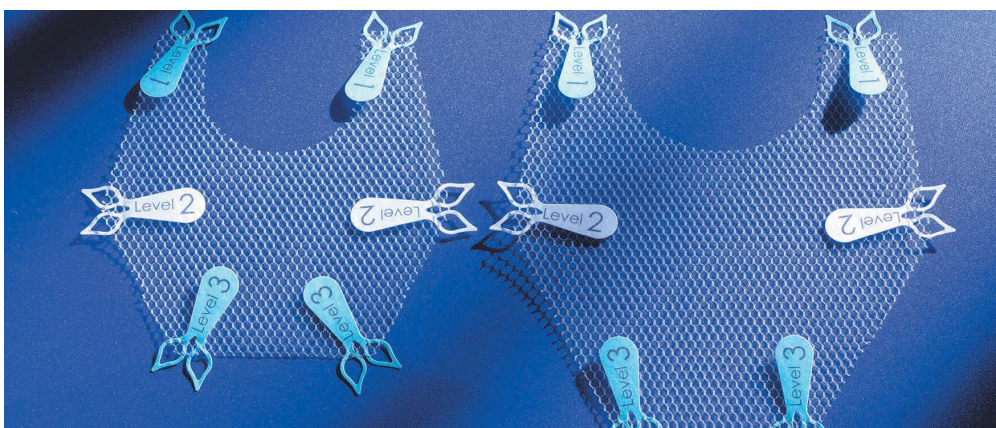


InGYNious

Issue 104755 | 14.08.2020



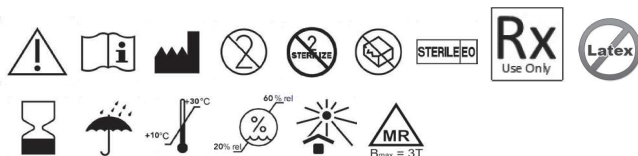
REF	Product name
PFR5571	InGYNious V
PFR5601	InGYNious D A L
PFR5611	InGYNious D A S
PFR5621	InGYNious D P L
PFR5631	InGYNious D P S
IGY5921	InGYNious V
IGY5551	InGYNious D A L-PP

REF	Product name
IGY5561	InGYNious D A S-PP
IGY5571	InGYNious D P L-PP
IGY5581	InGYNious D P S-PP
IGY5951	InGYNious D A L
IGY5961	InGYNious D A S
IGY5971	InGYNious D P L
IGY5981	InGYNious D P S

Operating manual
Gebrauchsanweisung
Manuale operativo

Manual de instrucciones
Manual operacional
Čeština
Slovenčina

CE0297 PFR5571, PFR5601, PFR5611, PFR5621, PFR5631



A.M.I.[®]

1. Product description

All types of InGYNious mesh implants are made of an ultralight monofilament polypropylene mesh with hexagonal structure. The combination of ultralight mesh material and a multiple point suture fixation allows effective repair of various pelvic floor defects through one single vaginal incision. This allows treatment of cystocele, rectocele and to reconstruct the proximal vagina.

The InGYNious mesh implants are available in three different shape variants

D A = Direct Anterior vaginal wall prolapse - two different sizes (S, L)

D P = Direct Posterior vaginal wall prolapse - two different sizes (S, L)

V = Vaginal vault prolapse

All mesh variants are offered with a ready-to-use set of either PP- (blue) or PET-sutures (white/ green) onto stainless steel devices for surgical suture attachment, which are intended to be used in combination with the mesh implant during implantation

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

The InGYNious Bar is an optional accessory to the InGYNious mesh implants to keep control of all attachment sutures in order to reduce unintentional suture cross overs. It is a multiple use, stainless steel device to support surgeon's orientation with pre-positioned suture slots for each pre-defined suture fixation position. The InGYNious Bar is positioned ventral to the vaginal orifice onto the patient's sterile drape, with the two ends pointing downwards, so it does not have direct patient contact.

REF	Name	Component	Description
IGY5551	InGYNious D A L-PP	InGYNious D A L mesh	Mesh implant
		i-stitch loading unit PP 0 (6x)	Loading unit to use with the A.M.I. i-stitch instrument

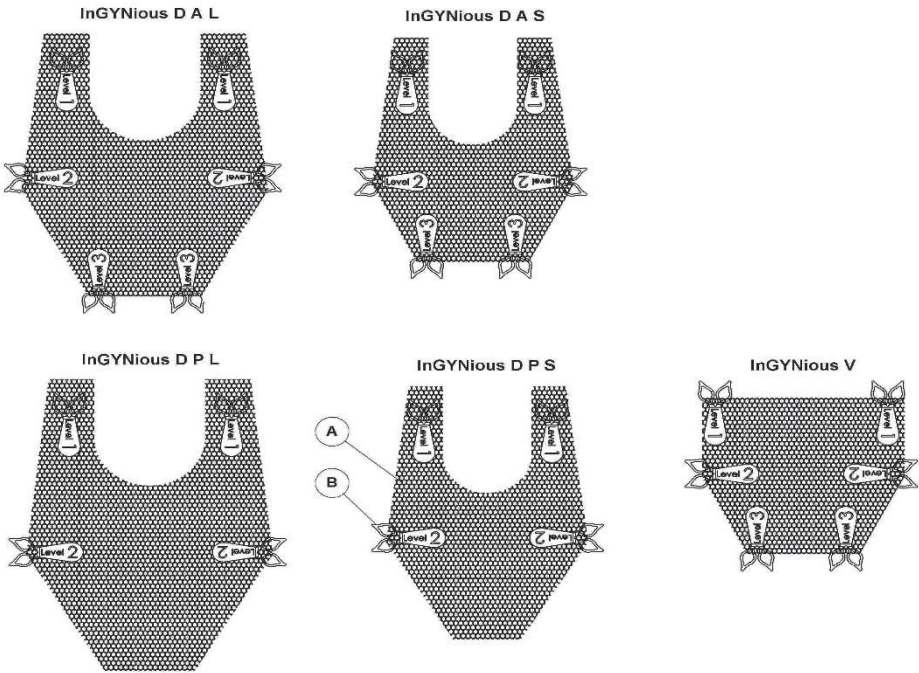
IGY5561	InGYNious D A S-PP	InGYNious D A S mesh	Mesh implant
		i-stitch loading unit PP 0 (6x)	Loading unit to use with the A.M.I. i-stitch instrument
IGY5571	InGYNious D P L-PP	InGYNious D P L mesh	Mesh implant
		i-stitch loading unit PP 0 (4x)	Loading unit to use with the A.M.I. i-stitch instrument
IGY5581	InGYNious D P S-PP	InGYNious D P S mesh	Mesh implant
		i-stitch loading unit PP 0 (4x)	Loading unit to use with the A.M.I. i-stitch instrument
IGY5921	InGYNious V	InGYNious V mesh	Mesh implant
		i-stitch loading unit PET 0 WHITE (2x)	Loading unit to use with the A.M.I. i-stitch instrument
		i-stitch loading unit PET 0 GREEN (5x)	
IGY5951	InGYNious D A L	InGYNious D A L mesh	Mesh implant
		i-stitch loading unit PET 0 WHITE (2x)	Loading unit to use with the A.M.I. i-stitch instrument
		i-stitch loading unit PET 0 GREEN (5x)	
IGY5961	InGYNious D A S	InGYNious D A S mesh	Mesh implant
		i-stitch loading unit PET 0 WHITE (2x)	Loading unit to use with the A.M.I. i-stitch instrument
		i-stitch loading unit PET 0 GREEN (5x)	
IGY5971	InGYNious D P L	InGYNious D P L mesh	Mesh implant
		i-stitch loading unit PET 0 WHITE (2x)	Loading unit to use with the A.M.I. i-stitch instrument
		i-stitch loading unit PET 0 GREEN (3x)	
IGY5981	InGYNious D P S	InGYNious D P S mesh	Mesh implant
		i-stitch loading unit PET 0 WHITE (2x)	Loading unit to use with the A.M.I. i-stitch instrument
		i-stitch loading unit PET 0 GREEN (3x)	

2. Intended use

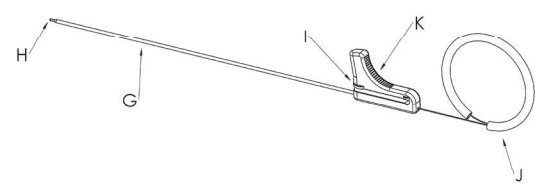
Transvaginal mesh implant for surgical treatment of female pelvic organ prolapse (POP).

3. Definition

No.	Description	Function
A	Mesh	Recreates anatomical structures
B	Suture navigator	Navigation aid for correct positioning of the sutures



i-stitch loading unit:



No.	Description
G	Cannulated needle
H	Blunt suture tip
I	Sliding guide
J	Suture dispenser
K	Needle slider

4. Product features and clinical benefits

- 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

5. User group/ user qualifications

The products are intended for use by qualified and expert medical specialists. An understanding of the principles of the appropriate surgical techniques is a prerequisite.



Warning! Pelvic reconstructive surgery with and without implants requires knowledgeable (e.g. anatomy) and experienced surgeons as pointed out in various guidelines and recommendations of medical societies (e.g. SCENIHR, FIGO, AGUB, EAU/EUGA):

- Especially the use of surgical meshes for POP surgery is only advised for trained surgeons who are educated in the surgical technique of this treatment.
- Furthermore, the surgeons should be trained on the usage of the specific mesh products.
- It is strongly advised to perform such complex surgeries in specialized and experienced multidisciplinary medical centres or hospitals only.

A.M.I. GmbH offers and highly recommends workshops wherein the usage and handling of the product in question is shown. Please contact the local distributor or the manufacturer to get the details/ information about the workshops.

6. Patient group

Physically mature, at least 18 years old female patients with symptomatic genital prolapse with or without urinary incontinence.

7. Indications

InGYNious is indicated for transvaginal reconstructive surgery of symptomatic pelvic organ prolapse (POP) with or without urinary incontinence, restricted to

- (a) cervical-,
- (b) uterine-,
- (c) vault prolapse,
- (d) cystocele or
- (e) rectocele
- (i) in complex cases,
- (ii) as secondary surgical treatment or
- (iii) in case of high risk of POP recurrence.

8. Contraindications

The use of the product is contraindicated in case of:

- pregnancy and/or patients who consider future pregnancies
- adolescent/ pubescent patients
- existence of a known sensitivity/ allergy against plastic materials such as polypropylene, polyester, etc.
- any pathology, including known or suspected uterine pathology, which would compromise placement of the implant/mesh (e.g. anatomical distortion or abnormalities)
- known anticoagulation disorder
- anticoagulant therapy
- autoimmune connective tissue disease
- renal insufficiency and upper urinary tract obstruction

- cancer illnesses of the vagina / cervix / rectum
- undergone radiation therapy on the vagina, cervix, rectum
- planned or emergency opening of the gastro-intestinal tract, as this could cause a risk of product contamination that could lead to infection that would require removal of the implant/device
- active or latent infection especially of the genital system and/or urinary tract

The use of the product is generally deemed contraindicated, if the method as such or the use under consideration of the patient's general condition is seen as contraindicated by decision of the attending physician.

9. Patient information

The surgeon performing the implantation should ensure that patients or their representatives, are correctly and comprehensively informed on the benefits and risks associated with the use of synthetic non-absorbable polypropylene meshes. Before the mesh procedure, the patient must be informed of the following additional issues:

- Mesh placement route (abdominal, transvaginal)
- Mesh is considered a permanent implant; removal of mesh or correction of mesh-related complications may involve subsequent surgery/surgeries
- Surgeon's assessment of risk-benefit ratio taking into consideration patient age, severity of prolapse, severity of symptoms, possible future complications that are specific to mesh explantation
- Limitations of mesh removal and correction of post-operative complications
- Specific complications/ residual risks associated with the proposed procedure
- Suitability of the patient's condition for mesh implantation
 - Patients with family planning completed (i.e. exclusion of pregnant patients and/or patients with planned pregnancy)
 - Level of sexually activity
- Evidence/ level of experience of the performing surgeon with the surgical procedure
- Alternative treatment options (advantages and disadvantages in relation to specific patient condition)
 - Non-surgical treatment as primary treatment before surgery
 - Different surgical treatment options (including native tissue repair)
 - Different implantation routes for mesh implants (abdominal and trans-vaginal)

Education of the patient about the fact that all publications about outcome of surgical and non-surgical treatment may have a bias that complications are underrepresent-

ed since there is an increased likelihood that patients with complications will not attend (voluntary) follow-up visits in conjunction with studies. Therefore, the possibility of a complication / adverse event is likely to be higher than reported in studies.

10. Possible complications / adverse events

Possible complications include but are not limited to:

Frequently or (implant) specific reported complications:

- de novo urge urinary incontinence,
- post-op bowel obstruction/ constipation,
- dyspareunia,
- prolapse/ recurring prolapse,
- de novo urinary incontinence,
- mesh erosion, mesh extrusion,
- pain (acute or chronic),
- faecal incontinence,

Additional reported complications:

- hematoma,
- hemorrhage,
- post-operative bleeding,
- inflammation (acute or chronic),
- infection,
- abscesses,
- fistulae development/ formation,
- wound dehiscence,
- reaction against foreign body,
- adhesion formation,
- ischuria,
- difficulties while urinating / dysuria,
- urinary retention,
- contractions,

- nerve damage,
- perforation of vessels, nerves, bladder, urinary tract, large bowel and other structures,
- vaginal shortening/ stenosis,
- necrosis,
- mesh or tissue contraction,
- vaginal discharge
- scar tissue formation
- emotional and psychological condition

Pain can be experienced in the area of the product in the early post-operative phase. Continuous persisting pain in the area of the mesh requires a more detailed medical clarification.

The effectiveness of the product is greatly affected by applied surgical techniques, the inter-operative maintenance of sterility, the correct dimensions and positioning.

Any incontinence which might already have existed can become obvious following the rectification of the incident.

Unwanted tissue reactions can require a part or complete explanation of the product.

When securing the product, care needs to be taken not to damage (e.g. cut or rip) the mesh implant with the securing fixtures being used (e.g. surgical sutures).

11. Safety related information

Danger



The keyword „danger“ indicates a hazard with a potentially high risk, which if the hazard is not avoided, the consequences are severe injuries or death

Warning



The keyword „warning“ indicates a hazard with a medium risk, which if the hazard is not avoided, the consequences are severe injuries

Caution



















The keyword „caution“ indicates a hazard with a low risk, which if the hazard is not avoided, the consequences are minor or moderate injuries









Note



The keyword „note“ indicates a safety information which shows a condition which has to be complied, information for understanding, as well as tips and recommendations for the effective use of the product

12. Warnings and precautions

	Danger! Pelvic reconstructive surgery (implantation and explantation of mesh implants) requires knowledgeable (e.g. anatomy) and highly experienced surgeons as pointed out in various guidelines and recommendations of medical societies (e.g. SCENIHR, FIGO, AGUB, EAU/EUGA) Implantation and explantation of mesh implants should only be done in specialized medical centres or hospitals with sufficient expertise.	
	Warning! The information in the current instructions for use, as well as the information accompanying the products used in combination must be adhered to.	
	Warning! The product must not be used for any purposes other than the purpose mentioned above.	
	Warning! Do not attempt to alter this product in any way. Doing so may endanger the patient and / or user.	
	Warning! The use of damaged products or products which do not function perfectly is to be avoided.	
	Warning! Do not re-sterilize or reuse disposable products	 
	Warning! Do not use the product after the expiry date.	
	Warning! Do not use products that have open or defective sterile barrier packaging	
	Warning! In case of any explantation, the product holds a biological hazard. The disposal has to be carried out according to current national laws and recommendation guidelines (e.g. RKI recommendations) for clinical waste.	
	Warning! Proper fixation of the InGYNious Bar, if used, has to be checked. Any slippage could result in excessive tension on the prepositioned fixation suture	
	Warning! Vaginal or urinary tract infections should be cured completely prior to the implantation.	

	Warning! The product is only to be used in the case of patients who have been classed as suitable following a medical examination carried out in advance.
	Warning! The implanted product must not have any direct contact to intestine or other intra-abdominal organs and must therefore always be covered by the peritoneum.
	Warning! The product should be placed without tension.
	Warning! The implantation of the mesh requires an extensive dissection of the pelvis, vagina and rectum including the paravesical and pararectal space. This can cause complications such as bleeding and others (see section 10 Possible complications/ adverse events) requiring immediate surgical intervention and repair.
	<p>Warning! Mesh implantation can cause or lead to various complications (see 10 Possible complications/ adverse events)</p> <p>All publications about outcome of surgical and non-surgical treatment may have a bias that complications are underrepresented since there is an increased likelihood that patients with complications will not attend (voluntary) follow-up visits in conjunction with studies.</p>
	Warning! Patients must be advised accordingly to seek immediate medical attention in case of the occurrence of unusual post-operative pain.
	<p>Warning! Only moderate force is allowed to be put on the suture navigators to avoid damage of the navigators.</p> <p>Complete removal of the suture navigators from the mesh has to be assured before the mesh is implanted to avoid any residues in the situs.</p>
	Warning! Keep the pre set sutures neatly organized. If the sutures get twisted this could lead to a wrong attachment of the implant



Warning! The user has to come to a joint decision in a medical multidisciplinary board of a specialized pelvic floor centre where the benefit-risk-ratio for the individual patient is in focus that the surgical treatment of the patient is appropriate.

The following issues have to be considered:

- Conservative treatment options
- Degree of suffering is present
- Severity of prolapse
- Consideration of patient-specific surgical details
- Appropriate pre-operative diagnostics
- Comprehensive patient information, incl. e.g. different treatment options, impact of patient age corresponding to risk of explantation and the related complications/ adverse events
- Follow-up and medical care till freedom of symptoms



Note: The product is suitable for MRI examination up to 3 Tesla.

13. Product combinations and accessories

The A.M.I. InGYNious meshes are principally suitable to be used in combination with the A.M.I. i-stitch suture instrument.

For more detailed information regarding the products used in combination with the InGYNious mesh implants please refer to the specific instructions for use of these products.

14. Surgical instructions

Checklist before use:

The product has to undergo a visual check before use whereby attention must be paid to the following:

- Integrity of the sterile barrier packing
- Expiry date on the sterile barrier packing
- Damage due to inappropriate transport or storage

The surgical technique varies according the site of the pelvic organ prolapse.

14.1 Reconstruction of the anterior compartment

This step by step instructions describes the reconstruction of the anterior compartment using the InGYNious Direct Anterior mesh in case of preserving the uterus, or the InGYNious Vault mesh in case of vault prolapse or concomitant hysterectomy.

1. First infiltrate the anterior vaginal wall using sterile saline (0.9%) 40-60 ml +/- adrenaline.
2. Perform a dissection of the anterior vaginal wall. The incision of the anterior vaginal wall is made from the middle urethra to the cervix or the apex. Make a full thickness vertical incision, deep enough to reach the layer under the pubovesical fascia. A blunt bilateral dissection of the paravesical space is performed toward the ischial spine and coccygeal muscle. Identify the ischial spines, sacrospinous ligaments and arcus tendineus fasciae pelvis.
3. Create the anterior apical attachments, using a non-absorbable suture, that should be attached bilaterally to the sacrospinous ligament, 2-3 cm medial from the ischial spine (Level I fixation), using the specially designed A.M.I. i-stitch instrument, a narrow suture instrument which can easily access the sacrospinous ligament.
4. Create the anterior lateral attachments, placed on each side in the arcus tendineus fascia pelvis, 1-2 cm before the ischial spine, using the A.M.I. i-stitch instrument (Level II fixation).
5. Create a Level III attachments, placed to the arcus tendineus fasciae pelvis before the retropubic insertion point with the help of the A.M.I. i-stitch up instrument (recommended).
6. Placement of the mesh, using suture navigators to pass the sutures in their correct position through the mesh.
 - Feed both attachment suture ends through the loops of the suture navigators.
 - Hold and align the mesh close to the suture navigators.
 - Pull both sutures through the mesh by pulling the opposite part of the suture navigators.



Warning! Use only moderate force on the suture navigators to avoid damage of the navigators.

Ensure that the suture navigators are completely removed from the mesh to avoid any residues in the situs.

7. Slide the mesh in place and attach it to the ligament structures by tying all sutures following the order of level attachments.
8. Close vaginal incision, insert a urethral catheter and place vaginal tamponade.

14.2 Reconstruction of the posterior compartment

This step by step instructions describes the reconstruction of the posterior compartment using the InGYNious Direct Posterior mesh:

1. First infiltrate and make an incision in the posterior vaginal wall. Open the pararectal space bilaterally. Once the ischial spine is reached, identify the sacrospinous ligament and iliococcygeus muscles.
2. Create the posterior apical attachments placed on each side in the sacrospinous ligament (Level I fixation) 2-3 cm medial to the ischial spine and the posterior lateral attachments placed on each side in the iliococcygeus muscle (Level II fixation), 1-2 cm below the ischial spine.
3. Again, place the mesh and use the suture navigators to pass the sutures in their correct position through the mesh.
 - Feed both attachment suture ends through the loops of the suture navigators.
 - Hold and align the mesh close to the suture navigators.
 - Pull both sutures through the mesh by pulling the opposite part of the suture navigators.



Warning! Use only moderate force on the suture navigators to avoid damage of the navigators.

Ensure that the suture navigators are completely removed from the mesh to avoid any residues in the situs.

4. Slide the mesh in place and attach it to the ligament structures by tying all sutures following the order of level attachments.
5. The posterior superficial attachment of the mesh is performed with lateral suture fixation on each side to the perineal body (Level III fixation).
6. Close vaginal incision, insert urethral catheter, place vaginal tamponade and perform rectal examination.

15. Explantation of the product

Patient information

Transvaginal / open or laparoscopic mesh removal is a technically complex surgical procedure that requires qualified surgeons with appropriate experience and skill in surgery and knowledge in pelvic anatomy.

Because transvaginal mesh is considered a permanent implant, surgery to remove the mesh can be difficult and may increase a woman's risk of additional complications.

Mesh removal surgery may not address all of the symptoms that a patient may be experiencing. For this reason, mesh removal may not always be the appropriate treatment of symptoms.

Due to tissue growth into and around the mesh, removing the mesh without damaging the surrounding tissue and organs may not always be possible.

Depending on potentially affected organs, surgical mesh removal should be carried out in a multidisciplinary approach, potentially comprising of urologists, colorectal surgeons, pain specialists and specialist pelvic floor physiotherapists.

15.1 Partial resection (e.g. erosion, pain, dyspareunia, p.v. discharge, bleeding)



Warning! Pelvic reconstructive surgery with and without implants requires knowledgeable (e.g. anatomy) and experienced surgeons as pointed out in various guidelines and recommendations of medical societies (e.g. SCENIHR, FIGO, AGUB, EAU/EUGA):

- Especially the removal of surgical meshes for POP is only advised for trained surgeons who are educated in the surgical technique of this treatment.
- Furthermore, the surgeons should be trained on the usage of the specific mesh products.
- It is strongly advised to perform such complex surgeries in specialized and experienced multidisciplinary medical centres or hospitals only.

Patient is in dorsal lithotomy position. Apply an intravenous single- shot antibiotic. Place a Foley catheter before the beginning of the procedure to prevent bladder and urethra injury.

It is advised not to use electrocautery instruments in the vaginal space for surgical mesh removal.

Sharp dissection around the affected area depending on the size of the erosion. In regard to a small exposure, it is sufficient to grasp the mesh with a clamp, pull it carefully within the vaginal cavity and cut it below the level of the vaginal skin. In case of pain due to too much tension, it is sufficient to transect the fixation point. Reconstruct the defect and close the incision with sufficient overlap of vaginal tissue. Ensure at all times that structures / organs are unimpaired. Depending on the surgical site, potentially use cystoscopy, urethroscopy and / or rectoscopy. In case of perforation of adjacent viscera search collaboration with other medical specialties, such as urology or colorectal surgery. Consider referral to a clinician with appropriate training and experience.

15.2 Total resection (e.g. pain, inflammation, abscess)



Warning! Pelvic reconstructive surgery with and without implants requires knowledgeable (e.g. anatomy) and experienced surgeons as pointed out in various guidelines and recommendations of medical societies (e.g. SCENIHR, FIGO, AGUB, EAU/EUGA):

- Especially the removal of surgical meshes for POP is only advised for trained surgeons who are educated in the surgical technique of this treatment.
- Furthermore, the surgeons should be trained on the usage of the specific mesh products.
- It is strongly advised to perform such complex surgeries in specialized and experienced multidisciplinary medical centres or hospitals only.

Patient is in dorsal lithotomy position. Apply an intravenous single- shot antibiotic. Place a Foley catheter before the beginning of the procedure to prevent bladder and urethra injury.

It is advised not to use electrocautery instruments in the vaginal space for surgical mesh removal.

Identify the mesh via a vaginal incision along the relevant landmarks by aqua dissection (additionally with adrenaline, if needed).

Once the mesh is detected, remove / excise as much of the exposed mesh material as possible.

Depending on the indication for surgery, it may not necessarily be advisable to excise the entire mesh.

Reconstruct the defect and close the incision with sufficient overlap of vaginal tissue. Ensure at all times that structures / organs are unimpaired. Depending on the surgical site, potentially use cystoscopy, urethroscopy and / or rectoscopy. In case of perforation of adjacent viscera search collaboration with other medical specialties, such as urology or colorectal surgery. Consider referral to a clinician with appropriate training and experience.

16. Disposal of the product



After the usage of the product (explantation, removal etc.) it bears a potential biological hazard and has to be disposed according to current national laws and recommendation guidelines (e.g. RKI recommendations) for clinical waste.

17. Storage and transport conditions

Avoid strong vibrations during transport. Transport and storage should be in a dry and clean environment, protected from water and other fluids, sunlight, dust, salt and other substances.

Storage temperature: max. +25°C

18. Return and repair

Return consignments are only accepted if all components have been cleaned and sterilized beforehand. Contaminated components must be correspondingly labeled for the return consignments.

In the event of a defect, the entire product including the description of the defect must be sent back to the manufacturer.

19. Additional information

This description is only a guide for the proper and safe use of this product by the user (medical staff / surgeon or their representation in the form of a health care facility). It does not constitute as a recommendation for surgical procedures. By using this product, the user declares and warrants that it is familiar with the operating method described here and that all regulations applicable in the country concerned with respect to this method are complied with. Care must be taken to ensure that this product is prepared and used appropriately by qualified staff. The institution (hospital, health care facility) and the surgeon performing the surgery are jointly







responsible for ensuring that the qualified infrastructure necessary is in place and that only surgeons qualified in mesh POP surgery perform the surgery.













A.M.I. GmbH recommends that pelvic reconstructive surgery incl. mesh implantation and explantation is only performed in specialized medical centers or hospitals with sufficient expertise.

Defects and damages due to natural wear and tear, improper use, or modifications to the product which do not correspond to the user information are excluded from warranty. A.M.I. GmbH or its authorized specialist dealers are neither responsible for, nor obliged to compensate the surgeon or health care facility for incidental or causally determined losses, damages, or expenses arising directly or indirectly from the use of this product. A.M.I. GmbH will assume liability for product defects that existed before the product was shipped only if these defects are determined and reported before the product is used. Such cases will constitute only as a claim for replacement of the defective product.

All major incidents in relation to the product must be reported to the manufacturer and the appropriate authorities of the member state in which the user and/or patient is registered/located.

20. Symbols

Symbol	Description
	Refer to instructions for use
	Caution! Follow the accompanying documents
	Do not use if packaging is damaged
	Manufacturer
	Date of manufacture
	Do not reuse

	Do not re-sterilize
	Sterilized using ethylene oxide
	Latex free
	The US Federal Law restricts this product to be sold by or ordered by an approved physician
	Batch code (The first two digits indicate the year of manufacture)
	Reference number (order number)
	Expiry date
	This product complies with the applicable European Directives. The trailing four-digit number identifies the Notified Body.
	Keep dry
	Keep away from sunlight
	Temperature limit (high)
	This product is compatible with MRI with magnetic field strengths of up to 3 Tesla

21. Specifications

General mesh specifications:	
Grammage:	21 g/m ²
Thickness:	0.38 mm
Diameter of thread:	76 µm
Shape of mesh weave:	Hexagonal
Volume material fraction:	< 10 %
Stitch width:	2.2 mm lengthwise
	2.4 mm crosswise
Interstitial pore size:	100 -150 µm

InGYNious D A L/ IGY5951 InGYNious D A L-PP/ IGY5551		
Dimensions:	Width (max.)	110 mm
	Height	135 mm
Weight:	0.2 g (mesh only)	
Sterilization method:	Ethylene Oxide (EO)	

InGYNious D A S/ IGY5961 InGYNious D A S-PP/ IGY5561		
Dimensions:	Width (max.)	95 mm
	Height	125 mm
Weight:	0.14 g (mesh only)	
Sterilization method:	Ethylene Oxide (EO)	

InGYNious D P L/ IGY5971 InGYNious D P L_PP/ IGY5571		
Dimensions:	Width (max.)	110 mm
	Height	150 mm
Weight:	0.2 g (mesh only)	
Sterilization method:	Ethylene Oxide (EO)	

InGYNious D P S/ IGY5981 InGYNious D P S-PP/ IGY5581		
Dimensions:	Width (max.)	90 mm
	Height	130 mm
Weight:		0.15 g (mesh only)
Sterilization method:		Ethylene Oxide (EO)

InGYNious V/ IGY5921		
Dimensions:	Width (max.)	90 mm
	Height	80 mm
Weight:		0.13 g (mesh only)
Sterilization method:		Ethylene Oxide (EO)

i-stitch loading unit	
Suture material, thread size	PP, monofilament USP 0 PET, braided USP 0
Needle length	166,5 mm
Needle diameter	1,5 mm
Needle tip type	Blunt tip
Total suture length	700 mm

22. Materials

IGY5551, IGY5561, IGY5571, IGY5581:

Material	Mass, surface area etc.	Type of contact
Polypropylene (mesh implant)	0,05g	Implanted device
Polypropylene (suture)		Implanted

IGY5921, IGY5951, IGY5961, IGY5971, IGY5981:

Material	Mass, surface area etc.	Type of contact
Polypropylene (mesh implant)	0,05g	Implanted device
Polyester (suture)		Implanted

23. Conformity

The product complies with the requirements of Medical Device Directive 93/42/EEC and is labelled with the CE mark accordingly.

CE 0297