

Ethicon's Instructions For Use Fall Short On "Risk of Nerve Entrapment" for Mid-Urethral Slings

Ethicon's current IFU for mid-urethral slings fall short of what is required by their settlement and consent agreements with attorneys general in forty states.

SANTA BARBARA, CA, UNITED STATES, February 4, 2022 /EINPresswire.com/ -- "Ethicon's current Instructions for Use for its mid-urethral slings fall short of what is required by their settlement and consent agreements with attorneys general in forty states, as they do not include the specific risk of nerve entrapment caused by the mesh," states Greg Vigna, MD, JD.

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..language from Ethicon's TVT-O and Abbrevio IFU doesn't include.. 'nerve entrapment', 'pudendal neuralgia', & 'obturator neuralgia' and doesn't warn women that these diagnoses are caused by the mesh."

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

Greg Vigna, MD, JD, continues, "The language from Ethicon's TVT-O and Abbrevio Instructions for Use (IFU) does not include the words 'nerve entrapment', 'pudendal neuralgia', and 'obturator neuralgia' and does not warn women that these diagnoses are caused by the mesh."

Dr. Vigna adds, "The American Urogynecological Society (AUGS), the International Urogynecological Association

(IUGA), Society of Gynecological Surgeons (SGS), and American Association of Gynecological Laparoscopists (AAGL) have endorsed the 2020 AUGS-IUGA Joint Position Statement on the Management of Mesh-Related Complications for the FPMRS Specialist that included treatment recommendations for 'extrapelvic pain' caused by the arms of the transobturator sling related to pudendal and obturator neuralgia from nerve entrapment."

Dr. Vigna continues, "Ethicon's position is that their current TVT-O and TVT Abbrevio IFU is sufficient to warn women of the risks of pudendal and obturator neuralgia while at the same time many of Ethicon's retained experts are testifying that nerve entrapment, pudendal neuralgia, and obturator neuralgia are not complications of properly positioned transobturator slings. At the same time other Ethicon experts are testifying that these diagnoses have been known by doctors for a very long time but are rare or are extremely rare complications and the warnings are sufficient."

Dr. Vigna concludes, "Many Consent Orders and Judgments require that 'Ethicon shall evaluate Risk information for Surgical Mesh, and as soon as practicable, modify Ethicon's Surgical Mesh IFUs to include any such emerging Risk information and communicate any modification of the Risk information in the Surgical Mesh IFUs. Ethicon has failed to warn women of these specific neurological injuries for over a decade and has failed to live up to their obligations they agreed to in their Consent Order and Judgment as part of their \$116.9 million dollar settlement with forty state attorneys general as women continue to be seriously injured without warning."

Symptoms of neurological injury to the pudendal and obturator nerve from the transobturator slings include:

- 1) Groin pain
- 2) Hip pain
- 3) Inability to wear tight pants
- 4) Clitoral pain or numbness
- 5) Severe pain that makes vaginal penetration impossible
- 6) Tailbone pain
- 7) Anorectal pain
- 8) Painful bladder
- 9) Pain with sitting

[Learn more](#) on the anatomical basis for TOT complications including obturator and pudendal neuralgia and the treatments of obturator and pudendal neuralgia. Access our [FREE BOOK](#) on Vaginal Mesh Pain and for articles, video resources, and information visit the [Pudendal Neuralgia Educational Portal](#) or <https://tvm.lifecare123.com/>. For information regarding sling related complications visit: <https://tvm.lifecare123.com/slingebook.html>

References and Consent Order:

https://www.clydeco.com/clyde/media/fileslibrary/Consent_Judgment_-_Ethicon.pdf

2020 AUGS-IUGA Joint Position Statement on the Management of Mesh-Related Complications for the FPMRS Specialist (See extrapelvic pain):

https://www.augs.org/assets/1/6/Joint_Position_Statement_on_the_Management_of.99428.pdf

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