Boston Scientific
Advancing science for life™

DEAR VALUED CUSTOMER:

A recent segment on the CBS television show *60 Minutes* called into question the quality of our urogynecological mesh products. Although the segment was inaccurate, we recognize that it may have been concerning and that you – and your patients – may have questions.

I want to assure you that our urogynecological mesh is responsibly sourced. Our rigorous testing and review demonstrated that the polypropylene resin currently used in our products matches the original U.S.-produced resin. Furthermore, the FDA concluded that the change in our mesh supplier raised no new safety or effectiveness concerns.

We provided a statement and background information to assist *60 Minutes* with presenting a more accurate report. They did not use this information or correct inaccuracies in the segment. They also did not include the perspectives of the women who have benefitted from Boston Scientific's mesh and their doctors. Instead, they interviewed plastics experts with no medical experience, who were involved in litigation against mesh manufacturers for monetary gain and who were not hired to provide unbiased or objective opinions.

Every day, we strive to develop and produce safe and effective products to improve the health and lives of patients. We know that decisions about medical implantations are serious. While the nature of medical practice is never without risk, millions of patients have benefitted from our innovations. That's why, in the U.S., we offer a full guarantee on the quality of our mesh products for hospitals, clinics and implanting physicians.

Enclosed is important information that was not revealed in the segment to help you address questions from your patients. We hope these facts, and the information on our website, are helpful in answering your – and your patients' – questions.

As you know firsthand, women need effective treatment options for these debilitating and embarrassing conditions. We share your mission of caring for the nearly one-third of women who will experience pelvic organ prolapse or a related condition in their lifetime and the 20 to 40 percent of women who experience or will experience SUI.[i]

Thank you for your continued commitment and trust.

Sincerely,

Mike Mahoney
Chairman and Chief Executive Officer, Boston Scientific

THE FACTS ABOUT BOSTON SCIENTIFIC'S MESH

Our urogynecological mesh is made with polypropylene resin.

- Our resin was **made in the U.S.** and then shipped to, stored in and distributed from China.
- We conducted rigorous testing and have established the resin **matched the original U.S.-produced resin.**
- In 2017, the FDA completed its review, which included our raw materials and finished mesh, and concluded that the change in resin supplier presented no new safety or effectiveness concerns. The agency publicly posted its conclusion and took no new regulatory action.[ii]

The segment referenced a statement from our supplier regarding the use of their resin for medical implantation. This type of statement is standard practice for raw material suppliers to communicate. The purchaser of the raw material is responsible for conducting the relevant testing, depending on the use of the raw material. In this case, the supplier agreed to sell us an additional stock of resin in 2005, after they issued that statement. Moreover, Boston Scientific, per its obligation as the purchaser, conducted the appropriate biocompatibility testing when the mesh products were developed and again subsequent to that during the 2016 – 2017 FDA review. The FDA concluded that the change in resin supplier presented no new safety or effectiveness concerns.

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The health and safety of patients is our top priority. Our products meet rigorous internal safety standards and the FDA's and other regulatory and international standards.

Polypropylene material has been used in medical procedures for **more than 50 years**, including in hernia repair and surgical sutures.[iii]

Leading physician societies, specifically the American Urogynecologic Society and the Society for Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, have issued supporting statements for MUS for SUI.

3M+ WOMEN

Have been treated with mid-urethral slings.[iv]

MOST-STUDIED

Mono-filament polypropylene mid-urethral slings are the most-studied **anti-incontinence procedure in history.**[iv]

1M WOMEN

Have been successfully treated with Boston Scientific's mesh products.

$31M INVESTED IN ONGOING CLINICAL STUDIES

$2M ON MEDICAL EDUCATION FOR PHYSICIANS IN 2018.

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[i] https://www.webmd.com/urinary-incontinence-oab/pelvic-organ-prolapse#1
[ii] U.S. Food and Drug Administration, Urogynecologic Surgical Mesh Implants, 2017
[iii] 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
[iv] AUGS/SUFU Joint Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence. 2014; updated 2016 and 2018. https://www.augs.org/clinical-practice/position-statements/

Figures on Boston Scientific's investment and number of patients: data on file with Boston Scientific