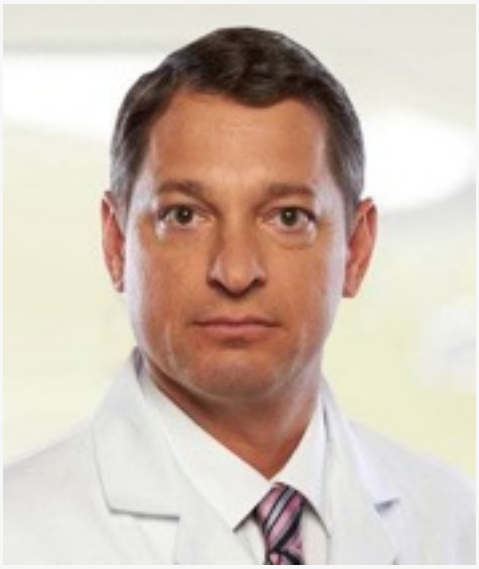
Pelvic Organ Prolapse: FDA Banned Vaginal Mesh Because Of Complications

The FDA on April 16, 2019 banned the current and future sales, distribution, and manufacturing of transvaginal mesh devices used for pelvic organ prolapse.



SANTA BARBARA, CA, UNITED STATES OF AMERICA, July 26, 2019 /EINPresswire.com/ -- The FDA on April 16, 2019 banned the current and future sales, distribution, and manufacturing of transvaginal mesh devices used for pelvic organ prolapse because 'Boston Scientific and Coloplast have not demonstrated reasonable assurance of safety and effectiveness for these devices... to assure that the probable benefits of these devices outweigh their probable risks.'

This is exceptionally unusual, as the FDA had only banned one other medical device prior to 2016 and that was prosthetic hair fibers because the FDA found there was no public health benefit to this device. More recently on December 19, 2016 the FDA banned powdered gloves as these gloves posed an unreasonable and substantial risk of illness and injury and unpowdered gloves posed no such risk.

The FDA recommends women who have had prolapse surgery to ask their doctors if mesh was used and for those who had mesh implanted to seek medical attention if there is groin pain, pain with sexual intercourse, or pelvic pain. Unfortunately, to date there has been no medical monitoring ordered for women who have undergone this banned surgery.

> "(Mesh) injuries occur and will continue to occur as these polypropylene mesh devices contracts, hardens, breaks, and twist inside the pelvis of women as it degrades."
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> *Dr. Greg Vigna*

Dr. Greg Vigna, a practicing physician, national pharmaceutical injury attorney, and Certified Life Care Planner has concerns, "We are representing women 8-10 years out from transobturator sling implantation, including the Boston Scientific Obtryx sling, with newly diagnosed pudendal neuralgia and life changing pain. We represent women with the banned pelvic organ prolapse devices with newly diagnosed pudendal neuralgia. Women with Ethicon's Prolift device, which was 'voluntarily' removed from the market place, and Boston Scientific Uphold and Pinnacle, are getting diagnosed with pudendal neuralgia 6-8 years after implantation. These injuries occur and will continue to occur as these polypropylene mesh devices contracts, hardens, breaks, and twist inside the pelvis of women as it degrades."

Dr. Vigna has more concerns, "The American Urogynecologic Society has done little to advocate for women's safety and continues to do nothing. They have not required mandatory Continued Medical Education on the neurological complications of the vaginal mesh devices to allow for timely diagnosis and treatment by its members. It continues to stand on the sidelines as its members implant transobturator slings which offer no improved efficacy over retropubic slings but place the obturator and pudendal nerve in peril to acute and chronic injuries from these

devices. It is my opinion that transobturator slings will be banned by the FDA in 5-10 years much like the FDA banned the use of prosthetic hair fibers and powdered surgical gloves. The risk and magnitude of harm far outweighs the utility of these devices. Unfortunately, catastrophic injuries continue on."

For articles, video resources, and information on the neurological complications of TVM visit the Pudendal Neuralgia Educational Portal or https://tvm.lifecare123.com/. We also have a new eBook discussing the consequences of sling implantation.

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