

Unanticipated Adverse Event with Altis Sling, 7 out of 125 Patients with Groin Pain

Questioning Altis sling's groin pain warning, citing a study showing 14.1% of women experience it three years post-implantation.

SANTA BARBARA , CALIFORNIA , UNITED STATES , November 1, 2023 /EINPresswire.com/ -- Greg

“

Dr. Lucente, reported 'unanticipated adverse events' related to 'groin pain' following the surgical implantation of the Coloplast Altis sling with data collected to six weeks post-op.”

Greg Vigna, MD, JD

Vigna, MD, JD, national neurological injury malpractice attorney, mid-urethral sling attorney, “Dr. Vincent Lucente described the groin pain following the implantation of an Altis sling as ‘unanticipated’. That begs the question, what does the Altis warning describe?”

What does the Coloplast's Instructions For Use (IFU) say? “A mesh sling procedure is a surgical solution that has risks such as mesh extrusion, pelvic/urogenital pain, groin pain, hip pain, urinary retention, bleeding, new onset (de novo) urgency, delayed wound healing, painful intercourse (dyspareunia), inflammation, nausea, overactive bladder,

pain, pelvic hematoma, reaction to antibiotic, slight discomfort upon return to work, urinary tract infection, urine stream decreased, and voiding dysfunction.”

[Dr. Vigna](#) continues, “I'm not sure why Dr. Lucente described groin pain as unanticipated as it is disclosed in the IFU. What is not described in the IFU is the frequency of groin pain and the severity.”

Is there a study that describes the frequency and severity of groin pain with mini-slings, like the Altis?

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 mid-urethral 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 mid-urethral sling group ... At 36 months, the percentage of patients with groin or thigh pain was 14.1% with mini-slings and 14.9% with mid-urethral 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 mid-urethral sling group.”... Abdel-Fattah, M.D., et al.

Dr. Vigna continues, “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’. Common complications should include the frequency of the adverse event. 14.1% is common and that, in my opinion, requires a warning.”

Dr. Vigna concludes, “The mini-sling group had 14.1% groin pain and the mini-sling group included the Altis sling and another that has been removed from the market by Bard. We are looking forward to discovering what the company knows regarding the underlying data between the Bard device and the Altis in this pivotal study.”



Dr. Greg Vigna

Dr. Vigna RED FLAP WARNING SYMPTOMS of neurological injury or myofascial pain caused by the Coloplast Altis sling include:

- 1) Groin pain
- 2) Hip pain
- 3) Inability to wear tight-fitting 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.

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.

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.

<https://www.nejm.org/doi/full/10.1056/NEJMoa2111815>

<https://pubmed.ncbi.nlm.nih.gov/37088282/>

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>

<https://www.femalepelvicsolutions.com/sui/how-altis-works/>

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