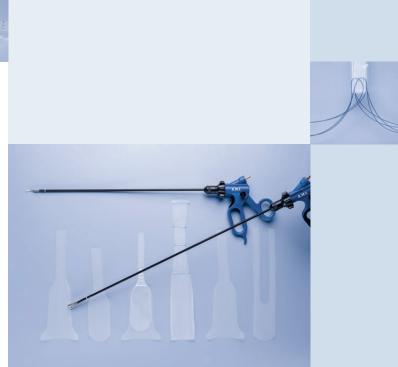
InGYNious BSC Mesh i-Stitch EndoGYNious PelviGYNious ProGYNious HyGYNious EasyInstruments A.M.I. Multi Purpose Sling A.M.I. TVA Sling A.M.I. TOA Sling sensiTVT sensiTVT-A Tunneller i-Cut More-Cell-Safe







Solutions for **Urogynecology**



Less pain and discomfort as well as higher safety for the patients, through innovative surgical techniques in the fields of Coloproctology, Urology and Urogynecology: 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.

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

Innovative solutions for improved quality of life.









Precision from Austria

Made in Europe.

Urogynecology

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

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Laparoscopic mesh procedure: EndoGYNious 13 PelviGYNious 14 ProGYNious 15 HyGYNious 16





Our company

- Leading manufacturer of medical technology with headquarter in Austria/Europe
- Over 20 years of experience in the fields of Coloproctology, Urogynecology and Urology
- High quality manufacturing in Europe
- Subsidiaries in Germany, Norway, Sweden, 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

- Innovative product development for pain-reducing, minimally-invasive surgery methods
- Meeting the highest quality requirements of surgeons and hospitals
- Constant optimization of all processes related to development, production and service
- Constructive exchange and consultation of users through our specially trained on site sales team
- Creating and implementing innovative ideas through close cooperation with experts, surgeons, technicians and scientists

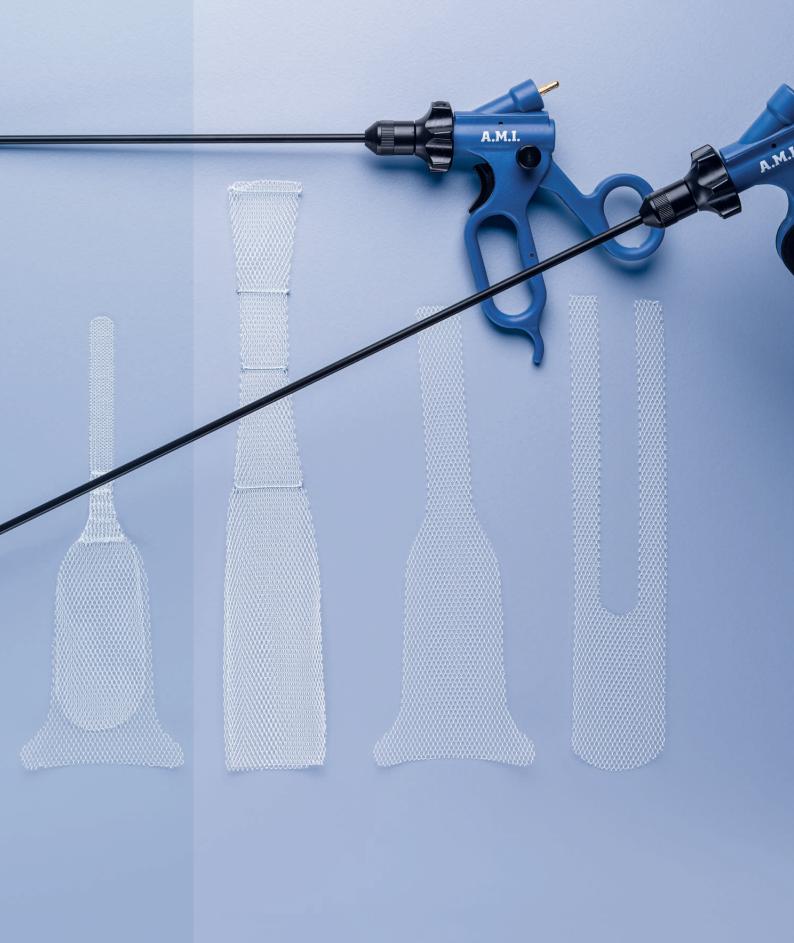
Treatment of **Pelvic Organ Prolapse**

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/m²	Wide-pore structure (macroporous): Pore size: ≥ 1.9 mm
	Biocompatible	Extra-large inter- stitial mircopores: 100-150 µm
		93% porosity
		Monofilament polypropylene
		\downarrow
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		
* Measurements in mm • 100 μm Ο 150 μm		

Surgical approach	Transvaginal single-incision	Transvaginal single-incision
Overview	InGYNious	BSC Mesh
Treatment of Pelvic Organ Prolapse		
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.	BSC Mesh is designed to induce the formation of neo-ligaments. It offers symmetrical, bilateral suspension.
Treatment options	Cervical-, Vaginal Vault- or Uterine Prolapse, Cystocele or Rectocele	Cervical-, Vaginal Vault- or Uterine Prolapse
+ _{Accessories}	i-Stitch, i-Stitch up i-Stitch loading unit InGYNious Bar	i-Stitch i-Stitch loading unit
	A CONTRACT OF THE OWNER	

Laparoscopic mesh procedure	Laparoscopic mesh procedure	Laparoscopic mesh procedure	Laparoscopic mesh procedure
EndoGYNious	PelviGYNious	ProGYNious	HyGYNious
		K	AU
EndoGYNious is a Y-shaped mesh appli- cable for the well- established procedures sacrocolpopexy and sacrocervicopexy. The proximal end is double-layered for a firm fixation.	PelviGYNious consists of two, differently shaped meshes (ante- rior and posterior). It is applicable for the well- established procedures sacrocolpopexy and sacrocervicopexy.	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 appli- cable for the well- established procedures sacrocolpopexy and sacrocervicopexy.	HyGYNious is pre- shaped in a bifurcated form (enlongated U-form) that enables easier surgical placement. It is appli- cable for the well- established procedure sacrohysteropexy.
Cervical-, or Vaginal Vault Prolapse Cystocele or Rectocele	Cervical-, or Vaginal Vault Prolapse Cystocele or Rectocele	Cervical-, or Vaginal Vault Prolapse Cystocele or Rectocele	Uterine Prolapse Cystocele or Rectocele
EasyInstruments	EasyInstruments	EasyInstruments	EasyInstruments











Single-incision vaginal mesh procedure

InGYNious 3-level support.

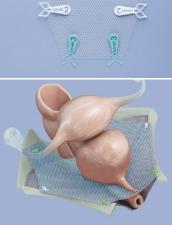
InGYNious offers a 3-level support in the gentlest possible way. It is a six-point fixation mesh which allows effective repair of various pelvic floor defects through a single vaginal incision to enable a total pelvic floor reconstruction.

Facts

- 6-point suture fixation = 3-Level support for effective repair of various pelvic floor defects
- Level 1: Apical support which is created by a suspension suture connecting the apex of the mesh with the sacrospinous ligament (anterior and posterior)
- Level 2: Lateral attachments placed on each side in the arcus tendineus fascia pelvis (anterior) or iliococcygeus muscle (posterior)
- Level 3: Attachment to arcus tendineus fascia pelvis retropubic (anterior) or perineal body (posterior)
- Suture navigators indicate correct positioning of the sutures
- Treatment of anterior, posterior and apical compartments possible

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:

- Complex cases
- Secondary surgical treatment
- High risk for POP recurrence
 - Cervical prolapse
 - Vaginal vault prolapse
 - Uterine prolapse
 - Cystocele
 - Rectocele

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.

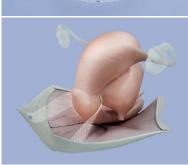
BSC Mesh is designed to induce the formation of neo-ligaments by establishing symmetrical, bilateral suspension of the vaginal vault from the sacrospinous ligament. It recreates the support previously provided by the natural ligaments, which are no longer functioning.

Facts

- 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)



Urogynecology

Indication of BSC Mesh

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

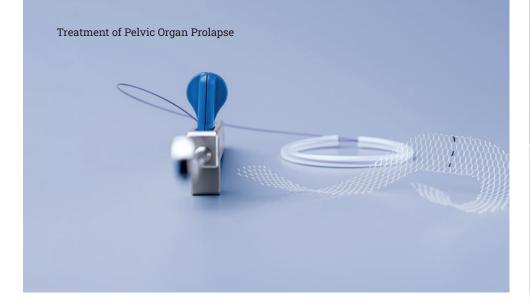
- Complex cases
- Secondary surgical treatment
- High risk for POP recurrence
 - Cervical prolapse
 - Vaginal vault prolapse
 - Uterine prolapse

"[...] 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% $^{13,\,14,\,15,\,16}$



Accessories for single-incision vaginal mesh procedure

+ i-Stitch The perfect accessory for 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 facilitates the attachment of sutures to structures that are difficult to reach without extensive dissection.

Benefits ^{8, 10, 18, 19, 20, 21, 22}

- Safe, precise and reproducible application for suture fixation
- Minimal transvaginal dissection needed, without excessive preparation. No visualization of sacrospinous ligament is required.
- Very low intra-operative complications (e.g. minimal blood loss)
- Reduced operating time
- Easy access to pelvic floor tissue structures
- i-Stitch and i-Stitch up support a good usability for the surgeon. Comfortable suture placement and instrument handling.

Easy handling

Just a few steps are necessary to easily use the instrument:

- 1. Secure the suture in the suture clamp of i-Stitch loading unit. Load i-Stitch with the loading unit.
- 2. i-Stitch is guided along surgeon's finger to intended suture attachment point, push tip into tissue.
- 3. Push loading unit forward, suture penetrates tissue.
- 4. Release suture from suture clamp and remove loading unit completely.
- 5. Carefully retrieve i-Stitch instrument. Suture will remain firmly in place. Tie the knot.

Technical features

- Blunt, non-cutting suture tip
- Resorbable or nonresorbable suture material
- Additional suture clamp option
- Suitable cleaning accessories

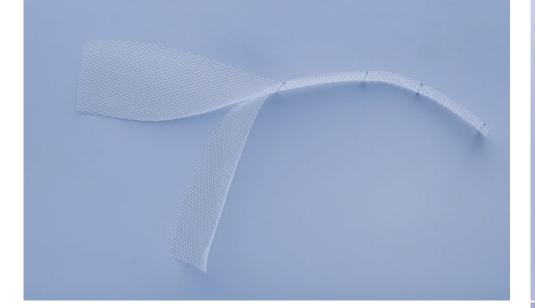
Available in two variants:

- 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.



Animation 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."



Laparoscopic mesh procedure

EndoGYNious Y-shaped mesh for apical vaginal support.

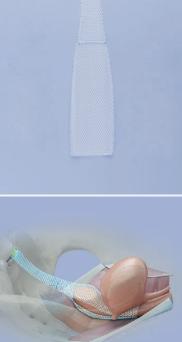
EndoGYNious is a Y-shaped mesh prosthesis. It is a double-layer mesh on the proximal end, for firm fixation to the longitudinal ligament at level of sacral promontory. The iso-elastic single-layer mesh body, which is positioned between vagina and rectum and vagina and bladder, maintains vaginal flexibility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

Facts

- Applicable for the well-established procedure sacrocolpopexy and sacrocervicopexy
- Double-layer mesh on proximal part for firm fixation
- Positioning between vagina and rectum and vagina and bladder
- Apical stabilisation for POP correction

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%)



Urogynecology

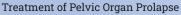
Indication of EndoGYNious

Symptomatic POP with or without urinary incontinence:

- Cervical prolapse
- Vaginal vault prolapse
- Cystocele
- Rectocele



Surgery video





Laparoscopic mesh procedure

PelviGYNious Laparoscopic sacrocolpopexy and sacrocervicopexy.

PelviGYNious consists of two, differently shaped meshes with a hexagonal structure. 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. Both meshes have an apical component for Level 1 suspension to prevent vaginal prolapse.

Facts

- Applicable for the well-established procedure sacrocolpopexy and sacrocervicopexy
- Apical fixation to correct POP
- Two differently shaped meshes (anterior and posterior) - proximal ends of both are fixed at level of sacral promontory to the longitudinal ligament

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%)



Surgery video

Indication of PelviGYNious

Symptomatic POP with or without urinary incontinence:

- Cervical prolapse
- Vaginal vault prolapse
- Cystocele
- Rectocele



Laparoscopic mesh procedure

ProGYNious Lightweight mesh body and strong mesh neck.

ProGYNious is made from two types of polypropylene mesh material. It combines the best of both materials to maintain elasticity and to give strong support at once! **1. Mesh body:** The ultra-lightweight hexagonal shaped mesh, with a wide pore structure, is used to reduce foreign body tissue reaction and to allow good integration in the vaginal area.

2. Mesh neck: The mesh neck is made of firmer, denser mesh material for a stable fixation to the longitudinal ligament at the level of the sacral promontory.

Facts

- Two mesh materials: Combination of ultralight, large pore, soft, iso-elastic mesh at the vaginal level and denser, less elastic mesh for firm suspension
- Applicable for the well-established procedure sacrocolpopexy and sacro-cervicopexy
- Apical component for level 1 suspension to prevent vaginal prolapse
- Stiffer mesh neck is fixed at level of sacral promontory to the longitudinal ligament

Benefits

Different ProGYNious variants for different patient's needs:

- **ProGYNious A** (anterior) is placed between vagina and bladder to prevent from recurrent cystocele
- **ProGYNious P** (posterior) is placed between vagina and rectum to prevent from recurrent rectocele
- **ProGYnious** is a Y-shaped mesh prosthesis which combines the features of the ProGYNious A and the ProGYNious P

Urogynecology

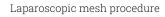


Indication of ProGYNious

Symptomatic POP with or without urinary incontinence:

- Cervical prolapse
- Vaginal vault prolapse
- Cystocele
- Rectocele

Treatment of Pelvic Organ Prolapse



HyGYNious Laparoscopic Sacrohysteropexy.

HyGYNious is a special preformed mesh for uterus-preserving procedures. The anterior mesh has an elongated form to fit around the cervix. The posterior mesh is placed between vagina and rectum. The mesh neck then will be fixed at level of sacral promontory to the longitudinal ligament.

Facts

- Applicable for the well-established procedure sacrohysteropexy
- Restores normal support of vagina, suspends uterus back in its anatomical position
- Reinforces weakened ligaments

Benefits

- HyGYNious mesh can be used in uterus preserving procedures for transabdominal pelvic floor repair
- HyGYNious can successfully cure patients with pelvic organ prolapse



Surgery video

Indication of HyGYNious

Symptomatic POP with or without urinary incontinence:

- Uterine prolapse
- Cystocele
- Rectocele

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

O'Dwyer et al. (2005) 4

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

9

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

Kuszka 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

References

Treatment of Pelvic Organ 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 Castaño et al. (2015)

Colposuspensión bilateral del ligamento sacroespinoso 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 Sacrospineous 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

Overview Treatment of Pelvic Organ Prolapse

Single-incision vaginal mesh procedures

Order Code		Product description	Included in delivery
BSC5001	H	BSC Mesh PP 0 Ultralight, iso-elastic mesh implant with i-Stitch loading units for bilateral, apical suspension to correct pelvic organ prolapse.	 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, iso-elastic polypropylene mesh with i-Stitch loading units for 3-level 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, iso-elastic polypropylene mesh with i-Stitch loading units for 3-level 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, iso-elastic polyproylene mesh with rectum cavity for 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, iso-elastic polypropylene mesh with rectum cavity for 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, iso-elastic polypropylene mesh with i-Stitch loading units for 3-level 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 * Ultra-light, iso-elastic polypropylene mesh with i-Stitch loading units for 3-level 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, iso-elastic polypropylene mesh with rectum cavity for 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, iso-elastic polypropylene mesh with rectum cavity for 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, iso-elastic 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

Accessories

Order Code		Product description	Included in delivery
IST1010		i-Stitch Reusable instrument for easy fixation of suture material to tissue, particularly in obstructed areas. For use with the i-Stitch Loading Units.	1 box, delivered non-sterile, steam autoclavable: 1 x i-Stitch 1 x i-Stitch Cleaning Brush
IST1040		i-Stitch up Reusable instrument for easy fixation of suture material to tissue, particularly in obstructed areas. 180° rotated tip. For use with the i-Stitch Loading Units.	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 Combination of hollow needle slider and specially formed, non-absorbable suture material for single-use with 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 Combination of hollow needle slider and specially formed, non-absorbable suture material for single-use with 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 Combination of hollow needle slider and specially formed, absorbable suture material for single-use with 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	O	i-Stitch loading unit PDO 0 Combination of hollow needle slider and specially formed, absorbable suture material for single-use with 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	Jan Ja	InGYNious Bar Help tool for procedures for prolapse surgery with InGYNious.	1 box, delivered non-sterile : 1 x InGYNious Bar

Laparosopic mesh procedures

Overview Treatment of Pelvic Organ Prolapse

Order Code		Product description	Included in delivery
PFR5641	7	EndoGYNious Y-shaped, ultralight, iso-elastic poly- propylene mesh for sacrocolpopexy to treat pelvic organ prolapse.	1 box, delivered sterile: 1 x EndoGYNious (anterior + posterior mesh combined)
PFR5651		PelviGYNious Anatomically shaped anterior and posterior ultralight, iso-elastic polypropylene mesh. For sacrocolpopexy to treat pelvic organ prolapse.	1 box, delivered sterile: 1 x PelviGYNious (anterior + posterior mesh, 2 pieces)
PFR5681		HyGYNious Ultralight, iso-elastic polypropylene mesh for laparoscopic sacrohysteropexy.	1 box, delivered sterile: 1 x HyGYNious (anterior + posterior mesh, 2 pieces)
PFR5731		ProGYNious Ultralight, iso-elastic polypropylene mesh body and denser, less elastic mesh neck for firm suspension. For sacrocolpopexy and sacrocervicopexy.	1 box, delivered sterile: 1 x ProGYNious (anterior + posterior mesh combined)
PFR5711		ProGYNious A – Anterior mesh Ultralight, iso-elastic polypropylene mesh body and denser, less elastic mesh neck for firm suspension. For sacrocolpopexy and sacrocervicopexy.	1 box, delivered sterile: 1 x ProGYNious A (anterior mesh)
PFR5721		ProGYNious P – Posterior mesh Ultra-light, iso-elastic polypropylene mesh body and denser, less elastic mesh neck for firm suspension. For sacrocolpopexy and sacrocervicopexy.	1 box, delivered sterile: 1 x ProGYNious P (posterior mesh)

CE

The products contained in this brochure meet the requirements of the Medical Device Directive 93/42/EEC and are accordingly marked with the CE mark: IST1010, IST1040, TVA5030, TVA5040, TOA5130, TOA5170, TOA5140, TOA5180, IGY-BAR

CE

The products contained in this brochure meet the requirements of REGULATION (EU) 2017/745 and are labelled with the CE mark accordingly: ECA1020, ECA1030, ECA1040, ECA1110, ICT5010, IST1020, IST1050, IST1060

CE₀₂₉₇

The products contained in this brochure meet the requirements of the Medical Device Directive 93/42/EEC and are accordingly marked with the CE mark: BSC5001, IGY5961, IGY5951, IGY5561, IGY5551, IGY5981, IGY5971, IGY5581, IGY5571, IGY5921, IST1011, IST1031, IST1021, IST1051, PFR5641, PFR5651, PFR5681, PFR5731, PFR5711, PFR5721, ESI1510, ESI1520, ESI1530, ESI1310, ESI1320, EIR1510, EIR1520, EIR1530, EIR1310, EIR1320, EAS1510, EAS1520, EAS1530, EAS1310, EAS1320, ESH1510, ESH1520, ESH1530, ESH1310, ESH1320, ESI1131, ESI1151, ESI1120, ECI1031, ECI1020, EDI1031, EDI1020, EDI1051, EVI1011, ESM1011, EDM1011, ECM1011, PFR5021, TVA5021, T0A5121, SUI5011, SUI5021, ICT5011, MCS5151

The product More-Cell-Safe is approved in the USA under the name More-Cell-System.510(k) number: K192898

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