

## Serious Complications with Surgical Mesh for Gynecologic Surgery

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The FDA is alerting healthcare professionals about rare but serious complications associated with the surgical mesh used to treat pelvic organ prolapse and stress urinary incontinence. The mesh is usually placed transvaginally using minimally invasive techniques.

Over the past three years, FDA has received over a thousand reports of complications. The most frequent included erosion of the mesh through the vaginal epithelium, infection, pain, urinary problems, and recurrence of the prolapse or the incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in quality of life due to discomfort and pain, including dyspareunia.

Treatment of the complications included IV therapy, blood transfusions, drainage of hematomas or abscesses, and additional surgical procedures, in some cases to remove the mesh.

Clinicians using mesh for treatment of pelvic organ prolapse and stress urinary incontinence should:

- Obtain specialized training for each mesh placement technique, and be aware of its risks.
- Be vigilant for potential adverse events from the mesh, especially erosion and infection, and also from the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
- Inform patients about the potential for serious complications and their effect on quality of life, including scarring and pain during sexual intercourse. Patients should also be informed that implantation of surgical mesh is permanent, and that some complications associated with the mesh may require additional surgery that may or may not correct the problem.
- Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if it is available.

### Additional Information:

FDA MedWatch Safety Alert. Transvaginal Placement of Surgical Mesh. October 21, 2008.

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm079028.htm>

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