

New Altis Study: "Pain Was Reported as an Adverse Event in 64 Instances (11.3%)"

Study on the Altis sling noted a high 46% attrition rate over 3 years, with 11.3% reporting post-surgery pain and serious adverse events documented.

SANTA BARBARA , CALIFORNIA , UNITED STATES , July 24, 2024 /EINPresswire.com/ -- "There are some weakness to this data ... 564 were analyzed ... at year one, data for 427 subjects was available ... for attrition rate of 24.3% ... After 3 years, 307 were available for evaluation (46% attrition rate)" says Dr. Frank Van der Aa, Department of Urology. University Hospitals Leuven, Belgium.

What else did Dr. Van der Aa's study, "A Prospective Multicenter European Observation Study of a Single Incision Sling (Altis): A Safe and Effective Treatment Option for Women", published in Continence 10(2024) 101310?:



Dr. Greg Vigna

"11.3% reported pain, and there were instances of serious adverse events.

Our study examined the incidence of pain in great detail. Postoperatively, at the first follow-up

Mini-slings didn't reduce groin pain when compared to full-length mid-urethral slings and had 2.5x the risk of resulting in dyspareunia or painful sex."

Greg Vigna, MD, JD

visit, 14.4% (n = 77) of subjects reported pain at the site of surgery. Investigators documented pain as an adverse event after Altis implant in 11.3% (n = 64) of the cases in our 3-year follow-up."

To read Dr. Van der Aa's study: <u>https://www.sciencedirect.com/science/article/pii/S277297</u> <u>3724002431?ref=cra_js_challenge&fr=RR-1</u>

Dr. Greg Vigna states, "This study had 11.3% adverse event

of pain reported by investigators and there was 46% of those implanted did not continue in the study for the three year data. The rate 11.3% is likely higher because of the high attrition rate. This study aligns with the data for mini-slings, that included the Altis device, published in the 2022 New England Journal of Medicine Study that revealed that mini-slings didn't reduce groin

pain when compared to full-length mid-urethral slings and had 2.5x the risk of resulting in dyspareunia or painful sex."

New England Journal of Medicine: <u>https://www.nejm.org/doi/full/10.1056/NEJMoa2111815</u>

Dr. Vigna concludes, "It is our opinion that no women would consent to the Altis device had they known of the risks described in this study and the risks known to Coloplast."

<u>Vigna Law Group</u> is investigating the Red Flag Warning symptoms of neurological injury from mid-urethral slings, including:

- 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. Vigna is a California and Washington DC lawyer who focuses on catastrophic pain syndromes caused by mini-slings that include Coloplast Altis sling that include pudendal neuralgia and obturator neuralgia. He represents women with the <u>Ben Martin Law Group</u>, a national pharmaceutical injury law firm in Dallas, Texas. The attorneys are product liability and medical malpractice attorneys, and they represent neurological injuries across the country.

Click here for a FREE BOOK on vaginal mesh pain: <u>https://vignalawgroup.com/publications/</u>

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