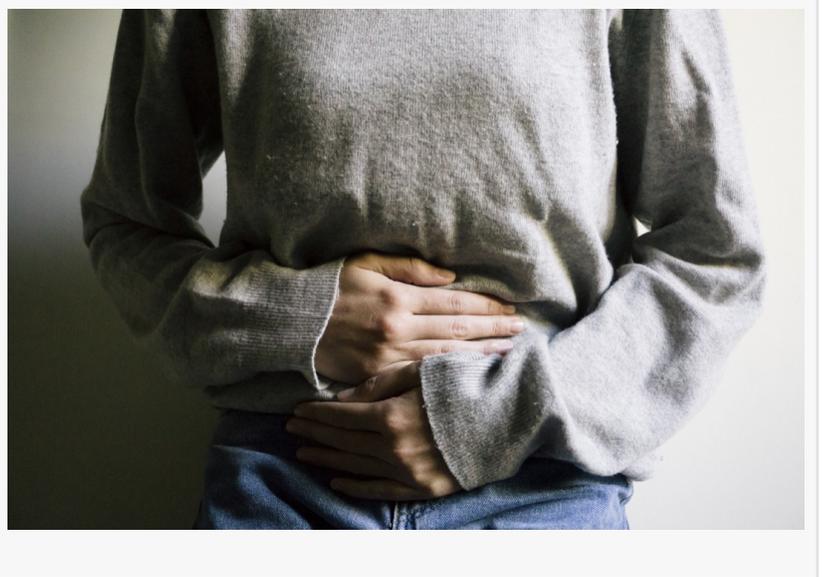


# FDA's Current Position is that Safety and Efficacy of Mini-slings Have Not Been Adequately Demonstrated

*The Coloplast Altis sling and the Boston Scientific Solyx sling remain on the market despite the continued FDA position.*

SANTA BARBARA, CA, UNITED STATES, August 16, 2023 /EINPresswire.com/ -- "Women have not been warned of the FDA's current position that 'The safety and effectiveness of mini-slings for female SUI have not been adequately demonstrated' which is a big problem for the implanting doctors," states Greg Vigna, MD, JD, national neurological injury malpractice attorney.



According to The New England Journal of Medicine, (386; 13, March 31, 2022), "A total of 298 women were assigned to receive mini-slings and 298 were assigned to receive midurethral slings. At 15 months, success was reported by 212 of 268 patients (79.1%) in the mini-sling group and by 189 of 250 patients (75.6%) in the midurethral-sling group... At 36 months, the percentage of patients with groin or thigh pain was 14.1% with mini-slings and 14.9% with midurethral slings.... Outcomes with respect to quality of life and sexual function were similar in the two groups, with the exception of dyspareunia; among 290 women responding to a validated questionnaire, dyspareunia was reported by 11.7% in the mini-sling group and 4.8% in the midurethral-sling group."

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Women have not been warned of the FDA's current position that 'The safety and effectiveness of mini-slings for female SUI have not been adequately demonstrated.'"

*Greg Vigna, MD, JD*

Dr. Vigna continues, "The Coloplast Altis sling and the Boston Scientific Solyx sling remain on the market despite the continued FDA position and the above data. We doubt any woman would

consent to the Altis or the Solyx if they had received warning of the actual risk of groin pain and the increased risk of dyspareunia compared to other alternatives.”

Dr. Vigna adds, “Women outside of the United States have access to mid-urethral slings that are made of PVDF that reduces the risk of pain and erosions because it causes less chronic inflammation than polypropylene.”

Dr. Vigna concludes, “Statute of limitations for medical malpractice tend to be shorter than for product liability claims. It is essential for women to preserve their rights against their implanting physician as they have a duty to inform women of the material risks of these devices.”

Dr. Vigna states the RED FLAG WARNING SYMPTOMS of neurological injury or myofascial pain caused by the Coloplast Altis and Aris transobturator slings and Boston Scientific Solyx and Obtryx 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

[Click here](#) to learn the current literature on slings.

Read our [FREE BOOK](#) on Vaginal Mesh Pain.

Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic injuries and the neurological injuries caused by mid-urethral slings including [pudendal neuralgia](#), obturator neuralgia, ilioinguinal neuralgia, and complex regional pain syndrome. Ben Martin is a national pharmaceutical injury attorney in Dallas, Texas. The lawyers represent women in courts across the country. Visit our website to learn more.

Resources:

[https://www.augs.org/assets/1/6/Joint\\_Position\\_Statement\\_on\\_the\\_Management\\_of.99428.pdf](https://www.augs.org/assets/1/6/Joint_Position_Statement_on_the_Management_of.99428.pdf)

[https://cdn.mdedge.com/files/s3fs-public/issues/articles/obgm0340813\\_evidence\\_iglesia.pdf](https://cdn.mdedge.com/files/s3fs-public/issues/articles/obgm0340813_evidence_iglesia.pdf)

<https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1111/jog.12899>

<https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-mesh-sui>

Abdel-Fattah, et al. Single-Incision Mini-Slings for Stress Urinary Incontinence in Women. The New England Journal of Medicine. March 31, 2022.

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