

**Request for a scientific opinion
on “The Safety of surgical meshes used in urogynecological surgery”**

1. General Background

According to the Council Directive 93/42/EEC medical devices may only be placed on the market if they meet the essential requirements laid down in the Annex I of the directive, in particular in relation to the health and safety of the patients.

A specific category of medical devices are surgical meshes. A surgical mesh is a metallic or polymeric screen intended to be implanted to reinforce soft tissue or bone where weakness exists.

Surgical meshes have been used since the 1950s to repair abdominal hernias. Implantable meshes have played a significant role in the treatment of complex hernias and other abdominal wall reconstruction procedures. In the 1990s, gynecologists began using the same surgical mesh for surgical treatment of Stress Urinary Incontinence – SUI – the first procedure was called the tension free vaginal tape procedure – and was considered an alternative to the traditional surgery either using patients’ own tissue or forming a hitch of the vagina and bladder base – a so-called colposuspension. The technique designed for the treatment of SUI involved a transabdominal or transvaginal approach, which subsequently evolved into a purely vaginal approach – the so-called transobdurator tape procedure. Responding to the perceived need of the medical community, the medical devices manufacturers produced mesh kits containing the pre-shaped mesh implant(s) as well as the accessory tools needed for the placement of the device. Surgical mesh kits continue to evolve, adding new insertion tools, tissue fixation anchors, surgical techniques and absorbable and biologic materials.

Surgical mesh materials can be divided into four categories (1) non-absorbable synthetic, (2) absorbable synthetic (3) biologic (4) composite. Different types of designs are available aimed at better integration in the organism after implantation.

Pelvic floor dysfunction is a major health issue for older women, as shown by the 11,4% (women aged 45-85 years) lifetime risk of undergoing a single operation for pelvic organ prolapse and urinary incontinence, as well as the large proportion of reoperations (29.2%) and the time intervals between repeated procedures that decreases with each successive repair.

Stress Urinary Incontinence – SUI – affects an estimated 20-40% of women (approximately one in three). A Norwegian study¹ reported the percentage of patients with SUI to be approximately half of all women with incontinence, the remainder characterized as urge (11%) and mixed incontinence (36%).

¹ Hunskaar S, Arnold EP, Burgio K, Diokno AC, Herzog AR, Mallett VT. Epidemiology and natural history of urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct.* 2000;11:301

The surgical repair of Pelvic Organ Prolapse – POP proved a longstanding challenge with high failure rates for primary repair. As a consequence clinicians turned to the use of substitute materials to augment the native tissue reaction, and included in this was the development of kits using mesh. The rapid and widespread transition from traditional pelvic organ prolapse surgery using native tissue, to mesh-augmented prolapse repair aimed to improve the often unsatisfactory outcomes after conventional pelvic organ prolapse surgery with native tissue.

Pelvic organ prolapse – POP is a major health issue in older women and one of the most common indications for gynaecological surgery. Generally the lifetime risk for a woman of undergoing surgical treatment for pelvic organ prolapse is 7-20%. Despite the fact that pelvic organ prolapse is one of the most usual indications for gynecologic surgery, epidemiological studies on incidence and prevalence are rare.

With the increasing life expectancy and the changing lifestyle of elderly women, it may be anticipated a further increase in the demand of pelvic floor surgery in the future. This is already expressed in recent data on the lifetime risk for a woman to undergo a single operation for POP or SUI, which has been adjusted upwards from 11% in 1997 to 19-20% at present. A vast group of women seems to prefer surgical correction of the vaginal anatomy.

Current data suggest that the use of mesh in surgery is associated with both benefits and risks but few randomized controlled trials have been published. The use of such mesh in repair surgery may lead to various complications, such as rejection, tissue erosion, mesh exposure and shrinkage. The rate of success of such interventions varies depending on the type of the anatomical defect, its severity and the presence of risk factors. Some women suffer from significant side effects after this type of surgery such as pain and sexual dysfunction.

2. Terms of reference

In the light of the above considerations, the Scientific Committee on Emerging and Newly Identified Health Risks is requested to provide a scientific opinion on "The safety of surgical meshes used in urogynecological surgery". Based on the latest scientific and technical knowledge the committee is requested to assess the risk of meshes used in urogynecological surgery and more generally for other uses, in particular covering the points listed below.

- **Risks associated with the use of meshes in urogynecological surgery**
 - Are specific meshes, in terms of designs and/or materials, considered to be of a higher risk? If possible list and describe the risks.
 - Are certain surgery techniques of higher risk? If possible list and describe the risks.
 - Are any combinations of the above (designs/materials and surgical techniques) of a higher risk?
 - Are there specific limitations (e.g. clinical, designs/materials, surgical techniques) to the use of meshes in urogynecological surgery?
 - What are the risks of surgical interventions using mesh compared to classic surgical interventions?
 - What factors could affect the outcome of the surgical interventions?

- **Identification of high risk patient groups**
 - Are there patients groups (e.g. in relation to age, weight or other co-morbidities) for which the use of meshes would carry a specific risk?

- **In the light of the above, identify risks associated with use(s) of meshes other than for urogynecological surgery and advise if further assessment in this field(s) is needed**

In its assessment SCENIHR is invited to:

- **Take into account the established registries in the field.**

Deadline: January 2015