screws. This shows the relative strength of J&J in this segment and explains the high increments the transaction would bring about in the individual countries.

- (282) The parties would have high combined market shares in cancellous cannulated screws in many Member States. In 14 markets, the combined market shares are superior to 60% and in six even higher than 80%. The increment added through the proposed transaction is, with five exceptions, superior to 10% and in five cases significantly over 20%.

Table 15: Group 1 markets in cancellous cannulated screws (shares 2010, in %).

	J&J	Synthes	Comb.	Stryker	S&N	Zimmer	Acumed	Others
LU	[30-40]*	[60-70]*	[90-100]*	[0-5]*		[0-5]*		
LV	[10-20]*	[80-90]*	[90-100]*					
SI	[5-10]*	[90-100]*	[90-100]*		[0-5]*	[0-5]*		
EE	[30-40]*	[60-70]*	[90-100]*	[0-5]*				Königsee [0-5]*
NE	[0-5]*	[80-90]*	[80-90]*	[10-20]*	[0-5]*	[0-5]*		Biomet [0-5]*
AT	[10-20]*	[70-80]*	[80-90]*	[0-5]*		[0-5]*		ITS [10-20]*; Königsee, Wright Medical together [0-5]*
BE	[10-20]*	[50-60]*	[70-80]*	[0-5]*	[5-10]*	[0-5]*	[10-20]*	
PL	[5-10]*	[60-70]*	[60-70]*	[0-5]*				ChM [20-30]*; Medgal, Biomet together [0-5]*
FR	[30-40]*	[30-40]*	[60-70]*	[20-30]*	[0-5]*	[5-10]*		Königsee, Biomet and Tornier together [0-5]*
UK	[30-40]*	[20-30]*	[60-70]*	[10-20]*	[5-10]*	[0-5]*	[5-10]*	Ortho, Biomet, Tornier, Lima, Wright together [5-10]*
ES	[20-30]*	[30-40]*	[60-70]*	[10-20]*	[0-5]*	[5-10]*		Surgival, Biomet, Laffit, Tornier, Wright, Marquardt together [5-10]*
SK	[40-50]*	[10-20]*	[60-70]*					Medin [30-40]*
PT	[5-10]*	[50-60]*	[60-70]*	[10-20]*	[0-5]*	[0-5]*	[0-5]*	Biomet[10-20]*, Marquardt[5-10]*, Surgival [0-5]*
IE	[10-20]*	[40-50]*	[60-70]*	[10-20]*	[5-10]*	[0-5]*	[10-20]*	Marquardt [0-5]*
DE	[10-20]*	[30-40]*	[40-50]*	[20-30]*	[0-5]*	[0-5]*	[0-5]*	Königsee [10-20]*, Axomed [5-10]*, Sanatmetal, Wright, Tornier together [0-5]*
LI	[10-20]*	[20-30]*	[40-50]*	[5-10]*				ChM [40-50]*
EL	[20-30]*	[10-20]*	[40-50]*	[20-30]*	[5-10]*	[0-5]*		Sanatmetal [5-10]*, Surgival, Biomet, Tornier, Marquardt, Wright, Laffit together [5-10]*
IT	[5-10]*	[30-40]*	[30-40]*	[10-20]*	[0-5]*	[5-10]*	[30-40]*	[5-10]* Lima; Königsee, Tornier, Sanatmetal, and Marquardt together [0-5]*

Source: market reconstruction

- (283) Synthes offers nine types of cancellous cannulated screws of different lengths, among them one headless. J&J has a broad portfolio of different cannulated screws which are particularly branded: ACE, SS, Hip Fix Ti, SCFE, Olmed Screw, FRS, and the Barouk cannulated screw, used mostly for foot surgery, [...]\*. The merger would join two very strong suppliers of cannulated screws with branded products and a wide portfolio including for example cortical cannulated screws. Stryker (Asnis III) and Zimmer (Magna FX, CEP, and Herbert) also offer a diversity of branded cannulated screws. Smith & Nephew has an assortment of non-labelled cannulated screws with different length, alloy and thread (cancellous and cortical).
- (284) As shown in the table above, the transaction reinforces substantially the position of the market leader. In Latvia, the transaction would even result in a monopoly. Therefore, the Commission concludes that the transaction would result in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for cancellous cannulated screws in Latvia.
- (285) In Austria, Belgium, Estonia, France, Luxembourg, Slovenia, Spain, and the United Kingdom, the transaction would lead to a merger between the current market leader (usually Synthes with the exception the United Kingdom, where it is J&J) and the number two, which has in most cases substantial market shares of more than 20%. The market structure is thus significantly changed widening the gap between the respective market leader and the number 2 in the market. In all these countries there would remain only one or no competitor with a considerable market presence. In France, the parties are the two largest players with market shares of [30-40%]\*. Post-merger the merged entity would be the clear market leader [60-70]\*%, considerably stronger than the next players, namely Stryker [20-30]\* and Zimmer [5-10]\*%. Regarding market specificities in individual countries, it should be noted that in Austria tenders are less common than in other countries. In Belgium and Austria purchasers are particularly price insensitive or only moderately price sensitive, which is reflected in the high price levels in these countries where the role of surgeons' preferences in the purchasing decisions is particularly strong.
- (286) The proposed transaction increases the already high level of concentration in these markets, as well as the distance between the leading player and the remaining competitors. Therefore, it is likely that it would result in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in the market for cancellous cannulated screws in Austria, Belgium, Estonia, France, Luxembourg, Slovenia, Spain, and the United Kingdom.
- (287) In the Netherlands, J&J would add a small increment to the already very high market share of Synthes of [80-90]\*% and only one competitor (Stryker) with a market share higher than the increment added by J&J would be left post merger. The other three remaining competitors achieve together a market share similar to J&J's. Given the high starting point the proposed transaction worsens further the market structure. Therefore, the Commission concludes that the transaction would result in a significant impediment to effective competition by creating a

dominant position or further strengthening the dominant position of the parties in the market for cancellous cannulated screws in the Netherlands.

- (288) The distance between the merged entity and the remaining competitors would be very large in all these countries so that these competitors would not be in a position to sufficiently constrain the merged entity. It can therefore be concluded that the proposed transaction would lead to a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in Austria, Belgium, Estonia, France, Latvia, Luxembourg, the Netherlands, Slovenia, Spain, and the United Kingdom. Given the very high combined market shares, the competition concerns and the reasoning are still valid even if the parties' combined market shares were reduced by 20% on the basis of an alternative overall market for cannulated screws.
- (289) The combined market shares are also high in Ireland, Poland, Portugal, and Slovakia. In Poland, J&J adds a moderate increment of [5-10]\*% to the strong position of Synthes with a market share of [50-60]\*%. However, one significant competitor, the regional player ChM with [20-30]\*% would remain post-merger. Besides ChM, there are other international players present, e.g. Stryker, achieving a not insignificant market share. Poland is a country where tendering is widespread and where surgeons play a comparatively small role in the purchasing process (see Recital (184)). ChM is a low-cost, full-line supplier, based in Poland. On this basis, it is likely that the proposed transaction would not lead to a significant impediment to effective competition in Poland.
- (290) In Slovakia, Synthes adds a considerable increment of [10-20]\*% to the strong position of J&J leading to a combined market share of [60-70]\*%. Post-merger there would be one competitor left, Medin with a significant market share of [30-40]\*%. Medin is a full-line supplier and as a Czech company for historical reason well accepted in Slovakia. Given its firm and established position in the market it is likely that it would continue to constrain the merged entity and that the proposed transaction would not lead to a significant impediment of effective competition in Slovakia.
- (291) The increment brought by J&J is with [5-10]\*% moderate in Portugal and is [10-20]\*% in Ireland. There are, however, in both countries at least two well established players present in the market with market shares of more than 10% each. Furthermore, Smith & Nephew and Zimmer are present in these markets and so are some other smaller suppliers.
- (292) The same applies to Italy and Germany, where the combined market shares are significantly lower than in Portugal and Ireland (below 50%) with similar increments.
- (293) The Polish supplier ChM is currently by far the market leader in Lithuania. After the proposed transaction, the combined market share of J&J and Synthes would be slightly below ChM's. Furthermore, there is with Stryker a strong international player active in the country with a moderate market share.

- (294) In Greece, J&J has a stronger presence than Synthes. The merged entity would replace the current market leader Stryker with combined market shares of [30-40]\*%. Stryker and Acumed both have an established position in the market. Smith & Nephew and the low cost supplier Sanatmetal have a moderate market presence, and there are a number of other competitors selling cancellous cannulated screws in Greece, among others Zimmer. Given this, no significant impediment of effective competition is likely in Greece due to the notified transaction.
- (295) Therefore, sufficient competitors, capable to constrain the merged entity, would remain present post-merger in Germany, Greece, Ireland, Lithuania and Portugal.
- (296) In view of the foregoing and taking into account the market characteristics as described in Sections 6.2 and 6.3.2, the Commission concludes that the proposed transaction would result in a significant impediment to effective competition in the markets for cannulated screws (irrespective of whether or not cancellous cannulated screws are considered as a separate market) in Austria, Belgium, Estonia, France, Latvia, Luxembourg, the Netherlands, Slovenia, Spain and the United Kingdom.

#### 6.3.3.6. Ancillaries

- (297) On an overall market for ancillaries the transaction would result in five group 1 markets<sup>188</sup>. On the basis of markets for individual sub-segments, the proposed transaction would result in 13 group 1 markets for pins<sup>189</sup> (small nails used to fix and connect bones) and four group 1 market for wires<sup>190</sup> (thin metal cables to be wrapped around a tendon or a bone). The combined market shares in these group 1 markets range from [40-50]\*% to [80-90]\*%. J&J is not active in staples, general screws and cables and thus there is no overlap in these sub-segments.
- (298) As discussed in Section 5.1.1.7., pins and wires are cheap, generic products offered by most competitors, which in turn often source them from contract manufacturers. As a lot of hospitals have some kind of volume discounts in their framework contracts with one of their main suppliers, they tend to source pins and wires under these framework contracts to increase the volume leading to higher reductions over all products which outweigh possible savings by sourcing pins separately. They also avoid transaction costs, not only as regards the purchasing process but also as regards logistics and stocking and it is accordingly in general not worth their while to source pins from cheaper third suppliers. In some cases, pins are part of the plating systems as the plate can be fixed to the bone by both screws and pins.<sup>191</sup> Therefore, the strong position of Synthes in general trauma products translates into high market shares in ancillaries in some countries. Although pins and also wires could under both demand and supply side

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<sup>188</sup> Estonia, Ireland, Luxembourg, Slovenia, and Sweden.

<sup>189</sup> These are Austria, Belgium, Czech Republic, Estonia, Germany, Ireland, Luxembourg, Portugal, Slovakia, Slovenia, Spain, Sweden.

<sup>190</sup> Belgium, Greece, Portugal and the United Kingdom.

<sup>191</sup> For example J&J's wrist plate (DVR) has holes for both pins and screws.

substitutability be regarded as product markets of their own, a significant separate demand of hospitals for such devices naturally does not exist as is reflected in the hospitals' tender or purchasing lots. In the absence of specific market transactions, i.e. as the products are not bought separately, it is likely that the proposed transaction would not significantly impede competition in these markets. However, in case the merged entity would significantly raise prices for these ancillaries, it is likely that the hospitals would source the products from third suppliers given that the products are generic and widely available and have no particular specifications.

#### 6.3.3.7. External fixation

(299) According to the information provided by the parties the proposed transaction would not result in any group 1 markets in the area of external fixation devices. There is only one affected market, namely Germany, where J&J's market share is below [0-5]\*% and where J&J's sales have been de minimis[...] (less than EUR [...] in 2010). J&J no longer actively promotes external fixation devices in Europe and only makes legacy sales. Accordingly, the transaction would not result in a significant impediment to effective competition as regards any external fixation market.

#### 6.3.4. Conglomerate effects

(300) In the market investigation some competitors raised concerns that the merged entity might start bundling trauma devices with other orthopaedic devices such as joint reconstruction or prostheses. Before the merger, Synthes was the leading trauma devices supplier in many EEA countries, while J&J is said to be strong in joint reconstruction, so that post-merger J&J might have a leading position in several orthopaedic implant markets. However, the market investigation showed trauma devices and prosthetic/joint replacements are not very frequently bought together<sup>192</sup> nor offered together as a package by manufacturers.<sup>193</sup> In addition, other suppliers would be able to offer packages for trauma and joint replacement devices as they have a similarly broad portfolio.

(301) There were in particular concerns that the merged entity could expand the scope of the AOF and thereby leverage Synthes' exclusive partnership with the AOF in trauma, spine and CMF to other markets such as joint reconstruction or prosthetics.<sup>194</sup> However, the market investigation confirmed that this was not likely. Under the current cooperation agreement between Synthes and the AOF, the cooperation is limited to Synthes and the AOF and it is not open to other manufacturers. The reach of the agreement is also independent of the question of who is the owner of Synthes, which means the agreement would not automatically be extended to J&J's products when the proposed transaction is implemented. According to the representatives of the AOF, [...]\*, entering into new fields has not proved to be as successful for the AOF as its activities in

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<sup>192</sup> See replies to question 167 of Q 28 – Phase II Questionnaire to customers (Hospitals).

<sup>193</sup> See replies to question 168 of Q 28 – Phase II Questionnaire to customers (Hospitals).

<sup>194</sup> See minutes of telephone call with Aesculap, [ID 2447]\*.



trauma for it requires both surgeon competences and interest in new fields of R&D, teaching and 'recruiting' of volunteers from the surgeon community which today are in general commercially remunerated by private medtech companies.<sup>195</sup>

- (302) Taking this into account the risk of conglomerate effects resulting from the proposed transaction can be excluded.

### 6.3.5. Conclusion

- (303) More than half of the competitors expressed concerns that the transaction could affect their business.<sup>196</sup> Customers also raised concerns that the merged entity could post-merger raise prices<sup>197</sup> or slow down innovation<sup>198</sup> and affect negatively competition<sup>199</sup>. The reasons are in particular linked to the already strong position of Synthes<sup>200</sup>, its relationship with the AOF<sup>201</sup>, and the strength of the merged entity's sales force<sup>202</sup>.
- (304) Based on the above and the market characteristics explained in Section 6.3.2. the Commission concludes that the merged entity would strengthen the very strong position of Synthes (and in some markets J&J) resulting in a significant impediment to effective competition by creating a dominant position or further strengthening the dominant position of the parties in substantial parts of the internal market. This holds for the following markets: (i) non anatomic plating systems in Denmark, Norway, Slovenia, Sweden, and the United Kingdom; (ii) anatomic wrist plating systems in Norway, Portugal, Spain, Sweden, and the United Kingdom; (iii) anatomic shoulder plating systems in Portugal, Sweden, and the United Kingdom; (iv) anatomic ankle plating systems in France, Germany, Portugal, and the United Kingdom; (v) anatomic knee plating systems in the Czech Republic, Portugal, and Slovenia; (vi) anatomic elbow plating systems in Portugal; and (vii) cannulated screws (irrespective of whether cancellous cannulated screws are considered as a separate market or not) in

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<sup>195</sup> See minutes of the meeting with AOF representatives, [...]\*, [ID 5932]\*.

<sup>196</sup> Minutes of a conference call with Aesculap on 4 November 2011, [ID 2447]\*; reply of Aesculap to question 55 of Q17- questionnaire to competitors (Trauma), [ID 2246]\*.

<sup>197</sup> Reply of Königsee to question 55 of Q17- questionnaire to competitors (Trauma), [ID 2359]\*; Replies of NHS Commercial Solutions, Az. Ospedaliera Antonio e Biagio, Trauma Surgery district hospital to question 85 or 86 of Q18- questionnaire to customers (hospitals), [ID 1519, 2006, 1730]\*.

<sup>198</sup> Replies of Azianda U.S.L.N., Tiroler Landeskrankenanstalten to question 85 or 86 of Q18- questionnaire to customers (hospitals), [ID 1715, 1726]\*.

<sup>199</sup> Replies of Akademiska Sjukhuset, Allgemeines Krankenhaus Linz, Az. Ospedaliera Policlinico di Modena, Az. Ospedaliera Antonio e Biagio, Leeds Teaching Hospitals, Wojewodzki Szpital Specjalistyczny w Czestochowie, ZKH. Group Twente, Trauma Surgery District Hospital, Onze Lieve Vrouwe Gasthuis Verhees, Vivantes to question 85 or 86 of Q18- questionnaire to customers (hospitals), [ ID 1774, 1629, 1982, 2006, 1744, 1708, 1684, 1730, 2140, 2281]\*.

<sup>200</sup> Replies of Zimmer and ITS to question 55 of Q17- questionnaire to competitors (Trauma), [ID 1521 and 1425]\*; Replies of Akademisch Medisch Centrum, Sunderby Sjukhus, Linköpings Universitetssjukhus to question 85 or 86 of Q18- questionnaire to customers (hospitals), [ ID 1728, 1656, 2369]\*.

<sup>201</sup> Reply of Citieffe to question 55 of Q17- questionnaire to competitors (Trauma), [ID 2270]\*.

<sup>202</sup> Reply of ChM to question 55 of Q17- questionnaire to competitors (Trauma), [ID 1394]\*.

Austria, Belgium, Estonia, France, Latvia, Luxembourg, the Netherlands, Slovenia, Spain and the United Kingdom.

#### **6.4. Spine - compatibility with the internal market**

##### *6.4.1. Parties' view and general market characteristics*

- (305) The parties argue that large players as well as new entrants and small players pose an important competitive constraint on J&J and Synthes, aggressively competing with high quality products and routinely winning business from both parties. The parties also maintain that historic market shares for 2010 alone do not accurately represent the competitive dynamics in the spine markets, especially in view of many recent entrants into the EEA with spine devices over the last five years (e.g. K2M, Nuvasive, Alphatec, Biomet, and Globus, which are large international orthopaedic or spine devices companies), and expansion of strong regional and local players such as LDR Holding Corporation ("LDR"), Ulrich GmbH & Co.KG ("Ulrich"). The Notifying Party is of the view that spine market growth combined with low barriers to entry/expansion creates opportunities for new entrants and other players. Furthermore, spine markets are characterised by pro-competitive hospital purchasing patterns (joint purchasing and multisourcing) and strong countervailing buyer power and that the downward pricing pressures applying across the whole health sector make the likelihood of price increases unlikely.
- (306) The Notifying Party also claims that J&J and Synthes are not each other's closest competitors and that spine device markets are subject to constraints not only from equivalent devices, but also from respective neighbouring product areas, e.g. traditional fixation devices face constraints from motion preserving implants, while interbody cages are constrained by artificial discs, etc. For the purposes of this Decision, it can be left open whether competitive constraints stemming from neighbouring markets, such as motion preserving stabilisation systems or artificial discs, have a meaningful constraining effect on traditional fixation devices, given that in any event a sufficient number of competitors active in the respective devices would remain in all group 1 market concerned by this Decision.
- (307) Compared to trauma, spine markets are more dynamic and innovative. According to Millennium Research Group reports,<sup>203</sup> the European market for spinal implants is growing steadily due to an expanding elderly population and a correlated increase in procedure volumes at a moderate compound annual growth rate of approximately 5.5% until 2014. A number of product segments drive innovation in spinal implants. There is an increasing demand for minimally invasive surgical approaches ("MIS", e.g., minimally invasive thoracolumbar fixation products, or VCF treatment devices), products for the aging spine, spinal non-fusion technologies, interbody cages with inherent fixation, and navigation

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<sup>203</sup> European Markets for Spinal Implants 2010 (France, Germany, Italy, Spain, UK), Millenium Research Group, August 2010.

and image guided surgery technologies. Although traditional spine fusion devices still represent the preferred method of treating spine related pain in Europe, those new methods (for example, minimally invasive techniques), are growing more rapidly than the overall spine market and it is likely that they will continue to grow as better procedure outcomes will increase adoption of novel techniques.

#### 6.4.2. Spine Fusion

##### 6.4.2.1. Market Structure and competitors

- (308) As regards the market structure, based on the Commission's market reconstruction data, the European spine market is characterised by several leading players, pioneered overall by Medtronic ([20-30%]\*), then by J&J, Synthes and Stryker each accounting for ([10-20]\*%), followed by a number of other international players, i.e. Aesculap ([0-5]\*%), Zimmer ([0-5]\*%), Alphatec ([0-5]\*%), Biomet ([0-5]\*%), more local/regional players (e.g. Ulrich, LDR)\* and relatively recent US-based entrants, such as K2M, Nuvasive, or Globus.
- (309) In recent years, spinal implant markets have seen a number of entries by US-based companies, i.e. K2M (2008), Nuvasive (2009), Globus (2009), Alphatec Spine Ltd ("Alphatec") (through acquisition of the French medical device company Scient'x in 2010) and Biomet (2005), which are all large and international companies. Given the size and growth of the US market, these new entrants started in the US and established themselves as successful and innovative companies and continue to expand overseas. Typically new entrants would enter through the United Kingdom or Germany and then expand into other countries (Sweden is used as a gateway to the Nordic region). The expansion of regional European players into neighbouring countries (e.g., LDR, Ulrich, LfC) can also be observed.

##### Competition from Medtronic

- (310) Medtronic is considered as the global and EEA-wide leader of today's spine market, currently offering the widest range of spine devices across all segments (fusion, non-fusion, VCF). Medtronic is an innovative supplier, focusing its recent technological developments on minimally invasive techniques (in spinal fusion and other areas), dynamic stabilisation (non-fusion), and kyphoplasty treatments (VCF). In 2010, Medtronic acquired Axon Surgical, active in another innovative area, spinal neuromonitoring technology. Medtronic is also a leading player in a number of markets across the EEA.
- (311) In the market investigation, several competitors raised concerns that after the merger Medtronic and J&J/Synthes would form a "duopoly" driving the spinal business and that due to their strength smaller competitors would not be able to enter the market.<sup>204</sup> However, as set out in Section 6.4.5 below, a theory of harm based on coordinated effects is difficult to maintain.

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<sup>204</sup> Reply to concluding questions of Q14 - questionnaire to competitors (spine).

- (312) In the SO, the Commission took the preliminary view that post-merger Medtronic might not have sufficient incentives to effectively constrain the merged entity in 24 group 1 spine fusion markets, where based on 2010 market reconstruction data, Medtronic appeared as the only remaining competitor with a market share of over 10% in a given group 1 market.<sup>205</sup> The Commission considered that this could be possible in situations where before the merger J&J was confronted with the risk of losing sales to only two remaining established players, namely Synthes and Medtronic, in case of a hypothetical price increase. After the reduction in the number of established players in these markets Medtronic and J&J/Synthes would no longer run the risk of not being selected at all by hospitals, especially in those cases where both need to be retained (for example, due to security of supply reasons or because of different surgeons preferences coexisting in the same hospital. The Commission's view was largely based on hospital replies indicating that a minimum of three suppliers is required in order to ensure a competitive supply of implants, strong surgeons' preferences and reluctance to switch from their main suppliers.<sup>206</sup>
- (313) In reply to the SO, the parties have pointed out that such a theory would only be hypothetical and in any case would not be supported by the facts or the results of the market investigation. The Commission has carried out a further investigation and the analysis of the case file showed that even in hypothetical cases where only two out of three suppliers are retained by hospitals, in all group 1 markets Medtronic and J&J/Synthes would not be the only credible suppliers capable of playing the role of the "main" and "secondary" supplier.<sup>207</sup>
- (314) The Commission has found that in cases where hospitals source from several suppliers, the differences in volume between the main supplier and the secondary supplier can be as high as 60%. Therefore, Medtronic and J&J/Synthes would still have incentives to compete with each other for the position of the main supplier with the greatest share of volume, rather than resign itself to the role of secondary supplier. The investigation has confirmed that typically the selection of suppliers does not guarantee volumes and it is likely that suppliers continue to compete to maximise purchase orders. Finally, looking forward, some competitors have pointed out that there is a growing tendency for hospitals to source a significant portion of demand from a "one-stop-shop" thereby saving

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<sup>205</sup> In United Kingdom, Austria, Norway, Estonia, Latvia, Slovenia, Slovakia, Hungary, Luxembourg, Ireland, and Czech Republic in one or more of the following product segments; thoracolumbar pedicle screw systems, cervical pedicle screw systems, cervical plating systems, TLIF devices, thoracolumbar corpectomy and cervical corpectomy devices.

<sup>206</sup> Based on replies to question 3, column 3 of Q18 - questionnaire to customers (hospitals).

<sup>207</sup> For example, according to replies of Austrian hospitals, customers tend to multisource and conclude contracts with two to four suppliers (or more in case of purchasing groups), allocating up to 80% of sales volumes to the main supplier (such as, Medtronic, Synthes, J&J, Aesculap, Stryker, or Hofer), and the remaining to one or more other suppliers (such as, Medtronic, Synthes, J&J, Zimmer, Aesculap, and others). See replies of hospitals and purchasing groups to question 3, column 3 of Q18 – questionnaire to customers (hospitals). This view is also consistent with numerous hospital replies indicating that there are many other credible alternatives to the products of the parties in spine fusion (replies to question 32, 37, 38, 41, 49, 50, 52, 61, 62, 64, 82, 91, 92, 94, 109, 130 of Q28 - Phase II - questionnaire to customers hospitals).

time and costs, benefiting from discounts on volume and easier inventory management. It can reasonably be expected that such a trend is likely to further intensify competition between the merged entity and Medtronic.

- (315) Based on the above, the Commission concludes that even in a situation where hospitals source from only two suppliers, Medtronic would still have incentives to compete and would be a credible competitor capable of effectively constraining the merged entity.

#### Competition from other players

- (316) In addition to the top three players, there are numerous companies active across Europe in the field of spine devices, most notably the players identified in Recitals ((317))-((325)), which continue to innovate and invest in new products<sup>208</sup>:
- (317) Stryker is a global leader of orthopaedic devices, also active in spinal implants with a broad product portfolio across spine fusion, non-fusion and VCF. Most recently, Stryker is reported to have launched a minimally invasive lateral access product, a segment still pioneered by Nuvasive.
- (318) Zimmer is also a global player active in various orthopaedic devices, including spine medical devices. Zimmer's strongest competitive arm is its dynamic stabilisation systems (Dynesys and Wallis). It also offers products in all major spine fusion and non-fusion categories. In 2008, Zimmer acquired Abbot Spine, boosting Zimmer's presence in spine markets.
- (319) Aesculap is a surgical devices division of the Germany-based company B. Braun Melsungen AG ("B. Braun"), one of the largest healthcare suppliers globally. Aesculap has a broad product portfolio of spinal implants and has a strong footprint in a number of countries across the EEA.
- (320) Alphatec is a relatively recent US-based entrant, active in spinal products. Alphatec has entered the European markets only in 2008 and in 2010 has acquired the French-based Scient'x. Alphatec offers a wide range of spinal implants for fusion, non-fusion and VCF procedures and only recently (2010) started introducing Alphatec innovative products from the US in the EEA markets (including thoracolumbar pedicle screw system Zodiac and MIS Illico/OsseoScrew).
- (321) Biomet is a global orthopaedics company, headquartered in the US. Biomet has been present in Europe for over ten years and offers a broad range of spinal devices, with a main focus on fusion devices. Biomet also offer VCF products.
- (322) K2M is a US-based and relatively new spine-only company (established by leading surgeons in 2005), which entered the EEA market only in 2008 via the

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<sup>208</sup> See replies to question 90 of Q14 – questionnaire to competitors (spine) and replies to Annex 1 of follow-up request for information dated 30 January 2011.

UK market. Like other players K2M offers a broad range of spinal fusion implants. K2M is an innovative entrant, with a unique focus on innovative approaches to complex spinal deformity treatment and minimally invasive approaches. K2M has also built a complete degenerative portfolio and recently announced the launch of a lateral interbody device.

- (323) Nuvasive is another relatively new company (founded in 1997 in the US), which has recently entered the EEA, and specializes in spinal devices. Nuvasive entered the EEA in 2008 through the United Kingdom, and is now active in at least six countries across the EEA and is increasing its presence. Nuvasive has pioneered the lateral surgical approach to the spine fusion market with the development of a lateral LLIF interbody cage, minimally invasive surgical platform, and nerve avoidance monitoring system. Beyond LLIF, Nuvasive offers a broad range of products, covering most of the spine segments.
- (324) Globus is also a recent US-based entrant, a spine-only company, founded in 2003 and active in the EEA since 2008. Globus has a broad range of spine fusion devices and has been expanding into adjacent more novel areas, such as non-fusion technologies. Globus also offers a very broad "suit of spinal products".
- (325) Ulrich Medical is a German-based company, active across major spine fusion product categories and dynamic stabilisation devices (non-fusion). Ulrich's competitive arm is in its innovative implants, including corpectomy cages, and easy-to use instruments. Ulrich continuously extends its presence across Europe and is already present in at least 12 countries in the EEA.
- (326) In addition to these larger companies there are other international players (e.g. Integra Lifesciences Corporation ("Integra Lifesciences"), Lanx LLC ("Lanx")) and smaller regional players which focus on certain Member States or groups of Member States, e.g. French based LDR, Medicrea International ("Medicrea") and Spine Vision, Swiss Spine Art and Pina Medizintechnik Vertriebs AG ("Pina Medizintechnik"), Polish LfC Sp. z o.o. ("LfC"), German Peter Brehm GmbH ("Peter Brehm") and many others.<sup>209</sup>
- (327) In the SO, the Commission took the preliminary view that post-merger such "smaller" players in the group 1 markets, where the Commission raised objections, would not be able to pose a real competitive constraint on the merged entity and that there was no convincing evidence in support of the view that new entrants would be more successful than other "small" players currently present in these markets. The Commission's view was based on the "small" market shares of these players (in most cases less than 10%); the fact that other players are not equivalent to Medtronic, J&J and Synthes in terms of other important parameters, such as strength of sales forces and overall surgeon training capacity; and because

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<sup>209</sup> For example, AMT, Biotech, CHM, Coligne, Hofer, Icotec AG ("Icotec"), Kiscomedica, MAXXSPINE Ltd ("MaXX Spine"), MBA Group, NovaSpine LLC ("NovaSpine"), Permedica Manufacturing ("Permedica"), ProSpon spol. s r.o. ("Prospoon"), Southern Medical (Pty) Ltd. ("Southern Medical"), SpineCraft, LLC ("Spine Craft").

the isolated customer switching examples provided by the parties were not reliable as solid evidence (partly due to the lack of transparency in the market).

- (328) Following up on the SO, the Commission carried out a further investigation and reconstructed the market share evolution data for 2009 and 2011. The parties claimed that in the spine area the market reconstruction of only one year is not likely to be reliable due to the dynamic nature of the market and recent entry of aggressive competitors. The new data confirmed the parties' view that the market shares of J&J, Synthes and Medtronic are contestable. As set out in the product specific sections, the investigation also showed that some of the existing established "smaller" players as well as new innovative companies have been able to gain meaningful market shares in recent years in a number of countries concerned by the SO. The investigation also confirmed further entry plans for a number of markets. As regards the small markets, the new data showed that market shares can be highly volatile, especially given overall high prices for spine surgical procedures and relatively small number thereof in those markets.<sup>210</sup> Finally, as already pointed out, the vast majority of customer replies confirmed that products of so-called "smaller" players are credible alternatives to the products of the parties and hospitals consider them as capable of meeting significant hospital demand for spine devices.<sup>211</sup>
- (329) The Commission concludes, based on the results of the market investigation, that these competitors can exercise a sufficient competitive constraint on the parties in their areas of activity.

#### 6.4.2.2. Barriers to entry and expansion

##### Ability to offer surgeon training and education

- (330) The need for manufacturers to offer a sufficient level of surgeon training and education in their devices is also a typical feature of spine markets. However, in the spine markets, AOF has a much more limited reach than in trauma.<sup>212</sup> In the area of spine Medtronic has the largest training capacity in terms of number of surgeons trained and a historic reputation in the area of spine.
- (331) While AO Spine is exclusive to Synthes, other spine market players participate in internationally renowned spine society meetings, such as EuroSpine (Spine Society of Europe)<sup>213</sup>, CSRS (Cervical Spine Research Society), ISSLS International Society for the Lumbar Spine, Spine Week (combined meeting of

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<sup>210</sup> For example, Estonia has the smallest number of spine surgical procedures in the Baltics; there are only four hospitals that carry out spine surgeries and even the largest hospital employs only one spine surgeon.

<sup>211</sup> See replies to questions 32, 37, 38, 41, 49, 50, 52, 61, 62, 64, 82, 91, 92, 94, 109, 130 of Q28 - Phase II – questionnaire to customers (hospitals).

<sup>212</sup> When the AOF was founded, it originally focused on trauma, while it entered spine only later, and did not achieve there the same outstanding position that it achieved in the field of trauma.

<sup>213</sup> EuroSpine is the major European spine trade conference. In 2011 EuroSpine had over 100 exhibitors, most of which are suppliers of spine implants (Submission of the Notifying Party of 1 November 2011).

leading spine societies), IMAST (International Meeting of Advanced Spine Techniques) and other more local/regional societies (for example, the Deutsche Wirbelsäulengesellschaft in Germany or the Congreso de la Sociedad Española para el Estudio de las Enfermedades del Raquis in Spain). In addition, most market players offer a variety of surgeon educational opportunities on a regular basis, including instructional trainings, hands-on cadaveric trainings, learning centre trainings, symposia/congresses and visitations<sup>214</sup>. Companies also tend to involve surgeons in their product development initiatives. All companies offer product-specific training sessions to end-users on the use of new devices. Although in relation to their size, many market players have somewhat lower surgeon training rates in terms of number of surgeons trained or number of training events held compared to the market leaders, Medtronic, Synthes or J&J<sup>215</sup>, the training of other players is of no significantly lower quality or efficacy, as acknowledged by most competitors in reply to the market investigation.<sup>216</sup>

- (332) In reply to the SO, the parties provided further witness evidence to this effect. For example, surgeon [...] from [...] Hospital in [...] (UK) stated for spine devices that *"the quality of training and the level of service is not determined by the size of a manufacturer or by how established it is. In particular, the training opportunities offered by some of the new entrants such as K2M can be particularly interesting because of the opportunity to meet and discuss cases with other leading surgeons around the world. This is particularly the case in a market where company representatives move readily between suppliers. I have no concerns that a newer entrant to the UK market, such as K2M suffers from deficiencies in the quality of its training and services."*<sup>217</sup>
- (333) The Commission, therefore, concludes that the ability to offer surgeon training could be a barrier for a new entrant. However, for group 1 markets this barrier is of less importance, especially given that a number of players are already present in the given markets and have training infrastructures of comparable quality and efficacy in their respective fields of activity.

The role of surgeons preferences in the procurement process

- (334) Similarly, as in other surgical devices markets, surgeons play an important role in the selection of surgical devices for the correction of spinal disorders. Accordingly, across all countries the majority of hospitals have considered that surgeons' preferences are an important, very important or the most important criterion in purchasing decisions.<sup>218</sup> In view of this, the change of a supplier

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<sup>214</sup> For example, where visiting surgeons may attend procedures of host surgeons.

<sup>215</sup> Replies to Question 3 of Q30 – Phase II - questionnaire to competitors (spine). The reply of Synthes to EC request of 8 December 2011 (p.4-5), also acknowledged that Medtronic, Synthes and J&J are the strongest players in terms of surgeon training capacity in Europe, followed by Aesculap.

<sup>216</sup> Replies to question 4 of Q30 – Phase II - Questionnaire to competitors (Spine).

<sup>217</sup> Annex 1 to the Reply to SO by the Notifying Party.

<sup>218</sup> See replies to question 48 of Q18 - questionnaire to customers (hospitals).



without the backing of surgeons appears to be difficult, although such a trend in some countries is more pronounced than in others.<sup>219</sup>

- (335) However, based on the results of the market investigation, surgeons' preferences are only one of several important criteria in the selection of spinal implant suppliers. Along with surgeons' preferences, hospitals more often considered product specifications, service levels, reputation, level of innovation and prices as important, very important or the most important criterion in purchasing decisions.<sup>220</sup> According to competitors, the most important criteria include prices, reputation, surgeons' preferences, quality, product range, level of service, innovation and training. In the coming three to five years, the role of price, innovation and product range are likely to play a more prominent role in spine device purchasing (most notably, the role of price on average is expected to increase from 30% to 40%).<sup>221</sup>
- (336) Although the response rate of hospitals in the relevant countries was not high enough to reliably measure whether there is a significant portion of surgeons in any given country with a particularly strong preference or loyalty to either Synthes or J&J's products, the scant replies received suggest that, unlike in trauma, surgeons' preferences are not focused on either J&J or Synthes and can vary significantly depending on the surgeons' training and experience with a product.<sup>222</sup> In most cases, the decision to change suppliers is taken by the hospital administration in collaboration with hospital surgeons. According to hospitals, changing suppliers takes from several weeks to several months and in most cases is likely in case of a permanent 10% price increase.<sup>223</sup> Only in case of very new techniques or products is more time needed for familiarisation with a product. In this regard the parties have also provided witness evidence. Professor [...]\*

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<sup>219</sup> For example, only for the United Kingdom, Spain, Netherlands, and Czech Republic more than half of hospitals considered that surgeon preferences would strongly influence the selection of supplier for the whole product category; for Sweden, Slovenia, Ireland and Hungary more than half of hospitals specified that surgeons preferences would influence the selection and the supplier would be retained as a second tier supplier; for Latvia, Poland, Finland, Luxembourg and Slovakia the majority of replies have specified that surgeons preferences would not prevent hospital from delisting a supplier. Replies from Italy, Portugal; and Austria were more equally split. For example, in 40% of hospitals surgeons would have a strong influence, in 40% preferred suppliers would be retained as second tier suppliers and 20% considered that surgeons could not prevent hospital from delisting a supplier. However, the amount of hospitals answering to this question in the respective countries is not big enough to reliably measure the influence of surgeons in the supplier selection process. See replies to question 49 of Q18 - questionnaire to customers (hospitals).

<sup>220</sup> Reply to question 48 of Q18 - questionnaire to customers (hospitals).

<sup>221</sup> Reply to question 33 of Q14 – questionnaire to competitors (spine).

<sup>222</sup> Based on replies to question 3 of Q18 – questionnaire to customers (hospitals), in Ireland, Poland, Slovakia, United Kingdom, Italy, Czech Republic, Spain and Germany some hospitals indicated surgeons having strong preferences to one or more of the following suppliers: Medtronic, Synthes, J&J, Stryker, Aesculap, Surgi C, Zimmer, Biomet, Alphatec. A few replies from Slovenia (1/1), Belgium (1/5), Austria (2/8), Germany (2/4) and Netherlands (1/9) specified only Synthes and/or J&J, while the remaining respondents did not provide a particular name for a "preferred" supplier. The reply rate for these countries is either negligible or not reliable to measure the overall loyalty of surgeons in a given country.

<sup>223</sup> Reply of hospitals to follow-up questions to replies to Q28 – Phase II – questionnaire to customers (hospitals). Also replies to Q28 – Phase II – questionnaire to customers (hospitals).

([...]\*, Sweden) specifies that: "*switching between different pedicle screw systems is very easy since all of the systems available have similar features. Therefore the training required to switch is minimal and a couple of hours with a supplier sales representatives is sufficient*".<sup>224</sup> Mr [...]\* ([...]\*[...]\*, UK) provided two recent examples of migration from J&J Expedium and Medtronic's Legacy systems to the respective systems of Stryker and K2M within a relatively short trial period of a few months.<sup>225</sup>

- (337) The Commission therefore concludes that surgeons' preferences could constitute a barrier for a brand new entrant, for example an entrant who is not yet active in a given market or not able to leverage its reputation from other geographies, such as the United States of America. However, for all group 1 markets such a barrier is of less importance, especially given that a number of players that are already present in the given markets are well known companies or globally accepted innovative players.

#### The role of direct sales force and qualified distributors

- (338) In the SO, the Commission preliminarily considered that the combination of J&J and Synthes dedicated sales staff would increase the merged entity's ability to induce or maintain customer loyalty and increase barriers to expansion for other players. In particular, this view was based on the fact that no other player (except for Medtronic) would be comparable to the parties at the level of combined direct sales forces in certain group 1 markets.
- (339) In reply to the SO, the parties stated that, in the field of spine devices, the sales forces of the merged entity would not constitute a barrier to entry and expansion of small players. In practice, effective access to hospitals can be established through qualified distributors and cross-hiring sales representatives from other competitors, which is a common practice in the industry. The Notifying Party provided several examples of new entrants growing their sales forces through cross-hiring of sales personnel. For example, [...]\* has recently poached sales representatives from Synthes and/or from J&J in [...]\*. Similar examples were provided for other companies, [...]\*, cross-hiring from J&J. The Notifying Party also maintained that presence through a distributor is not the second best option. Instead, in some countries the distributor model is the most suited, given that distributors have good relationships with hospitals.
- (340) The Commission's follow-up investigation has largely confirmed that in spine market there exist obvious advantages of being directly present in a country, such as the absence of a need to sell instruments to a distributor (they can be offered on consignment basis to hospitals), the ability to be more flexible on prices of replenishments of devices (no need to share margin with a distributor) and that overall direct sales presence allows more control over the commercial strategy of a company in that particular country and more synergies/coordination with the

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<sup>224</sup> Annex 2 to Reply to the SO by the Notifying Party.

<sup>225</sup> Annex 1 to Reply to the SO by the Notifying Party.

overall strategic objectives of the company. However, the market investigation data also shows that the number of sales representatives is not necessarily reflective of actual competitive strength in a given market. For example, K2M has been growing ahead of market leaders in several countries (e.g. United Kingdom, Ireland) despite still being in the process of building comparable sales forces.

- (341) The Commission's follow-up investigation also supports the view that access to certain markets through a qualified distributor can have advantages. According to the market investigation respondents, advantages of distributors are the knowledge of the market structure, relationships with hospitals, and physicians, knowledge of local requirements and successful business models.<sup>226</sup> Access to the market through a distributor also offers companies with smaller product ranges a possibility to compete on full-line opportunities. For example, in Ireland, both K2M and Stryker are active through qualified distributors, while Synthes is directly present. However, Stryker ([20-30]\*%) achieved more sales than Synthes [10-20]\*%, while K2M [10-20]\*% is comparable to Synthes in its overall spine market share of 2010. One distributor from Slovenia explained: "*we as distributor provide not just equivalent, but better services as manufacturer own sales force due to frequent changes in sales personnel in manufacturer companies, especially in J&J in Slovenia*". Although distributors are generally available, the vast majority of spine distributors pointed out that before a company can start marketing products it might take significant time to retrain the distributors' sales forces on new devices. Although a few competitors have encountered difficulties in finding distributors,<sup>227</sup> the investigation also showed a number of successful examples of recent entries by competitors into the spine markets, where presence via a distributor is common, e.g., Zimmer has entered Slovenia, K2M and Ulrich have entered Scandinavia through distributors, K2M has now started building a direct presence.
- (342) The Commission, therefore, considers that having a strong sales force or being able to rely on specialized distributors is a competitive advantage and in some cases may constitute an entry barrier for brand new entrants. However, this parameter is of little relevance, given that a sufficient number of credible companies are either already present in group 1 markets or have already started building a direct presence or presence through distributors.

#### The role of Research and Development investments

- (343) Finally, a need for R&D investments for a brand new entry can also be considered as a barrier to entry into the field of spine, especially for companies still not active in a given product market. However, this parameter is of little relevance for spine devices, given that the market dynamics in spine devices demonstrates that a sufficient number of companies are either already active or have recently entered and are further expanding their presence. New innovative

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<sup>226</sup> Reply to Annex 1 of request for information dated 30 January 2012.

<sup>227</sup> Replies to Annex 1 of request for information dated 30 January 2012.

entrants that have recently entered the EEA, mostly from the US, have started introducing their successful product portfolios developed outside of the EEA. The role of the AOF in the field of spine is also not unique and, unlike in trauma, it does not create a significant barrier to entry for other players. Medtronic is still the leading spine company and a number of other competitors offer a broad range of both traditional and innovative spine devices in the EEA. Based on the market investigation, all main players (such as Medtronic, J&J, Synthes, Stryker, and Alphatec) typically engage internationally known surgeons in their product development activities.<sup>228</sup>

- (344) The Commission therefore considers that while a need for R&D investments could constitute a barrier to entry for a company not active in a given product market, for the purposes of this assessment such a barrier to entry is of little relevance given the presence in group 1 markets of a sufficient number of innovative companies .

#### 6.4.2.3. Competitive assessment of individual markets

- (345) On the basis of the market reconstruction (2010 data) there are overall 99 group 1 markets in spine fusion, spread over 19 countries, based on the most likely market definitions, namely thoracolumbar pedicle screw/rod based systems, cervical pedicle screw rod based systems, cervical plating systems, ALIF/TLIF/PLIF/LLF devices, ACIF devices, thoracolumbar corpectomy cages, and cervical corpectomy cages. Should the market comprising all fusion devices be considered as the relevant product market, there would be 14 group 1 markets.
- (346) For the vast majority of group 1 markets, the 2010 market reconstruction data already supported the parties' view that a number of competitors which can exercise sufficient competitive constraint on the parties would remain post-merger. In particular, for those markets the data have demonstrated that at least two other competitors would remain, both, in the majority of cases, having a significant market share (namely above 10%) and/or a market share equal or greater than the increment.
- (347) For other group 1 markets, primarily in Slovenia, Latvia, Norway, Estonia, Austria, the United Kingdom, Slovakia, Hungary, Luxembourg, Ireland, the Czech Republic, Denmark, Poland and Portugal, the initial results of the market reconstruction (based on 2010 data) showed more concentrated market structures, where in most cases the merged entity was facing only one other competitor with a market share of over 10%, namely, Medtronic. However, in view of the more dynamic and innovative characteristics of spine markets, the Commission has further reconstructed the market share evolution for the years 2009 and 2011, which ultimately confirmed the parties' view that 2010 data alone was not an accurate basis for measuring the competitive constraint exercised by other players in spine markets. On the contrary, as argued by the Notifying Party, the market shares of J&J and Synthes in the area of spine proved to be contestable not only

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Replies to Annex 1 of request for information dated 30 January 2012.

by established players, such as Medtronic or Stryker, but also by new aggressive entrants, such as K2M, Nuvasive and others.

- (348) Taking this into account, the following Sections set out the analysis of each group 1 market affected by the proposed transaction. The following sections present the competitive analysis based on the most likely market definitions. Should the market comprising all fusion devices be considered as the relevant product market, the competitive assessment would not be materially different, since the key market players are active across major fusion categories and a sufficient number of competitors which can exercise sufficient competitive constraint on the parties would remain in all group 1 markets for spine fusion devices.<sup>229</sup>

#### Thoracolumbar pedicle screw/rod based fixation devices

- (349) According to iData sources, demand for thoracolumbar fixation devices continues to grow and the total European thoracolumbar fixation market will continue to increase at a moderate compound annual growth rate of 4.1%, driven by an aging population, favourable demographics and innovation driven growth in the sub-segments of minimally invasive procedures (MIS) and pedicle screws for the ageing spine. Thoracolumbar pedicle screw/rod based fixation systems represent the "backbone" of sales in spine fusion devices, accounting for up to 70% of spine fusion sales in the affected markets.
- (350) A number of competitors have recently launched minimally invasive products or plan to do so. Many companies innovate in the field of minimally invasive devices, for example, Medtronic (Horizon Anteres, TSRH, Solera), Globus (Revolve, Pivot), Alphatec (Illico MIS), Aesculap (S4 MIS cannulated pedicle screw), Zimmer (Pathfinder MIS), Stryker (Mantis) and Nuvasive (SpheRx DBR), K2M (Serengeti, Denali), and others. According to the Notifying Party, while Synthes was relatively late to launch its MIS devices, J&J has a stronger MIS portfolio.
- (351) In the area of development of products for the aging spine (osteoporotic bone), innovation has taken place through the development of screws with additional fixation (fenestrated screw or screws with an extendable peg/limb). For example, Alphatec introduced OsseoScrew implant, Medtronic its CD Horizon fenestrated screw spinal system and new Solera system, Ulrich introduced its Tango RS implant, J&J offers Expedium Plus implant, Biomet Omega 21 expandable screw,

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<sup>229</sup> Based on 2010 data, group 1 markets (all spine fusion devices) would arise in Germany ([30-40]\*%; J&J [20-30]\*%, Synthes [10-20]\*%), Italy ([30-40]\*%; J&J [20-30]\*%, Synthes [5-10]\*%), Netherlands ([30-40]\*%; J&J [10-20]\*%, Synthes [20-30]\*%), Slovakia ([30-40]\*%; J&J [10-20]\*%, Synthes [10-20]\*%), Finland ([40-50]\*%; J&J [10-20]\*%, Synthes [20-30]\*%), Hungary ([40-50]\*%; J&J [20-30]\*%, Synthes [40-50]\*%), Sweden ([40-50]\*%; J&J [30-40]\*%, Synthes [10-20]\*%), and the United Kingdom ([50-60]\*%; J&J [20-30]\*%, Synthes [20-30]\*%), Austria ([50-60]\*%; J&J [20-30]\*%, Synthes [30-40]\*%), Ireland ([50-60]\*%; J&J [30-40]\*%, Synthes [10-20]\*%), Estonia ([60-70]\*%; J&J [10-20]\*%, Synthes [50-60]\*%), Latvia ([60-70]\*%; J&J [50-60]\*%, Synthes [5-10]\*%), Norway ([60-70]\*%; J&J [10-20]\*%, Synthes [50-60]\*%), Slovenia ([60-70]\*%; J&J [5-10]\*%, Synthes [50-60]\*%).

Aesculap S4 cannulated pedicle screw. Synthes has launched Pangea perforated USS screws only in 2011.

- (352) The market players also innovate in the navigation and image guided surgery technologies which improve surgeons' visibility during the surgery and are particularly useful in MIS procedures. For example, Nuvasive is particularly known in this area with its Maximum Access Surgery platform and a nerve avoidance monitoring system. Medtronic has also developed its own system for navigation and intra-operative monitoring (integrated with the recently launched Solera pedicle screw system).
- (353) Both parties offer a wide range of thoracolumbar pedicle screw/rod based fixation systems. The parties' [...] systems are Expedium for J&J and USS/USS II/USS LP, Pangea, Click'x and URS for Synthes, indicated for the treatment of various spine pathologies (deformity, degenerative and trauma).<sup>230</sup> Synthes has also recently introduced a new Matrix system, indicated for degenerative and deformity pathologies. Both Synthes and J&J sell specific systems for fracture treatment (i.e., Synthes' USS fracture and J&J's Reco<sup>231</sup>). Expedium is J&J's [...]\*, which according to some respondents is the most comprehensive fixation system on the market. Synthes' has several [...] products depending on the country. J&J's [...] products in the group 1 markets, Expedium and Viper, are top-loading systems, while Synthes offers USS/USS II/USS LP systems which are side-loading systems, and Pangea, Click'x and/or URS systems which are top-loading systems.<sup>232</sup> In view of this, the Notifying Party submitted that J&J does not consider Synthes as the closest competitor in this product category. While Synthes' [...] USS is a side-loading system, J&J's Expedium (and most other competitors' systems) is top loading. The two systems differ in term of required surgeon training and surgical philosophies. As a result, the parties consider that surgeons using J&J's systems may be more likely to switch to one of the top-loading systems rather than to Synthes' USS systems. The key differences in product characteristics between Synthes' USS side-loading system and the top-loading systems of competing suppliers have been confirmed by the market investigation<sup>233</sup> and were further substantiated by KOL witness statements and

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<sup>230</sup> Synthes' Click'x is not indicated for deformity.

<sup>231</sup> Reco is a pedicle screw/rod systems indicated for fracture treatment, distributed by J&J under a license agreement with MTM, [...] (since 2002). [...] The overlap is therefore taken into account for the purposes of this decision.

<sup>232</sup> The terms 'top-loading' and side-loading refer to the placement of a rod, once screws have been placed. "Top-loading" systems typically use poly-axial or mono axial screws, having an open slot in the screw head facing posterior, in which the rod will be inserted. The rod is inserted into the top of the screw. "Side-loading" systems typically use screws without poly-axiality, having a machine-threaded post onto which a connector is fixed that containing the rod. The rod and connector are fixed at the side of the screw.

<sup>233</sup> See, amongst others, an email of a key incumbent of 17 January 2011 (time stamped 11:10 am) addressed to Ms Garcia Castillo. Also see a reply of Medtronic to question 5 of Questionnaire 14 to spine competitors. In view of Medtronic, unlike J&J, Synthes has "no major systems for deformity or complex cases, USS is still very appreciated for its trauma usage and because of its lower price".

[...]\*.<sup>234</sup> According to the Notifying Party[...] Based on the above, the Commission concludes that the USS systems of Synthes cannot be considered as the closest alternatives to Expedium of J&J. On the contrary, the products of J&J are closer alternatives to other top-loading devices.

- (354) Other market players also offer top-loading systems (including both traditional and minimally invasive approaches), i.e. Stryker (Xia, Mantis, Trio, Opus, Radius, SR90D, Diapason, Techtonix), K2M (Mesa, Denali, Range, Serengeti), Hofer GmbH & Co KG ("Hofer") (HISS Pedicle Screw), Zimmer (Universal, Optima, InCompass, Sequoia, BacFix, Instinct), Ulrich (Tango, Krypton), Pioneer (Quantum Spinal Rod System / QSRS MIS), SpineArt Inc ("SpineArt") (Romeo), Aesculap (S4, Socon, SSE), Biomet (Polaris; Omega; Array; Synergy; Ballista; Coligne EVOS) and others. No other player offers side-loading systems equivalent to the USS system of Synthes.
- (355) In the area of minimally invasive ("MIS") thoracolumbar pedicles crew systems, Synthes is also not the closest competitor to J&J in terms of product characteristics compared to other players.<sup>235</sup> Synthes is a relatively recent player in this segment, unlike J&J and other players (i.e. a pioneer Medtronic, Stryker, Zimmer, K2M and others). Of the two parties, J&J has the stronger portfolio for MIS systems with Spotlight, Pipeline and Viper 2. J&J's [...] Viper system is a percutaneous system and is designed for many levels of fixation, while Synthes' new Matrix MIS is designed for a mini-open approach and can be used to treat only up to three levels of spine. In the segment of MIS devices, J&J is a closer competitor to Medtronic with its percutaneous systems and other players with percutaneous systems. According to a key incumbent, Medtronic and J&J are the only two companies in the market providing a Peek rod component and are closer in terms of quality and price.<sup>236</sup>
- (356) Overall, based on product performance (ease of use and the level of control implants provide to surgeons), the Notifying Party considers that [...] is the closest competitor to J&J in this segment, followed by [...]\*. According to market investigation respondents,<sup>237</sup> it can also be considered that the closest competitor to the parties is Medtronic, which currently offers the broadest range of products in this category, including its top-loading Legacy system with latest additions like Longitude trauma distractor or Rod Capture instrumentation, TSRH 3D/3D MPA, and a newly launched Solera system, Colorado, and Praxis systems.
- (357) Based on 2010 data, the parties would achieve high or very high combined market shares in the range of [30-40]\*% to [70-80]\*% in 14 group 1 markets.

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<sup>234</sup> In reply to the SO, the Notifying Party provided witness statements of two Europe's leading surgeons, Mr Marks from Royal Orthopaedics Hospital Birmingham and Professor Troop from Linköping University Hospital in Sweden, confirming that Synthes' USS systems and J&J Expedium system should not be considered as particularly close substitutes. [...]\*

<sup>235</sup> [...]\*

<sup>236</sup> Reply question 5 of Q14 - questionnaire to competitors (spine).

<sup>237</sup> See replies to question 9 of Q14 - questionnaire to competitors (spine) and replies to questions 24 to Q30 – Phase II -questionnaire to competitors(spine).

Table 16: Group 1 markets in thoracolumbar pedicle screw/rod fixation systems

2010	J&J	Synthes	Comb.	Medtronic	Stryker	Aesculap	Zimmer	Others <sup>238</sup>
SL	[10-20]*	[60-70]*	[70-80]*	[20-30]*	0	0	0	-
NO	[10-20]*	[40-50]*	[60-70]*	[30-40]*	[0-5]*	[0-5]*	0	SpineArt [0-5]*, Biomet [0-5]*
EE	[5-10]*	[50-60]*	[60-70]*	[30-40]*	[0-5]*	0	0	-
LV	[40-50]*	[5-10]*	[50-60]*	[10-20]*	-	[20-30]*	-	-
AT	[20-30]*	[30-40]*	[50-60]*	[20-30]*	[5-10]*	[0-5]*	[0-5]*	Hofer [5-10]*, Nuvasive, Alphatec, K2M, Signus, SpineArt, LDR and Biomet [0-5]* each
UK	[20-30]*	[20-30]*	[50-60]*	[10-20]*	[5-10]*	[0-5]*	[0-5]*	K2M [10-20]*, Nuvasive, Globus, Medicea, Alphatec, SurgiC, Ulrich, Signus, Biomet [0-5]* each
SE	[30-40]*	[10-20]*	[40-50]*	[40-50]*	[0-5]*	0	[0-5]*	Biomet, Ulrich, K2M, Ossano [0-5]* each
IE	[30-40]*	[10-20]*	[40-50]*	[5-10]*	[20-30]*	0	[0-5]*	K2M [10-20]*, SpineVision [0-5]*
DE	[20-30]*	[10-20]*	[40-50]*	[10-20]*	[20-30]*	[0-5]*	[0-5]*	Ulrich, Alphatec, Globus, K2M, AMT, Signus, SpineArt, Biomet, Nuvasive [0-5]* each
FI	[10-20]*	[20-30]*	[40-50]*	[40-50]*	[5-10]*	0	[0-5]*	Biomet [5-10]*
IT	[30-40]*	[5-10]*	[40-50]*	[30-40]*	[5-10]*	[0-5]*	[5-10]*	SpineVision, Biomet Alphatec, Nuvasive, Sintea, SpineArt, Ulrich, AMT, LDR, Medicea, Kisco, Coligne [0-5]* each
SK	[20-30]*	[10-20]*	[30-40]*	[10-20]*	0	[20-30]*	[0-5]*	Alphatec [10-20]*
HU	[30-40]*	[0-5]*	[30-40]*	[30-40]*	[0-5]*	[5-10]*	[0-5]*	Alphatec [10-20]*
NL	[10-20]*	[20-30]*	[30-40]*	[30-40]*	[5-10]*	[0-5]*	[0-5]*	Biomet [10-20]*, Pioneer [5-10]* K2M, SpineVision [0-5]* each

Source: market reconstruction

- (358) In Austria, the proposed transaction does not give rise to concerns due to the strong position of Medtronic [20-30]\*%, and the presence of other established

<sup>238</sup>

The category "others" comprises the companies explicitly listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might be also active in the respective markets.



competitors Stryker [5-10]\*%, Hofer [5-10]\*%, Aesculap [0-5]\*%) and others;<sup>239</sup> recent entry and expansion of new aggressive entrants, and confirmed further entry into the Austrian market. For example, Nuvasive entered the Austrian market very recently and has gradually increased its presence,<sup>240</sup> while K2M and Globus have also entered the Austrian market recently and have been well perceived by Austrian hospitals and are regarded as a competitive threat by key competitors.<sup>241</sup> The market investigation has also confirmed further entry into Austria.<sup>242</sup> Furthermore, over [...] \*% of Synthes' sales came from its side-loading system which is not the closest alternative to the top-loading system of J&J. Taking this into account, it is likely that these established players as well as new aggressive entrants would continue to constrain the parties post-merger.

- (359) In Germany, the proposed transaction does not raise concerns due to the strong position of Stryker with a market share of [20-30]\*%, Medtronic with a market share of [10-20]\*%, and a number of others (including new entrants K2M, Nuvasive, Alphatec, Globus Medical Inc. ("Globus")). Post-merger the merged entity would have a combined market share below 50%, it would be facing at least two strong and well recognized competitors in the market for thoracolumbar pedicle screw systems and it is likely that these players would continue to constrain the parties.
- (360) In the United Kingdom, the proposed transaction does not give rise to concerns due to the strong position of Medtronic [10-20]\*%, a new aggressive entrant K2M [10-20]\*%, and the presence of Stryker [5-10]\*% and others.<sup>243</sup> According to one key incumbent, Globus also exercises a strong competitive influence in the United Kingdom through innovation.<sup>244</sup> The market share evolution data of 2009-2011 for the United Kingdom also confirmed that the historic market shares of J&J and Synthes are contestable, e.g. in the period of 2009-2011 both J&J and

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<sup>239</sup> Based on customer replies all of the mentioned competitors are capable of meeting hospitals' demand (replies to question 32, 36-38, 41 of Q28 – Phase II - questionnaire to customers (hospitals) (Austria)). Hospital replies also suggest that Synthes and J&J are not particularly close competitors: only four out of 12 respondents considered J&J and Synthes as their first best choices. Other customers would first prefer Medtronic, Biomet, or Stryker as the first best alternative to their main supplier, while many others would also be credible.

<sup>240</sup> The market share evolution data of 2009-2011 confirmed that historic market shares of leading players are contestable, for example in the period of 2009-2001 both Synthes and Medtronic have lost market shares, while new entrant Nuvasive has gradually increased its presence. Another example is Hofer, a local Austrian company, which in 2005, upon start of activities, took nearly [10-20]\* of J&J sales in this segment.

<sup>241</sup> For example, see reply of an Austrian hospital in reply to follow up questions, dated 8 February 2012 (email time stamped 4:04 pm). According to Medtronic, both Globus and K2M exercise a strong competitive influence in Austria through innovation (reply to question 24.1 of Questionnaire 30 to spine competitors).

<sup>242</sup> Replies to question 26 of Q14 - questionnaire to competitors (spine).

<sup>243</sup> Based on customer replies all of the mentioned competitors, and more, are capable of meeting hospitals' demand (replies to question 32, 36-38, 41 of Q28 - questionnaire to customers (hospitals) (UK)). Hospital replies also suggest that Synthes and J&J are not particularly close competitors: only three out of 9 respondents considered J&J and Synthes as their first best choices. Other customers would first prefer Medtronic, Aesculap, K2M or Stryker as the first best alternative to their main supplier, while many others would also be credible.

<sup>244</sup> Reply of a third party to question 24.12 of Questionnaire 30 to spine competitors.

Medtronic have lost market share, while new entrants K2M, Nuvasive and Globus have gained sales.<sup>245</sup> It is likely that these established players as well as new aggressive entrants would continue to constrain the parties post-merger. Furthermore, nearly [...] % of Synthes' sales came from its side-loading system which is not the closest alternative to the top-loading system of J&J.

- (361) In Ireland, the proposed transaction does not raise concerns due to the strong position of Stryker with a market share of [20-30] % and a new successful entrant K2M with a market share of [10-20] %. Medtronic is also present (5-10%) in Ireland, followed by Zimmer and French-based SpineVision, Inc ("SpineVision") ([0-5] % each). Post-merger the merged entity's combined market share would not exceed 50%; it would be facing at least three well recognized competitors in the market for thoracolumbar pedicle screw systems and it is likely that these players would continue to constrain the parties. Furthermore, over [...] % of Synthes' sales came from its side-loading system which is not the closest alternative to the top-loading system of J&J.
- (362) In Sweden, the proposed transaction does not raise concerns due to the leading position of Medtronic with a market share of [40-50] % and the presence of several other established players (Stryker [0-5] %, Zimmer [0-5] %, Biomet, Spine Art), and two very recent aggressive entrants, K2M and Globus.<sup>246</sup> The market investigation has also confirmed future entry into Sweden. Sweden is a tender market, where market shares can change in one year depending on the outcome of the tender.<sup>247</sup> Taking this into account, it is likely that these established players as well as new aggressive entrants would continue to constrain the parties post-merger. Furthermore, nearly [...] % of Synthes sales came from its side-loading system which is not the closest alternative to the top-loading system of J&J.
- (363) In Finland, the proposed transaction does not raise concerns due to the leading position of Medtronic with a market share of [40-50] % and the presence of several other established competitors (Stryker [5-10] %, Biomet [5-10] % and Zimmer [0-5] %) and new entrants (K2M). The market investigation has also confirmed future entry into Finland. Taking this into account, it is likely that these established players as well as new aggressive entrants would continue to constrain the parties post-merger. Furthermore, nearly [...] % of Synthes sales came from its side-loading system which is not the closest alternative to the top-loading system of J&J.

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<sup>245</sup> From 2009 to 2011, the market share of J&J decreased by more than 10% and the market shares of Synthes and Medtronic decreased by [0-5] %, while K2M increased from [0-5] % to [10-20] % and Nuvasive from nearly 0% to [0-5] %.

<sup>246</sup> Based on customer replies all of the above-mentioned competitors, and more, are capable of meeting hospitals' demand (replies to question 32, 36-38, 41 of Q28 - questionnaire to customers (hospitals) (Sweden)). Hospital replies also suggest that Synthes and J&J are not particularly close competitors: none of 7 respondents considered J&J and Synthes as their first best choices to their main suppliers.

<sup>247</sup> Replies to Annex 1 of follow-up questions of 30 January 2011.

- (364) In Norway, the proposed transaction does not give rise to concerns due to the strong position of the second largest player, Medtronic [30-40]\*%, and the presence of other credible players, including Stryker [0-5]\*%, Aesculap [0-5]\*%, Biomet and Zimmer, which are all capable of meeting hospitals' demand for the respective devices.<sup>248</sup> According to one key incumbent, Globus also exercises a strong competitive influence in Norway through innovative thoracolumbar products.<sup>249</sup> Furthermore, the market investigation has also confirmed further entry into the Norwegian market within the next two years.<sup>250</sup> Norway is a tender market, where the parties' shares are contestable and can change from year to year depending on the outcome of subsequent tenders.<sup>251</sup> Taking this into account, it is likely that these established players as well as new aggressive entrants would continue to constrain the parties post-merger.
- (365) In the Netherlands, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [30-40]\*%, Biomet with a market share of [10-20]\*%, Pioneer Surgical Technology Inc ("Pioneer Surgical") and Stryker with [5-10]\*% each. Post-merger the merged entity would have a combined markets share below 40%, it would be facing at least two strong and well recognized competitors in the market for thoracolumbar pedicle screw systems and it is likely that these players would continue to constrain the parties.
- (366) In Italy, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [30-40]\*%, followed by Stryker [5-10]\*% and Zimmer [5-10]\*%, each with market shares comparable to the increment added by Synthes [5-10]\*%. Post-merger the merged entity would have a combined market share below 50%, and would be facing at least three well recognized competitors in the market for thoracolumbar pedicle screw systems. It is likely that these players would continue to constrain the parties. Apart from these players, there are more than 10 other companies, including established players (Aesculap, Biomet) and recent entrants (e.g. Nuvasive, Alphatec) in Italy.<sup>252</sup>

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<sup>248</sup> Replies to question 32, 36-38, 41 of Q28 - questionnaire to customers (hospitals) (Norway). Hospital replies suggest that J&J and Synthes are not perceived as the closest competitors. Out of three hospitals only one hospital considered that Synthes and J&J as the first best choices, while others would have stronger preferences to other suppliers (Medtronic, Biomet, K2M and even Zimmer).

<sup>249</sup> Reply of Medtronic to question 24.8 of Q30 – Phase II - questionnaire to competitors (spine).

<sup>250</sup> Replies to question 1 of Q30 - questionnaire to competitors (spine); replies to question 3 of Annex 1 of request for information dated 30 January 2012. Other companies are already present in a neighbouring country, Sweden, which is typically an entry port into the Scandinavian markets (i.e. Zimmer, Globus) and would be able to enter Norway should the merged entity attempt to increase prices and make market entry more attractive.

<sup>251</sup> For example, based on market reconstruction data, from 2009 to 2010, Synthes gained over 10%, while Aesculap lost [5-10]\*% in the same period.

<sup>252</sup> Based on customer replies all of the above-mentioned competitors, are capable of meeting hospitals' demand (replies to questions 32, 36-38, 41 of questionnaire 28 to hospitals (Italy)). Hospital replies suggest that J&J and Synthes are not perceived as the closest competitors.

- (367) In Slovenia, the proposed transaction does not give rise to competition concerns due to the strong position of Medtronic ([20-30]\*%) and the presence of several competitors, including recent entrant Ulrich. Stryker, Aesculap, Zimmer, and Biomet are also present and are all capable to meet hospital demand for thoracolumbar devices. The leading hospital in Slovenia has confirmed that competitive tendering processes are put in place to ensure competition and reduction in prices; the hospital sources from several alternative suppliers and is price-sensitive.<sup>253</sup> It is likely that these players would continue to constrain the parties post-merger. In addition, in 2010 nearly [...] of Synthes' sales derived from side-loading USS systems and USS fracture components which are not the closest alternatives to the top-loading system of J&J.
- (368) In Estonia, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [30-40]\*% and the presence of another credible player Stryker, both capable of meeting hospitals' demand for thoracolumbar pedicle screw devices.<sup>254</sup> Aesculap and Biotech GmbH ("Biotech") have also been indicated as credible alternatives by Estonian hospitals. The Estonian market is very small and therefore highly volatile, given high prices for respective surgical procedures.<sup>255</sup> Although post-merger the merged entity would have a combined market share of [60-70]\*%, the increment added by J&J is small and the merged entity would be facing one very strong and several other well recognized competitors. It is likely that these players would continue to constrain the parties. Furthermore, nearly [...] of Synthes' sales derive from its side-loading USS system, while J&J achieved [...] of its sales from its Reco fracture device, which is [...]\*.
- (369) In Latvia, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [10-20]\*% and Aesculap with a market share of [20-30]\*%. Synthes essentially sells its side-loading USS system (over [...] of Synthes sales in 2010 were achieved from side-loading USS II), which is not the closest alternative to the top-loading systems of J&J and other players. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, it would be facing at least two strong and well recognized competitors in the market for thoracolumbar pedicle screw systems and it is likely that these players would continue to constrain the parties. Furthermore, despite the relatively small market size, entry into the Latvian market is possible, as shown for example by the recent entry of Ulrich into the Latvian spine market.

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<sup>253</sup> Reply of University Medical Centre Ljubljana to follow up questions dated 7 February 2012 (email time stamped 1:25 pm).

<sup>254</sup> Replies to question 32, 36-38, 41 of Q28 – Phase II - questionnaire to customers (hospitals) (Estonia).

<sup>255</sup> Based on Commission's reconstruction data, the market for thoracolumbar pedicle screw devices in Estonia does not exceed EUR 150 000. According to the parties, spinal procedure with Synthes' products on average costs from EUR [3 000-4 000]\* for complex deformity to EUR [1 000-2 000]\* for degenerative procedure. This translates into maximum 100 procedures per year.

- (370) In Slovakia, the proposed transaction does not raise concerns due to the strong position of Aesculap with a market share of [20-30]\*%, Alphatec with a market share of [10-20]\*% and Medtronic with [10-20]\*%. Post-merger the merged entity would have a combined market share below 40%, it would be facing at least three strong and well recognized competitors in the market for thoracolumbar pedicle screw systems and it is likely that these players would continue to constrain the parties.
- (371) In Hungary, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [30-40]\* % and Alphatec with a market share of [10-20]\* %. Post-merger the merged entity would have a combined market share below 40%, it would be facing at least two strong and well recognized competitors in the market for thoracolumbar pedicle screw systems and it is likely that these players would continue to constrain the parties.
- (372) The Notifying Party has also argued that there are competitive constraints stemming from neighbouring markets, such as motion preserving implants or hybrid implants (i.e. implants combining rigid fusion and flexible rods). For the purposes of this Decision it can be left open whether such novel devices have a meaningful constraining effect on traditional fixation devices, given that a sufficient number of competitors active in traditional pedicle screw fixation devices would remain in all group 1 markets post-merger. Yet, it can be noted that market investigation replies indicated that there is a separate demand for posterior dynamic pedicle screw stabilisation systems ("PDS") as opposed to traditional fixation devices. PDS are used for motion preserving procedures, where motion preservation is specifically indicated at an early stage of pathology (special patient indications), while for advanced pathologies surgeons always use traditional fusion procedures. Furthermore, PDS systems are not as widely accepted due to negative publicity and lack of clinical evidence. Motion preserving implants are premium priced and therefore do not generally compare in prices to traditional pedicle screw and rod based fixation devices.<sup>256</sup> In view of this, it is likely that constraints coming from motion preserving devices are limited.
- (373) In any event, should the market be defined as comprising both motion preserving implants (PDS) or hybrid implants (i.e. implants combining rigid fusion and flexible rods) and traditional pedicle screw/rod systems, the assessment would not change materially. The market structure would similarly not change materially should ISS devices be included, given that only Synthes is active in this segment and has achieved relatively small sales from ISS devices compared to traditional fixation devices. In particular, on the basis of such broader market definitions no additional group 1 market would arise and the combined market shares of the parties would be either comparable to or lower than those presented in Table 16.<sup>257</sup>

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<sup>256</sup> See replies to Questions 42-48 of Q30 – Phase II - questionnaire to competitors (spine).

<sup>257</sup> Under the market definition comprising both traditional fixation devices and PDS, the parties' combined market shares do not change in four group 1 markets and decrease by [0-10]\*% (or even

- (374) In view of the foregoing and taking into account the market characteristics as described in Section 6.4.2, the Commission concludes that the proposed transaction would not result in a significant impediment to effective competition in the market for thoracolumbar pedicle screw/rod based fixation devices in Austria, Estonia, Finland, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Norway, Slovakia, Slovenia, Sweden, and the UK. It is unlikely that the merged entity would have the ability to increase prices, as the remaining competitors would be able to exercise sufficient competitive constraint.<sup>258</sup>

#### Cervical fixation devices: general remarks

- (375) Based on industry reports the overall demand for cervical fixation devices is expected to grow at a compound annual growth rate of 2.4% by 2017 due to the aging population, positive reimbursement conditions and continued product and technological innovation.<sup>259</sup> In Europe the demand for posterior cervical fixation devices is lower compared to anterior fixation systems (plating systems), given easier access of cervical spine from the front.
- (376) Should the market be defined as comprising both cervical pedicle screw/rod systems and cervical plating systems, the assessment and market structure would not change materially compared to the assessment under narrower categories, presented in the following Sections "Cervical pedicle screw/rod fixation systems" and "Cervical plating systems". In particular, on the basis of such broader alternative market definitions no additional group 1 market would arise and the market structures would be either comparable to (the parties and their main competitors are active in both segments) the market structures presented under a narrower segmentation or less concentrated.<sup>260</sup>
- (377) The Notifying Party also notes that industry reports acknowledge increasing competition from alternative treatment options with stand-alone cervical cages and non-fusion devices, such as artificial discs. For the purposes of this Decision it is not relevant whether competitive constraints stemming from neighbouring markets, such as stand-alone fixation devices (i.e. cages with inherent fixation) or artificial discs would have a meaningful constraining effect on traditional cervical fixation devices, given that a sufficient number of competitors active in traditional systems would remain in all group 1 markets post-merger. Yet, it can

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[10-20]\*% in case of Slovenia) in 10 group 1 markets at the expense of other players active with PDS devices, such as Zimmer, Pioneer Surgical or Paradigm Spine. The inclusion of Synthes' ISS sales would also have a minute effect on the combined market shares, which would not change by more than [0-5]\*% in any group 1 market (only in the United Kingdom, the combined market share would increase by [0-5]\*%).

<sup>258</sup> It is to be noted that nearly 80% of competitors have considered that the merged entity post-merger would not be in a position to increase its pricing for any particular product segment.

<sup>259</sup> iData – European Markets for Spinal Implants and VCF 2011, pp. 164-165.

<sup>260</sup> In Austria, Estonia, Finland, Germany, Hungary, Ireland, Latvia, Luxembourg, Netherlands, Norway, Slovenia, Spain, Sweden and the United Kingdom the combined market shares of the parties and their main competitors would be closely comparable to the situation under the narrower market segmentations. In Denmark, Italy, Portugal, Slovakia no group 1 market would arise under a broader market definition comprising both pedicle screw and plating systems.

be noted that the market investigation indicated that there is a separate demand for artificial discs (motion preservation indication, younger patients, multi-level surgeries) as opposed to fusion devices (old patients, advanced pathologies, requiring fusion)<sup>261</sup>. In particular, this is due to different patient needs and surgeon preferences, significant price differences, and differences in indications and reimbursement.<sup>262</sup>

- (378) In any event; should the market be defined on a broader level as comprising traditional cervical fixation and artificial discs, the assessment and market structure would not change materially compared to the assessment under the narrower categories. The market structure would similarly not change materially should stand-alone cervical fixation devices and/or ACIF devices be included. In particular, on the basis of such broader market definitions no additional group 1 market would arise and the combined market shares of the parties would be either comparable to or lower than those presented under the narrower market segmentations.<sup>263</sup>
- (379) The following two Sections entitled "Cervical pedicle screw/rod fixation devices" and "Cervical plating systems" assess the competitive situation in group 1 markets based on the narrowest market definitions. The competition in the market of ACIFs (including stand-alone cages) is presented in Section "Cervical Interbody cages: ACIF devices".

#### *Cervical pedicle screw/rod fixation systems*

- (380) Both parties market cervical pedicle screw/rod fixation systems: J&J mainly markets its Summit and Mountaineer systems, while Synthes' sells Synapse and Axon devices.<sup>264</sup> Based on the market investigation, the parties are comparable in this segment in terms of treated pathology, innovation and pricing.<sup>265</sup> Many other players offer comparable devices, i.e. Medtronic (Vertex), Stryker (Oasys), Aesculap (S4 cervical), Zimmer (Nex-Link, OctaFix), Alphatec (Solanas/Oria Alis), Ulrich (Neon, Dens), Globus (Protex CT, Ellipse), Biomet (Altius), K2M (Caspian), Nuvasive (Vuepoint), and others.

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<sup>261</sup> See vast majority of replies to questions 69 to 70 of Q30 – Phase II - questionnaire to competitors (spine).

<sup>262</sup> Millennium Research Group report "European Markets for Spinal Implants 2010" acknowledge that surgeons are hesitant to apply non-fusion technologies across multiple levels of spine due to lack of positive clinical data (p.28).

<sup>263</sup> Under the alternative market comprising all cervical fixation devices and cervical artificial discs, the parties' combined market shares would in most cases decrease and in a few countries would remain comparable to the market shares under a market definition comprising only cervical pedicle screw devices and/or cervical plating systems. Should ACIFs be included, the market structures would also not change materially.

<sup>264</sup> Synthes' occiput rod in the Axon system is unique. Based on market respondents, other systems require occiput plate with a separate rod connection (replies to question 32.2 of questionnaire 14 to spine competitors).

<sup>265</sup> See reply of competitors, in particular Medtronic, to question 5 of Q14 - questionnaire to competitors (spine).

- (381) Although [...]\*, there is nothing [...]\* suggesting that Synthes and J&J would be closer competitors to each other (in term of product characteristics) compared to other players [...]\*, i.e. Medtronic, Stryker, Globus, Zimmer, Ulrich and others.<sup>266</sup> J&J and Synthes are therefore two of a number of competitors that offer comparable cervical posterior fixation devices.

Table 17: Group 1 markets in cervical pedicle screw/rod fixation systems

2010	J&J	Synthes	Comb.	Medtronic	Stryker	Aesculap	Zimmer	Others <sup>267</sup>
SL	[0-5]*	[90-100]*	[90-100]*	0	0	0	0	
SK	[30-40]*	[40-50]*	[80-90]*	[5-10]*	0	[5-10]*	0	
NO	[5-10]*	[60-70]*	[70-80]*	[20-30]*	0	-	0	Ossano (Ulrich) [0-5]*
HU	[10-20]*	[50-60]*	[60-70]*	[30-40]*	0	0	0	
IE	[50-60]*	[10-20]*	[60-70]*	[10-20]*	[10-20]*	0	0	
UK	[20-30]*	[30-40]*	[60-70]*	[10-20]*	[5-10]*	[0-5]*	0	K2M, Ulrich, Globus [0-5]* each
AT	[10-20]*	[40-50]*	[60-70]*	[30-40]*	[0-5]*	[0-5]*	[0-5]*	Ulrich [0-5]*
SE	[10-20]*	[30-40]*	[50-60]*	[40-50]*	[0-5]*	0	0	Ossano (Ulrich) [0-5]*
DE	[10-20]*	[20-30]*	[40-50]*	[5-10]*	[10-20]*	[5-10]*	0	Ulrich [20-30]*, Globus, Biomet, Nuvasive [0-5]* each
IT	[30-40]*	[10-20]*	[40-50]*	[40-50]*	[0-5]*	[0-5]*	[0-5]*	Nuvasive, Ulrich, Biomet [0-5]* each
ES	[10-20]*	[20-30]*	[30-40]*	[20-30]*	[0-5]*	[0-5]*	[0-5]*	K2M [10-20]*, Biomet [5-10]* Alphatec, Ulrich [0-5]* each
PT	[10-20]*	[10-20]*	[30-40]*	[60-70]*	0	0	0	Biomet [0-5]* each
NL	[10-20]*	[10-20]*	[30-40]*	[30-40]*	[0-5]*	[20-30]*	0	
FI	[0-5]*	[30-40]*	[30-40]*	[60-70]*	0	0	0	Ulrich [0-5]* each

Source: market reconstruction

- (382) In Austria, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [30-40]\*%, the presence of other established players (Stryker, Aesculap, Zimmer, and Ulrich), all capable of

<sup>266</sup> For example see [...]\*

<sup>267</sup> The category "others" comprises the companies explicitly listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might also be active in the respective markets.



meeting hospital demand for cervical pedicle screw systems,<sup>268</sup> and very recent entries by K2M and Nuvasive. The market investigation data show that the market shares of the parties are contestable and can change from year to year depending on the outcome of subsequent tenders or price enquiries.<sup>269</sup> Although post-merger the merged entity would have a high combined market share of [60-70]\*%, the merged entity is facing at least one strong well recognized established player and several other competitors which can exercise a sufficient competitive constraint on the parties, including recent entrants. It is likely that these players would continue to constrain the parties post-merger.

- (383) In Germany, the proposed transaction does not raise concerns due to the strong position of Ulrich with a market share of [20-30]\*% and Stryker with a market share of [10-20]\*%. Moreover, Medtronic and Aesculap are also present with market shares of [5-10]\*%. Post-merger the merged entity would have a combined market share below 50%, it would be facing at least four strong and well recognized competitors in the market for cervical pedicle screw/rod fixation systems and it is likely that these players would continue to constrain the parties. A number of other players, including recent entrants, are also present in Germany.
- (384) In the Netherlands, the proposed transaction does not raise competition concerns due to the position of Medtronic with a market share of [30-40]\* % and Aesculap with a market share of [20-30]\*%. Post-merger the merged entity would have a combined market share of below 40% and it would be facing at least two strong and well recognized competitors in the market for cervical pedicle screw based systems. It is likely that these players would continue to constrain the parties.
- (385) In the UK, the proposed transaction does not give rise to concerns due to the presence of Medtronic with [10-20]\*%, Stryker with [5-10]\*%, and recent entrants (K2M, Nuvasive, Globus) that are gradually increasing their market presence in the UK. Several other suppliers capable of meeting hospital demand for cervical posterior devices are also present.<sup>270</sup> The market investigation data show that the market shares of the parties are contestable and can change from year to year depending on the outcome of subsequent tenders or price enquiries.<sup>271</sup> Although post-merger the merged entity would have a high combined market share of [60-70]\*%, the merged entity is facing at least two well recognized established players and several others, including recent entrants. It is likely that these players would continue to constrain the parties post-merger.

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<sup>268</sup> Replies to question 32, 49-50, 52 of Q28 – Phase II questionnaire to customers (hospitals) (Austria).

<sup>269</sup> For example, J&J market shares have decreased from [10-20]\*% in 2010, to [5-10]\*% in 2011. In the same period Synthes and Ulrich both lost [0-5]\*%, while Medtronic gained [5-10]\*% and Stryker gained [0-5]\*%.

<sup>270</sup> Replies to question 32, 49-50, 52 of Q28 – Phase II - questionnaire to customers (hospitals) (UK).

<sup>271</sup> For example, J&J market shares has changed from [30-40]\*% in 2009, to [20-30]\*% in 2010 and back to [30-40]\*% in 2011. In the same period Synthes gained and then lost [0-5]\*%. Medtronic lost from [10-20]\*% in 2010 to [5-10]\*% in 2011. Stryker, Aesculap, K2M, Globus and Nuvasive each increased by [0-5]\*% from 2010 to 2011.

- (386) In Ireland, the proposed transaction does not raise concerns due to the position of Stryker with a market share of [10-20]\*% and Medtronic with a market share of [10-20]\*%. Although post-merger the merged entity would have a combined market share of [60-70]\*%, it would be facing at least two strong and well recognized competitors in the market for cervical pedicle screw based systems. It is likely that these players would continue to constrain the parties.
- (387) In Norway, the proposed transaction does not give rise to concerns due to the strong position of the second largest player, Medtronic, with [20-30]\*%, and the presence of other credible players, such as Ulrich ([0-5]\*%), and also Stryker, Zimmer and Biomet. The market investigation also confirmed new entry into the Norwegian market within the next two years.<sup>272</sup> The market investigation data suggest that in Norway, which is a tender market, market shares are contestable and can change from year to year depending on the outcome of subsequent tenders.<sup>273</sup> Taking this into account, it is likely that these established players as well as new aggressive entrants would continue to constrain the parties post-merger.
- (388) In Finland, the concentration does not raise concerns due to the leading position of Medtronic with a market share of [60-70]\*% and the presence of several other established competitors (e.g., Stryker, Biomet), all capable of meeting hospitals demand for cervical pedicle screw fixation devices. Ulrich ([0-5]\*%) and a new entrant K2M are also present in Finland. The market investigation has also confirmed future entry. Taking this into account, it is likely that these established players as well as new aggressive entrants will continue to constrain the parties post-merger.
- (389) In Italy, the proposed transaction does not raise concerns due to the leading position of Medtronic with a market share of [40-50]\*%, which would be still ahead of the merged entity. A number of other established players (e.g. Stryker [0-5]\*%, Aesculap [0-5]\*% and Zimmer [0-5]\*%) and new entrants (e.g. Nuvasive) are also present and capable to meet hospital demand for posterior cervical devices.<sup>274</sup> Apart from the companies that achieved sales in 2010, there are nearly ten other companies present in Italy that offer cervical pedicle screw devices. Post-merger the merged entity would have a combined market share below 50%, facing at least one formidable competitor and a number of other established players and new entrants. It is likely that these players would continue to constrain the parties.
- (390) In Portugal, the proposed transaction does not raise concerns due to the clear leading position of Medtronic with a market share of [60-70]\*%, which is almost two times larger than the market share of the merged entity of [30-40]\*%. A

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<sup>272</sup> Replies to question 1 of Q30 – Phase II - questionnaire to competitors (spine); replies to question 3 of Annex 1 of request for information dated 30 January 2012.

<sup>273</sup> From 2010 to 2011, Synthes gained over 10%, while J&J and Medtronic lost [0-5]\*% and [5-10]\*% respectively in the same period. The market for cervical pedicle screw devices is relatively small, i.e. less than EUR 400 000.

<sup>274</sup> Replies to question 32, 49-50, 52 of Q28 – Phase II - questionnaire to customers (hospitals) (Italy).

number of other credible players are also active in Portugal, i.e. Biomet, Zimmer, Stryker, and could potentially meet the demand of hospitals for cervical devices, as confirmed by the hospital replies.<sup>275</sup> It is likely that these players would continue to constrain the parties.

- (391) In Spain, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [20-30]\*%, a new aggressive entrant K2M with a market share of [10-20]\*%, and Biomet with [5-10]\*%. A number of other credible players are also active in Spain, such as Aesculap, Zimmer and Ulrich. Post-merger the merged entity would have a combined market share below 40%, it would be facing at least two strong and well recognized competitors and a number of other players in the market for cervical pedicle screw/rod fixation systems. It is likely that these players would continue to constrain the parties.
- (392) In Slovenia, the proposed transaction does not give rise to concerns due to the presence of Medtronic, Stryker, Aesculap, Biomet and recent entrant Ulrich, all capable of meeting hospitals' demand for posterior cervical fixation devices.<sup>276</sup> The leading hospital in Slovenia has confirmed that competitive tendering processes are put in place to ensure competition and reduction in prices, that it is open for a wide range of alternative suppliers for cervical products and is willing to change in case of price increases.<sup>277</sup> The Slovenian market is very small and therefore highly volatile: in 2011 Medtronic gained a share of [60-70%]\*, Ulrich [5-10]\*%, while J&J and Synthes shares decreased (from [0-5]\*% to [0-5]\*% for J&J and from [90-100]\*% to [20-30]\*% for Synthes).<sup>278</sup> It is likely that the other players would continue to constrain the parties post-merger.
- (393) In Slovakia, the proposed transaction does not give rise to concerns due to the presence of Medtronic with [5-10]\*%, Aesculap with [5-10]\*%, and recent entrant Ulrich with [0-5]\*%, all capable of meeting hospital demand for cervical pedicle screw devices.<sup>279</sup> Medtronic and Aesculap are well-established in Slovakia, with market shares of [20-30]\*% and [10-20]\*%, respectively in the overall spine market. The market for cervical pedicle screw devices is very small in Slovakia and therefore highly volatile.<sup>280</sup> It is likely that these players would continue to constrain the parties post-merger.

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<sup>275</sup> Replies to question 32, 49-50, 52 of Q28 – Phase II - questionnaire to customers (hospitals) (Portugal).

<sup>276</sup> Replies to question 32, 49-50, 52 of Q28 – Phase II - questionnaire to customers (hospitals) (Slovenia).

<sup>277</sup> Reply of University Medical Centre Ljubljana to follow-up questions dated 7 February 2012 (email time stamped 1:25 pm).

<sup>278</sup> Based on the Commission's reconstruction data, the market for cervical pedicle screw devices in Slovenia does not exceed EUR 350 000. According to the parties, spinal procedure with Synthes' products on average costs EUR [1 500-2 000]\*.

<sup>279</sup> Replies to question 32, 49-50, 52 of Q28 – Phase II - questionnaire to customers (hospitals) (Slovakia). Apart from Medtronic and Aesculap, hospitals considered Ulrich, Zimmer, Nuvasive Stryker and several others as credible.

<sup>280</sup> Based on the Commission's reconstruction data, the market for cervical pedicle screw devices in Slovakia does not exceed 50 TEUR. According to the parties, spinal procedure with Synthes'

- (394) In Hungary, the proposed transaction does not give rise to concerns due to the presence of Medtronic with [30-40]\*% and Aesculap, both capable of meeting hospital demand for cervical pedicle screw devices.<sup>281</sup> The market for cervical pedicle screw devices is very small in Hungary and therefore highly volatile. For example in 2011 Aesculap achieved a market share of [5-10]\*% compared to [0-5]\*% in 2010.<sup>282</sup> Biomet, Zimmer, Stryker are also present. It is likely that these players would continue to constrain the parties post-merger.
- (395) In view of the foregoing and taking into account the market characteristics as described in Section 6.4.2, the Commission concludes that the proposed transaction would not result in a significant impediment of effective competition in the market for cervical pedicle screw/rod based fixation devices in Austria, Estonia, Finland, Germany, Hungary, Ireland, Italy, Netherlands, Norway, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. It is unlikely that the merged entity would have the ability to increase prices, as the remaining competitors would be able to exercise a sufficient competitive constraint.

#### *Cervical plating systems*

- (396) According to the Notifying Party, demand for anterior cervical fixation devices continues to grow due to favourable demographics and continued innovation. The Notifying Party also notes that industry reports acknowledge increasing competition from alternative treatment options (standalone cervical cages, artificial discs).
- (397) Both parties market cervical plating systems, namely, J&J markets Skyline, Slimlock, Uniplate, Eagle and Swift plates, while Synthes sells Vectra, Vectra-One, CSLP and Vectra-T plates. Based on the market investigation, both parties are comparable in this segment in terms of treated pathology, innovation and pricing.<sup>283</sup>
- (398) Apart from traditional plating systems Synthes also markets the Zero-P plate and cage device, which offers both cages and inherent plate fixation in a single device, and is not the closest substitute to traditional cervical plates. J&J and Synthes are therefore not particularly close competitors with respect to Synthes' Zero-P device. Instead, e.g. Alphatec's PCB/PCB Evolution plate/cage devices or Spine Art's Tryptic MC are closer substitutes to Zero-P of Synthes.<sup>284</sup> The [...]\*.

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products on average costs from [2.5-4.5]\* TEUR, depending on whether a cervical cage is also used.

<sup>281</sup> Replies to questions 32, 49-50, 52 of Q28 – Phase II - questionnaire to customers (hospitals) (Hungary). Apart from Medtronic and Aesculap, hospitals considered Ulrich, Zimmer and Spine Art as credible.

<sup>282</sup> From 2009 to 2011, Synthes lost over 10%, while Medtronic gained over 10%, and Aesculap also moderately increased by [5-10]\*%. Based on the Commission's reconstruction data, the market for cervical pedicle screw devices in Hungary is small, i.e. it does not exceed EUR 150 000.

<sup>283</sup> See reply of competitors, in particular Medtronic, to question 5 of Q14 - questionnaire to competitors (spine).

<sup>284</sup> Synthes [...]\*.

However, for the purposes of this assessment, such competitive constraint would be of little importance, given that the parties overlap only in respect of traditional cervical plating systems as J&J does not offer stand-alone cervical devices. Instead Zero-P is facing a number of other competitors (such as Alphatec's PCB, Globus' Coalition and others). The parties' offers in the cervical segment are complementary as regards stand-alone devices.

- (399) Other players also offer traditional cervical plating systems: e.g., Medtronic (Venture), Alphatec (Trestle), Hofer (HWS M2), Stryker (Reflex Hybrid and Zero Profile), Aesculap (Caspar, ABC, and Quintex), Ulrich (Mambo and Osmium), K2M (Pyrenees), LDR (C plate).

Table 18: Group 1 markets in cervical plating systems

2010	J&J	Synthes	Comb.	Medtronic	Stryker	Aesculap	Zimmer	Others <sup>285</sup>
SL	[5-10]*	[80-90]*	[90-100]*	[5-10]*	0	0	0	
EE	[20-30]*	[60-70]*	[80-90]*	[10-20]*	0	0	0	
DK	[0-5]*	[70-80]*	[70-80]*	[10-20]*	0	[0-5]*	0.0	Ulrich [0-5]*
IE	[40-50]*	[30-40]*	[70-80]*	[0-5]*	[0-5]*	0	[0-5]*	SpineVision [10-20]*
UK	[10-20]*	[40-50]*	[60-70]*	[10-20]*	[0-5]*	[0-5]*	[0-5]*	Alphatec, Ulrich, Globus, K2M, Biomet, Pioneer [0-5]* each
AT	[5-10]*	[50-60]*	[50-60]*	[20-30]*	[0-5]*	[0-5]*	[0-5]*	Hofer, Ulrich, SpineArt, LDR, Biomet [0-5]* each
HU	[10-20]*	[30-40]*	[50-60]*	[10-20]*	0	[30-40]*	0	
LV	[20-30]*	[30-40]*	[50-60]*	[20-30]*	-	0	-	Ulrich [10-20]*
NL	[10-20]*	[40-50]*	[50-60]*	[5-10]*	[10-20]*	[5-10]*	[0-5]*	Ulrich [10-20]* Biomet [0-5]*
DE	[10-20]*	[20-30]*	[40-50]*	[10-20]*	[0-5]*	[10-20]*	[0-5]*	Ulrich [5-10]* Signus, Alphatec, Maxspine, Spineart, Biomet, Globus, AMT, Nuvasive, Pioneer [0-5]* each
LU	[10-20]*	[20-30]*	[40-50]*	[40-50]*	0	0	[5-10]*	Ulrich, SpineArt [0-5]* each
PL	[0-5]*	[30-40]*	[40-50]*	[20-30]*	[0-5]*	[0-5]*		LfC [5-10]* Biomet [5-10]* Alphatec, CHM, SpineArt, Pioneer [0-5]* each
CZ	[0-5]*	[40-50]*	[40-50]*	[20-30]*	-	[20-30]*	[0-5]*	Signus [0-5]*
ES	[5-10]*	[20-30]*	[30-40]*	[10-20]*	[5-10]*	[5-10]*	[5-10]*	K2M [5-10]* Biomet [5-10]* Alphatec, Ulrich, Signus, SpineArt, LDR [0-5]* each

Source: market reconstruction

<sup>285</sup>

The category "others" comprises the companies explicitly listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might be also active in the respective markets.

- (400) In Austria, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [20-30]\*% and a number of other competitors present with cervical plates (including Stryker, Aesculap, also Zimmer, K2M, LDR, Ulrich, Hofer). The market share evolution data show that market shares of the parties are contestable. In 2011 Medtronic, Synthes, LDR, Stryker, Aesculap, Hofer lost [0-5]\*%, while J&J, Ulrich and Nuvasive (recent entrant) each gained [0-5]\*%. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, it would be faced with several competitors which can exercise a sufficient competitive constraint on the parties. It is likely that these players would continue to constrain the parties. Furthermore, Synthes achieved [...] of its sales from Zero-P device, which is not the closest substitute to J&J's cervical plates.<sup>286</sup>
- (401) In Germany, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [10-20]\*%, Aesculap with a market share of [10-20]\*% and Ulrich with [5-10]\*%. Post-merger the merged entity would have a combined market share of below 50%, it would be facing at least three strong and well recognized competitors in the market for cervical plating systems and it is likely that these players would continue to constrain the parties.
- (402) In the United Kingdom, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [10-20]\*% and a number of other competitors present with cervical plates (e.g. Stryker, Aesculap, Zimmer, K2M, Ulrich).<sup>287</sup> The market share evolution data show that market shares of the parties are contestable, most notably new entrants Alphatec and Nuvasive both gained a share of [5-10]\*%, Globus and Ulrich also slightly increased to [0-5]\*% in 2011. Although post-merger the merged entity would have a high combined market share of [60-70]\*%, it would face several well recognized competitors in the market for cervical plating systems which can exercise a sufficient competitive constraint on the parties. It is likely that these players would continue to constrain the parties. Furthermore, Synthes achieved over [...] of its sales from Zero-P device, which is not the closest substitute to J&J's plates.
- (403) In Ireland, the proposed transaction does not raise concerns due to the strong position of SpineVision with a market share of [20-30]\*% and the presence of Medtronic and Stryker, each with market shares of [5-10]\*%, both well established players in Ireland. Zimmer is also active, while the new entrant K2M also has a strong position in Ireland (i.e. [10-20%]\* of overall spine market) and

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<sup>286</sup> Based on hospital replies, J&J and Synthes are not the closest competitors in this category (replies to questions 32, 60-62, 82 of Q28 – Phase II - questionnaire to customers (hospitals) (Austria)). Out of 13 respondents only two hospitals considered J&J and Synthes as their first best choices. Others considered that Synthes is closer to Aesculap, Medtronic, Stryker, and even Biomet. One J&J hospital would consider first Ulrich and Biomet and only then Synthes.

<sup>287</sup> Based on hospital replies all of those companies, and more, are capable of meeting hospitals' demand for cervical plates (replies to questions 32, 60-62, 82 of Q28 – Phase II - questionnaire to customers (hospitals) (UK)). Only one hospital out of 9, considered J&J and Synthes as their first best choices. Others would first consider Medtronic, Stryker, Ulrich, Zimmer Aesculap, or K2M in exchange for their main supplier.

offers a cervical plating system. Post-merger the merged entity would have a moderate combined market share of below 50% and would be faced with several competitors well recognized in the market for cervical plating systems. It is likely that these players would continue to constrain the parties.

- (404) In Denmark, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [10-20]\*% and Ulrich with a market share of [0-5]\*%, both higher than the increment added by J&J. Although post-merger the merged entity would have a high combined market share of [70-80]\*%, the increment added by J&J is insignificant with [0-5]\*% and two other competitors achieved higher sales than the increment added by the Notifying Party. All of the above competitors are well recognized in the market for cervical plating systems and it is likely that these players would continue to constrain the parties.
- (405) In the Netherlands, the proposed transaction does not raise concerns due to the strong position of Ulrich with a market share of [10-20]\*%, Stryker with a market share of [10-20]\*% and Medtronic and Aesculap with [5-10]\*% each. Although post-merger the merged entity would have a combined market share of [50-60]\*%, it would be facing several strong and well recognized competitors in the market for cervical plating systems and it is likely that these players would continue to constrain the parties.
- (406) In Luxembourg, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [40-50]\*% and Zimmer with [5-10]\*%. Post-merger the merged entity would have a combined market share of below 50%, it would be facing at least two well recognized competitors in the market for cervical plating systems and it is likely that these players would continue to constrain the parties. Ulrich, Spine Vision and Spine Art are also active in Luxembourg with cervical plates in their portfolio.
- (407) In Slovenia, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [10-20]\*% and the presence of recent entrant Ulrich. The market for cervical plating systems in Slovenia is very small and volatile, while prices for cervical plates are relatively high.<sup>288</sup> From 2010 to 2011 Medtronic increased its share to [50-60]\*%, Ulrich has gained [0-5]\*%, while J&J lost [0-5]\*%, and Synthes decreased from [80-90]\*% to [30-40]\*% in this market. Based on 2010 data for Slovenia, J&J and Synthes are also not particularly close competitors, given that the majority of Synthes' sales were achieved from its Zero-P device, which is not the closest substitute to the cervical plates of J&J. Although post-merger the merged entity would have a high combined market share of [90-100]\*% based on 2010 data, it is faced with at least two well-established competitors which can exercise a sufficient competitive constraint on the parties. It is likely that they would continue to

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Based on the Commission's reconstruction data, the market for cervical plates in Slovenia did not exceed EUR 110 000 in 2010. According to the parties, a cervical procedure with parties' products on average costs on average EUR [...]\*, or more if cervical cage is also used.



constrain the merged entity. Zimmer is also a recent entrant into the Slovenian market.

- (408) In Estonia, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [10-20]\*% and the presence of other credible players, Aesculap and Stryker, in Estonia. The market for cervical plating systems in Estonia is very small and volatile, while prices for cervical plates are relatively high.<sup>289</sup> The market share evolution data show that the position of the parties is contestable, e.g. in 2011 J&J increased by [10-20]\*% and Medtronic by [0-5]\*%, while Synthes lost [10-20]\*% of sales. Although post-merger the merged entity would have a high combined market share of [80-90]\*% based on 2010 data, it is faced with one strong and two other competitors which can exercise a sufficient competitive constraint on the parties. It is likely that they would continue to constrain the merged entity.
- (409) In Latvia, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [20-30]\*% and recent entrant Ulrich with a market share of [10-30]\*%. Although post-merger the merged entity would have a combined market share of [50-60]\*%, it would be facing at least two strong and well recognized competitors in the market for cervical plating systems and it is likely that these players would continue to constrain the parties.
- (410) In Hungary, the proposed transaction does not raise concerns due to the strong position of Aesculap with a market share of [30-40]\*% and Medtronic with a market share of [10-20]\*%. Although post-merger the merged entity would have a combined market share of [50-60]\*%, it would be facing at least two strong and well recognized competitors in the market for cervical plating systems and it is likely that these players would continue to constrain the parties. Other players (e.g. Alphatec, Biomet) are also active in Hungary.
- (411) In Poland, the concentration does not raise concerns due to the position of Medtronic with a market share of [20-30]\*%, a strong local player LfC with a market share of [5-10]\*%, Biomet with [5-10]\*%, Aesculap with [0-5]\*%, Stryker with [0-5]\*%, and Alphatec with [0-5]\*% which are all higher than the increment added by J&J. Post-merger the merged entity would have a combined market share of below 50%, the increment added by J&J is small [0-5]\*% and several other competitors achieved comparable or higher sales than the increment added by J&J. All of those competitors are well recognized in the market for cervical plating systems and it is likely that these players will continue to constrain the parties. Furthermore, Synthes achieved [...] of its sales from Zero-P device, which is not the closest substitute to J&J's cervical plates.
- (412) In the Czech Republic, the concentration does not raise concerns due to the position of Medtronic with a market share of [20-30]\*% and Aesculap with [20-

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<sup>289</sup> Based on Commission's reconstruction data, the market for cervical plates in Estonia did not exceed EUR 70 000 in 2010. According to the parties, a cervical procedure with parties' products on average costs on average EUR [...]\*, or more if a cervical cage is also used.

30]\*%. Post-merger the merged entity would have a combined market share of below 50%, the increment added by J&J is small [0-5]\*% and two other competitors achieved significant sales considerably higher than the increment added by J&J. All of those competitors are well recognized in the market for cervical plating systems and it is likely that these players will continue to constrain the parties. Furthermore, Synthes achieved nearly [...] of its sales from its Zero-P hybrid device, which is not the closest alternative to J&J's cervical plating systems.

- (413) In Spain, the concentration does not raise concerns due to the position of Medtronic with a market share of [10-20]\*%, Aesculap with [5-10]\*%, Stryker with [5-10]\*%, Biomet with [5-10]\*%, Zimmer with [5-10]\*%, and new entrant K2M with [5-10]\*% market share, which are higher than the increment added by J&J. Post-merger the merged entity would have a combined market share of below 40%, the increment added by J&J is moderate [5-10]\*% and several other competitors achieved comparable or higher sales than the increment added by J&J. All of those competitors are well recognized in the market for cervical plating systems and it is likely that these players will continue to constrain the parties. Furthermore, Synthes achieved more than [...] of its sales from its Zero-P hybrid device, which is not the closest alternative to J&J's cervical plating systems.
- (414) It can be left open for the purposes of the present decision whether competitive constraints stemming from neighbouring markets, such as stand-alone fixation devices (i.e. cages with inherent fixation) or artificial discs would have a meaningful constraining effect on traditional cervical posterior fixation devices, given that a sufficient number of competitors active in traditional systems would remain in all group 1 markets post-merger.
- (415) In view of the foregoing and taking into account the market characteristics as described in Section 6.4.2, the Commission concludes that the proposed transaction would not result in a significant impediment of effective competition in the market for cervical plating systems in Austria, the Czech Republic, Denmark, Estonia, Germany, Hungary, Luxembourg, Netherlands, Poland, Slovenia, Spain, and the United Kingdom. In case of a hypothetical attempt to increase prices in these markets, the merged entity would risk losing sales and market share to Medtronic or other competitors.

Interbody cages: general remarks

- (416) Based on industry reports, the demand for interbody cages continues to grow at an expected compound annual growth rate of 8.1%.<sup>290</sup> The reports also acknowledge that *"the large and growing number of competitors offering IBDs in Europe has resulted in a fairly commoditized market, in particular for fairly established ALIF, PLIF and TLIF approaches. [...] it is fairly easy to produce*

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<sup>290</sup>

iData – European Markets for Spinal Implants and VCF 2011, pp. 245, 320.

*an IBD cage relative to some of the other spinal implant products, thereby allowing smaller companies to introduce products".*<sup>291</sup>

- (417) In addition, continued innovation still plays a role. Synthes is an important innovator in this segment as an originator of stand-alone interbody devices with inherent fixation,<sup>292</sup> a technology that has also been incorporated into the product lines of many other competitors. Unlike Synthes, J&J does not produce its own stand-alone ALIF or ACIF devices.<sup>293</sup> The latest innovation in the interbody area is the introduction of a lateral interbody fusion device (LLIF) by Nuvasive,<sup>294</sup> which is also increasingly being added to the portfolios of other competitors (e.g. Medtronic, Synthes, K2M, Alphatec, Globus, Zimmer)<sup>295</sup>. Unlike Synthes, [...]\*.<sup>296</sup> TLIFs are also growing in popularity as their minimally invasive approach is gaining support. The industry reports also note increasing use of alternative materials, such as bioresorbable material or trabecular metal that facilitate a greater bond and fusion.
- (418) Overall, J&J's and Synthes' portfolios across interbody devices are rather complementary. J&J achieves most of its sales from [...]\* devices, it is hardly present in [...]\*and is a much smaller player in [...]\*compared to Synthes. Synthes, by contrast, is more focused on [...]\*and [...]\*compared to J&J. Synthes' [...]\* cage Synfix LR, a stand-alone ALIF device, accounted for [...]\* of its sales in 2010. In the area of cervical cages, only Synthes offers a closely related products, a standalone cage and plate device, Zero-P.
- (419) Should the market comprising all lumbar interbody cages be considered as the relevant product market, it would not materially affect the competitive assessment presented below, given that a sufficient number of players would remain active in all product segments where the parties overlap closely. Under such an alternative market definition there would be only seven group 1 markets, i.e. Austria, Denmark, Estonia, Hungary, Latvia, Luxembourg and Norway.

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<sup>291</sup> Millenium Research Group – "European Markets for Spinal Implants 2011", p. 116.

<sup>292</sup> These devices allow surgeons to implant interbody cages with fixation in one step, which may be easier, less invasive and less time-consuming than implanting a cage and then securing it with a separate fixation device, such as a plate.

<sup>293</sup> It should also be noted that J&J distributes a stand-alone STALIF TT device of Surgicraft, [...]\* it has achieved[...]\* sales.

<sup>294</sup> The lateral approach requires a nerve avoidance monitoring system, which Nuvasive and some other suppliers have. [...]\*.

<sup>295</sup> Companies continue to innovate in this area. For example, Alphatec recently launched its Guided Lumbar Interbody Fusion technique, providing for direct visualisation and access to the disc space; Globus has announced the launch of Caliber L, a vertically expanding minimally invasive lateral implant as its latest LLIF device. Globus also sells several plate and cage integrated systems, such as Independence and InterContinental.

<sup>296</sup> According to the Notifying Party, [...]\*

Table 19: Group 1 markets in lumbar interbody cages

2010	J&J	Synthes	Comb.	Medtronic	Stryker	Aesculap	Zimmer	Others <sup>297</sup>
<b>NO</b>	[20-30]*	[40-50]*	[70-80]*	[10-20]*	[0-5]*	[5-10]*	[0-5]*	Biomet [0-5]*, SpineArt [0-5]*
<b>LV</b>	[40-50]*	[20-30]*	[60-70]*	[30-40]*	-	0	-	
<b>AT</b>	[10-20]*	[40-50]*	[60-70]*	[10-20]*	[0-5]*	[0-5]*	[0-5]*	Hofer [5-10]*, LDR, Nuvasive, Ulrich, AMT, Spineart [0-5]* each
<b>EE</b>	[5-10]*	[60-70]*	[60-70]*	[10-20]*	[10-20]*	0	-	-
<b>HU</b>	[30-40]*	[10-20]*	[50-60]*	[40-50]*	[0-5]*	0	0	Biomet [0-5]*
<b>LU</b>	[20-30]*	[5-10]*	[30-40]*	[50-60]*			[0-5]*	Ulrich [0-5]*
<b>DK</b>	[0-5]*	[30-40]*	[30-40]*	[50-60]*	[0-5]*	[5-10]*	[0-5]*	Biomet [0-5]*

Source: market reconstruction

- (420) In Norway, the proposed transaction does not raise concerns due to the presence of Medtronic with a market share of [10-20]\*% and Aesculap with a market share of [5-10]\*%. Medtronic is active with all four types of interbody cages, while Aesculap offers three types of devices, i.e. ALIF, TLIF, PLIF. The market investigation has also confirmed further entry in Norway. Biomet and Zimmer are also present in Norway and offer all four types of interbody cages, while Stryker and Spine Art offer three types of devices (ALIF, TLIF, and PLIF). The parties mostly overlap in [...] devices, which are offered by all major competitors. [...] Synthes is also active with [...]\*, primarily facing Medtronic and Biomet. Although post-merger the merged entity would achieve a market share of [70-80]\*%, it would be facing at least two strong competitors in each segment and further entry. It is likely that these players would continue to constrain the merged entity.
- (421) In Latvia, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [30-40]\*% and recent entry by Ulrich. The parties closely overlap only in relation to [...] devices, while Synthes also sells [...]\*, a segment currently led by Medtronic in Latvia. Both, Medtronic and Ulrich, offer [...] devices. The market for interbody cages in Latvia is relatively small (market shares are therefore not necessarily indicative of the market power)

<sup>297</sup> The category "others" comprises the companies explicitly listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might be also active in the respective markets.

and volatile, while the devices are expensive.<sup>298</sup> For example, based on market share evolution data, in 2011 Ulrich gained a non-insignificant [0-5]\*% market share in [...] in just one year, while the market share of J&J has decreased by nearly the same number. Although post-merger the merged entity would achieve a high market share of [60-70]\*%, it would be facing at least two strong competitors. It is likely that these players would continue to constrain the merged entity.

- (422) In Austria, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [10-20]\*% and the presence of several other established players (e.g., Stryker, Aesculap, Zimmer). The parties closely overlap only in relation to [...] devices, while Synthes also sells [...]. Medtronic, Zimmer, Nuvasive and LDR offer all four types of devices, while many others (Ulrich, Stryker, Aesculap, K2M) have three main types of cages in their portfolio. AMT AG ("AMT"), a specialized interbody device company, also active with [0-5]\*% market share and [...] cages. Market share evolution data show that the market shares of the parties are contestable.<sup>299</sup> Although based on 2010 data post-merger the merged entity would achieve a high market share of [60-70]\*%, it would be facing several competitors which can exercise a sufficient competitive constraint on the parties. It is likely that these players would continue to constrain the merged entity.
- (423) In Luxembourg, the proposed transaction does not raise concerns due to the leading position of Medtronic with a market share of [50-60]\*% and the presence of several other established players, Zimmer and Ulrich with [0-5]\*% each. Spine Art is also active in Luxembourg with three main types of cages, while Spine Vision offers TLIFs and PLIFs. In Luxembourg the parties mostly overlap in [...] with an increment of only [0-5]\*% brought by J&J. Only Synthes is active to a non-insignificant extent with other devices, i.e. [...], facing Medtronic, Zimmer and Ulrich, and in [...], facing Medtronic and Zimmer. Post-merger the merged entity would achieve a market share below 40% and it would be facing several competitors which can exercise sufficient competitive constraint on the parties. It is likely that these players would continue to constrain the merged entity.
- (424) In Denmark, the proposed transaction does not raise concerns due to the leading position of Medtronic with a market share of [50-60]\*% and the presence of several other established players, Aesculap with [5-10]\*%, and others (Stryker, Biomet and Zimmer). Medtronic, Zimmer and Biomet offer all four types of devices, while others are active with the three main types (ALIFs, TLIFs, and PLIFs). The parties overlap only in [...] (with a small increment of [0-5]\*%) and in [...] (with an increment of [5-10]\*%), facing Medtronic and other

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<sup>298</sup> Based on the Commission's reconstruction data, the market for interbody cages in Latvia did not exceed EUR 60 000 in 2010. For example, according to the parties, procedure with parties' TLIFs on average costs on average EUR [...], and even more if pedicle screws are used.

<sup>299</sup> For example in [...], in 2011 J&J sales decreased by [...]%, while for Medtronic market share increased by [5-10]\*%, and Synthes's increased by [0-5]\*%; most notably a new entrant Nuvasive increased from [0-5]\*% to [5-10]\*% in just one year in Austria

competitors. Post-merger the merged entity would achieve a market share below 40% and it would be facing several competitors which can exercise a sufficient competitive constraint on the parties, with market share exceeding the small increment added by J&J. It is likely that these players would continue to constrain the merged entity.

- (425) In Estonia, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [10-20]\*% and Stryker with a market share of [10-20]\*%. Medtronic offers all four types of interbody cages, while Stryker is active in the three main categories (ALIFs, TLIFs, and PLIFs). The parties overlap only in [...] (with an small increment of [0-5]\*%), facing Medtronic and Stryker, each with [20-30]\*% market share in this segment. Although post-merger the merged entity would have a combined market share of [60-70]\*%, it would be facing at least two strong and well recognized competitors in interbody devices and it is likely that these players would continue to constrain the parties.
- (426) In Hungary, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [40-50]\*% and the presence of other established players (Stryker, Biomet) with a market share of [0-5]\*%. Medtronic and Biomet offer all four types of interbody cages, while Stryker is active in the three main categories (ALIFs, TLIFs, and PLIFs). The parties overlap only in [...] (with an small increment of [0-5]\*%), facing Medtronic and Stryker, each with [10-20]\*% market share in this segment. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, it would be faced with several competitors that are well recognized in the market for interbody devices and it is likely that these players would continue to constrain the parties. Several other players (e.g., Aesculap, Zimmer, Alphatec) are also present in Hungary and offer various types of interbody cages.
- (427) The following section assesses the competitive situation in group 1 markets based on the narrowest market definitions, i.e., ALIF, TLIF, PLIF, and ACIF devices.

*Thoracolumbar Interbody cages: ALIF devices*

- (428) Both parties market ALIF devices, i.e. J&J markets Cougar and Stalif,<sup>300</sup> while Synthes sells Syncage, Visios, and SynFix devices. J&J and Synthes are not the closest competitors with respect to ALIF cages with inherent fixation. Synthes achieved [...] sales from a self-fixating device Synfix, while J&J from [...]. Due to inherent fixation, SynFix of Synthes is more closely comparable to other innovative devices, such as Medtronic's Sovereign, LDR's ROI-A, Alphatec's Solus, Biomet's Solitaire or Globus' Independence and other standalone devices,<sup>301</sup> while J&J's [...] is a closer alternative to Aeculap's A-Space,

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<sup>300</sup> J&J markets a third party product Stalif licenced from Surgicraft, [...] it achieved [...] sales in 2010.

<sup>301</sup> Based on the market investigation even more companies either already market stand-alone ALIFs or plan to introduce such devices in the coming years (replies to question 52 of questionnaire 30 to spine competitors).

Synthes' Syncage, Stryker's AVS AL, Alphatec's Novel ALS. Compared to Synthes, J&J is a smaller player in this segment.

- (429) Other players offer the following traditional ALIFs cages and self-fixation devices: Medtronic (Sovereign, Perimeter, Hydrosorb mesh, Prevail); Alphatec (Antelys, Kla, Solus); Aesculap (A-space); Zimmer (Fidji, Infix, TM (trabecular metal), BAK, BP); Biomet (Solitaire, Accuvision); Ulrich (Pezo A, Topaz); Nuvasive (CoRoent XLR); Globus (Sustain and Independence), Mediecrea (Impix); Spine Art (Juliet AN); LDR (ROI-A), K2M (Aleutian ALIF) and others.

Table 20: Group 1 markets in ALIF devices

2010	J&J	Synthes	Comb.	Medtronic	Stryker	Aesculap	Zimmer	Others <sup>302</sup>
SE	[5-10]*	[60-70]*	[70-80]*	[5-10]*	0		[10-20]*	
NL	[5-10]*	[50-60]*	[60-70]*	[20-30]*	0	0	[0-5]*	Biomet [5-10]*, Coligne [0-5]*
EE	[10-20]*	[40-50]*	[50-60]*	[20-30]*	[20-30]*	0	0	
DK	[0-5]*	[40-50]*	[40-50]*	[50-60]*	0	0	0	Biomet [0-5]*
UK	[5-10]*	[30-40]*	[40-50]*	[20-30]*	[0-5]*	[0-5]*	[0-5]*	Nuvasive [5-10]*, LDR [5-10]* K2M, Alphatec, Globus, Ulrich, Mediecrea, Biomet [0-5]*% each
DE	[5-10]*	[20-30]*	[30-40]*	[20-30]*	[5-10]*	[0-5]*	[10-20]*	Alphatec [5-10]*, Ulrich [5-10]*, Globus, Signus, Spineart, LDR, Maxspine, Nuvasive [0-5]* each
BE	[0-5]*	[30-40]*	[30-40]*	[50-60]*	[0-5]*	0	[0-5]*	Coligne, Globus, Ulrich, Sugnus, Biomet [0-5]* each

Source: market reconstruction

- (430) In the United Kingdom, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [20-30]\*% and a new aggressive entrant Nuvasive with a market share of [5-10]\*%. Post-merger the merged entity would have a combined market share below 50%, the increment added by J&J is moderate with [5-10]\*% and two other competitors achieved higher sales than the increment added by the Notifying Party. All of the above competitors are well recognized in the market for ALIF cages and it is likely that these players would continue to constrain the parties. Furthermore, Synthes achieved the [...] sales from its stand-alone SynFix LR, which is not the closest

<sup>302</sup> The category "others" comprises the companies listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might also be active in the respective markets.

substitute to J&J's [...] device. Medtronic, LDR, Alphatec and some other players also offer standalone ALIFs.

- (431) In Germany, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [20-30]\*% and Zimmer with a market share of [10-20]\*%. Post-merger the merged entity would have a combined market share below 50%, it would be facing at least two strong and well recognized competitors in the market for ALIF devices and it is likely that these players would continue to constrain the parties. Furthermore, Synthes achieved nearly [...] of its sales from its stand-alone SynFix LR, which is not the closest substitute to J&J's [...] device. Medtronic, LDR, Alphatec and some other players also offer standalone ALIFs.
- (432) In the Netherlands, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [20-30]\*% and Biomet with a market share of [5-10]\*%, both exceeding the increment added by J&J. Although post-merger the merged entity would have a high combined market share of [60-70]\*%, the increment added by J&J is moderate with [5-10]\*% and two other competitors achieved higher sales than the increment added by the Notifying Party. All of the above competitors are well recognized in the market for ALIF cages and it is likely that these players would continue to constrain the parties. A number of other players are also present in the Netherlands, e.g, Zimmer, Coligne, Aesculap, Stryker, LDR.
- (433) In Sweden, the proposed transaction does not raise concerns due to the position of Zimmer with a market share of [10-20]\*% and Medtronic with a market share of [5-10]\*%. Although post-merger the merged entity would have a high combined market share of [70-80]\*%, the increment added by J&J is only [5-10]\*% and two other competitors achieved higher sales than the increment added by the Notifying Party. New entrants, K2M and Globus, and also Ulrich and Biomet are already active, while further entry was also confirmed in the market investigation. All of those competitors are well recognized in the market for ALIF cages and it is likely that these players would continue to constrain the parties. Furthermore, Synthes achieved [...] sales from SynFix LR, which is not the closest substitute to J&J's [...] device.
- (434) In Denmark, the proposed transaction does not raise concerns due to the strong position of Medtronic with a leading market share of [50-60]\*% and the presence of a number of other established players in Denmark (Aesculap, Stryker and Biomet). Post-merger the merged entity would have a combined market share below 50 % and it would be facing at least one very strong and several other well recognized competitors in the market for ALIF devices. It is likely that these players would continue to constrain the parties. Furthermore, the vast majority of Synthes' sales in Denmark came from SynFix LR, which is not the closest alternative to traditional ALIFs, such as J&J's [...] cage.
- (435) In Estonia, the proposed transaction does not raise concerns due to the strong position of Stryker with a market share of [20-30]\*% and Medtronic with a market share of [20-30]\*%. Although post-merger the merged entity would have a combined market share of [50-60]\*%, it would be facing at least two strong and



well recognized competitors in the market for ALIF devices and it is likely that these players would continue to constrain the parties. Furthermore, Synthes achieved the [...] sales from SynFix LR, which is not the closest alternative to J&J's [...] device in terms of product characteristics.

- (436) In Belgium, the concentration does not raise concerns due to the strong position of Medtronic with a market share of [50-60]\*%, Zimmer and Coligne with a market shares of [0-5]\*%, which are higher or closely comparable to the increment added by J&J. Post-merger the merged entity would have a combined market share of below 40%, the increment added by J&J is small [0-5]\*% and three other competitors achieved comparable or higher sales than the increment added by J&J. All of those competitors are well recognized in the market for ALIF devices and it is likely that these players will continue to constrain the parties. In addition, several other companies, including new entrants, offer ALIF devices in Belgium. Furthermore, Synthes achieved nearly [...] of its sales from its stand-alone SynFix LR, which is not the closest substitute to J&J's [...] device.
- (437) In view of the foregoing and taking into account the market characteristics as described in Section 6.4.2, the Commission concludes that the proposed transaction would not result in a significant impediment of effective competition in the market for ALIF devices in Belgium, Denmark, Estonia, Germany, the Netherlands, Sweden and the United Kingdom. It is unlikely that the merged entity would have the ability to increase prices, as the remaining competitors would be able to exercise sufficient competitive constraint.

#### *Thoracolumbar Interbody cages: TLIF devices*

- (438) According to [...] and industry reports, the TLIF market is the most rapidly growing segment of IBDs with an expected growth of 14.1% (compared to 8% for overall interbody fusion) and is characterised by an increase in competition.<sup>303</sup> TLIF devices represent an innovative segment and are very popular, as their minimally invasive approach is gaining support. For example Globus' "Signature" TLIF system includes an articulating implant that enables surgeons to utilise a single instrument. Based on the results of the market reconstruction, TLIF is the largest interbody segment representing over 35% of total interbody cages market.
- (439) Both parties market TLIF devices, J&J markets Concrod, Devex and Leopard while Synthes' sells Travios, TPAL (articulating)<sup>304</sup>, and Opal branded cages. Other players also offer TLIF devices: e.g., Medtronic (Capstone), Zimmer (Trestle), SpineArt (Juliet), Aesculap (T-Space), Stryker (AVS TL Peek), LDR (Roi-T), Globus (Signature articulating cage), Zimmer (TM 300, Traxis, Ardis,

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<sup>303</sup> iData - European Markets for Spinal Implants and VCF 2011, p. 245 and Millennium research Group – European Markets for Spinal Implants 2011, p. 118.

<sup>304</sup> Articulating cages are an innovative type of device, allowing surgeons to utilise a single instrument – from insertion through final placement – to deliver the cage into correct position while performing a TLIF procedure.

Trinica (trabecular metal). Synthes' "TPAL" cage is an articulating cage, a type of cage that J&J does not offer.

Table 21: Group 1 markets in TLIF devices

2010	J&J	Synthes	Comb.	Medtronic	Stryker	Aesculap	Zimmer	Others <sup>305</sup>
NO	[30-40]*	[40-50]*	[80-90]*	[0-5]*	0	[10-20]*	0	SpineArt [0-5]*
LV	[70-80]*	[20-30]*	[90-100]*	[5-10]	-	0	-	
AT	[30-40]*	[30-40]*	[60-70]*	[10-20]*	[0-5]*	[0-5]*	[0-5]*	Ulrich, AMT, Spineart, LDR, Nuvasive [0-5]* each
LU	[50-60]*	[0-5]*	[60-70]*	[30-40]*	-	-	[0-5]*	
HU	[50-60]*	[0-5]*	[50-60]*	[30-40]*	[0-5]*	0	0	
PL	[30-40]*	[20-30]*	[50-60]*	[10-20]*	[5-10]*	[10-20]*	-	Spine Art [5-10]*
FI	[10-20]*	[30-40]*	[50-60]*	[40-50]*	[0-5]*	-	[0-5]*	
UK	[30-40]*	[10-20]*	[40-50]*	[10-20]*	[0-5]*	[0-5]*	[5-10]*	Nuvasive [10-20]* Globus, K2M, Medicea, Alphatec, SurgiC, Signus, Peter Brehm [0-5]* each
ES	[20-30]*	[20-30]*	[40-50]*	[20-30]*	[5-10]*	[0-5]*	[5-10]*	Alphatec [5-10]*, K2M, Ulrich, Signus, SpineArt, SpineVision, LDR, Medicea, Kisco [0-5]* each
DK	[5-10]*	[30-40]*	[40-50]*	[40-50]*	[0-5]*	[5-10]*	[0-5]*	
SE	[20-30]*	[10-20]*	[30-40]*	[30-40]*	[20-30]*	0	[5-10]*	
IT	[30-40]*	[0-5]*	[30-40]*	[10-20]*	[0-5]*	[0-5]*	[5-10]*	SpineVision [10-20]* Nuvasive [5-10]*, Biomet [5-10]* Spineart, Coligne, Alphatec, Ulrich [0-5]* each
DE	[20-30]*	[5-10]*	[30-40]*	[20-30]*	[5-10]*	[5-10]*	[5-10]*	Signus [5-10]* Maxspine, AMT, Ulrich, Alphatec, Globus, SpineArt, SpineVision LDR, , Nuvasive [0-5]* each

Source: market reconstruction

<sup>305</sup>

The category "others" comprises the companies listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might also be active in the respective markets.

- (440) In Austria, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [10-20]\*% and the presence of several other established players (Stryker, Aesculap, Zimmer). AMT, a specialized interbody device company, and several others are also active with [0-5]\*% market shares. Market share evolution data show that the market shares of the parties are contestable, e.g. in 2011 J&J sales decreased by [10-20]\*%, while Medtronic's market share increased by [5-10]\*%, and Synthes's increased by [0-5]\*%; most notably a new entrant Nuvasive increased from [0-5]\*% to [5-10]\*% just in one year in Austria. Although based on 2010 data post-merger the merged entity would achieve a high market share of [60-70]\*%, it would be facing several competitors which can exercise sufficient competitive constraint on the parties. It is likely that these players would continue to constrain the merged entity.
- (441) In Germany, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [20-30]\*%, and Stryker and Aesculap with non-insignificant market shares of [5-10]\*% each. Post-merger the merged entity would have a combined market share below 50%, the increment added by Synthes is moderate of [5-10]\*% and two other competitors achieved comparable or higher sales than the increment added by Synthes. All of those competitors are well recognized in the market for TLIF devices and it is likely that these players would continue to constrain the parties. Numerous other players are also active in Germany.
- (442) In the United Kingdom, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [10-20]\*% and a new aggressive entrant Nuvasive with a market share of [10-20]\*%. A number of other credible players, and new entrants, are active in the UK market. Post-merger the merged entity would have a combined market share below 50% and it would be facing at least two strong competitors, including an aggressive entrant. It is likely that these players would continue to constrain the merged entity. Numerous other players are also active in the United Kingdom.
- (443) In Denmark, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [40-50]\*% and Aesculap with a non-insignificant market share of [5-10]\*%. Post-merger the merged entity would have a combined market share below 50%, the increment added by J&J is moderate (of [5-10]\*%) and two other competitors achieved sales higher than the increment added by J&J. All of the competitors are well recognized in the market for TLIF devices and it is likely that these players would continue to constrain the parties. Zimmer and Stryker are also active in Denmark.
- (444) In Sweden, the proposed transaction does not raise concerns due to the strong positions of Medtronic with a market share of [30-40]\*%, Stryker with a market share of [20-30]\*% and Zimmer with [5-10]\*%. The market investigation also confirmed further entry into Sweden. K2M, Ulrich, and Biomet are already present, while further entry was also confirmed. Post-merger the merged entity would have a combined market share below 50%, it would be facing at least three strong and well recognized competitors in the market for TLIF devices and it is likely that these players would continue to constrain the parties.

- (445) In Norway, the proposed transaction does not raise concerns due to the presence of Aesculap with a market share of [10-20]\*% and Medtronic with a market share of [0-5]\*%. Based on market share evolution data, the market in Norway is volatile, e.g. Medtronic achieved [10-20]\*% market share in 2009 and only [0-5]\*% in 2010. Norway is a tender market where market shares can change significantly depending on the outcomes of subsequent tenders. The market investigation has also confirmed further entry in Norway. Although based on 2010 data, post-merger, the merged entity would achieve a market share of [80-90]\* %, it would be facing at least two strong competitors and further entry. It is likely that these players would continue to constrain the merged entity.
- (446) In Finland, the concentration does not raise concerns due to the strong position of Medtronic with a market share of [40-50]\*% and the presence of several other established competitors (Stryker ([0-5]\*%, Zimmer [0-5]\*%), all capable of meeting hospitals demand for TLIF devices. Biomet, Ulrich, Coligne and new entrant K2M are also present in Finland. The market investigation has also confirmed future entry. Taking this into account, it is likely that these established players as well as new aggressive entrants will continue to constrain the parties post-merger.
- (447) In Italy, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [10-20]\*% and SpineVision with a market share of [10-20]\*%. There are numerous other players present in Italy that also offer TLIF devices. Post-merger the merged entity would have a combined market share below 50%, it would be facing at least two strong and well recognized competitors in the market for TLIF devices and it is likely that these players would continue to constrain the parties.
- (448) In Spain, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [20-30]\*%, and Stryker and Aesculap with non-insignificant market shares of [5-10]\*% each. There are numerous other players present in Italy that also offer TLIF devices. Post-merger the merged entity would have a combined market share below 50%, it would be facing at least three strong and well recognized competitors in the market for TLIF devices and it is likely that these players would continue to constrain the parties.
- (449) In Latvia, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [5-10]\*% and recent entry by Ulrich. Based on market share evolution data, in 2011 Ulrich gained a non-insignificant [0-5]\*% market share just in one year, while the market share of J&J has decreased by nearly the same number. The market for TLIFs in Latvia is relatively small (market shares are therefore not necessarily indicative of the market power) and volatile, while the devices are expensive.<sup>306</sup> Although based on 2010 data, post-

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<sup>306</sup> Based on the Commission's reconstruction data, the market for TLIFs in Latvia did not exceed EUR 40 000 in 2010. According to the parties, a TLIF procedure with parties' products on average costs on average EUR [...]\*, and even more if pedicle screws are used.

merger the merged entity would achieved a very high market share of [90-100]\*%, it would be facing at least two strong competitors. It is likely that these players would continue to constrain the merged entity.

- (450) In Hungary, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [30-40]\*% and Stryker with a market share of [0-5]\*%, which is comparable to the increment added by Synthes. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, the increment added by Synthes is small [0-5]\*% and two other competitors achieved comparable or higher sales than the increment added by Synthes. All of those competitors are well recognized in the market for TLIF devices and it is likely that these players would continue to constrain the parties.
- (451) In Poland, the concentration does not raise concerns due to the position of Medtronic with a market share of [10-20]\*%, Aesculap with [10-20]\*%, Stryker and Spine Art each with [5-10]\*%. Although post-merger the merged entity would have a combined market share of [50-60]\*%, the merged entity would be faced with at least four well recognized competitors in the market for TLIFs and it is likely that these players will continue to constrain the parties.
- (452) In Luxembourg, the concentration does not raise concerns due to the strong position of Medtronic with a market share of [30-40]\*%, and Zimmer with a market share of [0-5]\*% which is closely comparable to the increment added by Synthes. Although post-merger the merged entity would have a combined market share of [60-70]\*%, the increment added by J&J is small [0-5]\*% and at least two other competitors achieved higher or closely comparable sales to the increment added by Synthes. All of those competitors are well recognized in the market for TLIF devices and it is likely that these players will continue to constrain the parties. In addition, several other companies (e.g., Ulrich, Spine Art, Spine Vision) are present in Luxembourg and offer TLIF devices.
- (453) In view of the foregoing and taking into account the market characteristics as described in Section 6.4.2, the Commission concludes that the proposed transaction would not result in a significant impediment of effective competition in the market for TLIF devices in Austria, Denmark, Finland, Germany, Hungary, Italy, Latvia, Luxembourg, Norway, Poland, Spain, Sweden and the United Kingdom. It is unlikely that the merged entity would have the ability to increase prices, as the remaining competitors would be able to exercise sufficient competitive constraint.

#### *Thoracolumbar Interbody cages: PLIF devices*

- (454) Both parties market PLIF devices, i.e. J&J markets Jaguar, Iriom and Saber devices, while Synthes' sells Contact, Plivios and Pliviopore cages. Other players also offer PLIFs cages: e.g., Medtronic (Capstone, Crescent, Telamon and others); Stryker (OIC, AVS); Aesculap (ProSpace); Biomet (IBEX, Neolif, ESL); Coligne (PLIF); Zimmer (Fidji, Ardis, BAK, BP); Alphatec (Oria Natura/CO/CC); Hofer (HISS); Spine Art (Juliet PO), and others. J&J and Synthes are complementary in relation to prefilled cages (Plivios) of Synthes and

CFRP materials used in J&J cages. Compared to Synthes, J&J is a smaller player in this segment.

Table 22: Group 1 markets in PLIF devices

2010	J&J	Synthes	Comb.	Medtronic	Stryker	Aesculap	Biomet	Others <sup>307</sup>
NO	[20-30]*	[20-30]*	[50-60]*	[30-40]*	[10-20]*	0	[0-5]*	
AT	[5-10]*	[40-50]*	[50-60]*	[10-20]*	[0-5]*	[0-5]*	0	Hofer [10-20]*, Nuvasive, Ulrich, AMT, LDR, Zimmer [0-5]* each
PT	[30-40]*	[0-5]*	[40-50]*	0	[0-5]*	0	[30-40]*	Medicrea [5-10]*, Zimmer [0-5]*
IT	[20-30]*	[10-20]*	[40-50]*	[5-10]*	[5-10]*	[5-10]*	[10-20]*	Zimmer [5-10]*, SpineArt [5-10]*, Coligne, Alphatec, Sinteal, Ulrich, Signus, Nuvasive [0-5]* each
BE	[30-40]*	[5-10]*	[40-50]*	[20-30]*	[5-10]*	[0-5]*	[0-5]*	Coligne [5-10]*, Zimmer [5-10]*, Globus, K2M, SpieArt [0-5]* each

Source: market reconstruction

- (455) In Austria, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [20-30]\*% and Hofer with a market share of [10-20]\*%. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, the increment added by the transaction is small and the merged entity is facing several established players, including new entrants such as Nuvasive (with a market share [0-5]\*%) and K2M (entered in 2011). All of those competitors are well recognized in the market for PLIF device and it is likely that these players would continue to constrain the parties. Stryker ([0-5]\*%), Aesculap ([0-5]\*%) and several other suppliers (AMT, LDR and Zimmer, [0-5]\*% each) are also present in Austria.
- (456) In Norway, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [30-40]\*% and Stryker with a market share of [10-20]\*%. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, it would be facing at least two strong and well recognized competitors in the market for PLIF devices and it is likely that those players would continue to constrain the parties. The market investigation has also confirmed further entry into Norway in the coming two years.

<sup>307</sup> The category "others" comprises the companies listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might also be active in the respective markets.

- (457) In Portugal, the proposed transaction does not raise concerns due to the strong position of Biomet with a market share of [30-40]\*% and Medicea with a market share of [5-10]\*%. Post-merger the merged entity would have a combined market share below 50%, the increment added by Synthes is small ([0-5]\*%) and two other competitors achieved higher sales than the increment added by the Notifying Party. All of the those competitors are well recognized in the market for PLIF devices and it is likely that these players would continue to constrain the parties. Zimmer and Stryker are also active in Portugal.
- (458) In Italy, the proposed transaction does not raise concerns due to the strong position of Biomet with a market share of [10-20]\*% and numerous other players, Zimmer, Aesculap, Stryker and Medtronic each having a market share of [5-10%]\*. Although post-merger the merged entity would have a combined market share below 50%, it would be facing several strong and well recognized competitors in the market for PLIF devices and it is likely that these players would continue to constrain the parties.
- (459) In Belgium, the concentration does not raise concerns due to the position of Medtronic with a market share of [20-30]\*%, Zimmer with a market share of [5-10]\*% and Stryker with [5-10%]\*, which are higher than the increment added by Synthes. Post-merger the merged entity would have a combined market share of below 50%, the increment added by J&J is moderate [5-10]\*% and three other competitors achieved comparable or higher sales than the increment added by Synthes. All of those competitors are well recognized in the market for PLIF devices and it is likely that these players will continue to constrain the parties. In addition, several other companies, including new entrants, offer PLIFs devices in Belgium.
- (460) In view of the foregoing and taking into account the market characteristics as described in Section 6.4.2, the Commission concludes that the proposed transaction would not result in a significant impediment of effective competition in the market for PLIF devices in Austria, Belgium, Italy, Norway, and Portugal. It is unlikely that the merged entity would have the ability to increase prices, as the remaining competitors would be able to exercise sufficient competitive constraint.

*Cervical Interbody cages: ACIF devices*

- (461) The demand for cervical interbody cages is significantly lower than that for lumbar cages. However, this segment also continues to grow. According to the Notifying Party, market reports predict that demand for cervical cages would continue to grow due to high patient demand for the procedure.<sup>308</sup> Similarly to lumbar devices, innovation continues for cervical implants due to the introduction of cervical cages with inherent fixation and increasing use of resorbable materials (e.g., bioresorbable and trabecular metal) that facilitate greater fusion.

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iData Report "European Markets for Spinal Implants and VCF 2011", p. 321. Millenium Research Group Report "European Market for Spinal Implants 2011", p. 119.

- (462) Both parties market ACIF devices, i.e. J&J markets Bengal and Crystal, while Synthes sells SynCage-C and Cervios (prefilled). In terms of product characteristics, J&J's and Synthes' products are not the closest substitutes in this category. While J&J's [...] Bengal device is from CFRP material, Synthes' cages are Titanium and PEEK material and Cervios is a prefilled cage. According to the Notifying Party, the Bengal cage is [...].\*
- (463) Numerous other players also offer ACIF cages: e.g., Medtronic (Affinity and Peek Prevail (stand-alone)); Stryker (Solis), Zimmer (TM/Fortitude), Alphatec (Samarys/CBK), Hofer (HISS cervical), K2M (Aleutian),<sup>309</sup> Nuvasive (CoRoent Small), Medicea (Impix), Biomet (NeoCif), LDR (ROI-C, standalone), Globus (Coalition, standalone cage), and others.
- (464) In addition to cervical cages, a number of market players (e.g. Synthes, Alphatec, Spine Art) offer cervical plate and cage combination devices, which like some ACIFs are also stand-alone implants used for cervical stabilisation procedures, replacing a combination of a traditional plate and cervical cage. The inclusion of such devices into the ACIF market would have only a minimal effect on the assessment and would not in any event affect the competitive assessment, especially given that J&J does not offer an equivalent plate and cage device in this category.<sup>310</sup>

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<sup>309</sup> According to the Notifying Party, K2M portfolio also includes Chesapeake (stand-alone) devices.

<sup>310</sup> Should plate/cage devices be included in the ACIF market, only two additional group 1 markets would arise, namely Belgium and the Czech Republic, while the market shares of the parties and their main competitors in other group 1 countries would change only negligibly. In Belgium, the merged entity would have a combined market share of [40-50]\*%, facing Zimmer with [20-30]\*%, Spine Art with [5-10]\*%, and Coligne with [5-10]\*%, all exceeding the increment added by J&J of [5-10]\*%, and numerous other competitors, for example Medtronic, Aesculap, Stryker, Globus, Alphatec, Ulrich, AMT and others. In Check Republic, the merged entity would have a combined market share of [40-50]\*%, facing Aesculap with [40-50]\*%, also several other established competitors, such as Medtronic and Zimmer, and others. It can be expected that these players will continue to restrain the merged entity in Belgium and the Czech Republic in a market for ACIF devices.



Table 23: Group 1 markets in ACIF devices

2010	J&J	Synthes	Comb.	Medtronic	Stryker	Aesculap	Zimmer	Others <sup>311</sup>
EE	[90-100]*	[0-5]*	[90-100]*	[0-5]*	0	0	-	
IE	[80-90]*	[0-5]*	[80-90]*	[5-10]*	[5-10]*	-	[0-5]*	
AT	[20-30]*	[40-50]*	[70-80]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	LDR [10-20]*, Hofer [5-10]*, AMT, Signus, Spineart [0-5]* each
IT	[20-30]*	[20-30]*	[50-60]*	[5-10]*	[5-10]*	[0-5]*	[5-10]*	Biomet [5-10]* Alphatec, LDR, Spineart,, Sinteia, Ulrich, Signus, Kisko, Coligne [0-5]* each
NL	[10-20]*	[30-40]*	[50-60]*	[0-5]*	[10-20]*	[5-10]*	[0-5]*	Biomet [5-10]*, Sinteia [5-10]* Alphatec, Medicea, Coligne [0-5]* each
HU	[20-30]*	[10-20]*	[40-50]*	0	[20-30]*	[10-20]*	0	Biomet [10-20]*, Medicea [0-5]*
SE	[0-5]*	[30-40]*	[30-40]*	[0-5]*	[0-5]*	0	[30-40]*	Biomet [10-20]*, Kisko, Ulrich [0-5]* each
UK	[20-30]*	[10-20]*	[30-40]*	[5-10]*	[10-20]*	[5-10]*	[0-5]*	Nuvasive [5-10]*, Medicea [5-10]*, SurgiC [5-10]*, Signus [5-10]* Alphatec, Globus, Ulrich, K2M, Biomet, [0-5 each]*
SL	[10-20]*	[10-20]*	[30-40]*	[60-70]*	-	-	0	
PT	[10-20]*	[10-20]*	[30-40]*	[0-5]*	[5-10]*	0	[10-20]*	Alphatec [10-20]*, Medicea [10-20]*, Biomet [5-10]* Signus, Spineart, Spinevison [0-5]* each

Source: market reconstruction

- (465) In Austria, the proposed transaction does not raise concerns due to the position of LDR with a market share of [10-20]\*%, Hofer with a market share of [5-10]\*%, and the presence of a number of other players (e.g. Medtronic, Zimmer, Stryker, Ulrich) with ACIF devices. Although post-merger the merged entity would have a high combined market share of [70-80]\*%, it would face at least two well established and several other competitors which can exercise sufficient competitive constraint on the parties. All of those competitors are well recognized in the market for ACIF devices and it is likely that these players would continue

<sup>311</sup> The category "others" comprises the companies listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might also be active in the respective markets.

to constrain the parties. New entrants K2M and Nuvasive are also active in Austria.<sup>312</sup>

- (466) In the United Kingdom, the proposed transaction does not raise concerns due to the position of Stryker with a market share of [10-20]\*% and numerous other competitors, Medtronic, Aesculap, Nuvasive, Medicea, SurgiC and Signus Medical, LLC ("Signus") with moderate market shares of [5-10]\*% each. Post-merger the merged entity would have a combined market share below 40%, and the merged entity would be facing numerous other competitors. Most of those competitors are well recognized in the market for ACIF devices and it is likely that these players would continue to constrain the parties.<sup>313</sup>
- (467) In Ireland, the proposed transaction does not raise concerns due to the position of Medtronic, Stryker, and Zimmer with market shares of [0-5]\*% each and recent entry by K2M. Although post-merger the merged entity would have a high combined market share of [80-90]\* %, the merged entity faces several competitors achieving sales higher than the increment added by Synthes, as well as a new innovative entrant K2M. All of those competitors are well recognized in the market for ACIF devices and it is likely that these players would continue to constrain the parties.<sup>314</sup> France-based SpineVision is also active in Ireland.
- (468) In Sweden, the proposed transaction does not raise concerns due to the strong position of Zimmer with a market share of [30-40]\*%, Biomet with a market share of [10-20]\*% and two other competitors, Medtronic and Stryker with market shares higher than the increment added by J&J of [0-5]\*%. Post-merger the merged entity would have a combined market share below 40%, the increment added by Synthes is small [0-5]\*% and numerous other competitors achieved sales higher than the increment added by the Notifying Party. All of those competitors are well recognized in the market for ACIF devices and it is likely that these players would continue to constrain the parties.
- (469) In Portugal, the proposed transaction does not raise concerns due to the position of Zimmer, Alphatec and Medicea with significant market share of [10-20]\*% each, and also Stryker and Biomet with moderate market shares of [5-10]\*%. Medtronic is also present in Portugal. Post-merger the merged entity would have a combined market share below 40% and would face numerous competitors. All of those competitors are well recognized in the market for ACIF devices and it is likely that these players would continue to constrain the parties.

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<sup>312</sup> Based on the replies of Austrian hospitals (replies to questions 90-92 and 94 of Q28 – Phase II - questionnaire to customers (hospitals) (Austria), all of the above suppliers (and more) are credible for the supply of ACIFs.

<sup>313</sup> Based on the replies of UK hospitals (replies to questions 90-92 and 94 of Q28 – Phase II - questionnaire to customers (hospitals) (UK), all of the above suppliers (and more) are credible for the supply of ACIFs.

<sup>314</sup> Based on the replies of Irish hospitals (replies to questions 90-92 and 94 of Q28 – Phase II - questionnaire to customers (hospitals) (Ireland), all of the above suppliers (and more) are credible for the supply of ACIFs.

- (470) In Italy, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [5-10]\*%, Zimmer with a market share of [5-10]\*% , Stryker with a market share of [5-10]\*% and Biomet with a market share of [5-10]\*%. Numerous other competitors are also active in Italy with ACIF devices. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, it would face at least four other competitors which can exercise sufficient competitive constraint on the parties. All of those competitors are well recognized in the market for ACIF devices and it is likely that these players would continue to constrain the parties.<sup>315</sup>
- (471) In the Netherlands, the proposed transaction does not raise concerns due to the position of Stryker with a market share of [10-20]\*% and Aesculap, Biomet and Sintea Plustek ("Sintea")with market shares of [5-10]\*% each. Numerous other competitors are also active in the Netherlands with ACIF devices, including key incumbent Medtronic. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, it would be facing at least four other competitors which can exercise sufficient competitive constraint on the parties. All of the above competitors are well recognized in the market for ACIF devices and it is likely that these players would continue to constrain the parties.
- (472) In Hungary, the proposed transaction does not raise concerns due to the position of Stryker with a market share of [20-30]\*%, Aesculap with a market share of [10-20]\*% and Biomet with a market share of [10-20]\*%. Medtronic is also active in Hungary with ACIF devices. Post-merger the merged entity would have a combined market share below 50%, and would be facing three other competitors which can exercise sufficient competitive constraint on the parties. All of the above competitors are well recognized in the market for ACIF devices and it is likely that these players would continue to constrain the parties.
- (473) In Estonia, the proposed transaction does not raise concerns due to the presence of Medtronic with [0-5]\*% and the presence of Stryker, both capable of meeting hospital demand for ACIF devices. Medtronic is the second largest player in the Estonian market for spinal implants. It achieves a [20-30]\*% market share of all spine implants in Estonia. Stryker is also an established player in Estonia, it achieves [5-10]\*% market share in the overall spine market. Based on market reconstruction data, the market for ACIFs in Estonia is extremely small, i.e. does not exceed EUR 50 000, and market shares are therefore not necessarily indicative of market power. It is likely that Medtronic and Stryker would continue to constrain the parties in this small segment.
- (474) In Slovenia, the proposed transaction does not raise concerns due to the leading position of Medtronic with a market share of [60-70]\*%. Recent entrants Ulrich and Zimmer are also active in the Slovenian market, which is very small and therefore volatile. Post-merger the merged entity would have a combined market

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<sup>315</sup> Based on the replies of Italian hospitals (replies to questions 90-92 and 94 of Q28 – Phase II - questionnaire to customers (hospitals) (Italy), all of the above suppliers (and more) are credible for the supply of ACIFs.

share below 40% and would face Medtronic and two other competitors which can exercise sufficient competitive constraint on the parties. As set out previously, Slovenian hospitals organise tenders in order to promote competitive purchasing and are open for alternative suppliers. All of the above competitors are well recognized in the market for ACIF devices and it is likely that these players would continue to constrain the parties.

- (475) In view of the foregoing and taking into account the market characteristics as described in Section 6.4.2, the Commission concludes that the proposed transaction would not result in a significant impediment to effective competition in the market for ACIF devices in Austria, Estonia, Hungary, Ireland, Italy, the Netherlands, Slovenia, Sweden, Portugal and the UK. It is unlikely that the merged entity would have the ability to increase prices as the remaining competitors would be able to exercise sufficient competitive constraint.

#### Corpectomy devices

- (476) Although the demand for corpectomy devices is relatively small<sup>316</sup>, the parties argue that corpectomy markets are dynamic, characterised by a large number of suppliers, new entry and continued innovation,<sup>317</sup> all of which would continue to guarantee a competitive environment post-merger. Demand is small but nevertheless growing (due to an increase of tumour cases). The market data collected by the Commission have confirmed that corpectomy markets are attractive both to more established broad range suppliers as well as smaller players.
- (477) According to the market data collected by the Commission, corpectomy markets are very small compared to other fusion markets, and therefore largely volatile. In nearly half of the group 1 markets concerned, the demand for corpectomy cages does not exceed EUR 100 000, and in most cases is significantly smaller. In larger countries, the demand for corpectomy devices is also very small, accounting for only up to 3% of all spine fusion markets. On the other hand, corpectomy devices are relatively expensive.<sup>318</sup> Therefore, changes in market shares can take place in a very short period of time, depending on the outcome of subsequent tenders or price enquiries, as was demonstrated by the market share evolution data (for example, Ireland, see Recital (484)).<sup>319</sup>

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<sup>316</sup> J&J's sales for corpectomy devices account for around [...] % of its total interbody sales, while Synthes' sales of corpectomy devices account for around [...] % of its total interbody sales (Form CO, tables 95 and 103).

<sup>317</sup> Submission of the Notifying Party entitled "Competition in corpectomy cages in Europe" of 24 November 2011.

<sup>318</sup> For example according to the Notifying Party, a mesh corpectomy cage of J&J would cost EUR [...] in Ireland and nearly EUR [...] in the Czech Republic. Expandable and stackable cages are typically more expensive.

<sup>319</sup> Based on 2010 data, the Commission has preliminarily concluded in the SO, that the proposed transaction might lead to a significant impediment to competition in the Irish market for thoracolumbar corpectomy devices. However, further investigation has shown that market share of the parties in this segment in Ireland are contestable and highly volatile.

- (478) The following two Sections "Thoracolumbar corpectomy devices" and "Cervical corpectomy devices" assesses the competitive situation in the group 1 markets concerned based on the narrowest market definitions. Should a broader market comprising both types of devices be considered as the relevant market, this would not materially change the competitive assessment presented below, given that a sufficient number of competitors active in the areas where the parties overlap most closely would remain.

#### *Thoracolumbar corpectomy devices*

- (479) Both parties market thoracolumbar corpectomy devices. J&J sells Ocelot (stackable cages), X-Mesh (expandable), and ST & LT Mesh (trimmable mesh devices), while Synthes markets Synex (expandable), SynMesh (trimmable mesh) corpectomy devices for thoracolumbar spine. In the vast majority of markets, the parties are not each other's closest competitors, given that only J&J offers stackable devices, while Synthes' main focus is on expandable cages.<sup>320</sup> Although both parties offer mesh devices, these are the oldest type of corpectomy cages and are facing increasing competition from new generation devices, stackable and expandable cages.<sup>321</sup>
- (480) Based on 2010 data, the leading EEA players in thoracolumbar corpectomy are Ulrich ([20-30]\*%), Medtronic, Synthes, Stryker (each accounting for [10-20]\*%), followed by Aesculap, J&J ([5-10]\*%), and others (Globus, Biomet, etc.). Therefore Ulrich is a well-recognized and leading player in this product market well known for its innovative offer in Europe.
- (481) Medtronic, Stryker, Ulrich, Aesculap, Biomet, Globus, Nuvasive and others market the following corpectomy cages for thoracolumbar spine: e.g., Medtronic (XVBR, Vertespan (expandable), Pyramesh, Sceptor (mesh), Vertestack (stackable)); Stryker (Vlift (expandable) and VBoss (mesh)); Ulrich (Obelisk and VBR (expandable)); Aesculap (Hydrolift, expandable); Globus (Xpand, expandable); Biomet (AVR (mesh) and TPS (expandable)); Coligne (VBR, stackable); Nuvasive (X Core, expandable); Alphatec (TeCorp-TL, expandable); Sinteia (DSC, expandable).

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<sup>320</sup> According to the Notifying Party, [...]\*

<sup>321</sup> This view has been confirmed by the market investigation indicating that companies gradually expand their portfolio to complete them with corpectomy devices.

Table 24: Group 1 markets in thoracolumbar corpectomy devices

2010	J&J	Synthes	Comb.	Medtronic	Ulrich	Stryker	Aesculap	Biomet	Others <sup>322</sup>
NO	[10-20]*	[80-90]*	[90-100]*	0	-	0	0	0	-
IE	[60-70]*	[10-20]*	[80-90]*	[10-20]*	-	0	-		-
HU	[10-20]*	[50-60]*	[70-80]*	[20-30]*	-	0	0	0	
AT	[0-5]*	[30-40]*	[40-50]*	[10-20]*	[20-30]*	[10-20]*	[5-10]*	0	Alphatec [0-5]*
PT	[0-5]*	[30-40]*	[40-50]*	[50-60]*	-	0	-	0	
FI	[5-10]*	[30-40]*	[40-50]*	0	[0-5]*	[50-60]*	-	0	
UK	[5-10]*	[30-40]*	[30-40]*	[10-20]*	[5-10]*	[5-10]*	[0-5]*	[0-5]*	Globus [20-30]*, Nuvasive, Alphatec [0-5]* each
ES	[20-30]*	[10-20]*	[30-40]*	[40-50]*	[0-5]*	[5-10]*	[0-5]*	[0-5]*	Alphatec [0-5]*

Source: market reconstruction

- (482) In Austria, the proposed transaction does not raise concerns due to the strong position of Ulrich with a market share of [20-30]\*%, Medtronic with a market share of [10-20]\*% and Stryker with [10-20]\*%. Post-merger the merged entity would have a combined market share below 50%, it would be facing at least three strong and well recognized competitors in the market for thoracolumbar corpectomy devices and it is likely that these players would continue to constrain the parties. Furthermore, the new entrants Nuvasive and Biomet are also active in Austria.
- (483) In the United Kingdom, the proposed transaction does not raise concerns due to the position of Medtronic with a market share of [10-20]\*%, a new aggressive entrant Globus with a significant market share of [20-30]\*%, and Stryker and Ulrich with a market share of [5-10]\*% each, all higher than the increment added by J&J. Post-merger the merged entity would have a combined market share below 40%, the increment added by J&J is small ([5-10]\*%) and several other competitors achieved higher sales than the increment added by the Notifying Party. All of those competitors are well recognized in the market for thoracolumbar corpectomy devices and it is likely that these players would continue to constrain the parties. A new entrant Nuvasive has also gained a non-

<sup>322</sup> The category "others" comprises the companies listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might also be active in the respective markets.

insignificant share of [0-5]\*% in just one year. Biomet and Aesculap are also present, both to a non-insignificant extent.

- (484) In Ireland, the proposed transaction does not raise concerns due to the presence of two well established players in thoracolumbar corpectomy, namely Medtronic with [10-20]\*% and Stryker, each capable of meeting hospital demands for thoracolumbar corpectomy. Based on 2010 market reconstruction data, the market for thoracolumbar corpectomy in Ireland was extremely small, i.e. it did not exceed EUR 50 000 in 2010. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity, especially taking into account that market shares can change from year to year depending on the outcome of a subsequent tender or price enquiry. For example, from 2009 to 2010 Synthes increased its share from 0% to [10-20]\*%, and to [30-40]\*% in 2011; Medtronic has increased its market share from 0% in 2009, to [10-20]\*% in 2010, and to [40-50]\*% in 2011. At the same time J&J's market share decreased from [90-100]\*% in 2009 to [60-70]\*% in 2010 and [5-10]\*% in 2011. Stryker gained [5-10]\*% market share just in one year from 2010 to 2011. It is likely that these players would constrain the parties, should they attempt to increase prices for their corpectomy devices in Ireland.
- (485) In Norway, the proposed transaction does not raise concerns due to the presence of four well established players in thoracolumbar corpectomy, namely Medtronic, Stryker, Aesculap and Biomet, each capable of meeting hospital demands for thoracolumbar corpectomy. Based on 2010 market reconstruction data, the market for thoracolumbar corpectomy in Norway is extremely small, i.e. it did not exceed EUR 40 000 in 2010. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity, especially taking into account that Norway is a tender market and market shares can change from year to year depending on the outcome of a subsequent tender (e.g. in 2009 Biomet had a market share of [5-10]\*% in Norway, decreasing in 2010 to 0%, and J&J's market share decreased from [10-20]\*% in 2010 to [0-5]\*% in 2011). It is likely that the other players would constrain the parties should they attempt to increase prices for their corpectomy devices in Norway. Finally, the market investigation has confirmed further entry into Norway in the coming two years.
- (486) In Finland, the proposed transaction does not raise concerns due to the leading position of Stryker with a market share of [50-60]\*% and the presence of well-established players in thoracolumbar corpectomy, namely Ulrich ([0-5]\*%), and Medtronic, all capable of meeting hospital demands for thoracolumbar corpectomy. In addition, Biomet and Coligne are active in Finland. The market for thoracolumbar corpectomy in Finland is relatively small, i.e. did not exceed 100 000 EUR in 2010 based on market reconstruction data. Post-merger the merged entity would have a combined market share below 40%, and would be facing at least one strong competitor and several other players. It is likely that the other players would constrain the parties should they attempt to increase prices for their corpectomy devices in Finland.
- (487) In Hungary, the proposed transaction does not raise concerns due to the presence of three well established players in thoracolumbar corpectomy, namely Medtronic

with [20-30]\*%, Aesculap and Alphatec (both well-established in spine fusion in Hungary), and also Stryker and Biomet, all capable of meeting hospital demands for thoracolumbar corpectomy. Based on 2010 market reconstruction data, the market for thoracolumbar corpectomy in Hungary is very small, i.e. it did not exceed EUR 100 000. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity, especially taking into account that market shares can change from year to year depending on the outcome of a subsequent tender or price enquiry. It is likely that the other players would constrain the parties should they attempt to increase prices for their corpectomy devices in Hungary. A specialized niche player, Metrimed Kft ("Metrimed"), also offers its stackable cages in Hungary.

- (488) In Portugal, the proposed transaction does not raise concerns due to the leading position of Medtronic with [50-60]\*% and the presence of several other credible suppliers, Stryker, Biomet and Alphatec, each capable of meeting hospital demands for thoracolumbar corpectomy. Based on 2010 market reconstruction data, the market for thoracolumbar corpectomy in Portugal is very small, i.e. it did not exceed EUR 120 000 in 2010. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity. Post-merger the merged entity would have a combined market share below 50%, the increment added by J&J is small [0-5]\*%, and the merged entity would be facing at least one very strong and several other competitors which can exercise a sufficient competitive constraint on the parties. It is likely that these players would continue to constrain the parties. Furthermore, a regional player Sinteia is also active in Portugal with expandable cages in its portfolio.
- (489) In Spain, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [40-50]\*% and Stryker with a market share of [5-10]\*%. Several other credible players, both established in Spain (Aesculap, Biomet) and new entrants (Alphatec and Ulrich) are also present. Post-merger the merged entity would have a combined market share below 40%, it would be facing at least two strong and well recognized competitors in the market for thoracolumbar corpectomy devices and it is likely that these players would continue to constrain the parties.
- (490) In view of the foregoing and taking into account the market characteristics as described in Section 6.4.2, the Commission concludes that the proposed transaction would not result in a significant impediment of effective competition in the market for thoracolumbar corpectomy devices in Austria, Hungary, Ireland, Norway, Portugal, Spain and the United Kingdom. It is unlikely that the merged entity would have the ability to increase prices, as the remaining competitors would be able to exercise a sufficient competitive constraint.

#### *Cervical corpectomy devices*

- (491) Both parties also market corpectomy cages for cervical spine, i.e. J&J Bengal (stackable) and ST Mesh (trimmable mesh), while Synthes has ECD (expandable), SynMesh C (trimmable mesh) devices. In the vast majority of markets, the parties are not each other's closest competitors, given that only J&J offer stackable devices, while Synthes' main focus is on expandable cages.



Although both parties offer mesh devices, these are the oldest type of corpectomy cage and are facing increasing competition from new generation devices, stackable and expandable cages.

- (492) Medtronic, J&J and Ulrich are the leading EEA players in the niche of cervical corpectomy (each accounting for over 20% of EEA market share), followed by Synthes ([10-20]\*%), and others, including Stryker, Alphatec, Signus and others (each [0-5]\*%).
- (493) Other suppliers offer a variety of cervical corpectomy devices: e.g., Medtronic (XVBR, Vertespan (expandable), Pyramesh, Sceptor (mesh), and Vertestack (stackable)); Stryker (Modulics, CerviLift (expandable), VBoss" (mesh)); Ulrich (ADD, ADD plus, expandable); Biomet (AVR (mesh), TPS (expandable); Coligne (VBR, stackable); Alphatec (TeCorp-C, expandable); Metrimed (CK Type, stackable); Signus (Athlete, stackable).

Table 25: Group 1 markets in cervical corpectomy devices

2010	J&J	Synthes	Comb.	Medtronic	Stryker	Ulrich	Alphatec	Others <sup>323</sup>
SL	[5-10]*	[90-100]*	[90-100]*	0	-	0.0	-	-
NO	[30-40]*	[60-70]*	100.0	0	0	-	-	-
SK	[10-20]*	[60-70]*	[70-80]*	0	0	[0-5]*	[20-30]*	-
CZ	[5-10]*	[50-60]*	[60-70]*	[30-40]*	-	0.0	-	
LV	[50-60]*	[0-5]*	[50-60]*	0	0	[40-50]*	0	
UK	[10-20]*	[30-40]*	[50-60]*	[10-20]*	[5-10]*	[20-30]*	[0-5]*	SurgiC, Signus together [0-5]*
AT	[10-20]*	[30-40]*	[50-60]*	[40-50]*	0	[0-5]*	0	
DE	[30-40]*	[5-10]*	[40-50]*	[10-20]*	[0-5]*	[30-40]*	0	Signus [10-20]*
ES	[30-40]*	[10-20]*	[40-50]*	[40-50]*	[0-5]*	[0-5]*	[0-5]*	Biomet [0-5]*
HU	[10-20]*	[20-30]*	[40-50]*	[40-50]*	0	-	0	Metrimed [10-20]*
PL	[0-5]*	[30-40]*	[40-50]*	[30-40]*	0	0	0	Coligne [10-20]*, LFC [0-5]*

Source: market reconstruction

- (494) In Austria, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [40-50]\*% and Ulrich with a market

<sup>323</sup> The category "others" comprises the companies listed in this column, but is not limited to these. Accordingly, further competitors with small to very small market shares might also be active in the respective markets.

share of [0-5]\*%, both leading players in cervical corpectomy and capable of meeting hospital demand for cervical corpectomy. Based on 2010 market reconstruction data, the market for thoracolumbar corpectomy in Austria was very small, i.e. it did not exceed EUR 140 000. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, it would be facing at least two strong and well recognized competitors in the market for cervical corpectomy devices and it is likely that these players would continue to constrain the parties. Alphatec, Biomet and Signus are also present in Austria.

- (495) In Germany, the proposed transaction does not raise concerns due to the strong position of Ulrich with a market share of [30-40]\*%, Medtronic with a market share of [10-20]\*% and Signus with [10-20]\*%. Although post-merger the merged entity would have a combined market share below 50%, it would be facing at least two leading and well recognized competitors, and a strong regional player in the market for cervical corpectomy devices and it is likely that those players would continue to constrain the parties.
- (496) In the United Kingdom, the proposed transaction does not raise concerns due to the strong position of Ulrich with a market share of [20-30]\*%, Medtronic with a market share of [10-20]\*% and Stryker with [5-10]\*%. Although post-merger the merged entity would have a high combined market share of [50-60]\*%, it would be facing at least three strong and well recognized competitors in the market for cervical corpectomy devices and it is likely that these players would continue to constrain the parties.
- (497) In Norway, the proposed transaction does not raise concerns due to the presence of a leading player Medtronic and a credible player Stryker, both capable of meeting hospital demand for cervical corpectomy. Based on 2010 market reconstruction data, the market for cervical corpectomy in Norway was extremely small, i.e. it did not exceed EUR 20 000. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity, especially taking into account that market shares can change from year to year depending on the outcome of a subsequent tender or price enquiry. It is likely that the other players would continue to constrain the parties. Finally, the market investigation has confirmed further entry into Norway in the coming two years.
- (498) In Spain, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [40-50]\*%, and presence of other credible suppliers, Ulrich [0-5]\*%, Stryker [0-5]\*%, Alphatec [0-5]\*% and Biomet [0-5]\*%. Although post-merger the merged entity would have a combined markets share below 50%, it would be facing at least one very strong and several other well recognized competitors in the market for cervical corpectomy devices. It is likely that these players would continue to constrain the parties.
- (499) In Latvia, the proposed transaction does not raise concerns due to the strong position of Ulrich with a market share of [40-50]\*% and the presence of another

credible player, Medtronic, both capable of meeting hospital demand for cervical corpectomy. Based on 2010 market reconstruction data, the market for cervical corpectomy in Latvia is very small, i.e. it did not exceed EUR 40 000. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity. It is likely that the other players would continue to constrain the parties.

- (500) In Slovenia, the proposed transaction does not raise concerns due to the presence of two credible and leading competitors in cervical corpectomy, i.e. Medtronic and recent entrant Ulrich, both capable of meeting hospitals' demand for cervical corpectomy. Based on 2010 market reconstruction data, the market for cervical corpectomy in Slovenia is extremely small, i.e. it did not exceed EUR 20 000. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity, especially taking into account that market shares can change from year to year depending on the outcome of a subsequent tender or price enquiry. It is likely that the other players would continue to constrain the parties.
- (501) In Slovakia, the proposed transaction does not raise concerns due to the strong position of Alphatac [20-30]\*% and the presence of other credible players, recent entrant Ulrich [0-5]\*%, Medtronic and Stryker, all capable of meeting hospital demand for cervical corpectomy. Based on 2010 market reconstruction data, the market for cervical corpectomy in Slovakia is very small, i.e. it did not exceed EUR 110 000. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity, especially taking into account that market shares can change from year to year depending on the outcome of a subsequent tender or price enquiry. It is likely that the other players would continue to constrain the parties.
- (502) In the Czech Republic, the proposed transaction does not raise concerns due to the strong position of Medtronic [30-40]\*% and the presence of a recent entrant Ulrich, both capable of meeting hospital demand for cervical corpectomy. Based on 2010 market reconstruction data, the market for cervical corpectomy in Czech Republic is very small, i.e. it did not exceed EUR 100 000 in 2010. Therefore, historic market shares of Synthes and J&J for one year do not accurately reflect the competitive strength of the merged entity, especially taking into account that market shares can change from year to year depending on the outcome of a subsequent tender or price enquiry. For example, based on market share evolution data, in 2011 Ulrich has gained a significant share of [20-30]\*% in just one year. It is likely that the other players would continue to constrain the parties. Signus and Biomet are also present in the Czech Republic.
- (503) In Hungary, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [40-50]\*% and a specialized player Metrimed with a market share of [10-20]\*%. Post-merger the merged entity would have a combined market share below 50%, it would be facing at least one strong and well recognized competitor and a strong niche player in the market for cervical corpectomy devices and it is likely that these players would continue to constrain the parties. Stryker and Biomet are also active in Hungary.

- (504) In Poland, the proposed transaction does not raise concerns due to the strong position of Medtronic with a market share of [30-40]\*% and Coligne with a market share of [10-20]\*%. Although post-merger the merged entity would have a combined market share below 50%, it would be facing at least two strong and well recognized competitors in the market for cervical corpectomy devices and it is likely that these players would continue to constrain the parties.
- (505) In view of the foregoing and taking into account the market characteristics as described in Section 6.4.2, the Commission concludes that the proposed transaction would not result in a significant impediment of effective competition in the market for cervical corpectomy devices in Austria, Germany, Hungary, Latvia, Poland, Slovakia, Slovenia, Spain, and the United Kingdom. It is unlikely that the merged entity would have the ability to increase prices, as the remaining competitors would be able to exercise sufficient competitive constraint.

#### 6.4.3. *Non-fusion*

- (506) As opposed to fusion, there is a clear difference between the parties' strength and overall presence in non-fusion. While Synthes has significant activities in both dynamic mobilisation (PDS, interspinous devices) and artificial discs, J&J is only active in the latter<sup>324</sup>.
- (507) The proposed transaction leads to group 1 markets only in artificial discs (overall category and/or sub-segments of cervical and/or lumbar). Such instances are however isolated and neither the market investigation nor the market reconstruction indicated concerns in any product category or in any particular country across product categories (with the exception of one complaint as addressed below).

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<sup>324</sup> Synthes is active in both PDS and interspinous devices. [...] \* The market investigation showed that in the PDS market Synthes is currently facing strong competition from several competitors, including Zimmer (the originator of the technology), Paradigm Spine, Ulrich, Medtronic and Alphatec. Furthermore, the market investigation did not indicate [...] \* – see replies to questions 97 and 98 of Q30 – Phase II – questionnaire to competitors (spine).

Table 26: Group 1 markets in artificial discs

	Type of disc	J&J	Synthes	Comb.	Med-tronic	Aescu-lap	LDR	Spinal Kinetics	Stryker	Spine Art	Others
SI	Cervical	[90-100]*	[0-5]*	[90-100]*							
SE	Cervical	[60-70]*	[0-5]*	[60-70]*	[30-40]*						
LU	Lumbar	[0-5]*	[50-60]*	[50-60]*	[40-50]*						
FR	Lumbar	[0-5]*	[50-60]*	[50-60]*	[20-30]*		[10-20]*			[5-10]*	Zimmer [0-5]*
HU	Cervical	[30-40]*	[5-10]*	[40-50]*	[10-20]*	[30-40]*					Medi crea [5-10]*
FI	All types	[0-5]*	[30-40]*	[30-40]*	[50-60]*				[5-10]*		
AT	Cervical	[10-20]*	[20-30]*	[30-40]*	[20-30]*		[20-30]*	[5-10]*		[0-5]*	
SE	All	[30-40]*	[0-5]*	[30-40]*	[60-70]*						

Note: In Slovenia and Hungary, the market shares are identical if all artificial discs are considered. This is because the market reconstruction did not identify any sales of lumbar artificial discs in these countries.

Source: Market reconstruction

- (508) Both industry reports and the market investigation (competitors<sup>325</sup>) indicate that the artificial disc market is expected to grow in the coming years. One industry report estimates a compound annual growth rate of 8%, (4% for lumbar, 9% for cervical). Respondents in the market investigation indicated moderate to significant likely growth<sup>326</sup>.
- (509) Both parties supply both types of artificial discs. Whilst Synthes is a significant competitor across the EEA, J&J is generally not a strong player. This is especially the case in lumbar artificial discs, where J&J experienced safety concerns with its product (Charite), leading to declining sales<sup>327</sup>.
- (510) In general, industry reports point to a certain degree of reluctance by surgeons towards the adoption of artificial discs, especially lumbar, due mainly to safety concerns and the difficult nature of the surgical procedure. According to industry reports, growth of the market would primarily come from innovation both in terms of the safety and product characteristics and the surgical procedure as well as from the increased familiarity of surgeons with the anterior surgical

<sup>325</sup> See replies to Question 92 of Questionnaire 30.

<sup>326</sup> See replies to Question 94 of Questionnaire 30.

<sup>327</sup> Whilst J&J reintroduced and rebranded its product, the modifications were not substantial – see iData report 2011, p. 397.

procedure<sup>328</sup>. An example of innovation for product characteristics is Spinal Kinetics' M6 product range, whilst examples of innovation for the surgical approach include NuVasive's development of the XL TDR disc based on the lateral IBD fusion technique, "XLIF" (launch expected in 2014) and Globus Medical's development of a disc that can be implanted using the posterior approach<sup>329</sup>. The market investigation confirmed that innovation is likely to have a significant impact on the market and demand for artificial discs in the coming years.<sup>330</sup> Whilst both parties previously acquired products which, at the time, were considered innovative, the market investigation indicated that neither of the parties are considered presently to be particularly innovative. In addition, both parties' products are implanted using the more difficult anterior approach. Hospital replies also confirmed that neither Synthes', nor J&J's artificial discs are significantly better than other suppliers' in terms of performance, longevity, ease of use and associated services (e.g. training)<sup>331</sup>.

- (511) In general, the recent and successful entry of a specialised supplier of a new innovative product, Spinal Kinetics, into eight countries already (including a large market like Germany where they had in 2010 a market share of [30-40]\*% in both cervical and lumbar discs) shows that artificial disc markets are contestable even in large markets. This is also a strong indication that innovation in general is a key parameter of competition in these markets. For example, according to one industry report "*Spinal Kinetics have been successful at expanding the European artificial disc markets because surgeons, who had previously refused to implant other discs perceive the M6 discs to be a significant improvement to other artificial discs. Spinal Kinetics is expected to gain market share over the forecast period*"<sup>332</sup>. The market investigation also indicated Spinal Kinetics as a successful new entrant.
- (512) The relatively small competitive constraint exercised by J&J in artificial discs was broadly confirmed by the market investigation: a significant majority of competitors replying to the relevant question considered that Synthes would not obtain through the transaction any special assets or capabilities relating to artificial discs which would allow it to compete significantly more effectively for the sale of artificial discs than it already does<sup>333</sup>. Only two out of nine competitors (including Spinal Kinetics, a formal complainant) replying to the relevant question indicated that broadening the portfolio and/or the combination of distribution resources through the transaction would help Synthes to compete significantly more effectively<sup>334</sup>. These replies do not point consistently to any

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<sup>328</sup> See European markets for Spinal Implants and VCF by iData Research, 2011 and the 2011 Millenium Research Group report on European Markets for Spinal Implants.

<sup>329</sup> US Markets for Minimally Invasive Spine Technologies –2011 - Report of the Millenium Research Group, p.182.

<sup>330</sup> See replies of competitors to question 91 of Questionnaire 30 to competitors.

<sup>331</sup> See replies to question 30 of Questionnaire 28 to hospitals.

<sup>332</sup> European markets for Spinal Implants and VCF – 2011 – iData Research p.396.

<sup>333</sup> See replies to question 94 of Questionnaire 30 to competitors.

<sup>334</sup> One smaller local player (not a direct artificial disc competitor) indicated a combination of general capabilities of the parties.

significant barrier to entry or expansion specific to artificial discs, which would be worsened by the merger. One of the two competitors also acknowledged in the same reply that the impact of the broadening of the portfolio is unknown.

- (513) Whilst sales and distribution are important parameters of competition across spine segments, in artificial discs other parameters (including product quality and innovation as explained in Recital (510) appear to be equally, if not more, important. In artificial discs markets competitors without sales and distribution capabilities comparable to the parties can succeed, as evidenced by the market shares emerging from the market reconstruction. This includes Spinal Kinetics itself, which achieved significant market shares in the countries where it entered (becoming one of the leading players in the EEA within 2-3 years). Other competitors, such as SpineArt also achieve significant market shares in several countries without having sales and distribution resources comparable to the parties. By contrast, J&J has not managed to translate its sales and distribution capabilities into a strong position in artificial discs and remains in both types of disc markets a small player across the EEA (its market shares not exceeding [0-5]\*% in either type of disc at the EEA level, based on the market reconstruction). In addition, the parties would post-merger still be facing strong competition from Medtronic, which itself has comparable capabilities to the merged entity. In general, sales and distribution have not been broadly confirmed as a significant barrier to entry by competitors.<sup>335</sup> Barriers indicated for cervical discs are for example the presence of many other competitors in the market and the need to have an innovative product<sup>336</sup>. Spinal Kinetics itself, which indicates sales and distribution as a barrier to entry, states in another submission<sup>337</sup> "*Spinal Kinetics developed the business with [ ]\* independent network of distributors [-]\* by showing the superiority of the technology and finally making the artificial disc market a competitive scenario.*" This further confirms that the key parameter for competition in artificial discs is innovation.
- (514) As for the combination of portfolios, this is not a specific issue to artificial discs or non-fusion. Synthes already has all the types of non-fusion products J&J has and more. J&J's products (See Recitals (509) - (510)) are not particularly innovative or "must-have" products (just the opposite in lumbar discs as explained above). This is therefore a general issue that would be addressed under the conglomerate effects analysis in Section 6.4.6.
- (515) Whilst, based on the market reconstruction, the proposed transaction would give rise to group 1 markets in either or both types of artificial discs also in Austria, Finland, France and Hungary, the market structure is indicative of possible concerns only in Sweden, Luxembourg and in Slovenia. In the other markets the parties achieve only moderate combined market shares and/or only a small increment and at least two other significant competitors remain which can exercise a sufficient competitive constraint on the parties.

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<sup>335</sup> See replies to question 95 of Questionnaire 30 to competitors.

<sup>336</sup> See replies to Question 95.1 of Questionnaire 30 to competitors.

<sup>337</sup> Letter of Spinal Kinetics of 22 September 2011.

- (516) In Slovenia, the merger would lead to a monopoly in cervical artificial discs, which is the only type of disc implant procedure that seems to be performed in the country. However, the overall market is very small and the sales of Synthes in 2010 were EUR [small]\* (which is not enough to sell even one disc). It is therefore clear that market shares in this market are not a reliable indicator of competition. In particular, the two hospitals that replied indicated that Medtronic and Aesculap are credible alternative suppliers to the parties and confirmed that neither party's products are technically superior or cheaper than others on the market.
- (517) In Sweden and Luxembourg the proposed transaction would lead to a duopoly in cervical and lumbar discs respectively, but the increment in both cases is only [0-5]\*%. This suggests that competition takes place primarily between Medtronic and Synthes in the lumbar disc market in Luxembourg and between J&J and Medtronic in the Swedish cervical disc market. In Sweden, the transaction also leads to a combined market share of just over 35% if sales of both types of artificial discs are taken into account. However, the combined market share of the parties would still be moderate with a small increment added by Synthes. Medtronic, due to its very strong position in lumbar artificial discs, would remain the market leader with [60-70]\*% (J&J [...]\*).
- (518) In light of the small value of the markets, general indications of possible entry in this product segment and the competitive constraint stemming from other, significant competitors (including Medtronic) in the same and neighbouring countries, competition concerns can be excluded in Luxembourg, Slovenia, and Sweden as well.
- (519) Despite the apparent lack of competition concerns in artificial discs, the Commission received a formal complaint about the merger from the successful new entrant, Spinal Kinetics. Spinal Kinetics is a new entrant in the EEA, which, as explained in Recital (511), has made significant inroads into the artificial disc markets. Spinal Kinetics has been facing patent litigation in the US and Europe (Germany) brought against it by Synthes<sup>338</sup>. Spinal Kinetics initially complained that the cost of the lawsuit would drive it out of business and therefore reduce innovation and competition in the EEA. It argued that through the infringement litigation Synthes may "*remove the only true competition they have in the artificial disc market*"<sup>339</sup>. In a later submission<sup>340</sup> Spinal Kinetics clarified that the information provided on the litigation was only to highlight the "*tremendous advantages*" large companies like Synthes would have in relation to smaller companies like Spinal Kinetics, which would allow them to drive smaller companies out of business. Spinal Kinetics also argues that in the case of its exit from the market, the merger would create two major players (the merged entity and Medtronic) and this would impede competition. In its comments on the

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<sup>338</sup> In its letter of 22 February 2012, Spinal Kinetics informed the Commission that the trial in the United States ended on 13 December 2011 with the jury finding the Synthes patent to be invalid.

<sup>339</sup> Letters of Spinal Kinetics 22 September 2011 and of 24 November 2011.

<sup>340</sup> Letter of Spinal Kinetics of 22 February 2012.



summary of SO it also mentions that Spinal Kinetics may be foreclosed due to the parties' *"strong market position in fusion product lines"*, including interbody cages. This last point relates to conglomerate effects, which would be addressed in Section 6.4.6

- (520) The Commission's market investigation and market reconstruction did not confirm the above claims. Even assuming the worst case scenario, i.e. that Spinal Kinetics is forced out of the market (for which the Commission has not received documentary evidence and which is rendered less likely by the conclusion of the infringement proceedings in the US) and that Spinal Kinetics could as a result not be considered as a long term competitive constraint, competition in the EEA would not be significantly impeded in artificial discs and/or any sub-segment thereof as a result of the merger. In particular, the parties would continue to face strong competition from the market leader in the EEA, Medtronic. In addition, there would be several other significant players remaining in the EEA (for both cervical and lumbar discs) with comparable or higher market shares than J&J, i.e. Aesculap, Spineart, Alphatec and LDR. This, based on the market reconstruction figures, also holds for the specific countries where Spinal Kinetics is active, where there would remain at least two other competitors with market shares higher (in most cases considerably higher) than J&J's (whose market shares are often below 5%). If anything, Spinal Kinetics' entry is evidence of established market positions in these markets being clearly contestable, even in large markets like Germany, where the sales and distribution advantages of established full-line competitors would in principle be relatively more difficult to overcome (due for example to the higher number of physicians to be targeted and trained).
- (521) Based on the above, the transaction does not lead to a significant impediment to effective competition in non-fusion or in any sub-segments thereof.

#### 6.4.4. *Vertebral Compression Fractures ("VCF")*

##### 6.4.4.1. The Commission's preliminary conclusions and the parties' arguments

- (522) In the SO, the Commission preliminarily concluded that the proposed merger would result in a significant impediment to effective competition in relation to vertebroplasty products in Austria, Czech Republic, Denmark, Hungary, Latvia, Slovakia, Portugal and Poland through the significant strengthening of the market leader and the elimination of a close (and sometimes the only significant) competitor. The competitive pressure stemming from much smaller remaining competitors and the threat of entry by other competitors was not considered sufficient to constrain the merged entity. In three of these countries (Czech Republic, Hungary, Latvia) the Commission preliminarily concluded that the proposed transaction would result in a significant impediment to effective competition also considering all sales of VCF products, as the proposed transaction was considered to combine two strong players which are close competitors and removes the constraint they exert on each other which consequently would give the resulting entity increased market power and the ability and incentive to stop/reverse the current price erosion trend.

- (523) In reply to the SO the parties contest the conclusions of the SO and reiterate the following arguments: (i) The parties are not close competitors due to J&J's [...] product, *Confidence*, competing with kyphoplasty products. (ii) There is a sufficient number of competitors remaining in the EEA that are able to supply vertebroplasty products. Several of these competitors are considered credible by the hospitals in the countries included in the SO. (iii) Barriers to entry and expansion are low.
- (524) Following the SO the parties submitted additional evidence. The Commission also carried out a follow-up investigation concerning the markets in Austria, the Czech Republic, Denmark, Hungary, Latvia, Slovakia, Poland and Portugal. This also included a market reconstruction for 2009 and 2011 to complement its original 2010 market reconstruction and the extension of the reconstruction to certain competitors referred to by the parties in the reply to the SO.
- (525) In the light of the new evidence, considered together with the evidence from the phase 1 and phase 2 investigation, competition concerns can be excluded in all the countries where the parties overlap, including Austria, Czech Republic, Denmark, Hungary, Latvia, Slovakia, Poland and Portugal.

#### 6.4.4.2. Market structure and competitors

- (526) The VCF market is relatively young when compared to, for example, certain mature fusion markets (and even more so when compared to the trauma market). Percutaneous vertebroplasty was invented in the 1980s and was introduced on a significant scale only in the 1990s whilst kyphoplasty was introduced a decade ago. VCFs had not, prior to the invention of vertebroplasty, been treated to a significant extent by surgical procedures (i.e. internal fixation/spinal fusion) due to these procedures being highly invasive and involving significant risks. VCFs had previously been treated with traditional therapies such as pain medication, physical therapy and others or had remained undiagnosed. Patients that do not undergo VCF treatments still account for a large part of the patient base (as explained in Section 5.1.2.4.).
- (527) The parties argue that the EEA market for VCF treatments (in particular the vertebral augmentation segment) is attractive and is expected to grow due to the aging population on the one hand and the large untapped part of the patient base on the other. This would attract and facilitate entry – which is already happening. This has been broadly confirmed in the market investigation. Growth comes from the wider awareness and acceptance of minimally invasive VCF treatments<sup>341</sup> and the increased use in non-osteoporotic indications.<sup>342</sup> IData estimates the

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<sup>341</sup> Global Markets for Minimally Invasive Vertebral Compressure Fracture Treatments – Report by the Millenium Research Group, 2011, see p. 99.

<sup>342</sup> Global Markets for Minimally Invasive Vertebral Compressure Fracture Treatments – Report by the Millenium Research Group, 2011, see p. 4582; See also See J&J's document No 605 submitted in response to Question 5 of the RFI of 17 November 2011 – *Evaluating trends in MIS and VBA* – p.32.

compound annual growth rate for VCF in the coming 5 years at 8% (vertebral augmentation 10%, vertebroplasty 3%)<sup>343</sup>.

- (528) The competitive landscape of VCF markets is quite different from fusion and non-fusion markets. There are a number of international VCF competitors which are not active in fusion or non-fusion spine devices or orthopaedic markets in general (e.g. Cook Medical Inc. ("Cook"), OptiMed Medizinische Instrumente GmbH ("Optimed") CareFusion Corporation ("CareFusion"), DFine Inc. (DFine), Benvenue Medical Inc. (Benvenue)). Some of these companies have significant activities in other therapeutic areas unrelated to spine and orthopaedics (e.g. Optimed, Cook, CareFusion) and some others offer only VCF or a small number of specialised spine treatments using similar techniques to VCF (e.g. Benvenue or Dfine). As regards their VCF product offering, whilst some of these companies focus on the premium-priced, innovative end of the market, several of these suppliers offer more "generic"/mature products used in standard vertebroplasty procedures. Even the VCF market leader, Medtronic, became the market leader through the acquisition (in 2007) of a more specialised company, Kyphon, that originally introduced kyphoplasty.
- (529) The main spine competitors which have their own VCF product (either through internal product development or acquisition) are the parties, Medtronic, Stryker, Alphatec and Biomet. By contrast, several spine companies active in fusion and/or non-fusion do not have their own VCF products (for example Aesculap, Zimmer, Nuvasive, K2M etc). This notwithstanding, the market investigation showed examples of such companies entering into distribution and/or supply partnerships with more specialised companies (in both product segments of VCF) or considering developing their own products. Acquisition of a product range or a company (e.g. J&J's acquisition of Confidence or Medtronic's acquisition of Kyphon) is also possible. As described in more detail under section 6.4.4.5, these all appear to be feasible strategies for spine companies to fill any VCF-related gaps in their portfolio should there be a demand for doing so.
- (530) The differences in the competitive landscape as described in Recitals (528)-(529) can to some extent be explained by the differences between VCF treatments and spinal implants in terms of the procedure and the customer base (e.g. a major part of demand coming from physicians other than spine or neurosurgeons). Due to the specificities of the VCF procedure, activities in areas other than orthopaedics (e.g. biopsy, interventional radiology, biomaterials etc) have significant synergies with activities in VCF in terms of, for example, know-how, product development, marketing or sales.
- (531) Based on the Commission's market reconstruction, the proposed transaction would lead to nine group 1 markets in overall VCF and 17 group 1 markets in vertebroplasty. The proposed transaction does not lead to group 1 markets in kyphoplasty.

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<sup>343</sup>

European Markets for Spinal Implants and VCF – report by iData Research, 2011.

- (532) Due to the larger number and variety of competitors in VCF markets as compared to other spine markets, the market reconstruction may not have captured some vertebroplasty competitors which may be supplying products in some countries (in particular if these companies supply only bone cement and not complete vertebroplasty kits and/or are present through distributors and/or supply other spine companies).
- (533) This notwithstanding, competition concerns in a majority of group 1 markets can be excluded based on the data obtained by the Commission during its market reconstruction. The question whether the parties would face competition from additional suppliers in these countries does not therefore alter the assessment. In some countries (especially Portugal) there are significant indications from the market investigation pointing to the presence of more competitors than the competitors that provided data in the market reconstruction. Where this is the case, this issue would be specifically addressed in the country specific assessments in Section 6.4.4.6.

Table 27: Group 1 markets in VCF – 2010<sup>344</sup>.

VCF	J&J	Synthes	Comb.	Med-tronic	Stryker	Cook	Alphatec	Arthro-care (now Neurotherm)	Optimed	Other
LV	[50-60]*	[10-20]*	[70-80]*	[20-30]*						
EE	[10-20]*	[50-60]*	[70-80]*	[10-30]*	[5-10]*				[0-5]*	
NO	[50-60]*	[10-20]*	[60-70]*	[10-20]*	[10-20]*	[10-20]*				
PL	[[50-60]*	[10-20]*	[60-70]*	[10-20]*	[10-20]*	[0-5]*		[0-5]*	[0-5]*	Biomet Bone Support, Competitor 1 and Competitor 2 Combined [0-5]*
HU	[20-30]*	[40-50]*	[60-70]*	[30-40]*						Biomet [0-5]*
DK	[10-20]*	[50-60]*	[60-70]*	[10-20]*	[0-5]*	[5-10]*	[10-20]*	[0-5]*		
CZ	[10-20]*	[30-40]*	[50-60]*	[40-50]*						Competitor 1 and Competitor 4 Combined [5-10]*%
FI	[5-10]*	[40-50]*	[40-50]*	[10-20]*	[5-10]*	[20-30]*		[5-10]*		
SK	[20-30]*	[20-30]*	[40-50]*	[40-50]*					[5-10]*	DFine [0-5]*

Source: Market reconstruction

<sup>344</sup>

In the table the name of some competitors are redacted due to confidentiality issues. Such issues arise for example when the competitor does not sell under its own brand, but under the distributor's brand.

Table 28: Group 1 markets in vertebroplasty – 2010.

	J&J	Synthes	Comb.	Stryker	Cook	Optimed	Arthro-care (now Neurotherm)	Bio-met	Care Fusion	Other
LV	[80-90]*	[10-20]*	[90-100]*							
HU	[60-70]*	[20-30]*	[90-100]*					[0-5]*		
PT	[90-100]*	[0-5]*	[90-100]*		[0-5]*			[0-5]*		Competitor 4 and Sinte Combined [0-5]*
AT	[70-80]*	[10-20]*	[80-90]*	[5-10]*	[0-5]*	[0-5]*		[0-5]*	[0-5]*	Bone Support, Competitor 1, Competitor 4 Combined [0-5]*
CZ	[40-50]*	[30-40]*	[80-90-]*							Competitor 1 [10-20]* Competitor 4 [0-5]*
SK	[60-70]*	[10-20]*	[80-90]*			[10-20]*				
EE	[30-40]*	[40-50]*	[70-80]*	[10-20]*		[0-5]*				
DK	[20-30]*	[40-50]*	[70-80]*	[5-10]*	[10-20]*		[0-5]*			
PL	[60-70]*	[5-10]*	[70-80]*	[20-30]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*		Bone Support, Competitor 1 and Competitor 2 combined [0-5]*
NO	[60-70]*	[5-10]*	[70-80]*	[10-20]*	[10-20]*					
UK	[60-70]*	[0-5]*	[60-70]*	[10-20]*	[5-10]*	[0-5]*	[0-5]*	[0-5]*	[0-5]*	
ES	[50-60]*	[5-10]*	[50-60]*	[5-10]*	[0-5]*	[10-20]*	[0-5]*	[10-20]*	[5-10]*	
SE	[20-30]*	[20-30]*	[50-60]*	[0-5]*	[40-50]*					
EL	[40-50]*	[5-10]*	[50-60]*		[5-10]*	[30-40]	[0-5]*	[0-5]*		
DE	[40-50]*	[0-5]*	[40-50]*	[10-20]*	[0-5]*	[10-20]*	[0-5]*	[0-5]*	[0-5]*	MaxSpine [5-10]*, SpineWave [5-10]*, Sinte [0-5]*
FI	[5-10]*	[30-40]*	[30-40]*	[10-20]*	[30-40]*		[10-20]*			
IT	[30-40]*	[5-10]*	[30-40]*	[20-30]*	[5-10]*	[10-20]*	[5-10]*	[0-5]*	[5-10]*	Sinte [0-5]*

Source: market reconstruction

#### 6.4.4.3. The parties are close competitors

- (534) The main overlap in the parties' activities is in vertebroplasty<sup>345</sup>. J&J offers a standard vertebroplasty product, but also has a premium-priced innovative vertebroplasty product (Confidence) that is promoted on the basis of increased safety. Synthes' vertebroplasty product is not indicated by the market investigation to have any unique characteristics. In addition, Synthes offers a kyphoplasty product with a unique stent technology building on technologies used in trauma procedures<sup>346</sup>.
- (535) The parties argue that they are not close competitors in vertebroplasty. They submit that the average selling price of Confidence is [...] \* higher than that of Synthes' vertebroplasty product (and provide country-per-country average sales price ("ASP") data in support). J&J positions and prices Confidence against [competitor's] \* kyphoplasty products, which is also confirmed by internal documents. This notwithstanding, the price of Confidence seems to be constrained by vertebroplasty products and not by kyphoplasty products according to the information from iData. As iData reports, J&J was unsuccessful in obtaining reimbursement status for Confidence at the level a kyphoplasty product would have had and *"was forced to reduce the ASP of the device significantly in order to remain competitive in the lower priced vertebroplasty market"*<sup>347</sup>. On the other hand, it should be noted that Confidence was granted kyphoplasty reimbursement status in the biggest kyphoplasty market in Europe, namely Germany. This again shows that the delineation of these product markets is not rigid and that the competition between vertebroplasty and kyphoplasty/VA products can be influenced by country-specific factors. In its reply to the SO and a later submission<sup>348</sup> the Notifying Party provided further arguments to show that Confidence does not compete with standard vertebroplasty products. Besides the reiterated price differences, the parties also show that the training involved in switching a physician from a standard vertebroplasty product to a Confidence product is more extensive than switching a physician to another standard vertebroplasty product<sup>349</sup>. In particular, the physician needs to train specifically on [...] \* that is specific to Confidence due to (and equally the Confidence cement cannot be used with any other vertebroplasty delivery system, unlike most standard vertebroplasty cements) and learn a new [...] \*. In support of its view that Confidence is not a close competitor to standard vertebroplasty products, the Notifying Party also points in its reply to the SO to an internal training document (to sales personnel) to show that Confidence competes with [...] \*<sup>350</sup>. Another

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<sup>345</sup> J&J has a version of its premium-priced Confidence product (called Perimeter) with an add-on device that it tries to market as a kyphoplasty product (See for example, [...] \*) [...] \*.

<sup>346</sup> See [...] \*

<sup>347</sup> European Markets for Spinal Implants and VCF – report by iData Research, 2011, Section 12.5, p.432.

<sup>348</sup> Submission of the Notifying Party of 16 February 2012.

<sup>349</sup> Submission of the Notifying Party 16 February 2012.

<sup>350</sup> [...] \*

internal document confirms that the VBA strategy of J&J is focused on the targeting [...]\*.<sup>351</sup>

- (536) The follow-up market investigation aimed to verify the efforts needed to switch a surgeon from one vertebroplasty product to another. Based on the follow-up market investigation it does indeed appear that Confidence requires additional training as compared to such efforts in general (at least considering more standard vertebroplasty products). Furthermore, the ASPs submitted by the parties do, as described above, show Confidence to be significantly higher priced than vertebroplasty products (the EEA ASP of Confidence is EUR [...]\*)<sup>352</sup>). As for the internal document referred to by the Notifying Party in its reply to the SO, it [...]\*. The document suggests that the unique selling points of Confidence are safety/controlled delivery (which, [...]\*)differentiates it significantly from standard vertebroplasty and is in general considered a common selling point with kyphoplasty) and simplicity of use (which appears to be highlighted in the product's marketing as an advantage versus kyphoplasty).
- (537) The Commission has not, since the issuing of the SO, received conclusive additional evidence to show that Confidence should not be considered as a vertebroplasty product. In fact, the new Millenium Research Group report on VCF submitted by the parties also confirms Confidence as a vertebroplasty product (as does the other major industry report, iData)<sup>353</sup>. This notwithstanding, it is clear that Confidence is differentiated to a significant extent from standard vertebroplasty products in terms of product features, marketing and price and that it is marketed to a significant extent as an alternative to kyphoplasty/VA products. It is also apparent that competition between Confidence and VA products, such as Medtronic's Kyphon range, is likely to be closer than between standard vertebroplasty products and VA products – as also acknowledged by the US FTC's decision during its review of Kyphon's acquisition of Disc-O-Tech<sup>354</sup>, the original manufacturer of Confidence<sup>355</sup>. Confidence does not appear to be competing closely in the price-sensitive part of demand and is unlikely to play a strong role in price competition in the vertebroplasty segment. Its marketing is clearly focused on innovation rather than price. In particular, it focuses strongly on safety due to the higher viscosity of the cement. Safety is also a key selling point of kyphoplasty / VA and high viscosity cement is often used in kyphoplasty / VA product (e.g. Medtronic, DFine). Such similarities already led to the reimbursement of Confidence at a kyphoplasty rate in Germany. However, this does not change the fact that Confidence is not *as such* a VA product, and that it

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<sup>351</sup> [...]\*

<sup>352</sup> Submission of 16 February.

<sup>353</sup> Global Markets for Minimally Invasive Vertebral Compression Fracture Treatments – Report by the Millenium Research Group, 2011, see p.30, European Markets for Spinal Implants, by iData 2011 p.432.

<sup>354</sup> Analysis of agreement containing consent orders to aid public comment - In the Matter of Kyphon Inc., Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation), and Discotech Orthopedic Technologies Inc. File No. 071-0101 – available at <http://www.ftc.gov/os/caselist/0710101/07analysis.pdf>.

<sup>355</sup> The clearance of the transaction was conditional on the divestment of the Confidence product range, which was subsequently acquired by J&J (De Puy).



competes with other vertebroplasty products. It is therefore considered, for the purposes of this Decision, to be a vertebroplasty product. This notwithstanding, the Commission notes (as also explained in Section 5.1.2.4.) that the delineation of the vertebroplasty and kyphoplasty/VA markets is not static and there is a degree of competition taking place especially with regard to more innovative products. The degree of competition is likely to be influenced by reimbursement, which has a direct impact on the price-sensitivity of demand.

- (538) Irrespective of the position of Confidence in the market, it should also be noted that J&J does market a standard, mature vertebroplasty system (Vertebroplastic cement and VMax delivery system) that was introduced in the mid-2000s. It closely competes with the vertebroplasty product of Synthes (and other vertebroplasty products) considering characteristics and price. This is also acknowledged by the parties. In addition, the market investigation provided several examples in group 1 countries where both J&J and Synthes participate in vertebroplasty tenders of the same hospitals further confirming the closeness of competition between the parties<sup>356</sup>.
- (539) Furthermore, in the assessment of the closeness of competition, product characteristics and price are important, but are not the only criteria. The parties are both comparatively strong on other parameters of competition, namely distribution strength, access to surgeons and training capacities.
- (540) In general, as explained in the SO, the phase 2 market investigation did not support the argument that the parties are not close competitors. In particular, it is clear from competitors' replies that the two closest competitors in VCF to each of the parties are Medtronic and the other party<sup>357</sup>. Hospital replies also indicate Synthes to be a close competitor to J&J<sup>358</sup>. Furthermore, it does not transpire from hospital replies<sup>359</sup> that hospitals themselves would perceive J&J to be a higher priced vertebroplasty supplier than Synthes.
- (541) Lastly, the argument that the parties are not close competitors would in any event carry less weight in markets where the parties would achieve post-merger very high combined market shares with a significant increment and where alternatives are limited.
- (542) The Commission therefore concludes, whilst acknowledging the differentiating characteristics of Confidence and some common characteristics it shares with kyphoplasty/VA products, that the parties are close competitors in vertebroplasty.

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<sup>356</sup> Replies to question 2 of Q28 – Phase II – questionnaire to customers (hospitals).

<sup>357</sup> Replies to Questions 21 and 22 of Q14 – questionnaire to competitors (spine).

<sup>358</sup> A clear majority of hospitals in Austria, the Czech Republic, Denmark, Hungary, Latvia, Poland, Portugal and Slovakia which replied to questions 51 and 52 of Q18 – questionnaire to customers (hospitals) indicated Synthes among the companies offering the most comparable product in vertebroplasty to that offered by J&J.

<sup>359</sup> Replies to question 12 of Q28 – Phase II – questionnaire to customers (hospitals).

#### 6.4.4.4. Medtronic and Alphatec are defined as primarily kyphoplasty / VA suppliers

- (543) The parties refer to Medtronic and Alphatec<sup>360</sup> as being among their main vertebroplasty competitors. Despite acknowledging that Medtronic's "*primary strength is in kyphoplasty*" the parties submit that the delivery system and bone cement of Medtronic's kyphoplasty offering is also available separately on the market<sup>361</sup>. They therefore consider that Medtronic offers vertebroplasty products by making these available separately.
- (544) The Commission's SO preliminarily concluded that both Medtronic and Alphatec are primarily kyphoplasty/VA competitors and should not be considered as offering products for simple vertebroplasty procedures to a significant extent. On the one hand, Alphatec confirmed that height restoration is a key feature of the Osseofix product<sup>362</sup>. This suggests that Osseofix is a VA, not a vertebroplasty product. Osseofix is therefore counted as a vertebral augmentation product for the purposes of the competitive assessment and the market reconstruction. This notwithstanding, Alphatec also states in its own report that "*our Osseofix product consists of our bone cement and a mixing and delivery system that can be used in a stand-alone vertebroplasty procedure*"<sup>363</sup> and considers that its own system competes with both kyphoplasty and vertebroplasty.<sup>364</sup>
- (545) As for Medtronic, despite significant indications from hospital replies that Medtronic may be considered as a competitor for vertebroplasty<sup>365</sup>, such indications are not sufficiently clear and conclusive to confirm Medtronic as a significant vertebroplasty supplier (whilst some of its cement may be used by some hospitals in vertebroplasty procedures<sup>366</sup>). It must be noted to this effect that there seems to be a degree of ambiguity regarding the terminology used in VCF treatments as also demonstrated by the parties' own use of the terminology during the phase 1 and 2 investigation. Medtronic does not consider itself to be one of the companies that exercise the strongest constraint on either J&J or Synthes in vertebroplasty and does not consider that it could increase sales in vertebroplasty in case of a 10% increase of the merged entity's products (whilst this would be possible for kyphoplasty) in several countries<sup>367</sup>. The examples the parties themselves provide to show that they lose contracts and face downward

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<sup>360</sup> See for example submission of 16 November 2011.

<sup>361</sup> See submissions of 16 November 2011 and 5 January 2012.

<sup>362</sup> See email from Mr Kohlbecher of 18 January 2011 [ID6252]\*.

<sup>363</sup> Alphatec's Form 10-k for year ending 31 Dec 2010, p.6 – see Annex 11 of the parties' submission of 16 November 2011.

<sup>364</sup> See email from Mr Kohlbecher of 18 January 2011 [ID6252]\*.

<sup>365</sup> See replies to Questions 1-3 of Q28 – Phase II – questionnaire to customers (hospitals).

<sup>366</sup> In its reply to the SO the Notifying Party provides for example an email from a doctor in the National Spine Center in Hungary (accounting for 40% of demand in Hungary according to the parties), according to which half of the vertebroplasty procedures performed in the hospital are carried out using Medtronic's system without the balloon device needed for kyphoplasty.

<sup>367</sup> Reply of Medtronic to questions 125, 126 and 128 of Q30 – Phase II – questionnaire to competitors (spine) – the questions related to the Czech Republic, Estonia, Hungary, Latvia, Poland and Slovakia.

price pressure for their vertebroplasty products<sup>368</sup> involve suppliers of[...]\*[not Medtronic]\*. Furthermore, an internal document of Synthes listing vertebroplasty and kyphoplasty competitors identifies Kyphon (Medtronic) as a kyphoplasty-only supplier<sup>369</sup>. The document also explains that Kyphon is investing significantly into studies comparing the efficacy of kyphoplasty vs vertebroplasty<sup>370</sup>. It is unlikely that Medtronic would undertake such investments to increase the acceptance of kyphoplasty at the expense of vertebroplasty if it was a significant vertebroplasty competitor (especially since both markets are growing markets overall with a large untreated common patient base). The 2011 iData report also identifies Medtronic as a kyphoplasty competitor without hinting at any Medtronic products or activities – however ancillary or indirect - in vertebroplasty<sup>371</sup>.

- (546) The follow-up market investigation did not provide any conclusive evidence that would lead the Commission to alter these findings. On the contrary, the Millenium Research Report report on VCF submitted by the Notifying Party following its reply to the SO confirmed both Alphatec and Medtronic to be VA competitors.
- (547) Whilst it is true that both Medtronic and Alphatec may be targeting vertebroplasty users for their VA products and that both may compete to some extent with vertebroplasty suppliers (due to the degree of competition from kyphoplasty/VA outlined in Section 5.1.2.4), and that some of their cement and other components sold *à la carte* may be used in vertebroplasty procedures, this does not alter the fact that both Medtronic and Alphatec are primarily VA competitors. They are therefore considered as such for the purposes of this Decision. In most countries, competition concerns can be excluded based on this assumption, i.e. based on a strict delineation of vertebroplasty and kyphoplasty / VA markets. In these countries, the question whether the parties face additional constraints in vertebroplasty from Medtronic and Alphatec does not alter the assessment. However, in the countries where this is relevant for the assessment, the competitive constraints stemming from Medtronic and Alphatec on the parties' sales of vertebroplasty products would be taken into account (see the country-specific assessments in Section 6.4.4.6.)

#### 6.4.4.5. Barriers to entry and expansion

- (548) The parties argue that there are low barriers to entry and expansion in vertebroplasty and that there are a large number of competitors remaining in the market. The Commission preliminarily concluded in its SO that this was not

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<sup>368</sup> See reply to Question 4 in the parties' submission of 5 January 2012.

They mention one example of lost sales in Austria in their submission of 8 January 2012, but without any supporting evidence.

<sup>369</sup> See the table on p.4 of Synthes' internal document No 232 submitted in response to Question 5 a of RFI of 17 November 2011.

<sup>370</sup> Also confirmed by the 2011 MRG report on Minimally Invasive VCF treatments submitted on 16 February.

<sup>371</sup> Section 12.5 of the 2011 iData report on European Markets for Spinal Implants and VCF.

confirmed by the market investigation for Austria, the Czech Republic, Denmark, Hungary, Latvia, Poland, Portugal and Slovakia. In particular, the phase 2 market investigation indicated<sup>372</sup> distribution and training resources and reluctance by surgeons to switch products as barriers to entry and expansion in Austria, the Czech Republic, Denmark, Hungary, Latvia, Poland, Portugal and Slovakia. The Commission also referred, in the SO, to a Synthes internal document<sup>373</sup> to highlight the importance of training capabilities [...]\*. Whilst it was acknowledged in the SO that surgeons' reluctance to switch to other products was arguably an inherent feature of the market, the strong growth of the parties' own VCF sales suggested that the parties were particularly efficient in overcoming this particular barrier to entry/expansion. In its SO, the Commission therefore preliminarily concluded that relative training and distribution capabilities would significantly be changed due to the merger in favour of the parties. In other words, the Commission preliminarily identified the concern that the already limited ability to enter or expand of small/potential players would be further hindered as a result of the combination of the parties' key assets for access to the market (notably, sales force and training capacities) which would raise the existing barriers to entry/expansion.

- (549) In its reply to the SO, the Notifying Party contests that barriers to entry and expansion are significant, maintains that there are examples of successful entry and expansion and that there are a large number of suppliers of vertebroplasty products remaining, including small suppliers that enter markets through established distributors. Furthermore, the Notifying Party argues that manufacturers offering complete vertebroplasty kits (like the parties) also face competition from suppliers of bone cement as physicians can and do use standard equipment (e.g. biopsy needles) to apply bone cement to the vertebrae and/or mix and match the cement and delivery system of different suppliers. Finally, the Notifying Party points to an internal analysis of J&J<sup>374</sup> that refers to [...]\*.
- (550) The findings of the Commission's follow up investigation provided support for the parties' views. The follow-up market investigation showed that barriers to entry and expansion (mostly training and distribution capabilities) are in VCF in general not so significant so as to prevent competitors from challenging the parties' combined positions. In addition, the follow-up investigation provided, in several countries, concrete examples of successful entry and plans to enter, which confirms these general indications.

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<sup>372</sup> Replies to question 4 of Q28 – Phase II - questionnaire to customers (hospitals) from Austria, the Czech Republic, Denmark, Hungary, Latvia, Poland, Portugal and Slovakia. Replies to questions 111 to 121 in Questionnaire Q30 – Phase II – questionnaire to competitors (spine) and questions 14-24 in Q31 – Phase II – questionnaire to competitors (VCF treatments). Whilst the need to retrain and surgeon's reluctance to switch is most evident in Austria, Czech Republic, Portugal and Slovakia, where a clear majority of hospitals indicated either of both as a reason why they would not switch suppliers, it was mentioned by hospitals also in the remaining countries mentioned above.

<sup>373</sup> [...]\* (Synthes internal document No 236 submitted in response to Question 5 of the RFI of 17 November 2011 p.15 and p.18).

<sup>374</sup> See J&J's internal document No 47 submitted in response to Q5a of the Commission's RFI of 17 November 2011.

- (551) Firstly, the follow-up investigation showed that the retraining involved in switching an experienced physician from one standard vertebroplasty product to another is not significant and some experienced physicians may not even need such additional training<sup>375</sup>. Training does not therefore appear to be a significant barrier to entry as preliminarily concluded in the SO.
- (552) Secondly, the Commission's extended follow-up market reconstruction (extended in time and in terms of competitors covered) showed several examples of successful entry and expansion in the markets where the Commission identified concerns on a preliminary basis. The market reconstruction further confirmed that a specialised company can achieve significant market shares in a country not only through direct presence (where the parties have an advantage over several of their competitors) but also by partnering with a distributor or even a full-line spine company. The follow-up investigation revealed several examples of such successful partnerships leading to successful entry as detailed below in the country-specific assessment (e.g. in Poland, the Czech Republic). The fact that hospitals in the VCF market investigation often referred to the distributor and not the manufacturer when identifying actual or potential suppliers<sup>376</sup> also confirms the importance of established local distributors in the competitive process and the possibility for smaller companies to get access to such distributors. One competitor, which is not active in other spine areas and is active through distributors explicitly confirmed that *"finding a distributor is generally not difficult in the EEA."*<sup>377</sup>
- (553) The follow-up market investigation also indicated that it was not difficult for a spine company supplying fusion and non-fusion products to start supplying vertebroplasty products in a country where it is already present<sup>378</sup> and that these products are available from a number of smaller/specialised companies in Europe, which lack the distribution capabilities of larger multinational spine companies. Spine companies without a VCF or vertebroplasty product may therefore also enter the VCF market in countries where they are present with other spine products and take advantage of their customer base. The market investigation showed examples of such partnerships (existing or future) for both types of VCF products (for example Zimmer / Benvenue or Aesculap / Dfine<sup>379</sup>).
- (554) Adding VCF products to a spine company's portfolio is also possible through internal product development, which allows an innovative company to leverage its existing know-how and strength (e.g. Synthes' stent technology in its kyphoplasty product comes from trauma). For example, Alphatec has recently launched its OsseoFix system which already gained significant market shares in a

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<sup>375</sup> See replies of competitors to Annex 1 of the Commission's request for information of 30 January 2012.

<sup>376</sup> See hospital replies to questions 1-3 and 5 of Q28 – Phase II – questionnaire to customers (hospitals).

<sup>377</sup> See agreed non confidential minutes of the call with CareFusion dated 21 December 2011.

<sup>378</sup> See for example the replies of one competitor in the follow-up market investigation, which has experience in such partnerships.

<sup>379</sup> In Slovakia and the Czech Republic.

number of countries. One important recent spine entrant, K2M, which is strong in other types of minimally invasive procedures, also confirmed that VCF is an attractive market which it would consider entering in the future. The main reason why K2M has not thus far entered this market is not related to the strength of existing players that may act as a deterrent or the lack of opportunities, but the fact that the core customer base for VCF products is not the traditional customer base of spine companies. Furthermore, acquisition of a more specialised company or a VCF product range is also an effective way for a spine company to enter VCF markets as shown by the example of Medtronic's acquisition of Kyphon. J&J itself acquired the Confidence product range from another company, Disc-O-Tech, in 2007.

- (555) The Commission also takes note of an internal analysis of J&J<sup>380</sup> that shows that J&J itself considers that it faces competitive constraints from [...] vertebral suppliers [...].
- (556) Thirdly, the follow-up market investigation revealed concrete examples of recent and planned entries in a number of countries included in the SO as detailed in Section 6.5.5.6.
- (557) Fourthly, the follow-up market investigation also provided indications for the flexible use of bone cement and needle devices (biopsy needles) for vertebroplasty procedures as also argued by the parties<sup>381</sup>. Such flexible use would suggest on the one hand relatively lower barriers to switching and on the other that the parties may face additional competitive constraints in vertebroplasty markets that do not show up in the market reconstruction (i.e. suppliers of generic bone cement or biopsy needles not covered by the market reconstruction).
- (558) Fifthly, the follow-up investigation also provided further indications as to the importance of IRs and INRs in the vertebroplasty markets. As one competitor put it, there is *"a different call pattern involved in the VCF segment due to the migration from spine surgeons to interventionist radiologists over the past decade"*.<sup>382</sup> The training and distribution advantages of the parties primarily relate

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<sup>380</sup> Referred to in recital 552.

<sup>381</sup> See for example Section 3.2.1.4 and 4.3.1 of the 2011 Millenium Research Group Report on Global Markets for Minimally Invasive VCF Treatments submitted on 16 February 2012: "[...] *the vertebroplasty segment in Europe remains highly fragmented, with no single company holding a dominant share. This is partially due to the continued practice of physician and hospital-made vertebroplasty systems, which are basically made from generic products like syringes and orthopedic bone cement.*" – p.101. The reply of one cement supplier in the follow-up investigation also confirmed the flexibility on the physicians' side in using cement with different delivery systems.

<sup>382</sup> Agreed Minutes with K2M of the conference call dated 3 February 2012. See also + 2011 Millenium Research Group Report on Global Markets for Minimally Invasive VCF Treatments submitted on 16 February 2012.

to spine surgeons and such advantages are not apparent in the non-surgeon segment of the market<sup>383</sup>.

- (559) Finally, the follow-up market investigation provided further confirmation of the overall growth of the market, which generally facilitates entry and expansion by smaller competitors. This growth may come from increased acceptance of VCF treatments and increased referrals by general practitioners of patients and increased possibilities for using VCF treatments outside of the current core use of osteoporosis-related fractures<sup>384</sup>.
- (560) The Commission therefore concludes that in general there appear to be a sufficient number of competitors remaining in the EEA countries which supply vertebroplasty products. In addition, barriers to entry and expansion are not significant in vertebroplasty markets and such entry and expansion is possible and is happening and is facilitated overall by the growth and attractiveness of the VCF market.
- (561) These findings are also consistent with earlier indications (also mentioned in the SO) of the phase 2 investigation from competitors<sup>385</sup> and hospitals<sup>386</sup>, which pointed to the possibility of expansion by competitors and to the existence of alternative credible suppliers for hospitals. Whilst, as explained in the SO, these indications in themselves were not deemed sufficiently conclusive and robust to dismiss concerns in the national markets included in the SO, they give solid support to the further findings of the market investigation.

#### 6.4.4.6. Country-specific analysis

- (562) In Finland, Germany and Italy the combined market shares of the parties do not exceed 50% in vertebroplasty. In Spain and Greece, the parties' combined market shares are slightly higher ([50-60]\*%) in vertebroplasty. In addition, the increment is very small in Germany [0-5%]\* and small [5-10]\*% in Italy, Finland, Greece and Spain There are at least three competitors in each country that would remain with market shares at least as high as the increment, often with significantly higher market shares. These competitors are internationally active, credible vertebroplasty competitors and achieve significant market shares in other countries as well. In the absence of any indications from the market investigation that Synthes would have a more significant role in competition in Germany, Italy, Greece and Spain than what is suggested by its moderate market position, or J&J in Finland, and in the absence of significant barriers to entry and expansion and in the absence of any concerns voiced in the market investigation either by

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<sup>383</sup> See for example Synthes' internal document submitted in response to Q5a of the Commission's RFI of 17 November 2011, [...]\*

<sup>384</sup> Global Markets for Minimally Invasive Vertebral Compression Fracture Treatments – Report by the Millenium Research Group, 2011, see p.45.

<sup>385</sup> Questions 128 of Q30 – Phase II – questionnaire to competitors (spine) and question 31 of Q31 – Phase II – questionnaire to competitors (VCF treatments). (These questions referred to the Group 1 VCF markets originally identified by the parties: the Czech Republic, Estonia, Hungary, Latvia, Slovakia, Poland).

<sup>386</sup> Replies to questions 1, 3 and 5 of Q28 – Phase II - questionnaire to customers (hospitals)

competitors or hospitals, the Commission concludes that the proposed transaction does not lead to a significant impediment to effective competition in these vertebroplasty markets. In addition, given that in the wider VCF market in Finland (a group 1 market as well), the parties would be constrained in addition by Medtronic, the Commission concludes that the proposed transaction does not lead to a significant impediment to effective competition in this market<sup>387</sup>.

- (563) In the United Kingdom the parties achieve higher combined market shares in vertebroplasty<sup>388</sup> ([60-70]\*%) but, again, with a very small increment of [0-5]\*%. There are five competitors remaining with comparable or higher market shares than Synthes, two of them (Stryker and Cook) with significantly higher market shares. All these competitors are internationally active with significant market shares in other countries as well. In addition, hospital replies pointed to a number of other suppliers (some active through distributors) as credible alternatives that had not been contacted in the market investigation. In the absence of any indications from the market investigation that Synthes would have a more significant role in competition in the United Kingdom than what is suggested by its moderate market position, in the absence of significant barriers to entry and expansion and in the absence of any concerns voiced in the market investigation either by competitors or hospitals in relation to the vertebroplasty market in the United Kingdom, the Commission concludes that the transaction does not lead to a significant impediment to effective competition.
- (564) In Poland and the Czech Republic it is evident how contestable vertebroplasty markets, and in particular, incumbents' market positions are. It should also be noted that, as opposed to most countries in the EEA, entry in the Czech Republic is relatively more difficult as suppliers are required to apply for reimbursement status (see Recital (158)). Despite this, entry has occurred on a significant scale.
- (565) The phase 2 market reconstruction of 2010 figures suggested a very concentrated market in both countries leading to a monopoly in vertebroplasty and a duopoly in VCF in the Czech Republic and a combined market share of [70-80]\*% in vertebroplasty with only one other significant competitor (Stryker) remaining in Poland<sup>389</sup>. In the absence of any robust evidence concerning the possibilities of entry/expansion, the Commission preliminary concluded that the proposed transaction would lead to a significant impediment of effective competition in these markets. The follow-up market investigation and the extended market reconstruction did on the other hand provide such robust evidence for both entry and expansion. In the Czech Republic, the extended market reconstruction identified two additional competitors, which together held a market share of [10-20]\*% in 2010. In addition, due to both expansion and new entry (via distributor), the parties' combined market shares dropped to only [50-60]\*% in 2011. Through entry and expansion competitors gained [20-30]\*% of the market between 2010 and 2011. In Poland, the combined market share of the parties fell from [70-

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<sup>387</sup> In the other countries VCF is not a group 1 market.

<sup>388</sup> VCF is not a group 1 market in the UK.

<sup>389</sup> VCF is not a group 1 market in Poland.



80]\*% in 2010 to [60-70]\*% in 2011. This is mainly at the expense of the market leader J&J[...]\* Again, a competitor with minimal sales in 2010 achieved a [5-10]\*% market share in less than a year through a distribution partnership. These indications provide a solid backing to the more anecdotal indications of phase 2 hospital replies of the willingness to switch vertebroplasty suppliers (and examples of switching for price reasons) and the availability of other credible suppliers. The follow-up market investigation also revealed other plans of entry and the existence of further distribution partnerships in both countries (although exact sales data could not always be acquired for the purposes of the market reconstruction). In light of the robust evidence of the competitive constraint stemming from both existing and potential competitors and in the absence of concerns voiced either by hospitals or competitors, the Commission concludes that the proposed transaction does not lead to a significant impediment to effective competition in relation to vertebroplasty markets in the Czech Republic and in Poland. Since in the wider VCF market the parties would face additional competitive constraints from Medtronic, competition concerns can be excluded in the wider market as well.

- (566) In Slovakia the market reconstruction shows a highly concentrated market structure in vertebroplasty with combined market shares of [80-90]\*% and one additional competitor (Optimed) remaining. In the wider VCF market the parties would face strong competition in addition from Medtronic and from a recent entrant (the innovative company DFine that is distributed by BBraun/Aesculap). The follow-up investigation revealed another competitor being distributed by an established spine company, but the exact sales data could not be verified. Hospital replies confirm 6-7 competitors besides the parties as actual suppliers or potential credible suppliers<sup>390</sup>, some of which have not been included in the market reconstruction. Furthermore, as J&J points out in its reply to the SO, its own sales [significantly decreased]\* between 2010 and 2011 and [...]\* by Synthes. All this suggests that there are significant competitive constraints stemming from other competitors that have not been captured by the market reconstruction. In addition, hospitals appear to be price-sensitive and eager to drive competition: roughly half of the hospital respondents either switched or tried to renegotiate their existing VCF contracts (also using the possibility to switch as a threat in these negotiations) in order to get better offers and/or to multisource<sup>391</sup>. Such behaviour would further facilitate entry or expansion by other competitors. In addition, the market investigation did not identify any country-specific barriers to entry that would prevent new entrants from achieving the same success in Slovakia as they do in the Czech Republic. In fact, the follow-up market investigation indicates future entry into Slovakia. The Commission therefore concludes that the proposed transaction does not lead to a significant impediment to effective competition in relation to the vertebroplasty market in Slovakia based on the indications that a number of competitors are present which can exercise a sufficient competitive constraint on the parties (despite what the market reconstruction suggests), possibilities for entry and a

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<sup>390</sup> Replies to questions 1-3 and 5 of Q28 – Phase II – questionnaire to customers (hospitals).

<sup>391</sup> Replies to question 13 to 17 of Q28 – Phase II – questionnaire to customers (hospitals).

general openness of hospitals to consider a number of credible alternative suppliers. As in the wider VCF market the parties would face additional competitive constraints from Medtronic and Dfine, concerns in the wider market can also be excluded.

(567) In Sweden, Norway, Estonia, Hungary and Latvia the market reconstruction indicated small overall market sizes below and also significantly below EUR 100 000. By way of example, Synthes achieved a [10-20]\*% market share in Latvia in 2010 by selling only [...] units of its vertebroplasty system. In Hungary J&J achieved a market leader position of [60-70]\*% by selling products sufficient for only around [...] procedures in 2010. By contrast, in Poland J&J achieved a similar market position by selling more than [...] times as many procedures<sup>392</sup>. In light of these market sizes and considering that only a limited number of spine hospitals perform these procedures (and some hospitals perform only a few procedures a year), high market shares are not necessarily indicative of market power. In particular, these markets appear to be more easily contestable (i.e. training/converting a few surgeons or gaining only one or two contracts may already have a significant effect on the market structure). This is in particular the case when considering that in standard vertebroplasty the effort involved in retraining an experienced physician on another product does not seem to be significant. Despite the small market sizes, there are at least two internationally active credible competitors remaining besides the parties in Sweden, Norway and Estonia. In Latvia, there are two competitors which together had [30-40]\*%<sup>393</sup> of the market in 2009, but achieve no or small market shares in 2010 and 2011. This clearly shows the volatility of such small markets. It should also be noted that Synthes achieved a [10-20]\*% market share in Latvia in 2010 by selling only [...] units of its vertebroplasty system. This is clearly a competitive constraint that can easily be replicated by another competitor. In Hungary the follow-up investigation confirmed the recent entry by two competitors, one of which was already indicated by hospitals in the phase 2 market investigation as a credible competitor and even an actual supplier<sup>394</sup>. There are also other internationally active competitors present in the market, albeit with small or no sales for the moment. The follow-up market investigation also provided evidence of training activities by one internationally significant competitor. In addition, the replies of Hungarian hospitals revealed an openness to other VCF suppliers, even to general spine companies which do not currently carry VCF or vertebroplasty products<sup>395</sup>. Finally, the market investigation did not identify any country-specific barriers to entry or expansion in these countries that would lead the Commission to conclude that entry or expansion would be more difficult than in the Czech Republic or Poland.

(568) In light of the presence of other established competitors and/or recent entrants and considering that in addition to barriers to entry and expansion not generally

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<sup>392</sup> Data based on the parties' submission of 16 February 2012.

<sup>393</sup> One competitor achieves [20-30]\*% and another [5-10]\*%. Both are present on the market through distributors.

<sup>394</sup> Replies to Questions 1-3 and 5 of Q28 – Phase II – questionnaire to customers (hospitals).

<sup>395</sup> Replies to Questions 1-3 and 5 of Q28 – Phase II – questionnaire to customers (hospitals).

being significant in vertebroplasty markets, such entry and expansion is further facilitated by the small size of these markets, the Commission concludes that the transaction does not lead to a significant impediment to effective competition in Estonia, Hungary, Latvia, Norway and Sweden in relation to vertebroplasty markets. Given that the proposed transaction does not lead to concerns in the narrower market of vertebroplasty and given that in the wider VCF market the parties face additional competitive constraints from Medtronic, competition concerns can be excluded also in the wider VCF market in Estonia, Hungary, Latvia and Norway<sup>396</sup>.

(569) According to the market investigation the Danish vertebroplasty market has suffered some setbacks in recent years due to factors relating to the acceptance and reimbursement of vertebroplasty in general. However, this setback appears to be temporary and the market has generally been confirmed in the follow-up investigation as being attractive. The follow up market reconstruction does not show a material change in the basic market structure in Denmark between 2010 and 2011. Whilst the transaction would result in the merging of the current number 1 and number 2, there are two internationally active credible competitors remaining with significant market shares. In addition, as a further sign of the attractiveness of the Danish vertebroplasty market, the market investigation revealed future entry. In light of these specific indications and the general indications on the absence of significant barriers to entry and expansion and in the absence of any specific concerns indicated by the market investigation in relation to vertebroplasty markets in Denmark, the Commission concludes that the transaction does not lead to a significant impediment of effective competition in the Danish vertebroplasty market. On the wider VCF market, the parties would face, in addition, competition from Medtronic and Alphatec, both with significant market shares. The transaction would therefore not significantly impede effective competition in the wider VCF market in Denmark.

(570) In Portugal, the market reconstruction reveals a very concentrated market, which, based on 2011 data, slightly worsened as the increment by Synthes increased to [5-10%]\*. Based on the concentrated market structure and general barriers to entry and expansion indicated by the phase 2 market investigation, the Commission preliminarily concluded in the SO that the transaction raised concerns in the Portuguese vertebroplasty market while recognising that phase 2 hospital replies indicated a number of alternative suppliers<sup>397</sup>. The reply rate of hospitals was particularly high in Portugal considering the size of the market (14 hospitals, including important VCF customers) and hence gives a good overview of the competitive dynamics. What emerges from these replies is that there are several other competitors supplying hospitals and/or actively participating in hospital tenders<sup>398</sup> and considered as credible alternatives by hospitals<sup>399</sup> (that

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<sup>396</sup> Sweden is not a VCF group 1 market.

<sup>397</sup> Reply of hospitals to question 3 and 5 of Q28 – Phase II – questionnaire to customers (hospitals).

<sup>398</sup> Reply of hospitals to Questions 1-2 of Q28 – Phase II – questionnaire to customers (hospitals).

<sup>399</sup> Replies to question 3 and 5 of Q28 – Phase II – questionnaire to customers (hospitals). – credible alternatives are defined in the relevant question as *"companies that offer comparable (or even*

offer comparable or even better products and services as their present suppliers and which could meet the demand of the hospital concerned). The phase 2 market investigation also revealed examples whereby hospitals switched to other competitors and/or renegotiated their current terms of supply by threatening to switch to another supplier<sup>400</sup>. Synthes does not emerge from hospital replies as having a particular role in driving this behaviour<sup>401</sup> or as a particularly strong competitive constraint on J&J. In particular, out of the 6 hospitals indicating J&J as their main supplier, only two indicated Synthes as their first or second preferred alternative to switch to in case of problems. Based on the same replies, Biomet was indicated by three hospitals and hence appears to be as significant a constraint to J&J as Synthes despite its lower market shares.

- (571) In the case of Portugal, the discrepancies between the market reconstruction and the market investigation are such that it is doubtful that the market investigation provides a representative overview of the competitive landscape for VCF in that country. The replies of Portuguese hospitals indicated a number of local distributors or spine companies without their own vertebroplasty products as present or past suppliers and/or credible alternative suppliers. These local distributors and/or spine companies were not indicated by any company in the market reconstruction as their distributor in Portugal. It follows that these companies are likely to distribute products of companies that have not provided data in the market reconstruction. Altogether half of the hospitals refer to companies that supply/distribute vertebroplasty products that do not appear to be captured by the market reconstruction. In its reply to the SO, the Notifying Party also provides a copy of a 2011 public tender document of a large hospital, which shows that the hospital ordered from four competitors besides J&J, three of which were not covered by the phase 2 market reconstruction.<sup>402</sup> The follow-up market reconstruction confirmed for example the presence of one other competitor through a distributor that is mentioned by a number of hospitals as a past and/or present supplier. In addition to the presence of more competitors than suggested by the market reconstruction, the follow-up market investigation also indicated future entry.
- (572) It should also be mentioned with respect to Portugal that around [high]\*% of J&J's sales come from Confidence. Considering only standard vertebroplasty products, J&J's sales amount only to around EUR [...]\*. The ASP of Confidence in Portugal (EUR [...]\* in 2010) seems to be [...]\* than in [...]\* other group 1 markets [...]\*which suggests [...]\*. In fact the ASP is more or less the same as

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*better) products, prices and service as your present supplier(s) and that could meet at least a significant part of your hospital's need for vertebroplasty products".*

<sup>400</sup> See replies to questions 13 to 17 of Q28 – Phase II – questionnaire to customers (hospitals).

<sup>401</sup> See replies to questions 13 – 17 of Q28 – Phase II – questionnaire to customers (hospitals), which indicate Synthes as only one of several companies that hospitals switched to or threatened to switch to. See also replies to question 12 which indicate that an overwhelming majority of hospitals did not perceive Synthes to offer lower vertebroplasty prices than those offered by J&J.

<sup>402</sup> One of these three competitors already confirmed its presence through a distributor in the follow-up market investigation. It also appears that the combined value of orders from the four competitors is more than double the value of the order from J&J.

[...]\*. In addition, hospitals do not seem to make a rigid distinction between vertebroplasty and kyphoplasty. Roughly 80% of the respondents indicated Medtronic as an actual or a credible alternative for vertebroplasty. This suggests that the boundaries between vertebroplasty and kyphoplasty are relatively more fluid in Portugal and that there is a significant degree of competition between vertebroplasty and kyphoplasty/VA suppliers<sup>403</sup>.

- (573) Based on the above, it appears that the competitive constraint from alternative vertebroplasty suppliers is significantly stronger than what is suggested by the market share data and that there are a sufficient number of credible suppliers remaining in Portugal. Besides suppliers of vertebroplasty products, which appear to present a credible competitive constraint, it also appears that the merged entity would continue to be constrained in the premium-priced, innovative segment of the market by VA suppliers (Medtronic in particular). Future entry presents an additional competitive constraint. In light of this and the findings that barriers to entry and expansion in vertebroplasty are in general not high, and in the absence of any concerns voiced by competitors or customers in relation to the vertebroplasty market in Portugal, the Commission concludes that the transaction does not lead to a significant impediment to effective competition in the vertebroplasty market in Portugal.
- (574) Austria has a large VCF market in comparison with its population size. This is not because of vertebroplasty, but because of the relatively high take-up of kyphoplasty. Austria was the second country after Germany where kyphoplasty and is still the fourth largest kyphoplasty market in Europe after Germany, Italy and Spain. The spread of kyphoplasty has been greatly facilitated by a generous reimbursement regime. This also means that Austria is one of the few countries where the kyphoplasty segment not only accounts for the overwhelming majority of the market in terms of value sales, but has already overtaken vertebroplasty in terms of the number of procedures. Given these characteristics, Austria would be one of the examples where competition between kyphoplasty and vertebroplasty would be relatively more pronounced.
- (575) The combined market share of the parties would be below 35% in the overall VCF market due to the strong position of Medtronic. However, the combined market share of the parties is very high in vertebroplasty ([90-100]\*% with a [10-20]\*% increment by Synthes). The only other vertebroplasty competitor with a meaningful market share would be Stryker with [5-10]\*% market share. There is a tail end of other competitors achieving only marginal sales together accounting for [0-5]\*%. (This market structure has not materially changed in the past three years.). In light of the market structure and the preliminary conclusion on significant barriers to entry and expansion the Commission preliminarily concluded in the SO that the proposed transaction would lead to a significant impediment of effective competition in vertebroplasty markets in Austria.

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<sup>403</sup> VCF is not a group 1 market in Portugal due to the strong position of Medtronic. In addition, the parties would face competitive constraints from Alphatec's product.

- (576) In terms of the overall VCF market, competitors considered Medtronic and Synthes to be the closest competitors to J&J in Austria<sup>404</sup>. Again, as in the case of Portugal, hospitals do not seem to make a rigid distinction between vertebroplasty and kyphoplasty as evidenced by the relatively frequent mention of Medtronic and other kyphoplasty/VA competitors as alternatives for vertebroplasty.<sup>405</sup> (In addition, one competitor in the follow-up investigation referred to a vertebroplasty contract gained from Medtronic in Austria.) There are, in any event, at least five competitors supplying vertebroplasty products that hospitals identified as credible<sup>406</sup> alternative suppliers they could switch to. These competitors confirmed their presence in the Austrian market.
- (577) Demand in Austria does not appear to be particularly price sensitive as evidenced by the high proportion of kyphoplasty and relatively low levels of switching indicated by hospitals (as compared to e.g. Poland). This suggests a significant degree of competition from Medtronic at least for the parties' core customer base of surgeons. This is reflected also in hospital replies (see Recital (576)). Again, as in Portugal, the [...] sales come from Confidence (and the sales of their cheaper product declined from [...] of J&J's total vertebroplasty sales in 2009 to [...] in 2011). This suggests that J&J does not play an important role in price competition. For price conscious customers or customers with a preference for simpler, low-cost products, there are several alternatives remaining on the market, confirmed as credible by the market investigation. For the premium-priced end of the market (which would include Confidence and the kyphoplasty product of Synthes), the parties would continue to face significant competition from Medtronic and a number of other VA providers also indicated by hospitals as credible alternatives in the market investigation (including Alphatec, DFine, and Hofer).
- (578) In addition to already existing competitors, the follow-up market investigation revealed entry plans, including examples of the type of distribution partnership that led to successful entries into some neighbouring countries. Furthermore, as explained in Recital (358), competition is intensifying in Austria in other segments, like thoracolumbar fixation with several new competitors entering the market, some without a VCF product. As also explained in Recitals 543 and 544, it is feasible for spine companies to add VCF products to their portfolio to respond to the requirements of demand.
- (579) In light of the availability of several credible alternatives for both low-cost standard vertebroplasty products as well as for premium priced, more innovative products, the indications of the follow-up market investigation of the possibility of entry (confirmed also by concrete entry plans with respect to Austria), the

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<sup>404</sup> Replies to Questions 21 and 22 of Q14 – questionnaire to competitors (spine).

<sup>405</sup> Around half of the hospitals identified Medtronic and competitors with only kyphoplasty products as their actual or potential suppliers of vertebroplasty products – See replies to Questions 1 and 3 of Q28 – Phase II – questionnaire to customers (hospitals).

<sup>406</sup> Credible alternatives are defined in the relevant question as "*companies that offer comparable (or even better) products, prices and service as your present supplier(s) and that could meet at least a significant part of your hospital's need for vertebroplasty products*".

indications from Austrian hospitals of a general openness to alternatives be it vertebroplasty suppliers or kyphoplasty/VA suppliers and in the absence of specific concerns voiced by hospitals or competitors, the Commission concludes that the proposed transaction does not lead to a significant impediment to effective competition in relation to the vertebroplasty market in Austria.

#### 6.4.4.7. Potential competition in kyphoplasty

- (580) The phase 2 market investigation revealed that a recently launched product of J&J, which J&J identified as a vertebroplasty product in the notification (Confidence Perimeter, a Confidence product with an add-on device), is in fact marketed as a kyphoplasty product and gets kyphoplasty reimbursement in Germany, Austria and the Czech Republic. [...] The parties submit that even if their recently launched product is considered to be a kyphoplasty product, in light of its minimal sales in 2010, it does not lead to concerns. [...], they submit that there are numerous innovative as well as "me too" kyphoplasty products recently launched or coming onto the EEA market (which are based on Medtronic's technology).
- (581) Medtronic is still the leading player in kyphoplasty/VA with market share of [90-100]\*% of the EEA market in 2010. Synthes already supplies in kyphoplasty a product that is based on a different technology than Medtronic's and which appears to have a strong focus on height restoration. Its market share at the EEA level is [5-10]\*%, but in three (smaller) markets it has over 50%<sup>407</sup>. Stryker and Alphatec also have kyphoplasty/VA products as well as a number of smaller, innovative companies (e.g. Dfine, Benvenue). There is evidence of these smaller companies concluding distribution agreements with larger spine competitors with more established distribution capabilities (e.g. Zimmer and Benvenue). The parties' arguments regarding recent launches and expected entries were broadly confirmed in the market investigation. A significant decrease in prices is expected as a result of these market developments. [...] was not singled out as a particularly important innovator in kyphoplasty/VA - in fact, innovation is likely to come from smaller players.
- (582) It therefore does not appear that [...] would present a stronger potential competitive constraint in the kyphoplasty/VA segment than other existing and potential competitors. Concerns can therefore be excluded for the kyphoplasty segment.

#### 6.4.4.8. Conclusion – VCF

- (583) The Commission concludes that the proposed transaction does not lead to a significant impediment to effective competition in relation to VCF markets, including the sub-segments of vertebroplasty and kyphoplasty/VA products in any group 1 national market. This is particularly so because barriers to entry and

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<sup>407</sup> Estonia, Denmark, Finland: all group 1 markets based on the wider VCF segment and hence assessed in Sections 6.4.4.6

expansion in VCF are not significant enough to prevent remaining and potential competitors from efficiently constraining the merged entity

#### 6.4.5. *Coordinated effects- Spine*

- (584) Despite the relatively high level of proposed transaction in some markets for spine devices, in particular in certain markets for fusion devices, where the merged entity and Medtronic would together have considerable market shares, a theory based on coordinated effects is difficult to maintain. The complex purchasing patterns in the market, the heterogeneity (differentiation) of products, the lack of transparency as regards market shares, contracts won and prices, strong evidence of recent entry and innovation, as well as the absence of any indication of past coordination speak against such a theory. In particular, there are a significant number of credible competitors remaining in each spine segment which, in the absence of significant barriers to entry and expansion, would jeopardise any potential coordination.
- (585) The Commission therefore concludes that the proposed transaction does not lead to a significant impediment of effective competition resulting from coordinated effects in any spine market.

#### 6.4.6. *Conglomerate effects – Spine*

- (586) Certain participants in the market investigation have expressed concerns about the enlarged product portfolio of the merged entity and the risk of not being able to successfully compete in full-line tender scenarios because of their limited portfolios.<sup>408</sup> In its comments on the summary of the SO, Spinal Kinetics also expressed concerns about the merged entity's expanded products portfolio.<sup>409</sup> More precisely it considers that the merged entity's expanded product range would enhance its position in many markets and would allow it to create bundles of products and product lines which would be impossible for smaller, more specialised competitors in either segment to match. In particular, it considers that bundling would allow the merged entity to lower the prices of interbody cages (and adjacent fixation devices) specifically, which, as explained in Recital (52), have a similar patient base to that for artificial discs. This, in Spinal Kinetics' view, would drive demand away from artificial discs.
- (587) As set out in the Section 6.1.1.3, the combination of products resulting from a merger only gives rise to non-coordinated effects likely to significantly impede effective competition if such a combination confers on the merged entity the ability and incentive to leverage a strong position from one market to another by means of tying, bundling or other exclusionary practices so that actual or potential rivals' access to markets is hampered and the merged entity might increase prices. In assessing the likelihood of such a scenario, the Commission examines whether the merged entity would have the ability to foreclose its rivals, whether it would have sufficient economic incentives to do so and whether a

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<sup>408</sup> See, for example, replies to question 6 of Q14 – Questionnaire to spine competitors.

<sup>409</sup> Letter of Spinal Kinetics of 2 March 2012 addressed to Mr Csiszar.



foreclosure strategy would have a significant detrimental effect on competition (e.g. price increases), thus causing harm to consumers.

- (588) In this case the merged entity would indeed have an enlarged product portfolio. However, according to the information available to the Commission, the conditions required for non-coordinated effects to significantly impede effective competition are not met.<sup>410</sup>
- (589) The complementarity between J&J's and Synthes' portfolios comes from the types of materials used (e.g. J&J offers carbon fibre reinforced polymer cages), product differentiation (e.g. Synthes offers cages pre-filled with biologic materials, articulating cages), certain paediatric solutions (Veptr of Synthes), surgical approaches (e.g., Synthes offer a mini-open MIS approach, while J&J percutaneous MIS) and certain specific products (e.g., Synthes adds to the J&J portfolio expandable corpectomy devices for cervical spine, the anterior stabilisation device ArcoFix, interspinous spacer devices, and the posterior dynamic stabilisation system).<sup>411</sup> Compared to J&J, Synthes is active in more product segments, covering not only fusion, but also all three non-fusion segments. According to respondents, Synthes' product offer would be mostly improved by J&J's line for thoracolumbar pedicle screw/rod fixation segment (Expedium and Viper product lines). This is due to product differentiation and the somewhat different focus of the two companies.
- (590) In spite of its enlarged product portfolio the merged entity would not acquire as a result of the proposed transaction the ability to foreclose its competitors.
- (591) In order to be able to foreclose its competitors, the merged entity must have a significant degree of market power, which does not necessarily amount to dominance, in one of the markets concerned. The orthopaedic medical devices market is a differentiated goods market which implies that each firm holds a certain degree of market power. The effects of bundling can only be expected to be substantial, however, if either of the parties has a significant degree of market power in one of the product markets which is used in the bundle. This can happen, for instance, when at least one of the parties' products is viewed by many customers as particularly important and there are few relevant alternatives for that product ("must stock" products).
- (592) In this respect it is to be noted that hardly any customer having participated in the market investigation considered either J&J's or Synthes' products as "must stock" products.<sup>412</sup> Also, only three out of 14 important competitors considered that J&J has spine products where only few valid alternatives exist, and the replies were

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<sup>410</sup> Non-horizontal merger guidelines, paragraphs 93-94.

<sup>411</sup> See replies to questions 11, 21, 33, 56 and 78 of Q30 - questionnaire to competitors (spine).

<sup>412</sup> Replies to questions 137 and 138 of Questionnaire 28 to hospitals. For most countries, no such products were indicated. The only exceptions are a few hospitals in Austria, Sweden, Norway, Italy and Czech Republic, where the number of relevant replies is insignificant to conclude that there would be a large pool of customers which would regard any given product of the parties' as "must stock".

mixed as to the concrete products.<sup>413</sup> In relation to Synthes' products, nearly half of the respondents indicated that such products have few alternatives but replies were also mixed as to the concrete products.<sup>414</sup>

- (593) In addition, the degree of market power seems generally to be limited given that spine markets are dynamic and characterised by new entries and innovation. For example, the Mesa product introduced by K2M competes for instance with the Expedium product of J&J and other deformity products. The CoRoent cages introduced by NuVasive competes with interbody cages of J&J and Synthes. Medtronic is also the key incumbent in the overall spine market and currently has the largest spine portfolio. More specifically, as set out in the product specific sections, the merged entity would face a number of competitors that can exercise a sufficient constraint on the merged entity in each of the overlapping product markets. The merged entity would also not have a significant market position in any other complementary product market for spine devices, where the parties do not currently overlap (such as PDS or interspinous spacers).
- (594) The purchasing patterns in the market are also unlikely to facilitate the implementation of foreclosure strategies by the merged entity. Indeed, there are no strong indications that there would be a significant pool of hospitals in any given country which tend to buy all spine products instead of individual devices or narrower groups of devices. While some hospitals may, in the short term, value the lower prices achieved through bundling, the price and product range are not necessarily the key selection criteria in spine markets, where the level of innovation, product characteristics, surgeons' preferences and levels of services play equally or even more important roles (see Recital (335)). This is in particular the case in artificial discs, where innovation in terms of product characteristics and/or implantation techniques play a key role in driving demand (See Recital (510)). In view of these market characteristics, hospitals are likely to continue purchasing the products that their surgeons value most. To be able to select the products with technical attributes that surgeons value most was the main reason given by hospitals in reply to questions why they employ multisourcing strategies which currently outweigh the advantages of having a single supplier with a complete range. There are many examples in the spine markets of suppliers with smaller ranges than the merged entity which are currently able to compete on innovation and differentiated product offers (e.g., K2M is not active in non-fusion, but has shown a significant growth, while Spinal Kinetics is active in artificial discs only but has also gained significant shares in a number of countries). There are no reasons to consider that these market characteristics would change significantly post-merger.

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<sup>413</sup> Replies to questions 14 and 15 of questionnaire 30 to spine competitors. Out of 14 respondents only three important competitors specified that J&J offers such products, but all replies specified different products, while one competitor listed 16 differentiated products of J&J.

<sup>414</sup> For Synthes, out of 14 respondents 6 important competitors specified products of Synthes having few alternatives, but the replies were very mixed. Only one product was mentioned more than once, i.e. Veptr deformity system for paediatric use. However, Veptr system is a very niche product accounting for a [...] of Synthes sales.

- (595) In any event, both parties already have very broad spine product lines (including fusion, non-fusion and VCF products)<sup>415</sup> and the market investigation does not point towards an increased ability for foreclosure arising from the proposed transaction.<sup>416</sup> This is in particular the case given that Medtronic's present portfolio is already comparable to that of the merged entity and a number of other players also offer product lines broadly comparable to the parties' (e.g., Stryker, Biomet, Aesculap, Alphatec, Globus, Nuvasive, Zimmer, K2M, Ulrich), and are active in the segments where most of the parties' revenues are generated.<sup>417</sup> Possibilities for bundling are therefore apparent already for both the parties and several other competitors (and in particular, the market leader Medtronic).
- (596) Finally, concerns of foreclosure as a result of the merger would be dependent on the parties being able to increase prices after the exit of undertakings from the market. This in turn would only be possible if there were substantial entry barriers. However, the market characteristics in the spine market are such that entry is possible which is also corroborated by the substantial amount of smaller (even specialized) firms having entered the spine market. It is an important feature of this market that hospitals tend to multisource from several suppliers and, if needed, they can purchase spine devices outside formal tenders. In fact, a number of already important competitors currently achieve meaningful sales outside formal tenders.<sup>418</sup> A theory based on foreclosure leading to higher prices as a result of exit of some undertakings is therefore difficult to sustain.
- (597) Based on the above, even if the specific concern of Spinal Kinetics regarding the falling prices of interbody cages driving demand away from artificial discs were to materialise, this would not be the result of exclusionary practices (which could not be sustained) but of the competitive dynamics within and between the respective markets for interbody cages and artificial discs.
- (598) Against this background the risk of foreclosure (non-coordinated effects) resulting from the proposed transaction can be excluded in spine devices.

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<sup>415</sup> The parties overlap in nearly all spine product segments, except for interspinous spacers, posterior dynamic stabilisation systems, LLIFs, standalone cages, and some niche technologies where only Synthes is active currently (for example, Veptr, USS Schantz screws). These non-overlapping areas account for a small portion of parties' spine revenues.

<sup>416</sup> On the contrary, the evidence provided by the Notifying Party in relation to [...] shows that [...].

<sup>417</sup> All these companies are active in the segments where the parties generate from [...] to [...] of their EEA revenues. For example, open thoracolumbar pedicle screw fixation systems (where nearly all major competitors are active) accounted for [...] of J&J revenues and [...] of Synthes' revenues in the EEA in 2010. See replies to question 7 of Questionnaire 14 to spine competitors.

<sup>418</sup> See replies to question 4 of Q1 – Questionnaire to spine competitors (and respective questions of Q9, Q11 and Q12).

## 6.5. Shoulder implants

### 6.5.1. Parties' views on market characteristics

- (599) As explained in Section 5.1.3, shoulder replacement is indicated for shoulder fractures and also for degenerative conditions. In addition, there is a procedure for reverse shoulder replacement. J&J produces shoulder implants for all three pathologies (the *GLOBAL Advantage*, *AP* and *CAP* for the degenerative market, the *Global FX* for the fracture market and the *DELTA Xtend* for the reverse market). Synthes' current product *Epoca Shoulder Prosthesis System* can be used for both degenerative and fracture conditions. It currently has no reverse shoulder implant product on the market, but has a pipeline product which is due to be launched in the second half of 2013.
- (600) The Notifying Party argues that in each of the product markets and despite the often high combined market shares of the parties in some countries, the competitive landscape will not change as a result of the proposed transaction. In particular, it submits the following:
- Synthes is not a unique competitive constraint on J&J which would be removed by the transaction. While J&J's product offering comprises several differentiated shoulder prostheses for each of the fracture, degenerative and reverse shoulder implants markets, Synthes offers only one replacement system, as a one-fits-all device designed for both fracture and degenerative indications.
  - Synthes is not a major player in shoulder implants, having for 2010 EEA sales below EUR [...]\*, corresponding to a share of well below 5% in the EEA.
  - The merged entity will continue to be constrained by a large number of well-established and reputable shoulder implant suppliers like Biomet, Tornier, Zimmer, Lima, Smith & Nephew and Stryker as well as local players. In the EEA, across shoulder implants as a whole, the combined market share of the merged entity remains below [30-40]\*%, and the addition of Synthes does not result in a significant increase in J&J's share.
  - Sales of shoulder prostheses in Europe have been growing over the past years and the industry is expected to continue expanding. Therefore the market is already highly competitive and it will continue to grow along with the number of competitors and the expanding sales opportunities. It submits estimates showing that the market will grow at an average rate of [10-20]\*% between 2009 and 2016.
  - Companies are investing in the development of new and innovative shoulder implants as can be seen by examples of recent launches by competitors. There are no barriers for new players to enter the market

or for existing players to expand through additional products or geographically.

#### 6.5.2. *General Observations*

- (601) The market structure in the shoulder markets differs from the market structure in the trauma and spine markets. In trauma<sup>419</sup> Synthes has a very strong position and is by far the market leader in most countries and segments, and J&J is one of five main competitors, while in spine<sup>420</sup> the parties are similarly strong with Medtronic being in general the number one in most markets.
- (602) On the basis of the market reconstruction, there are 14 group 1 markets. On an EEA basis, J&J is the market leader in shoulder implants, followed by a number of other internationally active competitors, such as Biomet, Tornier, Zimmer, Lima, and Arthrex. Synthes is number 7 in the market, followed by a number of smaller (Smith & Nephew, Implantcast GmbH ("Implantcast")), or regional players (Evolutis SA ("Evolutis") in France, Shark SA ("Shark") in Belgium, Beznoska s.r.o. ("Beznoska") in the Czech and Slovak Republics). However, account has to be taken of the fact that this picture also includes reverse shoulder implants, where J&J achieves [...] \* of its overall shoulder implant sales and where Synthes (as well as Arthrex) is not active yet.
- (603) Biomet, Tornier, Zimmer (like J&J), each provide different products specific to each of the three shoulder replacement segmentations. All three are leading and successful global orthopaedics companies, with a particular focus on shoulder implants. All three are present in the seven biggest national markets in the EEA (Germany, France, The United Kingdom, Italy, Spain, the Netherlands and Belgium). In general they vigorously compete with J&J and often their products are perceived to be more innovative than those of J&J.
- (604) Lima and Arthrex (like Synthes), provide only one product that can be used for both degenerative and fracture conditions<sup>421</sup>. However, both have products presenting a better modularity than that of Synthes.
- (605) The AOF is not active in shoulder implants. Training is provided by the manufacturers themselves (or their suppliers). This can be done either by hosting educational programs to provide to surgeons updates on new implants, therapies and treatments, or by sponsoring educational programs at medical conferences<sup>422</sup>. Additionally, ad-hoc training and assistance is provided to individual hospitals.
- (606) According to the data provided by the Notifying Party for the years 2008 to 2010, total EEA sales in the degenerative shoulder implants segment declined by

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<sup>419</sup> See Section 6.3 (trauma).

<sup>420</sup> See Section 6.4 (spine).

<sup>421</sup> In the case of Lima also for the reverse condition.

<sup>422</sup> Hospitals and universities are also often involved in educational activities as teaching centres for certain techniques or anatomical training. These may be sponsored by arthroplasty product manufacturers but in general the courses themselves will not focus on a particular manufacturer's products.

around [...]\*, while in the fracture shoulder implants segment they remained stable<sup>423</sup>. The growth mentioned by the parties is therefore exclusively due to growth in the reverse shoulder implants segment (around % in three years), where Synthes is not yet active.

- (607) To a very large extent J&J and Synthes are not perceived as being each other's closest competitors, either by other competitors<sup>424</sup> or by hospitals<sup>425</sup>. Surgeons' preferences were not ranked as a very important selection criterion for procurement by hospitals, either by competitors<sup>426</sup> or by the hospitals themselves<sup>427</sup>. Its importance is forecast to decline in the future in favour of price considerations. Moreover, no indication has been found in the internal documents of the parties that they would compete closely. As a general remark, neither hospitals nor competitors voiced particular concerns about the proposed transaction in the area of shoulder replacements<sup>428</sup>.
- (608) On the supply side, the majority of the international market players have confirmed that they could expand output and could enter a national market within one to two years in the event of an increased demand due for example to a price increase by the merged entity, especially if they were already active in neighbouring countries. There is widespread evidence, either through the market investigation<sup>429</sup>, or publicly available information that there have been recent entries in a number of national markets.
- (609) On the demand side, hospitals have confirmed that their surgeons would accept to switch suppliers in the event of a price increase, despite having to eventually be retrained<sup>430</sup>. All of the suppliers active in their respective countries were listed as competitors which can exercise sufficient competitive constraint on the parties and also as participating in their purchasing procedures.

### 6.5.3. Overall shoulder implants market

- (610) On the basis of the market reconstruction, there are twelve group 1 markets for overall shoulder implants (Austria, Belgium, Finland, Germany, Hungary, Luxembourg, Norway, Poland, Portugal, Sweden, Spain and the United Kingdom).

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<sup>423</sup> While the results of the Commission market investigation and the data provided by the Notifying Party differed considerably as far as the market shares for the year 2010 are concerned, there was no considerable difference between the total market sizes for the degenerative and fracture shoulder market sizes in euro resulting from the two exercises for this same year. The Commission can therefore confidently use the market sizes provided by the Parties for the years 2008 and 2009, in order to estimate whether the markets are growing, declining, or remaining stable.

<sup>424</sup> See replies to questions 8, 9, 10, 25, 26 and 27 of Q13 - questionnaire to competitors (shoulder).

<sup>425</sup> See replies to questions 57,59,61,62 of Q18 - questionnaire to customers (hospitals).

<sup>426</sup> See replies to questions 8, 9, 10, 25, 26 and 27 of Q13 - questionnaire to competitors (shoulder).

<sup>427</sup> See replies to question 65 of Q18 - questionnaire to customers (hospitals).

<sup>428</sup> See replies to questions 39, 40, 41 of Q13 - questionnaire to competitors (shoulder); questions 67, 85, 86, 87 of Q18 - questionnaire to customers (hospitals); questions 22 and 23 of Q26 Phase II - questionnaire to competitors (reverse shoulder).

<sup>429</sup> See replies to question 12 of Q13 - questionnaire to competitors (shoulder).

<sup>430</sup> See replies to questions 173 and 180 of Q28 Phase II - questionnaire to customers (hospitals).

Table 28: Group 1 markets in overall shoulder replacements

	J&J	Synthes	Comb.	Tornier	Biomet	Zimmer	Lima	Arthrex	S&N	Others
<b>PL</b>	[10-20]*	[30-40]*	[50-60]*		[20-30]*	[10-20]*		[0-5]*	[0-5]*	Implant-cast [0-5]*
<b>AU</b>	[40-50]*	[5-10]*	[50-60]*	[0-5]*	[5-10]*	[5-10]*	[10-20]*	[10-20]*		
<b>PO</b>	[40-50]*	[0-5]*	[50-60]*	[10-20]*	[10-20]*	[0-5]*	[10-20]*	[0-5]*		
<b>FI</b>	[30-40]*	[10-20]*	[40-50]*		[30-40]*	[10-20]*		[5-10]*		
<b>HU</b>	[20-30]*	[20-30]*	[40-50]*	[5-10]*						Biotech [40-50]*
<b>BE</b>	[40-50]*	[0-5]*	[40-50]*	[10-20]*	[20-30]*	[5-10]*		[0-5]*	[0-5]*	Shark [0-5]*
<b>SW</b>	[30-40]*	[5-10]*	[40-50]*	[5-10]*	[20-30]*	[10-20]*		[5-10]*	[0-5]*	
<b>GE</b>	[30-40]*	[5-10]*	[30-40]*	[10-20]*	[10-20]*	[10-20]*	[5-10]*	[10-20]*	[0-5]*	
<b>UK</b>	[30-40]*	[5-10]*	[30-40]*	[5-10]*	[40-50]*	[5-10]*	[0-5]*	[0-5]*		
<b>LU</b>	[30-40]*	[5-10]*	[30-40]*		[5-10]*	[50-60]*		[0-5]*		
<b>ES</b>	[30-40]*	[0-5]*	[30-40]*	[10-20]*	[10-20]*	[10-20]*	[20-30]*	[0-5]*	[0-5]*	
<b>NO</b>	[30-40]*	[0-5]*	[30-40]*	[5-10]*	[30-40]*	[5-10]*		[0-5]*		

Source: market reconstruction

- (611) In Poland, the parties have a combined market share of [50-60]\*% with J&J contributing an increment of [10-20]\*%. There are two suppliers with market shares above or around that of J&J (Biomet [20-30]\*% and Zimmer [10-20]\*%), while another two have market shares at [0-5]\*% (Arthrex and Smith & Nephew), so that enough sizeable competitors would continue to constrain the parties post-merger. Moreover, Tornier has confirmed that it entered this market in 2011<sup>431</sup>, so its lack of sales for 2010 does not fully reflect its actual position in the market. Taking also into account that neither hospitals nor competitors voiced concerns about the transaction and that the parties are not each other's closest competitors, it can be concluded that the transaction is not likely to significantly impede effective competition in Poland.
- (612) In Austria, the parties have a combined market share of [50-60]\*% with Synthes contributing an increment of [5-10]\*%. There are four suppliers with market shares above or around that of Synthes (Lima and Arthrex both have a market share of [10-20]\*%, Biomet and Zimmer both have a market share of [5-10]\*%), so that enough sizeable competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the

<sup>431</sup> See replies to question 12 of Q13 - questionnaire to competitors (shoulder).

transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Austria.

- (613) In Portugal, the parties have a combined market share of [50-60]\*% with Synthes contributing a small increment of [0-5]\*%. There are five suppliers with market shares above or around that of Synthes (Lima, Biomet and Tornier, all at [10-20]\*%, Zimmer and Arthrex, both at [0-5]\*%), so that enough sizeable competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Portugal.
- (614) In Finland, the parties have a combined market share of [40-50]\*% with Synthes contributing an increment of [10-20]\*%. There are two suppliers with a market share above or around Synthes' (Biomet [30-40]\*% and Zimmer [10-20]\*%), while another has a lower market share (Arthrex [5-10]\*%). In addition, during the market investigation there was no indication (either from hospitals or from competitors) that the parties are regarded as being each other's closest competitor in Finland.
- (615) In Hungary, the parties have a combined market share of [40-50]\*% (J&J has a market share of [20-30]\*%, Synthes one of [20-30]\*%). There is one local supplier, Biotech, with a market share similar to that of the merged entity. Tornier has a lower market share ([5-10]\*%). It is likely that Biotech and Tornier would be in a position to constrain the merged entity. Given also that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Hungary.
- (616) In Belgium, the parties have a combined market share of [40-50]\*% with Synthes adding a small increment of [0-5]\*%. There are four suppliers with market shares around or above that of Synthes (Biomet at [20-30]\*%, Tornier at [10-20]\*%, Zimmer at [5-10]\*% and Shark, a local supplier at [0-5]\*%), so that enough sizeable competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Belgium.
- (617) In Sweden, the parties have a combined market share of [40-50]\*% with Synthes adding a moderate increment of [5-10]\*%. There are four suppliers with market shares around or above that of Synthes (Biomet at [20-30]\*%, Zimmer at [10-20]\*%, Arthrex and Tornier at [5-10]\*%). Smith & Nephew has a market share of [0-5]\*%, so that enough sizeable competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Sweden.



- (618) In Germany, the parties have a combined market share of [30-40]\*% with Synthes contributing a small increment of [0-5]\*%. There are six suppliers with market shares around or above that of Synthes (Tornier, Zimmer, Biomet and Arthrex, all with a share of [10-20]\*%), Lima with a market share of [5-10]\*% and Smith & Nephew with a market share of [0-5]\*%), so that enough sizeable competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Germany.
- (619) In the United Kingdom, the parties have a combined market share of [30-40]\*% with Synthes contributing a small increment of [5-10]\*%. There are three suppliers with market shares around or above that of Synthes (Biomet at [40-50]\*%), Tornier and Zimmer at [5-10]\*%), while Lima and Arthrex have lower market shares [0-5]\*%, so that enough sizeable competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in the United Kingdom.
- (620) In Luxembourg, the parties have a combined market share of [30-40]\*% with Synthes contributing an increment [5-10]\*%). The merged entity would remain number two in the market, far behind Zimmer ([50-60]\*%), while Biomet has a market share of [0-5]\*%. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Luxembourg.
- (621) In Spain, the parties have a combined market share of [30-40]\*% with Synthes adding an increment of [0-5]\*%. There are six suppliers with market shares above or around Synthes' market share (Lima with [20-30]\*%, Tornier, Biomet and Zimmer all with a [10-20]\*% market share, Arthrex and Smith & Nephew with [0-5]\*%), so that enough sizeable competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Spain.
- (622) In Norway, the parties have a combined market share of [30-40]\*% with Synthes adding an increment of [0-5]\*%. There are four suppliers with market shares above or around Synthes' (Biomet at [30-40]\*%), Tornier, Biomet and Zimmer both at [5-10]\*%, Arthrex at [0-5]\*%), so that enough sizeable competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Norway.

6.5.4. *Degenerative shoulder implants market*

(623) On the basis of the market reconstruction for degenerative shoulder implants there are eight group 1 markets (Austria, Denmark, Finland, Hungary, Poland, Portugal, Sweden and the United Kingdom).

Table 29: Group 1 markets in degenerative shoulder replacements

	<b>J&amp;J</b>	<b>Synthes</b>	<b>Comb.</b>	<b>Tornier</b>	<b>Biomet</b>	<b>Zimmer</b>	<b>Lima</b>	<b>Arthrex</b>	<b>Others</b>
<b>PL</b>	[20-30]*	[50-60]*	[70-80]*		[10-20]*	[5-10]*		[0-5]*	[0-5]* Implantcast [0-5]* Stryker
<b>FI</b>	[30-40]*	[20-30]*	[60-70]*		[20-30]*	[5-10]*		[0-5]*	
<b>PT</b>	[30-40]*	[5-10]*	[40-50]*	[10-20]*	[5-10]*	[10-20]*	[10-20]*		[0-5]* Stryker
<b>AT</b>	[10-20]*	[20-30]*	[40-50]*	[0-5]*	[10-20]*	[5-10]*	[5-10]*	[20-30]*	
<b>DK</b>	[30-40]*	[0-5]*	[30-40]*	[5-10]*	[10-20]*	[30-40]*		[0-5]*	
<b>UK</b>	[20-30]*	[10-20]*	[30-40]*	[10-20]*	[40-50]*	[5-10]*	[0-5]*	[0-5]*	
<b>HU</b>	[10-20]*	[10-20]*	[30-40]*	[5-10]*					[50-60]* Biotech
<b>SW</b>	[20-30]*	[10-20]*	[30-40]*	[5-10]*	[20-30]*	[20-30]*		[5-10]*	[0-5]* Stryker

Source: market reconstruction

(624) In Poland, the proposed transaction would combine the number 1 (J&J with a market share of [50-60]\*%) and the number 2 (Synthes with a market share of [20-30]\*%) and would result in a high combined market share of [70-80]\*%. However, J&J and Synthes are not each other's closest competitors in product terms since, as discussed, J&J has differentiated products while Synthes only has one used for both degenerative and fracture conditions. In addition, post-merger, one competitor with a market share around the increment would remain (Biomet with [10-20]\*%), together with two other competitors with lower market shares (Zimmer with [5-10]\*% and Arthrex with [0-5]\*). Moreover, two established international players, Tornier and Smith & Nephew, have confirmed that they have entered this market in 2011<sup>432</sup>, so their lack of sales for 2010 does not fully reflect their actual position in the market. Furthermore, Polish hospitals overwhelmingly indicated that they would switch suppliers in the event of a price increase<sup>433</sup> and listed all of the existing market players as competitors which can exercise sufficient competitive constraint on the parties and also as participating in their purchasing procedures (tendering)<sup>434</sup>. Finally, Polish hospitals routinely

<sup>432</sup> See replies to question 12 of Q13 - questionnaire to competitors (shoulder).

<sup>433</sup> See replies to question 173 of Q28 - Phase II - questionnaire to customers (hospitals).

<sup>434</sup> See replies to questions 170 and 171 of Q28 - questionnaire to customers (hospitals).

tender the majority of their orthopedical supplies, including shoulder implants. More than three suppliers participate on average in these tenders<sup>435</sup>. Therefore the transaction is not likely to significantly impede effective competition in Poland.

- (625) In Finland, the proposed transaction also combines the two strongest players: J&J's market share is [30-40]\*% and Synthes' is [20-30]\*%. Post-merger, the combined market share is high with [60-70]\*%. However there would be one competitor with a market share around the increment remaining post-merger (Biomet with [20-30]\*%), together with two other competitors with lower market shares (Zimmer with [5-10]\*% and Arthrex with [0-5]\*%). Tornier has confirmed that it entered this market in 2011<sup>436</sup>, so its lack of sales for 2010 does not fully reflect its actual position in the market. In addition, during the market investigation there was no indication (either from hospitals or from competitors) that the parties are regarded as being each other's closest competitor in Finland. Finnish hospitals indicated that they would switch suppliers in the event of a price increase<sup>437</sup> and listed Biomet and Zimmer as competitors which can exercise sufficient competitive constraint on the parties and also as participating in their purchasing procedures<sup>438</sup>. Finally, Finland, like other Nordic countries, is a bidding market, so Finnish hospitals routinely tender the majority of their orthopaedic supplies, including shoulder implants<sup>439</sup>. Therefore the transaction is not likely to significantly impede effective competition in Finland.
- (626) In Portugal, the parties have a combined market share of [40-50]\*% (J&J [30-40]\*%, Synthes [5-10]\*%) and there are four suppliers with market shares above Synthes' (Tornier [10-20]\*%, Lima [10-20]\*%, Zimmer [10-20]\*% and Biomet [5-10]\*%), so that a number of strong competitors would continue to constrain the parties post-merger. Taking also into account that neither hospitals nor competitors voiced concerns about the transaction and that the parties are not each other's closest competitors, it can be concluded that the transaction is not likely to significantly impede effective competition in Portugal.
- (627) In Austria, the parties have a combined market share of [40-50]\*% (J&J [10-20]\*%, Synthes [20-30]\*%) and there are two suppliers with market shares above or around J&J's (Arthrex [20-30]\*% and Biomet [10-20]\*%), while another two have market shares between 5% and 10% (Lima and Zimmer), so that enough sizeable competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Austria.
- (628) In Denmark, the parties have a combined market share not exceeding 40%. The increment brought about by the transaction is small (J&J [30-40]\*%, Synthes [0-

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<sup>435</sup> See replies to question 3 columns 2 and 3 of Q18 - questionnaire to customers (hospitals).

<sup>436</sup> See replies to question 12 of Q13 - questionnaire to competitors (shoulder).

<sup>437</sup> See replies to questions 173 of Q28 - Phase II - questionnaire to customers (hospitals).

<sup>438</sup> See replies to questions 170 and 171 of Q28 - Phase II - questionnaire to customers (hospitals).

<sup>439</sup> See replies to question 3, columns 2 and 3 of Q18 - questionnaire to customers (hospitals).

5]\*%). In addition, there are four competitors with market shares above Synthes' (Zimmer [30-40]\*%, Biomet [10-20]\*%, Tornier [5-10]\*% and Arthrex [0-5]\*%. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Denmark.

- (629) In the United Kingdom, the parties have a combined market share not exceeding 40% (J&J [20-30]\*%, Synthes [10-20]\*%). The merged entity would only be number two in the market, behind Biomet ([40-50]\*%). There are another two competitors with market shares equal or slightly below Synthes' (Tornier [10-20]\*% and Zimmer [0-5]\*%), so that a number of strong competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced particular concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in the United Kingdom.
- (630) In Hungary, the parties have a combined market share not exceeding 40% (J&J [10-20]\*%, Synthes [10-20]\*%). The merged entity would be only number two in the market, far behind a local supplier, Biotech ([50-60]\*%). Tornier is also present with [5-10]\*%. It is likely that Biotech together with Tornier, which only recently entered would be in a position to constrain the merged entity. Given also that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Hungary.
- (631) In Sweden, the parties have a combined market share not exceeding 40% (J&J [20-30]\*%, Synthes [10-20]\*%). In addition, there are two competitors with market shares above Synthes' (Biomet [20-30]\*%, Zimmer [20-30]\*%), so that a number of strong competitors would continue to constrain the parties post-merger. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Sweden.

#### 6.5.5. *Fracture shoulder implants market*

- (632) There are six group 1 markets for fracture shoulder implants (Finland, Luxembourg, Norway, Poland, Sweden and the United Kingdom).

Table 30: Group 1 markets in fracture shoulder replacements

	J&J	Synthes	Comb.	Tornier	Biomet	Zimmer	Lima	Arthrex	S&N
<b>PL</b>	[20-30]*	[40-50]*	[70-80]*		0	[5-10]*		[10-20]*	[0-5]*
<b>FI</b>	[40-50]*	[20-30]*	[60-70]*		[0-5]*	[0-5]*		[20-30]*	
<b>NO</b>	[50-60]*	[10-20]*	[60-70]*	[5-10]*	0	[10-20]*		[20-30]*	
<b>UK</b>	[30-40]*	[10-20]*	[50-60]*	[10-20]*	10]*	[10-20]*	[0-5]*	[10-20]*	[5-10]*
<b>SW</b>	[20-30]*	[10-20]*	[30-40]*	[5-10]*	[10-20]*	[5-10]*		[5-10]*	[20-30]*
<b>LU</b>	[20-30]*	[10-20]*	[30-40]*		0	[50-60]*		[5-10]*	

Source: market reconstruction

- (633) In Poland J&J and Synthes are number 1 and number 2 in the market with market shares of ([40-50]\*% and [20-30]\*% respectively. Post-merger, the combined market share is very high ([70-80]\*%). However a number of competitors would remain present, namely Arthrex ([10-20]\*%), Zimmer ([5-10]\*%), Smith & Nephew ([0-5]\*%), Implantcast, a local supplier ([0-5]\*%) and Stryker ([0-5]\*%). In addition, account has to be taken of the fact that the total market value is low (below EUR 80 000, with an average cost per implant of around[...]\*), so that the award of a tender to a different supplier can change the market shares significantly, and that the market shares thus might not correctly reflect the actual market strength. During the market investigation, there was no indication (either from hospitals or from competitors) that the parties are actually regarded as being each other's closest competitor in Poland. Tornier has indicated that it has recently entered the Polish market<sup>440</sup>. Furthermore, Polish hospitals indicated that they would indeed switch suppliers in the event of a price increase<sup>441</sup> and listed all of the suppliers present as competitors which can exercise a sufficient competitive constraint on the parties and also as participating in their purchasing procedures<sup>442</sup>. Finally, Polish hospitals routinely tender the majority of their orthopaedic supplies, including shoulder implants. More than three suppliers participate on average in these tenders<sup>443</sup>. Based on all these considerations it can be concluded that the transaction is not likely to significantly impede effective competition in Poland.
- (634) In Finland, the parties have a combined market share of [60-70]\*%, (J&J [40-50%]\*, Synthes [20-30]\*%). There is one supplier with market shares above or equal to Synthes' (Arthrex [20-30]\*%), while Biomet's market share is much lower ([5-10]\*%). Tornier has confirmed that it entered this market in 2011<sup>444</sup>, so

<sup>440</sup> See replies to question 12 of Q13 - questionnaire to competitors (shoulder).

<sup>441</sup> See reply to question 180 of Q28 Phase II - questionnaire to customers (hospitals).

<sup>442</sup> See replies to questions 177 and 178 of Q28 – Phase II - questionnaire to customers (hospitals).

<sup>443</sup> See replies to question 3 columns 2 & 3 of Q18 - questionnaire to customers (hospitals).

<sup>444</sup> See replies to question 12 of Q13 - questionnaire to competitors (shoulder).

its lack of sales for 2010 does not fully reflect its actual position in the market. Finnish hospitals indicated that they would switch suppliers in the event of a price increase<sup>445</sup>. Finally, Finland, like other Nordic countries, is a bidding market, so Finnish hospitals routinely tender the majority of their orthopaedic supplies, including shoulder implants<sup>446</sup>. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Finland.

- (635) In Norway the parties have a combined market share of [60-70]\*% (J&J [50-60]\*%, Synthes [10-20]\*%). Arthrex has a higher market share than Synthes [20-30]\*%, while Zimmer is equally strong at [10-20]\*%. It is likely that Arthrex and Zimmer would continue to constrain the merged entity. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Norway.
- (636) In the United Kingdom, the parties have a combined market share of [50-60]\*% (J&J [30-40]\*%, Synthes [10-20]\*%). There are three suppliers, namely Tornier, Zimmer and Arthrex, with market shares at [10-20]\*%. Biomet is at [5-10]\*% and Lima at [0-5]\*%. It is likely that the combined presence of the first three would continue to constrain the merged entity and together with the presence of the other two, competition is sufficient. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in the United Kingdom.
- (637) In Sweden, the parties have a combined market share not exceeding 40% with Synthes adding an increment of [10-20]\*%. Smith & Nephew and Biomet have higher market shares than the increment ([20-30]\*% and [10-20]\*% respectively), while Tornier and Arthrex both have market shares of [5-10]\*%. Therefore, the merged entity would be constrained by a sufficient number of sizeable competitors. Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Sweden.
- (638) In Luxembourg, the parties have a combined market share below 40%. The merged entity would remain number two in the market, far behind Zimmer ([60-70]\*%). Taking also into account that the parties are not each other's closest competitors and that neither hospitals nor competitors voiced concerns about the transaction, it can be concluded that the transaction is not likely to significantly impede effective competition in Luxembourg.

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<sup>445</sup> See replies to questions 180 of Q28 – Phase II - questionnaire to customers (hospitals).

<sup>446</sup> See replies to question 3 columns 2 & 3 of Q18 - questionnaire to customers (hospitals).

### 6.5.6. Reverse shoulder implants market

Table 31: EEA market in reverse shoulder replacements

	J&J	Synthes	Comb.	Tor-nier	Zimmer	Lima	S&N	Others
EEA	[50-60]*		[50-60]*	[20-30]*	[10-20]*	[10-20]*	[0-5]*	[0-5]*

Source: market reconstruction

- (639) According to the results of the market reconstruction, at present J&J holds a [50-60]\*% market share at EEA level and is the market leader in almost all the national markets. There is one strong competitor with a market share of [20-30]\*% (Tornier) and two further credible ones with market shares above 10% (Lima and Zimmer). It should be noted that Synthes is not yet active in this product market[...]\*
- (640) As already indicated in Section 6.5.2., the reverse shoulder implants market [...] - it grew by around [...] between 2008 and 2010 (from EUR [...] million to EUR [...] million)<sup>447</sup>.
- (641) In the market investigation competitors stated that they were not concerned about the impact the transaction might have on this market, even taking into account a hypothetical entry of Synthes into the market. On this basis the Commission considers that the proposed transaction is not likely to lead to a significant impediment to effective competition due to the planned launch by Synthes in 2013 of a reverse shoulder product.

### 6.5.7. Conclusion

- (642) Based on the above considerations the Commission concludes that the transaction does not lead to a significant impediment to effective competition in the area of shoulder implants.

## 6.6. CMF

### 6.6.1. The parties' views

- (643) The Notifying Party argues that despite the partially high combined market shares of the parties the transaction would not give rise to competition concerns because a wide range of competing suppliers would continue to constrain the merged entity across the full range of CMF products. It argues that J&J and Synthes are not each others' closest competitors. Codman's CMF sales are mainly focused on the cranial region, whereas Synthes sells mainly maxillofacial devices.
- (644) The Notifying Party explains that after the notification it has become clear that it has underestimated the aggregate sales<sup>448</sup> in the CMF area and therefore the market shares of the parties provided in the Form CO are overstated.<sup>449</sup>

<sup>447</sup> See footnote 301.

## 6.6.2. General observations

- (645) According to the data submitted by the Notifying Party, there are in total 21 national affected markets (12 in the cranial stock fixation devices and nine in the cranial custom-made fixation devices). In most cases either Synthes or J&J is already the market leader and the merger reinforces this position. In each market segment at least four to six competitors are always present (of which always three to four have market shares above 5%).
- (646) Competitors or customers have not expressed any concerns that the merged entity would be able to constrain competition, nor claimed in a substantiated way that there would be any negative effect on competition and prices.<sup>450</sup>
- (647) The results of the market reconstruction in CMF are not meaningful because the competitors who replied only cover a small part of the total market.<sup>451</sup> This is mainly due to the largely commoditised products which allow a high number of national and local suppliers to compete in the markets concerned, the various hospital laboratories which manufacture the implants themselves and the high volatility of demand in between years. Furthermore the cranial stock and custom-made implant markets are small on an EEA<sup>452</sup> and on a national level<sup>453</sup>. In small national markets about [...] units/kits are sold per year. The market shares can vary significantly from year to year depending on the sale of just a few units/kits.<sup>454</sup> Therefore the Commission decided to base its assessment on the market shares provided by the parties.<sup>455</sup>

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<sup>448</sup> For CMF relevant external market reports (i.e. MRG or iData) do not exist. The parties' market share estimates are based on their best estimate of the number of neurosurgery procedures. It is however difficult to translate that number into a reliable sales value estimate because price levels of the devices vary significantly from one country to another and from year to year.

<sup>449</sup> See section 1.1 of the response to the RFI of 24 November 2011, submitted on 1 December 2011.

<sup>450</sup> See replies to question 23 and 24 of Q15- questionnaire to competitors (CMF).

<sup>451</sup> In the CMF market reconstruction exercise the total market size amounts to about 40% of the total market according to the Form CO on an EEA level. In the custom-made implant market the total market size resulting from the market reconstruction reflects only 0% to 30% of the total market indicated in the Form CO in 20 out of 30 national markets (8 national markets in cranial stock implants). In the market reconstruction exercises in trauma, spine and shoulders the total markets overall sum up to 100% or more of the total market size which was provided in the Form CO.

<sup>452</sup> According to the Form CO, the cranial stock implant market achieves EUR [...] million on an EEA level, the custom-made implant market EUR [...] million on an EEA level.

<sup>453</sup> According to the Form CO, 13 national markets in the cranial stock implant area and 20 in the custom-made implant area are below EUR 250,000. The biggest national market is [...] with EUR [...] million for cranial stock implants and EUR [...] million for custom-made implants.

<sup>454</sup> For example in custom-made implants in Austria Synthes sold [...] units in 2008 and 2009, [...] in 2010 and [...] in 2011.

<sup>455</sup> The total market size estimates in the Form CO are based on assumed craniotomy incidences per capita in the respective countries and should therefore provide a good indication for the total market size in each country. Taking into account significant smaller total market sizes would lead to an overestimation of the market shares of the parties in these countries.



#### 6.6.2.1. Market structure and competitors

- (648) [...] % of J&J's CMF sales are focused on the cranial region. J&J is not a major player in the overall CMF business. Synthes manufactures and sells a full range of CMF implants, with maxillofacial devices representing [...] % of its sales.
- (649) J&J's closest global competitors are companies that similarly approach CMF from the cranial region and offer a range of products with a focus on neurosurgery, such as Medtronic or Aesculap. Synthes' closest competitors are companies which have historically approached CMF from the maxillofacial region (such as Stryker, KLS Martin GmbH&Co.KG ("KLS Martin"), Biomet and Medartis), starting by offering dedicated plating systems for this region of the skull, and then expanding their offer to include CMF implants for the cranial region as well. As regards closeness of competition, the Commission concludes that in the cranial stock implant and custom-made implant markets, J&J and Synthes are not close competitors.
- (650) Post-merger, several well established and international players, such as Aesculap, Biomet, Medtronic and Stryker would continue to compete strongly with the merged entity on an EEA level. Furthermore the competitive landscape in the CMF area is characterised by the presence of a high number of national, regional and local players<sup>456</sup> and niche players<sup>457</sup> which have achieved important market shares at a country level<sup>458</sup>. In addition there are a number of low-cost players from India, Turkey, South Korea<sup>459</sup> or China that compete in this market. Those low-cost players typically copy the design of more established players. Currently the low cost players are mainly active in Eastern European countries, such as Bulgaria, the Czech Republic, Greece and Romania but are well placed to enter other countries. Moreover various hospitals across the EEA have laboratories in which they manufacture custom-made implants themselves.<sup>460</sup> Some hospitals, especially in the United Kingdom and the Netherlands, also commercialise the custom-made implants that they manufacture.<sup>461</sup>
- (651) Cranial stock implants are largely commoditised and procurement is typically entrusted to the hospital administrations which are focussed on price, given the

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<sup>456</sup> For example Inion, Mondeal, Medicon, Neos Surgery, Prim, Acuna in cranial stock implants and Acuna, DDi Group, Tecres, Cavendish Implants Ltd ("Cavendish Implants") in custom-made implants.

<sup>457</sup> This means for example companies which focus on the manufacturing of custom-made implants in a specific material (i.e. ceramic) and in one country only.

<sup>458</sup> For example, in cranial stock implants Prim and Acuna in Spain, Inion Ltd. ("Inion") in Ireland, Mondeal in Germany and the Netherlands. In custom-made implants Tecres S.p.a. ("Tecres") in Italy and Greece, DDI Group Ltd. ("DDI Group") in Germany, Cavendish Implants in the United Kingdom.

<sup>459</sup> Jeil Medical.

<sup>460</sup> In particular the United Kingdom, the Dutch and Czech markets are characterised by the presence of a number of hospital laboratories, like for example the UCL Hospital of London, the Laboratory of the Czech Technical University in Prague or the Faculty Hospital in Ostrava.

<sup>461</sup> For example the UCL Hospital of London or the Faculty Hospital in Ostrava.

highly substitutable nature of competing products.<sup>462</sup> The replies of competitors and hospitals in the context of the market investigation show that the tender selection criterion "price" has a significant weight (competitors indicate that currently the weight of price is between 50% and 100%) and is considered to become more important in the next five years.<sup>463</sup> Hospitals are therefore able to choose between numerous competitors and exercise a certain degree of buying power.

- (652) Given that each implant is specifically produced and unique, custom-made implants are significantly more expensive than cranial or maxillofacial stock implants and a market price does not exist. Hospitals do not typically organise tenders for the purchase of custom-made implants as the surgeon will generally decide on case-by-case basis whether the patient needs a custom-made implant. Hospitals therefore usually make few requests for custom-made implants. Prices are determined on the basis of criteria such as material, weight and complexity.
- (653) In the presence of a high number of global and niche players, both markets have become highly competitive and price sensitive. At the same time local sales forces and contact points with hospitals are required. As a consequence, those markets become less attractive for the well established players (Medtronic, for example, has decreasing sales volumes in the cranial stock implant markets in recent years; [...]\*).

#### 6.6.2.2. Barriers to entry/expansion

- (654) Barriers to entry are low in the CMF device market. Market players have the ability to expand their CMF business.<sup>464</sup> A high number of competitors either have recently entered or have plans to enter a new national market.<sup>465</sup> In addition, low-cost suppliers from Turkey, India, Korea and China have also entered the market, first targeting Eastern-European countries, mainly in the maxillofacial area. Even if being able to provide the full range of CMF products constitutes a competitive advantage, most of the competitors are present only in certain CMF segments and consider that they are able to compete effectively against the merged parties. New players and established players use a combination of direct sales forces and distributors. For example CMF companies already active in the maxillofacial region have used their existing CMF sales force to expand into the cranial region.

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<sup>462</sup> See replies to question 75 of Q18 - questionnaire to customers (hospitals) and replies to question 19 of Q15- questionnaire to competitors (CMF).

<sup>463</sup> See replies to question 19 of Q15- questionnaire to competitors (CMF).

<sup>464</sup> See replies to questions 11, 12, 13 and 14 of Q15- questionnaire to competitors (CMF).

<sup>465</sup> For example Anatomics entered the markets in Finland and Norway in 2010, Medartis entered the Dutch and Belgian markets through local distributors (Dam Medical in the Netherlands and Arseus in Belgium) in 2010. Likewise Osteomed and KLS Martin have entered the Spanish and Portuguese markets through local distributors.

- (655) As confirmed by the market investigation, IP rights do not constitute a material obstacle to entry for CMF either. The vast majority of competitors confirm that the parties' patents do not restrict potential market entrants.<sup>466</sup>
- (656) The fact that barriers to entry, expansion and repositioning are low is also demonstrated by the large number of new entrants in recent years and their success in expanding.

### 6.6.3. Competitive assessment of individual markets

#### 6.6.3.1. Cranial stock implants

- (657) The following table shows that the cranial stock fixation device market is the area with the highest overlaps. Five out of the twelve affected markets in the cranial stock fixation device market are in the group 1 category (Belgium, Czech Republic, Italy, Portugal, and Spain).

Table 32: Group 1 markets in cranial stock fixation devices (shares 2010, in %)

	J&J	Synthes	Comb.	KLS Martin	Aesculap	Bio-met Lo-renz	Medtronic	Integra	Stryker	Other
<b>BE</b>	[30-40]*	[30-40]*	[70-80]*	[0-5]*	[10-20]*	[0-5]*	[0-5]*	-	-	[0-5]*
<b>ES</b>	[30-40]*	[30-40]*	[60-70]*	[10-20]*	[5-10]*	[0-5]*	[5-10]*	3	-	[0-5]*
<b>PO</b>	[30-40]*	[10-20]*	[50-60]*	[5-10]*	[20-30]*	[5-10]*	-	[5-10]*	-	[5-10]*
<b>IT</b>	[30-40]*	[10-20]*	[50-60]*	[5-10]*	[5-10]*	[10-20]*	[5-10]*	[5-10]*	[0-5]*	[5-10]*
<b>CZ</b>	[20-30]*	[10-20]*	[30-40]*	[10-20]*	[20-30]*	[10-20]*	[10-20]*	-	-	[0-5]*

Source: Form CO, estimates of the parties

- (658) In Belgium (combined market share of [70-80]\*%, Synthes [30-40]\*%, J&J [30-40]\*%), next to the four established competitors (KLS Martin, Aesculap, Biomet, Medtronic) Stryker, Medartis and Circle Medical have also realised significant sales in 2010. Other competitors like Medicon eG ("Medicon") are also present in the market. The received replies in the context of the market reconstruction exercise show that the market shares of the parties have been overestimated and would rather be below 60%. Although post-merger the merged entity would have a high combined market share of about 50-60%, the merged entity is facing at least two strong and well recognized established players (namely, Aesculap and Medartis) and several other credible competitors, including recent entrants. It is likely that these players would continue to restrain the parties post-merger.

<sup>466</sup> See replies to question 18 of Q15- questionnaire to competitors (CMF).

- (659) In Spain which has a combined market share of [60-70]\*% (Synthes [30-40]\*%, J&J [30-40]\*%), next to the five established competitors (KLS Martin, Aesculap, Biomet, Medtronic, Integra) Prim S.S. ("Prim") and Acuna y Fambona S.A ("Acuna") have also realised significant sales in 2010 which amount to two to five times the combined sales of the parties. The sales figures provided by Prim and Acuna show that that the market shares of the parties have been significantly overestimated. Post-merger the merged entity would have only a market share in the range of 10 – 20% and would face competition from the two market leaders, Prim and Acuna. Therefore it is likely that these players would continue to constrain the parties post-merger.
- (660) In Portugal with a combined market share of [50-60]\*% (Synthes [10-20]\*%, J&J [30-40]\*%), next to the four established competitors (KLS Martin, Aesculap, Biomet, Integra) Mondeal and Medicon have also realised sales in 2010. The replies received in the context of the market reconstruction show that Aesculap is nearly as strong as the merged entity and that post-merger the merged entity is facing competition from five other established players. Therefore it is likely that these players would continue to constrain the parties post-merger.
- (661) In Italy (combined market share of [50-60]\*%, Synthes [10-20]\*%, J&J [30-40]\*%), next to the six established competitors (KLS Martin, Aesculap, Biomet, Medtronic, Stryker and Integra) NeoSurgery S.L. ("Neo Surgery), Osteomed Corp ("Osteomed"), Mondeal and Medicon have also realised sales in 2010. The replies received in the context of the market reconstruction exercise show that the market shares of the parties have been overestimated and that post-merger the merged entity is facing competition from in total ten established players. Therefore it is likely that these players would continue to restrain the parties post-merger.
- (662) In the Czech Republic (combined market share of [30-40]\*%, Synthes [10-20]\*%, J&J [20-30]\*%), next to the four established competitors (KLS Martin, Aesculap, Biomet, Medtronic) ProSpon spol s.r.o. ("ProSpon") (distributor of Jeil Medical Corp ("Jeil Medical") from South Korea) and at least one laboratory of a major Czech hospital<sup>467</sup> have also realised non-insignificant sales in 2010. Post-merger the merged entity is facing competition from in total at least four well established and two local players. Therefore it is likely that these players would continue to constrain the parties post-merger.

#### 6.6.3.2. Custom-made implants

- (663) The following table shows that in the cranial stock implants market, one out of the nine affected markets is in the group 1 category (Austria).

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<sup>467</sup> Laboratory of the Czech Technical University in Prague.

Table 33: Group 1 markets in custom-made implants (shares 2010, in %)

	J&J	Synthes	Comb.	Biomet	Stryker	Osteomed	Other
AT	[10-20]*	[30-40]*	[40-50]*	[20-30]*	[10-20]*	[5-10]*	[10-20]*

Source: Form CO, based on the estimates of the parties

- (664) The Austrian market, which according to the Form CO had a total market size of about EUR [...] in 2010, is [...]\*. J&J has a limited presence in Austria, with [5-10]\* units sold in 2010 and [1-5]\* sold in 2011. Synthes had an exceptional high market share in 2010 ([20-30]\* units sold). This was due to a series of trials made at Austrian hospitals to familiarize surgeons with the product offerings as well as a clinical study carried out at the University hospital in Vienna. In 2008 and 2009 Synthes sold [5-10]\* units each and in 2011 [10-20]\* units. Therefore it is more appropriate to use 10-15 units as an indication of Synthes' position. That would give Synthes a share of [10-20]\*% in the Austrian custom-made implant market. J&J's market share in 2011, with [...] sold, is [0-5]\*%. Taking into account the above it can be concluded that the transaction is not likely to significantly impede effective competition in Austria.

#### 6.6.4. Conclusion

- (665) Based on the above considerations the Commission concludes that the transaction does not lead to a significant impediment to effective competition in the area of CMF implants.

### 6.7. Power tools

#### 6.7.1. Competitive Assessment

- (666) Both J&J and Synthes are present in the markets of (i) high speed power tools (capital equipment and consumables with the exclusion of cranial perforators) and (ii) cranial perforators.
- (667) J&J's presence in the market for high speed power tools (capital equipment and consumables with the exclusion of cranial perforators) is [...] (around EUR [...] for capital equipment and EUR [...] million for consumables, at the EEA level).
- (668) As mentioned in Recital (116), Synthes' cranial perforator does not compete with J&J in the cranial perforators market, because Synthes' cranial perforator can only be used with Synthes high speed power tools, but not with other high speed power tools, and the cranial perforators of other manufacturers, including J&J, cannot be used with Synthes' high speed power tools. Moreover, its market strength is almost immaterial (sales of EUR [...] at the EEA level for 2010). According to the Notifying Party, it can therefore be argued that the cranial perforators market is not an affected market. Based on the explanation provided and the [...] sales achieved by Synthes, the Commission agrees with this conclusion.

Table 34: The parties' sales by product category in the EEA (in 1000 EUR for 2010).

	Capital Equipment/High Speed Power Tools (a)	Consumables (excl. cranial perforators) (b)	Total a + b	Cranial perforators
<b>J&amp;J</b>	[...]*	[...]*	[...]*	[...]*
<b>Synthes</b>	[...]*	[...]*	[...]*	[...]*

Source: Form CO, estimates of the parties

- (669) In the Form CO, the Notifying Party submitted that it was not possible to obtain detailed market share data for each of the two markets proposed on a country by country basis and therefore submitted data for the overall aggregated market of high speed power tools and consumables.
- (670) On this basis and according to the data submitted by the Notifying Party, there are three affected national markets, of which two are group 3 markets and only one is a group 1 market. In view of the relatively small absolute and relative size of the parties' sales in this segment, the Commission did not include power tools in its market reconstruction exercise.

Table 35: Group 1 market in overall high speed power tools (2010).

	J&J	Synthes	Combined	Medtronic	B. Braun/Aesculap	Stryker	Others
<b>IT</b>	[0-5]*	[30-40]*	[40-50]*	[30-40]*	[10-20]*	[5-10]*	[5-10]*

Source: Form CO, estimates of the parties

- (671) In Italy Synthes is already the market leader and the merger reinforces this position. However, the increment added by J&J is small ([0-5]\*%), and there are at least three other well-established competitors, Medtronic [30-40]\*%, B. Braun/Aesculap [10-20]\*% and Stryker [5-10]\*%, so that the merger would not change the competitive pressure on the market leader. Therefore, the transaction is not likely to significantly impede effective competition in Italy.
- (672) The market investigation did not indicate any competition problems in any of the affected markets.

#### 6.7.2. Conclusion

- (673) Based on the above considerations the Commission concludes that the transaction does not lead to a significant impediment to effective competition in the area of power tools.

## 7. CONCLUSION

- (674) On the basis of the analysis outlined above, the Commission has come to the view that the notified transaction would significantly impede effective competition in the following markets in the field of trauma:

- non anatomic plating systems in Denmark, Norway, Slovenia, Sweden, and the United Kingdom;
  - anatomic wrist plating systems in Norway, Portugal, Spain, Sweden, and the United Kingdom;
  - anatomic shoulder plating systems in Portugal, Sweden, and the United Kingdom;
  - anatomic ankle plating systems in France, Germany, Portugal, and the United Kingdom;
  - anatomic knee plating systems in the Czech Republic, Portugal, and Slovenia;
  - anatomic elbow plating systems in Portugal; and
  - cannulated screws (irrespective of whether cancellous cannulated screws are considered being a separate market or not) in Austria, Belgium, Estonia, France, Latvia, Luxembourg, the Netherlands, Slovenia, Spain and the United Kingdom.
- (675) Therefore, the Commission has come to the conclusion that the notified transaction is incompatible with the internal market and the functioning of the EEA Agreement.

## **8. MODIFICATIONS OF THE PROPOSED TRANSACTION**

### **8.1. Description of the proposed commitments**

- (676) In order to remove the significant impediment to effective competition resulting from the proposed transaction, J&J formally submitted commitments to the Commission on 21 February 2012. Following the market test, the commitments were modified on 13 March 2012.
- (677) The commitments consist in the divestiture of J&J's entire trauma business currently operated by its subsidiary DePuy in the EEA. Therefore, in addition to the markets where a significant impediment to competition was identified it also includes further products such as IM nails, IM hip nails and compression hip screws, where no significant impediment was identified. Regarding the geographic scope, the divestment covers the entire EEA and not only the markets with a significant impediment to effective competition.
- (678) The divestment removes the entire overlap in each of the markets with a significant impediment to effective competition. The commitments would be implemented by way of an asset sale, most likely as part of a divestiture of DePuy's worldwide trauma business.
- (679) In addition to the divestment products, the divestment includes R&D facilities and a manufacturing plant. The commitments also foresee the provision of the

necessary technical assistance to allow the purchaser to manufacture the products or to make the necessary arrangements for third party manufacturing, as well as the transfer of personnel.

- (680) The detailed text of these commitments is annexed to this Decision. The main elements of the commitments, as modified, are summarised below.
- (681) The business to be divested (hereinafter “the Divestment Business”) includes all (i) tangible and (ii) intangible assets (including IPRs), in particular
- the Miami facility of DePuy comprising DePuy’s global R&D centre for trauma under the terms of the current lease;
  - if required by the purchaser, the portion of the DePuy production plant in Le Locle, Switzerland, utilized predominantly for the production of trauma devices, including access to related logistics, under the terms of the current lease and subject to the purchaser supplying J&J with support services during a transitional period;
  - the assignment (or perpetual, irrevocable, exclusive, royalty free licenses, if assignment is not reasonably practicable) of all patents (including patent applications) which are owned by DePuy, or patent rights licensed-in by DePuy, which contribute to the current operation of or are necessary to ensure the viability and competitiveness of the Divestment Business;
  - the trademarks listed in Annex 6 of the Schedule and the assignment (or perpetual, irrevocable, exclusive, royalty free licenses, if assignment is not reasonably practicable);
  - all technical and manufacturing know-how, trade secrets and designs which are owned or licensed-in by DePuy, and contribute to the current operation of or are necessary to ensure the viability and the competitiveness of the Divestment Business;
  - the assignment of all technical and manufacturing know-how.
- (682) The Divestment Business further includes (iii) all licenses, permits and authorisations issued by any governmental organisation in the EEA as well as all current and pending CE markings, (iv) all contracts, leases commitments and customer orders and (v) all customer, credit and other records.
- (683) The Divestment Business further includes transitional agreements for the supply of products and/or technical assistance for the duration of [...] months [...]\*.
- (684) In addition, the Divestment Business includes an option to hire key personnel, manufacturing personnel and members of the marketing and sales force in the different countries necessary to maintain the competitiveness of the Divestment Businesses.



## 8.2. Assessment of the Commitments

### 8.2.1. *Suitability for removing the significant impediment to effective competition*

- (685) The Divestment Business covers all overlaps in the field of trauma between the parties so that the commitment proposal leads to a complete removal of the overlap.
- (686) The technical assistance, transfer of tangible and intangible assets as well as transfer of key personnel, manufacturing personnel and marketing and sales personnel and the transitional supply arrangements provided for in the commitments ensure with the necessary degree of certainty the timely implementation of the commitments and the removal of the significant impediment to effective competition.
- (687) Given that the commitments lead to a complete removal of the overlap and have a wider scope in terms of products and countries than the markets where the significant impediment of effective competition was identified, the market test undertaken focussed on the viability of the divestment business, in particular on the duration and the scope of the transitional agreements and the transfer of personnel.

### 8.2.2. *Viability of the Divestment Business and modifications of the initial commitments in view of the market test*

- (688) The market test showed that the commitments would generally enable potential buyers to viably run the Divestment Business.
- (689) The technical assistance, the transfer of tangible assets such as the R&D facilities and the manufacturing plant, the transfer of intangible assets, the transfer of key personnel, manufacturing personnel and marketing and sales personnel and the transitional supply arrangements provided for in the commitments were seen as sufficient, so that potential buyers could viably run the Divestment Business. However, some scope for improvement was seen in particular regarding: (i) transitional supply arrangements and (ii) the number of sales representatives eligible for cross-hire and (iii) a requirement that the purchaser should have experience in the field of trauma or at least of orthopaedic devices.
- (690) As regards the transitional supply arrangements, it was brought to the Commission's attention that in some countries regulatory issues due to the re-registration of products following a change of manufacturer could cause a significant delay. Therefore, J&J included the possibility for the Monitoring Trustee to extend the supply arrangements' duration to [...] months in these cases
- (691) The importance of specifically trained sales representatives was highlighted. As in some countries the number of sales representatives made available to the purchaser might have been insufficient, J&J agreed to increase the number of sales personnel in [...].\*

- (692) Finally, following the comments in the market test J&J specified in the purchaser criteria that the purchaser must have experience in the orthopaedic industry.

### **8.3. Conclusion**

- (693) Based on the market test and in view of the above modifications by J&J, the Commission considers that the Divestment Business is a viable business and that the modalities foreseen for its transfer would enable its operation by the purchaser in a competitive and viable manner. The commitments address the significant impediment to effective competition identified in this Decision as they remove entirely the overlap between J&J and Synthes in the relevant markets. The Commission therefore considers that the commitments, as modified, are sufficient to remedy the adverse impacts of the proposed transaction on competition.

## **9. CONDITIONS AND OBLIGATIONS**

- (694) Pursuant to the second subparagraph of Article 8(2) of the Merger Regulation, the Commission may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into vis-à-vis the Commission with a view to rendering the proposed transaction compatible with the internal market.
- (695) The fulfilment of the measure that gives rise to the structural change of the market is a condition, whereas the implementing steps which are necessary to achieve this result are generally obligations on the parties. Where a condition is not fulfilled, the Commission's Decision declaring the concentration compatible with the internal market is no longer applicable. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance decision in accordance with Article 8(6) of the Merger Regulation. The undertakings concerned may also be subject to fines and periodic penalty payments under Articles 14(2) and 15(1) of the Merger Regulation.
- (696) In accordance with the basic distinction described in the above recital as regards conditions and obligations, this Decision should be made conditional on the full compliance by the Notifying Party with Section B (including the Schedule and Annexes 1 to 12) of the commitments submitted by the Notifying Party on 21 February 2012, as modified on 13 March 2012, and all other Sections should be obligations within the meaning of Article 8(2) of the Merger Regulation. The full text of the commitments is attached as an Annex to this Decision and forms an integral part thereof.

HAS ADOPTED THIS DECISION:

*Article 1*

The notified operation whereby Johnson & Johnson (USA) acquires sole control of *Synthes Inc.* (USA) within the meaning of Article 3(1)(b) of the Merger Regulation is hereby declared compatible with the internal market and the EEA Agreement.

*Article 2*

Article 1 is subject to compliance with the conditions set out in Section B of the Annex.

*Article 3*

Johnson & Johnson shall comply with the obligations set out in the sections of the Annex not referred to in Article 2.

*Article 4*

This Decision is addressed to:  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick - 08933 New Jersey  
(United States of America)

Done at Brussels, 18/04/2012

*For the Commission*  
*Signed*  
*Vice-President*

## Case No. COMP/M.6266 – Johnson & Johnson / Synthes

### Commitments to the European Commission

Pursuant to Articles 8(2) of Council Regulation (EC) No. 139/2004 as amended (the “**Merger Regulation**”), Johnson & Johnson (“**J&J**”) hereby provides the following Commitments (the “**Commitments**”) in order to enable the European Commission (the “**Commission**”) to declare the acquisition by J&J of Synthes Inc. (“**Synthes**”) (together with J&J, the “**Parties**”) compatible with the common market and the EEA Agreement by its decision pursuant to Article 8(2) of the Merger Regulation (the “**Decision**”).

The Commitments shall take effect upon the date of adoption of the Decision.

This text shall be interpreted in the light of the Decision to the extent that the Commitments are attached as conditions and obligations, in the general framework of Community law, in particular in the light of the Merger Regulation, and by reference to the Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004.

#### Section A. Definitions

For the purpose of the Commitments, the following terms shall have the following meaning:

**Affiliated Undertakings:** undertakings controlled by the Parties whereby the notion of control shall be interpreted pursuant to Article 3 Merger Regulation and in the light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings.

**Closing:** with regard to the Divestment Business the transfer of the legal title of the assets constituting the Divestment Business to the Purchaser.

**DePuy:** DePuy Orthopaedics, Inc., incorporated under the laws of Indiana, with its principal office at 700 Orthopaedic Drive, Warsaw, IN 46582, USA and affiliates.

**Divestment Business:** the business as defined in Section B and the Schedule that J&J commits to divest.

**Divestiture Trustee:** one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by J&J and who has received from J&J the exclusive Trustee Mandate to sell the Divestment Business to a Purchaser at no minimum price.

**Effective Date:** the date of adoption of the Decision.

**Extended Divestiture Period:** the period of [...] from the end of the First Divestiture Period within which the Divestiture Trustee shall have the irrevocable and exclusive mandate from J&J to sell the Divestiture Business if a binding agreement is not yet concluded at the end of the First Divestiture Period.

**First Divestiture Period:** the period of [...] from the Effective Date.

**Hold Separate Manager:** the person appointed by J&J to manage the day-to-day business of a Divestment Business under the supervision of the Monitoring Trustee.

**J&J:** Johnson & Johnson, incorporated under the laws of New Jersey, with its principal office at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, USA.

**Key Personnel:** the personnel necessary to maintain the viability and competitiveness of the Divestment Business, as listed in the Schedule.

**Monitoring Trustee:** one or more natural or legal person(s), independent from the Parties, who is approved by the Commission and appointed by J&J, and who has the duty to monitor the Parties' compliance with the conditions and obligations attached to the Decision.

**Personnel:** the personnel currently employed by the Divestment Business, including Key Personnel, as listed in the Schedule.

**Purchaser:** with regard to the Divestment Business, the entity approved by the Commission as acquirer of the Divestment Business in accordance with the criteria set out in Section D.

**Synthes:** Synthes Inc., incorporated under the laws of Delaware, with its registered office at 1302 Wrights Lane East, West Chester, PA 19380, USA.

**Trustee(s):** the Monitoring Trustee and the Divestiture Trustee.

## **Section B. The Divestment Business**

### **Commitment to divest**

1. In order to restore effective competition, J&J commits to divest, or procure the divestiture of, the Divestment Business by the end of the Extended Divestiture Period as a going concern to a Purchaser and on terms of sale approved by the Commission in accordance with the procedure described in paragraph 0. To carry out each divestiture, J&J commits to find a purchaser and to enter into a final binding sale and purchase agreement for the sale of the

Divestment Business within the First Divestiture Period. If J&J has not entered into such agreement at the end of the First Divestiture Period, J&J shall grant the Divestiture Trustee an exclusive mandate to sell the Divestment Business in accordance with the procedure described in paragraph 28 in the Extended Divestiture Period.

2. J&J shall be deemed to have complied with this commitment if, by the end of the Extended Divestiture Period, J&J has entered into a final binding sale and purchase agreement, if the Commission approves the Purchaser and the terms in accordance with the procedure described in paragraph 0 and if the closing of the sale of the Divestment Business takes place within a period not exceeding [...] after the approval of the purchaser and the terms of sale by the Commission.
3. In order to maintain the structural effect of the Commitments, the Parties shall, for a period of 10 years after the Effective Date, not acquire direct or indirect influence over the whole or part of the Divestment Business, unless the Commission has previously found that the structure of the market has changed to such an extent that the absence of influence over the Divestment Business is no longer necessary to render the proposed concentration compatible with the common market.
4. In any event, the sale of any Divestment Business must only occur if the J&J acquisition of Synthes has closed.

#### **Structure and definition of the Divestment Business**

5. The Divestment Business consists of the Trauma Divestment Business as further defined in the Schedule.
6. The divestiture of the Divestment Business will proceed by way of an asset transaction (including transfer, sale, assignment, license, as the case may be and in so far as legally permissible). As a general rule, the divestiture shall include the following elements, as more specifically defined in the Schedule:
  - (a) all tangible and intangible assets (including intellectual property rights), which contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Business;
  - (b) all licences, permits and authorisations issued by any governmental organisation for the benefit of the Divestment Business;
  - (c) to the extent transferable, all contracts, leases, commitments and customer orders of the Divestment Business; all customer, credit and other records of the Divestment Business (items referred to under (a)-(c) hereinafter collectively referred to as "**Assets**");
  - (d) the Personnel; and
  - (e) at the option of the Purchaser, transitional agreements with J&J or Affiliated Undertakings for the supply of products and/or technical assistance, as detailed in the Schedule.

7. For the avoidance of doubt, a Divestiture Business shall not include:
  - (a) Intellectual property rights which do not contribute to the current operation of the Divestment Business or are not necessary to ensure the viability and competitiveness of the Divestment Business;
  - (b) The Johnson & Johnson and DePuy (including any and all Affiliated Undertakings) names and logos in any form;
  - (c) Books and records required to be retained pursuant to any statute, rule, regulation or ordinance, provided that copies of such documents necessary for the Divestment Business shall be provided to the Purchaser, upon request, as detailed in the Schedule; and
  - (d) Any personnel records maintained by J&J and general books of account and books of original entry that comprise J&J's or an Affiliated Undertaking's permanent accounting or tax records provided that copies of such documents necessary for the Divestment Business shall be provided to the Purchaser upon request, as detailed in the Schedule.

## **Section C. Related commitments**

### **Preservation of Viability, Marketability and Competitiveness**

8. From the Effective Date until Closing, J&J shall preserve the economic viability, marketability and competitiveness of the Divestment Business, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Business. In particular J&J undertakes:
  - (a) not to carry out any act upon its own authority that might have a significant adverse impact on the value, management or competitiveness of the Divestment Business or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Business;
  - (b) to make available sufficient resources for the development of the Divestment Business, on the basis and continuation of the existing business plans;
  - (c) to take all reasonable steps, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Business through Closing.
9. J&J shall use reasonable best efforts to the extent permitted by law, to facilitate the transfer of Key Personnel and any other Personnel who are desired by the Purchaser. J&J will encourage Key Personnel to transfer and make other Personnel available for interview in accordance with the size of the business in each country. J&J shall provide relevant contact details for the Personnel, or otherwise make such Personnel available to the Purchaser subject to compliance with applicable laws. Prior to Closing, J&J shall facilitate interviews between such Personnel and the Purchaser, shall not discourage such employee from participating in such interviews and shall not interfere in employment negotiations between such Personnel and the Purchaser.
10. With respect to such Personnel who receive an offer for employment from the Purchaser (conditional on or following the Closing), J&J shall do the following: (i) not prevent, prohibit

or restrict or threaten to prevent, prohibit or restrict the Personnel from being employed by the Purchaser, and not offer any incentive to the Personnel to decline employment with the Purchaser; (ii) if the Personnel accepts such offer of employment from the Purchaser, J&J shall cooperate with the Purchaser in effecting transfer of the Personnel to the Purchaser and J&J shall amend or waive the relevant provisions of employment agreements of Personnel so that they do not suffer adverse consequences as a result of their negotiations with, or acceptance of an offer from, the Purchaser.

### **Hold-separate obligations of Parties**

11. J&J commits, from the Effective Date until Closing and subject to paragraph 8, to keep the Divestment Business separate from the businesses it is retaining and to ensure that Key Personnel of the Divestment Business – including the Hold Separate Manager – have no involvement in any business retained and vice versa. J&J shall also ensure that the Personnel do not report to any individual outside the Divestment Business (if applicable).
12. Until Closing, J&J shall assist the Monitoring Trustee in ensuring that the Divestment Business is managed as a distinct and saleable business separate from the businesses retained by the Parties. J&J shall appoint a Hold Separate Manager who shall be responsible for the management of the Divestment Business, under the supervision of the Monitoring Trustee. The Hold Separate Manager shall manage the Divestment Business independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability and competitiveness and its independence from the businesses retained by the Parties.

### **Ring-fencing**

13. J&J shall implement all necessary measures to ensure that it does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Business. The participation of a Divestment Business in a central information technology network shall be severed to the extent possible, without compromising the viability of the Divestment Business. J&J may obtain information relating to the Divestment Business which is reasonably necessary for the divestiture of the Divestment Business or whose disclosure to J&J is required by law.

### **Non-solicitation clause**

14. J&J undertakes subject to customary limitations, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with the Divestment Business for a period of [...] after Closing.

### **Due Diligence**

15. In order to enable potential purchasers to carry out a reasonable due diligence of the Divestment Business, J&J shall, subject to customary confidentiality assurances and dependent on the stage of the divestiture process:
  - (a) provide to potential Purchasers sufficient information as regards the Divestment Business;



- (b) provide to potential Purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

### **Reporting**

- 16. J&J shall submit written reports in English on potential purchasers of the Divestment Business and developments in the negotiations with such potential purchasers to the Commission and the Monitoring Trustee no later than 10 days after the end of every month following the Effective Date (or otherwise at the Commission's request).
- 17. J&J shall inform the Commission and the Monitoring Trustee on the preparation of the data room documentation and the due diligence procedure and shall submit a copy of an information memorandum to the Commission and the Monitoring Trustee promptly after the Effective Date.

### **Section D. The Purchaser**

- 18. In order to ensure the immediate restoration of effective competition, the Purchaser, in order to be approved by the Commission, must:
  - (a) have sufficient experience of and capability to supply products that are marketed in the orthopaedic sector;
  - (b) be independent of and unconnected to the Parties;
  - (c) have the financial resources, proven expertise and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors; and
  - (d) neither be likely to create, in the light of the information available to the Commission, prima facie competition concerns nor give rise to a risk that the implementation of the Commitments will be delayed, and must, in particular, reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Business.

The before-mentioned criteria for the Purchaser are hereafter referred to as the "**Purchaser Requirements**".

- 19. The final binding sale and purchase agreement shall be conditional on the Commission's approval. When J&J has reached an agreement with a purchaser, it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), to the Commission and the Monitoring Trustee. J&J must be able to demonstrate to the Commission that the Purchaser meets the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Commitments. For the approval, the Commission shall verify that the Purchaser fulfils the Purchaser Requirements and that the Divestment Business is being sold in a manner consistent with the Commitments. The Commission may approve the sale of the Divestment Business without one or more assets or members of the Personnel, if this does not affect the viability and competitiveness of the Divestment Business after the sale, taking account of the proposed Purchaser.

## **Section E. Trustee**

### **I. Appointment Procedure**

20. J&J shall appoint a Monitoring Trustee to carry out the functions specified in the Commitments for a Monitoring Trustee. If J&J has not entered into a binding sales and purchase agreement one month before the end of the First Divestiture Period or if the Commission has rejected a purchaser proposed by J&J at that time or thereafter, J&J shall appoint a Divestiture Trustee to carry out the functions specified in the Commitments for a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Extended Divestiture Period.
21. The Trustee shall be independent of the Parties, possess the necessary qualifications to carry out its mandate, for example as an investment bank or consultant or auditor, and shall neither have nor become exposed to a conflict of interest. The Trustee shall be remunerated by the Parties in a way that does not impede the independent and effective fulfilment of its mandate. In particular, where the remuneration package of a Divestiture Trustee includes a success premium linked to the final sale value of the Divestment Business, the fee shall also be linked to a divestiture within the Extended Divestiture Period.

### **Proposal by the Parties**

22. No later than one week after the Effective Date, J&J shall submit a list of one or more persons whom J&J proposes to appoint as the Monitoring Trustee to the Commission for approval. No later than one month before the end of the First Divestiture Period, J&J shall submit a list of one or more persons whom J&J proposes to appoint as Divestiture Trustee to the commission for approval. The proposal shall contain sufficient information for the Commission to verify that the proposed Trustee fulfils the requirements set out in paragraph 21 and shall include:
  - (a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Trustee to fulfil its duties under these Commitments;
  - (b) the outline of a work plan which describes how the Trustee intends to carry out its assigned tasks;
  - (c) an indication whether the proposed Trustee is to act as both Monitoring Trustee and Divestiture Trustee or whether different trustees are proposed for the two functions.

### **Approval or rejection by the Commission**

23. The Commission shall have the discretion to approve or reject the proposed Trustee(s) and to approve the proposed mandate subject to any modifications it deems necessary for the Trustee to fulfil its obligations. If only one name is approved, J&J shall appoint or cause to be appointed, the individual or institution concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, J&J shall be free to choose the Trustee to be appointed from among the names approved. The Trustee shall be appointed within one week of the Commission's approval, in accordance with the mandate approved by the Commission.

### **New proposal by the Parties**

24. If all the proposed Trustees are rejected, J&J shall submit the names of at least two more individuals or institutions within one week of being informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 20 and 23.

### **Trustee nominated by the Commission**

25. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom J&J shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

## **II. Functions of the Trustee**

26. The Trustee shall assume its specified duties in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or J&J, give any orders or instructions to the Trustee in order to ensure compliance with the conditions and obligations attached to the Decision.

### **Duties and obligations of the Monitoring Trustee**

27. The Monitoring Trustee shall:
- (i) propose in its first report to the Commission a detailed work plan describing how it intends to monitor compliance with the obligations and conditions attached to the Decision.
  - (ii) oversee the on-going management of the Divestment Business with a view to ensuring their continued economic viability, marketability and competitiveness and monitor compliance by J&J with the conditions and obligations attached to the Decision. To that end the Monitoring Trustee shall:
    - (a) monitor the preservation of the economic viability, marketability and competitiveness of the Divestment Business, and the keeping separate of the Divestment Business from the business retained by the Parties, in accordance with paragraphs 8 and 11 of the Commitments;
    - (b) supervise the management of the Divestment Business as a distinct and saleable entity, in accordance with paragraph 12 of the Commitments;
    - (c) (i) in consultation with J&J, determine all necessary measures to ensure that J&J does not after the Effective Date obtain any business secrets, know-how, commercial information, or any other information of a confidential or proprietary nature relating to the Divestment Business, in particular strive for the severing of the Divestment Business' participation in a central information technology network to the extent possible, without compromising the viability of the Divestment Business, and (ii) decide whether such information may be disclosed to J&J as the disclosure is reasonably necessary to allow J&J to carry out the divestiture or as the disclosure is required by law;

- (d) monitor the splitting of assets and the allocation of Personnel between the Divestment Business and J&J or Affiliated Undertakings;
- (iii) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision;
- (iv) propose to J&J such measures as the Monitoring Trustee considers necessary to ensure J&J's compliance with the conditions and obligations attached to the Decision, in particular the maintenance of the full economic viability, marketability or competitiveness of the Divestment Business, the holding separate of the Divestment Business and the non-disclosure of competitively sensitive information;
- (v) review and assess potential purchasers as well as the progress of the divestiture process and verify that, dependent on the stage of the divestiture process, (a) potential purchasers receive sufficient information relating to the Divestment Business and the Personnel in particular by reviewing, if available, the data room documentation, the information memorandum and the due diligence process, and (b) potential purchasers are granted reasonable access to the Personnel;
- (vi) provide to the Commission, sending J&J a non-confidential copy at the same time, a written report within 15 days after the end of every month. The report shall cover the operation and management of the Divestment Business so that the Commission can assess whether the business is held in a manner consistent with the Commitments and the progress of the divestiture process as well as potential purchasers. In addition to these reports, the Monitoring Trustee shall promptly report in writing to the Commission, sending J&J a non-confidential copy at the same time, if it concludes on reasonable grounds that J&J is failing to comply with these Commitments;
- (vii) within one week after receipt of the documented proposal referred to in paragraph 0, submit to the Commission a reasoned opinion as to the suitability and independence of the proposed purchaser and the viability of the Divestment Business after the sale and as to whether the Divestment Business is sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestment Business without one or more Assets or not all of the Personnel affects the viability of the Divestment Business after the sale, taking account of the proposed purchaser.

### **Duties and obligations of the Divestiture Trustee**

28. Within the Extended Divestiture Period, the Divestiture Trustee shall sell at no minimum price the Divestment Business to a purchaser, provided that the Commission has approved both the purchaser and the final binding sale and purchase agreement in accordance with the procedure laid down in paragraph 0. The Divestiture Trustee shall include in the sale and purchase agreement such terms and conditions as it considers appropriate for an expedient sale in the Extended Divestiture Period. In particular, the Divestiture Trustee may include in the sale and purchase agreement such customary representations and warranties and indemnities as are reasonably required to effect the sale. The Divestiture Trustee shall protect the legitimate financial interests of J&J, subject to J&J's unconditional obligation to divest at no minimum price in the Extended Divestiture Period.

29. In the Extended Divestiture Period (or otherwise at the Commission's request), the Divestiture Trustee shall provide the Commission with a comprehensive monthly report written in English on the progress of the divestiture process. Such reports shall be submitted within 15 days after the end of every month with a simultaneous copy to the Monitoring Trustee and a non-confidential copy to J&J.

### III. Duties and obligations of the Parties

30. J&J shall provide and shall cause its advisors to provide the Trustee with all such cooperation, assistance and information as the Trustee may reasonably require to perform its tasks. The Trustee shall have full and complete access to any of J&J's or the relevant Divestment Business' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and J&J and the Divestment Business shall provide the Trustee upon request with copies of any document. J&J and the Divestment Business shall make available to the Trustee one or more offices on their premises and shall be available for meetings in order to provide the Trustee with all information necessary for the performance of its tasks.
31. J&J shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Business. This shall include all administrative support functions relating to the Divestment Business which are currently carried out at headquarters level. J&J shall provide and shall cause its advisors to provide the Monitoring Trustee, on request, with the information submitted to potential purchasers, in particular give the Monitoring Trustee access to the data room documentation and all other information granted to potential purchasers in the due diligence procedure. J&J shall inform the Monitoring Trustee on possible purchasers, submit a list of potential purchasers, and keep the Monitoring Trustee informed of all developments in the divestiture process.
32. J&J shall grant or procure Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale, the Closing and all actions and declarations which the Divestiture Trustee considers necessary or appropriate to achieve the sale and the Closing, including the appointment of advisors to assist with the sale process. Upon request of the Divestiture Trustee, J&J shall cause the documents required for effecting the sale and the Closing to be duly executed.
33. J&J shall indemnify the Trustee and its employees and agents (each an "**Indemnified Party**") and hold each Indemnified Party harmless against, and hereby agrees that an Indemnified Party shall have no liability to J&J for any liabilities arising out of the performance of the Trustee's duties under the Commitments, except to the extent that such liabilities result from the wilful default, recklessness, gross negligence or bad faith of the Trustee, its employees, agents or advisors.
34. At the expense of J&J, the Trustee may appoint advisors (in particular for corporate finance or legal advice), subject to J&J's approval (this approval not to be unreasonably withheld or delayed) if the Trustee considers the appointment of such advisors necessary or appropriate for the performance of its duties and obligations under the Mandate, provided that any fees and other expenses incurred by the Trustee are reasonable. Should J&J refuse to approve the advisors proposed by the Trustee the Commission may approve the appointment of such advisors instead, after having heard J&J. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 33 shall apply mutatis mutandis. In the Extended

Divestiture Period, the Divestiture Trustee may use advisors who served J&J during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

#### **IV. Replacement, discharge and reappointment of the Trustee**

35. If the Trustee ceases to perform its functions under the Commitments or for any other good cause, including the exposure of the Trustee to a conflict of interest:
  - (a) the Commission may, after hearing the Trustee, require J&J to replace the Trustee; or
  - (b) J&J, with the prior approval of the Commission, may replace the Trustee.
36. If the Trustee is removed according to paragraph 35, the Trustee may be required to continue in its function until a new Trustee is in place to whom the Trustee has effected a full hand over of all relevant information. The new Trustee shall be appointed in accordance with the procedure referred to in paragraphs 20-25.
37. Beside the removal according to paragraph 35, the Trustee shall cease to act as Trustee only after the Commission has discharged it from its duties after all the Commitments with which the Trustee has been entrusted have been implemented. However, the Commission may at any time require the reappointment of the Monitoring Trustee if it subsequently appears that the relevant remedies might not have been fully and properly implemented.

#### **Section F. The Review Clause**

38. The Commission may, where appropriate, in response to a request from J&J showing good cause and accompanied by a report from the Monitoring Trustee:
  - (i) Grant an extension of the time periods foreseen in the Commitments, or
  - (ii) Waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments.

Where J&J seeks an extension of a time period, it shall submit a request to the Commission no later than one month before the expiry of that period, showing good cause. Only in exceptional circumstances shall J&J be entitled to request an extension within the last month of any period.

\*\*\*\*\*

duly authorised for and on behalf of Johnson & Johnson

Name: Jonas Koponen

Title: Partner, Linklaters LLP

Date: 12 March 2012



## Schedule

### The Trauma Divestment Business

1. The Trauma Divestment Business is currently operated by DePuy and includes DePuy's trauma devices in the EEA and associated instruments, all as described in **Annex 1** (the "**Trauma Products**"). The Trauma Divestment Business essentially includes DePuy's global trauma R&D facility, the rights to develop and produce, the main production facility or the production equipment if requested, the rights to market and to sell in the EEA, sales and marketing personnel in the EEA and rights under EEA customer contracts, all relating directly and predominantly to the Trauma Products.

The Trauma Divestment Business does not constitute a separate legal entity and will be divested by way of an asset purchase agreement, most likely as part of a wider divestiture of J&J's worldwide trauma business or a substantial part thereof.

2. Following paragraph 5 of these Commitments, the Trauma Divestment Business includes:
  - (a) The following main tangible assets:
    - (i) The Miami facility of DePuy comprising DePuy's global R&D centre for trauma devices as described in **Annex 2** [...] including all furniture, fixtures and fittings therein.
    - (ii) If required by the Purchaser, the portion of the DePuy facility in Le Locle, Switzerland, utilized predominantly for the production of Trauma Products, including access to related logistics, as described in **Annex 3** under the terms of the current lease including all furniture, fixtures and fittings therein, subject to the Purchaser supplying J&J with support services during a transitional period.
    - (iii) Alternatively, if required by the Purchaser, following completion of the transitional supply of finished Trauma Products (as described at paragraph 2.(h)(i) of this Schedule), certain manufacturing equipment, tooling and fixtures at the DePuy facility in Le Locle, Switzerland, that are used exclusively for the manufacturing of Trauma Products. These assets are listed in **Annex 4**.
    - (iv) Existing inventory of finished Trauma Products held by DePuy as at Closing.
    - (v) Copies of any and all design history files, technical files, drawings, product specifications, manufacturing process descriptions, validation documentation, packaging specifications, quality control standards and regulatory records, save that any parts thereof that do not relate predominantly to the Trauma Products may be redacted from such copies.
    - (vi) Any and all proprietary demonstration models, prototypes, samples, instruments, and supporting equipment utilized predominantly in connection with the Trauma Products for training purposes in the EEA and copies of



- any and all training materials that are used for training that is specific to the proper use of the Trauma Products and designed for use in the EEA, save that any parts thereof that do not relate predominantly to the Trauma Products may be redacted from such copies.
- (vii) Copies of any and all current proprietary advertising and promotional materials designed for the EEA and used in connection with the Trauma Products, save that any parts thereof that do not relate predominantly to the Trauma Products may be redacted from such copies.
  - (viii) Copies of any and all proprietary testing and clinical data, market research reports, marketing plans and other marketing-related information and materials that are used in connection with the Trauma Products and designed for the EEA, save that any parts thereof that do not relate predominantly to the Trauma Products may be redacted from such copies.
- (b) The following main intangible assets, to the extent that they are owned or licensed by DePuy:
- (i) The assignment (or perpetual, irrevocable, exclusive, royalty free licenses, if assignment is not reasonably practicable) of all patents (including patent applications) which are owned by DePuy, or patent rights licensed-in by DePuy, which contribute to the current operation of, or are necessary to ensure the viability and competitiveness of, the Trauma Divestment Business, including but not necessarily limited to those set out in **Annex 5**, subject to a perpetual, irrevocable, exclusive, royalty-free licence back to J&J as needed for retained businesses.
  - (ii) The trademarks listed in **Annex 6**.
  - (iii) The assignment (or perpetual, irrevocable, exclusive, royalty free licenses, if assignment is not reasonably practicable) of all technical and manufacturing know-how, trade secrets and designs which are owned or licensed-in by DePuy, and contribute to the current operation of or are necessary to ensure the viability and the competitiveness of the Trauma Divestment Business.
  - (iv) Any copyrights in J&J's marketing materials and support documents exclusively used in connection with the Trauma Products.
  - (v) The transfer of (either directly or by means of withdrawal and re-registration) the internet domain names relating exclusively to the Trauma Divestment Business as listed in **Annex 7**.
  - (vi) The transfer of, or, if not legally possible, access to, as appropriate, all licences, permits and authorisations issued by any governmental organisation in the EEA and held by J&J or its Affiliated Undertakings necessary to develop and/or manufacture the Trauma Products and/or to market and sell them within the EEA, including all relevant dossiers relating to the current and/or pending authorisations held or sought by J&J or its Affiliated Undertakings relating exclusively to the Trauma Products, and, where necessary, reasonable assistance (which shall not require J&J to conduct or pay for any trial or study) related to the transfer to the Purchaser of such licenses, permits and authorizations, and providing reasonable

assistance (which shall not require J&J to conduct or pay for any trial or study) to the Purchaser to make any regulatory filings and obtain any authorisations that are necessary for the development and/or manufacture of the Trauma Products and/or their, marketing and/or sale in the EEA.

- (c) The transfer of, or, if not legally possible, access to all current and pending CE marks relating to the Trauma Products held by J&J or its Affiliated Undertakings including all relevant dossiers relating to the current and/or pending CE marks held or sought by J&J or its Affiliated Undertakings relating to the Trauma Products, and, where necessary, reasonable assistance (which shall not require J&J to conduct or pay for any trial or study) to the Purchaser to make any necessary regulatory filings and obtain any necessary authorisations within the EEA for product registration and CE-marking of Trauma Products under the Purchaser's brand names. J&J retains the right to reference the above material in J&J's own dossiers for its own future products.
- (d) Rights under the following main contracts, agreements, leases, commitments and understandings:
  - (i) If required by the Purchaser, and to the extent legally transferable, those rights under sub-contracting agreements to the extent such rights relate to the manufacture of Trauma Products (**Annex 8**). In the event that such arrangements cannot be made, J&J will conclude back-to-back supply agreements with the Purchaser to make the relevant devices available to the Purchaser on a cost-plus basis for a transitional period of up to 24 months. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Purchaser demonstrates delays in securing regulatory approvals required to sell one or more Trauma Products in an EEA country.
  - (ii) If required by the Purchaser, and to the extent legally transferable, those rights under the supply agreements to the extent such rights relate to the Trauma Products (Annex 8). In the event that such arrangements cannot be made, J&J is willing to conclude back-to-back supply agreements with the Purchaser to make the relevant input materials available to the Purchaser on a cost-plus basis for a transitional period of up to 24 months. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Purchaser demonstrates delays in securing regulatory approvals required to sell one or more Trauma Products in an EEA country.
  - (iii) If required by the Purchaser, and to the extent legally transferrable, those rights under the distribution and agency agreements listed in Annex 8 to the extent such rights relate to the marketing and sale of the Trauma Products in the EEA. J&J is willing to waive any rights to exclusivity for a period of up to 12 months after Closing.
  - (iv) If required by the Purchaser, and to the extent legally transferrable, those rights under the consultancy agreements concluded with key opinion leaders ("KOLs") to the extent such rights relate to the Trauma Products used or sold in the EEA.

- (v) If required by the Purchaser, and to the extent legally transferrable, those rights under the development agreements concluded with KOLs to the extent such rights relate to the Trauma Products used or sold in the EEA.
- (e) The following customer, credit and other records:
  - (i) Customer lists to the extent relating to the Trauma Products sold in the EEA as at the date of Closing; provided, however, that J&J may continue to use such lists to the extent they relate to its retained businesses; and provided further, that any parts of such customer lists that do not relate to the Trauma Products may be redacted from the lists delivered to the Purchaser. A customer list is attached as **Annex 9**.
  - (ii) Customer credit and other customer records relating to the Trauma Products sold in the EEA, provided, however, that J&J may continue to use such records to the extent they relate to its retained business; and provided further, that any parts of such customer records that do not relate to the Trauma Products may be redacted from the lists delivered to the Purchaser. To the extent that J&J is obliged to retain copies of such documents in support of legal obligations J&J shall be entitled to do so.
  - (iii) Copies of all books, ledgers and other business records to the extent that they relate predominantly to the Trauma Products, save that any parts thereof that do not relate to the Trauma Products may be redacted from such copies.
  - (iv) Clinical, regulatory, and customer sales databases supporting the Trauma Divestment Business that are incorporated into the J&J reporting systems, provided, however, that J&J may continue to use such databases to the extent they relate to its retained businesses; and provided further, that any parts of such databases that do not relate to the Trauma Products may be redacted from the databases delivered to the Purchaser.
- (f) J&J shall cause DePuy to incentivise (in accordance with normal business practices) the Key Personnel, as listed in **Annex 10**, to continue employment with the Divestment Business through Closing.
- (g) The Purchaser will be given an opportunity to solicit for employment the Personnel as further specified in **Annex 11** (including, if reasonably necessary, [...]), as described in paragraphs 9 to 10 of these Commitments.
- (h) If needed by the Purchaser, arrangements specified in **Annex 12** for the provision of the following products or services by J&J or Affiliated Undertakings during a transitional period of up to 24 months after Closing. This period may be extended by the Monitoring Trustee for a further period of up to 12 months if the Purchaser demonstrates delays in securing regulatory approvals required to sell one or more Trauma Products in an EEA country.
  - (i) The supply on a reasonable cost plus basis to be agreed with the Purchaser of the Trauma Products; and
  - (ii) Reasonable technical and transitional assistance to the Purchaser to assume responsibility for the manufacture, quality, sales and marketing, research and development, regulatory, professional education and

customer support of the Trauma Products on a reasonable cost plus basis to be agreed with the Purchaser.

3. In the event that materials to be transferred contain information that is confidential to J&J's retained businesses, this information shall be redacted as appropriate.
4. The Trauma Divestment Business shall not include:
  - (a) Any facilities of J&J or its Affiliated Undertakings (and all permits, licenses and authorisations relating thereto), save as provided for in Section 2 of this Schedule.
  - (b) Any furniture, fixtures, machinery, tooling or other equipment (and all permits, licenses and authorisations relating thereto), save as provided for in Section 2 of this Schedule.
  - (c) The distribution/logistics infrastructure supporting the Trauma Divestment Business.
  - (d) Any trademarks other than the trademarks listed in Annex 6. Common law trademarks including the company names of DePuy or any of its Affiliates are not included in the Trauma Divestment Business.
  - (e) Any internet domain names other than the domain names listed in Annex 7.
  - (f) Any patents or other intellectual property rights, save as provided for in Section 2 of this Schedule.
  - (g) All information management systems, and computer software and hardware.
  - (h) Any personnel not listed in Annexes 10 and 11.
  - (i) Any personnel records maintained by J&J and the general books of account and books of original entry that comprise J&J's or an Affiliated Undertaking's permanent accounting or tax records.
  - (j) Any insurance policies, nor any claims thereunder.
  - (k) Any rights or assets relating to any product not listed in Annex 1.
  - (l) Any books, records, materials, information or other assets that do not relate predominantly to the Trauma Products.
  - (m) Any authorisations which may not be transferred by their terms or without the consent of a third person and for which such consent has not been forthcoming, notwithstanding reasonable efforts by J&J to obtain such consent.
  - (n) Those portions of or rights under contracts that do not predominantly relate to the Trauma Products and (i) the purchase agreement with respect to the Trauma Divestment Business and all agreements ancillary thereto, and (ii) any contracts among J&J entities.
  - (o) Any assets or properties that are used by J&J or an Affiliated Undertaking to provide DePuy and / or other J&J businesses generally with services and support of an overhead, sales back office, administrative or managerial nature.
  - (p) Bank accounts, cash, accounts, receivables, VAT deposits, or hedging or other currency exchange agreements.
  - (q) Intellectual property rights relating to materials contained in the ORTHOSORB product or production of such materials.

- (r) All assets in, to or under which Synthes or any of its subsidiaries has any right, title or interest. \*\*\*\*\*

## Annex 1: The Trauma Products

The Trauma Divestiture Business includes the following products and associated instrumentation sold in the EEA, referred to collectively as Trauma Products. Associated instrumentation is that used exclusively in connection with the above-mentioned products in the EEA.

Device/Brand	Category
Pins (non-branded)	Ancillary devices / other
Staples (non-branded)	Ancillary devices / other
Wires (non-branded)	Ancillary devices / other
Hip Fx – SS cannulated screw	Large cannulated screw
Hip Fx – Ti cannulated screw	Large cannulated screw
ACE Cannulated screw	Medium cannulated screw
ACE Cannulated screw	Small cannulated screw
Barouk	Small cannulated screw
FRS	Small cannulated screw
Twist-Off	Small cannulated screw
SCFE	Small cannulated screw
Olmed Screw	Small cannulated screw
Captured Hip Screw	Compression Hip Screw
Compression Hip Screw	Compression Hip Screw
CIS Plates	Compression Hip Screw
Corso Plates	Compression Hip Screw
Glorion Screws	Compression Hip Screw
Maconor II Nail Plate	Compression Hip Screw
Ace-Fischer System	External fixation
Percy FX	External fixation
Other Ex-Fix	External fixation

<b>Device/Brand</b>	<b>Category</b>
Affixus	IM Hip Screw
ATN	IM Hip Screw
Versanail Femoral (incl. Troch Entry, Universal)	IM nail (femoral)
ACE (Femoral Nail, Supracondylar)	IM nail (femoral)
ART Nail	IM nail (femoral)
Versanail Humeral (incl. Universal, Proximal Humeral)	IM nail (humeral)
ACE Humeral	IM nail (humeral)
Versanail Tibial, Tibia	IM nail (tibial)
ACE (Tibial, Dynamic Tibial)	IM nail (tibial)
Versanail TTC	IM nail (ankle)
ALPS Distal Tib / Fib	Plates and screws
ALPS Elbow	Plates and screws
ALPS Meta Plate,	Plates and screws
ALPS Anterolateral Plate,	Plates and screws
ALPS Medial Pilon Plate	Plates and screws
ALPS Distal Fibula Composite Plate	Plates and screws
ALPS Calcaneus Plate	Plates and screws
ALPS Midfusion Plate	Plates and screws
ALPS Lateral Column Lengthening Plate	Plates and screws
ALPS 1st MTP Plate	Plates and screws
ALPS Navicular Plate	Plates and screws
ALPS Talus Plate	Plates and screws

<b>Device/Brand</b>	<b>Category</b>
DNP	Plates and screws
PolyAx	Plates and screws
S3	Plates and screws
ACE Large Frag	Plates and screws
ACE Small Frag	Plates and screws
ALPS Large Frag	Plates and screws
ALPS Small Frag	Plates and screws
SS Small Frag	Plates and screws
SS Mini Frag	Plates and screws
SS Large Frag	Plates and screws
F3 (Mini-Frag)	Plates and screws
ALPS Hand (Mini-Frag)	Plates and screws
DVR	Plates and screws (wrist)

The Trauma Products also include following pipeline products:

<b>Project</b>	<b>Category</b>
[...]	[...]



## **Annex 2: The Miami, FL, R&D facility**

### **1. The Facility**

The R&D Facility is located [...], Miami, [...]. The R&D facility is part of a multi-story, multi tenant office building of [...] office space.

The images below provide a visual description of the office building.



### **2. Assets**

The assets that will transfer with the R&D facility include all furniture, fixtures and fittings relating to R&D.

### Annex 3: The Le Locle, CH, Production facility (Girardet)

Manufacturing and production of the Trauma Products takes place at the LeLocle site in Switzerland. This site is [...] shared with other non-trauma related businesses.



## Le Locle

Trauma Divestment Business manufacturing is located [...] in a [...], multi-story, multi-use facility (the “**Girardet**” building). Manufacturing is limited to three of the four floors in the building. The other floor is occupied by [...], a non-trauma related business, [...]. There is no other trauma production on that site.

The following manufacturing technologies/capabilities related to the Trauma Divestment Business are employed on the relevant floors of Girardet:

- Clean Room Assembly
- Metal Machining
- Milling
- Packaging - Blister
- Packaging – Carton
- Cleaning
- Surface treatment (anodization)

## **Annex 4: Le Locle manufacturing assets**

The LeLocle facility offers a broad capability for the manufacture, assembly and packaging of the Trauma Products. If the Purchaser requests that the trauma production facility at the Le Locle site shall be part of the Trauma Divestment Business, J&J shall have the option to request the Purchaser to provide it with support services during a transitional period.

### **1. Equipment for Manufacture, Assembly and Final Packaging**

- Milling machinery and manufacturing equipment and tools
- Turning machinery and manufacturing equipment and tools
- Deburring and polishing machinery and manufacturing equipment and tools
- Marking machinery and manufacturing equipment and tools
- Cleaning and degreasing machinery and manufacturing equipment and tools
- Anodizing machinery and manufacturing equipment and tools
- Packaging machinery and tools
- Measuring equipment and tools
- Miscellaneous support machinery and tools

### **2. Facility Modifications**

- Cooling systems
- Fluid and air waste management systems
- Water and air purification systems
- Clean room facilities

### **3. Support Items**

- Office equipment
- Supporting hardware and software [...]

## Annex 5: Patents and patent rights

As at 1 February 2012 the patents owned and patent rights licensed to DePuy relating to the Trauma Divestment Business are as listed in the table below. [...]

Patent Family #	Short Title	Country	Event	Filing date	Filing number
[...]	[...]	[...]	[...]	[...]	[...]

## **Annex 6: Trademarks**

DePuy's interests in common law trademarks related to the Trauma Products listed in Annex 1 and the following registered trademarks form part of the Trauma Divestment Business:

- [...]

## **Annex 7: Internet domain names**

The following domain names form part of the Trauma Divestment Business:

- [...]

## Annex 8: Agreements

### 1 Suppliers of raw/input materials

The Trauma Divestment Business utilises various suppliers of raw and input materials. The key input for the production is titanium, which is sourced from [...]. Below we provide an overview of major suppliers.

Suppliers	Raw/input material	Location
[...]	[...]	[...]

### 2 Subcontracting agreements

The Trauma Divestment Business utilises certain third-party manufacturers/service providers to which parts of the production or certain production steps are outsourced. Below we provide an overview of major external manufacturers/service providers for various categories of devices/services.

Supplier	Provided devices/services	Location
[...]	[...]	[...]

### 3 Distribution agreements

The distribution agreements listed in the table below relate to the Trauma Divestment Business. J&J is willing to waive any exclusivity rights under these agreements for a period of up to [...] after Closing.

Distributor	Country of Distribution
[...]	Bulgaria
[...]	Estonia
[...]	France
[...]	Lithuania
[...]	Norway
[...]	Portugal
[...]	Spain

#### 4 Agency agreements

The agency agreements listed in the table below relate to the Trauma Divestment Business. J&J is willing to waive any exclusivity rights under these agreements for a period of up to [...] after Closing.

<b>Agent</b>	<b>Country of Agency</b>
[...]	Denmark
[...]	Ireland
[...]	Italy
[...]	Sweden



**Annex 9: Customer list (2011)**

Country	Customer (sold - to)	US\$ (2011)
[...]	[...]	[...]

**Annex 10: Key Personnel**

The Key Personnel for the Trauma Divestment Business are listed in the table below.

Employees at the Le Locle/Girardet facility in charge of the trauma production shall only be treated as Key Personnel if and as from the moment that the Purchaser requests the trauma facility to be included in the Trauma Divestment Business.

<b>Location</b>	<b>Function</b>
UK	[...]
UK	[...]
Miami, Florida	[...]
Le Locle/Girardet, Switzerland	[...]
Le Locle/Girardet, Switzerland	[...]

**Annex 11: Personnel**

The Personnel of the Trauma Divestment Business is identified below.

**1. Sales and Marketing**

The table below indicates the location and number of sales and marketing employees who will be made available to the Purchaser. Depending on the needs of the Purchaser, J&J would be willing to adjust this list.

<b>Country/Region</b>	<b>Function</b>	<b>Number of Employees available</b>
EMEA	[...]	2
Austria	[...]	1
Baltics	[...]	1
Benelux	[...]	2
Czech Republic	[...]	1
France	[...]	3
Germany	[...]	3
Italy	[...]	3
Poland	[...]	1
Portugal	[...]	2
Slovenia	[...]	1
Slovakia	[...]	1
Spain	[...]	3
UK	[...]	25
Total	[...]	49

Among the employees in the UK [...].

For each of the Benelux, France and Portugal, J&J may require that one non-dedicated sales employee (i.e., a person with sales and marketing responsibilities relating to trauma as well as [...]) who is referenced in this table and accepts an offer of employment from the Purchaser, not market, promote or sell [...] during a period of 12 months following Closing or, if the employee does not commence his or her

employment with the Purchaser at Closing, the subsequent date when the employee commences his or her employment with the Purchaser.

## **2. Production at Le Locle, Switzerland**

Approximately 235 employees are dedicated to the manufacture of the Trauma Products at the Le Locle production facility and will be made available should the Purchaser request that the production facility is included in the Trauma Divestment Business.

[...]

## **3. R&D Miami, Florida**

There are approximately 20 employees that form part of the trauma R&D team at the Miami R&D facility [...].

## **Annex 12: Transitional arrangements**

### **Products**

- The supply agreement will cover the Trauma Products (other than those supplied under third party contracts that are assigned to the Purchaser). The agreement will include appropriate provisions allowing the Purchaser to withdraw specific Trauma Products from the scope of the agreement, thus allowing it to self-supply or outsource once it is in a position to do so.
- During the Transitional Period, Trauma Products will be sold to the Purchaser on a reasonable cost-plus margin basis. Cost shall be defined in accordance with Generally Acceptable Accounting Principles and negotiated by J&J or DePuy and the Purchaser at a level consistent with standard industry practice.
- The supply agreement shall include appropriate provisions with regard to regulatory compliance.
- The Purchaser shall be required to send DePuy non-binding forecasts of its reasonably expected requirements for Trauma Products (firm and binding as to the next three months).
- The supply agreement shall include appropriate provisions with regard to DePuy building and keeping an adequate safety stock of products at all times during the duration of the transitional supply agreement. The Monitoring Trustee may recommend appropriate safety stock levels to ensure security of supply, or if necessary, such additional supply-related measures as may be reasonably needed to ensure that product is available to the Purchaser.
- The Purchaser may terminate the supply agreement at its discretion on [...] months' notice.
- Delivery of the Trauma Products will be made in a timely manner and according to a pre-defined schedule, in line with standard industry practice.

### **2. Technical and transitional assistance**

- DePuy shall be required to provide, on a reasonable cost plus basis in any application for product approval for Trauma Products from competent regulatory bodies in the EEA, support to the Purchaser, if needed in order to set up a in a timely manner a competitive business and in particular DePuy shall provide to the Purchaser or the regulatory body such information as is reasonably requested by that body.
- DePuy shall be required to provide support to the Purchaser on a reasonable cost plus basis with respect to certain administrative services that the purchaser needs in order to set up a in a timely manner a competitive business, including customer service, finance services and selling and marketing support.
- Technical support that the purchaser needs in order to set up a in a timely manner a competitive business shall be granted on a reasonable cost plus basis in accordance with good industry practice including as regards the timing and responsiveness with which this assistance is provided through the different stages of the transfer.
- The transitional services agreement may foresee an incentive mechanism aiming at reducing the overall duration of the contract below the maximum term.