FOR PATIENTS
What women should know about our pelvic floor products: A fact-based response to the "60 Minutes" mesh segment

Urogynecological mesh is used to treat stress urinary incontinence and pelvic organ prolapse, two conditions that are often debilitating and embarrassing for women. Few treatment options exist, but the nearly one million women who have been treated with Boston Scientific mesh products know the challenges of living with these conditions, as well as the benefits of these treatment options.

On May 13, 2018, the U.S. CBS television show "60 Minutes" aired a segment which suggested that our urogynecological mesh products contain counterfeit and smuggled materials. These allegations are completely false and misleading to women who currently have urogynecological mesh implants or are considering these treatment options. We are saddened by the anxiety and concern this may have caused for many individuals.

The decision to treat a medical condition with an implantable device is a serious one, to be made between a patient and doctor. We empathize with the patients who were featured in the story. As a medical device manufacturer, we recognize that every implant we make goes into a woman's body, and we take that responsibility seriously. We assure you that we are committed to providing safe and effective treatment options and stand behind our products.

The information below is intended to provide you with an objective review of the facts. We are confident this information will address the irresponsible and false claims that "60 Minutes" made.

GENERAL FACTS ABOUT THE "60 MINUTES" SEGMENT

- "60 Minutes" did not offer a balanced view on the value of the use of mesh in treating women with pelvic floor disorders.
- It did not present interviews with patients who have been successfully treated with mesh devices or physicians who are currently treating patients with mesh devices.
- The segment also did not include perspective from Boston Scientific. We provided a detailed statement and extensive supporting documentation prior to the segment airing, which were not reflected in the story.
- The individuals who were cited as plastic experts by "60 Minutes" do not have medical experience. In fact, both the plastic experts and the physician featured in the segment have been involved in legal cases against device companies for which they were paid for their testimonies.
- The documents and photos shown during the segment misrepresented internal employee communications and were depicted in ways to support this misleading story, not the truth.

POLYPROPYLENE RESIN: WHAT IS IT AND HOW WAS IT TESTED?

- A primary focus of the story was on the Boston Scientific supplier for polypropylene resin, a common ingredient in mesh and other medical devices.
- Polypropylene-based (plastic) devices have been a mainstay in many medical procedures for more than 50 years. It is commonly used as an implant for hernia and tendon repair, as well as in sutures and wound closure.
- In 2011, Boston Scientific changed suppliers for our resin, a common practice in medical device manufacturing. Prior to using resin from a new supplier, Boston Scientific investigated and rigorously

tested the resin to confirm that it matched the original U.S.-produced resin. After initial testing, we tested it again and reconfirmed our initial findings.

- Boston Scientific testing and investigations confirmed that the resin was the same as the resin that we had used up to that point. Testing and investigations also confirmed that the resin was manufactured in the U.S. and then shipped to, stored in and distributed from China.
- Boston Scientific shared all test results with the FDA.
- The data presented during the "60 Minutes" segment only represented a partial set of the initial testing conducted, and the conclusions in the segment were inaccurate and misleading. Again, the experts who interpreted the data during the segment do not have medical experience. They have been involved in legal cases against device companies for which they were paid for their testimonies.
- In the "60 Minutes" segment, a plastics expert referenced the "antioxidant stability" of the resin and characterized the product as inferior and likely to only last a few months in the human body. These statements are incorrect and misleading. The tests used to assess oxidation stability demonstrated that the resin currently used in our products is in no way inferior to the resin we had previously been using. All testing data was reviewed by Boston Scientific, third-party experts and the FDA.

THE FDA FINDINGS

- In September 2017, after an 18-month investigation, the U.S. Food and Drug Administration (FDA) concluded that resin used in our products did not raise any new safety or effectiveness concerns. No further actions were required by Boston Scientific.
    - While the FDA typically reviews the safety and effectiveness of finished products, in this instance, the agency analyzed both raw materials and finished product to fully address the allegations.
    - The FDA investigation included testing of the device, evaluation of Boston Scientific testing results, other quality information from Boston Scientific, and an on-site inspection of our facility.
    - The FDA also reviewed the details, methods and results of Boston Scientific testing, and took these results into account when issuing its final decision.

BOSTON SCIENTIFIC FOLLOWS SHIPPING LAWS AND REGULATIONS

- Resin is manufactured in the shape of small pellets and typically shipped in large containers to distributors, which then package the material in smaller bags.
- For shipping from the distributor in China, Boston Scientific packaged the resin in a second bag to prevent damage during transportation. During the first shipment, we learned that the bags may tear or be damaged during international transit without a protective second bag. The second packaging bag did not prevent customs officials from opening or further inspecting the bags.
- "60 Minutes" showed images of the packaging during shipping with an inaccurate explanation for why the material was shipped this way.
- There are numerous communications not shown by "60 Minutes," which demonstrated that Boston Scientific employees were committed to making sure that we complied with all import and export regulations in shipping the resin to the U.S. China and U.S. customs authorities did not raise any questions or concerns.
- The "60 Minutes" piece showed an empty, unused resin bag next to a bag of resin from the distributor in China with differences in appearance as an attempt to support the false claims of counterfeit material. The segment did not explain that the resin is shipped from the manufacturer in large containers, not in smaller bags. It is common practice for intermediate distributors to create bags using a manufacturer's label format and style from the respective manufacturer. For instance, the distributor of our previous supply of resin purchased through a U.S.-based manufacturer used plain white bags and placed its own label on them. Therefore, it is not unusual that there would be

differences in bags that came directly from the manufacturer and those that came from the distributor. The most important point is that the contents of the bags have been rigorously tested and shown to be resin from the original U.S.-based manufacturer.

MORE ABOUT BOSTON SCIENTIFIC UROGYNECOLOGICAL MESH PRODUCTS

- All Boston Scientific products meet rigorous internal safety standards. In addition, Boston Scientific products meet FDA standards and those of other regulatory bodies, as well as international standards.
- We stand firm in offering these products because without them, women would be left with few treatment options for these debilitating and often embarrassing conditions.
- We continue to partner with researchers and invest in studies to provide the medical community with additional clinical evidence to support ongoing treatment decisions.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

May 15, 2018