

Dropout of Patients in Coloplast Altis FDA 522 Study a Concern

Coloplast Altis 522 Study was plagued by dropout at 6 months.

SANTA BARBARA, CA, UNITED STATES, April 26, 2023 /EINPresswire.com/ -- "Coloplast Altis 522 Study was plagued by dropout at 6 months. Eleven percent dropout at 6-months is concerning and it makes interpretation of the results difficult at best"... Dr. Greg Vigna, national pharmaceutical injury attorney.



Dr. Roberta Blandon from the Mayo Clinic wrote in the article, Complications from vaginally placed mesh in pelvic reconstructive surgery, published by the International Urogynecology Journal in 2009, "One of our most important findings is that only 14% of patients were referred by the original surgeon....and the potential for underreporting of the rate and extent of these complications."

“ The study showed that pain at three days post-implant was significant but what happened to these women is difficult to interpret because of the dropout rate.”

Greg Vigna, MD, JD

Dr. Greg Vigna, MD, JD, national pharmaceutical injury attorney states, "The 2022 New England Journal of Medicine (NEJM) article, Single-Incision Mini-Slings for Stress Urinary Incontinence in Women, should sound the alarm as mini-slings had a 2.5x increased risk of painful sex when compared with full-length mid-urethral slings. There

was groin pain of 14.1% for the group of women who underwent mini-sling implantation at 3 years."

Dr. Greg Vigna adds, "In a recent study involving the Altis sling there was a dropout rate of 13 percent at six months. There were 168 women who were implanted with the Altis for stress urinary incontinence and 146 women returned for the 6-month followup. The study indicated that six percent of the Altis group reported 'pelvic/urogenital pain (groin)'."

Dr. Vigna concludes, "We represent those who complain of pain caused by the Altis sling

whenever it occurs. These are serious injuries.”

Dr. Vigna RED FLAP WARNING SYMPTOMS of neurological injury or the myofascial pain syndromes from Ethicon’s TVT-O and TVT-Abbrevio, Coloplast’s Altis, and Boston Scientific Obtryx, Lynx, and Advantage Fit included the following:

- 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

To learn more on the anatomical basis for TOT complications including obturator and pudendal neuralgia and the treatments of obturator and pudendal neuralgia click here:

<https://vignallawgroup.com/ebooks/pelvic-mesh-pain/#page=59>

Read our [FREE BOOK](https://vignallawgroup.com/publications/) on Vaginal Mesh Pain : <https://vignallawgroup.com/publications/>

For articles, video resources, and information visit the [Pudendal Neuralgia Educational Portal](#) or [this link](#).

Click the following link for information regarding sling related complications:

<https://tvm.lifecare123.com/slingebook.html>

Dr. Vigna is a California 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.

Abdel-Fattah, et al. Single-Incision Mini-Slings for Stress Urinary Incontinence in Women. The New England Journal of Medicine. March 31, 2022.

<https://www.auajournals.org/doi/epdf/10.1097/JU.0000000000003275.08>

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