

**PELVIC FLOOR
TREATMENT OPTIONS
TO SUPPORT YOU AND YOUR PATIENTS**



IT TAKES PASSION TO RESTORE QUALITY OF LIFE FOR WOMEN.

**EVERYTHING IT TAKES TO ADVANCE
SCIENCE FOR LIFE, WE LEARN WITH YOU.**

Stress urinary incontinence and pelvic organ prolapse impact the lives of far too many women. That's why Boston Scientific is investing in new technology, supporting clinical research globally, and developing physician and patient education to enhance your surgical experience and improve patient outcomes. We will continue to deliver our market leading portfolio of clinically supported products, to help you confidently treat these conditions in a way that best serves your patients. Boston Scientific is dedicated to you – and to bringing more life, more hope and more health to women around the world.

Visit [bostonscientific.com/PelvicFloor](https://www.bostonscientific.com/PelvicFloor)

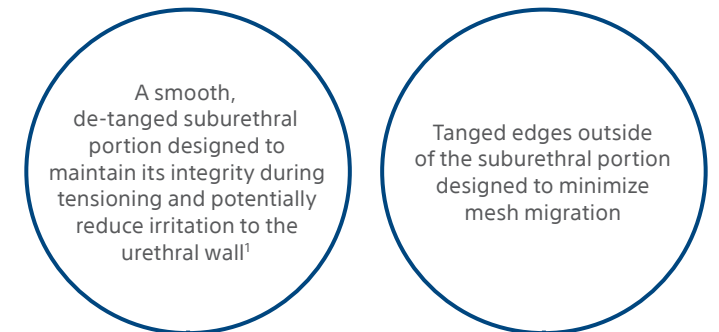
MID-URETHRAL SLINGS

CLINICALLY PROVEN MESH — USED IN MORE THAN 1 MILLION SLINGS¹

Advantage™ mesh is a biocompatible knitted polypropylene material which has been heat treated and de-tanged in the sub-urethral portion of the sling. This heat-sealed edge is designed to potentially reduce irritation to the anterior urethral wall.¹

The material is designed to reduce the risk of mesh deformation and maintain its integrity during tensioning. All Boston Scientific mid-urethral sling systems feature Advantage mesh, which has been used in more than 1 million slings to date.

Advantage mesh is also available in a vibrant, optical blue color for improved visibility during intra-operative sling tensioning and making it easier to locate post-operatively, if needed.



Fundamental difference in mesh design philosophy

Feature	BSC	J&J	Coloplast
30x magnification			
Pore size (microns) ²	1182	1379	374
Density (g/m ²)	100	100	70
Elasticity	High	High	Low
Knit pattern	Tricot	Tricot	Warp knit, pillar stitch with inlay
Edge design	Tanged ¹	Tanged	Sealed
Color	Clear and Blue ¹	Blue	Clear

MID-URETHRAL SLINGS

IMPROVED VISIBILITY. PROCEDURAL FLEXIBILITY. EVIDENCE BASED.

Physicians have a variety of preferred surgical approaches for the treatment of SUI. That's why Boston Scientific offers a wide range of products – including transobturator, retropubic and single incision slings. The full portfolio is also available with Advantage Blue mesh for improved visibility. Documented in more than 100+ publications to date, our SUI portfolio delivers the visibility to treat your patients with greater confidence, and the versatility to use the surgical approach you prefer.



Advantage Fit Blue Mid-urethral Sling.

The Advantage Fit™ Transvaginal Mid-Urethral Sling System was designed with a 46% thinner needle and 17% tighter curve than the Advantage System to reduce insertion force and deliver the mesh closer to the pubic bone, and farther away from critical structures.

Available in Advantage Blue or clear mesh.



Solyx Blue Single Incision Sling System

The Solyx™ Single Incision Sling System is designed to reduce dissection and associated risk, and to offer a procedure with fewer steps. The mesh carrier tip snap-fits to the delivery device allowing for advanced control and micro-adjustability during placement.

Available in Advantage Blue or clear mesh.



Obtryx II Mid-urethral Sling System

The Obtryx™ II Mid-Urethral Sling System is a transobturator sling with enhanced features designed for smooth sling placement, intra-operative adjustability with minimal tissue disruption, and increased visualization for physicians to aid in precise sling placement.

Available with halo or curved delivery devices.



Lynx Suprapubic Mid-urethral Sling System

The Lynx™ Suprapubic Mid-Urethral Sling System is designed to maneuver through challenging tissue with a smoother association mechanism in the suprapubic pathway.

Also available are the Advantage and Advantage Blue Transvaginal Mid-urethral Sling Systems and the Obtryx Mid-urethral Sling System.

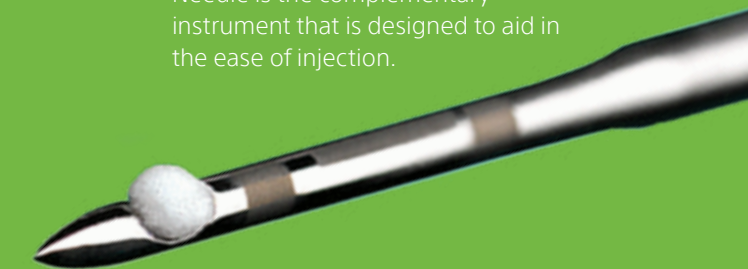
BULKING AGENTS

Our goal is to provide evidence-based treatment options for physicians and their patients.

In addition to our full portfolio of mid-urethral slings, Boston Scientific also offers bulking agents – providing you more flexibility and your patients more choice.

Coaptite Injectable Implant

Coaptite™ Injectable Implant is a bulking agent consisting of calcium Hydroxylapatite [CaHA] particles in a carrier gel, designed for durability and effectiveness. The Coaptite Sidekick™ Needle is the complementary instrument that is designed to aid in the ease of injection.



PELVIC ORGAN PROLAPSE

PHYSICIANS HAVE A VARIETY OF PREFERRED SURGICAL APPROACHES FOR THE TREATMENT OF PELVIC ORGAN PROLAPSE.

That's why Boston Scientific offers a range of products — including a sacrocolpopexy surgical option as well as a sheet mesh option. So you have the freedom to choose the best treatment option for you and your patient.



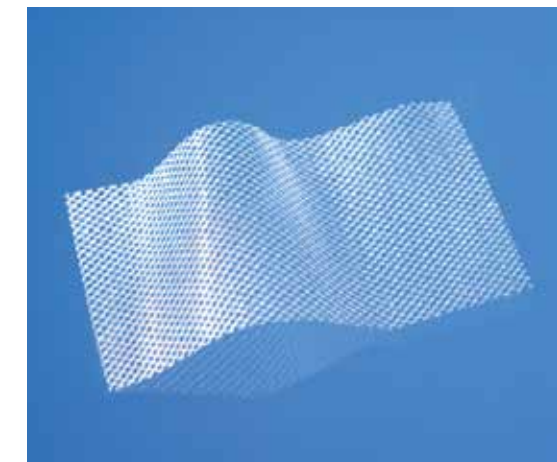
Sacrocolpopexy Option

The Upsilon™ Y-Mesh features lightweight, low surface area technology to minimize mesh contact with the vaginal wall following abdominal placement. The mesh handling characteristics, large pores and blue color are designed to ease positioning and fixation to assist with placement.

Colpassit Vaginal Manipulator

Sheet Mesh Option

Polyform™ Synthetic Mesh is offered for tissue reinforcement and stabilization of fascial structures of the pelvic floor via an abdominal approach.




FIXATION DEVICES

Capio SLIM Suture Capturing Device

The Capio™ SLIM Suture Capturing Device is designed to enable an intra-vaginal, trocar-free, minimally invasive prolapse repair. The Capio SLIM Suture Device facilitates the consistent placement of sutures in difficult to access locations during surgical procedures. The Capio SLIM Device features a reduced head width and shaft diameter to minimize the space occupied within the surgical field, easy suture loading and a funnel shaped catch, designed for consistent ease of use.





DELIVERING ON OUR COMMITMENT TO THE WOMEN WHO SUFFER FROM PELVIC FLOOR DISORDERS AND THE PHYSICIANS WHO TREAT THEM

To advance the treatment of pelvic floor disorders, Boston Scientific is dedicated to delivering clinically-supported products, investing in scientific research and providing our physicians with robust professional and patient education programs. We stand by the quality of our products and our overall commitment to women's health.



CLINICAL EXCELLENCE

3,500+ women treated with our pelvic floor repair products in clinical studies around the world

140+ physicians collaborating on ongoing investigator-sponsored studies

100+ articles and abstracts referencing Boston Scientific Pelvic Floor Reconstructive Surgical Devices

\$32 million invested in post-market 522 studies

Member of the American Urogynecologic Society (AUGS) Pelvic Floor Disorders Registry



PHYSICIAN TRAINING

Sacrocolpopexy (SCP) Preceptorships at a Center of Education

BSC/Intuitive Surgical co-sponsored SCP hands-on courses

Webinars and other educational offerings

FR-SUI preceptorship/proctorship opportunities

EDUCARE on-demand clinical education and training (educare.bostonscientific.com)

Resident and fellows programs



PATIENT EDUCATION

AUGS Break Free programs/Voices for PFD website (voicesforPFD.org)

Patient education materials and videos

Choose You patient website (chooseyou.com)

Virtual and in-person patient education seminars

ORDERING INFORMATION

Mid-Urethral Sling Systems

Advantage Fit™ System (Transvaginal)

Order Number	GTIN Number	Description	Unit
M0068502110	08714729772880	Advantage Fit System (single unit)	ea
M0068502120	08714729961925	Advantage Fit Blue System	ea

Each System includes One (1) Delivery Device and One (1) Mesh Assembly
Applicable HCPCS code: C1771 – repair device, urinary, incontinence, with sling graft

Advantage™ System (Transvaginal)

Order Number	GTIN Number	Description	Unit
M0068502000	08714729470274	Advantage System (single unit)	ea
M0068502050	08714729961918	Advantage Blue System	ea

Each System includes One (1) Delivery Device and One (1) Mesh Assembly
Applicable HCPCS code: C1771 – repair device, urinary, incontinence, with sling graft

Lynx™ System (Suprapubic)

Order Number	GTIN Number	Description	Unit
M0068503000	08714729718949	Lynx System (single unit)	ea
M0068503010	08714729961932	Lynx Blue System	ea

Each System includes Two (2) Delivery Devices and One (1) Mesh Assembly
Applicable HCPCS code: C1771 – repair device, urinary, incontinence, with sling graft

Obtryx™ II System with PrecisionBlue™ Design Halo or Curved (Transobturator)

Order Number	GTIN Number	Description	Unit
M0068504110	08714729839255	Obtryx II System – Curved (single unit)	ea
M0068505110	08714729837565	Obtryx II System – Halo (single unit)	ea

Each System includes Two (2) Delivery Devices and One (1) Mesh Assembly
Applicable HCPCS code: C1771 – repair device, urinary, incontinence, with sling graft

Obtryx™ System Halo or Curved (Transobturator)

Order Number	GTIN Number	Description	Unit
M0068504000	08714729718963	Obtryx System – Curved (single unit)	ea
M0068505000	08714729718987	Obtryx System – Halo (single unit)	ea

Each System includes Two (2) Delivery Devices and One (1) Mesh Assembly
Applicable HCPCS code: C1771 – repair device, urinary, incontinence, with sling graft

Solyx™ SIS System (Single Incision)

Order Number	GTIN Number	Description	Unit
M0068507000	08714729774044	Solyx SIS System (single unit)	ea
M0068507010	08714729961901	Solyx Blue SIS System	ea

Each System includes One (1) Delivery Device and One (1) Mesh Assembly
Applicable HCPCS code: C1771 – repair device, urinary, incontinence, with sling graft

Injectable Implants

Coaptite™ Injectable Implant

Order Number	GTIN Number	Description	Unit
M0068903000	08714729804796	1ml Syringe	ea
M0068903040	08714729819530	Sidekick™ Rigid Needle	ea

Applicable HCPCS code: L8606 – Injectable bulking agent, synthetic implant, urinary tract, 1ml syringe, includes shipping and necessary supplies

Suturing Systems

Capio™ SLIM Suture Capturing Device

Order Number	GTIN Number	Description	Unit
M0068318250	08714729838005	Capio SLIM Suture Capturing Device	ea
M0068318261	08714729842224	Capio SLIM Suture Capturing Device	bx 5

Applicable HCPCS code: C2631 – repair device, urinary, incontinence, without sling graft

Capio™ Suture Capturing Device

Order Number	GTIN Number	Description	Size	Unit
M0068311251	08714729257615	Open Access – for sensory/direct visual control where a trocar is not employed, i.e., Mini Incision Burch, Sacrospinous Fixation or Vaginal Paravaginal Repair	25cm length	bx 4
M0068312321	08714729257622	Standard – for direct vision endoscopic, open or transvaginal use	12mm x 32cm	bx 4

Applicable HCPCS code: C2631 – repair device, urinary, incontinence, without sling graft

Capio™ Sutures

Order Number	GTIN Number	Description	Size	Closest Equivalent	Unit
M0068331231	08714729257660	Non-absorbable, polypropylene monofilament, double armed with two TC tapercut needles (darts), 48"	0	Surgilene™ Sutures / Prolene™ Sutures	bx 12
M0068331241	08714729257677	Non-absorbable, polypropylene monofilament, double armed with a TC tapercut needle (dart) and a T 26mm, 1/2 circle taper needle, 36"	0	Surgilene Sutures / Prolene Sutures	bx 12
M0068331131	08714729257646	Non-absorbable, coated braided polyester, double armed with two TC tapercut needles (darts), 48"	0	TI-CRON™ Sutures / Ethibond™ Sutures	bx 12
M0068331141	08714729257653	Non-absorbable, coated braided polyester, double armed with a TC tapercut needle (dart) and a T 26mm, 1/2 circle taper needle, 36"	0	TI-CRON Sutures / Ethibond Sutures	bx 12
M0068331371	08714729761822	Monodek™ Absorbable, monofilament PDO, double armed with a TC tapercut needle (dart) and a T 26mm, 1/2 circle taper needle, 48"	0	PDS™ Sutures	bx 12
M0068332131	08714729298205	Bondek™ Plus Suture, absorbable, coated braided PGA, double armed with two TC tapercut needles (darts), 48"	0	Dexon™ II Mesh / Vicryl™ Mesh	bx 12

Applicable HCPCS code: There are no applicable HCPCS code for the above products.

Sacrocolpopexy

Upsilon™ Y-Mesh

Order Number	GTIN Number	Description	Unit
M0068318200	08714729839217	UPsylon Y-Mesh	ea
M0068318210	08714729848097	Colpassist™ Vaginal Positioning Device	ea
M0068318220	08714729848103	UPsylon Y-Mesh and Colpassist Vaginal Positioning Device Kit	ea

Applicable HCPCS code: C1763 – connective tissue, non-human (includes synthetic)

Polyform™ Synthetic Mesh

Order Number	GTIN Number	Description	Size	Unit
M0068402580	08714729839224	Polyform Synthetic Mesh	10 x 15 cm	ea
M0068402581	08714729839231	Polyform Synthetic Mesh	10 x 15 cm	bx 5
M0068402590	08714729845256	Polyform Synthetic Mesh	15 x 20 cm	ea

Applicable HCPCS code: C1763 – connective tissue, non-human (includes synthetic)

Pelvic Floor Accessories

Order Number	GTIN Number	Description	Unit
M0068201060	08714729077329	Single-Step™ Pelvic Drape	ea

Applicable HCPCS code: There are no applicable HCPCS code for the above products.



1. Data on file at Boston Scientific.
2. Moalli PA, Papas N, Meneffee S, et al. Tensile properties of five commonly used mid-urethral slings relative to the TVT. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 May;19(5):655-63.

For Advantage, Advantage Fit, Lynx, Obtryx, Obtryx II and Solyx: **CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.**

For Coaptite Injectable Implant: **INDICATIONS:** Coaptite Injectable Implant is indicated for soft tissue augmentation in the treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) in adult females. **CONTRAINDICATIONS:** The Coaptite Injectable Implant is contraindicated for use in a patient: who has significant history of urinary tract infections without resolution; who has current or acute conditions of cystitis or urethritis; who has fragile urethral mucosal lining. **POTENTIAL ADVERSE EFFECTS** that may occur include: genitourinary adverse events (i.e., urinary retention, hematuria, dysuria, UTI, urinary urgency and frequency), erosion, erythema, embolic phenomena, and vascular occlusion. **WARNINGS:** Note: Failure to follow any instructions or to heed any Warnings or Precautions could result in serious patient injury. **WARNING:** Following injection of Coaptite Implant, dissection of the device through tissue may lead to 1) tissue erosion and may require corrective surgery or 2) elevation of the bladder wall causing ureteral obstruction. This may be caused by improper injection technique using Coaptite Implant. (See adverse event section in IFU for further information.) **WARNING:** Women with peripheral vascular disease and prior pelvic surgery may be at increased risk for tissue erosion following injection of Coaptite Implant. (See adverse event section in IFU for further information.) Please refer to complete instructions for use for a complete listing of all warnings and potential adverse effects. **CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in diagnostic and therapeutic cystoscopy WH-550709-AA.**

For Polyform Synthetic Mesh: **CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.**

For Upsilon Y Mesh: **CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician trained in performing mesh procedures for surgical repair of pelvic organ prolapse.**

Accordingly for medical devices: CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

Please refer to package insert provided with these products for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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**Boston
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