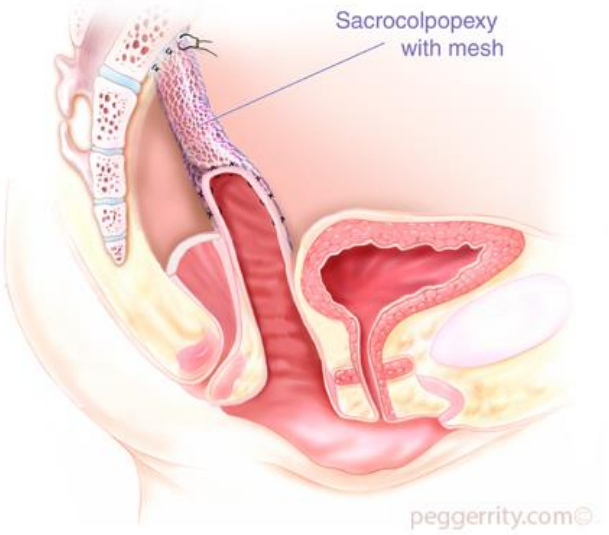
URGYN SAVANNAH

Surgical Mesh

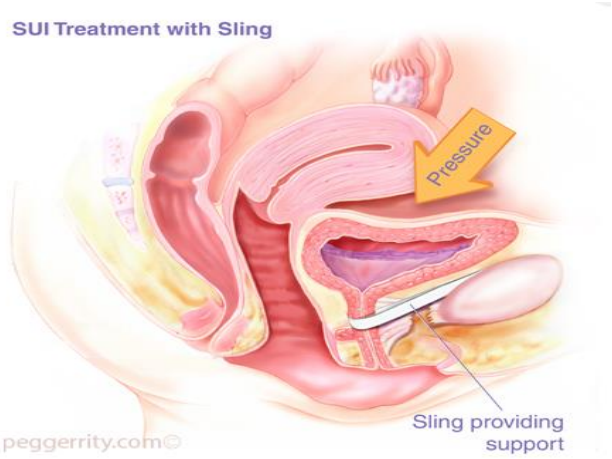
What is surgical mesh? Surgical mesh is a net-like medical implant that is used to provide support when repairing weakened or damaged tissue. Most surgical mesh comes from synthetic (man-made) materials or animal tissue. Mesh is used in a variety of medical procedures, including hernia repair and heart stents. The mesh used most often in female pelvic floor repair is polypropylene, which is man-made synthetic, medical grade plastic. This type of mesh is permanent, i.e., not absorbed by the body, and is designed for long-term use.

When did mesh start appearing in female pelvic floor repair? Polypropylene mesh has been used for abdominal hernias since the 1950s. In the 1970s, gynecologic and urologic surgeons began using mesh for pelvic organ prolapse repair, e.g., sacrocolpopexy.



The safety and effectiveness sacrocolpopexy with mesh are well established and compared to traditional vaginal surgery without mesh, sacrocolpopexy results in less recurrent prolapse.

In the 1990s mesh started being used to treat female stress urinary incontinence, and in 1996 the U.S. Food and Drug Administration (FDA) approved mesh for female stress urinary incontinence (SUI): the midurethral sling (MUS). The use of surgical mesh slings to treat SUI provides a less invasive approach than non-mesh repairs.



Types of Mesh. Mesh placed through incisions in the abdomen is called *transabdominal mesh* whereas placed through incisions in the vagina is called *transvaginal mesh*. While *transabdominal* and *transvaginal mesh* may be constructed the same or similarly, there has been much debate about *transvaginal mesh*, and in April 2019, the FDA ordered all manufacturers of *transvaginal mesh* intended pelvic organ prolapse repair to be removed from the US market. Transvaginal mesh for stress urinary incontinence, i.e., the midurethral sling (MUS), was not included in this edict.

Mesh Sling Complications. No surgery is 100% "risk free" and while serious complications are uncommon with midurethral mesh slings (MUS), complications can and do occur. As per the FDA the most common complications, in descending order of frequency, include:

- pain
- mesh erosion through the vagina
- infection
- urinary problems
- recurrent incontinence
- pain with sex (dyspareunia)
- bleeding
- organ perforation
- neuro-muscular problems
- vaginal scarring.

Many of these complications require additional medical intervention, and sometimes require surgical treatment and/or hospitalization. Except for mesh erosion, the above complications can with non-mesh repairs.

Support for the Midurethral Sling (MUS). The American Urogynecologic Society and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction [supporting organizations include The American Association of Gynecological Laparoscopists, The American College of Obstetricians and Gynecologists, The National Association for Continence, The International Urogynecological Association, The Society of Gynecologic Surgeons] support the use of mesh for female stress urinary incontinence. Justification for their position were based on the following:

- Polypropylene material is safe and effective as a surgical implant.
- The monofilament polypropylene mesh MUS is the most extensively studied anti-incontinence procedure in history.
- Polypropylene mesh midurethral slings are a standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition for our patients.
- The FDA has clearly stated that the polypropylene MUS is safe and effective in the treatment of SUI.

In November 2011 the American Urological Association adopted their position on midurethral slings (MUS), reaffirmed it October 2016, and revised it May 2019. Their position reads:

- Synthetic slings are an appropriate treatment choice for women with stress incontinence, with similar efficacy but less morbidity than conventional non-mesh sling techniques
- Advantages include shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction. Mesh-related complications can occur following polypropylene sling placement, but the rate of these complications is acceptably low.
- Furthermore, it is important to recognize that many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well.

The FDA provided some guidance for patients considering having surgery which mesh may be an option. In keeping with those guidelines, below are some questions for patients to address with their healthcare provider:

- What surgical or non-surgical treatment options are available?
- What can I expect after surgery?
- What is the recovery time?
- What if the surgery doesn't correct my problem?
- What are the pros and cons of mesh?
- Are recovery times different for mesh surgery compared to non-mesh surgery?
- What are possible complications of mesh?
- If I have a complication, how likely is it that the complication can be resolved?
- If I have a complication, will the implanting surgeon manage the complication, or will another surgeon/provider be required?

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