

## THE SAFETY AND QUALITY OF BOSTON SCIENTIFIC'S MESH

We know the recent *60 Minutes* segment might have caused some questions, and we want you to have all the information you need. Below are important details for women who have been implanted with urogynecological mesh, or who may be considering it to treat pelvic floor disorders, such as stress urinary incontinence (SUI) and pelvic organ prolapse (POP). If you have medical questions, we encourage you to speak with your physician.

### UROGYNECOLOGICAL MESH FOR POP AND SUI

Urogynecological mesh made from polypropylene is a treatment for pelvic floor disorders like POP and SUI.

- **For POP:** Many clinical studies support mesh-based repair (transvaginal and laparoscopic sacrocolpopexy) as an effective procedure for women with POP.<sup>i</sup>
- **For SUI:** Mid-urethral slings are form of gynecological mesh, and widely recognized by medical and regulatory experts as the standard of care for women with SUI.<sup>ii</sup> The use of these slings is well-established in clinical trials<sup>iii</sup> and leading expert physician societies have published supporting [statements](#) on mesh.<sup>iv</sup>

*The polypropylene midurethral sling has helped millions of women with SUI regain control of their lives by undergoing a simple outpatient procedure that allows them to return to daily life very quickly.”*

**The American Urogynecologic Society and the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction in a Joint Position Paper**

### MESH MATERIAL MADE IN THE U.S.

Our urogynecological mesh products are made with polypropylene resin.

- In 2011, Boston Scientific changed distributors for their resin, a common practice in medical device manufacturing.
- Resin was made in the U.S. and then shipped to, stored in and distributed from China.
- Our rigorous testing and review demonstrated that the polypropylene resin currently used in our products matches a formulation from the original U.S.-produced resin.
- Our testing determined it was in no way inferior to the resin we had previously been using.

### FINDINGS FROM FDA INVESTIGATION



An additional FDA review of the resin, which concluded in 2017, determined the change in supplier did not present any new safety or effectiveness concerns.<sup>v</sup> The review included:

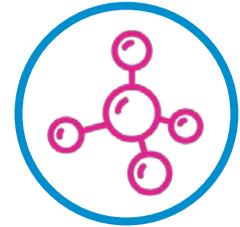
- An investigation of both the resin used to make our product, and the finished slings.
- Testing of the device and on-site inspection of our facility and other quality information.
- A full review and evaluation of details, methods and results of Boston Scientific's testing.

The plastics experts who were interviewed in the recent *60 Minutes* segment did not have medical experience, were involved in litigation against mesh manufacturers for monetary gain, and were not hired to provide unbiased or objective opinions.

## POLYPROPYLENE IS LONG-STUDIED AND WELL-SUPPORTED AS A MATERIAL FOR USE IN UROGYNECOLOGICAL MESH

Polypropylene material has been used in medical procedures for more than 50 years, including in hernia repair and surgical sutures.<sup>vi</sup> Polypropylene material has been used in millions of patients and by surgeons worldwide.<sup>vi</sup>

Our supplier issued a statement regarding the use of their resin for medical implantation. This type of statement is standard practice for raw material suppliers to communicate. As the purchaser, Boston Scientific was responsible for conducting relevant testing. We conducted biocompatibility testing when the mesh products were developed and again during the 2016 - 2017 FDA review.



## PROTECTING RAW MATERIALS DURING STORAGE AND SHIPPING



When shipping resin, it is customary to ship it in large containers to distributors, and then package the material in smaller bags with different lot numbers.

When bagging the raw material, additional bags were used to avoid spillage, breakage and protect the material's integrity. This "security-bagging" was well documented and was not intended to, nor did it, prevent customs officials from opening or further inspecting the bags.

## OUR PRIORITY IS PATIENT HEALTH

Despite how many women are impacted by pelvic floor disorders, relatively few treatment options exist - and medical innovation has lagged for these conditions. While the nature of medical practice is never without risk, Boston Scientific's mesh has helped treat nearly one million women. We continue to partner with researchers and invest in studies to provide the medical community with the most up-to-date clinical evidence to support ongoing treatment decisions. Boston Scientific has been and continues to be focused on innovating to provide women with treatment options.

©2018 Boston Scientific Corporation or its affiliates. All rights reserved.

<sup>i</sup> Letouzey V, Ulrich D, Balenbois E, Cornille A, de Tayrac R, Fatton B. Utero-vaginal suspension using a bilateral vaginal anterior sacrospinous fixation with mesh. Intermediate results of a cohort study. *Int Urogynecol J.* 2015; 26:1803-1807; Granese, R., Candiani, M., Perino, A., & Cucinella, G. (2009). Laparoscopic sacrocolpopexy in the treatment of vaginal vault prolapse: 8 years experience. *European Journal of Obstetrics & Gynecology and Reproductive Biology*, 144(2), 227-231

<sup>ii</sup> AUGS/SUFU Joint Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence. 2014; updated 2016 and 2018. [https://www.augs.org/assets/1/6/AUGS-UFU\\_MUS\\_Position\\_Statement.pdf](https://www.augs.org/assets/1/6/AUGS-UFU_MUS_Position_Statement.pdf)

<sup>iii</sup> FDA, Considerations about Surgical Mesh for SUI, <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm>. 2013

<sup>iv</sup> AUGS/SUFU Joint Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence. 2014; updated 2016 and 2018. [https://www.augs.org/assets/1/6/AUGS-UFU\\_MUS\\_Position\\_Statement.pdf](https://www.augs.org/assets/1/6/AUGS-UFU_MUS_Position_Statement.pdf)

v U.S. Food and Drug Administration, *Urogynecologic Surgical Mesh Implants*, 2017

vi Gilbert A., Graham M., Young J. (2004) Polypropylene: the Standard of Mesh Materials. In: Schumpelick V., Nyhus L.M. (eds) *Meshes: Benefits and Risks*. Springer, Berlin, Heidelberg, pg. 102