Boston Scientific

Boston Scientific Perspective on “60 Minutes” Transvaginal Mesh Segment

Read the facts about our pelvic floor products

April 28, 2019 Update

The original reporting by “60 Minutes” on our transvaginal mesh products remains inaccurate. Their claims are unrelated to the U.S. Food and Drug Administration’s April 2019 decision to halt the sale and distribution of mesh products used for transvaginal repair of pelvic organ prolapse (POP).

We are deeply disappointed by the FDA’s decision and believe the inaccessibility of these products will severely limit treatment options for the 50% of women in the U.S. who will suffer from POP during their lives. We have been working with the FDA for many years to develop the clinical evidence necessary to keep these important treatment options available. Unfortunately, the FDA’s decision removes that possibility for the foreseeable future.

It's important for patients to know that the FDA’s action is specific to one pelvic floor disorder. Our mesh products used to treat stress urinary incontinence (SUI) and for the abdominal repair of POP remain on the market.

A message from our leadership in response to the original May 2018 segment:

To patients, caregivers, medical professionals and the Boston Scientific community:

The CBS network television show “60 Minutes” recently aired an investigative story with completely false claims that suggested that our transvaginal mesh products contain counterfeited and smuggled materials. We want you to know the facts and understand our perspective.

The broadcast resurfaced outdated and previously disproven allegations first made by attorneys in 2016. Our rigorous testing and investigation have shown that the resin currently used in our products matches a formulation from the original U.S. produced resin. This information was also reviewed by the U.S. Food and Drug Administration (FDA) and was part of the basis of their conclusions.

We believe that this story was irresponsible and misleading. We provided the show with a statement and are disappointed that our perspective, and those of medical societies and the healthcare community, were not fully reflected in the broadcast.

Instead, the show offered a one-sided view and commentary from clinicians and plastic experts involved with litigious actions. It is important to keep in mind that polypropylene-based (plastic) devices have been a mainstay in many medical procedures for more than 50 years, including hernia and tendon repair, sutures, and wound closure. Furthermore, our products meet rigorous internal safety standards, international standards, as well the standards of the FDA and other regulatory bodies. Leading physician societies **have issued supporting statements on mesh**, and the **American Urogynecologic Society** recently shared its perspective.

The segment also showed documents and photos that were taken out of context. Numerous communications not shown by “60 Minutes” demonstrated that our employees were committed to making sure that we complied with all import and export regulations in shipping the resin to the U.S. The steps taken by Boston Scientific depicted in this segment were inaccurate. We packaged the materials to prevent them from damage during transportation. This was well-documented and would not have prevented customs officials from opening or further inspecting the bags.

Our top priority is providing safe and effective products. We stand firm in our support of women with pelvic floor disorders who continue to need effective treatment options. Nearly one million women have been successfully treated with our transvaginal mesh products.

Our mesh products contribute to only one percent of annual sales to our company. Continuing to provide these mesh products is not about profits. It is about doing what is right for patients. Without these products, women would be left with few treatment options for these debilitating and often embarrassing conditions.

Across Boston Scientific, our employees work diligently to bring forward important medical devices that help people around the world to live longer, healthier lives. We remain steadfast in our commitment to patients.

Sincerely,

Dave Pierce
Executive Vice President
MedSurg, Boston Scientific
President, Urology and Pelvic

https://news.bostonscientific.com/60minutes

Mike Mahoney
Chairman and
Chief Executive
Officer