

2025 Altis Mid-urethral Sling Litigation: Nerve Damage Cases Moving Forward

Dr. Vigna criticizes the Coloplast Altis sling, citing safety concerns from stiff design, pain, and misleading efficacy data

SANTA BARBARA , CA, UNITED STATES, January 2, 2025 /EINPresswire.com/ -- "The Altis mid-urethral sling was a bad device during the IDE study and there is nothing reassuring about the safety of this device in the FDA ordered Altis 522 study. The SIMS trial revealed that the Altis sling had more pain at all time points compared with full-length mid-urethral slings. The authors of the SIMS trial point are misleading or 'interesting' data that is hard to believe from the Coloplast sponsored IDE study," states [Greg Vigna, MD, JD](#), national mid-urethral sling attorney.

What does the Vigna Law Group allege as it relates to the Coloplast Altis device?:

- 1) Defendants failed to inform all users of the unreasonable stiff design that is 17x stiffer than other slings that cause increased frequency of clinically significant pain compared with other mid-urethral slings on the market.
- 2) The Coloplast Defendants failed to inform all users of the unreasonable stiff design that causes more dyspareunia compared with retropubic slings and transobturator slings and pain at all time points.

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Greg Vigna, MD, JD



Dr. Greg Vigna

Dr. Greg Vigna, national mid-urethral sling attorney, states, "The Coloplast Altis 2-year IDE data isn't in the ballpark as it relates to being reliable, and it should be retracted. The SIMS trial authors used the word 'interestingly' when they analyzed the Coloplast IDE 2-year data that was used to market the device with unusual efficacy data and unusual adverse event data."

"The results of a post hoc analysis for patient-reported 'cure' using the strict definition of a response of 'no leakage' on the ICIQ-UI-SF were as follows: SIMS group, 38.6%; SMUS group, 33.2% ... Interestingly, in one observational study (IDE 2-year study) for the mid-term safety and efficacy of the SIMS Altis, using the same strict definition, the patient-reported cure rate was 88.2% among 110 women." (pg. 96, SIMS trial).

"interestingly, no further new AEs at 24 months' follow-up" (from 12-month IDE Data that were reported in the 2-year IDE Data; pg. 104 SIMS trial)."

Read the "Single-incision mini-slings versus standard synthetic mid-urethral slings for surgical treatment of stress urinary incontinence in women: The SIMS RCT":

https://www.ncbi.nlm.nih.gov/books/NBK587586/pdf/Bookshelf_NBK587586.pdf

Dr. Vigna adds, "There is no reliable data that supports the ongoing use of this device given the safer alternative designs that are being implanted outside of the United States. PVDF and P4HB reduce and eliminate the chronic inflammation associated with polypropylene and are better for safety when compared to the unreasonably stiff Altis design that works more like a razor than a sling in a significant percentage of women."

Red Flag Warning symptoms of neurological injury from mid-urethral slings include:

- 1) "Other: Non-pelvic pain" including anatomic groin pain (inner leg pain), thigh pain, hip pain
- 2) "Pelvic/Urogenital (groin) pain": Pain not including the inner leg, thigh, or hip which may include:
 - 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 retropubic slings, full-length transobturator slings, and mini-slings, also referred to as single-incision slings that include the Coloplast Altis sling. Complications include dyspareunia and pelvic pain syndromes, including pudendal neuralgia and/or obturator neuralgia. Dr. Vigna 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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