Boston Scientific

Boston Scientific Participates in FDA General Issues Panel on Transvaginal Surgical Mesh for Pelvic Organ Prolapse

On February 12, 2019, the U.S. Food and Drug Administration (FDA) convened an advisory panel of experts to discuss the safety and effectiveness of surgical mesh placed transvaginally to treat pelvic organ prolapse (POP). Patient safety is always our highest priority, and we appreciate the panel's scientific and clinical input.

Up to 50% of women in the U.S. will suffer from POP during their lives, and we believe these women should have access to safe and effective treatment options.[1] As a global leader in the pelvic floor space, we remain steadfast in our commitment to helping women live better and healthier lives.

We also remain confident in the benefits and safety of our treatments for POP, and we look forward to continuing to work with the FDA on our premarket approval applications (PMAs) for the Uphold™ LITE Vaginal Support System and the Xenform™ Soft Tissue Repair Matrix, which are currently under review.

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[1] Barber, M.D. & Maher, C. Epidemiology and outcome assessment of pelvic organ prolapse. Int Urogynecol J (2013) 24: 1783.

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https://stage.mediaroom.com/bostonscientific/news-releases?item=136928