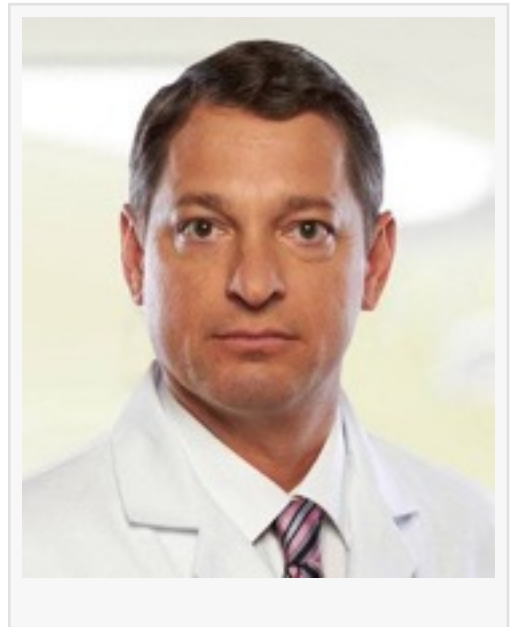


Failure to Warn Claim Viable Despite Ethicon's 2015 TVT-O IFU

An IFU must contain all warnings necessary to place doctors on notice of all material information when deciding the risk vs benefits of the medical device.

SANTA BARBARA, CALIFORNIA, UNITED STATES, September 1, 2020 /EINPresswire.com/ -- Ethicon in 2015 largely re-wrote its Instructions for Use (IFU) for its polypropylene transvaginal mesh (TVM) mid-urethral slings used in the surgical management of stress urinary incontinence (SUI). An IFU must contain all warnings necessary to place doctors on notice of all material information required when deciding on the risk versus benefits of using the medical device. The doctors in turn can then pass on that information to their patients while determining whether to use the device at all.



Ethicon's IFU for the Abbrevio and TVT-O devices—both [transobturator slings](#)—states the mesh material is “not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.” The IFU also list “Adverse Reactions,” and those that relate to neurological injuries are as follows: “1) Punctures or lacerations of nerves, 2) Acute and/or chronic pain, 3) Pain with

intercourse which in some patients may not resolve, 4) [Neuromuscular](#) problems including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.”

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Degradation of polypropylene transobturator slings within the obturator internus muscle leads to latent injuries.”

Dr. Greg Vigna

Greg Vigna, MD, JD, practicing physician, national pharmaceutical injury attorney, and Certified Life Care Planner states, “Polypropylene degrades and this has been known by manufacturers since the hamster study in the 1970's, and this subject has been studied since the early

70's with infrared spectroscopy and scanning electron microscopy. The conclusion is that polypropylene oxidizes and cracks over time. Either Ethicon doesn't understand the medical definition of degradation or they continue to deceive the public for financial gain.”

Dr. Vigna continues, “Ethicon's 2015 warning represents what the company knew in 2005 and

doesn't reflect what they know now as it relates to their dangerous TVT-O and Abbrevio transobturator slings. There is nothing in the IFU that relates to latent injuries to the pudendal nerve by way of traction or compression despite being outside the operative field. Pudendal neuralgia is directly related to perpetual inflammatory response from damage to the obturator internus muscle and the degradation of the mesh that passes through the muscle causing excessive scarification, contraction of the device, and ongoing free oxidative radical generation that cause pain."

Dr. Vigna adds, "[Obturator neuralgia](#) can be caused by direct puncture or laceration of the nerve during implantation consistent with the warning listed in Ethicon's IFU. This is deceitful for physicians as when they read the IFU this is not the usual mechanism for injury that causes obturator neuralgia from transobturator slings. In a vast majority of women who develop obturator neuralgia, during revision surgery the mesh is away from the nerve at a seemingly safe distance. Physicians are also largely unaware that the main branch of the pudendal nerve is at risk for injury or irritation from transobturator slings because the nerve is nowhere near the operative field. The pudendal nerve is, however, adjacent to the obturator internus muscle as it passes from the spine into the pelvis. Polypropylene devices that pierce and pass through muscles cause acute injury and spasms of the muscle. Every transobturator sling during implantation pierce and pass through the obturator internus muscle and will result in acute spasm and inflammation from direct injury. This may lead to traction or pulling of the adjacent obturator nerve and pudendal nerves and the result may be symptoms of acute obturator or pudendal neuralgia. Symptoms may be transient after implantation but in others the pain may continue chronically as the device degrades in the muscle causing further muscle shortening by way of fibrosis and spasm leading to traction and entrapment to the nerves."

Dr. Vigna concludes, "Degradation of polypropylene transobturator slings within the obturator internus muscle leads to latent injuries. Latent pain syndromes caused by transobturator slings (TOT) include pudendal and obturator neuralgia, and these latent pain syndromes sometimes develop slowly over years after implantation in patients who initially had no pain. Ethicon provides no warning as to latent neurological injuries caused by degradation of its devices. The mechanism is clear as it relates to injury or irritation to the main branch of the obturator and pudendal nerve. The mechanism is likely mesh degradation within the obturator internus muscle. Clearly the design of pelvic organ prolapse devices with transobturator arms and TOT slings was not a good idea in back in 2005 or later when Ethicon continued marketing these devices into 2020 despite what is known. The damage that this company has caused a generation of women is unconscionable."

Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic neurological injuries caused by transvaginal mesh devices including pudendal neuralgia, obturator neuralgia, ilioinguinal neuralgia, and Complex Regional Pain Syndrome. He has clients with these diagnoses filed around the country with Martin Baughman, a Dallas Texas firm. Ben Martin and Laura Baughman are national pharmaceutical injury trial attorneys in Dallas, Texas.

To learn more on the anatomical basis for TOT injury or irritation to the obturator and pudendal nerve and the treatments of obturator and pudendal neuralgia click here:

<https://vignallawgroup.com/ebooks/pelvic-mesh-pain/#page=59>

Click here for a FREE BOOK on Vaginal Mesh Pain : <https://vignallawgroup.com/publications/>
For articles, video resources, and information visit the Pudendal Neuralgia Educational Portal (<https://pudendalportal.lifecare123.com/>) or <https://tvm.lifecare123.com/>.

Click here for information regarding sling related complications:

<https://tvm.lifecare123.com/slidgebook.html>

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