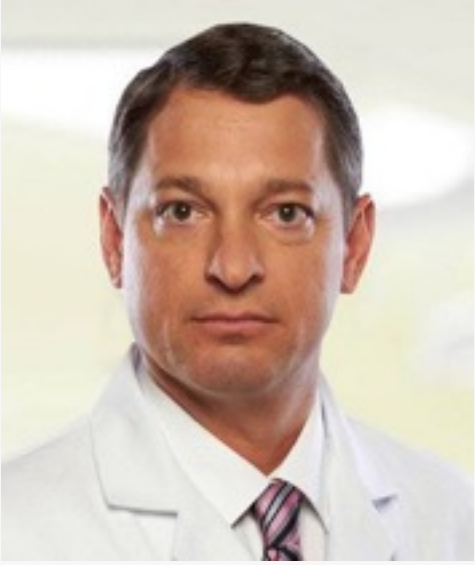
Post-2016: Can injuries caused from TVM devices be considered medical malpractice?

The FDA on April 16, 2019 moved to ban the use of transvaginal devices used in the repair of pelvic organ prolapse (POP) in the U.S.A.



SANTA BARBARA, CA, UNITED STATES, June 25, 2019 /EINPresswire.com/ -- The FDA on April 16, 2019 finally moved to ban the use of transvaginal devices used in the repair of pelvic organ prolapse (POP) in the U.S.A. to 'protect the health of thousands of women each year who undergo surgery.' The FDA acted because 'Boston Scientific and Coloplast have not demonstrated a reasonable assurance of safety and effectiveness for these devices.' Shamefully, the American Urogynecological Society (AUGS) failed to take this necessary step to protect women, believing physicians should have the 'ultimate judgment regarding any specific procedure or treatment' necessary in the care of women.

AUGS failed to act reasonably even after a significant change in the risk classification by the FDA for TVM devices used for POP on January 6, 2017. The FDA changed the risk of POP TVM devices from Class II to Class III which is a high risk device. Since this important FDA change, there remains a strong legal argument that all injuries from transvaginal mesh placement including the Boston Scientific Uphold device and Coloplast devices are medical malpractice as these devices are placed blindly which places women at a substantial and unreasonable risk of acute injuries to the pudendal nerves and obturator nerves and causes pudendal neuralgia and obturator neuralgia over time as the device degrades.

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> *Dr. Greg Vigna*

Are the neuromuscular injuries from transobturator (TOT) slings malpractice?

It is clear that transobturator (TOT) slings used for stress urinary incontinence (SUI) will be marching down the path to extinction similar to the devices used for pelvic organ prolapse. TOT slings are placed blindly like the POP devices, placing the obturator and pudendal nerves in peril to acute injuries during placement or over time as the polypropylene device shrinks. The literature is clear; TOTs cause pudendal neuralgia, obturator neuralgia, and complex regional pain syndrome and experts have testified that the occurrence of catastrophic pain syndromes are 10 times more frequent in TOT slings when compared to polypropylene retropubic slings. The risk and magnitude of harm does not support ongoing use of TOT slings and placement of a TOT is arguably medical malpractice.

Greg Vigna, MD, JD, practicing physician, national pharmaceutical injury attorney, and damages expert and his team of national pharmaceutical attorneys are evaluating catastrophic injuries caused by TOT devices and POP devices across the country. Dr. Vigna states, "Malpractice claims against doctors and hospitals along with a defective product claim against a device manufacturer

must be considered going forward for new injury cases from TOTs and those caused by TVM POP devices."

Dr. Vigna adds, "I don't see TOT slings including Ethicon's TVT-O, Boston Scientific Solyx and Obtryx, and Coloplast Aris and Altis being on the market in five years as doctors are finally pulled into the vaginal mesh debacle. TOTs provide no added benefit in efficacy when compare to retropubic slings and bring a 10x risk of catastrophic pain syndromes that destroy the lives of injured women."

For more information on Neurological Complications of Slings read our Free eBook. For articles, videos, and other valuable resources, visit https://tvm.lifecare123.com/ or our Pudendal Education Portal, https://pudendalportal.lifecare123.com/. We can also be reached at 800-761-9206.

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