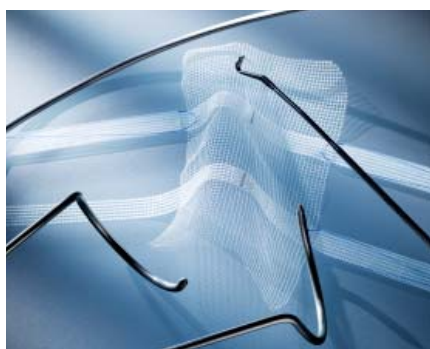
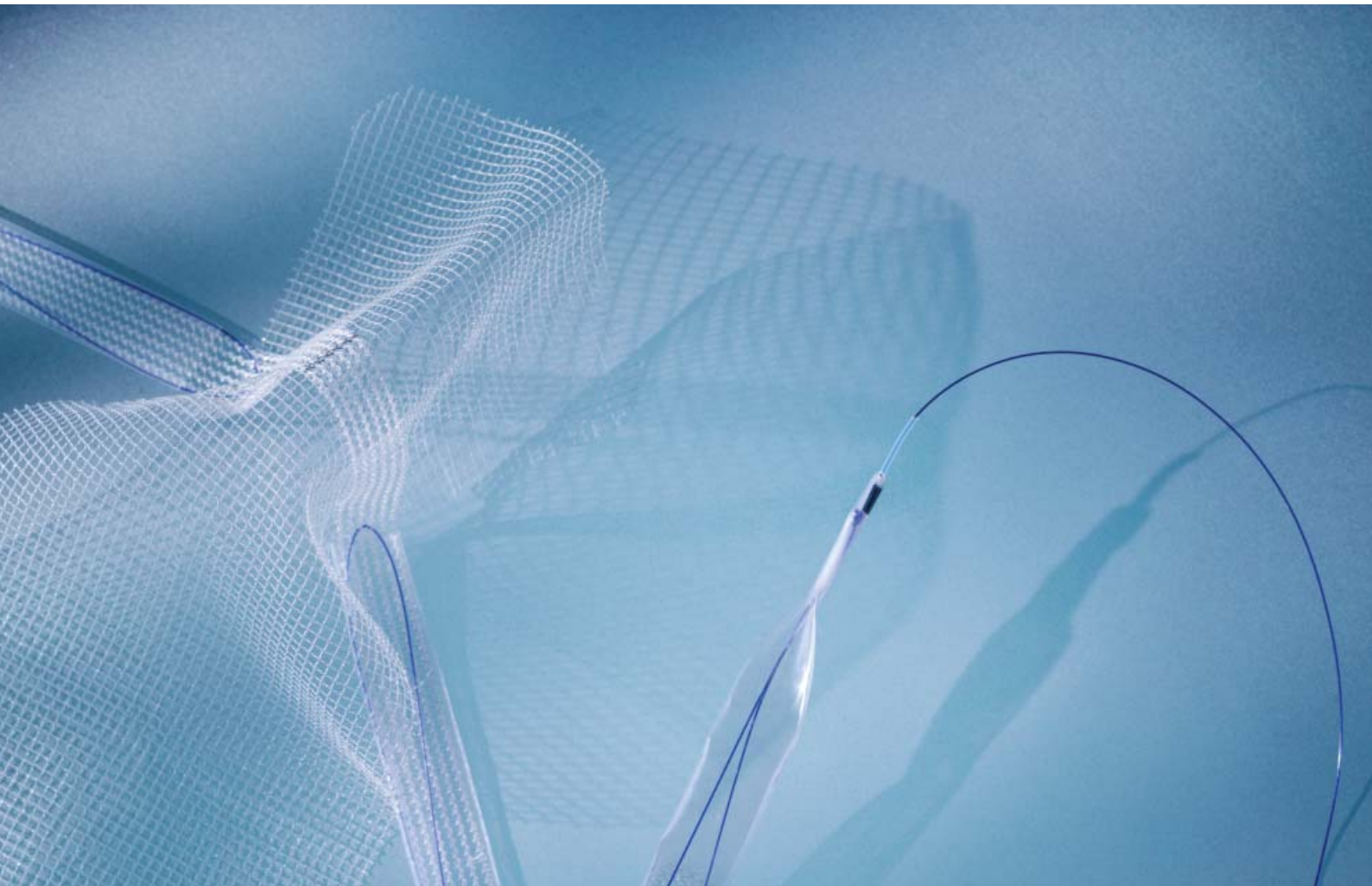


A.M.I.® Pelvic Floor Repair System

Product Group Urogynaecology | Issue 04/2010



> Comprehensive Three-Level Repair

A.M.I.'s integrated pelvic floor system* is made up of four components which offer total flexibility and the ability to customize each pelvic floor reconstruction to suit the patients' needs.

> A.M.I. CR-Mesh

For the treatment of cystocele or rectocele

> A.M.I. Multi Purpose Sling

For a wide range of applications used alone or in conjunction with the A.M.I. CR-Mesh or A.M.I. E-Mesh

> A.M.I. E-Mesh

For the treatment of enterocele

> i-Stitch

For the quick, secure fixation of suspension sutures to structures that are not easily accessible

* A.M.I. Anatomic Pelvic Floor Repair System - patent pending

A.M.I.® Pelvic Floor Repair System

Comprehensive 3-level repair of cystocele or rectocele

The system consists of four basic products, which can be used in various combinations to provide three levels of support (apical, lateral and distal).

Apical support is achieved by placing a non-absorbable suture into the origin of the uterosacral ligament on each side. Lateral support can be restored by a combination of traditional techniques and innovative new options using integrated sling arms.

These separate apical and lateral attachments enable true restoration of the anatomy with normal vaginal length and shape.

This in turn increases the effectiveness of other procedures to remove laxity or cure intussusception. Distal reattachment is achieved with polypropylene mesh extensions around the bladder neck (anterior) or through the perineum (posterior). All components are designed for use with the versatile range of A.M.I. tunnellers, which allow placement in either direction.

This innovative combination of prostheses reflects the varying functional requirements in different positions in the pelvis, and allows the surgeon complete flexibility to customize treatment to suit all patient shapes and configurations.

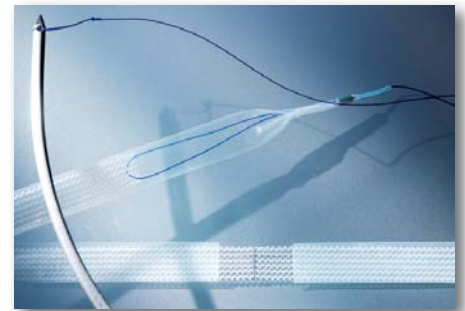
The mesh components



A.M.I. CR-Mesh



A.M.I. E-Mesh



A.M.I. Multi Purpose Sling

A.M.I. CR-Mesh

For repair of cystocele or rectocele, together with the i-Stitch level 1 attachment.

- Generous proportions enable the mesh to extend beyond the defect in every direction (all defects can be corrected)
- Medial insertion point of sling creates mesh skirt, which avoids secondary enterocele during procedure
- Distal mesh extensions create para-anal support and rebuild perineum, thereby promoting improved ano-rectal function and preventing perineal descent
- Anatomical reconstruction of posterior fornix reduces incidence of post mesh dyspareunia

Two A.M.I. CR-Meshes used together with the i-Stitch allow a full reconstruction.

A.M.I. E-Mesh

For treatment of enterocele

- Specially designed for use with the i-Stitch for level 1 reattachment when lower vaginal reconstruction is unnecessary
- Recreates apical support together with proximal trans-obturator and translevator slings

A.M.I. Multi Purpose Sling

- Posterior vaginal sling for retropubic or transobturator approach, inside/out or outside/in
- Can be used with the i-Stitch for modified bilateral sacrospinous fixation to prevent or treat high cystocele and lateral vaginal fornix defect
- Provides additional lateral attachments in any reconstructive procedure

A.M.I.® Pelvic Floor Repair System

Full reconstruction - anterior and posterior vaginal wall repair

Level 1 - Apical Support:

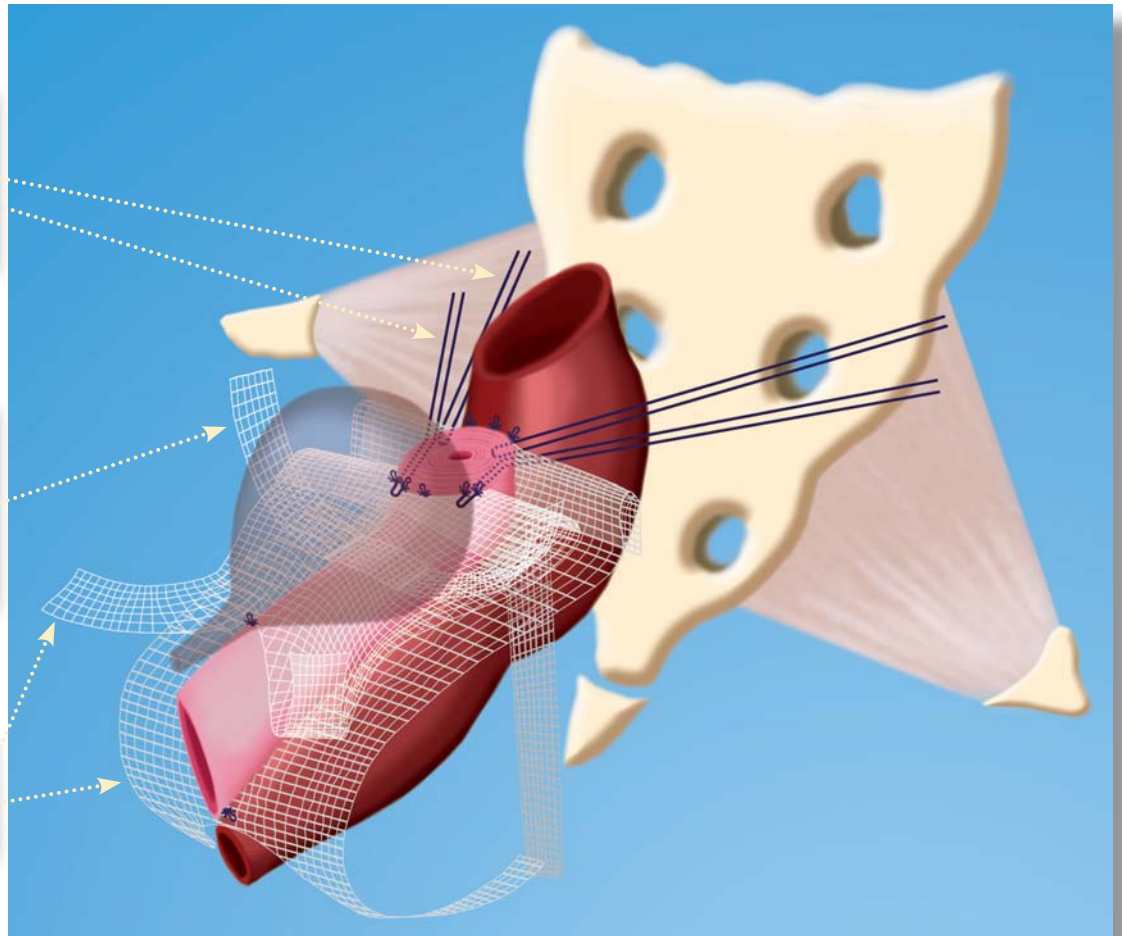
Provided by sutures suspended between top of mesh and medial end of sacrospinous ligament

Level 2 - Lateral Support:

Provided by sling arms for either anterior vaginal wall (cystocele) or posterior vaginal wall (rectocele), depending on placement

Level 3 - Distal Support:

Provided by two distal mesh extensions



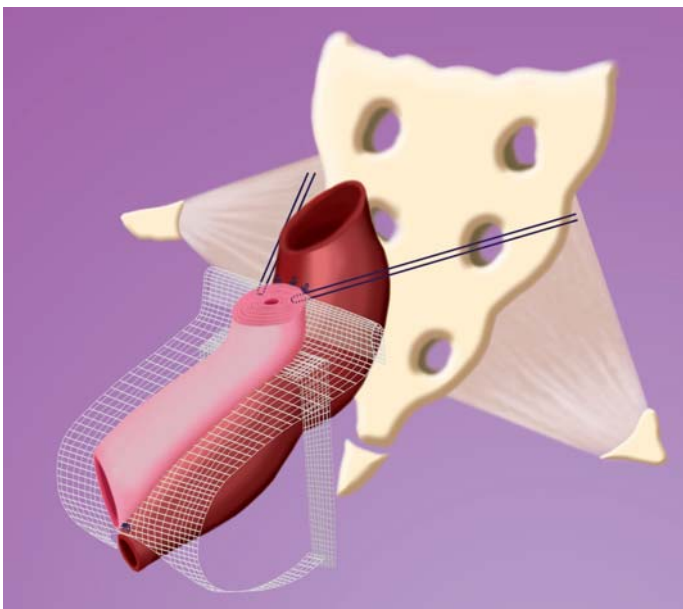
- Mesh body and distal extensions of ultralight, wide-pore bio-compatible material that is soft on tissue and allows optimal tissue ingrowth.

- Proximal sling arms recreate the firm, stable, virtually non-elastic support supplied by ligaments.

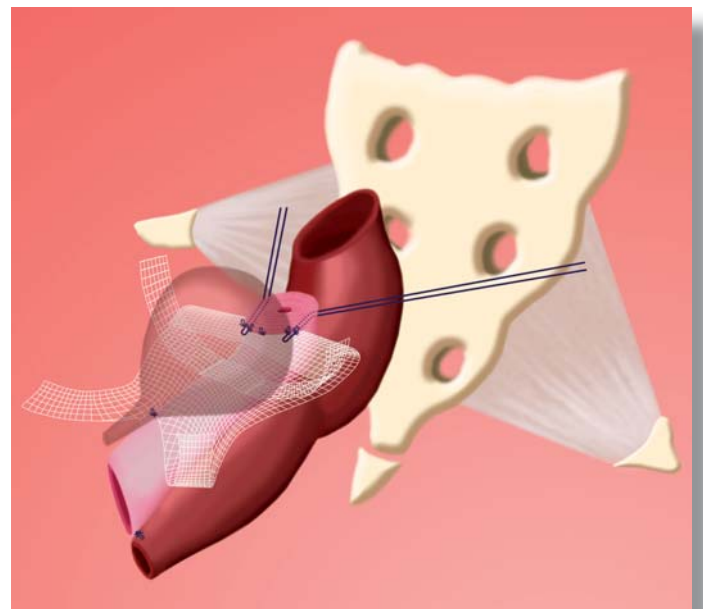
- Innovative construction with no glue, rivets or sutures reduces risk of infection and erosion.

- Temporary holding sutures connect the stable sling arms with the edge of the mesh body, thereby facilitating mesh stability and preventing distortion during placement.

Posterior vaginal wall repair



Anterior vaginal wall repair



A.M.I.[®] Pelvic Floor Repair System

| Order Code | A.M.I. APFR System | Technical Details |
|--------------------------------|--|---|
| PFR5021 | A.M.I. Multi Purpose Sling Polypropylene mesh sling for a wide range of applications in the treatment of pelvic floor disorders | Single-use, delivered sterile 1 sling |
| PFR5041 | A.M.I. CR-Mesh Body of polypropylene mesh with integrated sling for treatment of anterior or posterior compartment vaginal prolapse | Single-use, delivered sterile 1 mesh |
| PFR5081 | A.M.I. CR-Mesh Set (Single) Set consists of A.M.I. CR-Mesh (PFR5041) and 2 i-Stitch Loading Units PP 0 (IST1011) for treatment of anterior or posterior compartment vaginal prolapse | All single-use items, delivered sterile 1 mesh and 2 loading units in one box |
| PFR5401 | A.M.I. CR-Mesh (Total) 2 A.M.I. CR-Meshes (PFR5041) for total repair of anterior and posterior compartment vaginal prolapse | Single-use, delivered sterile 2 meshes in one box |
| PFR5091 | A.M.I. CR-Mesh Set (Total) Set consists of 2 A.M.I. CR-Meshes (PFR5041) and 4 i-Stitch Loading Units PP 0 (IST1011) for total repair | All single-use items, delivered sterile 2 meshes and 4 loading units in one box |
| PFR5121 | A.M.I. E-Mesh Repair Set Set consists of A.M.I. E-Mesh and 4 i-Stitch Loading Units PP 0 (IST1011) for treatment of enterocele Polypropylene mesh body with 2 integrated slings | All single-use items, delivered sterile 1 mesh and 4 loading units in one box |
| A.M.I. i-Stitch System | | |
| IST1010 | i-Stitch Reusable instrument for quick, secure fixation of suspension sutures to structures For use with the i-Stitch Loading Unit | Delivered non-sterile, steam autoclavable 1 instrument |
| IST1011 | i-Stitch Loading Unit PP 0 Combination of hollow needle, slider and specially-formed suture material for single use with the i-Stitch instrument | Length: 70 cm, 0 polypropylene suture Single-use, delivered sterile 10 loading units per box |
| IST1020 | i-Stitch Cleaning Brush Brush for cleaning the i-Stitch instrument | Reusable, delivered non-sterile 2 brushes per box |
| A.M.I. TVA / TOA System | | |
| TVA5030 | A.M.I. TVA Tunneller For transvaginal or retropubic approach | Length: 273 mm Delivered non-sterile, steam autoclavable 1 tunneller |
| TOA5130 | A.M.I. TOA Tunneller For outside-in transobturatoric approach | Length: 245 mm Delivered non-sterile, steam autoclavable 2 tunellers per box (left and right) |
| TOA5140 | A.M.I. TOA Tunneller Universal For outside-in and inside-out transobturatoric approach | Length: 229 mm Delivered non-sterile, steam autoclavable 2 tunellers per box (left and right) |

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