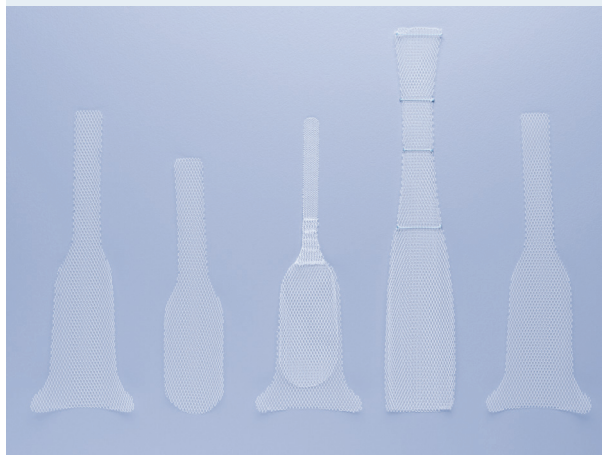
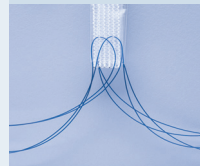


InGYNious
BSC Mesh
i-Stitch
ProGYNious
EndoGYNious
PelviGYNious
sensiTVT
sensiTVT-A
A.M.I. TVA Sling
A.M.I. TOA Sling
A.M.I. Multi Purpose Sling
Tunneller
i-Cut
More-Cell-Safe



Solutions for **Urogynecology**

A.M.I.[®]

Agency for Medical Innovations

Urogynecology

Empowering Innovation.
Empowering Lives.

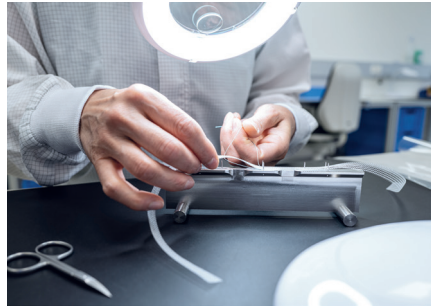
As a leading-edge technology company, A.M.I. Agency for Medical Innovations GmbH develops and manufactures high-quality medical products for surgeons and hospitals around the world. Through innovative surgical techniques in the fields of Coloproctology, Urology and Urogynecology, our products offer less pain and discomfort as well as higher safety for patients.

To assure the highest standards, our team collaborates with internationally recognized experts and surgeons. In this way, we will continue significant progress in innovative surgery.

Innovative solutions

for improved quality of life.





Precision from Austria

Made in Europe.



Our company

- Is a leading-edge manufacturer of medical technology with headquarters in Austria
- Over 20 years of experience in the fields of Coloproctology, Urology and Urogynecology
- High quality manufacturing in Europe
- Subsidiaries in Germany, France and USA
- Worldwide distribution network
- Development and manufacturing partner for medical technology companies with core competencies in precision mechanics, as well as plastics and silicone processing

Our vision

- Development of innovative products for pain-reducing, minimally invasive surgical methods
- Meeting the highest quality requirements of surgeons and patients
- Creating and implementing innovative ideas through close cooperation with experts, surgeons, technicians and scientists
- Our professional sales team continuously engages in constructive exchanges and consultations with our users
- A constant commitment to optimizing all processes related to development, production and service

A.M.I. offers various solutions for Urogynecology:

Treatment of Pelvic Organ Prolapse 04

Single-incision vaginal mesh procedure:

InGYNious	10
BSC Mesh	11
i-Stitch	12

Laparoscopic mesh procedure:

ProGYNious	13
PelviGYNious	14
EndoGYNious	15

Treatment of Stress Urinary Incontinence 16

Retropubic and transobturator mid-urethral sling procedure:

sensiTVT	20
sensiTVT-A	21
A.M.I. TVA Sling	22
A.M.I. TOA Sling	22
A.M.I. Multi Purpose Sling	23
Tunneller	24

Contained Laparoscopic Power Morcellation 25

Laparoscopic power morcellation:

i-Cut	27
-------	----

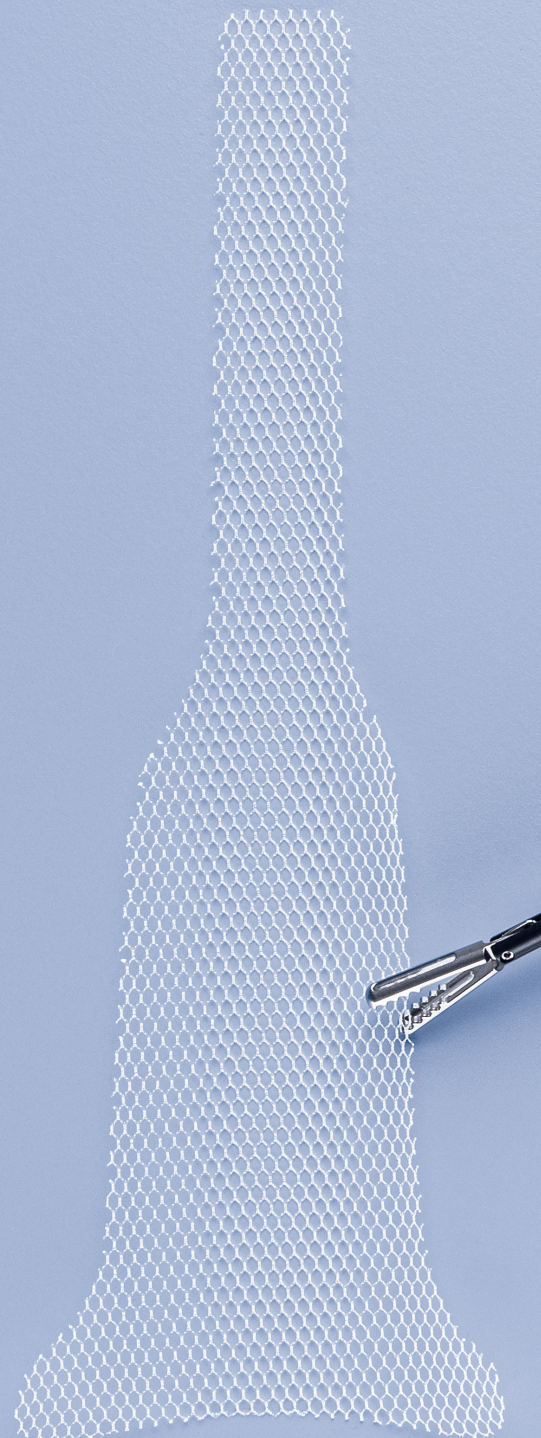
Containment bag system for power morcellation:

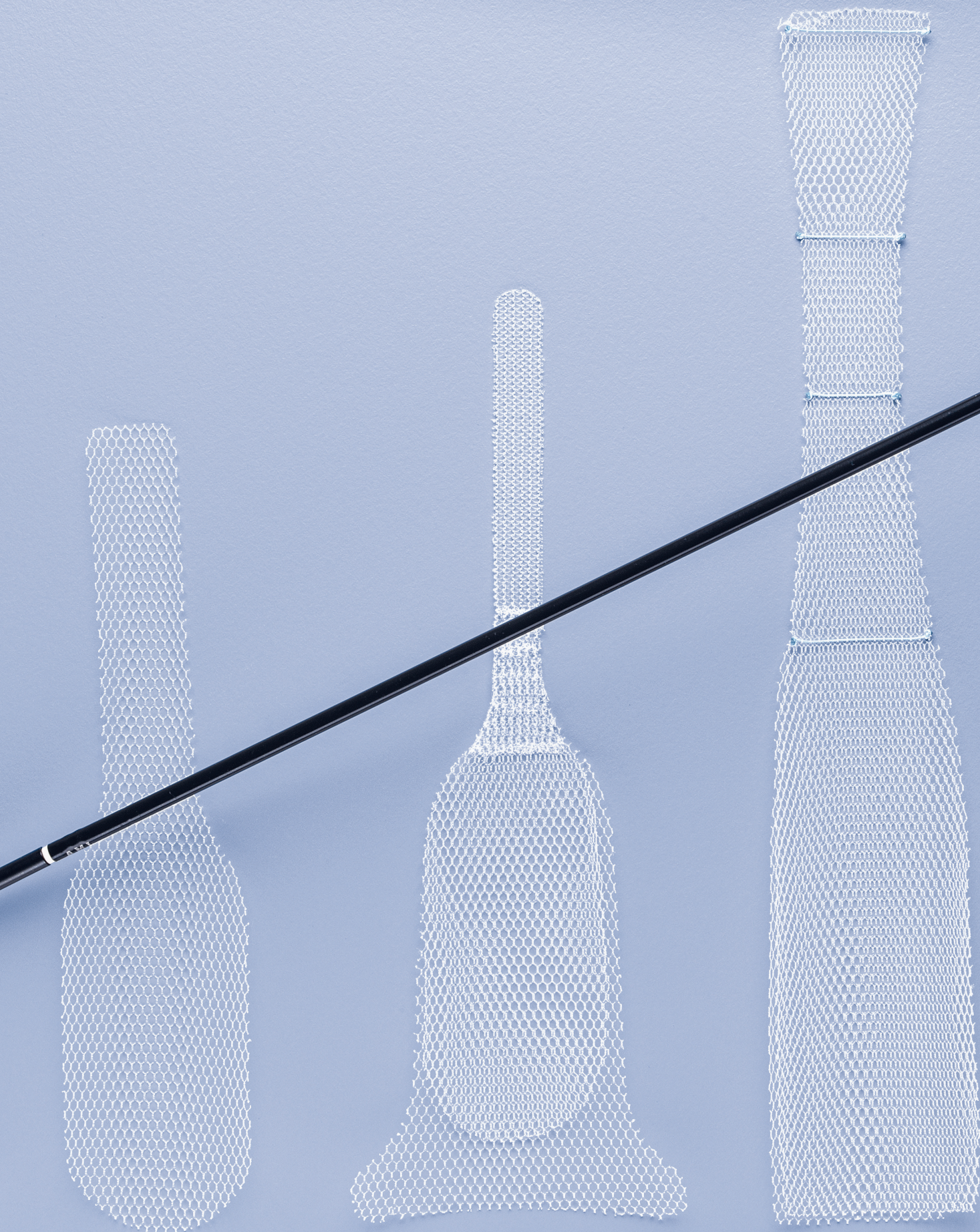
More-Cell-Safe	28
----------------	----

Treatment of **Pelvic Organ Prolapse**

Within the pelvic floor, the organs are held in place by ligaments, muscles and other connective tissue that help form a support structure. When this structure weakens, this may cause displacement of these organs from their natural position, also effecting nearby organs and tissues. Primary Pelvic Organ Prolapse (POP) occurs in up to 50% of women.¹

Surgical mesh prosthesis are used within reconstructive surgery in the field of gynecology for the treatment of urogenital prolapse in women.





A.M.I. offers a wide range of solutions for transvaginal and laparoscopic mesh procedures.

Unique

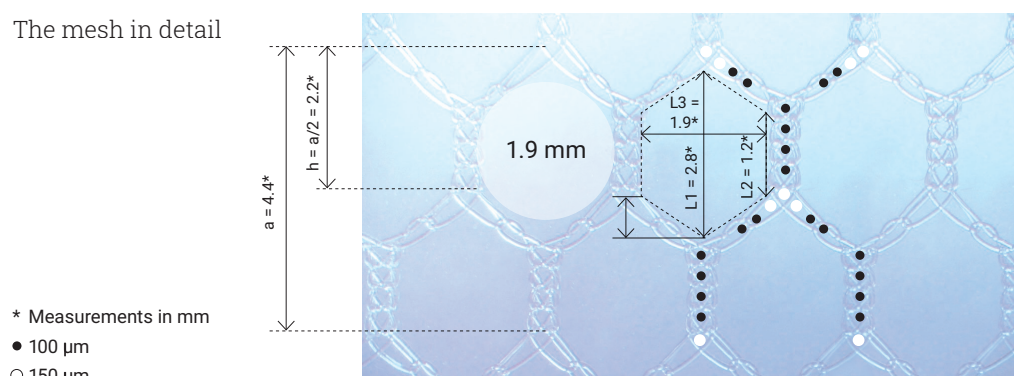
Pore for pore.

The A.M.I. HexaPro mesh.

What makes the A.M.I. HexaPro mesh material unique:

Hexagonal structure	Ultra-lightweight: 21g/m ²	Wide-pore structure (macroporous): Pore size: ≥ 1.9 mm
↓	Biocompatible	Extra-large interstitial micropores: 100-150 μ m
	↓	93% porosity
		Monofilament polypropylene
		↓
High degree of iso-elasticity	Rapid anatomical integration into human tissue	Reduce foreign body tissue reaction
Maintains vaginal elasticity and function	Decrease of chronic pain ^{2,3,4,5}	Less rigid scar tissue, shrinkage and chronic inflammatory reactions ^{2,3,4,5}
	Stability in shape ⁶	

The mesh in detail



Overview

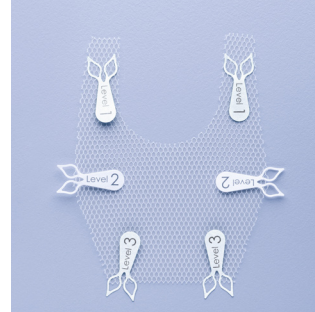
Treatment of Pelvic Organ Prolapse

Surgical approach

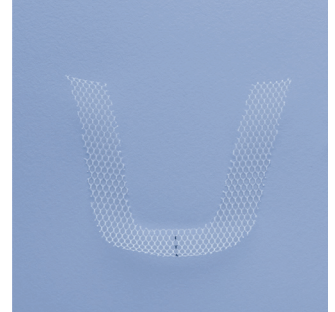
Transvaginal
single-incision

Transvaginal
single-incision

InGYNious



BSC Mesh



A.M.I. mesh implants

InGYNious offers a 3-level support. It is a six-point fixation mesh which allows effective repair of various pelvic floor defects through a single vaginal incision to enable a total pelvic floor reconstruction.

The BSC Mesh provides bilateral support for female pelvic organ prolapse by restoring the function of weakened pelvic ligaments. It enables a minimally invasive procedure using a small vaginal dissection and secure fixation to the sacrospinous ligaments with A.M.I.'s suture instrument i-Stitch

Treatment options

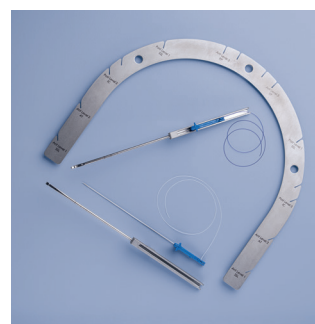
Cervical-, Vaginal Vault- or Uterine Prolapse, Cystocele or Rectocele

Cervical-, Vaginal Vault- or Uterine Prolapse

+ Combinable A.M.I. Products

i-Stitch, i-Stitch up
i-Stitch Loading units
InGYNious Bar

i-Stitch
i-Stitch loading unit



Laparoscopic mesh procedure

Laparoscopic mesh procedure

Laparoscopic mesh procedure

ProGYNious



ProGYNious is made from two types of polypropylene mesh. Ultra-lightweight material for the mesh body and a firmer, denser one for the mesh neck. It is applicable for the well-established procedures sacrocolpopexy and sacrocervicopexy.

Surgical treatment (laparotomy or laparoscopic approach) of pelvic floor prolapse

PelviGYNious



PelviGYNious consists of two, differently shaped meshes (anterior and posterior). It is applicable for the well-established procedures sacrocolpopexy and sacrocervicopexy.

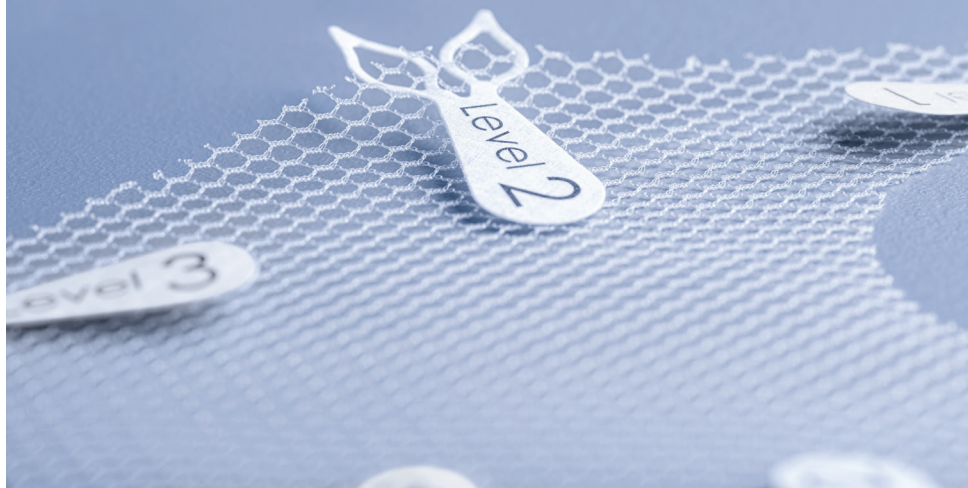
Surgical treatment of POP in apical, anterior and posterior compartment

EndoGYNious



EndoGYNious is a Y-shaped mesh applicable for the well-established procedures sacrocolpopexy and sacrocervicopexy. The proximal end is double-layered for a firm fixation.

Surgical treatment of POP in apical, anterior and posterior compartment



Single-incision vaginal mesh procedure

InGYNious 3-level support.

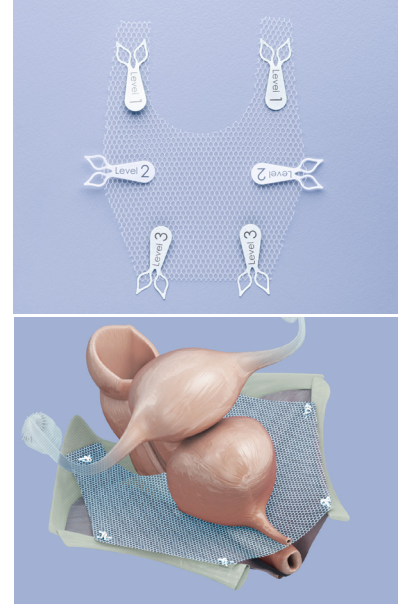
Together with a suitable suture instrument (e.g. A.M.I. i-Stitch), the InGYNious implant meshes allow apical (Level 1), fascial (Level 2) and distal (Level 3) support. Labelled, suture navigators indicate at which points the mesh should be attached to the tendinous arch, pelvic fascia or muscular tissue. The correct fixation points vary, depending on which compartment is treated and which shape of mesh is being used.

Features

- Implantation via transvaginal approach
- Multi-level mesh fixation for anterior and posterior mesh
- Implant is made of lightweight, wide-pore, biocompatible monofilament mesh material
- The range of implants offers flexibility in implant size and compartment to suit the patients' needs

Benefits ^{7, 8, 9, 10, 11}

- InGYNious can successfully cure pelvic organ prolapse in more than 90% of patients (in 36 months follow-up)
- InGYNious has low rates of erosion (<2% in 36 months follow-up)
- InGYNious significantly improves quality of life (in a 36 months follow-up)



Indication of InGYNious

Transvaginal reconstructive surgery of symptomatic POP with or without urinary incontinence, restricted to

Cervical prolapse

Uterine prolapse

Vaginal vault prolapse

Cystocele or Rectocele

- in complex cases
- as secondary surgical treatment
- in case of high risk for POP recurrence

Select the right InGYNious for your patients' needs

InGYNious has been developed in different sizes and variants to offer the best solution for the patient:

- Two sizes: Standard (S) and Large (L)
- Different variants for anterior and posterior compartments

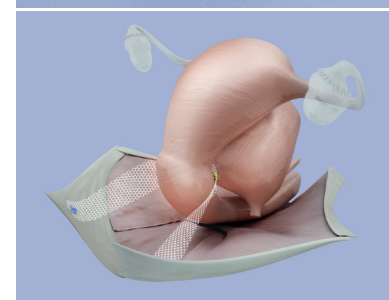
Clinical Data

Objective success rate:

91.0 – 93.9% ^{7, 8, 9}

Patient satisfaction up to 100% ¹⁰

Erosions between 0 – 2.0% ^{7, 9, 11, 12}



Single-incision vaginal mesh procedure

BSC Mesh Bilateral Sacrospinous Colposuspension.

The BSC Mesh is made of an ultralight monofilament polypropylene mesh with hexagonal structure. It is designed to induce the formation of neo-ligaments by establishing symmetrical, bilateral suspension of the vaginal vault from the sacrospinous ligament.

It is considered a minimally invasive form of correction for pelvic organ prolapse, as a vaginal dissection of just the size of the surgeon's finger is necessary to position the implant and fix it to the sacrospinous ligament by means of suitable suture instruments (e.g. A.M.I. i-Stitch).

Features

- Considered as a minimally invasive form of correction for POP
- Neo-ligament resuspends apical vaginal vault bilaterally to the sacrospinous ligament (Level 1 defect according to DeLancey)
- BSC Mesh can be fixed to the cervix/vaginal vault anterior or posterior.
- BSC Mesh can be combined with other reconstructive procedures:
 - With / without / after hysterectomy
 - With / without / after anterior / posterior colporrhaphy
 - With / without / after suburethral or transobturator sling placement

Benefits ^{6, 13}

- BSC Mesh can successfully cure pelvic organ prolapse in more than 90% of patients (in long-term follow-up with >5 years)
- BSC Mesh has low rates of erosion (<1.2% in long-term follow-up with >5 years)

Indication of BSC Mesh

Transvaginal reconstructive surgery of symptomatic POP with or without urinary incontinence, restricted to:

Cervical prolapse
Uterine prolapse
Vaginal vault prolapse

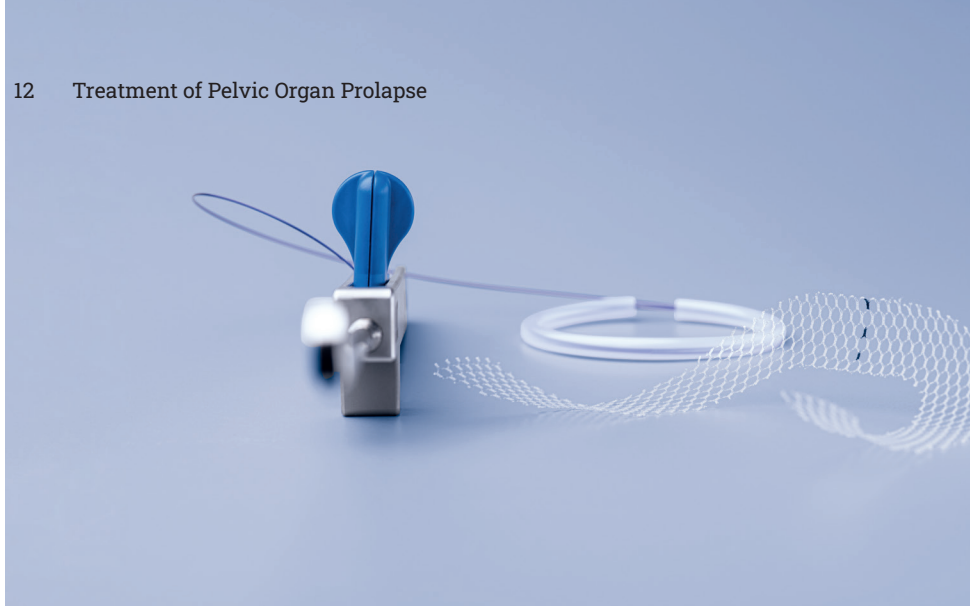
- in complex cases
- as secondary surgical treatment
- in case of high risk for POP recurrence

"[...] surgical treatment of an isolated apical defect using BSC mesh results in the subsidence of bothersome symptoms and improves the quality of life."

Zalewski et al. ¹⁷

Clinical Data

Objective success rate: 95.4% ^{6, 13}
Erosions between 0 – 1.9% ^{13, 14, 15, 16}



Instrument for native tissue repair or synthetic mesh placement

+ i-Stitch Combinable with BSC Mesh and InGYNious.

i-Stitch is a surgical instrument that is used for placing suspension sutures on tissue structures (Amreich-Richter) and/or surgical mesh implants during pelvic floor reconstruction.

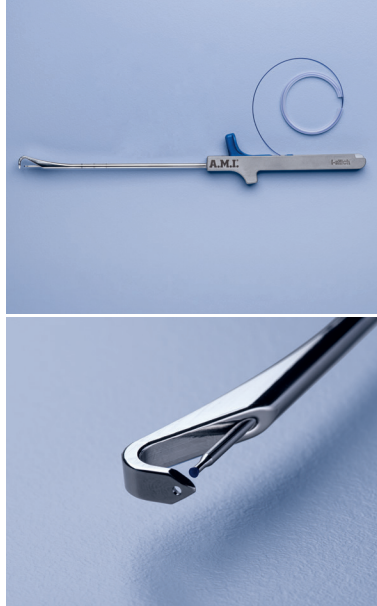
It consists of a reusable surgical instrument – i-Stitch or i-Stitch up – which, before use, must be equipped with a sterile, single-use Loading Unit carrying the surgical suture material.

Features

- Blunt, non-cutting suture tip
- Loading units with resorbable and non-resorbable suture material
- Additional suture clamp option
- Suitable cleaning accessories

Benefits 8, 10, 18, 19, 20, 21, 22

- i-Stitch ensures a safe, precise, and reproducible application for suture fixation.
- For i-Stitch application only a minimal transvaginal dissection is needed. No excessive preparation and no visualisation of the sacrospinous ligament is required.
- Very low intra-operative complications during application of i-Stitch (e.g. minimal blood loss).
- The transvaginal approach using i-Stitch lead to a reduced operating time compared to transabdominal approach in pelvic organ prolapse repair.
- i-Stitch enables an easy access for the surgeon to pelvic floor tissue structures.
- The two variants (i-Stitch and i-Stitch up) support a good usability for the surgeon. Suture placement and instrument handling is comfortable for the surgeon.



Indication

i-Stitch is indicated for pelvic floor reconstruction; for native tissue repair or synthetic mesh placement.

Available in two variants:

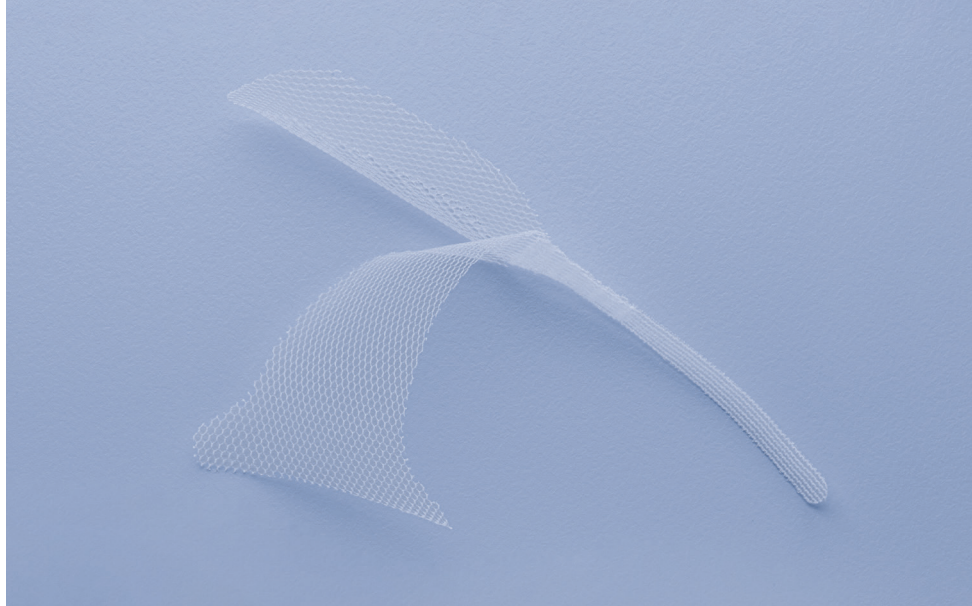
- i-Stitch: tip of i-Stitch shows in caudal direction. Usage for Level I and II.
- i-Stitch up: tip of i-Stitch up shows in cranial direction. Usage for Level III.



Animated video

“In order to fix the mesh in the pelvis in a safe and reproducible manner minimizing preparatory effort and tissue trauma the i-Stitch instrument was used.”

Brandt et al.⁸



Laparoscopic mesh procedure

ProGYNious **Lightweight mesh body** **and strong mesh neck.**

ProGYNious is a pre-shaped mesh prosthesis made of two types of polypropylene mesh material, for anatomic reconstruction of the female pelvic floor prolapse.

The lightweight hexagonal-shaped wide-pore structured mesh material is used for the mesh body, providing good tissue integration and reduction of foreign body reaction. The other firmer, denser mesh material is used for the mesh neck, ensuring strong fixation to the sacral promontory.

Features

- Implantation via laparoscopic or transabdominal (open surgery) approach
- Implant is a combination of ultra-light, large pore, soft, iso-elastic mesh at the vaginal level and a denser, less elastic mesh for firm suspension

Benefits

- ProGYNious can successfully cure patients with pelvic organ prolapse
- Low rates of erosion in a 3-month follow-up period (< 3%)
- Very low rate of intra-operative complications (< 0,5%)



Indication of ProGYNious

Surgical treatment (laparotomy or laparoscopic approach) of pelvic floor prolapse



Surgery video



Laparoscopic mesh procedure

PelviGYNious **Laparoscopic sacrocolpopexy** **and sacrocervicopexy.**

The pre-shaped mesh prosthesis is made from ultralight monofilament polypropylene with a wide pore structure to reduce foreign body tissue reaction and to allow good integration into human tissue. Hexagonal structured pores maintain vaginal elasticity and function.

The PelviGYNious consists of two, differently shaped meshes. An anterior mesh placed between vagina and bladder to prevent from recurrent cystocele, and a wider, posterior mesh between vagina and rectum to prevent from recurrent rectocele.

Features

- Implantation via laparoscopic or transabdominal (open surgery) approach
- Implant is made of lightweight, wide-pore, biocompatible monofilament-mesh material

Benefits ²³

- PelviGYNious can successfully cure patients with pelvic organ prolapse
- Low rates of erosion in a 3-month follow-up period (<3%)
- Low rates of severe post-operative pain in a 3-month follow-up period (<3%)



Indication of PelviGYNious

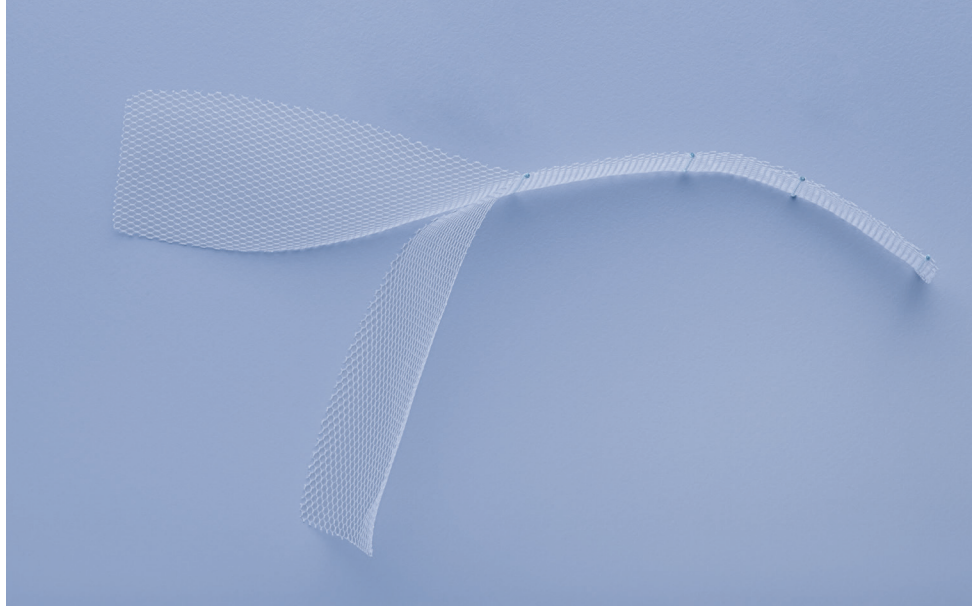
PelviGYNious is intended for the surgical treatment of symptomatic pelvic organ prolapse (POP) in the apical compartment, and, if present, in combination with either:

- anterior compartment
- posterior compartment
- both anterior and posterior compartments

where urinary incontinence may or may not be present.



Surgery video



Laparoscopic mesh procedure

EndoGYNious Y-shaped mesh for apical vaginal support.

The Y-shaped mesh prosthesis is made from ultralight monofilament polypropylene. The hexagonal structured pores maintain vaginal elasticity and function.

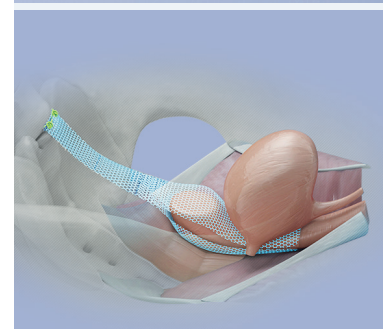
EndoGYNious is a double-layer mesh on the proximal end, for firm fixation to the longitudinal ligament at the sacral promontory level. The isoelastic single-layer mesh body, which is positioned between vagina/rectum and vagina/bladder, maintains vaginal flexibility and function and prevents the patient from recurrent cystocele and rectocele.

Features

- Implantation via laparoscopic or transabdominal (open surgery) approach
- Implant is made of lightweight, wide-pore, biocompatible monofilament mesh material

Benefits ²³

- EndoGYNious can successfully cure patients with pelvic organ prolapse
- Low rates of erosion in a 3-month follow-up period (<3%)
- Low rates of severe post-operative pain in a 3-month follow-up period (<3%)
- Very low rate of intra-operative complications (<0.5%)



Indication of EndoGYNious

EndoGYNious is intended for the surgical treatment of symptomatic pelvic organ prolapse (POP) in the apical compartment, and, if present, in combination with either:

- anterior compartment
- posterior compartment
- both anterior and posterior compartments

where urinary incontinence may or may not be present.

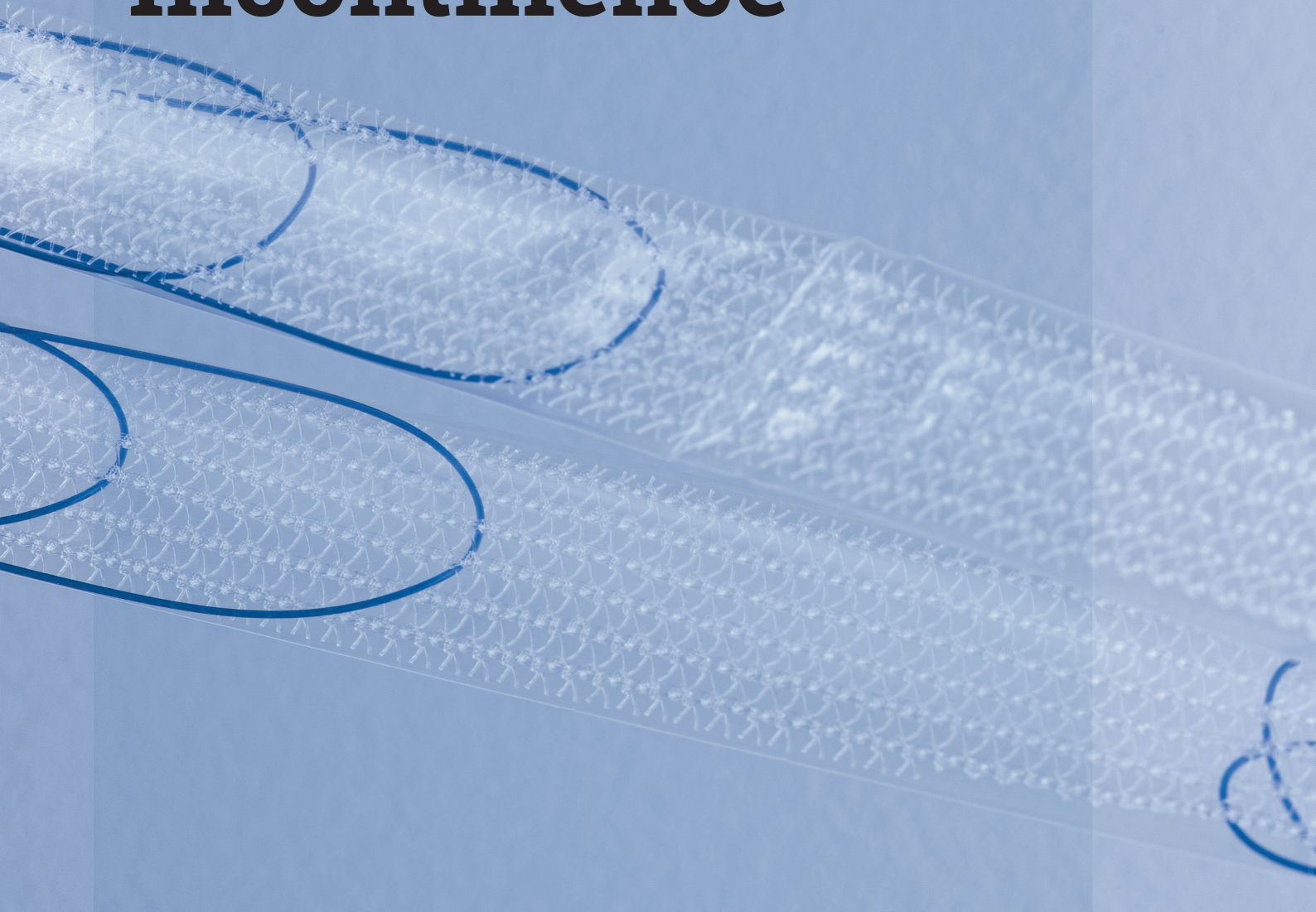


Surgery video

Stress Urinary Incontinence (SUI) can be a major cause for reducing the quality of life for women. A.M.I. offers a wide range of solutions for retropubic and transobturator mid-urethral sling procedures. The adjustable slings offer the possibility to loosen or tighten post-operatively.

Treatment of

Stress Urinary Incontinence





Overview

Treatment of Stress Urinary Incontinence (SUI)

Surgical approach

Retropubic or
Transobturator

A.M.I. Multi Purpose Sling



A.M.I. sling implants

- Midurethral sling implant
- Sling's center is positioned directly midurethral, while the lateral sling arms serve for fixation in the tissue

Indication

SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD)

+ Reusable instruments for sling implantation

A.M.I. TVA Tunneller
A.M.I. TOA Tunneller



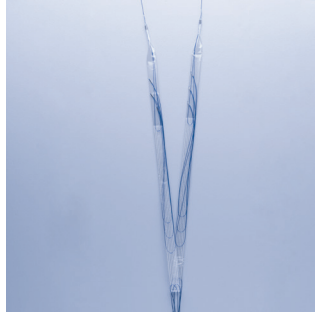
Retropubic

A.M.I. TVA Sling – Trans Vaginal Adjustable


- Midurethral sling implant with adjustment sutures
- Adjustability allows post-operatively correction of ongoing incontinence or urinary retention

SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD)

Transobturator

A.M.I. TOA Sling – Trans Obturator Adjustable


- Midurethral sling implant with adjustment sutures
- Adjustability allows post-operatively correction of ongoing incontinence or urinary retention

SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD)

Retropubic or Transobturator

sensiTVT


- Midurethral sling implant
- Implant design enables tilting of the lateral sling arms, while the slings center lays flat directly under the midurethra

SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD)

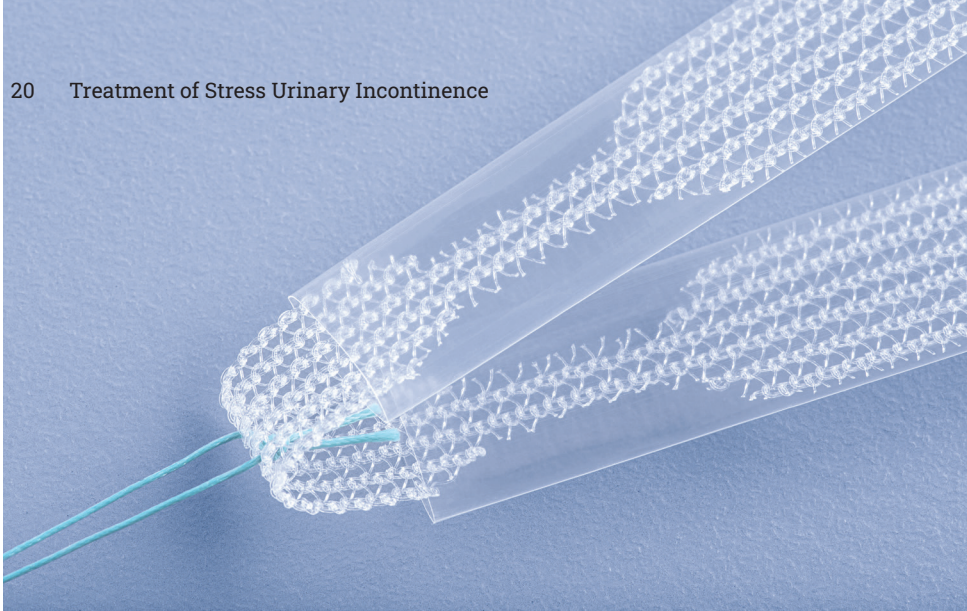
Retropubic or Transobturator

sensiTVT-A


- Midurethral sling implant with adjustment sutures
- Implant design intended to minimize edge bending toward the urethra and allows post-operative position adjustments

SUI resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD)

A.M.I. TVA Tunneller
A.M.I. TOA Tunneller
A.M.I. TVA Tunneller
A.M.I. TOA Tunneller
A.M.I. TVA Tunneller
A.M.I. TOA Tunneller

Retropubic or Transobturator

sensiTVT

Sling design intended to minimize edge bending toward the urethra

sensiTVT is a suburethral sling designed to remain flat beneath the midurethra, even when the lateral sling arms tilt.

Features

- The suburethral implant is made of a polypropylene mesh with attached pull-in sutures and a detachable pull-in aid
- sensiTVT provides midurethral support for female stress urinary incontinence. The center of the sling is intended to be positioned directly beneath the midurethra, while the lateral arms provide tissue fixation
- Implantation via retropubic or transobturator (outside-in or inside-out) approach possible

Benefits ⁶

- Efficient improvement of incontinence in female SUI patients
- The design of sensiTVT allows a rotation movement of the sling arms and a plane positioning of the sling below the urethra to avoid complications due to twisting of the sling



Indication of sensiTVT

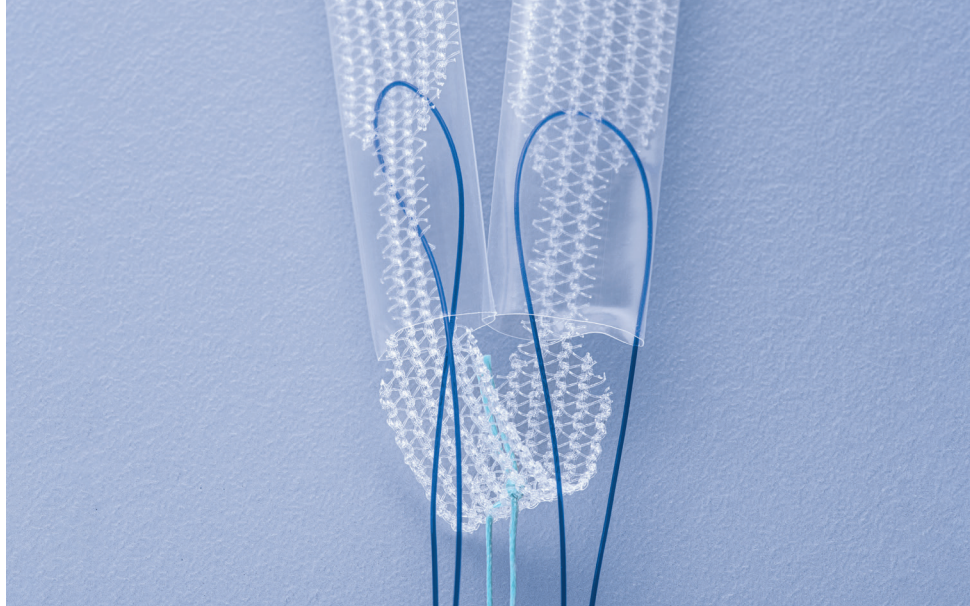
Surgical treatment of female SUI:

- Resulting from urethral hypermobility
- Resulting from intrinsic sphincter deficiency (ISD)

after failed conservative treatment methods



Animated video



Retropubic or Transobturator

sensiTVT-A

Sling design intended to minimize edge bending toward the urethra and allows post-operative position adjustments

sensiTVT-A is a suburethral sling designed to remain flat beneath the midurethra, even when the lateral sling arms tilt.

Features

- The adjustable suburethral implant is made of a polypropylene mesh with attached pull-in sutures, adjustment sutures and a detachable pull-in aid
- sensiTVT-A provides midurethral support for female stress urinary incontinence. The center of the sling is intended to be positioned directly beneath the midurethra, while the lateral arms provide tissue fixation.
- Special adjustment sutures allow small postoperative adaption up to 5 days in case of ongoing incontinence or urinary retention.
- Adjustment is in both directions possible. Cranial direction (tightening) in case of persisting incontinence and caudal direction (loosening) in case of over-correction (urinary retention)
- Implantation via retropubic or transobturator (outside-in or inside-out) approach possible

Benefits ⁶

- Possibility to adjust the implant post-operatively to improve efficacy without increased risk of complications
- Efficient improvement of incontinence in female SUI patients
- The design of sensiTVT-A allows a rotation movement of the sling arms and a plane positioning of the sling below the urethra to avoid complications due to twisting of the sling

Indication of sensiTVT-A

Surgical treatment of female SUI:

- Resulting from urethral hypermobility
- Resulting from intrinsic sphincter deficiency (ISD)

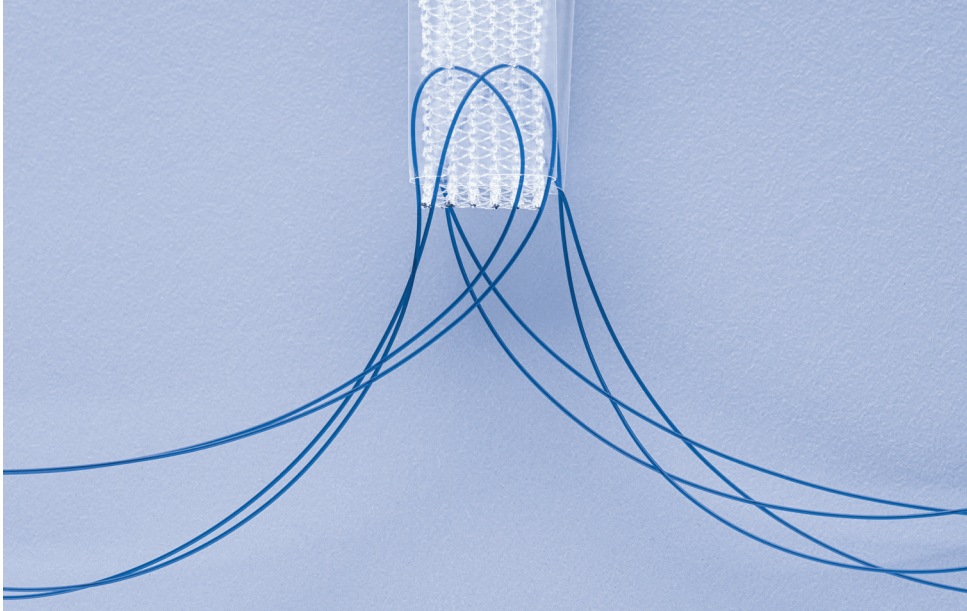
after failed conservative treatment methods



Surgery video



Animated video



Retropubic or Transobturator

A.M.I. TVA and TOA Sling Trans Vaginal Adjustable and Trans Obturator Adjustable.

TVA and TOA slings are sling implants for support of the mid-urethra which can be adjusted post-operatively. The TVA sling can be placed by retropubic approach and the TOA sling can be placed by transobturator approach. Sling implants are made of a polypropylene mesh, with pull-in sutures, adjustment sutures and a detachable pull-in aid.

Features

- Adjustment post-operatively is possible in cranial direction (tightening) in case of persisting incontinence and caudal direction (loosening) in case of over-correction

Benefits ^{24, 25, 26, 27, 28, 29, 30}

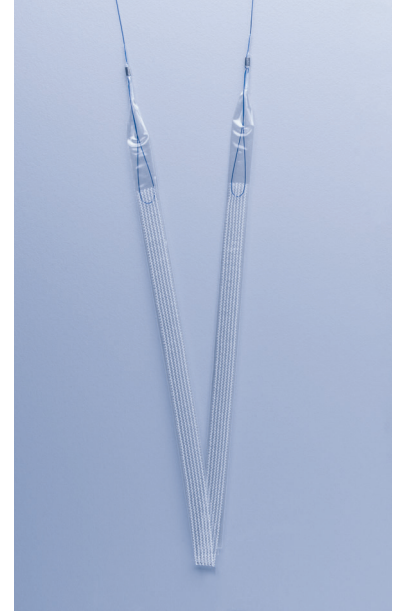
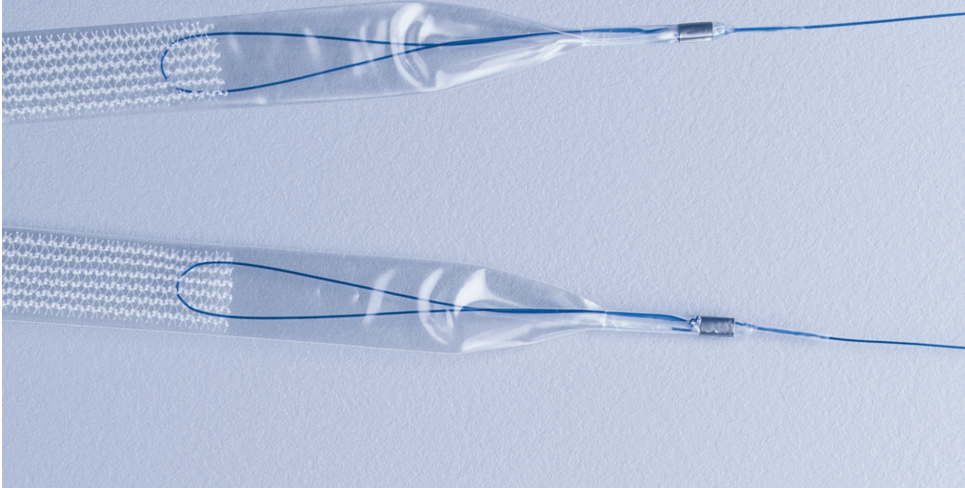
- Possibility to adjust the implant post-operatively to improve efficacy without increased risk of complications
- Efficient improvement of incontinence in female patients with SUI
- >90% patient satisfaction during mid-term follow-up (up to 24 month) in female SUI patients
- >80% objective cure rate long-term follow-up (up to 10 years) in female SUI patients

Indication of A.M.I. TVA/TOA Sling

Surgical treatment of female SUI:

- Resulting from urethral hypermobility
- Resulting from intrinsic sphincter deficiency (ISD) after failed conservative treatment methods





Retropubic or Transobturator

A.M.I. Multi Purpose Sling Mid-urethral sling implant.

The Multi Purpose Sling is a mid-urethral sling implant which is placed at the junction of the middle to the distal urethra. The lateral sling arms ensure a tension-free position in the tissue. The implant is made of polypropylene mesh, pull-in sutures and a detachable pull-in aid.

Features

- Implantation via retropubic or transobturator approach possible
- Mid-urethral sling placement
- Made of firm macroporous biocompatible monofilament polypropylene mesh
- A.M.I. Slings have a protective cover to facilitate a smooth and easy placement

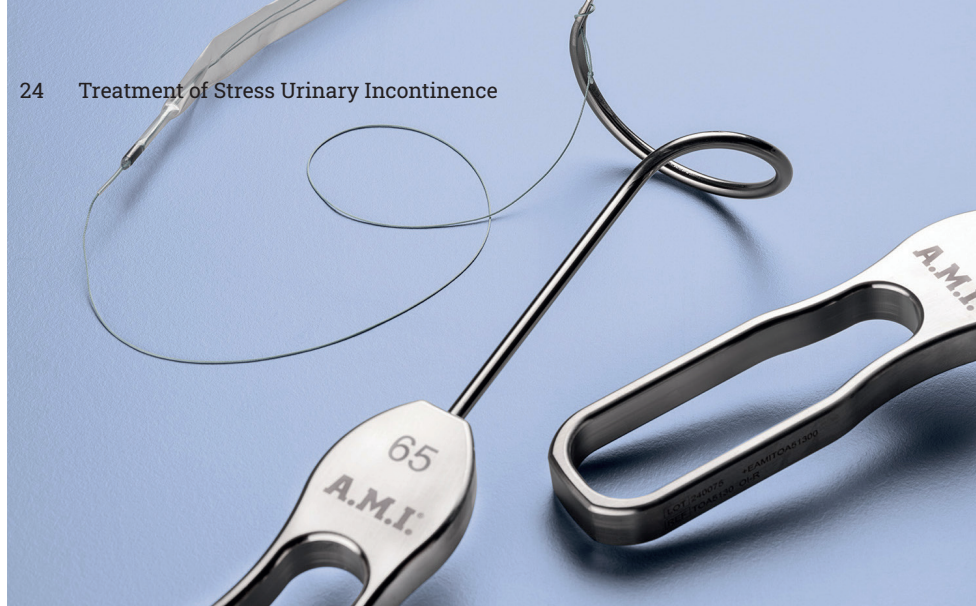
Benefits ⁶

- Efficient improvement of incontinence in female SUI patients
- Very low rate of intra-operative complications (<0.5%)
- Very low rate of post-operative complications in a 3-month follow-up period (<1%)

Indication of A.M.I. Multi Purpose Sling

Surgical treatment of female SUI:

- Resulting from urethral hypermobility
- Resulting from intrinsic sphincter deficiency (ISD) after failed conservative treatment methods



Reusable Instruments

+ A.M.I. Tunnellers

Perfect addition to A.M.I. mid-urethral sling procedures.

A.M.I. Tunnellers are multiple use devices, which are designed to meet the anatomic requirements for implant insertion. A slot at the tip enables the attachment of sling pull sutures, which are used to pull the implant in place.

Description

- The TVA5030 Tunneller for the retropubic approach is designed to meet the anatomic requirements for both sides of the patient's body, in one single device.
- The TOA5130 tunneller for the transobturatoric approach is offered pairwise (one for left and one for right side of the patient's body). It supports the outside-in and inside-out technique.

Features

- Ergonomically shaped handle
- Flattened and broad tip to create a slightly broader passage through the tissue
- Slot at the tip of the tunneller to connect the sling's pulling sutures with the tunneller device



Indication of A.M.I. TVA5030 and TOA5130

The Tunnellers are intended for the placement of A.M.I. urogynecological and urological mesh implants.



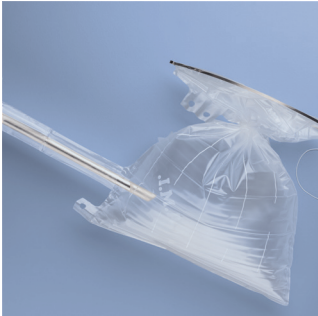
Contained

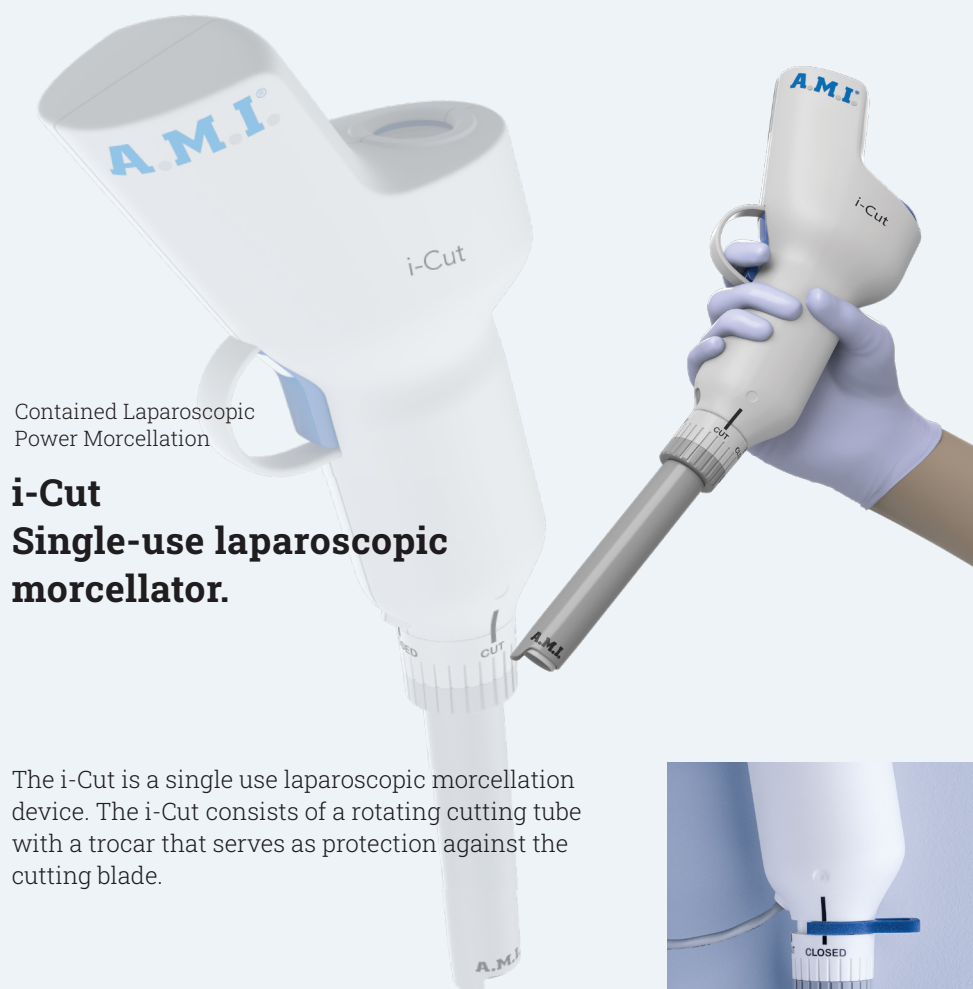
Laparoscopic Power Morcellation

Laparoscopic power morcellation is a minimally-invasive surgery for myomectomy and hysterectomy. Tissue morcellation during laparoscopic hysterectomy carries the risk of spreading cells from unsuspected malignancy. Contained morcellation inside a bag is supposed to minimize this risk.³¹

Overview

Contained Laparoscopic Power Morcellation

	Surgical approach	
	Laprascopic Power Morcellation	Contained Laparoscopic Power Morcellation
	i-Cut	More-Cell-Safe
		
A.M.I. Solution	i-Cut is an ergonomic and efficient power morcellator	More-Cell-Safe is a cell-tight bag, which significantly reduces the risk of unexpected cancer cell scatter
Indication	The i-Cut is indicated for morcellating and extracting tissue in laparoscopic, gynecologic surgical procedures	More-Cell-Safe is indicated for laparoscopic endoscopic tissue morcellation in gynecology



Contained Laparoscopic
Power Morcellation

i-Cut Single-use laparoscopic morcellator.

The i-Cut is a single use laparoscopic morcellation device. The i-Cut consists of a rotating cutting tube with a trocar that serves as protection against the cutting blade.



Surgery video



Animated video

Technical data:

Speed:	1000 rpm
Tip Diameter:	19 mm
Shaft length:	100 mm
Weight: approx.	400 g
Power:	24 V DC, 160 W

Features

- Single-use sterile product
- Reliably high cutting performance
- Large cutting tube diameter for the removal of large and hard tissue masses
- Double trocar sealing system prevents gas loss
- Multi-stage safety concept to protect the blade – “closed position” and locking clip to prevent unintentional exposure of the cutting blade
- Combined use with the More-Cell-Bag from A.M.I.

Functional Principle

The i-Cut device is used to cut tissue with a rotating cutting tube. The distal tip of the cutting tube represents the cutting blade. Standard grasper or Tenaculum forceps are used to pull tissue against the cutting blade and through the working lumen.

The i-Cut is electrically operated by a DC Motor which is powered by a 24V AC/DC mains adapter.

Indication

The i-Cut is indicated for morcellating and extracting tissue in laparoscopic, gynecologic surgical procedures.

The trocar of the device with the obturator in place is inserted into the patient's body. The locking clip and the adjustment wheel enhance the protection of the cutting blade. The activation button must be pressed to cut tissue.



Contained Laparoscopic
Power Morcellation

More-Cell-Safe Tissue containment system.

The More-Cell-Safe makes it possible to perform a gynecological laparoscopic tissue morcellation in a self-contained, isolated bag. Additional security is guaranteed by using the laparoscope protection Visi-Shield, which is offered as part of the system.

Features

- Cell and fluid tight bag
- Transparent bag allows clear visualisation of surrounding tissue during the procedure
- Use of Visi-Shield protects the optic against contamination
- Dual opening design allows separate insertion of morcellator and optic
- Suitable for the use with the A.M.I. i-Cut morcellator and other types of power morcellators (12-20 mm trocar diameter and 95-170 mm shaft working length)

Benefits ^{31, 32, 33}

- Safe minimal-access surgery which is feasible even for very large uteri (up to 1400 g)
- Minimizes the risk of inadvertent tissue dissemination
- Very low risk of intraoperative complications



Animated video

Indication

More-Cell-Safe is indicated for laparoscopic endoscopic tissue morcellation in Gynecology.

More-Cell Bag

Made of elastic, cell-tight material, which can be insufflated with CO₂. It features two openings. The major opening serves as insertion opening for transferring tissue intended to be morcellated into the bag as well as the access point for the morcellator device.

Visi-Shield / Visi-Shield 30

Special sleeve for 0°/30° laparoscopes to avoid contamination during morcellation.

References

Treatment of Pelvic Organ Prolapse

- 1 **Lowenstein et al. (2015)**
Incidence and lifetime risk of pelvic organ prolapse surgery in Denmark from 1977 to 2009
- 2 **Klinge et al. (2002)**
Impact of polymer pore size on the interface scar formation in a rat model
- 3 **Cobb et al. (2005)**
The argument for lightweight polypropylene mesh in hernia repair
- 4 **O'Dwyer et al. (2005)**
Randomized clinical trial assessing impact of a lightweight or heavyweight mesh on chronic pain after inguinal hernia repair
- 5 **Greca et al. (2001)**
The influence of differing pore sizes on the biocompatibility of two polypropylene meshes in the repair of abdominal defects
- 6 **Data on file**
- 7 **Mistrangelo et al. (2014)**
InGYNious single-incision advanced pelvic floor repair with hexapro-mesh
- 8 **Brandt et al. (2019)**
1-Year Outcome After Treatment of Uterovaginal Prolapse With a 6-Point Fixation Mesh
- 9 **Kuska et al. (2020)**
3 Year outcome after treatment of uterovaginal prolapse with a 6-point fixation mesh
- 10 **Deltetto et al. (2021)**
Effectiveness and Safety of Posterior Vaginal Repair with Single-Incision, Ultralightweight, Monofilament Propylene Mesh: First Evidence from a Case Series with Short-Term Results
- 11 **Mangano et al. (2021)**
More than a sacrospinous ligament fixation for prosthetic treatment of utero-vaginal prolapse: a six-point fixation mesh
- 12 **Deltetto et al. (2021)**
Efficacy and safety of an ultralight, six-point, polypropylene vaginal mesh in the treatment of urogenital prolapse
- 13 **Weiße et al. (2021)**
Bilaterale sacrospinale Zerviko-/Kolpofixation mittels BSC-Mesh im Rahmen der vaginalen Deszensuschirurgie – eine retrospektive Datenanalyse
- 14 **Ollig et al. (2014)**
Die Kolposuspension mit BSC direct – Minimal invasiv, maximal effektiv
- 15 **Ollig et al.**
Die Bilaterale Sakrospinale Kolposuspension – BSC wenig Nebenwirkungen
- 16 **Castañó et al. (2015)**
Colposuspensión bilateral del ligamento sacroespinal con malla BSC asociada a colporrafia anterior para el tratamiento del prolapso anterior y apical. Nuestra experiencia
- 17 **Zalewski et al. (2020)**
The assessment of quality of life and satisfaction with life of patients before and after surgery of an isolated apical defect using synthetic materials
- 18 **Hemptenmacher et al. (2020)**
Bilateral Sacrospinous Colposuspension (BSC) in the Treatment of Female Genital Prolapse: Risk-Benefit Considerations and Six Months Follow-up
- 19 **Haşegan et al. (2016)**
Sacrospinous ligament in urogenital prolapse repair using A.M.I. I-Stitch
- 20 **Retzke et al. (2013)**
Original article Caution 'FDA 2011': A modern pelvic floor mesh with a new form of cranial fixation. An observational study with 6-month follow-up on the A.M.I.® CR-Mesh and i-Stitch
- 21 **Kieback (2019)**
Bilateral Sacrospinous Colposuspension (BSC) for the treatment of vaginal vault prolapse – description of a novel method
- 22 **Haşegan et al. (2016)**
Transvaginal urogenital prolaps repair using i-Stitch
- 23 **Christmann-Schmid et al. (2018)**
Laparoscopic sacrocolpopexy with or without midurethral sling insertion: Is a two-step approach justified? A prospective study

References

Treatment of Stress Urinary Incontinence

- 24 Romero-Maroto et al. (2017)**
Is the adjustable TVA mesh effective for the long-term treatment of female stress incontinence?
- 25 Ko et al. (2012)**
Proper mesh placement using the outer cylinder of a ballpoint pen in the transobturator adjustable tape sling procedure for female stress urinary incontinence
- 26 Patrelli et al. (2015)**
Female stress urinary incontinence: Clinical efficacy and satisfaction after transobturator adjustable tape sling. An observational longitudinal cohort study
- 27 Romero Maroto et al. (2009)**
Transobturator adjustable tape (TOA) permits to correct post-operatively the tension applied in stress incontinence surgery
- 28 Romero Maroto et al. (2008)**
Transvaginal adjustable tape: an adjustable mesh for surgical treatment of female stress urinary incontinence
- 29 Zacharakis et al. (2016)**
Occult Stress Urinary Incontinence in Women With Pelvic Organ Prolapse: Is the One Step Surgical Approach a Risky Choice?
- 30 Youn et al. (2010)**
Comparison of TOA and TOT for treating female stress urinary incontinence: Short-term outcomes

References

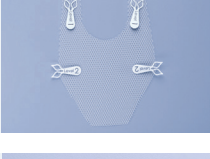
Contained Laparoscopic Power Morcellation

- 31 Rimbach et al. (2017)**
In-Bag Morcellation as a Routine for Laparoscopic Hysterectomy
- 32 Rimbach et al. (2016)**
First clinical experiences using a new in-bag morcellation system during laparoscopic hysterectomy
- 33 Lambat Emery et al. (2019)**
Cell Spillage after Contained Electromechanical Morcellation Using a Specially Designed In-Bag System for Laparoscopic Myomectomy: Prospective Cohort Pilot Study

Overview

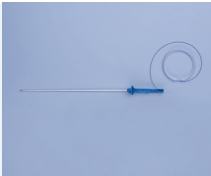
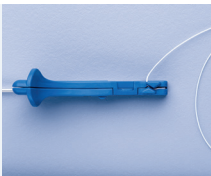
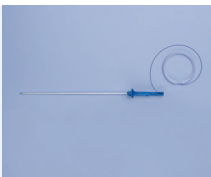
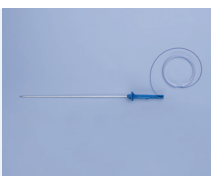
Treatment of Pelvic Organ Prolapse

Single-incision vaginal mesh procedures

Order Code		Product description	Included in delivery
BSC5001		BSC Mesh PP 0 Ultralight, polypropylene mesh designed to induce the formation of neo-ligaments by establishing symmetrical, bilateral suspension of the vaginal vault from the sacrospinous ligament.	1 box, all items delivered sterile: 1 x BSC Mesh 2 x i-Stitch loading unit PP 0 (from IST1011) • non-absorbable, polypropylene suture, USP 0
IGY5961		InGYNious D A S * Ultralight, polypropylene mesh with i-Stitch loading units for 3-level support of anterior vaginal wall prolapse.	1 box, all items delivered sterile: 1 x InGYNious D A S (Standard) 6 x i-Stitch loading unit PET 0 W (from IST1031) • non-absorbable, polyester suture, USP 0
IGY5951		InGYNious D A L * Ultralight, polypropylene mesh with i-Stitch loading units for 3-level support of anterior vaginal wall prolapse.	1 box, all items delivered sterile: 1 x InGYNious D A L (Large) 6 x i-Stitch loading unit PET 0 W (from IST1031) • non-absorbable, polyester suture, USP 0
IGY5561		InGYNious D A S-PP * Ultralight, polypropylene mesh with i-Stitch loading units for 3-level support of anterior vaginal wall prolapse.	1 box, all items delivered sterile: 1 x InGYNious D A S-PP (Standard) 6 x i-Stitch loading unit PP 0 (from IST1011) • non-absorbable, polypropylene suture, USP 0
IGY5551		InGYNious D A L-PP * Ultralight, polypropylene mesh with i-Stitch loading units for 3-level support of anterior vaginal wall prolapse.	1 box, all items delivered sterile: 1 x InGYNious D A L-PP (Large) 6 x i-Stitch loading unit PP 0 (from IST1011) • non-absorbable, polypropylene suture, USP 0
IGY5981		InGYNious D P S * Ultralight, polypropylene mesh with i-Stitch loading units for 3-level support of posterior vaginal wall prolapse.	1 box, all items delivered sterile: 1 x InGYNious D P S (Standard) 4 x i-Stitch loading unit PET 0 W (from IST1031) • non-absorbable, polyester suture, USP 0
IGY5971		InGYNious D P L * Ultralight, polypropylene mesh with i-Stitch loading units for 3-level support of posterior vaginal wall prolapse.	1 box, all items delivered sterile: 1 x InGYNious D P L (Large) 4 x i-Stitch loading unit PET 0 W (from IST1031) • non-absorbable, polyester suture, USP 0
IGY5581		InGYNious D P S-PP * Ultralight, polypropylene mesh with i-Stitch loading units for 3-level support of posterior vaginal wall prolapse.	1 box, all items delivered sterile: 1 x InGYNious D P S-PP (Standard) 4 x i-Stitch loading unit PP 0 (from IST1011) • non-absorbable, polypropylene suture, USP 0
IGY5571		InGYNious D P L-PP * Ultralight, polypropylene mesh with i-Stitch loading units for 3-level support of posterior vaginal wall prolapse.	1 box, all items delivered sterile: 1 x InGYNious D P L-PP (Large) 4 x i-Stitch loading unit PP 0 (from IST1011) • non-absorbable, polypropylene suture, USP 0
IGY5921		InGYNious V Ultralight, polypropylene mesh with i-Stitch loading units for 3-level repair of vaginal vault prolapse.	1 box, all items delivered sterile: 1 x InGYNious V 6 x i-Stitch Loading Unit PET 0 W (from IST1031) • non-absorbable, polyester suture, USP 0

* D = Direct A = Anterior P = Posterior
S = Standard L = Large

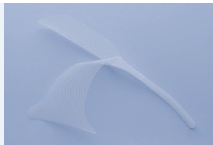
Overview
Treatment of Pelvic
Organ Prolapse

Order Code		Product description	Included in delivery
IST1010		i-Stitch Reusable instrument for pelvic floor reconstruction; for native tissue repair or synthetic mesh placement	1 box, delivered non-sterile, steam autoclavable: 1 x i-Stitch 1 x i-Stitch Cleaning Brush
IST1040		i-Stitch up Reusable instrument for pelvic floor reconstruction; for native tissue repair or synthetic mesh placement	1 box, delivered non-sterile, steam autoclavable: 1 x i-Stitch up 1 x i-Stitch Cleaning Brush
IST1011		i-Stitch loading unit PP 0 Disposable device consisting of a needle slider (incl. suture clamp), a cannulated needle, a suture dispenser, and a suture with a specially formed blunt, ball-shaped suture tip for the i-Stitch/i-Stitch up.	1 box, delivered sterile: 5 x i-Stitch loading unit PP 0 • non-absorbable, monofil polypropylene suture, suture size USP 0 • Colour: blue
IST1031		i-Stitch loading unit PET 0 W Disposable device consisting of a needle slider (incl. suture clamp), a cannulated needle, a suture dispenser, and a suture with a specially formed blunt, ball-shaped suture tip for the i-Stitch/i-Stitch up.	1 box, delivered sterile: 5 x i-Stitch loading unit PET 0 W • non-absorbable, braided polyester suture, suture size USP 0 • Colour: white
IST1021		i-Stitch loading unit PDO 2-0 Disposable device consisting of a needle slider (incl. suture clamp), a cannulated needle, a suture dispenser, and a suture with a specially formed blunt, ball-shaped suture tip for the i-Stitch/i-Stitch up.	1 box, delivered sterile: 5 x i-Stitch loading unit PDO 2-0 • absorbable, monofil polydioxanone PDO, suture size USP 2-0 • Colour: blue
IST1051		i-Stitch loading unit PDO 0 Disposable device consisting of a needle slider (incl. suture clamp), a cannulated needle, a suture dispenser, and a suture with a specially formed blunt, ball-shaped suture tip for the i-Stitch/i-Stitch up.	1 box, delivered sterile: 5 x i-Stitch loading unit PDO 0 • absorbable, monofil polydioxanone PDO, suture size USP 0 • Colour: blue
IST1020		i-Stitch Cleaning Brush Brush for cleaning the i-Stitch instruments.	1 box, delivered non-sterile: 2 x i-Stitch Cleaning Brushes
IST1050		i-Stitch Rinsing Needle Miele Connector	1 box, delivered non-sterile: 1 x i-Stitch Rinsing Needle Miele Connector
IST1060		i-Stitch Rinsing Needle Luer-Lock Connector	1 box, delivered non-sterile: 1 x i-Stitch Rinsing Needle Luer-Lock Connector
IGY-BAR		InGYNious Bar Help tool for procedures for prolapse surgery with InGYNious.	1 box, delivered non-sterile: 1 x InGYNious Bar

Laparoscopic mesh procedures

Overview

Treatment of Pelvic Organ Prolapse

Order Code		Product description	Included in delivery
PFR5731		ProGYNious Y-shaped mesh prosthesis for surgical treatment (laparotomy or laparoscopic approach) of pelvic floor prolapse	1 box, delivered sterile: 1 x ProGYNious (anterior + posterior mesh combined)
PFR5651		PelviGYNious Pre-shaped mesh prosthesis for surgical treatment (laparotomy or laparoscopic approach) of pelvic floor prolapse	1 box, delivered sterile: 1 x PelviGYNious (anterior + posterior mesh, 2 pieces)
PFR5641		EndoGYNious Y-shaped mesh prosthesis for surgical treatment (laparotomy or laparoscopic approach) of pelvic floor prolapse	1 box, delivered sterile: 1 x EndoGYNious (anterior + posterior mesh combined)

Overview

Treatment of Stress Urinary Incontinence

Retropubic mid-urethral sling procedure

Transobturator mid-urethral sling procedure

Order Code		Product description	Included in delivery
PFR5021		A.M.I. Multi Purpose Sling Sling for treatment of female stress urinary incontinence	1 box, delivered sterile: 1 x A.M.I. Multi Purpose Sling
TVA5021		A.M.I. TVA Sling Adjustable sling for treatment of female stress urinary incontinence	1 box, delivered sterile: 1 x A.M.I. TVA Sling
TOA5121		A.M.I. TOA Sling Adjustable sling for treatment of female stress urinary incontinence	1 box, delivered sterile: 1 x A.M.I. TOA Sling

OverviewTreatment of Stress
Urinary Incontinence

SUI5011		sensiTVT Sling of monofilament macropore polypropylene for treatment of female SUI with passively articulating joints and adaptable suburethral graft.	1 box, delivered sterile: 1 x sensiTVT
SUI5021		sensiTVT-A Sling of monofilament macropore polypropylene for treatment of female SUI. Equipped with: • passively articulating joints and adaptable suburethral graft • sutures for post-operative tension adjustment	1 box, delivered sterile: 1 x sensiTVT-A

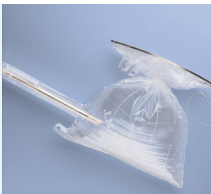
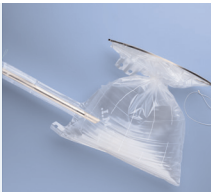
Combinable Products

Order Code		Product description	Included in delivery
TVA5030		A.M.I. TVA Tunneller Multiple use devices made of stainless steel for the placement of A.M.I. urogynecological sling implants (Retropubic technique)	1 box, delivered non-sterile, steam autoclavable: 1 x A.M.I. TVA Tunneller
TOA5130		A.M.I. TOA Tunneller Multiple use devices made of stainless steel for the placement of A.M.I. urogynecological sling implants (transobturator technique / outside-in / inside-out technique).	1 box, delivered non-sterile, steam autoclavable: 1 x Pair of A.M.I. TOA Tunneller

Overview

Contained Laparoscopic Power Morcellation

Laparoscopic power morcellation Containment bag system for power morcellation

Order Code		Product description	Included in delivery
ICT5011		i-Cut Single-use laparoscopic morcellation device.	1 box, delivered sterile: 1 x i-Cut incl. obturator
ICT5020		i-Cut Power Supply Typ C – Euro Reusable power supply unit for i-Cut ICT5011 Additionally available: ICT5030 i-Cut Power Supply Type G ICT5040 i-Cut Power Supply Type I ICT5050 i-Cut Power Supply Type A ICT5060 i-Cut Power Supply Type C - Korea ICT5070 i-Cut Power Supply Type C - Brazil	1 box, delivered non-sterile: 1 x i-Cut Power Supply (ICT5010) 1 x Country specific adapter (power cord)
MCS5111		More-Cell-Safe 0° System indicated for laparoscopic endoscopic tissue morcellation in gynecology. Including Visi-Shield for 0° optics to prevent camera contamination.	1 box, delivered sterile: 10 x More-Cell-Bag 10 x Visi-Shield 0°
MCS5151		More-Cell-Safe 30° System indicated for laparoscopic endoscopic tissue morcellation in gynecology. Including Visi-Shield for 30° optics to prevent camera contamination.	1 box, delivered sterile: 10 x More-Cell-Bag 10 x Visi-Shield 30°
MCS5131		More-Cell Bag System indicated for laparoscopic endoscopic tissue morcellation in gynecology. Made of elastic, cell-tight material, which can be insufflated with CO2.	1 box, delivered sterile: 10 x More-Cell-Bag

The products contained in this brochure are CE-marked or approved in accordance with various corresponding national regulations:

BSC5001, IGY5961, IGY5951, IGY5561, IGY5551, IGY5981, IGY5971, IGY5581, IGY5571, IGY5921, IST1011, IST1031, IST1021, IST1051, PFR5641, PFR5651, PFR5731, PFR5021, TVA5021, TOA5121, SUI5011, SUI5021, ICT5011, MCS5111, MCS5151, MCS 5131, IST1010, IST1040, IGY-BAR, ICT5010, IST1020, IST1050, IST1060, TVA5030, TOA5130

The product More-Cell-Safe is approved in the USA under the name More-Cell-System.510(k) number: K212659

A.M.I. Headquarters:

A.M.I. Agency for Medical
Innovations GmbH
Im Letten 1
6800 Feldkirch
Austria
T +43 5522 90505 0
F +43 5522 90505 4006
e info@ami.at



**Empowering Innovation.
Empowering Lives.**

www.ami.at