Ethicon Vaginal Mesh Consent Order and Judgment: Admits to no liability but admits the truth

Ethicon Consent Agreement does not list obturator neuralgia and pudendal neuralgia as risks of a transobturator sling.

SANTA BARBARA, CA, UNITED STATES, January 29, 2022 /EINPresswire.com/ -- “Ethicon’s Consent Agreement should have a far-reaching impact on the liability of the company going forward and opens the door to significant third-party liability for physicians who publicly endorse these products for compensation from Ethicon without disclosing the risks known to and admitted by the company.” shares Greg Vigna, MD, JD.

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> *Greg Vigna, M.D., J.D., Certified Life Care Planner*

Dr. Greg Vigna, practicing physician, national pharmaceutical injury attorney, and certified life care planner states, “Ethicon’s TVT-O and TVT-Abbrevo devices are transobturator slings that require the arms to puncture and pass through the obturator internus muscle of the pelvis which is the muscle adjacent to the obturator nerve as it exits the pelvis adjacent to the pudendal nerve at Alcock’s canal and is recognized as a cause of pudendal and obturator neuralgia.”

Dr. Vigna adds, “The 2020 Joint Position Statement for the Management of Mesh-Related Complications for the FPMRS Specialist by the American Urogynecological Society (AUGS) and the International Urogynecological Association (IUGA) refers to the unique pain syndromes caused by the arms of the transobturator sling as ‘Extrapelvic Pain’ and relate this pain, in part, to the occurrence of obturator and pudendal neuralgia.”

Dr. Vigna states, “It is difficult to understand how Ethicon in good faith, believes that it is compliant with the Consent Order and Judgment given they have not listed obturator neuralgia and pudendal neuralgia as a risk of a transobturator sling given that the 2020 Joint Position Statement was written by AUGS and the IUGA, and is endorsed by the American Association of Gynecologic Laparoscopist (AAGL), and is supported by the Society of Gynecologic Surgeons.”

From the Supreme Court of the State of New York, New York County:

1) Ethicon shall modify Ethicon Surgical Mesh IFUs to include any such emerging Risk information and communicate any modification of the Risk information in the Surgical Mesh IFU… and to individuals responsible for Ethicon Marketing so as to modify any Promotional communication for Surgical Mesh in accordance with any modified Risk information.

2) Risks include complications that cannot be eliminated with surgical technique and complications that are specifically associated with the use of Surgical Mesh (as opposed to non-mesh surgery).

3) Ensure that device labeling in the IFU for its Surgical Mesh devices do not represent the following:

a. That any inflammatory or foreign body reaction is only transient or, in all instances, minimal.


Dr. Greg Vigna

b. Do not represent that any inflammatory or foreign body reaction is only transient or, in all instances, minimal.

c. Do not represent that a foreign body reaction "may occur" with implantation of the device, but instead indicate that a foreign body reaction to the device will occur, the extent of which may differ and may result in adverse reactions, which may be ongoing.

d. State the Risks include excessive contraction or shrinkage of the tissue surrounding the mesh.

Dr. Vigna concludes, "I believe physicians that are paid as consultants by mesh manufacturers to provide education and training on the use of transobturator slings for marketing purposes, may have third-party liability if harm is caused by non-disclosure of material complications known to the manufacturer. A paid consultant who does not disclose the risks of pudendal and obturator neuralgia caused by the arms of a transobturator sling during educational events sponsored by the manufacturers might find themselves financially liable if an implanting physician reasonably relied on training when implanting a transobturator sling that caused injury."

Dr. Vigna is a California and Washington DC lawyer, and with Martin Baughman, PLLC, a national pharmaceutical injury law firm in Dallas, focuses on the neurological injuries caused by transvaginal mesh devices including pudendal neuralgia, obturator neuralgia, ilioinguinal neuralgia, and Complex Regional Pain Syndrome.

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.
Read our FREE BOOK on Vaginal Mesh Pain and listen to Podcasts from the Vigna Law Group:

For articles, video resources, and information visit the Pudendal Neuralgia Educational Portal at: https://pudendalportal.lifecare123.com/ or https://tvm.lifecare123.com/. Click the following link for information regarding sling related complications:
https://tvm.lifecare123.com/slingebook.html

References:
https://www.augs.org/assets/1/6/Joint_Position_Statement_on_the_Management_of.99428.pdf
https://www.clydeco.com/clyde/media/fileslibrary/Consent_Judgment_-_Ethicon.pdf

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