FDA Altis 522 Update: “Mini-slings Comparable Effectiveness to Mid-urethral Slings”

FDA's endorsement of mini-slings is criticized for not considering European study data showing higher dyspareunia rates and similar adverse events

SANTA BARBARA, CALIFORNIA, UNITED STATES, July 23, 2024 /EINPresswire.com/ -- “The weakness of the Altis 522 study include … high attrition rate (at 36-months, the attrition rate for the Altis arm was 23.9%, whereas the attrition rate for the Comparator arm was 40.9%)" according to the FDA Home 522 Postmarket Surveillance Studies Database.

Greg Vigna, MD, JD, national mid-urethral sling attorney, states “Unfortunately the FDA made their opinion that ‘mini-slings are as effective as traditional mid-urethral slings over a 36-month timeframe … (and) showed similar types and rates of adverse events and re-surgery compared to traditional mid-urethral slings through 36 months’ without the benefit of the internal data from the large, randomized trial done in Europe that was published in the The New England Journal of Medicine on March 31, 2022”:

> We are filing a medical malpractice case against implanting physicians and Coloplast based on a failure of informed consent because no reasonable physician would implant the device knowing the risks.”
>
> *Greg Vigna, MD, JD*

“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."

Read the Single-Incision Mini-Slings for Stress Urinary Incontinence in Women. The New England Journal of Medicine. March 31, 2022: https://www.nejm.org/doi/full/10.1056/NEJMoa2111815

Read the FDA Altis 522 Study results: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=337&c_id=854

Read the FDA April 11, 2024-Evaluation of final results: https://www.fda.gov/medical-devices/urogynecologic-surgical-mesh-implants/stress-urinary-incontinence-surgical-mesh-considerations-and-recommendations

Dr. Vigna continues, "The dropout in the NEJM study was less than 10 percent and specifically measured groin pain and dyspareunia during the three-year study. The results were not good for the mini-sling arm that included the Bard Ajust and the Coloplast Altis device. We want the internal data which I believe the data will show the Altis was the worst device tested in the study. The FDA, women, and doctors need this data as it is infinitely more reliable and believable than the Coloplast 522 study."

Dr. Vigna adds, "We are busy with discovery of the Altis device and believe there is material information that physicians and women would find important in the decision as it relates to the utility of this device. Based on the findings in the 2022 NEJM article we believe that no reasonably prudent physician would choose to use the Altis device because the mini-sling group carries a 2.5x risk of dyspareunia when compared with full length mid-urethral slings. "

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

Click here for a FREE BOOK on Vaginal Mesh Pain : https://vignalawgroup.com/publications/

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.

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