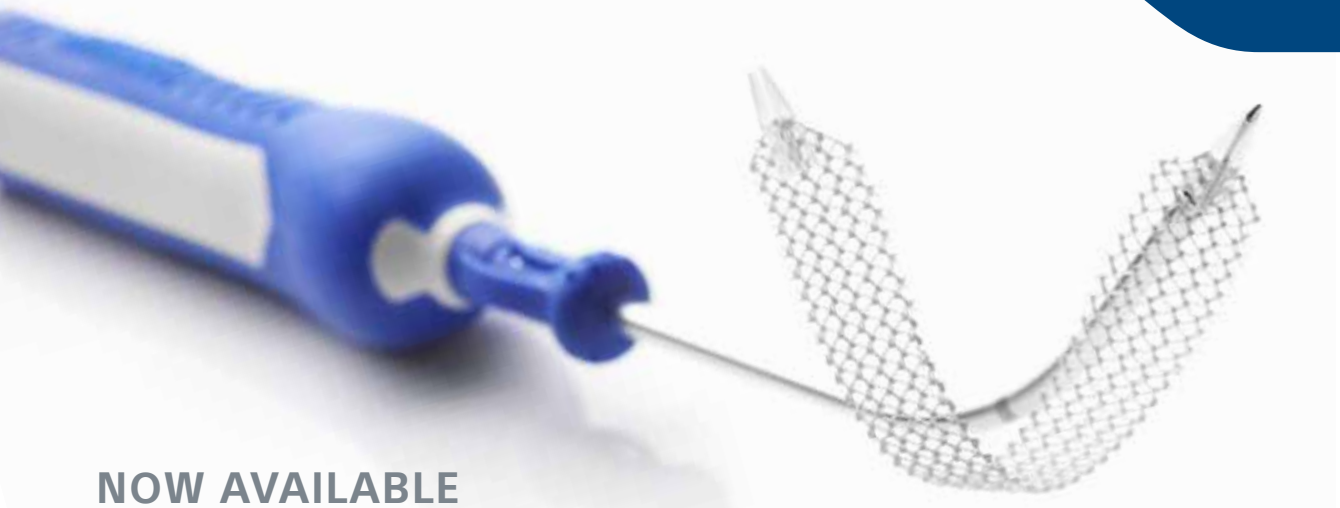
Boston Scientific
Advancing science for life™



NOW AVAILABLE

36-Month Data from Solyx Single Incision Sling System 522 Study

A Prospective Parallel Cohort, Multi-center Study of the Solyx™ Single Incision Sling System vs. the Obtryx™ II Transobturator Mid-Urethral Sling System for the Treatment of Women with Stress Urinary Incontinence: 3-Year Results.

281	21	2	25
PATIENTS	SITES	COUNTRIES	IMPLANTERS

Solyx Single Incision Sling System 522 post-market clinical study

The Solyx Single Incision Sling System 522 post-market clinical study is a prospective, parallel cohort, non-inferiority study to assess the safety and effectiveness of a single incision sling. This study evaluated the Solyx Single Incision Sling System as compared to the Obtryx II Transobturator Mid-Urethral Sling System, an approach considered one of the gold standards for the treatment of stress urinary incontinence (SUI).

This study is the first of three 522 post-market clinical studies that Boston Scientific will complete as requested by the FDA.

Primary Endpoint

Improvement in SUI by a composite of:

- Negative cough stress test, and
- Subject reported improvement in their condition by the Patient Global Impression of Improvement (PGI-I)

Primary Endpoint Results

The Solyx System met the primary endpoint validating that the single-incision sling is non-inferior to the transobturator device in effectiveness at 3-year follow-up.

Treatment Success	Solyx (n=104)	Obtryx II (n=108)
Composite	90.4%	88.9%
Objective	94.2%	91.7%
Subjective	94.2%	94.4%

Adverse Events

At 36 months, Solyx Single Incision Sling System and Obtryx II Transobturator Mid-Urethral Sling System subjects had similar rates of adverse events, including mesh-related complications, dyspareunia, pelvic pain and urinary retention.

Adverse Events[1]	Solyx Intent-to-Treat Subjects (N=141)		Obtryx II Intent-to-Treat Subjects (N=140)		
	Events	Proportion of Subjects with ≥1 Events	Events	Proportion of Subjects with ≥1 Events	p-value
Mesh Exposure[a]	4	2.8%	6	4.3%	0.541
Dyspareunia[b]	1	0.7%	0	0.0%	1.000
Mesh Erosion[c]	0	0.0%	1	0.7%	0.498
Pelvic Pain[d]	1	0.7%	0	0.0%	1.000
Urinary Retention[e]	4	2.8%	6	4.3%	0.541

a. Mesh exposure defined as the observation of mesh through the vaginal wall or epithelium.
b. Dyspareunia defined as any new onset pain associated with sexual activity that was not present during sexual activity preoperatively; or any worsening pain associated with sexual activity compared to preoperative state.
c. Mesh erosion defined as perforation of mesh into hollow organ or viscus.
d. Pelvic pain defined as any pain associated with worsening bother compared to preop occurring in the lower abdomen or genital area beyond 12 weeks post-operatively (excluding neuromuscular pain and dyspareunia).
e. Urinary retention defined as inability to completely empty the bladder.

Increasing Clinical Evidence for Solyx Single Incision Sling

Patients and physicians now have additional data to support treatment of SUI with mid-urethral slings in both the transobturator and single incision approach. These results are comparable to those of prior Solyx single incision sling studies. The results of existing Solyx studies are summarized here.

	Solyx Single Incision Sling System 522 Post-market Clinical Study	Long-Term Follow-up of the Solyx SIS in the Treatment of Female SUI[2]	Evaluation of clinical out- come and risk factors for failure of single-incision mid-urethral short tape procedure (Solyx™ tape) for stress urinary incontinence[3]
Follow-up	36 months	43 months*	12 months
N	281 (Solyx n=141)	69	113
Study design	Prospective	Retrospective	Retrospective
Mean age	49 (23-88)	67 (30-87)	58 (46-68)
Solyx Concomitant Repair	66.0%	55.1%	0%
Solyx Objective Success	94.2%	92.8%	90.3%
Solyx Subjective Success	94.2%	92.8%	85.8%

* Mean follow-up was 43 months (range 39 – 49)

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

1. White AB, Kahn BS, Yang G, Schaffer J. A Prospective Parallel Cohort, Multi-center Study of the Solyx™ Single Incision Sling System vs. the Obtryx™ II Sling System for the Treatment of Women with Stress Urinary Incontinence: 3 Year Results [abstract]. Paper presented at: 39th Annual Scientific Meeting of the American Urogynecologic Society; Oct 11; Chicago, IL.
2. Serels S, Douso M. Long term follow up of the Solyx Single Incision Sling in the treatment of female stress urinary incontinence (SUI). *Open J Urol.* 2014;4:13-7.
3. Lo TS, Shailaja N, Chua S. Evaluation of clinical outcome and risk factors for failure of single-incision mid-urethral short tape procedure (Solyx™ tape) for stress urinary incontinence. *J Minim Invasive Gynecol.* 2018 Jul 21. [Epub ahead of print]

Boston Scientific
Advancing science for life™

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

WH-578306-AA OCT 2018