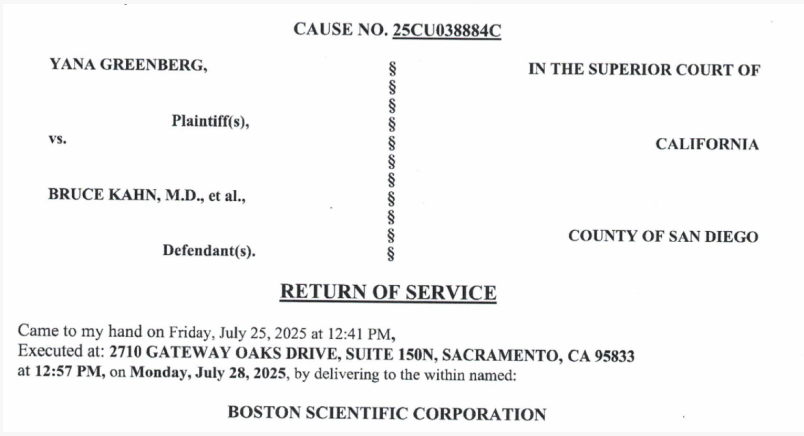
# Boston Scientific 522 Study Solyx and Obtryx: Meaningful Discovery Coming

*Concerns raised over Solyx and Obtryx sling study data, material safety, and patient outcomes*



CAUSE NO. 25CU038884C

YANA GREENBERG, Plaintiff(s), vs. BRUCE KAHN, M.D., et al., Defendant(s). § IN THE SUPERIOR COURT OF CALIFORNIA COUNTY OF SAN DIEGO

RETURN OF SERVICE

Came to my hand on Friday, July 25, 2025 at 12:41 PM,
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at 12:57 PM, on Monday, July 28, 2025, by delivering to the within named:

BOSTON SCIENTIFIC CORPORATION

Case No: 25CU038884C

LOS ANGELES, CA, UNITED STATES, August 21, 2025 /EINPresswire.com/ -- “We intend to obtain all internal documents that relate to the Boston Scientific 522 Study that compared the Solyx mini-sling to the full-length Obtryx. The reported data does not reflect the reality of these two devices," states Greg Vigna, MD, JD, national mid-urethral sling attorney.

Dr. Greg Vigna, national pudendal neuralgia and obturator neuralgia attorney, states, “We represent women implanted with mid-urethral slings who were not given timely diagnosis or treatment for serious pain syndromes caused by retropubic, transobturator, and mini-slings. For women who suffer early pain following implantation, the standard of care is complete mesh removal."

> “Litigation regarding serious adverse events from the Obtryx and Solyx slings will persist because they are made from Marlex, a technologically obsolete form of polypropylene from the 1950s.”
>
> *Greg Vigna, MD, JD*

Dr. Vigna adds, “We currently represent a woman in a case against Boston Scientific and Dr. Bruce Kahn, the second author of the Boston Scientific 522 Study comparing the Solyx to the Obtryx. Dr. Kahn diagnosed our client with a severe pain syndrome, which we allege was caused by the initial Solyx sling that he implanted. Despite this serious adverse event, Dr. Kahn proceeded to implant a second Solyx sling. We seek to understand Dr. Kahn’s role in reviewing adverse events within the 522 Study. Additional discovery is required to obtain internal documents between Boston Scientific and each of the study authors."

What was reported in the Boston Scientific 522 study that compared the Solyx mini-sling to the

Obtryx transobturator sling?

“Secondary study endpoints:
1. Mesh erosions: 0% Solyx, 0.7% Obtryx
2. Mesh exposures: 2.8% Solyx, 4.3% Obtryx
3. De novo dyspareunia: 0.7% Solyx, 0% Obtryx”

Read the outcome:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=279&c_id=684

Dr. Vigna adds, “De novo dyspareunia was reported as 0% in the Obtryx group and less than 1% in the Solyx group. Are the authors suggesting that none of the mesh exposures resulted in new-onset pain with intercourse? How many women in the study developed groin pain? How many reported dyspareunia? Were these adverse events attributed to the surgical procedure or the device itself, and what criteria was used to make those determinations?"

Dr. Vigna explains, “We are going to examine the data from the test sites that include: Amanda White, MD, Austin, Texas; Bruce Kahn, MD, San Diego, California; Ricardo Gonzales, MD, Houston, Texas, Jennifer Anger, MD, La Jolla, California; Karyn Eilber, MD, Los Angeles, California, Joseph Schaffer, MD, Oklahoma City, Oklahoma; Scott Serels, MD, Norwalk, Connecticut, Sam Siddighi, MD, Loma Linda, Pill Raja, MD, Odesa, Texas; Thomas Hutchens, MD, Bismarck, North Dakota; Barry Jarnagin, MD, Franklin, Tennessee; and Amanda White, MD, Austin, Texas.”

Dr. Vigna explains, “Litigation regarding serious adverse events from the Obtryx and Solyx slings will persist because they are made from Marlex, a technologically obsolete form of polypropylene from the 1950s. Safer alternatives to treat stress urinary incontinence, available outside of the United States, offer reduced or eliminated risks of chronic inflammation compared to Marlex, which is associated with complications, including pain."

What did Dr. Jordi Sabadell’s article “Polypropylene and polyvinylidene fluoride transobturator slings for the treatment of female stress urinary incontinence: 1-year outcomes from a multicentre randomized trial." Neurourology and Urodynamics. 2021: 40: 475-482, discuss?

“Polypropylene and PVDF slings showed similar high cure or improvement rate (91.0% vs. 95.6%)... A higher incidence of long-term pain events was observed in the polypropylene group."

Read Dr. Sabadell's article: https://onlinelibrary.wiley.com/doi/pdfdirect/10.1002/nau.24586.

Dr. Vigna concludes, “Implanting physicians and their patients will likely choose materials that reduce chronic inflammation with no change in efficacy, as described by Dr. Sabadell.”

Dr. Vigna is a California and Washington, D.C. lawyer who focuses on catastrophic pain

syndromes caused by the Boston Scientific and Coloplast Altis slings, 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, and they represent individuals suffering from neurological injuries across the country.

Click here for a free book on Vaginal Mesh Pain: https://vignalawgroup.com/ebooks/pelvic-mesh-pain/#page=1

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