Vaginal Mesh Implants: No Benefit Compared to Hysterectomy for Vaginal Prolapse

Clinical trial that included 183 women showed 'no differences in adverse events...but mesh hysteropexy group had an 8% mesh exposure rate.'

SANTA BARBARA, CA, UNITED STATES, September 20, 2019 / EINPresswire.com/ -- Three-year outcomes in a study paid for by the National Institutes of Health show no meaningful benefit in the treatment of vaginal prolapse when comparing hysterectomy with uterosacral ligament fixation of the vaginal remnant with transvaginal mesh placement without hysterectomy.

The clinical trial included 183 women at nine centers across the United States. Results of the study showed 'no differences in adverse events...but mesh hysteropexy group had an 8% mesh exposure rate.' The FDA banned the sale of transvaginal mesh device used for the treatment of pelvic organ prolapse (POP) on April 16, 2019 after results of this study were available.

> "This study is clear that there is no advantage to using transvaginal mesh for treatment of prolapse."
> *Dr. Greg Vigna*

Greg Vigna, MD, JD, national pharmaceutical injury attorney, practicing physician, and Certified Life Care Planner states, "This study is clear that there is no advantage to using transvaginal mesh for treatment of prolapse. It is a tragedy that doctors continued to implant these devices after these devices were re-classified from a Class 2 device to a Class 3. It goes to the lack of warning from the manufacturer as to the magnitude of risk. Going forward, hospitals may become defendants along with the likes of Coloplast and Boston Scientific and others as they allowed these devices to be put on their inventory shelves without questioning why countries across the world were banning these devices."

Dr. Vigna adds, "The neurological injuries from the vaginal mesh devices used for POP are life changing. Neuralgia pain interferes with all aspects of living. Women can't sit, have painful bladder filling, burning pain in the perineum, vaginal pain that makes penetration impossible, severe tailbone pain, and anorectal pain." He adds, "Our clients are working hard to obtain the care they need. Unfortunately, there continue to be barriers to state of the art care as few physicians are able to provide complete mesh removal and pudendal and obturator decompression. One barrier continues to be the lack of leadership of the American Urogynecologic Society in protecting American women from transobturator slings and educating its members on the neurological injuries related to these mesh devices, especially when the manufacturers fail to do so."

Greg Vigna, MD, JD, with a team of national pharmaceutical injury attorneys, represent women awaiting remand from the Multidistrict Litigation (MDL) in West Virginia and are filing new injury cases across the country in State Court as the MDL is closed to new cases.

For articles, video resources, and information visit the Pudendal Neuralgia Educational Portal or the TVM website and read our latest eBook for information regarding sling related complications.

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