FDA News Release

FDA takes action to protect women's health, orders manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse to stop selling all devices

For Immediate Release

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Release

The U.S. Food and Drug Administration today ordered the manufacturers of all remaining surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse (POP) to stop selling and distributing their products in the U.S. immediately. The order is the latest in a series of escalating safety actions related to protecting the health of the thousands of women each year who undergo surgery transvaginally to repair POP.

The FDA has determined that the manufacturers, Boston Scientific and Coloplast, have not demonstrated a reasonable assurance of safety and effectiveness for these devices, which is the premarket review standard that now applies to them since the agency reclassified them in class III (high risk) in 2016. As part of the 2016 reclassification, manufacturers were required to submit and obtain approval of premarket approval (PMA) applications, the agency's most stringent device review pathway, in order to continue marketing their devices in the U.S. The companies will have 10 days to submit their plan to withdraw these products from the market.

"In order for these mesh devices to stay on the market, we determined that we needed evidence that they worked better than surgery without the use of mesh to repair POP. That evidence was lacking in these premarket applications, and we couldn't assure women that these devices were safe and effective long term," said Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health. "Patient safety is our highest priority, and women must have access to safe medical devices that provide relief from symptoms and better management of their medical conditions. The FDA has committed to taking forceful new actions to enhance device safety and encourage innovations that lead to safer medical devices, so that patients have access to safe and effective medical devices and the information they need to make informed decisions about their care."

Surgical mesh has been used by surgeons since the 1950s to repair abdominal hernias. In the 1970s, gynecologists began implanting surgical mesh for abdominal repair of POP and, in the 1990s, for the transvaginal repair of POP. In 2002, the first mesh device for transvaginal repair of POP was cleared for use as a class II moderate-risk device. About 1 in 8 women has surgery to repair POP over her lifetime, and a subset of these

surgeries are completed transvaginally with the use of surgical mesh. However, the percentage of women undergoing transvaginal POP mesh procedures has decreased in recent years after the FDA began **issuing warnings (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm)** about the risks associated with using transvaginal mesh used for POP repair.

Two manufacturers have been marketing three surgical mesh products for transvaginal repair of POP. In reviewing the PMAs submitted by the two manufacturers, the agency determined they failed to provide an adequate assessment of the long-term safety of these devices and failed to demonstrate an acceptable long-term benefit of these devices compared to transvaginal surgical tissue repair without the use of mesh (native tissue repair). Since the FDA has not received sufficient evidence to assure that the probable benefits of these devices outweigh their probable risks, the agency has concluded that these products do not have a reasonable assurance of safety and effectiveness.

Boston Scientific filed two PMAs for its devices, the Uphold LITE Vaginal Support System and the Xenform Soft Tissue Repair System, and Coloplast filed a PMA for its device, Restorelle DirectFix Anterior. In February 2019, the FDA **convened an advisory panel (/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm630937.htm)** to solicit input from experts on how to evaluate the safety and effectiveness of surgical mesh for transvaginal repair of POP. The panel recommended that to support a favorable benefit-risk profile, the effectiveness of surgical mesh for transvaginal repair of POP should be superior to native tissue repair at 36 months and the safety outcomes for surgical mesh for transvaginal repair of POP should be comparable to native tissue repair. The FDA agreed with these recommendations, and because such data were not provided by manufacturers in their PMAs, the FDA decided not to approve them. Even though these products can no longer be used in patients moving forward, Boston Scientific and Coloplast are required to continue follow-up of the subjects already enrolled in their 522 studies.

Women who have had transvaginal mesh placed for the surgical repair of POP should continue with their annual and other routine check-ups and follow-up care. There is no need to take additional action if they are satisfied with their surgery and are not having complications or symptoms. Patients should notify their health care professionals if they have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex. They should also let their health care professional know if they have surgical mesh, especially if they plan to have another surgery or other medical procedures. Women who were planning to have mesh placed transvaginally for the repair of POP should discuss other treatment options with their doctors.

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. As a result, the agency has taken several, escalating actions for the protection of public health:

July 2011: FDA issued an **FDA Safety Communication (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf)**, which identified concerns and issued new recommendations about the use of surgical mesh for transvaginal repair of POP.

September 2011: FDA convened a public meeting of the **Obstetrics and Gynecology Devices Panel (/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm630937.htm)** to discuss the benefits and risks of this use. Subsequently, the FDA issued 131 orders to conduct postmarket surveillance studies ("**522 orders (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/PostmarketSurveillance/ucm134497.htm)**") to 34 manufacturers of surgical mesh for transvaginal repair of POP. Most manufacturers elected to stop marketing surgical mesh for transvaginal repair of POP after receiving their 522 orders.

January 2016: The FDA completed its **reclassification of surgical mesh (https://www.federalregister.gov/documents/2016/01/05/2015-33165/obstetrical-and-gynecological-devices-reclassification-of-surgical-mesh-for-transvaginal-pelvic)** for transvaginal repair of POP into the highest risk class of devices (class III), which requires premarket approval (PMA) applications, the agency's most stringent device review pathway, in order to stay on the market.

July 5, 2018: This was the deadline for applications to be filed **for premarket approval (https://www.federalregister.gov/documents/2016/01/05/2015-33163/effective-date-of-requirement-for-premarket-approval-for-surgical-mesh-for-transvaginal-pelvic-organ)** for any surgical mesh marketed for transvaginal POP repair. Manufacturers that did not file PMAs by this deadline were required to withdraw their products from the market. Those that did were allowed to keep their products on the market while the FDA reviewed their PMAs.

February 12, 2019: The FDA convened an **advisory committee meeting (/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm630937.htm)** to share the available evidence and seek expert opinion on how to evaluate the risks and benefits of these devices. The committee was asked to provide scientific and clinical input on assessing the effectiveness, safety, and benefit-risk of mesh placed transvaginally in the anterior vaginal compartment, as well as identifying the appropriate patient population and physician training needed for these devices.

The action today is part of the FDA's overarching commitment to advance women's health and improve access to safe and effective medical devices. This includes the issuance of a **Medical Device Safety Action Plan (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm604500.htm)** and the agency's work to implement a new active surveillance system to quickly detect new device safety signals and efforts to strengthen Coordinated Registry Networks (CRNs), which link different real-world data sources to generate clinical evidence about medical products used by patients. In particular, the FDA is focusing on addressing clinical questions on device therapies that are unique to women, such as the treatment of uterine fibroids and pelvic floor disorders including POP. The FDA partnered with the American College of Obstetricians and Gynecologists, the American Urogynecologic Society, the National Library of Medicine and others on this effort, known as the Women's Health Technologies CRN, or WHT-CRN. Providing patients with access to the safest possible medical devices on the market to meet their health care needs remains a top FDA priority.

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

- Urogynecologic Surgical Mesh Implants (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm)
- Reporting Problems with Mesh to the FDA (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm262304.htm)

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