Urogynecologic Surgical Mesh Implants

The FDA is aware of allegations that Boston Scientific's urogynecologic surgical mesh may contain counterfeit raw material. We are examining these allegations to determine any necessary and appropriate next steps. We are currently not aware that the alleged counterfeit raw material contributes to adverse events associated with these products.

It is not uncommon for a firm, based on its own appropriate evaluation of potential suppliers and raw material, to change the source of a raw material after the device has been cleared by the FDA, and such a change often does not require FDA premarket review. However, in light of the allegations, Boston Scientific will conduct additional testing relevant to the safety and effectiveness of the finished product.

Additional tests include chemical characterization and toxicological risk assessment of the raw material alleged to be counterfeit, as well as chemical characterization and biocompatibility of the final finished urogynecologic surgical mesh. The chemical characterization tests will identify and assess the chemicals present in the raw material and mesh, while the toxicological risk assessment will estimate the toxicity risks associated with each chemical. The biocompatibility tests will assess the ability of the mesh to come in contact with the human body without producing an adverse effect.

The additional testing should be sufficient for the FDA to determine whether or not the urogynecologic surgical mesh manufactured from the alleged counterfeit raw material are equivalent to the urogynecologic surgical mesh manufactured from the original raw material supplier. We expect that this testing will take several months to complete.

In the interim, the FDA believes that health care professionals and their patients should be aware of this investigation and the plan for FDA to review additional data from Boston Scientific so that they can make the most informed health care decisions.

For women who already have Boston Scientific urogynecologic surgical mesh implanted, the FDA is not recommending removal of this device since the available data do not suggest any decreased benefit associated with the device. Moreover, based on currently available information, the FDA believes the additional risks associated with mesh removal outweigh any risk that may be associated with the use of mesh manufactured from alleged counterfeit raw material.

We will continue to update this webpage as additional information becomes available.

Questions specific to currently marketed product should be directed to the manufacturer.

Surgical mesh is a medical device that is used to provide additional support when repairing weakened or damaged tissue. The majority of surgical mesh devices currently available for use are made from man-made (synthetic) materials or animal tissue.

Surgical mesh made of synthetic materials can be found in knitted mesh or non-knitted sheet forms. The synthetic materials used can be either absorbable, non-absorbable, or a combination of absorbable and non-absorbable materials.

Animal-derived mesh are made of animal tissue, such as intestine or skin, that have been processed and disinfected to be suitable for use as an implanted device. These animal-derived mesh are absorbable. The majority of tissue used to produce these mesh implants are from a pig (porcine) or cow (bovine).

Non-absorbable mesh will remain in the body indefinitely and is considered a permanent implant. It is used to provide permanent reinforcement in strength to the urogynecologic repair. Absorbable mesh will degrade and lose strength over time. It is not intended to provide long-term reinforcement to the repair site. As the material degrades, new tissue growth is intended to provide strength to the repair.

Surgical mesh can be used for urogynecologic procedures, including repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). It is permanently implanted to reinforce the weakened vaginal wall for POP repair or support the urethra or bladder neck for the repair of SUI. There are three main surgical procedures performed to treat pelvic floor disorders with surgical mesh:

- Transvaginal mesh to treat POP
- Transabdominal mesh to treat POP
- Mesh sling to treat SUI

Each of these procedures has unique risks and benefits and it is important not to confuse the procedures and the risks and benefits.

In this website, the FDA describes POP and SUI, the different surgical and non-surgical treatment options, recommendations for health care providers that treat women with POP and/or SUI, recommendations for patients who are considering surgery for these conditions and steps to report problems to the FDA. This information is to help patients make informed decisions about their health care and to facilitate a discussion between patients and

their health care providers about treatment options. The information provided on this website is not meant to replace a discussion with your health care provider.

Related Information

- **Federal Register Notice: Obstetrical and Gynecological Devices; Reclassification of Surgical Instrumentation for Use With Urogynecologic Surgical Mesh (https://www.federalregister.gov/documents/2017/01/06/2016-31862/medical-devices-obstetrical-and-gynecological-devices-reclassification-of-surgical-instrumentation)**
- **FDA Press Release: FDA strengthens requirements for surgical mesh for the transvaginal repair of pelvic organ prolapse to address safety risks (/NewsEvents/Newsroom/PressAnnouncements/ucm479732.htm)**
- **Final Order for Reclassification of Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair (https://www.federalregister.gov/documents/2016/01/05/2015-33165/obstetrical-and-gynecological-devices-reclassification-of-surgical-mesh-for-transvaginal-pelvic)**
- **Final Order for Effective Date of Requirement for Premarket Approval for Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair (https://www.federalregister.gov/documents/2016/01/05/2015-33163/effective-date-of-requirement-for-premarket-approval-for-surgical-mesh-for-transvaginal-pelvic-organ)**
- **UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication (/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm)** [ARCHIVED]
- **Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse (July 2011) (PDF - 243KB) (/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf)**
- **Federal Register Notice: Urogynecologic Surgical Mesh (http://www.gpo.gov/fdsys/pkg/FR-2011-07-14/pdf/2011-17695.pdf)**
- **Federal Register Notice Ammendment: Urogynecologic Surgical Mesh (http://www.gpo.gov/fdsys/pkg/FR-2011-08-15/pdf/2011-20644.pdf)**
- **2011 Meeting Materials of the Obstetrics and Gynecology Devices Panel (/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/ucm262488.htm)**