

U.S. Food and Drug Administration
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FDA NEWS RELEASE

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FDA issues proposals to address risks associated with surgical mesh for transvaginal repair of pelvic organ prolapse

The U.S. Food and Drug Administration today issued two proposed orders to address the health risks associated with surgical mesh used for transvaginal repair of pelvic organ prolapse (POP). If finalized, the orders would reclassify surgical mesh for transvaginal POP from a moderate-risk device (class II) to a high-risk device (class III) and require manufacturers to submit a premarket approval (PMA) application for the agency to evaluate safety and effectiveness.

POP occurs when the internal structures that support the pelvic organs such as the bladder, uterus and bowel, become so weak, stretched, or broken that the organs drop from their normal position and bulge (prolapse) into the vagina. While not a life-threatening condition, women with POP often experience pelvic discomfort, disruption of their sexual, urinary, and defecatory functions, and an overall reduction in their quality of life.

“The FDA has identified clear risks associated with surgical mesh for the transvaginal repair of pelvic organ prolapse and is now proposing to address those risks for more safe and effective products,” said William Maisel, M.D., M.P.H., deputy director of science and chief scientist at the FDA’s Center for Devices and Radiological Health. “If these proposals are finalized, we will require manufacturers to provide premarket clinical data to demonstrate a reasonable assurance of safety and effectiveness for surgical mesh used to treat transvaginal POP repair.”

Surgical mesh is a medical device that is used to provide additional support when repairing weakened or damaged tissue. Many mesh products come in kits that include instruments specifically designed to aid in insertion, placement, fixation, and anchoring of mesh in the body. Instruments provided in kits will be reviewed as part of the regulatory submission for the mesh product. Instruments are also provided separately from the mesh implant, and the FDA is proposing that this

urogynecologic surgical instrumentation be reclassified from low-risk devices (class I) to moderate-risk devices (class II).

Beginning in Jan. 2012, the FDA issued orders to manufacturers of urogynecologic surgical mesh devices to conduct **postmarket surveillance studies** (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/PostmarketSurveillance/ucm134497.htm>) (522 studies) to address specific safety and effectiveness concerns related to surgical mesh used for transvaginal repair of POP.

In Sept. 2011, the **FDA's Obstetrics and Gynecology Devices Panel** (<http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm262488.htm>) recommended that surgical mesh for transvaginal POP be reclassified from class II to class III and require PMAs.

In July 2011, the FDA provided an **updated safety communication** (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>) about serious complications associated with transvaginal placement of surgical mesh used to treat POP. At that time, the FDA also released a **review of urogynecologic surgical mesh** (<http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf>) adverse events and peer-reviewed scientific literature that identified serious safety and effectiveness concerns. The FDA previously communicated about serious complications associated with transvaginal placement of surgical mesh to treat POP and stress urinary incontinence (SUI) in an Oct. 2008 FDA Public Health Notification.

Surgical mesh indicated for surgical treatments of SUI, abdominal POP repair with mesh, hernia repair, and other non-urogynecologic indications are not part of this proposed order.

The FDA will take comments on the proposed order for 90 days.

For more information:

- **FDA Medical Devices** (<http://www.fda.gov/MedicalDevices/default.htm>)
- FDA: Proposed Order - **"Reclassification of Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair and Surgical Instrumentation for Urogynecologic Surgical Mesh Procedures; Designation of Special Controls for Urogynecologic Surgical Mesh Instrumentation"** (<https://www.federalregister.gov/articles/2014/05/01/2014-09907/surgical->

mesh-transvaginal-pelvic-organ-prolapse-repair-and-surgical-instrumentation-urogynecologic)

- FDA: Proposed Order - **“Premarket Approval for Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair”** (<https://www.federalregister.gov/articles/2014/05/01/2014-09909/surgical-mesh-for-transvaginal-pelvic-organ-prolapse-repair-premarket-approvals>)
- FDA: **Urogynecologic Surgical Mesh Implants** (<http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/urogynsurgicalmesh/default.htm>)

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