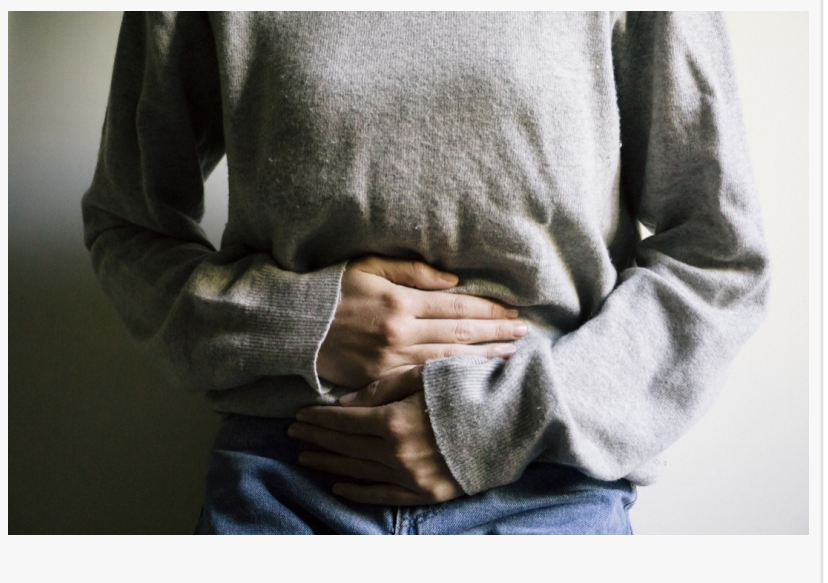


Unanticipated Adverse Event with Altis Sling: Study Reveals 7 out of 125 Patients with Groin Pain

In the JMIG study, 7 out of 125 women reported groin pain within 6 weeks of receiving an Altis Sling.

SANTA BARBARA, CA, UNITED STATES, September 6, 2023 /EINPresswire.com/ -- "125 women underwent a midurethral single incision sling...In the hospital based Ambulatory Surgical Unit... 2 patients reported unanticipated Adverse Events (AE's) ...The office based Ambulatory Surgical Unit...7 patients reported unanticipated AEs"....The Journal of Minimally Invasive Gynecology (JMIG). Vol 30, No.8, August 2023.



Greg Vigna, MD, JD, national neurological injury malpractice attorney, mid-urethral sling attorney, "The New England Journal of Medicine in 2022 studied mini-slings and it was determined that mini-slings don't materially reduce the risk of groin compared with full-length mid-urethral slings at three-years and appears to carry withit an increased risk of painful sexual intercourse."

“

Women are not getting warned of the risk of mini-slings and we are investigating these cases.”

Greg Vigna, MD, JD

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.”...Abdel-Fattah, M.D., et al.

Dr. Vigna continues, “In the JMIG study, 7 out of 125 women reported groin pain within 6 weeks of receiving an Altis and this complication was an ‘unanticipated adverse event’ according to the authors. The Fattah article reported that 14.1% of women who have undergone a mini-sling had groin pain at three-years with over half of these women requiring ‘any type of pain killer’. These are frequent complications that require a warning.”

Dr. Vigna adds, “The Dejene, 15-year study included 334,601 women who underwent mid-urethral slings. This study reported that 7.9% of these women required surgery to either cut the mesh and/or remove all or part of the mesh cut for complications caused by the sling. In addition, 17.9% of 334,601 underwent another surgery for the treatment of incontinence for a mid-urethral sling that failed.”

Dr. Vigna concludes, “Women are not getting warned of the risk of mini-slings and we are investigating these cases. Women are not getting warned that the FDA’s position on mini-slings is that ‘The safety and effectiveness of mini-slings for female stress urinary incontinence have not been adequately demonstrated’. Women deserve the truth.”

Dr. Vigna RED FLAP 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

[Dr. Greg Vigna, MD, JD](#) 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.

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

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

Resources:

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

Lucente, et al. Single Incision Midurethral Sling Site of Care: Office-based Ambulatory Surgical Unit versus Hospital-based Ambulatory Surgical Unit Setting. Journal of Minimally Invasive Gynecology. Vol. 30, No. 8, August 2023.

Dejene, et al. Long-Term Outcomes After Midurethral Mesh Sling Surgery for Stress Urinary Incontinence. Female Pelvic Med Reconstr Surg 2022; 28:188-193.

Greg Vigna, MD, JD

https://www.augs.org/assets/1/6/AUGS-SUFU_Joint_Publication.pdf

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

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