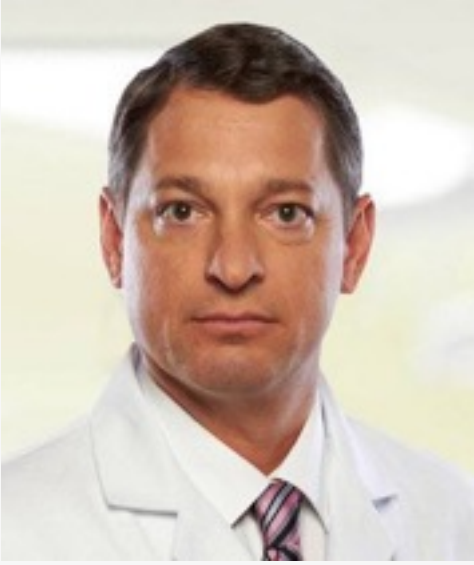
Boston Scientific and Urogynecologist Hit with Vaginal Mesh Lawsuit

Boston Scientific Corporation and urogynecologist Valerie Burkard, MD hit with a lawsuit filed by a woman who sustained grievous injuries from the Uphold TVM.



SANTA BARBARA, CALIFORNIA, UNITED STATES, November 13, 2019 /EINPresswire.com/ -- On October 17, 2019, Boston Scientific Corporation and urogynecologist Valerie Burkard, MD, was hit with a lawsuit filed by a woman who sustained grievous injuries caused by the placement of the Uphold transvaginal mesh (TVM) device used for the treatment of pelvic organ prolapse (POP) and the Obtryx sling used in the treatment of stress urinary incontinence in the State of New York, Supreme Court: County of Erie (Index No. 813745/2019).

In December 2011, the American College of Obstetrics and Gynecology (ACOG) and American Urogynecologic Society (AUGS) issued a joint committee opinion stating "pelvic organ prolapse mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk, such as individuals with recurrent prolapse (particularly of the anterior compartment) or with medical co-morbidities that preclude more invasive lengthier open and endoscopic procedures."

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>
> *Dr. Greg Vigna*

On March 26, 2013, AUGS issued a statement restating their position on use of pelvic organ prolapse mesh products and stressed the importance of appropriate informed consent and proper training for surgeons implanting the products in patients who only had recurrent prolapse after a non-mesh native tissue repair or who were at high risk for more invasive surgery due to co-morbidities.

Allegations against the named physician in the lawsuit is that the urogynecologist "failed to fully disclose to Plaintiff all risks associated with implantation and the frequency and severity of those risks.....(and) failed to inform Plaintiff that the polypropylene product was not recommended as a treatment for POP by AUGS or ACOGG for use in women, like her, who were not at high risk because they did not have recurrent prolapse or medical co-morbidities that precluded more invasive and lengthier open and endoscopic procedures."

Boston Scientific publicly continued to stand by the safety and effectiveness of the Uphold device even after the FDA in 2016 reclassified the POP device into class III (high risk), while other manufacturers such as Ethicon had long since removed from the market their portfolio of dangerous POP devices - the Prosima and Prolift. This is despite the design of the Uphold that requires the blind placement into the sacrospinous ligament which causes a predictable,

unavoidable, and unreasonable risk of pudendal nerve injury even in the hands of skilled and experienced surgeons.

On February 12, 2019, Boston Scientific Corporation stated their unreasonable position in their Executive Summary that presented prospective controlled 522 post market surveillance studies ordered by the FDA:
“Boston Scientific Corporation (BSC) firmly believes that the totality of clinical evidence supports the positive benefit/risk profile of transvaginal mesh devices to treat pelvic organ prolapse.”

On April 16, 2019, the FDA moved to ban the remaining polypropylene TVM devices from the market including the Uphold and Coloplast Restorelle device because the manufacturers “have not demonstrated reasonable assurance of safety and effectiveness of these devices.” Essentially, the FDA views the utility of TVM POP devices in the same category as other banned medical devices including prosthetic hair.

Greg Vigna, MD, JD, practicing physician, national pharmaceutical injury attorney, and Certified Life Care Planner states, “This case involves the so called dual product case that combines a sling and a POP device. The medical management of these women are exceptionally difficult and only a few centers in the country have the skill and experience to diagnose and manage the neurological complications of these devices.”

The Plaintiff and her husband are represented by Ben C. Martin and Laura Baughman of Martin Baughman, PLLC and Greg Vigna, MD, JD. Ben Martin and Laura Baughman are national pharmaceutical injury attorneys in Dallas, Texas. Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic injuries and the neurological injuries caused by transvaginal mesh devices including pudendal neuralgia, obturator neuralgia, and complex regional pain syndrome.

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