Pinnacle™

Pelvic Floor Repair Kit - Anterior/Apical

Boston Scientific

Delivering what's next.™

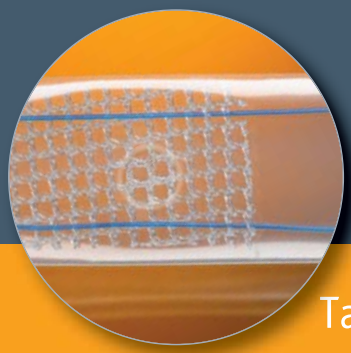
Pinnacle™ Pelvic Floor Repair Kit

Pinnacle Pelvic Floor Repair (PFR) Kit, Anterior/Apical is designed to repair multiple pelvic floor defects, streamlining surgery and eliminating blind trocar passes.

The Kit includes custom enhancements of proven technology, a Polyform® Synthetic Mesh Assembly and Capio® Suture Capture Device. Designed to anchor the mesh through the sacrospinous ligament (SSL), the gold standard fixation point, the Pinnacle Mesh is another Boston Scientific dynamic refinement in PFR.

Facilitates precise mesh leg placement

Leader Loop

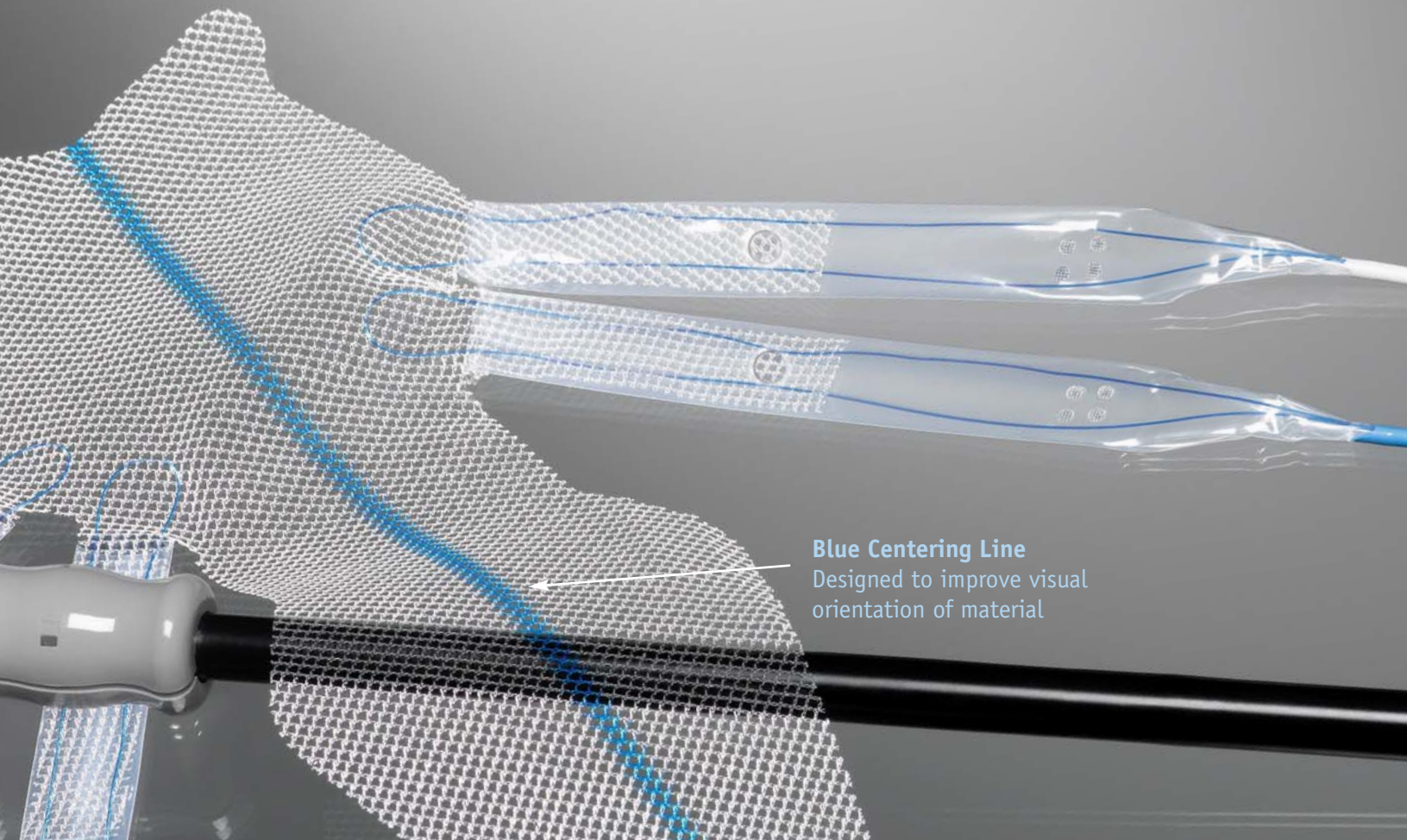


A simple solution to hold the mesh leg within the sleeve

Tack Weld

Pinnacle Mesh Leg Assembly

Designed to facilitate passage of the Pinnacle Synthetic Mesh Assembly through bodily tissues for placement through the SSL and arcus tendineous fascia pelvis. The Anterior/Apical mesh implant has four legs (sacrospinous ligament and arcus tendineous). Anterior and posterior portions can be trimmed to custom length.

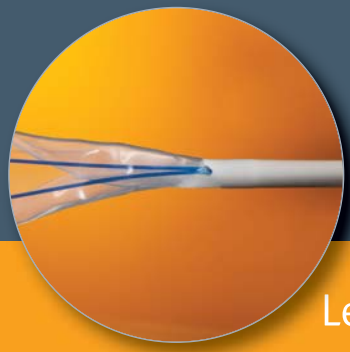


Polyform® Synthetic Mesh

Polyform Mesh is made from uncoated monofilament macroporous Polypropylene. This material has had a history of success in various parts of the body for over 30 years[1]. The goal was to improve upon this well known material and make it softer, smoother, thinner, and lighter with increased stretch compared to the leading synthetic mesh for pelvic organ prolapse[2].

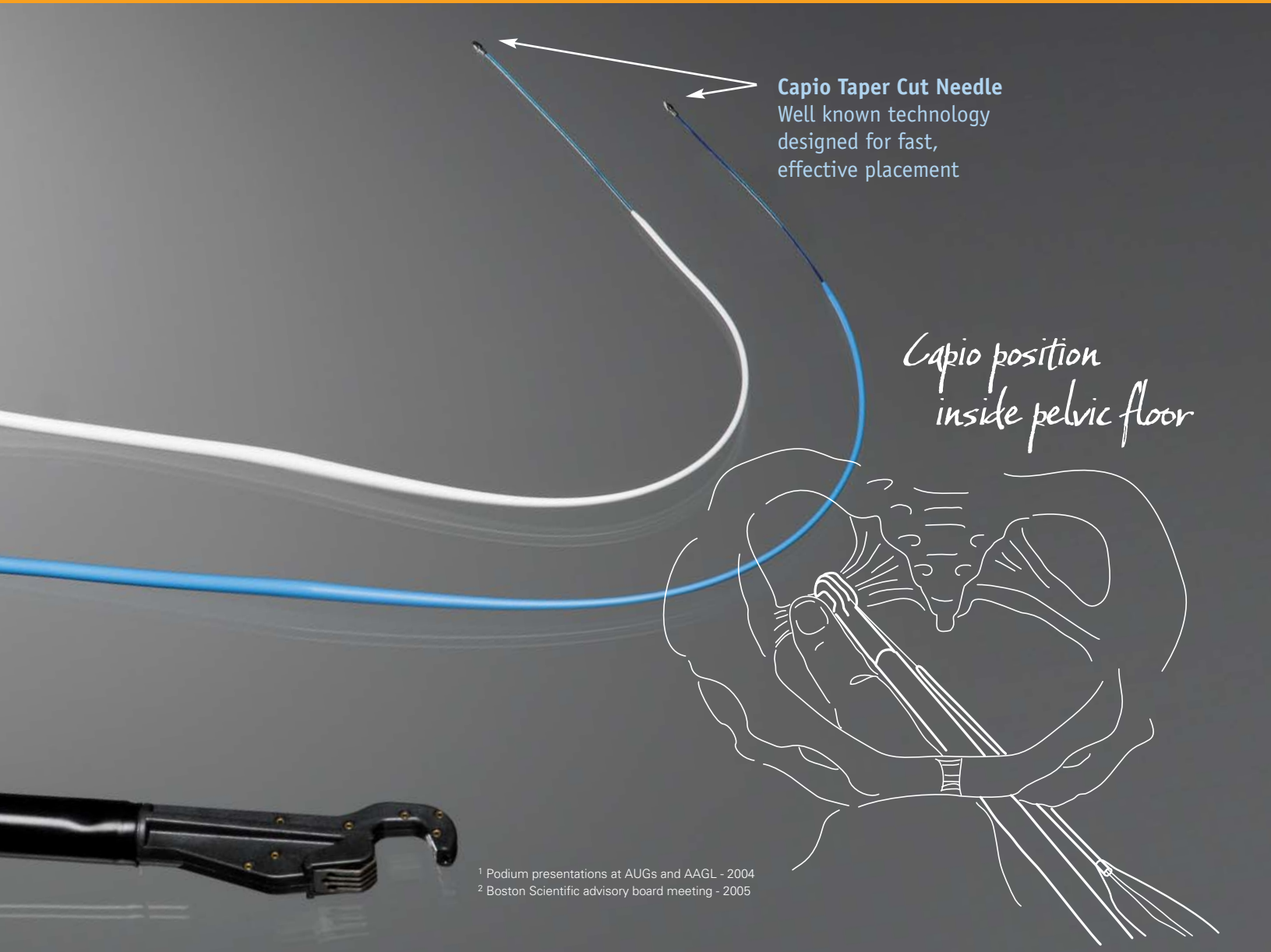
Aids access to a single lead for efficient trimming and removal of the protective sleeve

Separator Weld



White dilator defines proximal end of device for arcus tendineous placement, and blue defines distal end for placement in SSL

Lead Dilator Transition



[1] Podium presentations at AUGs and AAGL - 2004
[2] Boston Scientific advisory board meeting - 2005

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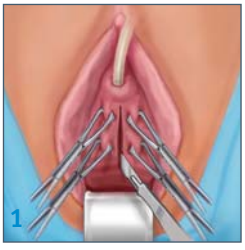
Procedural Steps

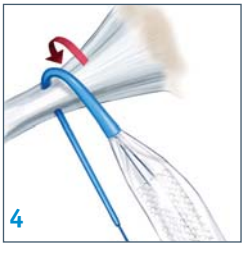


1. Dissect the anterior vaginal wall below the level of the vaginal muscularis to maintain a vascularized epithelium.

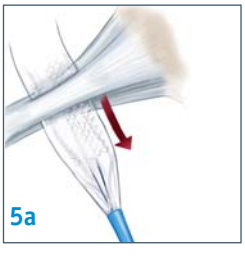
2. Insert the Capio® Device on to the desired location on the sacrospinous ligament medial to the ischial spine and hold in place with gentle pressure. For initial adjustment remove the Capio Device from the incision pulling the needle, lead, and dilator through the tissue thereby bringing the protective sleeve into the ligament. Pull the dilator into view and remove the slack on the remainder of the leg.

   This step is repeated on the contralateral sacrospinous ligament.

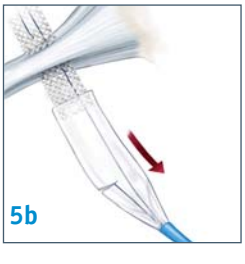
3. Reinsert the loaded Capio Device into the incision and position at the desired location of the arcus tendineous where the lead is to be placed. Hold in place with gentle pressure. The deepest portion of the arcus tendineous adjacent to the ischial spine has the most significant connective tissue for mesh fixation. This step is repeated on the contralateral arcus tendineous.



4. For final adjustment advance each of the mesh leg assemblies individually until the desired support is achieved. The sleeve may not pass completely through the tissue during final adjustment.



5a., 5b. In order to remove the protective sleeve, identify the leader loops and cut HALF way across the width of the sleeve, such that ONLY one side of the leader loop within the protective sleeve is cut. Gently pull the leg assembly and remove the sleeve and leader, leaving only the mesh in place. The anterior implant shoulders may be custom trimmed for width and absorbable stitches may be placed to tack the mesh in place at the bladder neck.



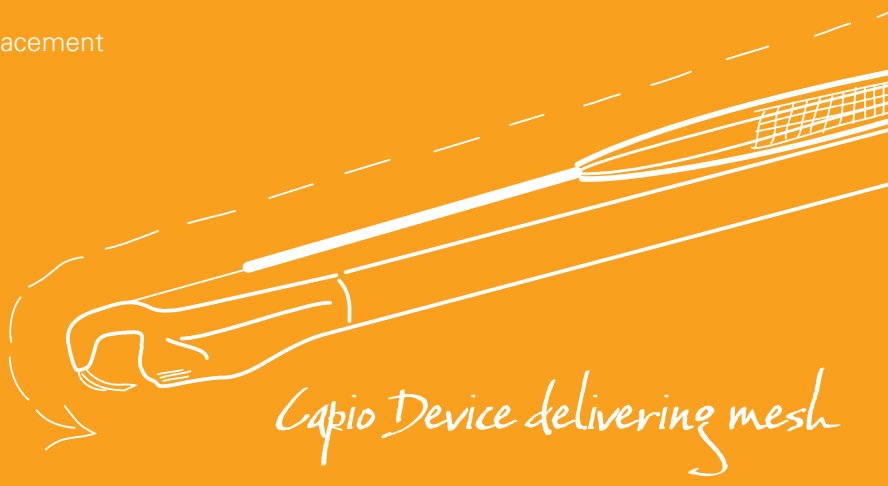
When using Pinnacle as a total repair:

6. For patients that do not have a uterus, the Pinnacle Anterior/Apical Mesh assembly may be utilized to perform a total repair. This procedure begins with dissection of the posterior vaginal wall. Good apical dissection is needed in the midline to allow creation of the tunnel that connects the anterior and posterior compartments. An instrument may be used to loosely position the mesh tail as it crosses the apex and enters the posterior compartment. After the distal posterior mesh is trimmed to custom length, additional tacking sutures are generally used to affix it to the rectovaginal septum or perineal body.

Capio®

Open Access Device

Automatically throw and place the Mesh Leg Assembly in one easy step, adjustability of the Mesh Leg Assembly provides precision control of mesh placement • Extend your reach into deep, difficult-to-access cavities for precise placement within a small incision • Increase procedural control by eliminating secondary instruments that obstruct your view of the site and restrict your freedom of movement • Facilitates precise, uniform placement



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Order Number	Description
*M006**8317050**	Pinnacle Anterior/Apical

Kit Includes: (1) Capio® Open Access Device and (1) Mesh Assembly

* Inquire for availability

Lead Loading and Removal Tips

Loading Needle into Device

Fully load needle tip into position on tip of carrier. Hold distal end of device in one hand. With the same hand, grasp needle between thumb and index finger. With the other hand, grasp lead and lay into slot on outer surface of shaft tip. Pull distal end of suture to retract needle fully into slot and onto tip of carrier.

Removing Lead from Device

Slide needle point downward to remove needle from rounded end of catch mechanism.

Boston Scientific

Delivering what's next.™

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www.bostonscientific.com/gynecology

Ordering Information
1.888.272.1001

Polyform Synthetic Mesh is manufactured by Proxy Biomedical and distributed by Boston Scientific.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.
Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effects, Warnings and Precautions prior to using this product.

BVU2460 7.5M 1/08-1/10