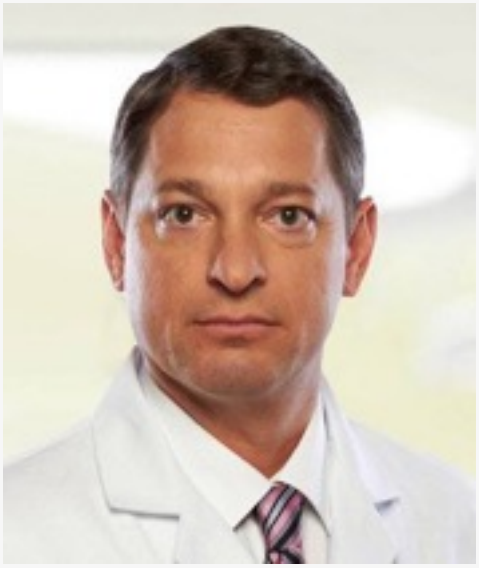
Litigation Update: Mini-Sling 522 Study and IDE Study Don't Prove Safety

Will transobturator polypropylene slings be next to be banned by the FDA?



SANTA BARBARA, CA, 93101, June 10, 2020 / EINPresswire.com/ -- On April 16, 2019 the FDA banned the transvaginal mesh devices used in the treatment of pelvic organ prolapse because there was no evidence that the devices worked better than non-mesh repair and there was no data to support that they were safe and effective long-term. The question remains, will transobturator polypropylene slings be next to be banned by the FDA?

Greg Vigna, MD, JD, national pharmaceutical injury attorney, physician, and Certified Life Care Planner comments, "Transobturator (TOT) slings by some are thought to have equal rates of achieving continence as non-mesh procedures, but there is no reliable data to support safety long-term. Clearly the foreseeable and unavoidable risk of catastrophic injury doesn't justify them being on the market. Coloplast sponsored an IDE Study and Boston Scientific sponsored a 522 Study and there was no evidence to show that there is a decreased risk of long-term pain from these devices compared to their predicates, the Aris and the Obtryx."

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>
> *Dr. Greg Vigna*

Dr. Vigna adds, "The MDL's Plaintiff Steering Committee largely dealt with erosion injuries and not neurological injuries. To date there have only been three pudendal neuralgia or obturator neuralgia cases that have gone to verdict. Considering their average verdict was seven million dollars, juries are very concerned about mesh created neurological injuries. With continued focus on TOT devices it is possible that these devices may also someday be banned. There is little doubt in my mind that manufacturers will throw in the towel on these devices as large verdicts come down against TOT and mini-sling device makers."

Dr. Vigna concludes, “As for retropubic slings, it will take some time for these devices to be taken off the market, but I am seeing a trend where newly injured women are getting diagnosed relatively early after implantation with Complex Regional Pain Syndrome and ilioinguinal neuralgia. Women are learning about the neurological injuries from a variety of sources and are getting diagnosed and treated for these pain syndromes more and more and thank goodness for that. We represent these women as well.”

Greg Vigna, MD, JD, is a California and Washington DC lawyer who focuses on catastrophic injuries caused by the TVM devices including pudendal neuralgia, obturator neuralgia, ilioinguinal neuralgia, and Complex Regional Pain Syndrome.

Click here to READ or receive a FREE BOOK Vaginal Mesh Pain by Greg Vigna,MD, JD:
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