

An ingenious combination:

- an ultra-lightweight mesh (21 g/m²)
- total implant weight of just 150 mg (standard size)
- a single-incision procedure
- 3-level support

It's InGYNious. Why settle for anything less?

InGYNious

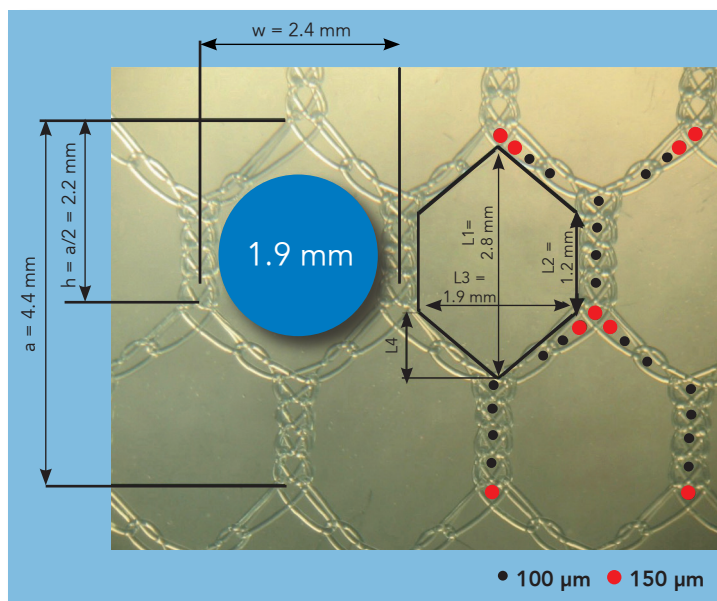
Just one incision and an ultralight mesh...

...enable a total pelvic floor reconstruction with 3-level support in the gentlest possible way.

Where's the genius in it?

A.M.I. has combined the ideal material with an innovative form of 6-point suture fixation (3-level support) to allow the effective repair of various pelvic floor defects through one single incision.

The material



Largest pores:
 $\geq 1.9 \text{ mm}$

Highest porosity:
93%

The mesh of monofilament polypropylene is ultralight in weight (21 g/m^2), with a wide-pore, hexagonal structure that lends the material a high degree of isoelasticity. Together, these features theoretically promote rapid tissue integration and reduce foreign body reaction in the very elastic vaginal tissue, as well as inducing the formation of mature collagen. Thus the defect is provided with a natural, very gentle means of support.

Mesh specifications at a glance:

- | | | |
|--|----------------------------|-------------------------|
| - Ultra-lightweight (21 g/m^2) | - Pore diameter (minimal): | 1.9 mm |
| - Monofilament polypropylene | (maximum): | 2.8 mm |
| | - Extra large micropores: | 100 - 150 μm |

Ultra-lightweight + optimised elasticity

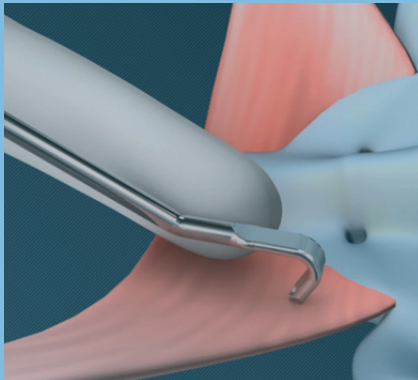
= reduced foreign body reaction

= increased patient comfort

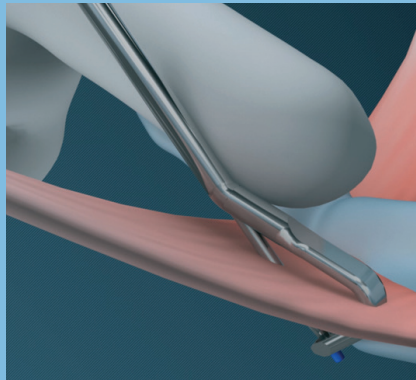
The suture fixation

Fixation to the sacrospinous ligament and suspension of the mesh is performed with the i-Stitch, an instrument for the safe, fast and minimally-invasive placement of sutures in hard-to-reach areas. The i-Stitch is designed for easy operation with just one hand.

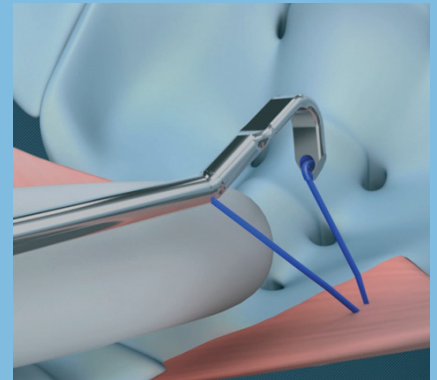
Example: i-Stitch for transvaginal sacrospinous fixation



Using the forefinger, the surgeon guides the i-Stitch into the desired position. The tip of the instrument is then pushed into the ligament.



By applying gentle pressure with the thumb, the tip of the loading unit is pushed all the way through until a click can be heard.



With the suture firmly attached to the tissue, the loading unit is drawn back and the instrument tip pulled away from the site. The suture stays in position.

Together with the i-Stitch, three different shapes and two sizes of mesh allow treatment of a wide range of pelvic floor defects. Level 1 support is created by a suspension suture connecting the apex of the InGYNious mesh - and therefore the apex of the vagina - with the sacrospinous ligament. For level 2 and level 3 support, labelled, colour-coded suture guides indicate at which points the mesh should be attached to the tendinous arch of pelvic fascia or muscular tissue. The correct fixation points vary, depending on which compartment is treated and which shape of mesh is being used.

To secure the mesh, the i-Stitch is inserted through the vagina - thus eliminating the need for "blind" tunnelling. This reduces the risk of intraoperative bleeding and trauma, and increases the patient's chance of a speedy recovery. i-Stitch is available in two different models - one for penetration from above and the other with the tip rotated 180° to allow a comfortable approach from underneath. As with the suture guides, the i-Stitch suture material is colour-coded according to the different levels of support.

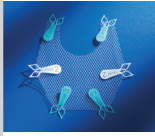



New improved design!


Stronger tip
Stability of shaft increased
Handle made of stainless steel



Advantages of the i-Stitch:

- Secure attachment of sutures
- Blunt, non-cutting suture end for pushing through tissue
- Reduced risk of bleeding from the suture puncture site
- Safe and quick, even in hard-to-reach places

For ANTERIOR vaginal wall prolapse			For POSTERIOR vaginal wall prolapse		
Size	Polyester sutures	Polypropylene sutures	Size	Polyester sutures	Polypropylene sutures
Standard	IGY5961 InGYNious D A S	IGY5561 InGYNious D A S-PP	Standard	IGY5981 InGYNious D P S	IGY5581 InGYNious D P S-PP
	1 x mesh 2 x IST1031 4 x IST1041 1 box, all items delivered sterile	1 x mesh 6 x IST1011 1 box, all items delivered sterile		1 x mesh 2 x IST1031 2 x IST1041 1 box, all items delivered sterile	1 x mesh 4 x IST1011 1 box, all items delivered sterile
Large	IGY5951 InGYNious D A L	IGY5551 InGYNious D A L-PP	Large	IGY5971 InGYNious D P L	IGY5571 InGYNious D P L-PP
	1 x mesh 2 x IST1031 4 x IST1041 1 box, all items delivered sterile	1 x mesh 6 x IST1011 1 box, all items delivered sterile		1 x mesh 2 x IST1031 2 x IST1041 1 box, all items delivered sterile	1 x mesh 4 x IST1011 1 box, all items delivered sterile

Order Code	Product	Technical Details
IGY5921	InGYNious V For vaginal vault prolapse, anterior mesh 1 x mesh 2 x i-Stitch Loading Unit PET 0 W (IST1031) 4 x i-Stitch Loading Unit PET 0 G (IST1041)	Mesh of ultra-lightweight polypropylene Suture material: Polyester (PET), green/white Size - USP 0 1 box, all items delivered sterile
IST1010	i-Stitch Reusable instrument for quick, secure fixation of suture material to tissue For use with the i-Stitch Loading Units	Delivered non-sterile Steam autoclavable 1 instrument
IST1040	i-Stitch up Instrument tip rotated 180°	Delivered non-sterile Steam autoclavable 1 instrument
	i-Stitch Loading Units Combination of hollow needle, slider and specially-formed suture material for use with the i-Stitch	10 units / box, delivered sterile Length: 70 cm
IST1011	i-Stitch Loading Unit PP 0	Polypropylene, size USP 0, non-absorbable
IST1031	i-Stitch Loading Unit PET 0 W	White
IST1041	i-Stitch Loading Unit PET 0 G	Green Material: Non-absorbable polyester (PET) Size: USP 0 Length: 70 cm 10 units / box, delivered sterile

International patent filed / pending / granted

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