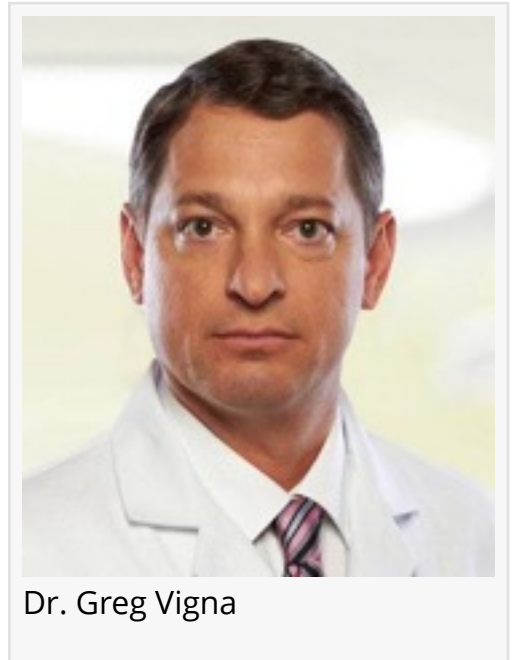


SIMS Trial: Risks of the Coloplast Altis Sling for Dyspareunia and Coital Incontinence Reported

Coloplast Altis sling linked to high risk of dyspareunia and coital incontinence as safer alternatives remain unavailable in the U.S.

SANTA BARBARA, CA, UNITED STATES, November 5, 2024 /EINPresswire.com/ -- "Clearly, the women who were assigned into the Coloplast Altis group 'drew the short straw' as their sexual function was placed at risk as a result of this device when compared with full-length mid-urethral slings" states [Greg Vigna, MD, JD](#), national mid-urethral sling attorney.

Dr. Greg Vigna, national mid-urethral sling attorney, states, "Level 1 Evidence from the 'Single-incision Mini-sling versus Standard Synthetic Mid-urethral Slings for Surgical Treatment of Stress Urinary Incontinence in Women: The SIMS RCT' reported a 20 percent risk of dyspareunia at 15 months and a 14 percent risk of coital incontinence for women in the Altis group. This is brutal news for the women assigned to the Altis group and for women implanted with this device outside of this study."



Dr. Greg Vigna

“

Mid-urethral slings made with PVDF represent a safer alternative design currently available across the world but still not available to women in the United States.”

Greg Vigna, MD, JD

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

What did the SIMS RCT report regarding DYS-PAREUNIA (pg. 51)? See Table 17 (Part 1).

What did the SIMS RCT report regarding COITAL INCONTINENCE (pg. 52)? See Table 17 (Part 2).

Dr. Vigna adds, “We are involved in discovery in cases filed in State Courts across the country for women who unfortunately drew the short straw when their doctors selected the Coloplast Altis device. Our position is that this device is too stiff and

causes an unacceptable risk of dyspareunia and coital incontinence compared to other slings.”

Dr. Vigna concludes, “Polypropylene transobturator slings perform poorly compared to full-length mid-urethral slings made of PVDF. Mid-urethral slings made with PVDF represent a safer alternative design currently available across the world, but still not available to women in the United States.”

TABLE 17 Summary of AEs, by procedure (continued)

AEs	Procedure, n (%)			
	Ajust (N = 62)	Altis (N = 199)	RP-TV/T (N = 126)	TO-TV/T (N = 147)
Dyspareunia	N = 30	N = 99	N = 68	N = 71
15 months	3 (10)	20 (20)	5 (7.4)	4 (5.6)
24 months	3 (10)	12 (12)	5 (7.4)	4 (5.6)
36 months	4 (13)	11 (11)	5 (7.4)	4 (5.6)

Table 17 (Part 1)

TABLE 17 Summary of AEs, by procedure (continued)

AEs	Procedure, n (%)			
	Ajust (N = 62)	Altis (N = 199)	RP-TV/T (N = 126)	TO-TV/T (N = 147)
Coital incontinence				
15 months	2 (6.7)	14 (14)	3 (4.4)	4 (5.6)
24 months	2 (6.7)	11 (11)	5 (7.4)	8 (11)
36 months	3 (10)	13 (13)	4 (5.9)	3 (4.2)

Table 17 (Part 2)

Read “Polypropylene and Polyvinylidene Fluoride Transobturator Slings for the Treatment of Female Stress Urinary Incontinence: 1-Year Outcomes from a Multicentre Randomized Trial” published in *Neurourology and Urodynamics*. Volume 40, Issue 1, pg. 475-482:

<https://onlinelibrary.wiley.com/doi/full/10.1002/nau.24586>

[Vigna Law Group](#) is investigating the red flag warning symptoms of neurological injury and catastrophic pain syndromes caused by mid-urethral slings, such as the Obtryx and the Altis device for physician negligence and/or product claims 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 such as the Coloplast Altis sling and Boston Scientific Solyx sling, including 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 who represent neurological injuries across the country.

[Click here](#) for a free book on Vaginal Mesh Pain.

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