Boston Scientific

Boston Scientific Responds to FDA's Decision to Remove Surgical Transvaginal Mesh as Treatment Option for POP

On April 16, 2019, the U.S. Food and Drug Administration (FDA) ordered manufacturers of surgical mesh intended for transvaginal repair of pelvic organ prolapse (POP) to stop selling and distributing these products.

We are deeply disappointed by this 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, today's announcement by the FDA removes that possibility for the foreseeable future.

In light of the FDA's decision and ongoing discussions with regulators outside of the U.S., Boston Scientific will stop global sales of its transvaginal mesh products indicated for pelvic organ prolapse: Uphold™ LITE Vaginal Support System, Xenform™ Soft Tissue Repair Matrix, Pinnacle™ Lite Posterior and Polyform™. After we review our plans with the FDA and other appropriate regulatory authorities, we will provide instruction following our approved process for removal of existing customer inventory in the coming days.

Consistent with FDA guidance, Boston Scientific recommends that women who have been implanted with the Uphold™ LITE Vaginal Support System and the Xenform™ Soft Tissue Repair Matrix should continue with annual routine check-ups with their doctor. There is no need for patients who are satisfied with their treatment to take additional action. However, any patient with questions or concerns should speak to her healthcare provider. Please refer to the full statement on the FDA website.

It is important to note that there are a variety of surgical mesh products designated for different conditions. The FDA's recent decision is limited to mesh for the transvaginal repair of pelvic organ prolapse and *does not extend to mesh used to treat stress urinary incontinence or for transabdominal repair*.

As a global leader in women's health, Boston Scientific remains steadfast in our commitment to helping women and all patients live better and healthier lives.

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https://news.bostonscientific.com/fda-decision-on-transvaginal-mesh-for-POP