U.S. Food and Drug Administration
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FDA News Release

FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks

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Release

Español (/NewsEvents/Newsroom/ComunicadosdePrensa/ucm480312.htm)

The U.S. Food and Drug Administration today issued two final orders to manufacturers and the public to strengthen the data requirements for surgical mesh to repair pelvic organ prolapse (POP) transvaginally, or through the vagina. The FDA issued one order to reclassify these medical devices from class II, which generally includes moderate-risk devices, to class III, which generally includes high-risk devices, and a second order that requires manufacturers to submit a premarket approval (PMA) application to support the safety and effectiveness of surgical mesh for the transvaginal repair of POP.

The orders will require manufacturers to address safety concerns, including severe pelvic pain and organ perforation, through a rigorous PMA pathway to demonstrate safety and effectiveness. The actions apply only to mesh devices marketed for the transvaginal repair of POP. These orders do not apply to surgical mesh for other indications, like stress urinary incontinence (SUI) or abdominal repair of POP.

“These stronger clinical requirements will help to address the significant risks associated with surgical mesh for repair of pelvic organ prolapse,” said William Maisel, M.D., M.P.H., deputy director of science and chief scientist for the FDA’s Center for Devices and Radiological Health. “We intend to continue monitoring how women with this device are faring months and years after surgery through continued postmarket surveillance measures.”

Surgical mesh has been used by surgeons since the 1950s to repair abdominal hernias; in the 1970s, gynecologists began implanting surgical mesh for the abdominal repair of POP and, in the 1990s, for the transvaginal repair of POP. In 2002, the first mesh device with this indication was cleared for use as a class II moderate-risk device, and there are five manufacturers who are currently marketing this product.

Over the past several years, the FDA has seen a significant increase in the number of reported adverse events associated with the use of surgical mesh for transvaginal POP repair, and an advisory panel of experts recommended in 2011 that more data is needed to establish the safety of the device. The FDA has since taken several actions to warn doctors and patients about the use of surgical mesh for transvaginal POP repair.

Manufacturers of surgical mesh to treat POP transvaginally will have 30 months, as required by federal law, to submit a PMA for devices that are already on the market. Manufacturers of new devices must submit a PMA before those devices can be approved for marketing.

POP (http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm262299.htm) occurs when the muscles and tissue of the pelvic floor become stretched, torn or weakened and can no longer support pelvic organs such as the bladder, bowel or uterus; as a result, the organs drop from their normal position and bulge (prolapse) into the vagina. While not a life-threatening condition, women with POP often experience low back pain or pelvic pressure, painful intercourse, constipation or urinary problems such as leakage or a chronic urge to urinate.

Doctors may perform surgery on women with POP who have significant symptoms, often using a minimally invasive transvaginal technique to reduce recuperation time. Surgical mesh may be permanently implanted during this surgery to reinforce the weakened pelvic floor muscles and repair POP, but over the past several years the FDA has received thousands of reports of complications involving the use of mesh for transvaginal POP repair. The most common problems reported include severe pelvic pain, pain during intercourse, infection, bleeding, organ perforation and urinary problems from mesh eroding into surrounding tissues.

To warn doctors and patients about the use of surgical mesh for transvaginal POP repair, the FDA has:

- Issued safety communications in 2008 and in 2011 warning doctors and consumers about an increase in adverse event reports related to mesh used for urogynecological procedures;
- Convened an advisory panel in September of 2011 to solicit recommendations on actions to take regarding urogynecologic surgical mesh for transvaginal POP repair;
- Issued orders to manufacturers in January 2012 to conduct postmarket surveillance studies to address specific safety and effectiveness concerns related to surgical mesh used for transvaginal repair of POP; and
- Issued two proposed orders in May 2014 to reclassify the devices from class II to class III and to require manufacturers to submit a PMA application.

Manufacturers may choose to submit a PMA before the 30-month deadline.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

Media

Deborah Kotz (mailto:deborah.kotz@fda.hhs.gov)
301-796-5349

Consumers

888-INFO-FDA

Related Information

- FDA: Medical Devices (/MedicalDevices/default.htm)
- FDA: Urogynecologic Surgical Mesh Implants (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm)
- Recommendations for Patients (PDF - 76KB) (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262756.pdf)

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