

# Mesh Information for Patients with Pelvic Floor Disorders

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On July 13, 2011, the FDA issued a safety communication and update, intending to inform patients and health care providers that “serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse are not rare.”

Pelvic floor disorders (PFDs) include leakage of urine, pelvic organ prolapse and bowel problems. Surgical mesh is a synthetic material that has been used in other kinds of hernia repairs as well as in surgical treatment of pelvic floor disorders. Surgical mesh is used to treat pelvic organ prolapse (POP), when the bladder, vagina or uterus, or rectum “drops,” and stress incontinence (SUI), leakage of urine with coughing, sneezing, or physical exercise due to weak ligaments and weak pelvic muscles.

For POP, surgical mesh can be placed both abdominally and vaginally. Mesh is placed abdominally to repair POP as part of an operation called a “sacral colpopexy.” This operation lifts the vagina to the tailbone often using a piece of mesh. This procedure can be performed through an open incision in the belly or through multiple tiny scars using a robotic or camera (laparoscopic) technique. Mesh placed vaginally is done through incisions in the vaginal walls. Mesh placed to treat POP can be individually tailored or can come as part of a “mesh kit” procedure. Mesh used to treat stress urinary incontinence is placed under the urethra (the tube that empties urine from the bladder). This operation is called a mid-urethral sling.

The American Urogynecologic Society (AUGS), a physician-based organization dedicated to research, education and sharing of best practices in Female Pelvic Medicine and Reconstructive Surgery that results in improved care for women, presented information to an FDA advisory panel in September 2011 and reiterates these same points to patients who have undergone treatment using mesh or may be candidates for treatment.

**There are different types of mesh for different purposes that have different outcomes.** There is not enough supporting evidence to justify taking mesh off the market. There are differences in the uses and outcomes related to synthetic mesh used to treat stress urinary incontinence and mesh used for transvaginal or abdominal repair of pelvic organ prolapse. Synthetic mesh in the form of mid-urethral slings is used to treat stress urinary incontinence. This is the standard of care and research shows that they are safe and effective.

**Mesh may be appropriate for repair of pelvic organ prolapse in some cases.** AUGS does not support the *routine* use of transvaginal mesh for the repair of pelvic organ prolapse, but there may be particular circumstances when the placement of transvaginal mesh is beneficial and appropriate. Placement of transvaginal mesh for pelvic organ prolapse should be used cautiously by experienced surgeons with extensive training in pelvic surgery.

**It is important for patients to be informed about all treatment options for pelvic organ prolapse are pluses and minuses of each.** There should be discussion between a doctor and a patient that identifies risks, benefits and possible adverse outcomes of all available treatment

options. You should be informed about non-surgical treatment options, surgical repairs that use your own tissues, and abdominal repairs and transvaginal mesh repairs.

**Additional information is required to make recommendations about mesh that is rooted in research.** AUGS recommends research trials to get more information for transvaginal mesh for pelvic organ prolapse. AUGS supports the FDA's call for better data upon to determine whether or not mesh devices are safe and effective.

**What you can do now – talk with your doctor:**

1. Let your doctor know about any problems you had in the past healing from mesh surgery or rejecting certain material. If you have been treated with mesh and are not experiencing any symptoms or side effects (recurring prolapse/incontinence, pelvic pain, etc.), you do not need to have the mesh removed.
2. If you are considering surgery for SUI or POP, ask your doctor what are all the options available for your particular case and what are the pros and cons of each.
3. If your doctor is recommending using transvaginal mesh, ask why he or she is recommending using mesh in your case versus using your own tissues for the repair.
4. Ask your doctor about his/her experience using mesh and handling complications associated with mesh placement. Find a specialist online at [www.voicesforpfd.org](http://www.voicesforpfd.org)
5. Ask your doctor what to expect after surgery, for how long, what side effects to look out for and if there are any restrictions after surgery.

You can report any problems related to mesh to the FDA's MedWatch Adverse Reporting program at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>