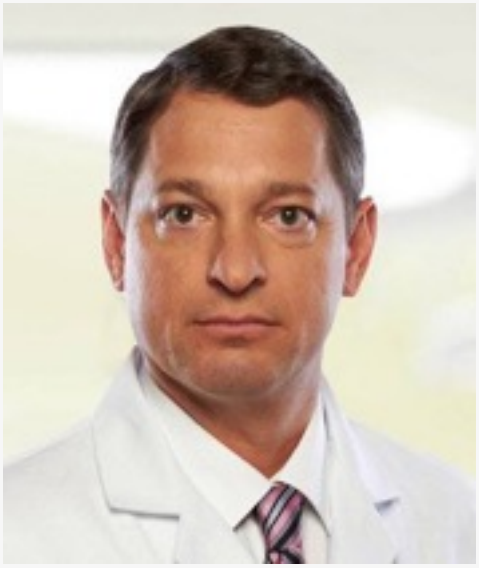
Altis IDE Study: Two Year Study Reveals No New AEs at 24 Months

Study of women using the Altis device revealed low rates of adverse events in the first year, but raises concerns about long-term effects and device design


Dr. Greg Vigna

SANTA BARBARA , CA, UNITED STATES, October 11, 2024 /EINPresswire.com/ -- “One prospective cohort study of 116 women receiving Altis reported groin/hip/thigh pain (8%), dyspareunia (1%), and tape exposure (3.5%) at 12 months’ follow-up, but, interestingly, no further new AEs at 24 months’ follow-up," according to Health Technology Assessment, No. 26.47.

Dr. Greg Vigna, national mid-urethral sling attorney states, “It's an Interesting point about the Altis IDE study. ‘No further new adverse events’ between year 1 and year 2’ begs the question of how the peer review process was provided in these studies that led the way for this device.”

Altis 1-year IDE study:

> “Our position is that this device is too stiff, and the single incision sling causes an unacceptable risk of dyspareunia compared to other slings based on the SIMS data.”
>
> *Greg Vigna, MD, JD*

“The most common device and/or procedure-related adverse event was nonpelvic pain occurring in 9 (8%) subjects. Nonpelvic pain consisted of groin, hip, or thigh pain reported from 2 sites. In all cases, nonpelvic pain was defined as procedure related with 1 site attributing a majority of the events to the lithotomy position required during the implant procedure.”

Read the 1-year study: https://www.sciencedirect.com/science/article/pii/S002253471403715X

Altis 2-year study:

“No new device- or procedure-related adverse events occurred between the 12 and 24-month visits."

Read the 2-year study: https://onlinelibrary.wiley.com/doi/abs/10.1002/nau.23156

Dr. Vigna concludes, “Discovery is ongoing on the Altis device. Our position is that this device is too stiff, and the single incision sling causes an unacceptable risk of dyspareunia compared to other slings based on the SIMS data.”

Read the SIMS trial (Health Technology Assessment, No. 26.47):
https://www.ncbi.nlm.nih.gov/books/NBK587586/

Vigna Law Group is investigating the red flag warning symptoms of neurological injury from the mid-urethral for physician negligence and/or product claim against the manufacturers of the device, including:

1) “Other: Non-pelvic pain” including anatomic groin pain (inner leg pain), thigh pain, and hip pain
2) “Pelvic/Urogenital (groin) pain”: Pain not including the inner leg, thigh, or hip including:
a) Inability to wear tight pants
b) Clitoral pain or numbness
c) Severe pain that makes vaginal penetration impossible
d) Tailbone pain
e) Anorectal pain
f) Painful bladder
g) 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 and Boston Scientific Solyx sling that include pudendal neuralgia and obturator neuralgia. He represents women with the Ben Martin Law Group, 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.

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