EUROPEAN COMMISSION
DG Competition

# *Case M.8060 - ABBOTT LABORATORIES / ST JUDE MEDICAL*

Only the English text is available and authentic.

## REGULATION (EC) No 139/2004
## MERGER PROCEDURE

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Article 6(1)(b) in conjunction with Art 6(2)
Date: 23/11/2016

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EUROPEAN COMMISSION

Brussels, 23.11.2016
C(2016) 7730 final

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus […]. Where possible the information omitted has been replaced by ranges of figures or a general description.

PUBLIC VERSION

MERGER PROCEDURE

**To the notifying party:**

Dear Madam(s) and/or Sir(s),

**Subject: Case M.8060 - Abbott Laboratories / St Jude Medical**
**Commission decision pursuant to Article 6(1)(b) in conjunction with Article 6(2) of Council Regulation No 139/2004[1] and Article 57 of the Agreement on the European Economic Area[2]**

(1) On 3 October 2016, the European Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004[3] by which Abbott Laboratories (Abbott, USA) acquires within the meaning of Article 3(1)(b) of the Merger Regulation control of the whole of St Jude Medical Inc. (St Jude, USA) by way of purchase of shares (hereinafter referred to as "the Transaction"). Abbott is also referred to as "the Notifying Party", and together with St Jude as "the Parties".

## I. THE PARTIES AND THE OPERATION

(2) **Abbott** is a US-based company active worldwide in the development, manufacturing and sale of various healthcare products, in particular nutritional

1 OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation'). 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.

2 OJ L 1, 3.1.1994, p. 3 (the 'EEA Agreement').

3 OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

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products, medical devices comprising vascular products, optical products and diabetes care, diagnostic products and pharmaceutical products.

(3) **St Jude** is a US-based company active in the development, manufacturing and sale of cardiovascular medical devices, including traditional cardiac rhythm management products, heart failure products, cardiovascular products, atrial fibrillation products and neuromodulation products.

(4) The Transaction involves Abbott acquiring St Jude through two subsidiary mergers. In result Abbott will acquire control of the whole of St Jude by way of purchase of shares. Therefore, the Transaction constitutes a concentration within the meaning of Article 3(1)(b) of the Merger Regulation.

## II. EU DIMENSION

(5) The undertakings concerned have a combined aggregate world-wide turnover of more than EUR 5 000 million[4] (Abbott: EUR 18 391 million; St Jude: EUR 5 343 million). Each of them has EU-wide turnover in excess of EUR 250 million (Abbott: EUR […] million; St Jude: EUR […] million), but neither achieves more than two-thirds of its aggregate EU-wide turnover within one and the same Member State. The notified operation therefore has an EU dimension under Article 1(2) of the Merger regulation.

## III. COMPETITIVE ASSESSMENT

### III.1. Introduction

(6) Both Abbott and St Jude are active in the field of cardiovascular products, with largely complementary portfolios.

(7) Cardiovascular products can be grouped into four main areas: vascular products (used for vascular access, such as vessel closure devices, guidewires, catheters and stents), electrophysiology devices (used for the diagnosis and treatment of abnormalities in the timing or pattern of the heartbeat, such as atrial fibrillation), structural heart (devices used in procedures to repair and replace heart valves) and cardiac rhythm management products, such as pacemakers.

(8) While Abbott has a very broad portfolio of vascular products (guidewires, catheters and stents) and is hardly present in the other cardiovascular areas, St Jude has a very strong presence in the EP devices (offering wide range of catheters, recording, mapping and navigation devices and EP accessories), in structural heart products (heart occluders, mechanical heart valves, valve repair) and cardiac rhythm management products (such as pacemakers and defibrillator systems and devices).

(9) The Parties' activities overlap in the following areas:

a. Within the area of vascular products: on the market for vessel closure devices (VCDs), on which both Parties offer products on the market;

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4 Turnover calculated in accordance with Article 5 of the Merger Regulation and the Commission Consolidated Jurisdictional Notice (OJ C 95, 16.4.2008, p. 1).

b. Within the area of devices used in electrophysiology (EP) procedures, on the market for transseptal sheaths, where St Jude is present on the market and Abbott has a pipeline product (market-to-pipeline overlap);[5]

c. Within the area of coronary products, on the market for devices used in structural heart diseases, on which both Parties develop competing products for transcatheter mitral valve replacement (TMVR) (pipeline-to-pipeline overlap).

## III.2. Vessel closure devices

### *III.2.1. Market definition*

(10) Cardiovascular disease is increasingly being treated using a technique known as 'vascular access', by which the physician accesses the heart or vascular system through a blood vessel, rather than by means of open heart surgery.

(11) Vascular access involves inserting a sheath into the vessel, through which the devices needed to perform the procedure are then guided towards the treatment site. The hole created in the artery as a result of this procedure then needs to be closed to prevent blood loss.

(12) There are a number of possible methods for closing the hole in the artery: manual compression, surgical suturing, closure assist devices (CADs) and vessel closure devices (VCDs). As explained by the Notifying Party, the appropriate method for vessel closure depends, in part, on the site of access (usually radial or femoral), the size of the hole (a two-way distinction normally being made between 'small' and 'large', as described below), and whether the hospital would prefer to be able to discharge patients the same day.

a. Manual compression is the application of pressure to the skin above the access site for several minutes, until the hole begins to heal naturally. The Parties maintain that manual compression is considered to be the 'gold standard' for vessel closure of small holes, and that it thus constitutes the standard against which VCDs are measured.

b. CADs are devices that help achieve hole closure either by compressing an artery or by secreting a blood clotting substance that speeds up healing. Manual compression and CADs can be used in combination.

c. Surgical suturing is the suturing of the vessel by hand.

d. VCDs are devices that are inserted into or placed on the hole in the artery. Each VCD is indicated for a specific range of hole sizes and there are a number of different types available, such as clips, plugs and suturing devices.

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5 In the area of EP devices, at the point in time when the Transaction was first notified there appeared to also be an overlap in ablation catheters, between St Jude's marketed products and the pipeline ablation catheter developed by a company in which Abbott had a call option. In the meantime, however, the commercial and contractual links between Abbott and that company have been terminated, and the potential overlap thus removed.

(13) Vessel closure devices are always indicated for use on a particular range of sizes of hole. The size of the hole in the artery is measured on a scale referred to as 'French' or 'F'.[6] Small holes are considered to be those up to and including 8F (the smallest standard size being 3F), and large holes those above 8F (the largest standard size being 24F).

(14) The Parties have the following products in the area of vessel closure.

Table 1: The Parties' vessel closure devices:

| Supplier | Product | Type of product | Indication | Use, according to parties | | EEA Sales figure |
|---|---|---|---|---|---|---|
| | | | | Small hole | Large hole | |
| **Abbott** | StarClose | Clip-based VCD | 5-6F, femoral | Y | | EUR [5-10]m |
| | ProGlide | Suture-based VCD | 5-21F, femoral | Y | Y | EUR [20-30]m |
| | ProStar | Suture-based VCD | 8.5-24F, femoral | | Y | EUR [5-10]m |
| **St Jude** | AngioSeal | Plug-based VCD | 6F, 8F, femoral | Y | | EUR [60-70]m |
| | FemoSeal | Plug-based VCD | ≤7F, femoral | Y | | EUR [10-20]m |
| | RadiStop | CAD | radial | Y | | EUR [5-10]m |
| | FemoStop | CAD | femoral | Y | | |

Source: Form CO

(15) The types of procedures requiring vessel closure can be broadly categorised as being either coronary or peripheral. Within each of these categories, a number of specific types of procedure can be identified, each of which is typically associated with a particular size of hole:

Table 2: Types of procedures requiring vessel closure devices:

| Procedure | | Purpose of procedure | Hole size |
|---|---|---|---|
| **Coronary** | Diagnostics (angiography) | Locate blockages and other problems | 4-6F |
| | Percutaneous coronary interventions (PCI) | Open blockages in the coronary arteries that supply the heart | 6-8F |
| | Structural heart | Correct problems with heart valves and other heart structures, including transcatheter aortic valve implantation (TAVI), transcatheter aortic valve repair (TAVR) and transcatheter mitral valve repair (TMVr) | ≥10F |
| **Peripheral** | Diagnostics (peripheral angiography) | Locate blockages and other problems | ≤8F |
| | Intervention | Unblock peripheral vessels and improve blood flow | ≤8F |
| | Endovascular aneurysm repair (EVAR), | Correct aneurysms of the peripheral vascular system | ≥10F |

[6] One French is equal to one third of millimetre.

| | |
|---|---|
| | including aortic aneurism repair (AAA) and thoracic endovascular aneurysm repair (TEVAR) |

Source: Form CO.

(16) The Commission has not previously considered the market for vessel closure devices.

(17) The Notifying Party claims that there are distinct sets of treatment options available to physicians for the closure of small and large holes, respectively.

(18) The Notifying Party considers the market for small-hole vessel closure to include manual compression,[7] CADs and small-hole VCDs, and the market for large hole vessel closure to include large-hole VCDs and surgical suturing.[8] The Notifying Party also maintains that there is no need to further separate the market according to: (i) closure method,[9] (ii) access point,[10] or (iii) type of procedure.[11]

(19) The results of the market investigation confirmed the view that there is, in general, a distinction between the devices/techniques used for small- and large-hole vessel closure respectively.[12] Although, as stated by the Notifying Party, the type of procedure does not, *per se*, determine the vessel closure device used, from a physician's point of view, certain VCDs (or other closure methods) are typically associated with certain procedures. This is because, for example, a TAVI procedure (as referred to in the table above) would almost always require large-hole closure, and the VCDs indicated for this size of hole would therefore be chosen. The responses to the market investigation generally showed a pattern, with the large majority of physicians using the same devices for particular procedures, corresponding to the size of hole to be closed. This confirmed the distinction made by the Parties, in terms of there being certain VCDs indicated and used for small-hole closure and others for large-hole closure. There are, however, some products,

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7 The Notifying Party argues that the relative cost of a VCD and of manual compression (measured as the time spent by medical professionals and the hospital bed time) is a factor influencing physicians' choice of whether or not to use a VCD.

8 The Notifying Party classifies clip- and plug-based VCDs as small-hole VCDs, and suture-based VCDs as large hole VCDs.

9 According to the Notifying Party, within each of the two markets (small holes and large holes), all of the techniques belonging to that market are available to physicians.

10 VCDs are indicated for use only in femoral (and not radial) procedures. The Notifying Party submits that CADs and manual compression, both of which are indicated for use on radial access points, are part of the same product market, which therefore implies that the product market covers both access points.

11 According to the Notifying Party, beyond determining the access method and size of the hole, the type of procedure does not have any further influence on the choice of closure device.

12 Product indications and physicians' practices suggest that the options available to physicians do depend, to a large extent, on the size of the hole (8F or smaller, or larger than 8F).

such as Abbott's ProGlide, whose indication covers both small and large holes, and which were mentioned in the context of various types of procedure.[13]

(20) Due to the fact that VCDs are used in a number of different procedures, belonging to different areas of medicine, physicians often only have experience of using these devices in one or a couple of their possible settings. The results of the market investigation showed that physicians tend to think in terms of procedures rather than making the distinction small hole v. large hole, as put forward by the Notifying Party. Nonetheless, each type of procedure is typically always a small-hole procedure or always a large hole procedure, and so this does not necessarily invalidate the division of the market by hole size. In order to give a truer reflection of the responses to the market investigation, the following paragraphs therefore discuss the devices used in different types of procedures, but it should be noted that the Commission has not considered this as a possible basis for division of the market, as the actual technique of vessel closure and the devices suitable for use are only dependent on the procedure insofar as the procedure determines the hole size.

(21) Respondents to the market investigation who performed any type of structural heart procedure (mainly TAVI or TAVR) generally reported using Abbott's ProStar or ProGlide. These two products were mentioned with roughly equal frequency, while mention of any other product was minimal.[14]

(22) Respondents to the market investigation who performed coronary interventions (PCI) mentioned that they use a wider range of products. St Jude's AngioSeal was, nonetheless, by far the most widely used product. Abbott's StarClose and St Jude's FemoSeal appeared to be roughly equal second-placed in terms of physician preferences, with Abbott's ProGlide slightly behind these two products.[15]

(23) For peripheral procedures (apart from endovascular aneurysm repair (EVAR)), AngioSeal and StarClose were the preferred products. ProGlide, and to a slightly lesser extent, ProStar appeared to be the standard products for all types of EVAR procedures (in particular TEVAR, FEVAR and AAA).[16]

(24) The necessity of VCDs was shown to depend mainly on the type of procedure. The vast majority of doctors who commented on these types of procedure considered VCDs essential for structural heart interventions (including transcatheter aortic valve implantation (TAVI)) and endovascular aneurysm repair (abdominal aortic aneurysms (AAA)), endovascular aneurysm repair (EVAR) and thoracic endovascular aortic repair (TEVAR). For all these procedures, access is through the femoral artery.

(25) For diagnostic and interventional coronary and peripheral procedures, meanwhile, access can be either radial or femoral, with VCDs only being used in the latter case. Unlike for structural heart procedures, VCDs are also not universally viewed as essential for 100% of femoral access coronary and peripheral procedures, but are very widely used by the majority of doctors. There are, nonetheless, a minority of

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13 Replies to Questionnaire Q2 – Questionnaire to Doctors, questions 3, 4 and 6.

14 Replies to Questionnaire Q2 – Questionnaire to Doctors, questions 3, 4 and 6.

15 Replies to Questionnaire Q2 – Questionnaire to Doctors, questions 3, 4 and 6.

16 Replies to Questionnaire Q2 – Questionnaire to Doctors, questions 3, 4 and 6.

doctors who use them in as few as 30% of femoral access procedures. The relative proportions of procedures performed using radial and femoral access respectively also varied significantly between hospitals, potentially due to national differences in practice.[17]

(26) A significant number of doctors mentioned the increasing use of radial access (rather than femoral access) in coronary interventions. VCDs are typically not used in procedures involving radial access, meaning that demand for VCDs will decline in this area of the market.[18]

(27) At the same time, however, the number of structural heart procedures performed via vascular access is increasing, and doctors stressed the importance of VCDs in this type of procedure. When referring to the various different large-hole procedures, including structural heart and also EVAR, doctors often described the use of VCDs as systematic, with usage in a high proportion of cases.[19]

(28) For small-hole closure, the results of the market investigation contradicted the Notifying Party's claim that manual compression is viewed as the 'gold standard', and thus acts as a constraint on VCDs. As mentioned above, VCDs are very much seen as the standard device for procedures performed via femoral access.[20] The main reasons for using VCDs in preference to manual compression or CADs are that it shortens the length of the stay in hospital (even potentially making it possible to perform procedures in an outpatient setting) and reduces the risk of complications. For many physicians, manual compression is not even seen as a feasible alternative. The main drawbacks mentioned are: physician time required, longer hospital stay, patient discomfort and risk of hematomas, continued bleeding, complications or failure. A significant number of doctors would, however, consider using manual compression, but only if there is a counter indication or other specific reason for not using VCDs. Use of CADs also appears to be quite limited. The main disadvantages mentioned included: patient discomfort, longer hospital stay, possible complications and risk of failure. Doctors' responses suggest that CADs are more often used following procedures performed via radial access (for which VCDs are typically not used). A number of physicians did, however, mention cost as a disadvantage of VCDs. Nonetheless, they did not suggest that this would be enough to make them switch to manual compression instead, as the hospital time associated with manual compression is also considered a cost. Furthermore, a number of doctors confirmed that VCDs account for a very small percentage of the total cost of the procedure. A minority of doctors also mentioned the risk of complications as a disadvantage of VCDs.[21]

(29) Similarly, for large-hole closure the results of the market investigation negated the Notifying Party's claim that suturing is considered a feasible alternative. Doctors' responses suggested that suturing is only used in quite specific cases, where the puncture is especially large. Many doctors were not familiar with this type of

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17 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 3.

18 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 3.

19 Replies to Questionnaire Q2 – Questionnaire to Doctors, questions 3 and 4.

20 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 3.

21 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 5.

closure method at all. The main disadvantages of suturing mentioned included: risk of failure, longer hospital stay, risk of infection, need for expertise (only performed by vascular surgeons) and the cost in terms of time in surgery and need for theatre staff. The very fact that it is a surgical procedure has implications for the hospital and for the patient, meaning that it would generally only be used when the hole is too large to close safely with a VCD. Nonetheless, a significant minority of respondents did consider it to have advantages in specific circumstances. In particular, the doctor can ascertain visually that the closure has been effective, and it is a reliable method in some cases.[22]

(30) The market investigation thus confirms that manual compression and CADs cannot be considered as alternatives to VCDs for small-hole closure involving femoral access, and similarly that surgical suturing cannot be considered as an alternative to VCDs for large-hole closure. The market investigation suggests that there is to some extent a natural divide between small-hole and large-hole closure, each being relevant for different types of procedures, and thus often performed by separate sets of physicians. Nonetheless, devices can be and are indicated for small- and large-hole closure (namely Abbott's ProGlide), implying that the markets are not entirely distinct. There would, under either assumption, be serious doubts as regards the compatibility of the Transaction with the internal market, and this distinction may, therefore, ultimately be left open.

III.2.2. *Geographic market*

(31) The Notifying Party submits that the geographic market for vessel closure devices is national, due to differences in reimbursement schemes, procurement processes and patterns, prices and market shares across the EEA.

(32) In previous cases the Commission considered that the geographic market for medical devices was national in scope, despite the fact that the applicable regulatory scheme (the CE mark) is EU-wide in scope. This is in particular due to the existence of national reimbursement schemes, the differences in procurement processes and patterns, significant price differences between countries and the significant variations in competitors' market shares seen across the EEA countries.[23]

(33) For the purpose of the present decision, the Commission concludes that the geographic markets in relation to vessel closure devices are national in scope.

*III.2.3. Competitive assessment*

(34) The tables below show the Parties' market shares in the markets for small- and large-hole VCDs and the market for small-hole VCDs. The market for large-hole VCDs would not be a market affected by the Transaction as only Abbott is present in this area.

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22 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 5.

23 See, e.g. M.7326 Medtronic/Covidien, recitals 64 to 67, M.3687 Johnson & Johnson / Guidant, recitals 67 to 69.

Table 3. Parties' and competitors' market shares in small- and large-hole VCDs, by value, 2015:

| Country | Abbott | St Jude | Combined share | Cardinal Health | Cardiva |
|---|---|---|---|---|---|
| Austria | [20-30]% | [50-60]% | [70-80]% | [20-30]% | [0-5]% |
| Belgium | [20-30]% | [30-40]% | [60-70]% | [20-30]% | [0-5]% |
| Bulgaria | [0-5]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% |
| Croatia | [0-5]% | [0-5]% | [0-5]% | [30-40]% | [0-5]% |
| Cyprus | [0-5]% | [60-70]% | [60-70]% | [0-5]% | [0-5]% |
| Czech Republic | [10-20]% | [30-40]% | [50-60]% | [20-30]% | [0-5]% |
| Denmark | [5-10]% | [50-60]% | [60-70]% | [20-30]% | [0-5]% |
| Estonia | [0-5]% | [50-60]% | [60-70]% | [10-20]% | [0-5]% |
| Finland | [40-50]% | [40-50]% | [80-90]% | [5-10]% | [0-5]% |
| France | [20-30]% | [30-40]% | [60-70]% | [5-10]% | [0-5]% |
| Germany | [10-20]% | [40-50]% | [60-70]% | [20-30]% | [0-5]% |
| Greece | [20-30]% | [0-5]% | [20-30]% | [10-20]% | [0-5]% |
| Hungary | [5-10]% | [20-30]% | [30-40]% | [20-30]% | [0-5]% |
| Ireland | [10-20]% | [30-40]% | [50-60]% | [20-30]% | [0-5]% |
| Italy | [20-30]% | [20-30]% | [40-50]% | [10-20]% | [0-5]% |
| Latvia | | | | | |
| Lithuania | [10-20]% | [20-30]% | [40-50]% | [20-30]% | [5-10]% |
| Luxembourg | [0-5]% | [50-60]% | [60-70]% | [20-30]% | [0-5]% |
| Malta | [0-5]% | [50-60]% | [60-70]% | [30-40]% | [0-5]% |
| Netherlands | [10-20]% | [40-50]% | [50-60]% | [20-30]% | [0-5]% |
| Poland | [5-10]% | [10-20]% | [20-30]% | [20-30]% | [0-5]% |
| Portugal | [20-30]% | [40-50]% | [60-70]% | [20-30]% | [0-5]% |
| Romania | [0-5]% | [5-10]% | [10-20]% | [20-30]% | [0-5]% |
| Slovakia | [20-30]% | [50-60]% | [80-90]% | [10-20]% | [0-5]% |
| Slovenia | [20-30]% | [40-50]% | [70-80]% | [20-30]% | [0-5]% |
| Spain | [30-40]% | [30-40]% | [60-70]% | [10-20]% | [0-5]% |
| Sweden | [30-40]% | [30-40]% | [60-70]% | [20-30]% | [0-5]% |
| United Kingdom | [10-20]% | [40-50]% | [60-70]% | [20-30]% | [0-5]% |
| Iceland | [0-5]% | [40-50]% | [40-50]% | [20-30]% | [0-5]% |
| Liechtenstein | | | | | |
| Norway | [20-30]% | [40-50]% | [60-70]% | [20-30]% | [0-5]% |
| **EEA total** | [20-30]**%** | [30-40]**%** | [50-60]**%** | [10-20]**%** | [0-5]**%** |

Source: Form CO.

Note: The Parties were unable to estimate market sizes in Liechtenstein (where they make no sales) and Latvia.

Table 4. Parties' and competitors' market shares in small-hole VCDs, by value, 2015:

| Country | Abbott | St Jude | Combined share | Cardinal Health | Cardiva |
|---|---|---|---|---|---|
| Austria | [10-20]% | [60-70]% | [70-80]% | [20-30]% | [0-5]% |
| Belgium | [10-20]% | [40-50]% | [50-60]% | [20-30]% | [0-5]% |
| Bulgaria | [0-5]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% |
| Croatia | [0-5]% | [0-5]% | [0-5]% | [30-40]% | [0-5]% |
| Cyprus | [0-5]% | [60-70]% | [60-70]% | [0-5]% | [0-5]% |
| Czech Republic | [0-5]% | [40-50]% | [40-50]% | [20-30]% | [0-5]% |
| Denmark | [0-5]% | [60-70]% | [60-70]% | [30-40]% | [0-5]% |
| Estonia | [0-5]% | [60-70]% | [60-70]% | [10-20]% | [0-5]% |
| Finland | [20-30]% | [50-60]% | [80-90]% | [10-20]% | [0-5]% |
| France | [0-20]% | [40-50]% | [50-60]% | [5-10]% | [0-5]% |
| Germany | [5-10]% | [40-50]% | [50-60]% | [20-30]% | [0-5]% |
| Greece | [10-20]% | [0-5]% | [10-20]% | [20-30]% | [0-5]% |
| Hungary | [0-5]% | [20-30]% | [30-40]% | [20-30]% | [0-5]% |
| Ireland | [10-20]% | [30-40]% | [50-60]% | [20-30]% | [0-5]% |

| | | | | | |
|---|---|---|---|---|---|
| Italy | [10-20]% | [20-30]% | [30-40]% | [10-20]% | [0-5]% |
| Latvia | | | | | |
| Lithuania | [5-10]% | [30-40]% | [30-40]% | [20-30]% | [5-10]% |
| Luxembourg | [0-5]% | [50-60]% | [60-70]% | [20-30]% | [0-5]% |
| Malta | [0-5]% | [50-60]% | [50-60]% | [30-40]% | [0-5]% |
| Netherlands | [0-5]% | [40-50]% | [50-60]% | [30-40]% | [0-5]% |
| Poland | [5-10]% | [10-20]% | [20-30]% | [20-30]% | [0-5]% |
| Portugal | [10-20]% | [50-60]% | [60-70]% | [30-40]% | [0-5]% |
| Romania | [0-5]% | [5-10]% | [10-20]% | [20-30]% | [0-5]% |
| Slovakia | [10-20]% | [60-70]% | [70-80]% | [10-20]% | [0-5]% |
| Slovenia | [10-20]% | [50-60]% | [60-70]% | [30-40]% | [0-5]% |
| Spain | [10-20]% | [40-50]% | [50-60]% | [10-20]% | [0-5]% |
| Sweden | [10-20]% | [30-40]% | [50-60]% | [20-30]% | [0-5]% |
| United Kingdom | [0-5]% | [50-60]% | [50-60]% | [20-30]% | [0-5]% |
| Iceland | [0-5]% | [40-50]% | [40-50]% | [20-30]% | [0-5]% |
| Liechtenstein | | | | | |
| Norway | [5-10]% | [50-60]% | [50-60]% | [20-30]% | [0-5]% |
| **EEA total** | [5-10]**%** | [40-50]% | [50-60]**%** | [20-30]**%** | [0-5]**%** |

Source: Form CO.

Note: The Parties were unable to estimate market sizes in Liechtenstein (where they make no sales) and Latvia.

(35) As can be seen from Table 3, in the market for small- and large-hole VCDs, the Parties have a very high combined market share in a number of markets (as high as [80-90]% in Finland, 50 % or above in 20 EEA Member States, and [50-60]% in the EEA as a whole) with an increment of up to [40-50]%. The market shares by value were very similar in previous years ([50-60]% in the EEA in 2014 and [50-60]% in 2013). If market shares were measured by volume (rather than value), the Parties' combined share would be even higher ([60-70]% in the EEA in 2015, above 50 % in 20 EEA Member States and as high as [90-100]% with a [30-40]% increment in Finland).

(36) In the narrower market for small-hole VCDs (Table 4), the Parties have a very high combined market share in a number of markets (as high as [80-90]% in Finland, 50 % or above in 19 EEA Member States, and [50-60]% in the EEA as a whole) with an increment of up to [20-30]%. The market shares by value were very similar in previous years ([50-60]% in the EEA in 2014 and [50-60]% in 2013). If market shares were measured by volume (rather than value), the Parties' combined share would be even higher ([60-70]% in the EEA in 2015, above [50-60]% in 21 EEA Member States and as high as [90-100]% with a [20-30]% increment in Finland).

(37) The Notifying Party argues that they are not close competitors in the area of vessel closure for the following reasons. First, the Notifying Party argues that there are a number of other suppliers of small-hole VCDs and CADs present in the EEA market. These include Cardinal Health (which has a number of VCDs), Cardiva Medical (which offers CADs and a VCD), Merit Medical Systems (CADs), Morris Innovative Research (VCDs) and Terumo (CAD). A number of other companies are thought to have products in the pipeline in this area.

(38) Second, according to the Notifying Party, the devices marketed by Abbott and St Jude are based on different techniques (St Jude's two VCDs are plug-based and Abbott's are clip- and suture-based respectively). Accordingly, physicians require different training and are likely to have a preference for one type of VCD over others. The Notifying Party claims that vascular surgeons and interventional radiologists are likely to prefer suture- and clip-based VCDs (as produced by

Abbott), while cardiologists would tend to choose plug-based VCDs (as produced by St Jude).

(39) Third, the Notifying Party submits that while Abbott mainly focuses on large-hole closure devices, St Jude is active exclusively in the area of small-hole vessel closure and St Jude VCDs are not indicated for use in large holes.

(40) Fourth, the Notifying Party notes that the Parties focus on different procedures. Abbott's sales and marketing of its vessel closure devices is oriented towards peripheral procedures, whereas St Jude's sales and marketing typically targets physicians performing coronary procedures.

(41) As reported in the section on market definition, the results of the market investigation clearly indicated that VCDs belong to a separate market from CADs. Other VCD suppliers present in the EEA market have relatively small market shares. Cardinal Health is the only competitor with a significant presence ([10-20]% market share in the EEA for small-hole closure excluding manual compression). Cardiva is significantly smaller with a [0-5]% market share and Morris Innovative Research has a very minimal presence (none of the doctors who responded to the market investigation reported that they use VCDs from Morris). Physicians do not therefore have many other options in the market for small-hole closure, beyond the devices offered by Abbott and St Jude (and only have Abbott as an option for large holes).

(42) The market investigation confirmed that Abbott and St Jude are perceived to be the main players in the market for vessel closure, which is consistent with their market share position. Their products were by far the most often named by customers as their products of choice, with other suppliers clearly playing a minor role.[24]

(43) The results of the market investigation confirmed that both Abbott and St Jude are active in small-hole VCDs. Whilst Abbott's ProGlide may also be used in large-hole procedures, its original indication is for use in small-hole closure, and it remains known as a product in this area. The results of the market investigation do, to some extent, support the Notifying Party's claim that Abbott's ProGlide has a stronger position in large-hole closure than small-hole closure (it being, together with Abbott's ProStar, one of the most popular products for large-hole closure). Doctors' responses also showed, however, that there is still significant usage of ProGlide for small-hole closure, thus countering the Parties' claim that large-hole vessel closure 'accounts for the great majority of its use'.[25]

(44) The results of the market investigation do not support the Parties' claim that physicians would tend to have a preference for either clip- and suture-based devices or plug-based devices, according to their specialisation. When asked which other device would be the closest substitute for Abbott's StarClose (a clip-based, small hole VCD), the majority of respondents who answered this question considered either AngioSeal or FemoSeal (St Jude's plug-based VCDs) to be the closest substitute. Similarly, of those respondents who named a closest substitute for

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24 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 4. Of 148 products named spontaneously by 77 respondents, 135 belonged to either Abbott or St Jude.

25 Replies to Questionnaire Q2 – Questionnaire to Doctors, questions 3, 4 and 6.

Abbott's ProGlide, a significant proportion considered this to be either AngioSeal or FemoSeal.[26]

(45) Considering substitution from St Jude's plug-based VCDs to Abbott's clip- and suture-based VCDs, a large proportion of respondents who specified a closest substitute for AngioSeal named either StarClose or ProGlide. For FemoSeal, the proportion of respondents citing StarClose or ProGlide was also significant.[27]

(46) Furthermore, the market investigation showed there to be widespread concern amongst customers that the merger would lead to an increase in prices and a reduction in competition and choice. A high proportion of doctors and the majority of competitors consider that the Transaction would have an impact on the market for VCDs.[28] The responses from doctors included the following comments:

*"AngioSeal, FemoSeal, StarClose, Proglide – all under one roof may influence competition and prices"*

[the merger will have an impact on the VCDs market because] *"all noteworthy VCDs come from these two companies"*

*"I think some of the VCDs will be taken away from marketing"*

*"In order to avoid duplication we can lose products we are used to. We are also afraid of higher prices"*[29]

(47) Only a minority of customers believed that the merger would allow greater investment in R&D, and mentioned there being similar products offered by other companies: "*A merger could enable the company to be more profitable and have greater funds for research and development*" (The same customer, however, mentioned being afraid of price increases).[30]

(48) In addition, the majority of competitors were also of the opinion that the merger would have an impact on the market for VCDs.[31] They mentioned the possible effect on choice and prices, and also that the merged entity would no longer have any need to innovate, due to its dominant market position. For example one of the competitors noted: "*Such a dominant market position would reduce the need to be competitive on price and reduce the need to innovate"*. Another respondent

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26 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 7.

27 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 7. It should also be noted that FemoSeal and AngioSeal were often named as each other's closest substitutes, with StarClose or ProGlide as second closest substitute.

28 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 9, replies to Questionnaire Q1 – Questionnaire to Competitors, question

29 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 9.1

30 Replies to Questionnaire Q2 – Questionnaire to Doctors, questions 9 and 9.1.

31 Replies to Questionnaire Q1 – Questionnaire to Competitors, question 7. It should also be noted that the only competitors who felt that the merger would *not* have an impact had stated at previous questions that they are not active in the VCD space and have no knowledge of this area.

explained: *"Why would they continue innovating if they have such power for these products (in a stagnating market)?"*.[32]

(49) In view of the considerations discussed above, the Commission concludes that the Transaction raises serious doubts as to its compatibility with the internal market in relation to the market for VCDs, irrespective of whether the market is considered to consist of all VCDs or of small-hole VCDs only.

## III.3. Electrophysiology

### *III.3.1. Introduction*

(50) Electrophysiology (EP) studies the electrical activity in the heart. EP devices are used to diagnose and treat abnormalities in the timing and pattern of the heartbeat, referred to as "arrhythmia", the most common of which is atrial fibrillation (AF). AF occurs when errant electrical signals cause the heart to beat quickly and irregularly. These signals usually originate from different places within the pulmonary veins and around the heart's left atrium. While AF often starts as brief periods of abnormal beating, over time these may become longer, and the abnormal beating may even become constant. AF is associated with an increased risk of heart failure, dementia and stroke.

(51) AF can be treated through medication, surgical ablation (via open heart surgery) or catheter ablation – a minimally invasive procedure which uses catheters to access and destroy the affected heart tissue. Ablation is the destruction or scarring of the heart tissue that produces the abnormal electrical signals which cause the fibrillation, thereby restoring the normal heart rhythm.

(52) Most minimally-invasive catheter ablation procedures rely on a technique known as pulmonary vein isolation ("PVI"). PVI procedures target abnormal electrical activity from the pulmonary veins. During PVI procedures, the physician enters the right atrium of the heart, most often from the vena cava. The physician then uses a transseptal needle to pierce the atrial septum and inserts a transseptal sheath in order to access the left atrium. A 3D navigation system and diagnostic catheters are used to create a model of the heart, allowing the physician to identify the location of the pulmonary veins. Using this model, the physician then navigates an ablation catheter to destroy the heart tissue by delivering energy to the outside portion of the pulmonary veins. The lesion at the ablation site blocks the errant electrical signals that caused the patient's AF.

(53) There is also an alternative theory to explain the cause of certain cases of AF, according to which AF is due to "rotors", that is tissue features from which spiral waves of electrical energy emanate. Rotors are not associated with a particular anatomical feature such as the pulmonary veins. Instead, it is though that rotors are present only in certain patients and that their location is specific to each affected patient. Rotor mapping systems are used, in conjunction with non-rotor ablation devices such as PVI, to detect these tissue features. In 2014, Abbott entered the market for electrophysiology devices, by purchasing a company called Topera. Topera developed medical devices for rotor mapping, namely a basket diagnostic catheter and a rotor mapping system.

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[32] Replies to Questionnaire Q1 – Questionnaire to Competitors, question 7.1.

(54) As explained by the Notifying Party, the proponents of rotor ablation believe that the combination of traditional ablation and rotor ablation will allow practitioners to target ablation more precisely, and thus improve results. The opponents of rotor ablation, meanwhile, view the procedure as largely ineffective. The market investigation gave a mixed picture of the perception of rotor ablation, in particular as regards its effectiveness. Some practitioners indicated that rotor mapping "*does not work*"[33], while other considered *"rotor ablation to be a very promising approach".*[34]

(55) The results of the market investigation, clearly indicated, however, that rotor ablation would not constitute a substitute for traditional ablation: "*Rotor ablation will not replace traditional ablation procedures, i.e. PVI, but it does offer a very good option in cases where the patient has not responded well to PVI. (…) All equipment needed for PVI will be used before or after rotor ablation."*[35] As shown in Table 5 below, the Parties' products in the area of electrophysiology are not, therefore, competing products, with the exception of transseptal sheaths – which can be used for both the traditional ablation and the rotor ablation.

Table 5: Parties' EP product portfolio:

| Electrophysiology Devices ("EP") | | | **Abbott** | **St Jude** |
|---|---|---|---|---|
| Catheters | Diagnostic | Conventional | - | Y |
| | | Loop | - | Y |
| | | Basket (rotor mapping) | Y | - |
| | Ablation | Ultrasound | - | Y |
| | | Conventional | - | Y |
| | | Irrigated-Tip[36] | - | Y |
| | | Ultrasound | - | - |
| | | Alternative Energy | - | - |
| Recording, Navigation, and Mapping Systems | | X-Ray Machines | - | - |
| | | Recording Workstations | - | Y |
| | | 3D Navigation Systems | - | Y |
| | | Rotor Mapping Systems | Y | - |
| Transseptal Access Devices | | Transseptal Needles | - | Y |
| | | Transseptal Sheaths | (Y) (Pipeline) | Y |
| EP Accessories | | | - | Y |

Source: Form CO.

33 See replies to questionnaire Q2 – Questionnaire to Doctors, question 24.

34 See non-confidential minutes of a call with a cardiologist specialised in electrophysiology of 16 September 2016.

35 See non-confidential minutes of a call with a cardiologist specialised in electrophysiology of 16 September 2016.

36 At the time of the notification of the Transaction Abbott also had access to pipeline ablation catheter, as it had a right to purchase […] a company which was developing an ablation catheter. However, on […] October 2016 Abbott has terminated the agreements with […] and thus any overlap between St Jude and Abbott in the area of ablation catheters ceased to exist.

*III.3.2. Transseptal sheaths*

*III.3.2.1. Market definition*

(56) Transseptal sheaths are used to introduce catheters from the right to the left side of the heart, crossing the septum (i.e. the wall between the left and the right sides of the heart), in order to find and ablate the AF trigger site. They are hollow tubes inserted in the hole of a transseptal puncture in the heart. Once inserted, they remain in place for the remainder of the procedure and provide for easy access for the insertion and removal of catheters into the left side of the heart.

(57) There are two different types of transseptal sheaths: fixed and steerable. Fixed transseptal sheaths are hollow tubes with a length of at least 60cm and fixed curves ranging from 15° to 150°. They are generally equipped with a dilator, which extends beyond the sheath tip to add structural support during the transseptal puncture. The tip and curvature of fixed transseptal introducer sheaths cannot be adjusted.

(58) Steerable transseptal sheaths are also hollow tubes of at least 60cm, but they have a steerable mechanism at the end. This mechanism assists with catheter stability and facilitates the placement of diagnostic and ablation catheters at various locations in the left side of the heart, which allows for targeted diagnosis and ablation of the AF trigger site(s). Steerable transseptal sheaths typically have a handle that controls the sheath tip with bi- or multi-directional deflection, and can have small curl or medium curl options.

(59) Transseptal sheaths exist in various sizes. The 7.5F and 8F sheaths can generally be used with most of the ablation catheters available on the market. There are also transseptal sheaths used in the EP procedures with a larger diameter, above 10F, which are used where larger devices or equipment needs to be inserted into the treatment site.

(60) The Commission has not previously assessed the market for transseptal sheaths.

(61) According to the Notifying Party, fixed and steerable transseptal sheaths are substitutable, as both are indicated for introducing catheters into the left side of the heart through the septum, for the purpose of treating AF. The Notifying Party submits that physician training is the same for both types of sheath, and that the choice between the two types generally depends on physicians' familiarity with the devices and general preferences.

(62) The Notifying Party argues that, even though fixed sheaths are cheaper (at an average price of around EUR 200-350, compared to steerable sheaths at around EUR 400-700), the total cost of using fixed or steerable sheaths is comparable. This is because fixed sheaths allow for less stability and manoeuvrability of catheters and, as a result, the total AF treatment time using a fixed sheath is longer than that for a steerable sheath. The use of a fixed sheath is therefore associated with higher costs in terms of EP lab time and medical staff time. The Notifying Party considers that, for these reasons, the total cost of using the two types of sheaths is comparable.

(63) The results of the market investigation are mixed as regards the distinction between steerable and fixed transseptal sheaths. In general, practitioners indicate that fixed sheaths tend to be used in particular for initial access to the atrium, and may be

replaced by steerable sheaths for the subsequent ablation procedure. At the same time, some market participants explained that practitioners may choose to use only one type of sheath throughout the entire procedure.[37]

(64) More generally, practitioners explained that, even though both types of sheaths are used in AF procedures, there are situations in which one type would be preferred over the other. Fixed sheaths may be preferred by some practitioners for the initial access to the left atrium, and they seem to be used more often in simpler, conventional AF procedures and in left atrial appendage closure.[38] The majority of doctors who provided information on this question felt that steerable sheaths provided the more precise control required in more complex procedures, in particular in complex AF or ventricular tachycardia ablations.[39] They can better support the more advanced ablation catheters.[40]

(65) The majority of respondents to the market investigation indicated that fixed sheaths tend to be cheaper than steerable. No respondents stated that the higher price of steerable sheaths could be offset by reduced procedure time, as claimed by the Notifying Party. The cost of using fixed transseptal sheaths is thus perceived as being lower.[41] One competitor explained that the European market uses fewer steerable sheaths than the US market due to the significant difference in cost.[42]

(66) According to the internal documents provided by Abbott, the number of procedures in which transseptal sheaths are used is growing rapidly. Moreover, there has been an increase in the number of more complex AF ablations. These tend to require more advanced ablation catheters, which are better supported by steerable transseptal sheaths. It is therefore expected that the use of steerable sheaths will increase in the coming years. In addition, the results of recent clinical trials appear to advocate their use.[43]

(67) The results of the market investigation revealed that, in addition to the distinction between fixed and steerable transseptal sheaths, transseptal sheaths can be segmented according to different sizes from 7F to 12F and more in diameter. The different sizes of sheath cannot be used as substitutes. Most of the transseptal sheaths used in typical AF procedures are 8.5F in diameter and they are suitable for use with most of the ablation catheters available on the market. There also, however, exist transseptal sheaths of a larger diameter (12F), for example the FlexCath Advanced sheath developed by Medtronic, which is specifically designed to be used in Cryoballooon procedures, which use alternative, cold-based energy (as opposed to heat-based energy, such as radiofrequency, "RF") to ablate the

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37 See replies to question 27 of Questionnaire Q2 to doctors.

38 Left atrial appendage occlusion is a treatment strategy to reduce the risk of left atrial appendage blood clots entering the bloodstream and causing a stroke in patients with non-vulvar atrial fibrillation.

39 Ventricular tachycardia is a type of regular and fast heart rate that arises from improper electrical activity in ventricles of the heart. It may result in cardiac arrest and turn into ventricular fibrillation.

40 See replies to question 27 of Questionnaire Q2 to doctors.

41 See replies to question 27 of Questionnaire Q2 to doctors.

42 Non-confidential minutes of the call with a competitor on 6 September 2016.

43 Internal documents of the Notifying Party: […].

abnormal tissue in the heart.[44] The results of the market investigation show that Medtronic's large transseptal sheath is a distinct type of product, which cannot be used as a substitute for the transseptal sheaths used in traditional AF procedures, which use RF ablation.

(68) This means that while the practitioner has choice when deciding on the type of ablation energy to use in the EP procedure, once it has been decided, the transseptal sheath will need to be compatible to support the catheter: for cryoballoon catheters (used in cryoballoon procedures, described in previous recital) only the FlexCath transseptal sheath of Medtronic, and this sheath will not be an option in case a RF ablation catheter is used.

(69) In view of the above the Commission concludes that the relevant product market comprises transseptal sheaths used in electrophysiology procedures that support traditional ablation catheters. The Commission considers that the question as to whether fixed and steerable sheaths form one product market, and whether or not transseptal sheaths of various sizes form distinct product markets, in particular whether the transseptal sheaths of large diameter offered by Medtronic should be included in the relevant market can be left open, as the Transaction raises serious doubts regarding its compatibility with the internal market irrespective of the exact product market definition.

*III.3.2.2. Geographic market*

(70) The Notifying Party does not contest the appropriateness of a national market definition for transseptal sheaths, in line with Commission precedents on medical devices. At the same time, the Notifying Party considers that, for transseptal access sheaths, EEA-wide data may provide a better picture of competition between the various suppliers. The Notifying Party notes that transseptal sheaths are small, high value items, for which the transportation costs account for a relatively small portion of the total cost of supply. Producers typically concentrate their global production in a relatively small number of locations, and ship from these sites to across the EEA and beyond. St Jude, for example, manufactures transseptal sheaths in one location only and ships them to customers globally.

(71) The market investigation did not reveal any facts related to transseptal sheaths which would lead to a different conclusion from that reached in previous Commission cases with regard to medical devices. In particular, the market investigation confirmed the existence of national reimbursement schemes, the differences in procurement processes and patterns, price differences between countries and the variations in competitors' market shares seen across the EEA countries.

(72) For the purpose of the present decision, the Commission therefore concludes that the geographic markets in relation to the transseptal access sheaths are national in scope.

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44 Replies to questionnaire Q1 to competitors, question 37.

*III.3.2.3. Competitive assessment*

(73) St Jude's steerable transseptal sheath, *Agilis* (diameter 8.5F), is a leading product in Europe. The company also offers a fixed transseptal sheath, *Swartz*. Abbott is a new entrant on the market. In 2016, it acquired Kalila Medical, which had developed the *Vado* steerable transseptal introducer sheath (with 8.8F diameter).

(74) Vado is already on sale in the US (but sales are limited as it only entered the market very recently), while in the EEA it received the CE mark in August 2016.[45] While Abbott has made no sales of transseptal sheaths in the EEA to date, it plans to launch the product in countries in which it offers other EP devices, namely […].

(75) Tables 6-8 below show the position of current suppliers and their market shares on the transseptal sheaths market in the EEA.

Table 6. St Jude's and competitors' Position in Fixed Transseptal Sheaths, irrespective of sheaths' diameter, by value, 2015:

| Country | St Jude | Boston Scientific | Biosense Webster | Medtronic | Others |
|---|---|---|---|---|---|
| Austria | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Belgium | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Bulgaria | [0-5]% | - | - | - | - |
| Croatia | [0-5]% | - | - | - | - |
| Cyprus | [0-5]% | - | - | - | - |
| Czech Republic | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Denmark | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Estonia | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Finland | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| France | [70-80]% | [5-10]% | [10-20]% | [5-10]% | [0-5]% |
| Germany | [40-50]% | [5-10]% | [20-30]% | [10-20]% | [5-10]% |
| Greece | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Hungary | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Ireland | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Italy | [40-50]% | [20-30]% | [10-20]% | [0-5]% | [5-10]% |
| Latvia | [0-5]% | - | - | - | - |
| Lithuania | [0-5]% | - | - | - | - |
| Luxembourg | [0-5]% | - | - | - | - |
| Malta | [0-5]% | - | - | - | - |
| Netherlands | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Poland | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Portugal | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Romania | [0-5]% | - | - | - | - |
| Slovakia | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Slovenia | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Spain | [30-40]% | - | [0-5]% | [40-50]% | [5-10]% |

[45] According to internal documents, an advanced version of the product (Vado 2.1) is expected to receive the CE mark by […].

| | | | | | |
|---|---|---|---|---|---|
| Sweden | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| UK | [40-50]% | [50-60]% | - | [0-5]% | [0-5]% |
| Iceland | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| Liechtenstein | [0-5]% | - | - | - | - |
| Norway | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [5-10]% |
| **EEA Total** | [40-50]**%** | [10-20]**%** | [10-20]**%** | [10-20]**%** | [5-10]**%** |

Source: Notifying Parties.

Table 7. St Jude's and competitors' Position in Steerable Transseptal Sheaths, irrespective of sheaths' diameter, by value, 2015:

| **Country** | **St Jude** | **Boston Scientific** | **Medtronic** | **Hansen Medical** |
|---|---|---|---|---|
| Austria | [40-50]% | [10-20]% | [30-40]% | [0-5]% |
| Belgium | [40-50]% | [10-20]% | [30-40]% | [0-5]% |
| Bulgaria | [0-5]% | - | - | - |
| Croatia | [0-5]% | - | - | - |
| Cyprus | [0-5]% | - | - | - |
| Czech Republic | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Denmark | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Estonia | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Finland | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| France | [10-20]% | [20-30]% | [50-60]% | - |
| Germany | [50-60]% | [5-10]% | [30-40]% | [0-5]% |
| Greece | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Hungary | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Ireland | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Italy | [30-40]% | [20-30]% | [40-50]% | - |
| Latvia | [0-5]% | - | - | - |
| Lithuania | [0-5]% | - | - | - |
| Luxembourg | [0-5]% | - | - | - |
| Malta | [0-5]% | - | - | - |
| Netherlands | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Poland | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Portugal | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Romania | [0-5]% | - | - | - |
| Slovakia | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Slovenia | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Spain | [20-30]% | [0-5]% | 74% | - |
| Sweden | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| UK | [70-80]% | [10-20]% | [5-10]% | |
| Iceland | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| Liechtenstein | [0-5]% | - | - | - |
| Norway | [40-50]% | [10-20]% | [40-50]% | [0-5]% |
| **EEA Total** | [40-50]**%** | [10-20]**%** | [40-50]**%** | [0-5]**%** |

Source: Notifying Parties.

Table 8. St Jude's and competitors' Position in Transseptal Sheaths (fixed and steerable combined), irrespective of sheaths' diameter, by value, 2015:

| Country | St Jude | Biosense Webster | Boston Scientific | Medtronic | Hansen Medical | Other |
|---|---|---|---|---|---|---|
| Austria | [40-50]% | [0-5]% | [10-20]% | [30-40]% | [0-5]% | [0-5]% |
| Belgium | [40-50]% | [10-20]% | [10-20]% | [10-20]% | [0-5]% | [0-5]% |
| Bulgaria | [0-5]% | - | - | - | - | - |
| Croatia | [0-5]% | - | - | - | - | - |
| Cyprus | [0-5]% | - | - | - | - | - |
| Czech Republic | [40-50]% | [5-10]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |
| Denmark | [40-50]% | [5-10]% | [10-20]% | [30-40]% | [0-5]% | [0-5]% |
| Estonia | [40-50]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% | [5-10]% |
| Finland | [40-50]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% | [5-10]% |
| France | [30-40]% | [0-5]% | [20-30]% | [40-50]% | - | [0-5]% |
| Germany | [40-50]% | [10-20]% | [5-10]% | [20-30]% | [0-5]% | [0-5]% |
| Greece | [40-50]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |
| Hungary | [40-50]% | [5-10]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |
| Ireland | [40-50]% | [5-10]% | [10-20]% | [30-40]% | [0-5]% | [0-5]% |
| Italy | [40-50]% | [5-10]% | [20-30]% | [10-20]% | - | [5-10]% |
| Latvia | [0-5]% | - | - | - | - | - |
| Lithuania | [0-5]% | - | - | - | - | - |
| Luxembourg | [0-5]% | - | - | - | - | - |
| Malta | [0-5]% | - | - | - | - | - |
| Netherlands | [40-50]% | [5-10]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |
| Poland | [40-50]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |
| Portugal | [40-50]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% | [5-10]% |
| Romania | [0-5]% | - | - | - | - | - |
| Slovakia | [40-50]% | [0-5]% | [10-20]% | [30-40]% | [0-5]% | [0-5]% |
| Slovenia | [40-50]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |
| Spain | [20-30]% | [0-5]% | [0-5]% | [60-70]% | - | [0-5]% |
| Sweden | [40-50]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |
| UK | [50-60]% | - | [30-40]% | [5-10]% | - | [0-5]% |
| Iceland | [40-50]% | [10-20]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |
| Liechtenstein | [0-5]% | - | - | - | - | - |
| Norway | [40-50]% | [5-10]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |
| **EEA Total** | [40-50]% | [5-10]% | [10-20]% | [20-30]% | [0-5]% | [0-5]% |

Source: Notifying Parties.

(76) The above tables 6-8 report market shares on the hypothetical markets for fixed and steerable sheaths, including all sizes. In such markets, there would be a very strong product differentiation between products of different size, as practitioners use the specific sized sheath that is compatible with the ablation catheter of choice.

(77) In such hypothetical markets irrespective of the distinction between fixed or steerable transseptal sheaths, and even when assuming that the Medtronic product (of larger diameter, compatible only with Medtronic cryo-ablation catheters) is part of the relevant product market, St Jude is the market leader.

(78) On the market for fixed transseptal sheaths St Jude market shares reach [40-50]% in the EEA overall and in most EEA countries for which reliable data is available. In some countries its position is even more important (for example in case of France its market share is estimated at approximately [70-80]%). The remaining competitors include Biosense Webster, Boston Scientific and Medtronic, with each of them having a market share below 20%.

(79) On the market for steerable sheaths only, St Jude is the market leader, with the market share of [40-50]% in the EEA and in most EEA countries. The only strong competitor on this differentiated market (including sheaths of larger diameter) would be Medtronic, with the estimated share of [40-50]%. The remaining suppliers have a significantly weaker position: Boston Scientific with estimated market share of [10-20]% in most countries and Hansen Medical with the estimated share of [0-5]% in most countries.

(80) On the overall transseptal sheaths market (including fixed and steerable sheaths), St Jude's market share amounts to [40-50]% in the EEA and in 17 EEA countries (in some countries more: [40-50]% in Germany and [50-60]% in the UK). Main competitors include Medtronic with the market share of [20-30]% in the EEA (in most countries above 20%), Boston Scientific with the market share of [10-20]% in the EEA and in most countries and Biosense Webster ([5-10]% in the EEA and in most EEA countries).

(81) In the hypothetical narrower markets of transseptal sheaths with a size of 7-8.5F (the most common type, where sheaths are more interchangeable), the market share of Medtronic would be greatly reduced, as its main transseptal sheath is a steerable sheath of size 12F. In such hypothetical markets the position of St Jude would be even stronger. On the market for steerable transseptal sheaths of standard diameter the market shares of St Jude exceed 70% in the EEA and in most EEA countries for which reliable data is available ([80-90]% in Germany, [80-90]% in Spain and [80-90]% in the UK). On the market for transseptal sheaths of standard diameter, fixed and steerable combined St Jude market shares would amount to [60-70]% in the EEA overall, and would exceed 50% or even 60% in all the countries for which reliable data is available.[46]

(82) If measured by volume, St Jude's market share would be even higher, in particular because the sheaths offered by competing suppliers tend to be more expensive.

(83) The market investigation confirmed that St Jude is a leading player in the area of transseptal sheaths in Europe (both in steerable and fixed sheaths). According to the market participants the closest competitor in the market for transseptal sheaths is Boston Scientific, with a significantly weaker position.[47]

(84) Irrespective of the exact market delineation, the vast majority of respondents consider St. Jude to be the market leader. Alternative products are used significantly

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46 For the market including only fixed transseptal sheaths, taking into account the diameter of sheaths does not lead to different market share results, since the Medtronic transseptal sheath if exceptionally large diameter is a steerable sheaths, while its fixed sheath if of standard diameter, so it should be included in both scenarios,

47 See replies to Questionnaire Q2 – Questionnaire to Doctors, question

less often.[48] The strong position enjoyed by St. Jude's Agilis sheath seems to be related to its inherent features: its specific shape and quality. According to the responses to the market investigation, Agilis is considered to be the best and most expensive device available. Several customers mentioned that Agilis has *"the best steerability of all"*. Another customer explained that *"Agilis and Swartz are the market leading products in EP".* This is also reflected in its price, which, at least in some countries, is significantly higher than that of competing products. Practitioners are aware of alternative products, but underline that they do not match Agilis in terms of quality.

(85) The vast majority of practitioners are not familiar with Vado and, hence, are not able to comment on the potential impact of Vado's launch on the market for transseptal sheaths. The market participants who had heard of Vado did, however, consider it a promising product. They indicated that Vado might have superior features when compared to Agilis, and that, once on the market, it could be a strong challenger to Agilis. This is corroborated by the very similar sizes of Agilis (8.5F) and Vado (8.8F), which would make them interchangeable from a technical perspective.

(86) Competitors also felt that Vado could exert strong competitive pressure on St Jude's products, in particular Agilis, often based on their experience gained on the US market, where Vado is already on sale. One competitor suggested that Vado may have *"potentially a better steering mechanism providing more stability using a coaxial steering vs. the traditional pull wires"* and that, as a result of having Vado, the merged entity would have *"the most promising sheath technology"*.[49] The same competitor suggested that Vado *"could potentially unseat Agilis at the top of the 7F steerable sheath market, and therefore, reduce prices"*. In view of this, "*losing Vado from the market would then seem to be harmful".*

(87) Furthermore the Commission notes that the internal documents demonstrate that, when Vado was developed and tested, it was benchmarked against Agilis and was considered as offering superior features, for example in terms of steerability. This is demonstrated, in particular, by the internal documents produced by Kalila Medical, the company which developed the Vado transseptal sheath before being taken over by Abbott in early 2016. For example, the document assessing Vado explains that […].[50]

(88) Finally, St Jude's Agilis sheath was the predicate device for Vado's regulatory approval in the US, meaning that Vado was proved to have the same intended use and fundamental scientific technology as Agilis. As explained in the summary of the US Food and Drug Administration approval of Vado "*the data presented demonstrate that the Vado Steerable sheath met its functional and performance characteristic in accordance with applicable industry standards and compares favourably to the predicated device* [St Jude's Agilis]".[51]

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48 See replies to question 29 of questionnaire Q2 to doctors.

49 Non-confidential minutes of the call with a competitor on 6 September 2016

50 Kalila Medical management presentation of […]: […] The document was submitted by the Notifying Party on 8 November 2016.

51 See FDA, Section, 510(k) Summary: https://www.accessdata.fda.gov/cdrh_docs/pdf14/K140420.pdf.

(89) The Commission considers that these elements prove that, absent the Transaction, Abbott would, with Vado, become a very close competitor of St Jude, and would thus exert significant competitive pressure on the transseptal sheaths market. Based on the results of the market investigation, the Commission considers it very likely that the potential withdrawal of Abbott's transseptal sheath would have a negative impact on the market for transseptal sheaths, by removing a competing product that would provide a valid alternative to practitioners and could prove superior to St Jude's existing offering.

(90) The Notifying Party submits that, first, it is uncertain whether Abbott would have launched Vado outside the countries where it currently sells rotor mapping products […].[52] The Notifying Party claims that it is very unlikely that Abbott would develop an independent EP sales force in other EEA countries to market Vado alone, […]. The Notifying Party also submits that there are likely to be other transseptal sheaths under development. It mentions, in particular, that a Chinese manufacturer of "low cost" transseptal sheaths may plan to enter the European market, and also that Biosense Webster may be working on improving its MobiCath transseptal sheath platform.

(91) […], the Commission notes that the results of the market investigation concerning the rotor ablation technology are mixed (as explained in Section III.3.1 above). Some practitioners who are familiar with this technology feel that rotor ablation may be a promising treatment, and could be complementary to traditional AF ablation.[53] It cannot therefore be concluded at this stage that […]. As a result, it cannot be excluded that Abbott would have a complementary portfolio to be marketed together with Vado. Furthermore, the Commission notes that the company which developed Vado, Kalila Medical, did not have the complementary portfolio and developed Vado as a stand-alone project. […].

(92) As regards potential alternative pipeline transseptal sheaths under development, the results of the market investigation showed that none of the potential alternative pipeline products is known to market participants. Vado, meanwhile, which has already entered the US market and has obtained the CE mark in Europe, would appear to be the most likely and the most imminent entrant on the transseptal sheaths market in the EEA.

(93) In view of the considerations discussed above, the Commission concludes that the Transaction raises serious doubts as to its compatibility with the internal market in relation to the market for transseptal sheaths.

## III.4. Structural heart

### *III.4.1. Market definition*

(94) Structural heart diseases are conditions that affect the normal functioning of the heart. They include structural and functional defects in the valves (aortic or mitral) or in the chambers of the heart. Diseases affecting the heart valves can be treated surgically or by means of a minimally invasive intervention (e.g. a transcatheter

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52 […] a recent study, OASIS, revealed that rotor mapping and ablation may not be effective, and if this is confirmed […].

53 Non-confidential minutes of the call with the Spanish practitioner of 16 September 2016.

procedure). According to the Notifying Party, structural heart is seen as a fast growing sector for medical devices.

(95) The area of transcatheter structural heart comprises four main types of procedure: transcatheter aortic valve (TAV), left atrial appendage (LAA), transcatheter mitral valve (TMV) and transcatheter tricuspid valve (TTV). Until relatively recently, this area was mainly focused on the repair and replacement of the aortic valve, but there is now significant activity in the development of TMV and TTV devices.

(96) The area of transcatheter mitral valve includes both transcatheter mitral valve repair (TMVr, a procedure whereby a device is placed on the patient's mitral valve to ensure it closes without causing blood reflux) and transcatheter mitral valve replacement (TMVR, a procedure whereby the mitral valve is replaced entirely). Abbott was the first, and is currently the only, manufacturer to offer a product for TMVr, the MitraClip, while both Parties are developing TMVR devices. The areas of TMVr and TMVR are both currently seeing significant research and development activity. The Notifying Party estimates there to be around 27 development programmes ongoing in the area of TMVr and around 30 in the area of TMVR.[54]

(97) TMVR devices can be categorised as being transapical (meaning that the mitral valve is accessed via a catheter inserted between the ribs and the valve is delivered through the apex of the left ventricle) or transfemoral (meaning that the mitral valve is accessed via a catheter through the femoral artery, and access to the left atrium is gained by crossing the atrial septum). The first devices to start being developed were transapical, and the Notifying Party submits that these are likely to be the first to market. The devices designed for transfemoral access are likely to reach the market later, but this access route does offer certain advantages over transapical access. The Notifying Party mentions that the procedure is less invasive and thus lower risk, but also that the process of operating the device is more complex.

(98) The Notifying Party maintains that the devices for treatment of different medical conditions within the area of structural heart (e.g. defects in the aortic valve, the left atrial appendage, the mitral valve and the tricuspid valve) each form a separate product market, as they are neither supply-side nor demand-side substitutable. The technical characteristics of the valves and the devices used for inserting valves mean that they could not be used interchangeably, and the risks associated with doing so are such that a physician would not contemplate using a product for a purpose for which it is not indicated.

(99) The Notifying Party further argues that the lack of supply-side substitutability between the techniques is demonstrated by the fact that Medtronic and Edwards, who are both leaders in TAVI products, have nonetheless acquired start-up companies that were developing TMVR devices. Were they able to make use of their existing expertise in the area of TAVI to develop a TMVR device based on the same technology, they would not have needed to do this.

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54 *Abbott Structural Heart and Abbott Venture. Competitive Landscape*. Provided as Annex 24(c) to Form CO.

(100) Within the area of mitral valve defects, the Notifying Party maintains that there is generally no demand- or supply-side substitutability between repair and replacement, and between surgical and transcatheter procedures. Instead, in each case, the doctor would choose whether to replace or repair the valve depending on the disease and the characteristics of the individual patient. From a supply-side point of view, TMVr and TMVR devices are also claimed to be sufficiently different that suppliers could not easily switch production from one to the other.

(101) The choice between surgery and a transcatheter procedure from a demand-side point of view (i.e. the doctor's decision) can, at present, of course only be observed for mitral valve repair, as there are no TMVR devices yet on the market. The Notifying Party maintains that surgical and transcatheter mitral valve repair are typically used for different patient populations, and require different types of devices, from a supply-side point of view. The Notifying Party expects the same scenario to emerge in the area of mitral valve replacement, once TMVR devices appear on the market.

(102) The results of the market investigation confirmed the Notifying Party's submission that devices for treatment of different medical conditions within the area of structural heart (e.g. defects in the aortic or mitral valve) each form a separate product market.

(103) The results of the market investigation did not entirely support the Notifying Party's claims, in terms of the distinction between surgical procedures and TMVR. While the Notifying Party claimed that each would be used for a separate set of patients and conditions, a competitor anticipated there being a gradual transition to TMVR, suggesting that doctors would have the choice of whether to perform a surgical or a transcatheter procedure, i.e. that either would be possible from a technical point of view. This competitor expressed reservations as to how quickly TMVR is likely to replace surgical procedures, making reference to the time it took for TAVI to become an established technique. A further factor which may slow the take up of TMVR devices is the lack of reimbursement.[55]

(104) Given that TMVR is not yet available to doctors, the choice between surgery and a transcatheter procedure can only be assessed on the basis of responses relating to mitral valve repair (rather than replacement). The majority of doctors were more inclined to favour surgery, indicating that they would only use TMVr in patients where surgery is not possible or not advisable. At the same time, however, they do recognise TMVr as having the advantage of being less invasive, and thus less traumatic for the patient. The overall picture was, nonetheless, that surgery is still very much the 'standard' procedure, which delivers the best outcomes, whilst TMVr is an alternative, that they might consider if surgery is not possible, or in very specific cases. This would seem to support the argument made by the competitor (referred to above), that TMVR will need to prove its worth before doctors are prepared to change their practice.[56]

(105) As concerns the distinction between repair and replacement, doctors' replies suggested that they do not consider the two as direct substitutes and that there would, thus, be an interest in having both available. The choice as to whether to replace or repair the mitral valve would depend to a large extent on the type of defect. Where

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55 Pre-notification calls with competitors.

56 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 35.

there is complete degeneration, the valve is more likely to be replaced, whereas where the structure around the valve is deteriorating but has not degenerated entirely, repairing the valve is likely to be the preferred approach. This was, nonetheless, expressed as a general tendency, and one doctor mentioned that there might also be cases of complete degeneration that could be treated with a TMVr device, such as Abbott's MitraClip. In general, a doctor would need to judge whether the valve is repairable or not, and the vast majority of responses suggested that if a valve *is* repairable, there would be a preference for repairing rather than replacing.[57] The market investigation therefore confirmed that TMVr and TMVR devices are not interchangeable, and do have distinct uses, but gave a slightly more nuanced picture than that presented by the Notifying Party, indicating that there is some overlap in their usage.

(106) In view of the above, the Commission concludes that the devices for treatment of different medical conditions within the area of structural heart (e.g. defects in the aortic valve, the left atrial appendage, the mitral valve and the tricuspid valve) may each form a separate product market, as maintained by the Notifying Party. There is also some evidence to suggest that, considering treatment of the mitral valve, there may be separate markets for repair (TMVr) and replacement (TVMR). In any event the question whether mitral valve repair (TMVr) and mitral valve replacement (TMVR) form one product market or distinct product markets can be left open for the purpose of this case, since the transaction does not raise serious doubts as regards its compatibility with the internal market under any possible product market definition.

*III.4.2. Geographic market*

(107) The Commission has consistently considered the markets for medical devices to be national. For pipeline products, the Commission previously considered that the geographic scope of the relevant market was at least EEA-wide.[58]

(108) There appears to be no reason to depart from this conclusion in the present case, since all overlaps related to TMVR devices concern pipeline products. The relevant geographic scope for the assessment of TMVR in the represent Transaction is therefore at least EEA-wide.

*III.4.3. Parties' and competitors' products*

(109) Abbott and St Jude are at different stages in the development of TMVR devices, with Abbott likely to be amongst the first companies to bring a product to market while St Jude's product is at a much earlier stage of development.

(110) Abbott is continuing the development of a pipeline TMVR device, which it obtained through the acquisition of Tendyne Holding in September 2015. […]. In July 2015, Abbott also secured an option to acquire Cephea Valve Technologies. Cephea is developing a transfemoral TMVR device […].

(111) St Jude is also developing a TMVR device. […].

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57 Pre-notification calls with doctors. Replies to Questionnaire Q2 – Questionnaire to Doctors, question 35.

58 See, e.g. cases M.7480 Actavis / Allergan, M.7275 Novartis / GlaxoSmithKlein Oncology Business.

(112) No TMVR devices have yet been commercialised in Europe (or elsewhere in the world), but there are a significant number of companies developing such devices. The products expected to reach the market first are the transapical devices being developed by NeoVasc (Tiara), Medtronic (Twelve), Edwards (CardiAQ) and Abbott (Tendyne). It is also thought that a number of companies, including Medtronic and Valtech Cardio, already have transfemoral access devices in development. According to the Notifying Party, the trend seen in TAVI, whereby transfemoral access devices have gradually replaced transapical devices, is likely to be replicated over time in the area of transcatheter mitral valve replacement. At the same time, however, the Notifying Party maintains that, ultimately, physicians will have a choice between transapical and transfemoral access devices, and will be able to choose on a case-by-case basis which is the most appropriate. It submits that, for some patients, only one or the other device will be suitable, depending, for example, on their anatomical characteristics and the type of mitral disease.

(113) The most advanced transapical pipeline products are the following:

Table 9: Transapical access TMVR devices in development:

| Manufacturer | Product name | Stage of development | Expected date for CE mark approval |
|---|---|---|---|
| **Abbott** | […] | […] | 2018 |
| **Edwards** | […] | […] | 2018 |
| **Medtronic** | […] | […] | 2018-2019 |
| **NeoVasc** | […] | […] | 2019 |
| **MValve** […] | *Not known* | […] | *Not known* |

Source: Form CO and Annexes.
*These products could be TA or TF.

(114) The first transfemoral devices are expected to reach the market later (although, as mentioned above and shown in the table above, there are some products in development for which it is not known whether they will be launched as transapical, transfemoral or both). In addition to those products mentioned in the table above that may be developed to be suitable for transfemoral as well as transapical access, the following (exclusively) transfemoral devices are also thought to be amongst those likely to reach the market first:

Table 10: Transfemoral access TMVR devices in development:

| Manufacturer | Product name | Stage of development | Expected date for CE mark approval |
|---|---|---|---|
| **Valtech Cardio** | […] | […] | *Not known* |
| **Mitrassist medical** | *Not known* | […] | *Not known* |
| **Caisson Interventional** | *Not known* | […] | *Not known* |

Source: Form CO and Annexes.

(115) The Notifying Party highlighted that the likelihood of success for any pipeline product in this area is very variable, and depends in part on the current stage of development. There are no published industry averages for success rates in the development of TMVr devices, but the Notifying Party estimates this to be around […]%. As no TMVR products have yet reached the market, it is not possible to draw any conclusions specific to this area, but devices are of course subject to the standard

CE mark approval process. The Notifying Party estimates the likelihood of commercialisation of the Tendyne TMVR to be around […]%.

*III.4.4. Competitive assessment*

(116) Competitors were generally aware of Abbott's acquisition of Tendyne and see the company as one of the main players in this area. In contrast, there was very little knowledge of St Jude's pipeline product, with competitors not aware that St Jude was investing in this area at all. This confirms the Notifying Party's claim that the product is still a long way from the market.[59]

(117) Doctors were generally aware of there being a lot of development ongoing in the area of TMVR. It is known that the vast majority of the major companies either have research ongoing in-house or are investing in start-ups that are developing devices (with a view to buying these out should they prove successful). Nonetheless, due to the confidential nature of product development, doctors did not always have a great deal of knowledge on specific projects. On the other hand, some doctors were aware of research projects, particularly those that are already at a more advanced stage, e.g. where clinical trials or even CE mark studies are under way. The projects mentioned most often included NeoVasc's Tiara, Abbott's Tendyne, Edward's CardiAQ (although doctors had heard that the latter had encountered some difficulties) and MValve's product (funded by Boston Scientific). Two doctors were aware of St Jude's pipeline product, but one viewed it as being at a very early stage and not necessarily especially promising.[60] Doctors' perceptions of the various research projects being carried out thus seemed to broadly correlate with the assessment provide by the Notifying Party, in terms of their respective stages and chances of success.

(118) No competitors claimed that Abbott's strong position in TMVr (with the MitraClip) would give it any advantage in developing a TMVR device.[61] A very small number of doctors did consider that Abbott's experience in TMVr might help it to enter the TMVR market, as it already has a customer base and has experience with transcatheter mitral technology. A number of doctors, however, also pointed out the technical differences between the products, which would make Abbott's experience in TMVr irrelevant. One answered, for example, *"from a technical perspective, the TMVr device (MitraClip) differs significantly from TMVR devices"*.[62]

(119) Similarly, no competitors felt that St Jude's presence in TAVI would give it an advantage in developing a TMVR device.[63] A minority of doctors did, however, claim that St Jude's experience in developing and marketing its TAVI device, Portico, would give it an advantage, as it has experience in transcatheter technologies, an existing customer base and contacts that could be useful for ensuring reimbursement for the device. Others, however, pointed out the difference

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59 Pre-notification calls with competitors.

60 Pre-notification calls with customers. Replies to Questionnaire Q2 – Questionnaire to Doctors, question 36.

61 Replies to Questionnaire Q1 – Questionnaire to Competitors, question 47.

62 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 37.

63 Replies to Questionnaire Q1 – Questionnaire to Competitors, question 48.

in the technological and anatomical characteristics of the two areas (mitral valves and aortic valves), which would minimise any potential advantage.[64]

(120) The results of the market investigation also confirmed the view expressed by the Notifying Party that transapical TMVR devices are likely to be the first to market, but that a 'second generation' of transfemoral devices is also expected to emerge a short time later. In addition to the reasoning given by the Notifying Party, competitors also saw this is being linked to the gradual 'miniaturisation' of the prostheses. The prostheses currently available are too large to be inserted via transfemoral access, and so transapical access is preferred, but as smaller prostheses become available, it is felt the focus might switch to transfemoral (and transseptal) access devices.[65]

(121) Competitors generally perceived there to be a significant advantage to being among the first to market in TMVR, as other manufacturers who launch products later will need to demonstrate that their products are in some way superior to those already available.[66] Doctors also shared this viewpoint, describing the first one or two competitors to reach the market as having a significant advantage over others. Furthermore, doctors were generally of the opinion that there would need to be three or four manufacturers on the market for TMVR in order for there to be sufficient competition, both in terms of price and innovation.[67] One doctor felt that there was room on the market for four or five manufacturers, but that a smaller number (up to three) would be expected to take the lead within five years.[68] A competitor had similar views on the number of manufacturers needed to be present on the market to cause prices to stabilise.[69]

(122) The results of the market investigation confirmed the Notifying Party's view that the success of early-stage pipeline products in this area is very uncertain, and difficult to assess. Market participants were even slightly more cautious than the Notifying Party in their assessment of companies' chances of bringing a particular product to market in this area, emphasising the difficulty of predicting the success of products in the early stages of development.[70]

(123) The only concerns expressed by competitors in relation to the effect of the Transaction in the area of structural heart related to conglomerate effects, in particular that the merged entity would have a broader portfolio (comprising St Jude's TAVI and LAA closure devices and Abbott's TMVr and TMVR pipeline).[71] The Notifying Party claims that these are separate product areas (i.e. the products would never be used in combination), and the market investigation did not provide

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64 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 38.

65 Pre-notification calls with competitors

66 Pre-notification calls with competitors.

67 Replies to Questionnaire Q2 – Questionnaire to Doctors, questions 39.2 and 39.3.

68 Pre-notification calls with doctors.

69 Replies to Questionnaire Q1 – Questionnaire to Competitors, question 49.2.

70 Pre-notification calls with doctors and competitors.

71 Replies to Questionnaire Q1 – Questionnaire to Competitors, question 51.1.

any evidence to the contrary. Nor was there any indication that manufacturers employ bundling strategies in this area.

(124) The Parties were not generally considered to be close competitors in the area of structural heart, but one competitor who did see there being a potential impact on innovation in this area viewed it as a positive one. Given that structural heart is seen as a growth area, this competitor thought that the merged entity might increase its R&D in this area, and thus be able to offer innovative products. Reference was also made to St Jude's IP in structural heart as a potential motivation for the Transaction, although no specific pipeline products were named.[72]

(125) Customers' views on the effect of the Transaction in the area of structural heart were generally similar. Only just under a quarter of doctors felt that the Transaction would have an impact in this area,[73] and those that were of this opinion more often identified a positive than a negative effect. Several doctors felt that the combined experience of the two companies could have a positive effect on the development of new products. One referred, for example to the "*positive impact on future developments by having experience from both companies"*. Their combined size was equally seen as an important factor by a number of respondents, including one who gave the following reply: *"They will be big enough to bring this field substantially forward - if too small they cannot compete against other big players"*. In a similar vein, another respondent mentioned a likely increase in investment, and the importance of being able to *"create competition to the bigger players namely Edwards and Medtronic"*. Nonetheless, a small minority of respondents also voiced concerns, including in relation to a slow-down in innovation, an increase in prices and a reduction in choice.[74]

(126) In view of the considerations discussed above, the Commission concludes that the proposed Transaction does not give rise to serious competition concerns in the area of structural heart, in particular in relation to transcatheter mitral valve replacement (TMVR) devices currently in development. Given that Abbott is expected to be amongst the first manufacturers to obtain CE mark approval, whilst St Jude is at a much earlier stage of development, the two products are not in close competition. There are around 30 research projects ongoing in this area, of which St Jude's is far from being in the leading group, and of which ultimately only three or four are expected to succeed and gain a place on the market.

## III.5. Conglomerate effects

### *III.5.1. Introduction*

(127) The Commission investigated whether the proposed Transaction would lead to conglomerate effects within the meaning of its Guidelines on the assessment of non-horizontal mergers (Non-horizontal merger guidelines)[75], in view of the fact that the

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72 Replies to Questionnaire Q1 – Questionnaire to Competitors, questions 57.1, 60.1 and 63.

73 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 40.

74 Replies to Questionnaire Q2 – Questionnaire to Doctors, question 40.1.

75 Commission's Guidelines on the assessment of non-horizontal mergers under the Council Regulation on the control of concentrations between undertakings (hereinafter "Non-horizontal merger guidelines"), paragraph 7.

Parties have broad and, to a large extent, complementary portfolios, including potentially some "must have" products.

(128) According to the Non-horizontal merger guidelines, while non-horizontal mergers are usually not anti-competitive, the combination of products in closely related markets may confer upon the merged entity the ability and incentive to leverage a strong market position in one market to another, by means of tying or bundling. Tying and bundling, as such, often have no anti-competitive effects, as companies engage in tying and bundling in order to provide their customers with better products or offerings in cost-effective ways. In certain circumstances, however, these practices may lead to a reduction in rivals' actual or potential ability or incentive to compete. This could, in turn, reduce the competitive pressure on the merged entity, thus allowing it to increase prices.[196]

*III.5.2. Products and markets concerned*

**III.5.2.1. Identification of relevant products in Abbott and St Jude's portfolios**

(129) In general, the Parties products are largely complementary. Although Abbott and St Jude each offer a portfolio of products, the Transaction does not, generally, combine "must have" products in closely related markets (i.e. complementary products which belong to a range of products that is generally purchased by the same set of customers for the same end use).[76] As explained in earlier sections, Abbott is active mainly in vascular products (guidewires, catheters and stents) and is hardly present in the other cardiovascular areas, while St Jude has a very strong presence in EP devices, in structural heart products and cardiac rhythm management products, while Abbott, apart from the TMVr MitraClip is hardly present.

(130) Based on the information submitted by the Notifying Party, and the results of the market investigation, the Commission identified the following pairs of products, where one product could potentially be used by the merged entity to leverage into the other market:

a. Large hole VCDs offered by Abbott, and other devices such as structural heart and other transcatheter devices offered by both Parties;

b. Coronary imaging products offered by St Jude and coronary interventional devices offered by Abbott;

**III.5.2.2. Competitive assessment**

*III.5.2.2.a VCDs and other cardiovascular devices offered by the Parties*

(131) In this section, the Commission assesses the extent to which the combination of Abbott's monopolistic position in large hole VCDs and St Jude's strong position in EP devices and structural heart devices could have anti-competitive effects.

(132) The Commission notes that Abbott is essentially the only supplier present on the market for large-hole VCDs. It is estimated that in TAVI St Jude's market share does not exceed [0-5]%, with the major players being Edwards Life Sciences and Medtronic, with market shares of [50-60]% and [20-30]% respectively. As regards

76 Non-horizontal merger guidelines, paragraph 91.

EP procedures, as submitted by the Notifying Party and confirmed by the results of the market investigation, St Jude is one of several major suppliers of EP devices, including Medtronic, Boston Scientific and Biosense Webster. St Jude has a strong position in diagnostic and ablation catheters, transseptal sheaths (as discussed in the section above) and navigation, mapping and recording devices.

(133) The Notifying Party submits that the merged entity will not be able to tie sales of large-hole VCDs to sales of TAVI or other structural heart or EP procedures for the following reasons. First, there is no concept of technical compatibility between large-hole VCDs and the other devices concerned. In general, the size of the device (structural heart or EP device) determines the size of the resulting hole, and this may not necessarily need to be closed using a large-hole VCD. Second, VCDs and the diagnostic and interventional products are typically sold to different purchasing departments, often at different times, and suppliers negotiate with different purchasing managers. Third, the Notifying Party submits that VCDs, TAVI and other relevant EP devices are typically sold through tenders designed to allow hospitals to procure from multiple suppliers. Suppliers are thus invited to provide separate bids for different devices, e.g. for VCDs, for EP devices etc. Moreover, hospitals typically hold stocks of VCDs, while transcatheter valve implants are often ordered shortly before a procedure. Fourth, VCDs form a negligible part of the cost of a typical TAVI or EP procedure and thus, the availability and pricing of VCDs will not drive purchasing decisions for more expensive devices that are critical to the procedure being performed.

(134) Furthermore, the Notifying Party submits that, post-Transaction, the merged entity will have no incentive to engage in anticompetitive tying or bundling. It emphasises St Jude’s low market share in TAVI devices, and the fact that the customer's choice of the main device (such as TAVI) is much more important than the hole closure method. In view of this, the Notifying Party argues that any bundling strategy would result in the loss of both TAVI and large-hole VCD sales, rendering the strategy unprofitable. The Notifying Party submits that Abbott anticipates significant growth in large-hole VCDs, and would not risk losing its opportunity to increase large-hole VCD sales by tying their availability to the customer’s commitment to purchase St Jude’s TAVI, whose position on the market is comparatively weak.

(135) Furthermore, the Notifying Party submits that EP procedures are complex procedures that involve the use of a range of devices, all of which are more expensive than large-hole VCDs. Consequently, other companies, such as Boston Scientific, Edwards and Medtronic, could offer alternative procedure-specific bundles, thus creating a scenario where there would be competition between various bundles.

(136) Finally, other companies could enter the large-hole VCD market. The Notifying Party claims that, in order to foreclose rival suppliers that offer similar bundles, Abbott would have to price its products at such a low level that it would forego significant profits, thus it would have no incentive to do this. This applies equally to the incentive to offer pure or mixed bundles, as rival suppliers could also offer customers discounted bundles that would allow them to minimise the overall cost of EP procedures, thus maintaining their share of output.

(137) More generally, the Notifying Party submits that any hypothetical tying or bundling could not significantly harm competition, as other significant global competitors with sizeable cardiovascular portfolios and strong positions across multiple products, including companies such as Boston Scientific, Edwards and Medtronic, could offer

comparable bundles of their own (alone or in partnership), and could not be foreclosed by a hypothetical tying or bundling strategy adopted by Abbott. The Notifying Party therefore argues that, in view of the presence of strong rival suppliers of EP devices, any bundling, even if possible, would only result in lower prices.

(138) Respondents to the market investigation were generally of the opinion that the combination of Abbott and St Jude's portfolios could have quite positive results. Overall, 72% of doctors who responded consider that companies that have a "must have" product are not able to impose the use of other products in their portfolio on practitioners (16% of respondents indicate that this can be done).[77] One of the respondents explained: "*Currently there is no company with a single must have product. Usually we have some alternatives".* Most of those respondents who considered that any kind of "bundling" in the cardiovascular area is possible referred to EP packages (steerable sheaths, ablation catheters, diagnostic catheters). One practitioner, for example, mentioned the strategy adopted by Medtronic, which offers cryoballoon catheters in combination with a complementary sheath. The doctor explained that *"this is useful, as these components work together without friction".*[78] The market investigation revealed that there are several companies that offer EP packages comprising complementary products, but practitioners do not view this as being detrimental. Instead, they feel they have a choice between the "EP packs", and, by purchasing in this way, they can be confident that the products contained in a pack will work well together.

(139) As regards tying other products to VCDs specifically, almost all practitioners explain that, when using a VCD produced by a particular company, they do not automatically use cardiovascular devices from the same company in the same procedure, be it for technical or convenience reasons. Almost all doctors explained that they choose the devices based on the patients' needs: *"We choose the most appropriate closure device for the individual patient (e.g. depends on vessels size, position of puncture relative to bifurcation, presence of calcifications, deepness of artery, etc.)".*[79] Some doctors explain that whilst it may happen that they use other devices from the same company, this would be coincidental, i.e. the VCD would not be a determining factor.[80]

(140) The responses of competitors regarding the possibility of pursuing the bundling strategy by Abbott post-Transaction were more nuanced, as in view of the very strong combined position of the Parties in VCDs (absent remedies) competitors feared that the merged entity could use its dominant position in VCDs to sell other cardiovascular products, for example, as suggested by one competitor, by bundling with St Jude TAVI or Abbott's coronary devices.[81] On the other hand, in particular as regards the EP devices one of the main suppliers on this market explained:

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77 See replies to Questionnaire Q2 – Questionnaire to Doctors, question 41.

78 See replies to Questionnaire Q2 – Questionnaire to Doctors, question 41.

79 See replies to Questionnaire Q2 – Questionnaire to Doctors, question 8.

80 See replies to Questionnaire Q2 – Questionnaire to Doctors, question 8.

81 See replies to Questionnaire Q1 – Questionnaire to Competitors, question 8.1.

*"In the field of EP, pricing is largely governed by the payers who have set the reimbursement levels for diagnosing and treating the various arrhythmias. As such, a new device is confined to fit within the existing reimbursement until it has sufficient evidence to justify incremental reimbursement. However, a truly unique product that offers significant user benefits should command a price premium, and new competing products would erode the price premium. It is our opinion that 2-3 competitive products would be required to see the pricing stabilise."*[82]

(141) The Commission considers that this shows that the procurement patterns and reimbursement schemes limit the suppliers' ability to increase prices. In view of this, suppliers incentives to pursue any bundling strategy designed to increase prices would be limited.

(142) Furthermore, the Commission notes that, absent the Transaction, Abbott was already the only supplier of large-hole VCDs. None of the market participants who replied to the market investigation suggested that Abbott would be able to leverage this position in order to tie these products to its other cardiovascular products, for example the MitraClip TMVr device.

(143) In light of the above considerations, it is unlikely that the merged entity would have the ability and the incentive to engage in bundling of VCDs with other cardiovascular devices.

*III.5.2.2.b Coronary imaging products offered by St Jude and coronary interventional devices offered by Abbott*

(144) In this section, the Commission assesses the possibility that the merged entity may be able to leverage its strong position in coronary imaging products, brought by St Jude, to influence the market for coronary interventional devices, on which Abbott is a relatively strong supplier. Coronary imaging products are used to diagnose coronary artery disease while coronary interventional devices, such as stents and balloons, are used to treat the artery disease by removing the arterial blockages and restoring blood flow.

(145) In the area of coronary imaging products, St Jude offers fractional flow reserve (FFR) measurements and Optical Coherence Tomography (OCT) machines. FFR measurements show the severity of blood flow blockages in the coronary arteries and allow physicians to identify and decide whether to stent the lesion or the blockage causing the restricted blood flow. OCT machines are used to aid the diagnosis and treatment of coronary artery disease, by adding light to obtain images of the vessels. St Jude's market share on the market for FFR measurement is estimated at [50-60]%, the competing suppliers being Philips Volcano with a market share of [30-40]%, ACIST Medical Systems with a market share of [0-5]% and Boston Scientific and Opsens Medical with estimated market shears of less than [0-5]% each. On the market for OCT machines it is estimated that St Jude has a market share of [80-90]%, with the remaining [10-20]% of the market belonging to Terumo.

(146) FFR measurement and OCT imaging are used in diagnostic procedures carried out in advance of performing interventional procedures, in which coronary interventional devices such as stents could be used.

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82 See replies to Questionnaire Q1 – questionnaire to Competitors, question 40.

(147) On the market for percutaneous coronary intervention (PCI) devices, such as stents and balloons, the Notifying Party estimates that Abbott has a market share of approximately [20-30]% in stents for peripheral procedures and [30-40]% in coronary procedures. According to the Notifying Party, a number of competitors are present on that market, including both suppliers of stents for both categories of procedures, such as Medtronic ([10-20]% market share in peripheral and [20-30]% market share in coronary procedures) and Boston Scientific ([10-20]% market share in peripheral and [20-30]% market share in coronary procedures), and suppliers more present in one type of procedure, such as Bard (with a market share of [10-20]% in stents for peripheral procedures), Biotronik ([10-20]% in stents for coronary procedures) and Cardinal Health/ Cordis ([10-20]% in stents for peripheral procedures).

(148) The Notifying Party submits that the use of the imaging systems is unconnected to the use of specific interventional devices such as stents and, in particular, there is no issue of technical compatibility.

(149) Furthermore, the Notifying Party submits that, post-Transaction, Abbott would not be able to tie the sale of coronary imaging devices supplied by St Jude to its sale of PCI devices (including stents), for the following reasons.

(150) First, there is no issue of technical compatibility between coronary imaging devices and PCI devices such as stents, and the type of diagnostic equipment used (such us coronary imaging devices) has no bearing on the selection of PCI devices and *vice versa*.

(151) Second, procurement of coronary imaging devices and PCI devices tends to be organised by different purchasing departments, at different times, and hospitals that issue tenders invite separate bids for the various PCI and imaging devices.

(152) Third, FFR measurement and OCT devices sold by St Jude are composed of a reusable hardware component and disposable accessories specific to the hardware. Bundling the hardware component of FFR measurement and OCT devices with PCI devices would not be possible, as customers buy coronary imaging hardware far less frequently than PCI devices, which are single use. Bundling the disposable imaging accessories with PCI devices is equally implausible for similar reasons.

(153) Fourth, the coronary imaging devices and PCI devices are typically sold through tenders designed to allow hospitals to procure from multiple suppliers. Accordingly, customers typically invite separate bids for imaging devices, guidewires, stents, VCDs, etc. Offering to supply coronary imaging devices together with PCI devices only in fixed proportions and only at the same time would not be feasible and, even if it were, would not be accepted by customers.

(154) Finally, the Notifying Party notes that Abbott and St Jude already have a co-marketing arrangement pursuant to which, in […] Abbott offers its customers St Jude's imaging devices with its own PCI devices, mostly at the request of customers. The arrangements have so far generated fairly limited revenue.[83] The Notifying

[83] In [country A] in 2015 this arrangement generated annual revenue of only EUR […], about […] % of Abbott's annual sales of PCI devices in [country A]. In [country B] in 2015 this arrangement generated annual revenues of EUR […] million, i.e. around […] % of Abbott's annual sales of PCI devices in [country B]. And in the [country C] in 2015 this arrangement generated annual revenues of only EUR […], around […] % of Abbott's annual sales of PCI devices in [country C].

Party submits that the Transaction will not change this dynamic by increasing Abbott's ability to bundle its stents and other PCI devices with St Jude's FFR measurement and OCT imaging devices.

(155) The Notifying Party argues that, post-Transaction, Abbott will also lack the incentive to engage in anticompetitive tying or bundling, as any attempt to engage in pure bundling would result in a significant loss of sales. This is because customers in most EEA countries prefer to procure via tenders that contain separate lots for imaging and PCI devices. And since PCIs are complex procedures that use multiple devices, other companies such as Terumo and Boston Scientific could also offer PCI-specific bundles comprising an FFR measurement or OCT imaging device and a PCI device. Other companies, such as Medtronic and Edwards, could offer other PCI-related bundles (e.g., including balloon catheters, valves and other PCI devices), which would be at least as valuable to customers. According to the Notifying Party, in order to foreclose rival suppliers that can offer similar bundles, the merged entity would therefore have to price its products at such a level that it would be foregoing significant profits.

(156) Finally, the Notifying Party submits that, in any event, any hypothetical tying or bundling could not significantly harm competition to the detriment of consumers, because other significant global competitors could offer comparable bundles of their own (alone or in partnership). Such competing companies include, for example, Terumo (which has in its portfolio OCT imaging and PCI devices), Boston Scientific (which offers FFR measurement and a broad range of PCI devices) and Philips/Volcano (which offers FFR measurement and PCI devices). Given the presence of strong rival suppliers of PCI devices, any bundling – assuming it were possible – would only result in lower prices.

(157) The Commission notes that Abbott and St Jude already have co-marketing arrangements in some countries, and that these have had a […] effect on sales, and were not the subject of any complaints raised in response to the market investigation. The Commission views this as an indication that the Transaction could not lead to a worsening of competition on the markets concerned.

(158) The Commission notes that the only possibility of bundling identified by the market participants in reply to the market investigation related to packages of EP devices (as explained in recital (138) above). Practitioners did not raise concerns regarding potential bundling of coronary imaging devices and PCI products. Instead, practitioners explained that hospitals tend to organise tenders in a way that does not allow for bundling of products, and in some countries, in particular in the public sector, purchasing in bundles is not permitted. This supports the Notifying Party's submission.[84]

(159) Furthermore, doctors emphasised that they tend to have a range of PCI devices available in the hospital, allowing them to choose the most appropriate product for the specific procedure and patient. Thus, with respect to patients' health, a hospital could not justify having only one type of PCI devices, offered by one manufacturer, merely on the grounds that they are sold in a bundle. While doctors acknowledged that they are asked to take prices into account in their choices (especially for devices which are less crucial for the procedure), the general view is that practitioners do

84 See non-confidential minutes of a call with a practitioner of 6 September 2016.

have the deciding vote in terms of which products the hospital needs to purchase. In particular doctors want to have products from several suppliers available to be able to choose the one that is the most suitable in a specific case for a specific patient.

(160) Some competitors, who in general were more sceptical regarding the impact of the Transaction, *("the combination of the two companies' collective sales force will strengthen their presence in the market"*[85]) indicated that it may have positive results:

"*the merger will likely impact innovation on other products where their combined strengthened position (guidewires, VCDs, valves, balloons, stents) will allow them to reduce price to attract the entire PCI portfolio (including therapy and diagnostic devices) or management services on a wider but related portfolio of products (PCI related, diabetes , vision, cardiology).*"[86]

(161) Furthermore, one of the major competitors that has a strong presence in CPI devices, Medtronic, explained that its subsidiary *"purchases VCDs of Abbott and St Jude and resells them through Medtronic subsidiaries to hospitals in the EU as part of material management services in fee-per-procedure packages which will also include stents, guidewires, catheters and TAVI systems, respectively"*.[87] This supports the Notifying Party's view that competing companies, alone or in a partnership, may offer alternative bundles of products, thereby strengthening competition rather than leading to anti-competitive effects.

(162) In light of the above, the Commission considers that it is unlikely that the merged entity would have the ability and the incentive to engage in bundling of coronary imaging devices with coronary interventional products.

*Conclusion*

(163) In light of the above, the Commission concludes, for the purpose of this decision, that the Transaction is unlikely to lead to conglomerate effects which would raise serious doubts as to the compatibility of the Transaction with the internal market.

## IV. PROPOSED REMEDIES

(164) In order to render the concentration compatible with the internal market, the undertakings concerned have modified the notified concentration by entering into the following commitments, which are annexed to this decision and form an integral part thereof (the "Commitments").

(165) To address the concerns identified during the market investigation in relation to VCDs, Abbott has committed to divest the entire global business of St Jude's VCDs, consisting of the technology, manufacturing, marketing, sales and distribution of St Jude VCDs, the AngioSeal and FemoSeal product lines ("the VCD Divestment Business"). To address the concerns identified during the market investigation in relation to transseptal sheaths, Abbott has committed to divest Kalila Medical Inc. ("Kalila Medical"), a company acquired by Abbott in early 2016 (see Section

85 See replies to question 64 to Questionnaire Q1 – Questionnaire to Competitors.

86 See replies to question 63.1 to Questionnaire Q1 – Questionnaire to Competitors.

87 See replies to Questionnaire Q1 – Questionnaire to Competitors, question 5.1.

III.3.2.3 above), that has developed a transseptal sheath sold under the Vado trademark ("the Vado Divestment Business"). The VCDs Divestment Business and the Vado Divestment Business are together referred to as the Divestment Businesses.

(166) The Divestment Businesses include all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the Divestment Businesses, in particular:

(167) The VCDs divestment business consists of:

a. part of the production facility of St Jude's Caguas plant (Puerto Rico), which is dedicated to the assembly of St Jude's main VCD product (AngioSeal). This facility manufactures the vast majority of St Jude's VCDs sold in the EEA;

b. St Jude's manufacturing equipment currently located in Minnesota (used for the production of AngioSeal VCDs for China and Argentina[88] and some components of AngioSeal and FemoSeal VCDs) and Costa Rica (used for the assembly of FemoSeal VCDs);

c. relevant personnel, who are working in the VCD business;

d. tangible and intangible assets, IP rights, expertise, customer records and contracts with suppliers and customers relating to AngioSeal and FemoSeal; and

e. arrangements for transitional support services to transfer the above manufacturing equipment from the operations retained by St Jude to the Caguas plant or to other plants owned by the purchaser.

(168) The Vado Divestment business includes Abbott's shareholding in Kalila Medical, which has developed the Vado sheath. Kalila Medical was bought by Abbott in early 2016 but was not integrated into its operations. The Vado Divestment Business includes the technology, relevant manufacturing arrangements (with a third party, CMO), patents, trademarks and transitional arrangements necessary for the purchaser to operate effectively and independently of the merged entity.

(169) In addition, the Divestment Businesses include the benefit, for a transitional period of two years, with a possibility to extend twice for an additional year, after Closing and on terms and conditions equivalent to those at present afforded to the Divestment Businesses, of all current arrangements under which St Jude and Abbot respectively and their Affiliated Undertakings supply products or services to the Divestment Businesses, unless otherwise agreed with the Purchaser. Strict firewall procedures will be adopted so as to ensure that any competitively sensitive information related to such transitional arrangements will not be shared with or passed on to anyone outside the Divestment Businesses.

(170) Abbott has also entered into related commitments, *inter alia* regarding the separation of the Divestment Businesses from their retained businesses, the preservation of the

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88 China and Argentina prohibit US-sourced bovine collagen, therefore for these countries the Minnesota facility uses collagen sourced from Australia.

viability, marketability and competitiveness of the divested businesses, including the appointment of a monitoring trustee and, if necessary, a divestiture trustee.

(171) Abbott and St Jude have identified Terumo as a purchaser for the Divestment Businesses. Terumo is a Japanese company active in the manufacture and supply of cardiovascular devices, with a turnover in Europe of approximately EUR 500 million.

(172) The Notifying Party submits that the Divestiture will eliminate the competition concerns entirely: the sale of the VCDs Divestment Businesses will eliminate completely any overlap in small-hole VCDs and the sale of the Vado Divestment Business will address any overlap in transseptal sheaths. The Notifying Party submits that the Divestment Businesses are comprehensive and effective: they include all the assets needed to compete effectively and the fact that Abbott has already identified a purchaser for the divestment Businesses confirms that the Divestment Businesses are complete and attractive. For the same reason, the Divestiture is capable of being implemented quickly, as Abbott, St Jude and Terumo have already agreed the terms under which Terumo will purchase the Divestment Businesses. Terumo has already conducted due diligence and is satisfied that the Divestment Businesses include all the elements Terumo needs in order to be able to operate them effectively immediately after closing.

## V. ASSESSMENT OF THE PROPOSED REMEDIES

(173) The Commission analysed the suitability of the proposed commitments to remedy serious doubts in this case against the standard set out in the Commission Notice on Remedies.[89]

### V.1. Framework for the Commission's assessment of the Commitments

(174) Where a notified concentration raises serious doubts as to its compatibility with the internal market, the parties may modify the notified concentration so as to remove the grounds for the serious doubts identified by the Commission, with a view to having it declared compatible with the internal market pursuant to Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation.

(175) As set out in the Commission Notice on Remedies, commitments must eliminate the Commission's serious doubts entirely, they must be comprehensive and effective from all points of view, and they must be capable of being implemented effectively within a short period of time, as the conditions of competition on the market will not be maintained until the commitments have been fulfilled.[90]

(176) In assessing whether or not commitments will restore effective competition, the Commission considers their type, scale and scope, by reference to the structure and the particular characteristics of the market in which the Commission has identified

89 Commission Notice on remedies acceptable under Council Regulation (EC) No 139/2004 and under Commission Regulation (EC) No 802/2004 (2008/C 267/01), (the "Commission Notice on Remedies").

90 Commission Notice on Remedies, paragraph 9.

serious doubts as to the compatibility of the notified concentration with the internal market.[91]

(177) Divestiture commitments are the best way to eliminate serious doubts resulting from horizontal overlaps in the merging parties' activities.[92] Other commitments (such as licensing) may be suitable to resolve serious doubts if these commitments are equivalent to divestitures in their effects. The divested activities must consist of a viable business that, if operated by a suitable purchaser, can compete effectively with the merged entity on a lasting basis and that is divested as a going concern.[93]

(178) The business to be divested must include all the assets which contribute to its current operation or which are necessary to ensure its viability and competitiveness, and all personnel which are currently employed or which are currently shared between the business to be divested and other businesses of the parties, but which contribute to the operation of the business or which are necessary to ensure its viability and competitiveness. Otherwise, the viability and competitiveness of the business to be divested would be endangered. Therefore, the business to be divested must contain the personnel providing essential functions for the business, at least in a sufficient proportion to meet the ongoing needs of the business to be divested.[94]

(179) Furthermore, the intended effect of the divestiture will only be achieved if and once the business is transferred to a suitable purchaser with proven relevant expertise and ability to maintain and develop the business to be divested as a viable and active competitive undertaking.

### V.2. **Results of the market test**

(180) To assess the suitability of the Commitments to remove serious doubts in this case, the Commission launched a market test on 3 November 2016.

(181) The market test indicated that the Commitments proposed in this case are suitable overall, in that they include all the necessary assets, provide for divestiture of two stand-alone businesses and are likely to lead to the emergence of a new player or new players in the area of VCDs and transseptal sheaths.

### V.3. Suitability of the proposed commitments to remedy serious doubts in the area of VCDs and transseptal sheaths

(182) The proposed commitments cover all problematic markets and include, for VCDs, the relevant manufacturing facility, and for transseptal sheaths, all the assets concerned, including the manufacturing arrangement. Following the sale of the VCDs Divestment Business, there would no longer be any overlap between Abbott and St Jude in the area of VCDs. The divestiture will also completely remove the overlap in transseptal sheaths.

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91 Commission Notice on Remedies, paragraph 12.

92 Commission Notice on Remedies, paragraph 17.

93 Commission Notice on Remedies, paragraph 23.

94 Commission Notice on Remedies, paragraphs 25 and 26.

(183) The VCD Divestment Business includes the relevant manufacturing facility in which the vast majority of the VCDs are manufactured, namely the production facility of St Jude's Caguas plant (Puerto Rico). The manufacturing equipment which will be transferred – used to make components for AngioSeal for China and Argentina, for bioabsorbable anchors and bypass tubes for all AngioSeal devices (located at St Jude's Minnesota plant) and for the assembly of FemoSeal (currently located at St Jude's Costa Rica plant) are easily transferrable.[95] The divestiture of other plants owned by St Jude would not be proportionate: the adjacent building in the Caguas plant produces unrelated products (valves) and the assembly of all FemoSeal devices, performed at St Jude's Costa Rica facility, occupies approximately 5% of the total manufacturing space within that facility.

(184) The transseptal sheaths business being divested includes all Abbott's existing assets related to the development, manufacturing ([…]) and sale of transseptal sheaths.

(185) Both Divestment Businesses include transitional arrangements. Abbott committed to offer transitional support services to the purchaser of the Divestment Businesses. With regard to the VCDs divestment Business the transitional arrangements include transitional support for the carve-out process, IT services, finance and accounting, supply chain, regulatory procedures, quality, sales and marketing support etc. With regard to the Vado divestment business the transitional arrangements relate to amongst others sales and marketing support, regulatory and testing support. According to the respondents to the market test the transitional arrangements are sufficient both in terms of scope and duration. They run for up to two years after the closure of the Transaction, with a possibility to extend them twice, each time for an additional year (thus making a maximum of four years in total). Finally, as an additional assurance the Commission notes that the transitional arrangements have already been negotiated by Abbott and St Jude with the proposed purchaser, Terumo.

(186) The results of the market test did not reveal any concerns as regards the feasibility of the transfer or the viability of the Divestment Businesses.

(187) For the avoidance of any doubt, it should be noted that this decision in no way constitutes the approval of Terumo as a buyer. The Commission will assess this subsequently in a separate decision.

(188) The market test confirmed that the proposed commitments are sufficient to remedy the serious doubts in this case and to generate a new competitive force in the market. According to the market participants, the package contains all the necessary assets for the purchaser to continue selling VCDs and commercialise the Vado transseptal sheath. As concerns the duration of the transitional agreements, most respondents to the market test considered that they are sufficient in scope and duration for the purchaser to begin to produce identical VCDs to those of St Jude and to enter the market with its own VCDs.

(189) The Commitments include the standard criteria for a suitable purchaser (contained in section D of the Commitments), in particular that the purchaser(s) must have proven

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95 Furthermore, prior to and independent from the Transaction, in order to reduce costs, St Jude had begun to transfer production of the components for AngioSeal for China and Argentina from the Minnesota to the Caguas Facility. This transfer is expected to be completed in […].

expertise and the incentive to maintain and develop the Divestment Businesses as viable and active competitive forces in competition with Abbott and other competitors.

(190) On this basis, the Commission considers the Commitments to be sufficient in scope and suitable to eliminate serious doubts as to the compatibility of the Transaction with the internal market in relation to VCDs and transseptal sheaths, given the purpose of Article 6(2) of the Merger Regulation.

### V.4. Conclusion on the Commitments

(191) On the basis of the above, the Commission concludes that the Commitments are suitable and sufficient to remedy the serious doubts raised by the Transaction in relation to VCDs and transseptal sheaths. Moreover, the Commitments are comprehensive and effective from all points of view, and are capable of being implemented effectively within a short period of time.

(192) The Commitments provide for a full divestment of the competing businesses and thus entirely remove the future overlap between the Parties in the EEA and the individual Member States, and worldwide.

(193) The Commitments will allow a new player(s) to emerge on the VCD market and on the transseptal sheaths market. In addition, given that the Vado Divestment Business comprises a pipeline product, which is perceived as having important superior features compared to products currently on the market, the Commitments will contribute to the creation of an entrant who will have the potential to further develop and improve the product.

## VI. CONDITIONS AND OBLIGATIONS

(194) Pursuant to the first sentence of the second subparagraph of Article 6(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 concentration compatible with the internal market.

(195) The achievement 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 and the EEA Agreement no longer stands. Where the undertakings concerned commit a breach of an obligation, the Commission may revoke the clearance decision in accordance with Article 8(6)(b) 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.

(196) In accordance with the basic distinction between conditions and obligations, the decision in this case is conditional on full compliance with the requirements set out in Section B of the final Commitments (including the Schedule), which constitute conditions. The remaining requirements set out in the other Sections of the said Commitments are considered to constitute obligations.

(197) The full text of the final Commitments is annexed to this Decision as Annex I and forms an integral part thereof.

## VII. CONCLUSION

(198) For the above reasons, the Commission has decided not to oppose the notified operation as modified by the commitments and to declare it compatible with the internal market and with the functioning of the EEA Agreement, subject to full compliance with the conditions in section B (including the Schedule) of the commitments annexed to the present decision and with the obligations contained in the other sections of the said commitments. This decision is adopted in application of Article 6(1)(b) in conjunction with Article 6(2) of the Merger Regulation and Article 57 of the EEA Agreement.

*For the Commission*

*(signed)*
*Margrethe VESTAGER*
*Member of the Commission*

October 31, 2016

**Case COMP/M.8060 – Abbott Laboratories/St. Jude Medical**

**COMMITMENTS TO THE EUROPEAN COMMISSION**

Pursuant to Article 6(2) of Council Regulation (EC) No. 139/2004 (the "Merger Regulation"), Abbott Laboratories ("Abbott") hereby enters into the following Commitments (the "Commitments") vis-à-vis the European Commission (the "Commission") with a view to rendering Abbott's acquisition of St. Jude Medical, Inc. ("SJM" and, together with Abbott, the "Parties") (the "Transaction") compatible with the internal market and the functioning of the EEA Agreement.

This text shall be interpreted in light of the Commission's decision pursuant to Article 6(1)(b) of the Merger Regulation to declare the Transaction compatible with the internal market and the functioning of the EEA Agreement (the "Decision"), in the general framework of European Union law, in particular in 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 (the "Remedies Notice").

For the avoidance of doubt, the Schedule and the Annexes (1-3) form an integral part of the Commitments.

**Section A. Definitions**

1. For the purpose of the Commitments, the following terms shall have the following meaning:

   **Abbott**: Abbott Laboratories, incorporated under the laws of the State of Illinois, with its headquarters at 100 Abbott Park Road, Abbott Park, Illinois 60064, United States.

   **Affiliated Undertakings**: undertakings controlled by the Parties, whereby the notion of control shall be interpreted pursuant to Article 3 of the Merger Regulation and in light of the Commission Consolidated Jurisdictional Notice under Council Regulation (EC) No 139/2004 on the control of concentrations between undertakings (the "Consolidated Jurisdictional Notice").

   **Angio-Seal**: VCDs developed and manufactured by SJM that are sold under the *Angio-Seal*™ trademark.

   **Assets:** assets that contribute to the current operation of, or are necessary to ensure the viability and competitiveness of, each Divestment Business as indicated in Section B and described in more detail in the Schedule.

   **Caguas Building B Facility**: the portion of the facility located at […], Puerto Rico, that is used by SJM to manufacture VCDs.

   **Closing**: the transfer of the Divestment Businesses to the Purchaser.

   **Closing Period**: the period of […] from the approval of the Purchaser and the terms of sale by the Commission.

**Confidential Information**: any business secrets, know-how, commercial information, or any other information of a proprietary nature that is not in the public domain.

**Conflict of Interest**: any conflict of interest that impairs the Trustee's objectivity and independence in discharging its duties under the Commitments.

**Costa Rica Facility:** the portion of the facility located at […], Alajuela, Costa Rica, that is used by SJM to manufacture VCDs.

**Divestment Business**: each of the VCD Business and the Vado Business, as defined in Section B and in the Schedule.

**Divestiture Trustee**: one or more natural or legal person(s) who is/are approved by the Commission and appointed by Abbott and who has/have received from Abbott the exclusive Trustee Mandate to sell the Divestment Businesses to one or more Purchasers at no minimum price.

**Effective Date**: the date of adoption of the Decision.

**FemoSeal**: VCDs developed and manufactured by SJM that are sold under the *FemoSeal*™ trademark.

**First Divestiture Period**: the period of […] from the Effective Date.

**Hold Separate Manager**: the person appointed by Abbott for the Divestment Businesses to manage the day-to-day business under the supervision of the Monitoring Trustee.

**Kalila Medical**: Kalila Medical, Inc., a Delaware corporation and indirect wholly-owned subsidiary of Abbott that manufactures and sells Transseptal Introducer Sheaths.

**Key Personnel**: all personnel necessary to maintain the viability and competitiveness of the Divestment Businesses, as listed in the Schedule, including the Hold Separate Manager(s).

**Minnesota Facility**: the portion of the premises used in connection with the manufacture of SJM's small hole VCDs and located at […], Minnetonka, MN 55345, United States.

**Monitoring Trustee**: one or more natural or legal person(s) approved by the Commission and appointed by Abbott who has/have the duty to monitor Abbott's compliance with the conditions and obligations attached to the Decision.

**Personnel**: all staff currently employed by the Divestment Businesses, including staff seconded to the Divestment Businesses, shared personnel as well as the additional personnel listed in the Schedule.

**Purchaser**: the entity or entities approved by the Commission to acquire each Divestment Business in accordance with the criteria set out in Section D.

**Purchaser Criteria**: the criteria laid down in paragraph 16 of these Commitments that the Purchaser must fulfil in order to be approved by the Commission.

**Schedule**: the schedule to these Commitments that describes the Divestment Businesses.

**SJM:** St. Jude Medical, Inc., incorporated under the laws of State of Minnesota, with its headquarters at One St. Jude Medical Drive, St Paul, Minnesota 55117, United States.

**Transitional Period**: the period during which Abbott or its Affiliated Undertakings provide Transitional Services to the Purchaser or Purchasers of the VCD Business and the Vado Business.

**Transseptal Introducer Sheath**: a sheath used to deliver diagnostic and therapeutic catheters to the left atrium of the heart.

**Transitional Services**: services provided by Abbott and/or its Affiliated Undertakings for the Transitional Period in respect of the VCD Business and the Vado Business as described in Annex 3.

**Trustee(s)**: the Monitoring Trustee and/or the Divestiture Trustee, if appointed, as the case may be.

**Trustee Divestiture Period**: the period of […] from the end of the First Divestiture Period.

**Vado**: Transseptal Introducer Sheaths developed and manufactured by Kalila Medical and sold under the *Vado*® trademark.

**Vado Business**: Abbott's global Transseptal Introducer Sheaths business comprised of its shareholding in Kalila Medical, which manufactures and sells Transseptal Introducer Sheaths sold under the *Vado*® trademark.

**VCD**: a vessel/vascular closure device used to close a hole created in an artery following a minimally invasive cardiovascular procedure.

**VCD Business**: SJM's global small hole VCD business comprised of its *Angio-Seal*™ and *FemoSeal*™ product lines.

## Section B. The Commitment to Divest and the Divestment Businesses

Commitment to Divest

2. In order to maintain effective competition, Abbott commits to divest, or procure the divestiture of, each Divestment Business by the end of the Trustee Divestiture Period as a going concern to a Purchaser on terms of sale approved by the Commission in accordance with the procedure described in paragraphs 17-18 of these Commitments. To carry out the divestiture, Abbott commits to find a Purchaser and to enter into a final binding sale and purchase agreement for the sale of each Divestment Business within the First Divestiture Period. If Abbott has not entered into such agreements in respect of each Divestment Business at the end of the First Divestiture Period, Abbott shall grant the Divestiture Trustee an exclusive mandate to sell either or both Divestment Businesses in accordance with the procedure described in paragraph 31 of the Commitments in the Trustee Divestiture Period.

3. Abbott shall be deemed to have complied with this commitment if:

   (a) by the end of the Trustee Divestiture Period, Abbott or the Divestiture Trustee has entered into a final binding sale and purchase agreement in respect of each Divestment Business and the Commission has approved the proposed Purchaser and the terms of sale as being consistent with the

Commitments in accordance with the procedure described in paragraphs 17-18 of the Commitments;

(b) the Closing of the sale of the Divestment Businesses to the Purchaser takes place within the Closing Period; and

(c) the transfer of manufacturing equipment and any associated know-how described in the Schedule has been completed and the provision of transitional manufacturing and services by Abbott has come to an end.

4. In order to maintain the structural effect of the Commitments, Abbott shall, for a period of ten (10) years after Closing, not acquire, whether directly or indirectly, the possibility of exercising influence (as defined in paragraph 43 of the Remedies Notice, footnote 3) over the whole or part of either Divestment Business, unless, following the submission of a reasoned request from Abbott showing good cause and accompanied by a report from the Monitoring Trustee (as provided in paragraph 44 of these Commitments), the Commission finds that the structure of the market has changed to such an extent that the absence of influence over the Divestment Businesses is no longer necessary to render the proposed concentration compatible with the internal market.

Structure and Definition of the Divestment Businesses

5. The Divestment Businesses comprise the VCD Business and the Vado Business. The legal and functional structure of the Divestment Businesses as operated to date, described in more detail in the Schedule, include all Assets and staff that contribute to the current operation of these Businesses or that are necessary to ensure their viability and competitiveness, in particular:

(a) all tangible and intangible assets (including intellectual property rights), including but not limited to those listed in the Schedule;

(b) all licenses, permits, and authorizations issued by any governmental organization for the benefit of the Divestment Businesses, including but not limited to those listed in the Schedule;

(c) all contracts, leases, commitments, and customer orders of the Divestment Businesses, including but not limited to those listed in the Schedule;

(d) all customer, credit and other records of the Divestment Businesses, including but not limited to those listed in the Schedule; and

(e) the Personnel, including but not limited to those individuals listed in the Schedule.

6. In addition, the VCD Business and the Vado Business will benefit on terms and conditions equivalent to those at present afforded to the Divestment Businesses from Transitional Services agreed with the Purchaser for the Transitional Period of up to 4 years after the closing. Strict firewall procedures will be adopted by Abbott so as to ensure that any competitively sensitive information related to, or arising from such supply arrangements (for example, product roadmaps) will not be shared with, or passed on to, anyone outside the department(s) providing these Transitional Services.

## Section C. Related Commitments

Preservation of Viability, Marketability and Competitiveness

7. From the Effective Date until Closing, Abbott shall preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses, in accordance with good business practice, and shall minimise as far as possible any risk of loss of competitive potential of the Divestment Businesses. In particular Abbott undertakes:

    (a) not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Businesses or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Businesses;

    (b) to make available, or procure to make available, sufficient resources for the advancement of the Divestment Businesses, on the basis and continuation of the existing business plans;

    (c) to take all reasonable steps, or procure that all reasonable steps are being taken, including appropriate incentive schemes (based on industry practice), to encourage all Key Personnel to remain with the Divestment Businesses, and not to solicit or move any Personnel to Abbott's remaining business. Where, nevertheless, individual members of the Key Personnel exceptionally leave the Divestment Businesses, Abbott shall provide a reasoned proposal to replace the person or persons concerned to the Commission and the Monitoring Trustee. Abbott must be able to demonstrate to the Commission that the replacement is well suited to carry out the functions exercised by those individual members of the Key Personnel. The replacement shall take place under the supervision of the Monitoring Trustee, who shall report to the Commission.

Hold-separate Obligations

8. Abbott commits, from the Effective Date until Closing, to procure that the Divestment Businesses are kept separate from the businesses that Abbott will be retaining and to ensure that, except as necessary to carry out the Transitional Services as described in paragraph 6 of these Commitments: (i) management and staff of the businesses retained by Abbott have no involvement in the Divestment Businesses; and (ii) the Key Personnel and Personnel of the Divestment Businesses have no involvement in any business retained by Abbott and do not report to any individual outside the Divestment Businesses.

9. From the Effective Date until Closing, Abbott shall assist the Monitoring Trustee in ensuring that the Divestment Businesses are managed as distinct and saleable entities separate from the businesses that Abbott is retaining. Immediately after the adoption of the Decision, Abbott shall appoint a Hold Separate Manager. The Hold Separate Manager, who shall be part of the Key Personnel, shall manage the Divestment Businesses independently and in the best interest of the Businesses with a view to ensuring their continued economic viability, marketability and competitiveness and their independence from the businesses retained by Abbott. The Hold Separate Manager shall closely cooperate with and report to the Monitoring Trustee and, if applicable, the Divestiture Trustee. Any replacement of the Hold Separate Manager shall be subject to

the procedure laid down in paragraph 7 (c) of these Commitments. The Commission may, after having heard Abbott, require Abbott to replace the Hold Separate Manager.

10. To ensure that the Vado Business is held and managed as a separate entity, the Monitoring Trustee shall exercise Abbott's rights as a shareholder in the legal entity that constitutes the Vado Business (except for its rights in respect of dividends that are due before Closing), with the aim of acting in the best interest of the business, which shall be determined on a stand-alone basis, as an independent financial investor, with a view to fulfilling Abbott's obligations under the Commitments. Furthermore the Monitoring Trustee shall have the power to replace members of the supervisory board or non-executive directors of the board of directors, who have been appointed on behalf of Abbott. Upon request of the Monitoring Trustee, Abbott shall resign as a member of the boards or shall cause such members of the boards to resign.

Ring-fencing

11. Abbott shall implement, or procure to implement, all necessary measures to ensure that it does not, after the Effective Date, obtain any Confidential Information relating to the Divestment Businesses and that any such Confidential Information obtained by Abbott before the Effective Date will be eliminated and not be used by Abbott. This includes measures vis-à-vis Abbott's appointees on the supervisory board and/or board of directors of the Vado Business. In particular, the participation of the Divestment Businesses in any central information technology network shall be served to the extent possible, without compromising the viability of the Divestment Businesses. Abbott may obtain or keep information relating to the Divestment Businesses which is reasonably necessary for the divestiture of the Divestment Businesses, the disclosure of which to Abbott is required by law, or the retention and use of which by Abbott is required to comply with any contract not transferred to the Purchaser, including contracts between Abbott and the Purchaser.

Non-solicitation Clause

12. The Parties undertake, subject to customary limitations and except as otherwise agreed with the Purchaser, not to solicit, and to procure that Affiliated Undertakings do not solicit, the Key Personnel transferred with the Divestment Businesses for a period of two (2) years after Closing.

Due Diligence

13. In order to enable potential Purchasers to carry out a reasonable due diligence of the Divestment Businesses, Abbott 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 Businesses;

    (b) provide to potential Purchasers sufficient information relating to the Personnel and allow them reasonable access to the Personnel.

Reporting

14. Abbott shall submit written reports in English on potential Purchasers of the Divestment Businesses 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). Abbott

shall submit a list of all potential Purchasers having expressed interest in acquiring either Divestment Business to the Commission at each and every stage of the divestiture process, as well as a copy of all the offers made by potential Purchasers within five days of their receipt.

15. Abbott 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 any information memorandum to the Commission and the Monitoring Trustee before sending the memorandum out to potential Purchasers.

**Section D. The Purchaser**

16. In order to be approved by the Commission, each Purchaser must fulfil the following criteria:

    (a) The Purchaser shall be independent of and unconnected to the Parties and their Affiliated Undertakings (this being assessed having regard to the situation following the divestiture).

    (b) The Purchaser shall have the financial resources, proven expertise and incentive to maintain and develop the Divestment Businesses as viable and active competitive forces in competition with the Parties and other competitors.

    (c) The acquisition of the Divestment Businesses by the Purchaser must neither be likely to create, in 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. In particular, the Purchaser must reasonably be expected to obtain all necessary approvals from the relevant regulatory authorities for the acquisition of the Divestment Businesses.

17. The final binding sale and purchase agreements (as well as ancillary agreements) relating to the divestment of the VCD Business and the Vado Business shall be conditional on the Commission's approval. When Abbott has reached such agreement (or agreements) with a Purchaser (or Purchasers), it shall submit a fully documented and reasoned proposal, including a copy of the final agreement(s), within one week to the Commission and the Monitoring Trustee.

18. Abbott must be able to demonstrate to the Commission that each purchaser fulfils the Purchaser Criteria and that the Divestment Businesses are being sold in a manner consistent with the Commission's Decision and the Commitments. For the approval, the Commission shall verify that each potential Purchaser fulfils the Purchaser Criteria and that each of the Divestment Businesses is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market. The Commission may approve the sale of either of the Divestment Businesses without one or more Assets or parts of the Personnel for the applicable Divestment Business, or by substituting one or more Assets or parts of the Personnel with one or more different assets or different personnel for the applicable Divestment Business, if this does not affect the viability and competitiveness of the applicable Divestment Business after the sale, taking account of the proposed Purchaser (or Purchasers).

**Section E. Trustee**

I. Appointment Procedure

19. Abbott shall appoint a Monitoring Trustee to carry out the functions specified for a Monitoring Trustee. Abbott commits not to close the Transaction before the appointment of a Monitoring Trustee.

20. If Abbott has not entered into one or more binding sale and purchase agreements regarding the Divestment Businesses […] before the end of the First Divestiture Period, or if the Commission has rejected a Purchaser (or Purchasers) proposed by Abbott at that time or thereafter, Abbott shall appoint a Divestiture Trustee. The appointment of the Divestiture Trustee shall take effect upon the commencement of the Trustee Divestiture Period.

21. The Monitoring Trustee and the Divestiture Trustee shall:

    (i) at the time of appointment, be independent of Abbott and its Affiliated Undertakings;

    (ii) possess the necessary qualifications to carry out its mandate, for example have sufficient relevant experience as an investment banker or consultant or auditor; and

    (iii) neither have nor become exposed to a Conflict of Interest.

22. The Monitoring Trustee and the Divestiture Trustee shall each be remunerated by Abbott 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 either of the Divestment Businesses, such success premium may only be earned if the divestiture takes place within the Trustee Divestiture Period.

*Proposal by Abbott*

23. No later than two (2) weeks after the Effective Date, Abbott shall submit to the Commission for approval the name or names of one or more natural or legal persons whom Abbott proposes to appoint as the Monitoring Trustee.

24. In the event either of the Divestment Businesses is not sold to an approved Purchaser before then, no later than one month before the end of the First Divestiture Period or on request by the Commission, Abbott shall submit a list of one or more persons whom Abbott proposes to appoint as Divestiture Trustee to the Commission for approval. The proposal shall contain sufficient information for the Commission to verify that the person or persons proposed as Trustee fulfil the requirements set out in paragraph 21 of the Commitments 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*

25. The Commission shall have the discretion to approve or reject a 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, Abbott shall appoint or cause to be appointed the person or persons concerned as Trustee, in accordance with the mandate approved by the Commission. If more than one name is approved, Abbott 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 Abbott*

26. If all the proposed Trustees are rejected, Abbott shall submit the names of at least two more natural or legal persons within one week of being informed of the rejection, in accordance with paragraphs 19 and 25 of these Commitments.

*Trustee nominated by the Commission*

27. If all further proposed Trustees are rejected by the Commission, the Commission shall nominate a Trustee, whom Abbott shall appoint, or cause to be appointed, in accordance with a trustee mandate approved by the Commission.

II. Functions of the Trustee

28. The Monitoring Trustee and, if appointed, the Divestiture Trustee, shall assume the duties and obligations specified in paragraphs 29-32 in order to ensure compliance with the Commitments. The Commission may, on its own initiative or at the request of the Trustee or Abbott, 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*

29. 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, in close co-operation with the Hold Separate Manager, the on-going management of the Divestment Businesses with a view to ensuring their continued economic viability, marketability and competitiveness and monitor compliance by Abbott 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 Businesses, and the keeping separate of the Divestment Businesses from the businesses retained by the Parties, in accordance with paragraphs 8 and 9 of these Commitments;

(b) supervise the management of the Divestment Businesses as distinct and saleable entities, in accordance with paragraph 10 of these Commitments;

(c) supervise the implementation of Transitional Services in respect of the VCD Business and the Vado Business as agreed with the Purchaser or Purchasers;

(d) with respect to Confidential Information:

- determine all necessary measures to ensure that Abbott does not after the Effective Date obtain any Confidential Information relating to the Divestment Businesses,

- in particular strive for the severing of the Divestment Businesses' participation in a central information technology networks to the extent possible, without compromising the viability of the Divestment Businesses,

- make sure that any Confidential Information relating to the Divestment Businesses obtained by Abbott before the Effective Date is eliminated and will not be used by Abbott, and

- decide whether such information may be disclosed to or kept by Abbott as the disclosure is reasonably necessary to allow Abbott to carry out the divestiture or as the disclosure is required by law;

(e) monitor the splitting of assets and the allocation of Personnel between the Divestment Businesses and Abbott or Affiliated Undertakings;

(iii) propose to Abbott such measures as the Monitoring Trustee considers necessary to ensure Abbott'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 Businesses, the holding separate of the Divestment Businesses and the non-disclosure of competitively sensitive information;

(iv) 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 and correct information relating to the Divestment Businesses 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;

(v) act as a contact point for any requests by third parties, in particular potential purchasers, in relation to the Commitments;

(vi) provide to the Commission, sending Abbott a non-confidential copy at the same time, a written report within 15 days after the end of every month that shall cover the operation and management of the Divestment Businesses as well as the splitting of assets and the allocation of Personnel so that the Commission can assess whether the Divestment Businesses are held in a manner consistent with

the Commitments, the progress of the divestiture process, as well as potential purchasers;

(vii) promptly report in writing to the Commission, sending Abbott a non-confidential copy at the same time, if it concludes on reasonable grounds that Abbott is failing to comply with these Commitments;

(viii) within one week after receipt of the documented proposal referred to in paragraph 17 of these Commitments, submit to the Commission, sending Abbott a non-confidential copy at the same time, a reasoned opinion as to the suitability and independence of the proposed Purchaser (or Purchasers) and the viability of each of the Divestment Businesses after the sale and as to whether the Divestment Businesses are sold in a manner consistent with the conditions and obligations attached to the Decision, in particular, if relevant, whether the sale of the Divestment Businesses without one or more Assets or not all of the Personnel affects the viability of the Divestment Businesses after the sale, taking account of the proposed Purchaser (or Purchasers); and

(ix) assume the other functions assigned to the Monitoring Trustee under the conditions and obligations attached to the Decision.

30. If a Divestiture Trustee is appointed and the Monitoring and Divestiture Trustee are not the same legal or natural persons, the Monitoring Trustee and the Divestiture Trustee shall cooperate closely with each other during and for the purpose of the preparation of the Trustee Divestiture Period in order to facilitate each other's tasks.

*Duties and Obligations of the Divestiture Trustee*

31. If appointed, the Divestiture Trustee shall sell at no minimum price the Divestment Businesses to a Purchaser (or Purchasers), provided that the Commission has approved both the Purchaser(s) and the final binding sale and purchase agreement(s) (and ancillary agreements) as in line with the Commission's Decision and the Commitments in accordance with paragraphs 16, 17, and 18 of these Commitments. The Divestiture Trustee, if appointed, shall include in such sale and purchase agreement(s) (as well as in any ancillary agreements) such terms and conditions as it considers appropriate for an expedient sale in the Trustee Divestiture Period. In particular, the Divestiture Trustee may include in such sale and purchase agreement(s) such customary representations and warranties and indemnities as are reasonably required to effect the sale. If appointed, the Divestiture Trustee, if appointed, shall protect the legitimate financial interests of Abbott, subject to Abbott's unconditional obligation to divest at no minimum price in the Trustee Divestiture Period.

32. In any Trustee 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 Abbott.

III. <u>Duties and Obligations of the Parties</u>

33. Abbott shall provide and shall cause its advisors to provide the Monitoring Trustee and any Divestiture Trustee with all such co-operation, assistance and information as the Trustee may reasonably require to perform its tasks as set out in paragraphs 28-32 of these Commitments. The Trustee shall have full and complete access to any of Abbott's

or the Divestment Businesses' books, records, documents, management or other personnel, facilities, sites and technical information necessary for fulfilling its duties under the Commitments and Abbott and the Divestment Businesses shall provide the Trustee upon request with copies of any document. Abbott and the Divestment Businesses 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.

34. Abbott shall provide the Monitoring Trustee with all managerial and administrative support that it may reasonably request on behalf of the management of the Divestment Businesses. This shall include all administrative support functions relating to the Divestment Businesses which are currently carried out at headquarters level. Abbott shall:

    (a) 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; and

    (b) inform the Monitoring Trustee on possible Purchasers, submit lists of potential Purchasers at each stage of the selection process, including the offers made by potential Purchasers at those stages, and keep the Monitoring Trustee informed of all developments in the divestiture process. Abbott shall grant or procure its Affiliated Undertakings to grant comprehensive powers of attorney, duly executed, to the Divestiture Trustee to effect the sale (including ancillary agreements), 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, Abbott shall cause the documents required for effecting the sale and the Closing to be duly executed.

35. Abbott 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 Abbott 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.

36. At the expense of Abbott, the Trustee may appoint advisors (in particular for financial legal advice), subject to Abbott'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 Abbott refuse to approve the advisors proposed by the Trustee, the Commission may approve the appointment of such advisors instead, after having heard Abbott. Only the Trustee shall be entitled to issue instructions to the advisors. Paragraph 35 of these Commitments shall apply *mutatis mutandis*. In the Trustee Divestiture Period, the Divestiture Trustee may use advisors who served Abbott during the Divestiture Period if the Divestiture Trustee considers this in the best interest of an expedient sale.

37. Abbott agrees that the Commission may share Confidential Information proprietary to Abbott with the Trustee. The Trustee shall not disclose such information and the

principles contained in Article 17 (1) and (2) of the Merger Regulation apply *mutatis mutandis*.

38. Abbott agrees that the contact details of the Monitoring Trustee are published on the website of the Commission's Directorate-General for Competition and they shall inform interested third parties of the identity and the tasks of the Monitoring Trustee.

39. For a period of 10 years from the Effective Date the Commission may request all information from the Parties that is reasonably necessary to monitor the effective implementation of these Commitments.

IV. Replacement, Discharge and Reappointment of the Trustee

40. If the Monitoring Trustee or any Divestiture 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 and Abbott, require Abbott to replace the Trustee; or

    (b) Abbott may, with the prior approval of the Commission, replace the Trustee.

41. If the Monitoring Trustee or any Divestiture Trustee is removed according to paragraph 40 of these Commitments, 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 19-27 of these Commitments.

42. Unless removed according to paragraph 40 of these Commitments, 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

43. The Commission may extend the time periods foreseen in the Commitments in response to a request from Abbott or, in appropriate cases, on its own initiative. Where Abbott requests an extension of a time period, it shall submit a reasoned request to the Commission no later than one month before the expiry of that period, showing good cause**.** This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to Abbott. Only in exceptional circumstances shall Abbott be entitled to request an extension within the last month of any period.

44. The Commission may further, in response to a reasoned request from Abbott showing good cause waive, modify or substitute, in exceptional circumstances, one or more of the undertakings in these Commitments. This request shall be accompanied by a report from the Monitoring Trustee, who shall, at the same time send a non-confidential copy of the report to Abbott. The request shall not have the effect of suspending the application of the undertaking and, in particular, of suspending the expiry of any time period in which the undertaking has to be complied with.

## Section G. Entry into Force

45. The Commitments shall take effect upon the date of adoption of the Decision.

# SCHEDULE

1. The Divestment Businesses comprise the VCD Business and the Vado Business.

**The VCD Business**

2. The VCD Business as operated to date comprises SJM's *Angio-Seal*™ and *FemoSeal*™ VCD product lines and includes:

    (a) a dedicated leased facility located in Caguas, Puerto Rico, which assembles *AngioSeal*™ products for sale worldwide excluding China and Argentina;

    (b) manufacturing capability of SJM's facilities in Minnetonka, Minnesota, which manufactures *AngioSeal*™ devices for sale in China and Argentina (which prohibit US-sourced bovine collagen, thus for these markets Australian collagen is used), bioabsorbable anchors and bypass tubes used in *AngioSeal*™ and *Angio-Seal*™ *Evolution* devices, and *FemoSeal*™ bioabsorbable molded polymer disks used in *FemoSeal*™*;*

    (c) manufacturing capability in Alajuela, Costa Rica, which assembles *FemoSeal*™ devices.

3. In accordance with paragraphs 5 and 6 of these Commitments, the VCD Business includes all assets and staff that contribute to the current operation or are necessary to ensure the viability and competitiveness of the VCD Business. In particular, it includes but is not limited to the assets and personnel identified below and listed in Annex 1.

    (a) tangible assets required for the Purchaser to manufacture, market, sell, and distribute *Angio-Seal*™ and *FemoSeal*™ VCDs, including:

        (i) the tangible assets and any associated know-how used or held for use in manufacturing *Angio-Seal*™ VCDs located at the Caguas Building B Facility, including manufacturing equipment, devices, office equipment and other tangible assets;

        (ii) the relevant manufacturing equipment and other assets used or held for use in manufacturing *Angio-Seal*™ and *FemoSeal*™ VCDs elsewhere (except those necessary for the provision of transitional manufacturing services, which will be transferred at the end of the transitional manufacturing period);

        (iii) all inventory used or held for use in the manufacture and packaging of *Angio-Seal*™ and *FemoSeal*™ VCDs (except the inventory used for the provision of transitional manufacturing, which will be transferred at the end of the transitional manufacturing period);

        (iv) all marketing and training materials, including website content and design of such websites protected by applicable laws, primarily related to the VCD Business; and

        (v) the laptops, printers, handheld devices, and personal computers used by Personnel to be transferred to the Purchaser.

(b) the following main intangible assets required for the Purchaser to manufacture, market, sell, and distribute *Angio-Seal*™ and *FemoSeal*™ VCDs, including:

(i) all intellectual property rights necessary to operate the VCD Business, including U.S., EU, and foreign patents and patent applications in each case filed, or in existence, on or before the Effective Date and covered under the patent families listed in Annex 1, and any renewal, derivation, divisions, reissues, continuations, continuations in-part, modifications, or extensions thereof.

(ii) trademarks used in conducting the VCD Business, as listed in Annex 1.

(iii) other intellectual property, including know-how, copyrights, trade secrets, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, development, and information other than patent and patent applications, to the extent used exclusively or primarily in the *Angio-Seal*™ and *FemoSeal*™ small hole VCD business, and co-ownership of an undivided interest in other intellectual property used in the VCD Business.

(c) the following main licenses, permits, and authorizations, as permitted by applicable law, required for the Purchaser to manufacture, market, sell, and distribute *Angio-Seal*™ and *FemoSeal*™ VCDs, including:

(i) all licenses, permits, and authorizations issued by any governmental organization and held by SJM that are necessary to manufacture *Angio-Seal*™ and *FemoSeal*™ VCDs at the Caguas Building B facility and/or sell *Angio-Seal*™ and *FemoSeal*™ VCDs, including any relevant dossiers relating to the current or pending authorizations available to SJM and, where necessary, reasonable assistance related to the transfer to the Purchaser of such licenses, permits, and authorizations concerning *Angio-Seal*™ and *FemoSeal*™ VCDs, and providing reasonable assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorizations; and

(ii) all CE marks relating to *Angio-Seal*™ and *FemoSeal*™ VCDs or a part thereof held by SJM, including any relevant dossiers relating to the current or pending CE marks relating to *Angio-Seal*™ and *FemoSeal*™ VCDs available to SJM and, where necessary, reasonable assistance to the Purchaser to make any necessary regulatory filings and obtain any necessary authorizations.

Any costs relating to the licenses, permits and authorization transfers shall be borne by Abbott (unless otherwise agreed with the Purchaser).

(d) the following main contracts, agreements, leases, commitments, and understandings required for the Purchaser to manufacture, market, sell, and distribute *Angio-Seal*™ and *FemoSeal*™ VCDs:

(i) the lease of the Caguas Building B Facility located in Caguas, Puerto Rico;

(ii) all contracts entered into with any suppliers for materials used to manufacture *Angio-Seal*™ and *FemoSeal*™ VCDs, including at the Caguas Building B Facility (except those used for the provision of transitional manufacturing, which will be transferred at the end of the transitional manufacturing period);

(iii) all commitments and orders for unshipped materials used to manufacture *Angio-Seal*™ and *FemoSeal*™ VCDs, including at the Caguas Building B Facility (except those used for the provision of transitional manufacturing, which will be transferred at the end of the transitional manufacturing period); and

(iv) all relevant contracts for the sale of *Angio-Seal*™ and *FemoSeal*™ VCDs (as selected by the Purchaser);

provided that, to the extent that the transfer of any of the foregoing main contracts, agreements, leases, commitments, and understandings requires third-party consent, (i) Abbott will use its best efforts to obtain such consents; and (ii) if any such consent cannot be obtained, Abbott will conclude appropriate alternative arrangements with the Purchaser.

(e) all customer, credit and other records, comprising books, records, and files related to the VCD Business;

(f) all Key Personnel, including […] and Personnel primarily dedicated to producing *Angio-Seal*™ VCDs at the Caguas Building B Facility, listed in Annex 2. The Purchaser will be given an option to interview and hire one or more Personnel; and

(g) the following transitional arrangements: quality assurance, logistics, human resources/ payroll, procurement, regulatory, compliance, information technology, shared services, supply chain, plant operations, facilities, environmental control, finance and accounting, tax management, sales and marketing, and customer support services.

4. All references to "exclusively or primarily" in the Commitments text and the Schedule should be interpreted as relating to the extent to which the relevant assets to be divested are used for the relevant Divestment Businesses as opposed to retained products.

5. The tangible or intangible assets and rights that relate exclusively or primarily to the Divestment Businesses will be offered to the Purchaser by means of assignment. The Purchaser will subsequently grant Abbott a licence, sublicense or otherwise access to those tangible or intangible assets and rights that relate primarily to the Divestment Businesses but are shared between the Divestment Businesses and the retained businesses. Concerning the tangible and intangible assets and rights that are shared between the Divestment Businesses and the retained businesses but relate primarily to the retained businesses, Abbott shall grant the Purchaser a licence, sub-licence, or access to such asset or right on a non-exclusive basis.

6. The VCD Businesses shall not include:

(a) SJM's *FemoStop*™ and *RadiStop*™ closure products; or

(b) SJM's Minnesota and Costa Rica Facilities.

**The Vado Business**

7. The Vado Business comprises Abbott's shareholding in Kalila Medical, which manufactures and sells Transseptal Introducer Sheaths sold under the *Vado*® trademark, and includes Assets related to *Vado*® Transseptal Introducer Sheaths globally, including product rights, intellectual property, manufacturing arrangements, inventory, design history files, regulatory documentation and clinical data and documentation, all Key Personnel and Personnel, as well as the transitional arrangements, described in more detail in Annex 3, including sales and marketing, distribution, information technology, regulatory testing, compliance, environmental control and quality assurance services.

ANNEX 1

VCD Business – Assets

| SJM Legal Entity | Location | Intellectual Property | Fixed Assets | Inventory | Registrations |
|---|---|---|---|---|---|
| […] | […] | […] | […] | […] | […] |

Angio-Seal Patents

| Angio-Seal On Product Issued | | | |
|---|---|---|---|
| Patent Number | Title | Original Expiration Date* | Entity |
| […] | […] | […] | […] |

| Angio-Seal On Product Pending | | | |
|---|---|---|---|
| Application/Publication Number | Title | Filing/Publication Date | Entity |
| […] | […] | […] | […] |

| Angio-Seal Related | | | | |
|---|---|---|---|---|
| Publication / Patent Number | Title | Original Expiration Date* | Validated Countries | Entity |
| […] | […] | […] | […] | […] |

FemoSeal Patents

| FemoSeal on Product Issued | | | | |
|---|---|---|---|---|
| Patent Number | Title | | Original Expiration Date* | Entity |
| […] | […] | […] | […] | […] |

| FemoSeal Related | | | | |
|---|---|---|---|---|
| Publication / Patent Number | Title | Publication / Issue Date | Original Expiration Date* | Entity |
| […] | […] | […] | […] | […] |

Angio-Seal and FemoSeal Trademarks

| FEMOSEAL™ | | |
|---|---|---|
| **Country** | **Registration Number** | **Entity** |
| […] | […] | […] |

| ANGIO-SEAL™ | | |
|---|---|---|
| **Country** | **Registration Number** | **Entity** |
| […] | […] | […] |

| ANGIO-SEAL™ NOTHING COMES CLOSER TO INSTANT HAEMOSTASIS™ | | |
|---|---|---|
| **Country** | **Registration Number** | **Entity** |
| […] | […] | […] |

| ANGIO-SEAL™ NOTHING COMES CLOSER TO INSTANT HAEMOSTASIS™ and design | | |
|---|---|---|
| **Country** | **Registration Number** | **Entity** |
| […] | […] | […] |

Angio-Seal and FemoSeal Product Registrations

| Region | Country | Product | Most Recent Approval Date | License Holder | External Distributors | Legal Manufacturer |
|---|---|---|---|---|---|---|
| […] | […] | […] | […] | […] | […] | […] |

ANNEX 2

# List of Caguas Facility Employees

## List of Caguas Facility Employees

| Last Name | First Name | Job Description |
|---|---|---|
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I, MOLDING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | PR-EXTERNAL JOB |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I, MOLDING |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | PR-EXTERNAL JOB |
| [redacted] | [redacted] | SENIOR PRODUCTION MANAGER |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR SR. |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |

| Last Name | First Name | Job Description |
|---|---|---|
| [redacted] | [redacted] | OPERATOR I, MOLDING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | EXTERNAL |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I, MOLDING |
| [redacted] | [redacted] | OPERATOR SPEC. |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN II, CALIBRATION |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | PR-EXTERNAL JOB |
| [redacted] | [redacted] | OPERATOR I |

| Last Name | First Name | Job Description |
|---|---|---|
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN II, COMPLIANCE |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | SUPERVISOR, PRODUCTION |
| [redacted] | [redacted] | PR-EXTERNAL JOB |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TRAINER II, PRODUCTION |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |

| Last Name | First Name | Job Description |
|---|---|---|
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | PR-EXTERNAL JOB |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | PR-EXTERNAL JOB |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
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| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | SUPERVISOR, PRODUCTION |
| [redacted] | [redacted] | OPERATOR SR. |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR SR. |
| [redacted] | [redacted] | COORDINATOR I, DOCUMENT CONTROL |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN II, LINE MAINTENANCE |
| [redacted] | [redacted] | TRAINER II, PRODUCTION |

| Last Name | First Name | Job Description |
|---|---|---|
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I, MOLDING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN II, LINE MAINTENANCE |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | PR-EXTERNAL JOB |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | PR-EXTERNAL JOB |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | ENGINEER II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR SPEC. |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I, MOLDING |

| Last Name | First Name | Job Description |
|---|---|---|
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | SFP REVIEWER I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | PR-EXTERNAL JOB |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | SUPERVISOR, PRODUCTION |
| [redacted] | [redacted] | OPERATOR SR. |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR SR. |

| Last Name | First Name | Job Description |
|---|---|---|
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN II, COMPLIANCE |
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| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR SR. |
| [redacted] | [redacted] | OPERATOR SR. |
| [redacted] | [redacted] | ENGINEER SR., MANUFACTURING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I, MOLDING |
| [redacted] | [redacted] | OPERATOR SR. |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN II, MANUFACTURING |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I, MOLDING |

| Last Name | First Name | Job Description |
|---|---|---|
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR II |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | OPERATOR I |
| [redacted] | [redacted] | TECHNICIAN SR., QUALITY |
| [redacted] | [redacted] | INSPECTOR II |
| [redacted] | [redacted] | ENGINEER II, QUALITY RELIABILITY |
| [redacted] | [redacted] | INSPECTOR I |
| [redacted] | [redacted] | INSPECTOR II |
| [redacted] | [redacted] | ENGINEER II, QUALITY RELIABILITY |
| [redacted] | [redacted] | INSPECTOR II |
| [redacted] | [redacted] | TECHNICIAN SR., QUALITY |
| [redacted] | [redacted] | INSPECTOR II |
| [redacted] | [redacted] | PLANNER/BUYER II |
| [redacted] | [redacted] | CLERK II, INVENTORY CONTROL |
| [redacted] | [redacted] | CLERK II, SHIPPING/RECEIVING |
| [redacted] | [redacted] | CLERK II, SHIPPING/RECEIVING |
| [redacted] | [redacted] | CLERK II, INVENTORY CONTROL |
| [redacted] | [redacted] | CLERK II, SHIPPING/RECEIVING |
| [redacted] | [redacted] | CLERK II, SHIPPING/RECEIVING |

ANNEX 3

# Transitional Arrangements

## SCHEDULE TO TRANSITION SERVICES AGREEMENT

### Services Provided by Abbott to Purchaser

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| **Operations support at Minnetonka** | | | | |
| 1 | QA | Abbott to provide continued quality system and complaint handling support, analysis and reporting to Purchaser. | Minnetonka Plant and new location designated by Purchaser | [redacted] |
| 2 | QA | Abbott to provide support for transfer of existing customer service and product returns handling process from Minnetonka to new location designated by Purchaser. Abbott to provide SMEs to investigate and do root cause analysis for all product performance issues associated with complaints. | Minnetonka Plant and new location designated by Purchaser | [redacted] |
| 3 | Logistics | Abbott to provide global warehousing, shipping coordination and customer transfer logistics services for the FemoSeal™ vascular closure devices and Angio-Seal™ vascular closure devices | Roseville and European EDC | [redacted] |
| **Carve out – Caguas Plant** | | | | |
| 1 | HR | Abbott to provide support for all 'life of an employee' services including: recruiting, onboarding, employee relations support, benefits, and payroll and transaction support. | Caguas Plant | [redacted] |
| 2 | Management | Abbott to provide the same level of leadership as existed | Caguas Plant | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| | | during the Reference Period | | |
| 3 | Production Engineering | To the extent not being provided by Transferred Employees, Abbott will maintain all equipment and facilities in good working order and per SOP as performed by non-transferred shared services personnel during the Reference Period. Abbott will resolve any machine obsolescence or capacity issue which would adversely impact finished good supply | Caguas Plant | [redacted] |
| 4 | Procurement | Abbott to provide Purchaser procurement team with OJT | Caguas Plant | [redacted] |
| 5 | QA | Abbott to provide Purchaser quality engineering team with on-site OJT at Caguas plant to learn plant's QA process | Caguas Plant | [redacted] |
| 6 | QA | Abbott to provide continued quality system support | Caguas Plant | [redacted] |
| 7 | Regulatory | Abbott to provide Purchaser quality engineering team with on-site OJT at Caguas plant to learn regulatory related procedures / SOPs | Caguas Plant | [redacted] |
| 8 | IT | Abbott to maintain, update and support the basic ERP system (SAP), the associated bolt-on's, hardware support and communications infrastructure as relates to the AngioSeal operations in respect of all the following functions: management information, manufacturing, quality, cost accounting, general accounting, payables, invoicing, and collection. Up-to-date accounting and process manuals and flow-charts will be handed over to Purchaser | Caguas Plant | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| | | for its perusal and staff training | | |
| 9 | IT | Purchaser IT team will be provided adequate OJT by Abbott in respect of the IT functions enumerated above (management information, manufacturing, quality, cost accounting, general accounting, payables, invoicing, and collection.) | Caguas Plant | [redacted] |
| 10 | IT | Abbott to provide IT support for the carve-out and transfer to purchaser all ERP and associated systems, including assigning any software maintenance agreements (if available) and provide available documentation and template regarding the applicable SAP system and all bolt-on software applications as it relates to the Caguas Plant. | Caguas Plant | [redacted] |
| 11 | Shared services | Abbott to provide Purchaser with all shared services which are necessary to maintain production of AngioSeal products at Caguas plant including (but not limited to):<br>• IT Servers and support<br>• Fire suppression system<br>• Hazardous materials handling<br>• Incoming inspection<br>• Microbiology lab<br>• Calibration services<br>• Cafeteria<br>• EHS services and support | Caguas Plant | [redacted] |
| 12 | Supply chain | Abbott to support product export and import process | Caguas Plant | [redacted] |
| 13 | Plant operations | To the extent not being provided by Transferred Employees, Abbott to maintain existing processes and controls | Caguas Plant | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| | | including KPI Dashboards and SLA (formal and informal). Abbott to share all related documentation – processes, formats, KPIs for overall effectiveness and business continuity | | |
| 14 | Finance and Accounting | Abbott to provide support for finance / accounting (monthly financial closing, and accounting receivable / payable management, reporting, cash and banks management) | Caguas Plant | [redacted] |
| 15 | Finance and Accounting | Abbott to provide Purchaser finance/accounting staff with OJT | Caguas Plant | [redacted] |
| 16 | Plant controlling | To the extent not being provided by Transferred Employees, Abbott to provide support for all plant controlling functions such as demand forcasting, KPI monitoring, planning & budgeting, plant variance analysis, reporting | Caguas Plant | [redacted] |
| 17 | Tax management | Abbott to support Purchaser for basic Tax compliance | Caguas Plant | [redacted] |
| **Corporate / Global Requirements** | | | | |
| 1 | Sales & Marketing | Abbott to conduct the following training events for Purchaser personnel:<br>• 1 Training Events (tech and sales) in the U.S.<br>• 3 Training Events (tech and sales) held in global locations (EU, Japan, TBD) | Global | [redacted] |
| 2 | Quality, Sales & Marketing / Customer Support | Abbott to support complaint investigation for all locations. Abbott will also provide product training and timely set up of communication lines and provide documentation/details | Global | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| | | on all ongoing complaints | | |
| 3 | Quality, Sales & Marketing / Customer Support | Abbott to conduct the following OJT training events in Minnetonka and Caguas facilities<br>• Production engineering<br>• Testing (analytical)<br>• QA process<br>• Quality engineering<br>• Supply chain<br>• Procurement<br>• IT<br>• R&D<br>• Customer service<br>• Finance & Accounting | Global | [redacted] |
| **Corporate / Global Requirements** | | | | |
| 1 | Compliance | Abbott to schedule meeting with Purchaser to discuss all relevant compliance related subjects | Global | [redacted] |
| 2 | Calibration | Abbott to support calibration activities and provide consultation | Caguas Plant | [redacted] |
| 3 | Calibration | Abbott to advise Purchaser on non-conformance issues (management support) for calibration type issues | Caguas Plant | [redacted] |
| 4 | Calibration/Quality | Abbott to provide one training event (train the trainer) in Puerto Rico for core group of Purchaser's employees to support transition | Caguas Plant | [redacted] |
| 5 | Environmental Control | Abbott to support testing and consultation in all environmental control operations to ensure full compliance and processes are maintained during transition to Purchaser | Caguas Plant | [redacted] |
| 6 | Environmental Control | Abbott agrees to one training event (train the trainer) in a Abbott United States location | U.S. | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| | | where environmental control activities occur for core group of Purchaser's employees to support transition | | |
| 7 | Coatings validation | Abbott to revalidate the coating process according to new guidance documents. Purchaser to consult with Abbott to facilitate re-validation | Caguas Plant | [redacted] |
| 8 | Coatings validation | Abbott to report on critical validations to allow for ongoing review of protocols and reports until transition is complete | Caguas Plant | [redacted] |
| 9 | IT | Abbott to provide access and facilitate<br><br>Transfer of all related systems (RM/WIP/FG<br><br>Labeling, CAPA, Supplier Quality & NCMR<br><br>Systems) | Caguas, Minnetonka & Costa Rica Plants | [redacted] |
| 10 | HR / Payroll | Abbott to administer all salary payments to Transferred Employees in Puerto Rico and VADO | Caguas Plant | [redacted] |
| 11 | HR / Payroll | Abbott to collect time and payroll for Transferred Employees | Caguas Plant | [redacted] |
| 12 | Finance | Abbott to provide all accounting and costing services to Purchaser during transition period for the facilities and operations | Caguas Plant | [redacted] |
| 13 | QA | Abbott to provide support to handle and process all customer complaints and product returns for AngioSeal, FemoSeal, and VADO products | Global | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| 14 | Distribution | Abbott to manage global end-user distribution network while Terumo sets up either a new distributor relationship with SJM, establishes a new distributor or chooses a direct model setup. | Global | [redacted] |
| **U.S. Region Specific Noncommercial Requirements (Incremental to Corporate Requirements)** | | | | |
| 1 | HR / Payroll | Abbott to extract data and explain relevant data structures in order for Purchaser to transfer HR and payroll data to Purchaser's ADP Payroll and HRIS systems | Caguas Plant | [redacted] |
| 2 | HR / Payroll | Abbott to assist in the transition and configuration of all available learning management courses to Purchaser's learning management platform | Caguas Plant | [redacted] |
| 3 | HR / Payroll | Abbott to provide support for the transition of all HR related services to Purchaser's personnel | Caguas Plant | [redacted] |
| 4 | QA | Abbott to host one training event to review past decisions and trending (MDR handling) | U.S. | [redacted] |
| 5 | Facilities | Abbott to provide all shared services, subject to the terms of the TSA, inclusive of cafeteria, parking, facilities maintenance, machine preventative maintenance and repair, as well provide reasonable assistance to facilitate utility separation and individual billing, to the extent included in these schedules | Caguas Plant | [redacted] |
| **Europe / MEA Region Specific Noncommercial Requirements (Incremental to Corporate Requirements)** | | | | |
| 1 | QA | Abbott to host one training event to review past decisions | Europe / MEA | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| | | and trending (vigilance reporting handling) | | |
| 2 | Sales & Marketing | Abbott to transition working knowledge of the bids program to Purchaser so that Purchaser can take over | Europe / MEA | [redacted] |
| **China Region Specific Commercial Requirements (Incremental to Corporate Requirements)** | | | | |
| 1 | Sales & Marketing | Abbott to transition working knowledge of the bids program to Purchaser so that Purchaser can take over | China | [redacted] |
| **China Region Specific Noncommercial Requirements (Incremental to Corporate Requirements)** | | | | |
| 1 | Regulatory | Abbott to provide documented support and knowledge transfer to Purchaser for CFDA license renewal so that Purchaser can handle renewals (China FDA License) | China | [redacted] |
| **VADO Operations**<br><br>Unless expressly noted elsewhere in this schedule, only the two Services listed immediately below and the following enumerated Services will be provided with respect to the Vado Business: Corporate / Global Requirements Service #1 on page 4 (except with respect to Japan), Corporate / Global Requirements Services #1, #6, #9-#14 on pages 5-6, and U.S. Region Specific Noncommercial Requirements (Incremental to Corporate Requirements) Service #4 on page 7. | | | | |
| 1 | Commercial | Sales and Marketing<br>• Abbott to transition knowledge to Purchaser team for future commercial activities<br>• Abbott to continue to sell Vado products until Purchaser has developed Sales capabilities | Kalila and Abbott EP | [redacted] |
| 2 | Regulatory / Testing | External testing for product – Abbott currently assists VADO team for external clinical tests such as Investigator Initiated | Kalila and Abbott EP | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| | | Sponsored Research<br><br>• Abbott to support ongoing external tests until completion and transition of knowledge to Purchaser<br>• Abbott agrees that Purchaser can utilize the test results for promotional activities | | |
| **Corporate IT Services** | | | | |
| 1 | IT | These items are services provided by the Abbott Global IT services<br><br>Abbott to provide the following services<br><br>• Provide continued development, maintenance and support service. Maintain current SLAs to minimize interruption for business operations<br>• Provide technical knowledge and skill set to carve out and firewall functions specific to transaction<br>• Provide technical knowledge in order to assist Purchaser team develop a separation plan<br>• Applications & Systems :<br>➢ Oracle HFM – Finance systems and financial planning suite<br>➢ CAFM - Application to support overall facility management<br>• End user day to day | Caguas Plant | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| | | business / desktop applications – Microsoft Office<br>• Phone system and services end user day to day voice communications – Cisco<br>• Help desk – End user support services<br>• E-mail services<br>• Applications monitoring and maintenance support<br>• Network and infrastructure support, monitoring and maintenance<br>• Hosting services - Services for data center hosting. A location where business applications are hosted on servers and other network infrastructure<br>• Third party connectivity - Connections from Abbott sites to third parties for data interaction or exchange. Or connections into Abbott network from third party for system maintenance<br>• Security - Microsoft System Center Endpoint Protection for anti-virus<br>• Travel expenses settlement system – Concur SAP | | |
| **Other Regulatory** | | | | |
| 1 | Regulatory Affairs | Pharmaceutical Affairs Registrations<br>• Abbott to provide services to assist | Global | [redacted] |

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| | | Purchaser in completing all pharmaceutical affairs registrations required, due to change in ownership for all countries | | |
| 2 | Regulatory Affairs | Abbott to continue printing and sealing products with additional regional labels as required by every country regulations, and share process knowledge with Purchaser so that Purchaser can sustainably take over the labelling process | Argentina, Colombia, Ecuador, Mexico, South Korea, China, Taiwan, Japan, India, Malaysia | [redacted] |
| 3 | Regulatory Affairs | Abbott to provide Purchaser quality engineering team on-site OJT to learn regulatory related procedures / SOPs | Global | [redacted] |

**Services Provided by Purchaser to Abbott**

| Item No. | Function | Description of Services | Service Scope | Maximum Duration |
|---|---|---|---|---|
| **Operations support at Minnetonka** | | | | |
| 1 | Facilities | Purchaser to provide facilities-related support at Caguas Plant as follows:<br>• Trash compactor<br>• Pallet recycling dumpster<br>• Hazardous Waste and Bio Medical Storage<br>• Chemical Storage<br>• Building and Grounds Storage | Caguas Plant | [redacted] |

| Acronym | Full Term |
|---|---|
| CAPA | Corrective and Preventive Actions |
| EHS | Environment Health and Safety |
| ERP | Enterprise Resource Planning |
| FDA | Food and Drug Administration |
| FG | Finished Goods |
| KPI | Key Performance Indicators |
| MDR | Medical Device Reporting |
| NCMR | Non-Conforming Material Report |
| OJT | On Job Training |
| QA | Quality Assurance |
| R&D | Research and Development |
| SLA | Service level Agreements |
| SOP | Standard Operating Procedure |
| WIP | Work In Progress |