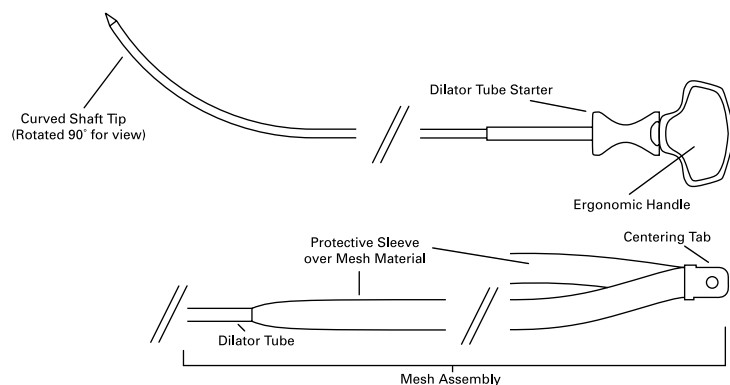


Female Continence - Mid-Urethral Sling Systems

Advantage™ System (Transvaginal) with CLEAR mesh



Order Number	Description
M0068502000	Advantage™ System (single unit)

Each System Includes One (1) Delivery Device and One (1) Mesh Assembly

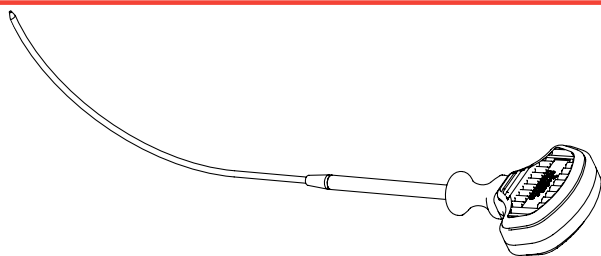
Advantage™ BLUE System

Order Number	Description
M0068502050	Advantage Blue™ System

Each System Includes One (1) Delivery Device and One (1) Mesh Assembly

Advantage Fit™ System (Transvaginal) with CLEAR mesh

poz.21.2



Order Number	Description
M0068502110	Advantage Fit™ System (single unit)

Each System Includes One (1) Delivery Device and One (1) Mesh Assembly

Advantage Fit™ BLUE System

Order Number	Description
M0068502120	Advantage Fit™ Blue System

Each System Includes One (1) Delivery Device and One (1) Mesh Assembly

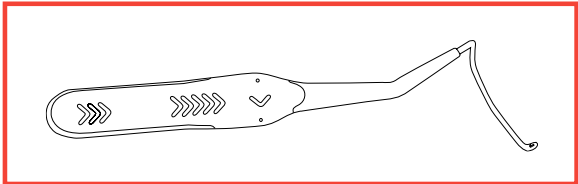
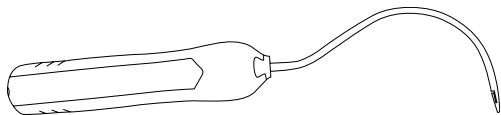
poz.21.2



Female Continence - Mid-Urethral Sling Systems Continued

Obtryx™ II System with Precision BLUE Design (Halo or Curved)

poz.21.1



Order Number	Description
M0068504110	Obtryx™ II Transobturator Sling System - Curved
M0068505110	Obtryx™ II Transobturator Sling System - Halo

Packaged with Two (2) Delivery Devices Per Box

Obtryx™ System Halo or Curved (Transobturator)

poz.21.1

Order Number	Description
M0068504000	Obtryx™ System Curved (single unit)
M0068505000	Obtryx™ System Halo (single unit)

Each System includes Two (2) Delivery Devices and One (1) Mesh Assembly

Obtryx™ II

Transobturator Mid-Urethral Sling System

Boston
Scientific

Featuring
PrecisionBlue™ Design



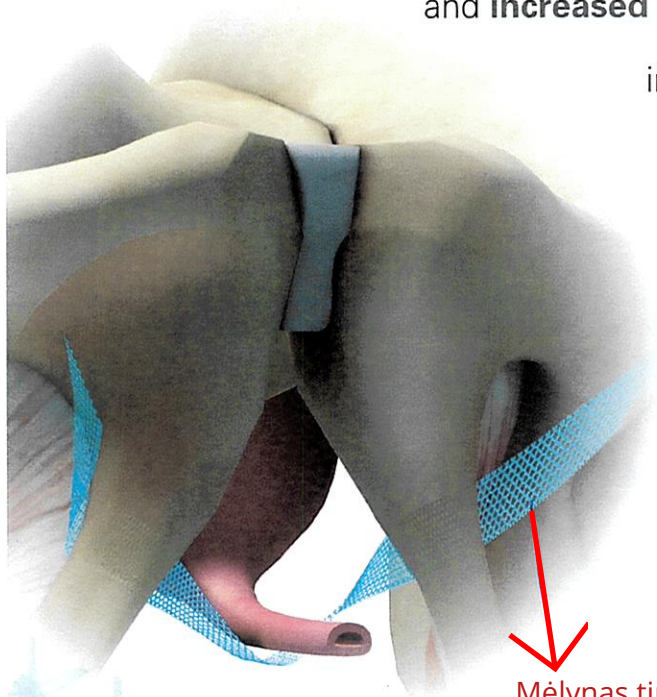
Always there.

Dedicated to Women's Health

Obtryx™ II Transobturator Mid-Urethral Sling System with PrecisionBlue™ Design

Mėlynas tinklelis

PrecisionBlue Design is a set of enhanced features that are designed to provide **smooth sling placement**, **intra-operative adjustability** with **minimal tissue disruption** and **increased physician visualization** that aids in **precise sling placement**.



Mėlynas tinklelis

Advantage™ Mesh Characteristics¹

Mesh thickness: 0.66 mm	storis
Pore size: 1182 µm	porų dydis
Fiber size (diameter): 0.15 mm	pluošto diametras
Weight (g/m2): 100	svoris

The Obtryx II System designed with blue Advantage Mesh

Mėlynas tinklelis

Commitment to Clinical Data

Boston Scientific is committed to providing clinical data across its Advantage Mesh mid-urethral sling products.

Prospective Study - Randomized Controlled Trial² 12 month follow-up

	Obtryx Halo System	Advantage™ System
Objective Cure* (p=0.577)	81% (68/84)	77% (67/87)
Subjective Cure (p=0.213)	98.8% (85/86)	92.6% (88/95)

Retrospective Study - Chart Review³ 18.1 month median follow-up

Obtryx Halo System	
Objective Cure (P < 0.005)	98% (184/188)
No longer wearing pads (P < 0.005)	93% (175/188)

*Cure defined as less than 1 gram urine leak in standardized pad test.

Blue mesh and dilator legs for better physician visualization, as compared to white or clear colored slings

Needle Design

- Needle tip length is designed to facilitate transobturator device passage
- Two needle configurations allow physicians to choose the needle that meets their preference

Du įvedėjai-adatos

Association Loop

- Designed to facilitate easy needle engagement and removal

Halo tipo arba ratilo formos

Fiksavimo vieta

CURVED NEEDLE

Plastikinė rankena

Plastikinė mova

- No sleeve coverage under the sub-urethra segment to allow for visibility and to aid in precise placement

Mėlynas tinklelis

HALO NEEDLE

Dilator Legs

- Designed to create a small delivery track due to thin leg size and provides smooth delivery of the sling through the anatomy allowing for minimal tissue disruption

Fiksavimo kabliukas

Centering Tab

Vidurio linijos plastikinis žymelis

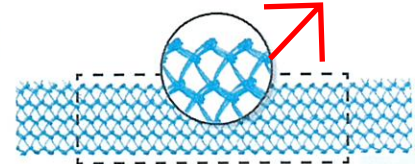
- Blue centering tab identifies the center of the mesh and provides for equal distribution of mesh on each side of the urethra
- The centering tab can be used to aid in tensioning the mesh implant

The Blue Advantage™ Mesh is a Polypropylene Material

Polypropylene has been proven over the years to be biocompatible in many medical applications. The blue Advantage Mesh has a suburethral segment that is de-tanged. This unique heat sealed edge is smoother allowing for these potential benefits:

- Reduced risk that the mesh will experience deformation during tensioning. The suburethral mesh segment is designed to maintain its integrity.
- The de-tanged mesh is designed to potentially reduce irritation to the urethral wall.

Nespurstantis kraštas, užsibaigia burbuliukais



Suburethral portion which sits under the urethra has de-tanged edges.

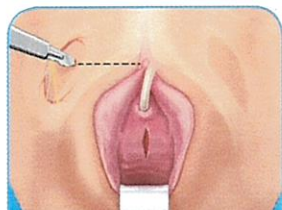
Advantage Mesh

Over 750,000 implanted to date

Procedural Steps

Obtryx™ II Transobturator Mid-Urethral Sling System with PrecisionBlue™ Design

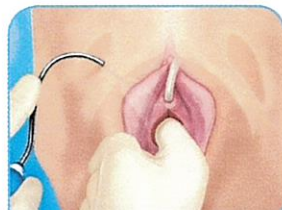
1



Patient Preparation

- Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
- Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the inferior portion of the inferior pubic ramus at the 45 degree angle off the midline creating a pathway for delivery device placement.
- Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and adductor longus muscle meet. Repeat on the contralateral side.

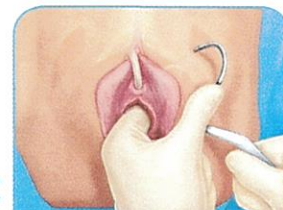
2



Curved Needle - Insertion

- Grasp the device handle and insert one needle through one skin incision, piercing through the obturator muscle and obturator foramen.
- Turn the handle at a 45° angle medial towards the midline. Place the opposite hand's forefinger into the lateral dissection of the vaginal incision, placing the fingertip on the distal end of the needle. Guide the distal end of the needle around the inferior pubic ramus through the vaginal incision, maintaining contact with the finger.

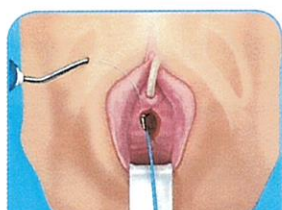
2



Halo Needle - Insertion

- Grasp the device handle for the patient's left side with the right hand.
- Place the left forefinger into the lateral dissection of the vaginal incision.
- Place the needle tip into the skin incision perpendicular to the skin with the handle at a 45° angle parallel to the thigh.
- Putting the left thumb on the outside of the needle curve, apply a downward force, piercing through the obturator muscle and membrane.
- Rotate the needle medially around the inferior pubic ramus to meet the left hand forefinger. Guide the needle tip through the vaginal incision.

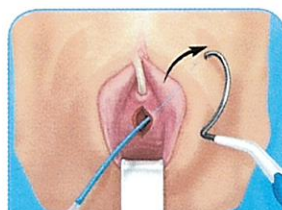
3



Loop Engagement

- Engage one association loop to the distal end of the needle.

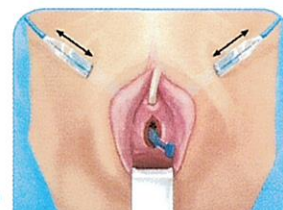
4



Needle Removal

- Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra with the blue centering tab positioned suburethrally, facing outward.
- Remove the association loop from the needle.
- Repeat Step 2 through Step 4.
- Cystoscopy may be performed at this time, to be determined at the physician's discretion.

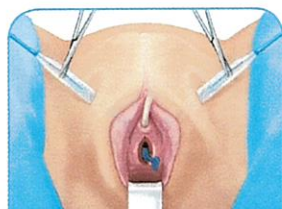
5



Mesh Adjustment

- Adjust the mesh/sleeve assembly by pulling outward on the dilators so that the blue centering tab is centered below the urethra.
- Appropriately tension the mesh/sleeve assembly according to physician preference.

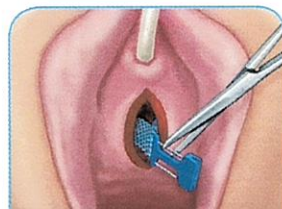
6



Sleeve Removal

- Once proper tension is achieved, cut the leader loop that is on the outside of the sleeve that is connecting the dilator leg and sleeve to the mesh. Pull outward on the dilator to remove the sleeve leaving the mesh in place. Repeat on the other side.

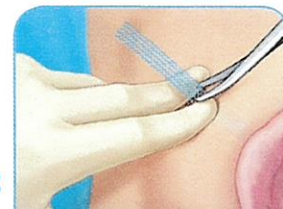
7



Centering Tab Removal

- Grasp the blue center tab and cut the center tab lead located on the side of the center tab to release the tab from the mesh. Remove the center tab and center tab lead from the vaginal canal.

8



Closing

- Gently push downward on the skin incisions, cut the distal ends of the mesh and confirm that the ends retract into the skin incisions.
- Close all incisions according to usual methods.

Ordering Information poz.27

Product Code	Description	Quantity
M0068504110	Obtryx™ II Transobturator Sling System - Curved	Single Unit
M0068504111	Obtryx II Transobturator Sling System - Curved	5 Pack
M0068505110	Obtryx II Transobturator Sling System - Halo	Single Unit
M0068505111	Obtryx II Transobturator Sling System - Halo	5 Pack

¹ Moali, Pamela, et al. Tensile properties of five commonly used mid-urethral slings relative to the TVT™ Int Urogynecol J (2008) 19: 655-663 DOI 10.1007/s00192-007-0499-1

² Ross, Sue, Robert, Magali, et al. Transobturator Tape Compared with Tension-Free Vaginal Tape for Stress Incontinence, A Randomized Controlled Trial, *Obstetrics & Gynecology*, 114 (6), Dec 2009, 1287-93.

³ Litviller S, et al. Long Term Efficacy and Safety of the Obtryx Transobturator Mid-Urethral Sling System for Treatment of Stress Urinary Incontinence in a Community Setting. An Analysis of Outcomes and Quality of Life. AUGS 2009, Hollywood, FL

All trademarks are the property of their respective owners.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

Boston Scientific

Advancing science for life™

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.pelvic-floor-institute.com

Ordering Information
1.888.272.1001

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WH-118616-AC SEP 2016

Pelvic Floor Institute
Women's Health Business of Boston Scientific

February 5, 2020

To whom it may concern,

The Obtryx System (Halo) and Obtryx II System (Halo) are each packaged with (2) Halo Delivery Device (1 patient left and 1 patient right) . The Delivery Devices for each of the systems are identical. The information for the needle shaft outer diameter (O.D) and bend radius and diameter is listed below.

įvedėjų diametras

Description	UPN	Needle Shaft diameter	Needle bend Radius
Obtryx System (Halo)	M0068504000	0.125"	1.10" (2.20" diameter)
Obtryx II System (Halo)	M0068504110	0.125"	1.10" (2.20" diameter)

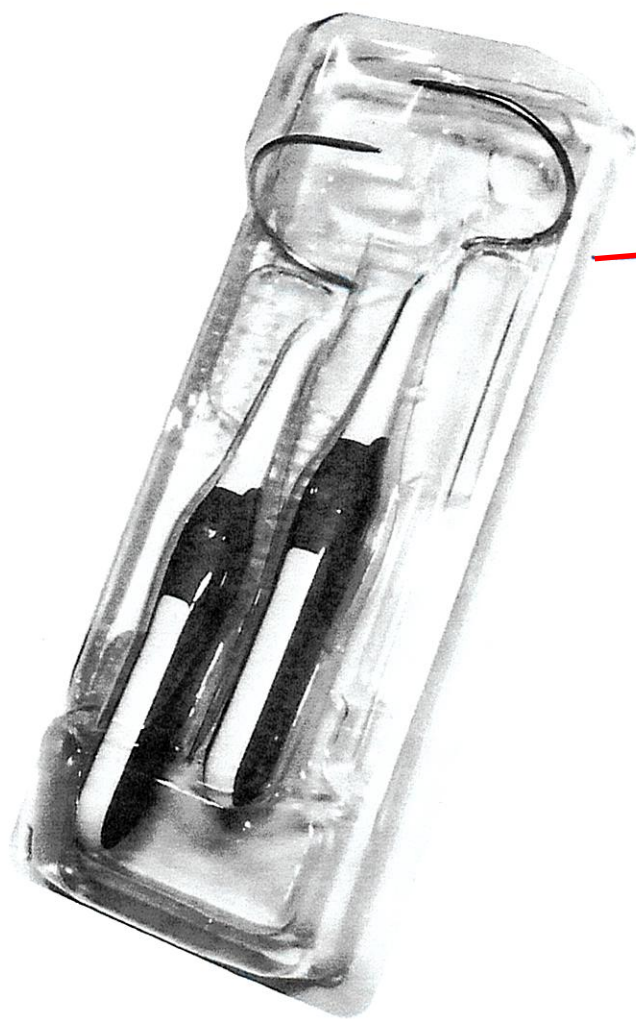
Sincerely,

February 5, 2020

Date

Specialist Global Regulatory
Affairs
Boston Scientific Corporation

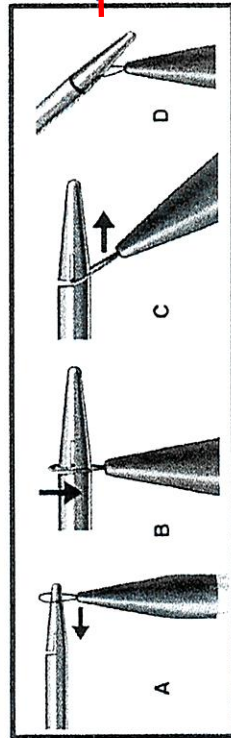
20



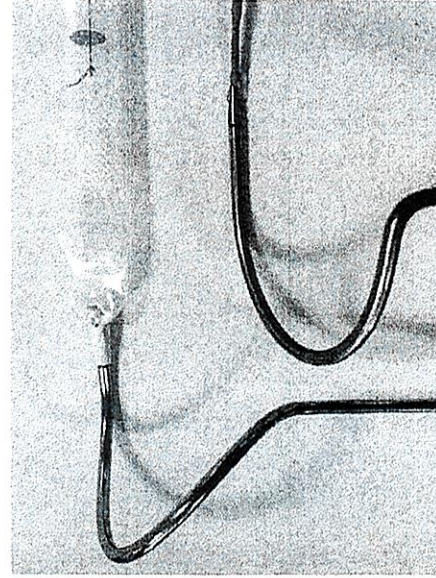
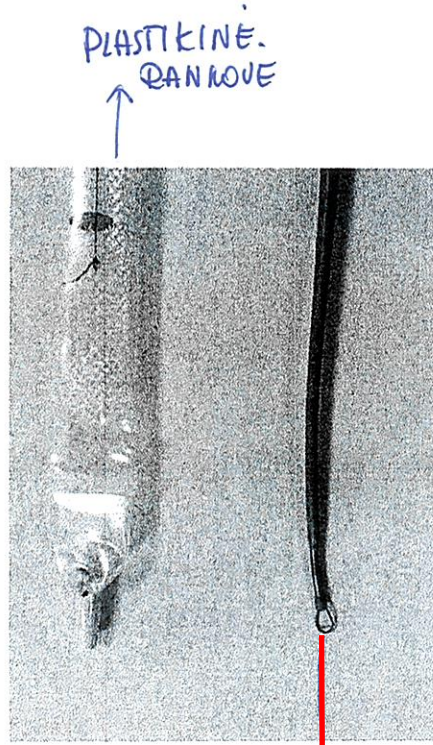
→ Rinkinyje du įvedėjai

Association Loop

- Mesh Assembly
- Association Loop



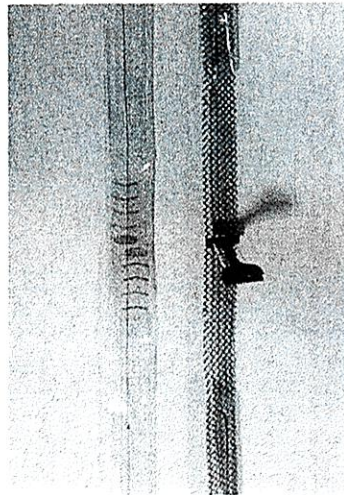
Tinklelio tvirtinimo vieta



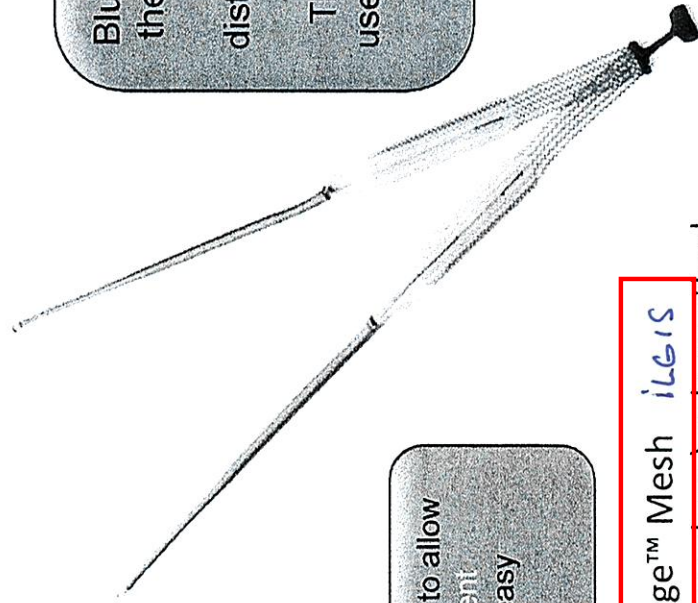
Dilator legs designed to create a small delivery track due to thin leg size and provide smooth delivery of the sling through the anatomy to potentially reduce tissue trauma
Loop can be detached if a vaginal fornix perforation has been detected

Mesh Design

Blue mesh and dilator legs for better physician visualization, as compared to white or clear colored slings



No sleeve coverage under the sub-urethral segment to allow for good visibility and to aid in more precise placement
No sleeve coverage under suburethral segment for easy removal of plastic sheet



Blue centering tab identifies the center of the mesh and provides for equal distribution of mesh on each side of the urethra
The centering tab can be used to aid in tensioning the mesh implant

22 cm. Advantage™ Mesh
4 cm Detached (Open edges) sub-urethral

Neaptraukto
mova tinklelio
ilgis



Width 1,1cm
Dydis

*Advantage*TM

Transvaginal Mid-Urethral Sling System

*Mid-urethral
sling system for
the treatment
of stress urinary
incontinence*



Advantage™

Transvaginal Mid-Urethral Sling System

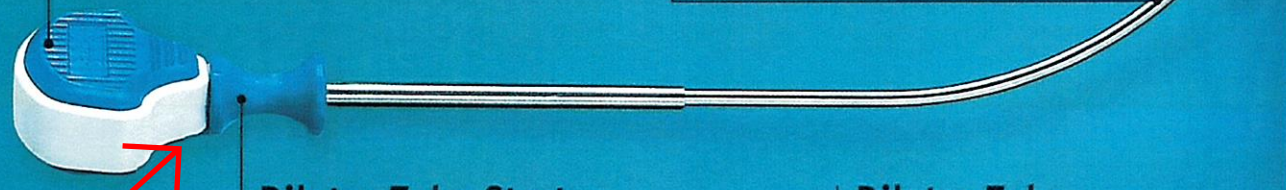
The Advantage Sling System is intended to be used to place a mid-urethral sling for the treatment of stress urinary incontinence and offers several advancements in delivery and tension, all of which are designed to meet the demands of the physician.

Delivery Device

- Non-skid grip prevents hands from slipping during intra-operative manipulation
- Ergonomic handle fits easily into operator's palm allowing for ambidextrous use
- Hard surface of the back rim transmits a tactile sensation from the distal tip to the operator's hand indicating contact with a solid surface like bone

Curved Needle Tip

- Needle curve is designed anatomically to fit behind the pubic bone, reducing the chance of adjacent organ injury
- Needle is 5 mm in diameter
- Needle tip is conically ground and is designed to easily pierce through tough tissue and minimise potential for "sharps" injury to operator



Ergonomine rankena

Dilator Tube Starter

- Extends the dilator tube 2.3 cm beyond the distal tip of the needle which gives the operator sufficient room to clamp the tube
- Starter is specifically intended to allow the operator one hand operation of the Advantage Delivery Device

Dilator Tube

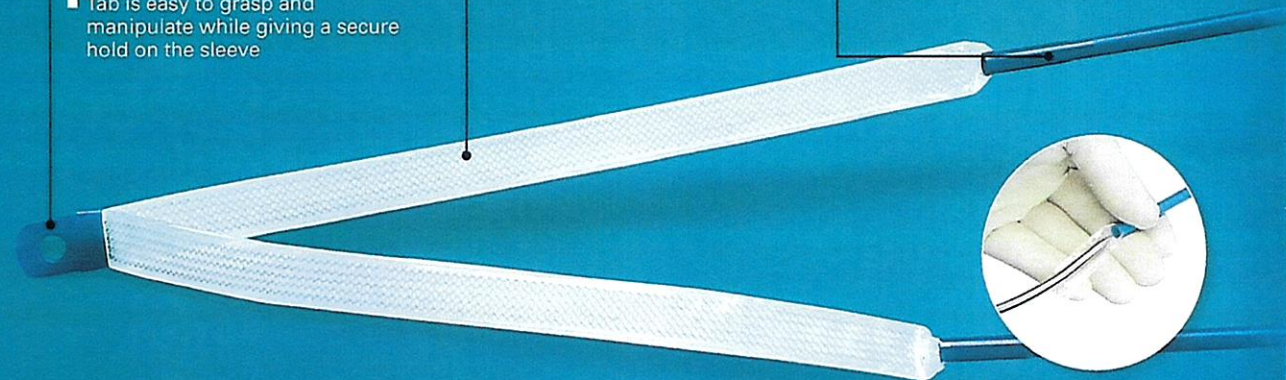
- Smooth tapered tip slides through tissue causing minimal disruption
- Easy slip-on/slip-off design allows for perioperative manipulation
- Blue colour shows up well in distorted field of vision
- Two tube system requires only one cystoscopy
- Tube configuration gives operator ability to untwist mesh in vivo should it twist during delivery

Centering Tab

- Blue centering tab identifies the centre of the mesh and provides for equal distribution of mesh on each side of the urethra
- Allows for counter tension to be applied on only the sleeve preserving mesh integrity
- Tab is easy to grasp and manipulate while giving a secure hold on the sleeve

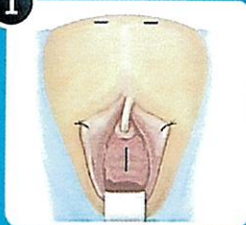
Mesh Assembly

- Mesh is free floating in the protective sleeve
- Ultra-smooth bond to dilator tube allows for a seamless transition with no "lip" to catch on tissue



Six Steps of the Advantage™ Sling Procedure**

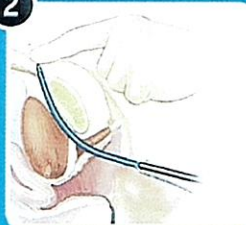
1



After preparation of the lower abdominal and vaginal operative sites, create two small transverse abdominal incisions approximately 0.5cm to 1cm on each side of the midline just above the symphysis.

Incise the anterior vaginal wall and dissect bilaterally in standard fashion.

2

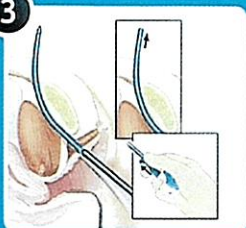


Resting the tip of the needle on the palmar surface of the non-dominant index finger, gently introduce the Delivery Device anterolaterally into the paraurethral space and perforate the endopelvic

fascia. Carefully pass the Delivery Device through the space of Retzius and perforate the rectus sheath and muscle.

Guide the device by palpation into the ipsilateral abdominal incision until the needle tip is exposed through the incision.

3

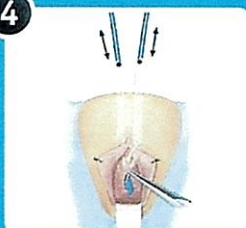


When the needle tip / dilator tube assembly extends extra-abdominally, advance the tube starter on the handle. This will cause the dilator tube to extend beyond the tip of the needle.

Grasp the dilator by placing a clamp or haemostat on the free end of the dilator end to temporarily secure it extra-abdominally. Remove the needle from inside the dilator by pulling it out of the dilator and out of the vagina. The dilator tube/mesh assembly should remain in place.

Repeat on the contra lateral side. At this point, the two dilator tubes will be in place and cystoscopy should be performed to confirm bladder integrity.

4

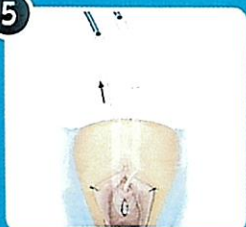


Tension the mesh by pulling upwards on both dilators simultaneously so that urine leakage is limited to no more than one or two drops.

When the appropriate tension is attained, grasp the blue centring

tab and cut the tab through the centre of the punch hole. Make sure to remove both halves of the blue tab.

5



Remove the protective sleeve by pulling upwards on both dilators simultaneously and verify the tension of the mesh, adjust if necessary.

6



Once the desired tension has been achieved, gently push downward on the abdomen, cut the distal ends of the mesh and allow those ends to retract into the incision.

Close the incisions in the usual manner.

AdvantageTM

Transvaginal Mid-Urethral Sling System

ADVANTAGETM TRANSVAGINAL MID-URETHRAL SLING SYSTEM*

Ordering Information

M0068502000

Advantage Single Handle Kit
(1 Delivery Device and 1 mesh assembly)

M006850200051

5-Pack Advantage System
(1x Delivery Device and 1x mesh assembly x 5 sets)

De-tanged Polypropylene Material

Polipropileno juosteles

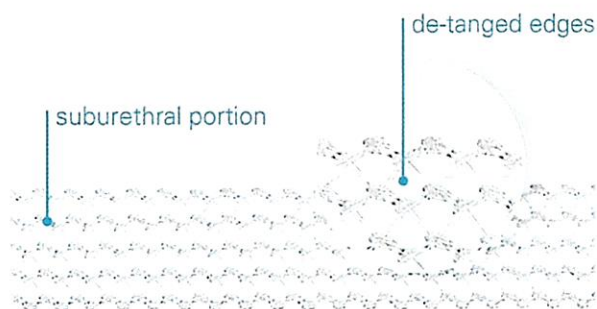
In mechanical testing, the Advantage mesh has been shown to be the most consistent commercially available tension-free sling material. Polypropylene material has been shown to be biocompatible.**

Designed to reduce irritation**

The polypropylene mesh is de-tanged in the suburethral portion to potentially reduce irritation to the anterior urethral wall.

Resists deformation**

The suburethral portion of the mesh is de-tanged to resist deformation.



**Boston
Scientific**

Defining tomorrow, today.™

www.bostonscientific-international.com
www.pelvic-floor-institute.com

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DINURO2061EB

* For complete "Instructions for Use", please refer to the DFU provided with the product.

** Data on file Boston Scientific Corporation

All cited trademarks are the property of their respective owners. CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

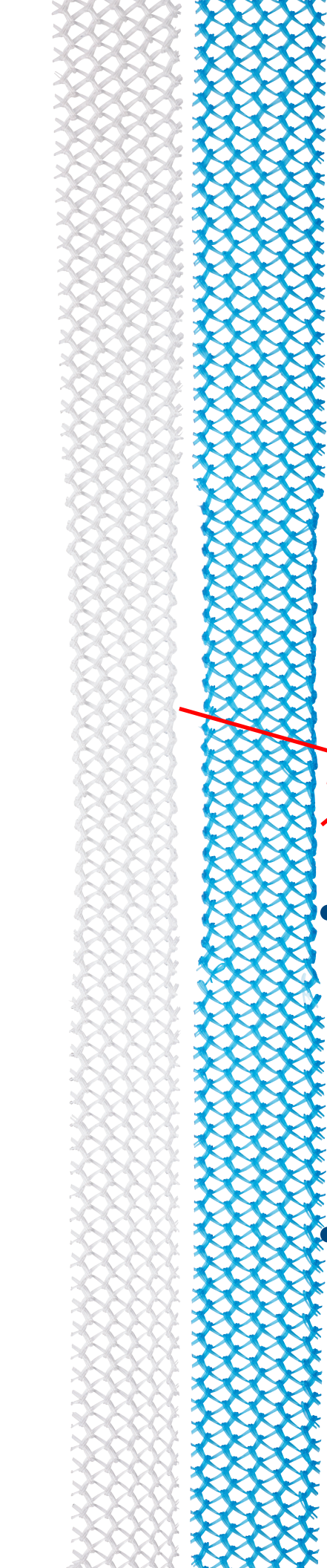
PSST 6245 Printed in Germany by medicalvision.



Advantage Fit™ and Advantage™

Transvaginal Mid-urethral Sling Systems

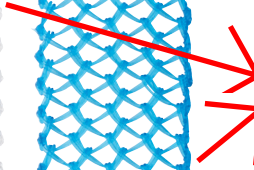
Advantage Fit Blue Sling System shown



Advantage Fit™ and Advantage™ Transvaginal Mid-urethral Sling Systems

Boston Scientific offers a full portfolio of solutions to treat stress urinary incontinence - giving you the control and confidence to treat patients with your preferred surgical approach.

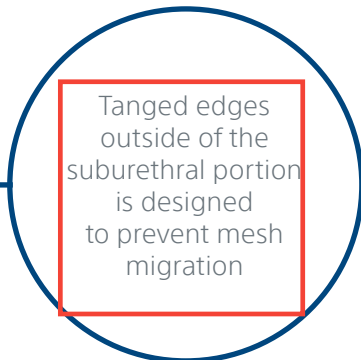
Advantage Fit and Advantage Mid-urethral Sling Systems are offered in original clear mesh, as well as Advantage™ blue mesh, providing improved visibility and used in over 1 Million Advantage products.*



Juostelè



A smooth, de-tanged suburethral portion designed to maintain its integrity during tensioning and potentially reduce irritation to the urethral wall



Tanged edges outside of the suburethral portion is designed to prevent mesh migration

Nespuriantis

Improved visibility. Evidence based.

- The same mesh properties as our patented Advantage mesh, which is documented in more than 100 publications to date
- The easy-to-see, optical blue color is designed to help improve your visibility for more accurate intra-operative sling tensioning and may make it easier to locate post-operatively**

Trusted polypropylene mesh¹

- Mesh thickness: 0.66 mm
- Pore size: 1182 µm
- Fiber size (diameter): 0.15 mm
- Weight: 100 g/m²; 44.5cm lenght

Tinklelio matmenys

* Data on File at Boston Scientific.

** Based on physician feedback.

Vidurio linijos žymė

Delivery device handle

Ergonomic handle designed to fit into physician's hand and allow for ambidextrous use.

Non-skid grip

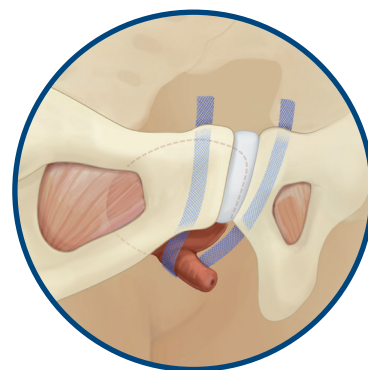
Designed for ergonomic grip and to prevent hands from slipping during intra-operative manipulation.

Pusher on Advantage Fit

Designed with a pusher for ergonomic finger placement that provides the user with greater needle stability and control during delivery.

Centering tab

Allows for proper alignment of the center of the mesh under the urethra. It also allows the physician to apply counter tension to the sling while preserving the mesh integrity.



Transvaginal approach

Įvedimo adata, jos matmenys

Needle radius and diameter

Thinner needle and tighter curve of Advantage Fit are intended to reduce insertion force and place the mesh closer to the pubic bone² and further away from critical structures.

- **Diameter Advantage needle: 5mm**
- **Diameter Advantage Fit needle: 2.7mm (46% thinner), 19cm length and 115 degree bend**

Plastikinė mova

17cm length Blue dilator

To improve visualization during cystoscopy.

Dilatatoriai

Advantage Fit Blue Sling
System shown

Ordering Information poz.21.2

Product code	Description	Quantity
M0068502120	Advantage Fit™ Blue System	1 Delivery Device and 1 Mesh Assembly
M0068502110	Advantage Fit™ System	1 Delivery Device and 1 Mesh Assembly
M0068502050	Advantage™ Blue System	1 Delivery Device and 1 Mesh Assembly
M0068502000	Advantage™ System	1 Delivery Device and 1 Mesh Assembly

1. Moali, Pamela, et al. Tensile properties of five commonly used mid-urethral slings relative to the TVT™
Int Urogynecol J (2008) 19:655–663 DOI 10.1007/s00192-007-0499-1.
2. As compared to Advantage™ Transvaginal Mid-Urethral Sling.

Caution: For Female Mid-Urethral Slings: Federal (US) 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.

The following adverse events have been reported due to suburethral sling placement, any of which may be ongoing, but are not limited to: As with all implants, local irritation at the wound site and/or a foreign body response may occur, Foreign body reaction may be acute or chronic, Pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia) (acute or chronic), Dyspareunia, Tissue responses to the mesh implant could include: erosion into organs (urethra, bladder or other surrounding tissues); exposure/extrusion into the vagina, Mesh contact with urine via erosion/exposure/extrusion may result in stone formation, scarring/scar contracture, Necrosis, fistula formation (acute or chronic), inflammation (acute or chronic), Mesh contracture, Tissue contracture, Vaginal shortening or stenosis that may result in dyspareunia and/or sexual dysfunction, Pain with intercourse that may not resolve, Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Sexual dysfunction, including the inability to have intercourse. Like all foreign bodies, the mesh may potentiate an existing infection. Allergic reaction has been reported. Known risks of surgical procedures for the treatment of incontinence include: pain, ongoing pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia), Severe, chronic pain, Aparaunia, Leg weakness, Infection, De novo detrusor instability, Complete failure of the procedure/failure to resolve a patient's stress urinary incontinence, Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention), Bruising, bleeding (vaginal, hematoma formation), Abscess, Vaginal discharge, Dehiscence of vaginal incision, Edema and erythema at the wound site, Perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement. The following additional adverse events have been reported for the Solyx SIS System: Dysuria, Hematuria. The occurrence of these events may require surgical intervention and possible removal of the entire mesh. In some instances, these events may persist as a permanent condition after surgical intervention or other treatment. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

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

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