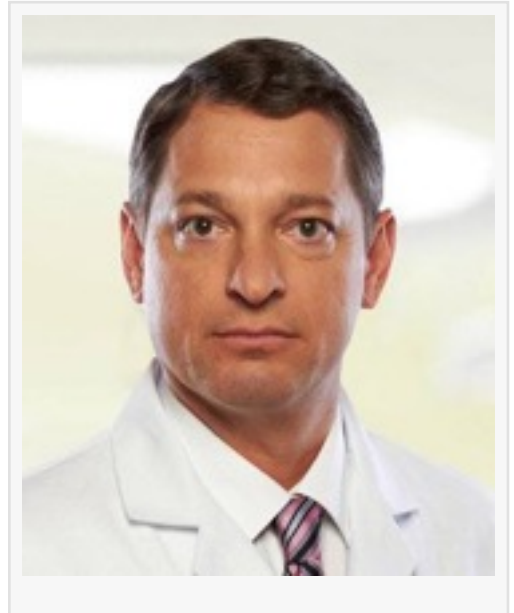


Left Behind by the Vaginal Mesh MDL: Survivors with Catastrophic Pain

After 2016, implantation of the Uphold and Restorelle Direct Fit is blatant malpractice involving both doctors and hospitals.

SANTA BARBARA, CALIFORNIA, UNITED STATES, July 5, 2019 /EINPresswire.com/ -- Dr. Frank Gamberdella, a gynecologist with 50 years of experience of clinical practice in Santa Barbara, was asked why he never implanted a vaginal mesh device, "I felt it in my hands, and it wasn't a device that belonged near the vagina, and all the non-mesh surgeries I provided for years worked well." Unfortunately, Dr. Gamberdella has retired with scores of other physicians trained by a different generation who provided autologous slings for the treatment of stress urinary incontinence (SUI), and non-mesh surgery for [pelvic organ prolapse](#).



The FDA moved on pelvic organ prolapse, making it a Class 3 'Dangerous Device' on January 6, 2017. Then the FDA formally banned polypropylene [transvaginal mesh](#) (TVM) devices that remained on the U.S. market on April 16, 2019.

A bad chapter in the Vaginal Mesh Debacle closed on that date as women will no longer suffer catastrophic pain from pudendal and [obturator neuralgia](#) caused by the likes of Boston Scientific Uphold device and Coloplast Restorelle Direct Fit used for pelvic organ prolapse. The remaining physician who were implanting these terrible devices are likely opening up their text books and going back to Dr. Gamberdella's non-mesh surgeries.

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Dr. Greg Vigna

The book is not closed on the Vaginal Mesh Debacle as manufacturers continue to sell transobturator (TOT) slings world-wide for the surgical management of stress urinary incontinence causing unnecessary neuromuscular complications including pudendal neuralgia and obturator neuralgia. This runs contra to logic and reason given every manufacturer sells a safer alternative design, the retropubic sling, that is 10 times safer than the TOT

devices as it relates to catastrophic pain.

Dr. Gamberdella, would testify like other experts in the field, that autologous slings cause no long-term pain and are as successful at curing incontinence as retropubic synthetic slings. Despite this the American Urogynecological Society (AUGS) continues to fail to take necessary steps to protect women by calling for the necessary warning to its members as it relates to the use of TOTs as they failed to protect women from TVM devices used for pelvic organ prolapse. If it weren't for the FDA ban on TVM prolapse device and Ethicon's financial decision to take Prolift off the market, women may be still be implanted by this monstrous mesh device.

Greg Vigna, MD, JD, practicing physician, national pharmaceutical injury attorney, and damages expert has issues with AUGS and the Board of Obstetrics and Gynecology and he believes that, "These influential Boards have been trusted to keep women safe and simply both have failed to

intervene. Pharmaceutical companies have recently pushed TVM prolapse devices and transobturator slings into the market place along with morcellators, and Essure device injuring thousands of women? These Boards need to mandate Continue Medical Education hours for the neuromuscular complications of TVM devices for its members, eliminate decision makers from their leadership who are on the pharmaceutical company's payroll, and simply do better at keeping women safe."

Dr. Vigna goes on, "After 2016, implantation of the Uphold and Restorelle Direct Fit is blatant malpractice involving both doctors and hospitals. Post-2017 pudendal neuralgia and obturator neuralgia victims of the TOT there is an argument of malpractice."

Soon the FDA will act to ban TOT devices as the magnitude of risk of individual harm far outweighs the benefit of the device and that will close the book on the Vaginal Mesh Debacle. Surgeons will return to the procedures provided by Dr. Gamberdella and injured women will slowly die off after suffering years of misery in the shadows: divorced, homeless, disabled, and in pain.

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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