

Information on Surgical Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence

FDA wants to inform you about the complications that can occur when surgical mesh is used to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI), and provide you with questions to ask your surgeon before having these procedures. This is part of our commitment to keep healthcare professionals and the public informed about the medical products we regulate.

FDA has received reports of complications associated with the placement of mesh through an incision made in the wall of the vagina. Although rare, these complications can have serious consequences. The reports have not been linked to a single brand or model of mesh.

The most frequent complications included erosion through the vagina, infection, pain, urinary problems and recurrence of the prolapse and/or incontinence.

In some cases, erosion of the mesh and scarring of the vagina led to discomfort and pain, including pain during sexual intercourse. Some patients needed additional surgery to remove the mesh that had eroded into the vagina. Other complications included injuries to nearby organs such as the bowel and bladder, or blood vessels.

Background

A pelvic organ prolapse (POP) occurs when a pelvic organ, such as your bladder, drops (“prolapses”) from its normal position and pushes against the walls of your vagina. This can happen if the muscles that hold your pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can drop at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum.

Pelvic organ prolapse can cause pain or problems with bowel and bladder functions or interfere with sexual activity.

Stress urinary incontinence (SUI) is a type of incontinence caused by leakage of urine during moments of physical stress.

Talking to your doctor

Before having an operation for POP or SUI, be sure to let your surgeon know if you’ve had a past reaction to mesh materials such as polypropylene.

Questions you should ask the surgeon before you agree to surgery in which mesh will be used:

- What are the pros and cons of using surgical mesh in my particular case? Can my repair be successfully performed without using mesh?
- If a mesh is to be used, what’s been your experience with implanting this particular product? What experience have your other patients had with this product?
- What’s been your experience in dealing with the complications that might occur?
- What can I expect to feel after surgery and for how long?
- Are there any specific side effects I should let you know about after the surgery?
- What if the mesh doesn’t correct my problem?
- If I have a complication related to the mesh, can the mesh be removed and what could the consequences be?
- If a mesh is to be used, is there patient information that comes with the product, and can I have a copy?

Reporting complications to the FDA

In order to help FDA learn more about possible problems with surgical mesh, it is important that both physicians and patients report complications that may be associated with this product.

You can report any problems to the FDA’s MedWatch Adverse Event Reporting program either online, by mail or FAX.

- Online : www.fda.gov/MedWatch/report.htm
- Mail : use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- FAX: 1-800-FDA-0178

The Pelvic Health Coalition (PHC) is a broad-based coalition representing leading obstetric, urologic, and gynecologic healthcare professionals as well as the major industry leaders involved with developing innovative technologies used to treat pelvic health disorders.

In October of 2008 the FDA released a Public Health Notification (PHN) titled “Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair for Pelvic Organ Prolapse and Stress Urinary Incontinence”. Listed below are the Pelvic Health Coalition’s responses to this notification.

- **The Public Health Notification (PHN) states that more than a 1,000 complications have been reported to the FDA in the last three years associated with surgical mesh devices used to repair pelvic organ prolapse and stress urinary incontinence.**
- **This represents approximately 0.1 percent complication rate when considering over 800,000 such procedures using mesh were performed during that time (2005-2007) in the United States (source: Millenium Research).**
- **Procedures that do not use a medical device mesh are not under the same FDA adverse event reporting requirements as procedures using the mesh device. The FDA does not have the ability to compare the numerator of the number of reported complications to the denominator of total mesh procedures performed in the US over the same time period of the reported complications to identify an incidence rate, as the total number of mesh procedures is not data which is available to the FDA.**
- **Information given to the public regarding the risks and benefits of a surgical mesh procedure should be contained within a broader and balanced discussion of the risks and benefits of any pelvic surgery without the use of mesh.**
- **Mesh-based pelvic organ prolapse and stress urinary incontinence procedures have been investigated in numerous clinical studies in the US and abroad. Many clinical studies have demonstrated the potential benefits of the devices, even with the complications noted in the Public Health Notification (PHN).**
- **The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) recently issued an interventional procedure guidance which stated that “*The evidence suggests that surgical repair of vaginal wall prolapse using mesh may be more efficacious than traditional surgical repair of vaginal wall prolapse without mesh.*”**
- **With the exception of mesh erosion, clinical evidence supports that “traditional” non-mesh repairs (such as anterior colporrhaphy, Burch colposuspension) have similar incidence of the complications listed in the Public Health Notification (PHN). Additionally, there is clinical literature that concludes that non-mesh procedures have a higher incidence of recurrence than mesh procedures, which may lead to additional surgical procedures for patients.**