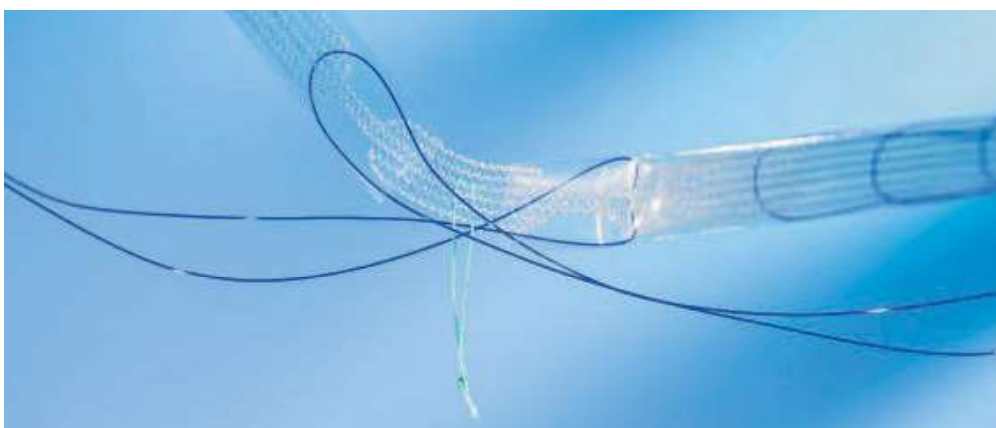


sensiTVT

Issue 14.08.2020 | 103021



REF	Product name
SUI5011	sensiTVT
SUI5021	sensiTVT-A

Operating manual
Gebrauchsanweisung
Manuale operativo
Mode d'emploi

Manual de instrucciones
Manual operacional
Návod k používání
Návod na používanie

CE0297 SUI5011, SUI5021



A.M.I.[®]

1. Product description

sensiTVT

This is a suburethral implant made from a polypropylene mesh, pull-in sutures and a detachable pull-in aid. The slings design enables tilting of the lateral sling arms, while the constricted space of the slings center lays constantly flat directly under the midurethra.

sensiTVT-A

This is an adjustable suburethral implant made from a polypropylene mesh, pull-in sutures, adjustment sutures and a detachable pull-in aid. The slings design enables tilting of the lateral sling arms, while the constricted space of in the slings center lays constantly flat directly under the midurethra. The sling's position might be adjusted post-operatively by means of the adjustment sutures. Adjustability allows for correction of

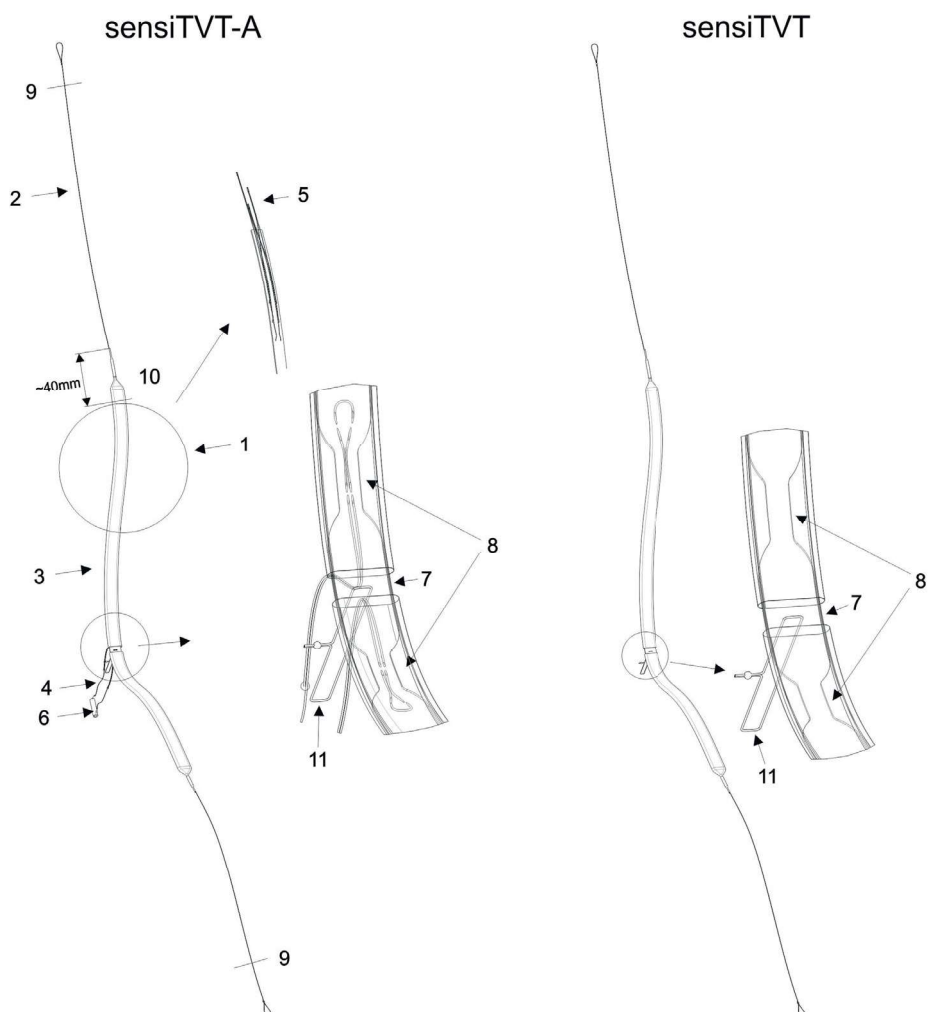
- Persisting incontinence by pulling the sling cranially
- Urinary retention by pulling the sling caudally

The slings are implanted in order to support the midurethra. The sling center is intended to be positioned directly midurethral, while the lateral ends serve for fixation in the tissue.

2. Intended use

Midurethral sling implant for the surgical treatment of female stress urinary incontinence.

3. Definition



Nr.	Description	Function
1	Sling arm	Sling fixation
2	Pull suture	Sling placement
3	Sling cover	For smooth insertion

Nr.	Description	Function
4	Vaginal adjustment sutures	To release tension
5	Supra-pubic adjustment sutures	To increase tension
6	Surgical needles	Tissue penetratio
7	Sub urethral mesh zone	Urethral support
8	Sling narrowing	Flexible joints
9	Pull suture cutting line	Detach from tunneller
10	Sling cover cutting lin	Cover removal
11	Midline marker	Orientation aid

4. Product features and clinical benefits

- Slings protective cover facilitates smooth and easy placement.
- Slings are made of firm macroporous biocompatible monofilament polypropylene mesh.
- SensiTVT-A offers post-operative adjustment of the sling to up to 5 days.
- SensiTVT-A offers tension adjustment in both directions. Cranial direction (tightening) in case of persisting incontinence and caudal direction (loosening) in case of urinary retention.

5. Patient group

Physically mature, at least 18 years old female patients with stress female urinary incontinence after failed conservative treatment methods.

6. Indications

SensiTVT and sensiTVT-A are indicated for the surgical treatment of female stress urinary incontinence resulting from

(a) urethral hypermobility and/or

(b) intrinsic sphincter deficiency (ISD)

after failed conservative treatment methods.

7. Contraindications

The use of these mesh implants is contraindicated in case of:

- Pregnant patients and/or patients that are considering future pregnancies
- Patients with potential for future growth (juvenile patients)
- Patients with any kind of soft tissue pathology into which the mesh implant is to be placed
- Patients with any pathology that could compromise the mesh implant placement
- Patients with any kind of pathology that could compromise healing
- Patients with hypertonic bladders
- Patients with vesicoureteral reflux
- Patients with known and/or unknown infection in the anatomical area of implantation
- Patients who have a known sensitivity/ allergy against plastic materials such as polypropylene, polyester, etc.
- Patients with a known anticoagulation disorder
- Patients with an anticoagulant therapy
- Patients with known autoimmune connective tissue disease
- Patients with active or latent infections especially of the genital system and/or urinary tract

8. Patient information

The surgeon performing the implantation should ensure that patient and / or their legal representative, 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
- Mesh is considered a permanent implant; removal of the mesh or correction of mesh-related complications may involve subsequent surgery/ surgeries
- Limitations of mesh removal and correction of post-operative complications
- Specific complications/ residual risks associated with the proposed procedure
- Suitability of patient's condition for mesh implantation
- Evidence/ level of experience of the performing surgeon with the surgical procedure

- 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 underrepresented 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.

Patients with SUI who are offered a retropubic sling are to be informed about the higher perioperative risk of complications in comparison to the transobturator sling.

Patients with SUI who have been offered a transobturatoric sling should be advised of the higher risk of long-term dyspareunia and pain.

9. Possible complications / adverse events

The following adverse events connected to any kind of mesh implantation are possible, but not limited to:

Frequently or (implant) specific reported complications:

- De novo urinary incontinence
- De novo urge urinary incontinence
- Pain (acute or chronic)
- Infection
- Erosion/exposure/extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
- Fistula formation and / or inflammation

Additional reported complications:

- Local irritation at the wound site
- Foreign body response
- Scarring/ scar contracture
- Implant migration
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention
- Pelvic, vaginal, groin/thigh pain (transient or permanent)
- dyspareunia
- Hemorrhage
- Detrusor instability

- Complete failure of the procedure
- Voiding dysfunction (incontinence; mild to moderate)
- Abscess
- Vaginal discharge
- Dehiscence of vaginal incision
- Edema and/ or erythema at the wound site
- Perforation or laceration of vessels, nerves, bladder, urethra or bowel during implantation

An occurrence of any of these events may require a surgical intervention. In some instances these events may persevere and remain a permanent condition even after intervention.

10. 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

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):

- The use of sling implants 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 sling products.

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.

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

11. Warnings and precautions



Warning! Pelvic reconstructive surgery (implantation and explantation) 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 sling 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 appropriately is to be avoided	
	Warning! The tunneller has to be reprocessed prior to each clinical application. Use sterile products only.	
	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! Implanting this product into a contaminated wound may result in infections requiring the removal of the product	
	Warning! The use of surgical mesh for the treatment of stress urinary incontinence has the potential to lead to adverse events including, but not limited to: acute or chronic pain in the groin, thigh, pelvic and/or abdominal area, mesh extrusion, exposure or erosion, infection, voiding dysfunction, dyspareunia, neuromuscular damage, organ perforation, recurrence of incontinence, bleeding or hemorrhage, vaginal scarring and/or tightening, mesh contraction and shrinkage, as well as rupturing of the mesh narrow points along with further complications. In addition, one or more revision surgeries may be necessary to treat these complications, while some complications may not always be completely corrected.	
	Warning! After implantation and sling adjustment make sure that only the mesh remains in the patient and all other parts (protective sleeve, sutures,...) are removed completely.	
	Warning! Advise the patient to consult a physician, if any unusual symptoms occur.	
	Warning! Do not use the marker suture as an intraoperative adjustment suture in order to avoid any excessive tensile forces occurring at the mesh centerpiece.	



Warning! Pulling too hard can cause the sling to rupture (high friction resistance) at the narrow sides of the SensiTVT and SensiTVT-A sling:

- Remove the protective sleeve only after intraoperative sling adjustment.
- Do not adjust SensiTVT postoperatively.
- Use the adjustable SensiTVT-A sling for patients that are most likely in need of adjustment after the surgery (e.g. rigid urethra, recurrence surgeries etc.).

Postoperative adjustment of SensiTVT-A can only be performed with the adjustment sutures designed for this.



Warning! The product is only to be used with the A.M.I. Tunnellers.



Warning! All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments should not be used and should be discarded.



Warning! Injuries of vessels, nerves, bladder or bowel may occur during tunneling and may require surgical repair



Warning! One or more revision surgeries may be necessary to treat these complications, while some complications may not always be completely corrected.

12. Product combinations and accessories

Implantation of the A.M.I.s sensiTVT and sensiTVT-A Slings is possible only with the A.M.I.'s TVA / TOA Tunnellers (TOA5130 / TOA5140 / TVA5030).

13. Surgical instructions

Implantation via retropubic approach with the TVA5030 tunneller:

Pre-operatively make sure that the patient's urine culture is sterile.

1. Place the patient in a dorsal lithotomy position using standard surgical practice, prepare and drape the patient and insert a Foley catheter.
2. Begin in the suprapubic field with identification of the exit incisions for the sling. The incisions are approximately 2 cm lateral to the midline in a transverse line above the superior symphysis pubis. Once the sites are identified make two small stab incisions.

3. Make a 1.5- 2 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect paraurethraly towards the retropubic space.
4. Hook loop of the pulling suture (2) in the tip of the tunneller (TVA5030).
5. Resting the tip of the tunneller (TVA5030) on the palmar surface of the non-dominant index finger, gently introduce the tunneller anterolaterally into the paraurethral space and perforate the endopelvic fascia. Lower the handle of the tunneller by pressing the tip of the tunneller against the back of the pubic bone. Carefully pass the tunneller (TVA5030) through the Retzius space keeping the tunneller tip in close contact with the pubic bone and perforate the rectus sheath and muscle. Guide the tunneller (TVA5030) by palpation into the ipsilateral abdominal incision until the tip of the tunneller is exposed through the incision.
6. When the tunneller tip (TVA5030) extends extra-abdominally grasp the pulling suture and secure it by placing a clamp on it, thus securing it temporarily extra-abdominally. Retrieve the tunneller out of the vagina.
7. Repeat on the contralateral side.



Warning! Make sure that the sling lies evenly and centrally under the urethra

8. At this point a cystoscopy should be performed to confirm bladder integrity.
9. Tension the mesh by pulling upwards on both pulling sutures simultaneously so that urine leakage is limited to no more than one or two drops.
10. **When implanting the sensiTVT-A adjustable sling:** pull on both of the vaginal adjustment sutures (4) (SensiTVT-A) with the use of the pre-attached sutures 1 cm lateral to the vaginal skin incision from the back of the vagina wall - through to the front of the vaginal wall by taking up with the needle provided.
11. **When implanting a sensiTVT-A adjustable sling** follow the next steps to conclude the procedure:
 - Cut the protruding mesh below skin level, leaving the adjustment sutures in place.
 - Cut the provided needles from the adjustment suture on both sides.
 - Close the incision in the usual manner.
 - Cover the protruding vaginal and inner thigh adjustment sutures (4,5) with a sterile dressing.
12. **When implanting a sensiTVT non- adjustable sling** follow the next steps to conclude the procedure: when the appropriate tension is achieved, cut the sling at position 10 (bilaterally) and remove the protective sleeve by pulling upwards on both sides simultaneously. Fix the sling in position to avoid sling tightening.

13. Close the incisions in the usual manner.

Make sure sufficient and qualified aftercare measures as well as an appropriate follow-up examination is in place.

SensiTVT/SensiTVT-A implantation via transobturator approach (outside-in) with the TA5130 tunneller:

Pre-operatively make sure that the patient's urine culture is sterile

1. Place the patient in a dorsal lithotomy position using standard surgical practice, prepare and drape the patient and insert a Foley catheter.
2. Make a 1.5 - 2 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra.
3. Perform a bilateral dissection towards the anterior obturator notch in the obturator foramen.
4. Make a 1 centimeter incision in the inner thigh, at the level of the clitoris and 1.5 centimeters below the adductor longus tendon bilaterally.
5. A helical tunneller (TOA5130) is passed from the inner thigh incision through the obturator foramen until it touches the opposite index finger. Then the tunneller is guided through the suburethral incision.
6. Hook loop of the pulling suture (2) in the tip of the helical tunneller (TOA5130)
7. Retrieve the tunneller out of the vagina.
8. When the helical tunneller tip extends extra-cutaneous, grasp the pulling suture and secure it by placing a clamp on it, thus securing it temporarily extra-cutaneously. Detach the pulling suture from the helical tunneller.
9. Repeat on the contralateral side.
10. Now the sensiTVT / sensiTVT-A sling is evenly and centrally placed in the suburethral incision, at the midurethral level.
11. **When implanting the sensiTVT-A adjustable sling:** draw both side vaginal adjustment sutures (4) (SensiTVT-A) with the use of the pre-attached sutures 1 cm lateral to the vaginal skin incision from the back of the vagina wall - through to the front of the vaginal wall by taking up with the needle provided.



Warning! Vaginal adjustment sutures (4) must be placed symmetric to the urethra. Sling (7) lies evenly and completely centrally under the urethra.

12. Tension the mesh by pulling upwards on both pulling sutures.

13. When the appropriate tension is achieved, cut the sling at position 10 (bilaterally) and remove the protective sleeve by pulling upwards on both sides simultaneously. Fix the adjusted sling in place by holding on to vaginal adjustment sutures.



NOTE: the sling can be adjusted via adjustment sutures up to 5 days postoperatively. After postoperative adjustment, remove all adjustment sutures by cutting one of the suture pair, and pull on the other for complete removal.

14. Cut the protruding mesh below skin level, leaving the adjustment sutures in place.
15. Cut the provided needles from the adjustment suture on both sides.
16. Close the incision in the usual manner.
17. Cover the protruding vaginal and inner thigh adjustment sutures (4,5) with sterile dressing.
18. **When implanting sensiTVT non-adjustable sling** follow the next steps to conclude the procedure: when the appropriate tension is achieved, cut the sling at position 10 (bilaterally) and remove the protective sleeve by pulling upwards on both sides simultaneously. Fix the sling in position to avoid sling tightening.
19. Close the incisions in the usual manner.

Make sure sufficient and qualified aftercare measures as well as an appropriate follow-up examination is in place.

SensiTVT/SensiTVT-A implantation via transobturator approach (inside-out) with the TOA5140 tunneller:

Pre-operatively make sure that the patient's urine culture is sterile.

1. Place the patient in a dorsal lithotomy position using standard surgical practice, prepare and drape the patient and insert a Foley catheter.
2. Make a 1.5 – 2 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Identify the points where the tunnellers will exit on the skin level and make two small incision stabs.
3. Perform bilateral dissection towards the anterior obturator notch in the obturator foramen.
4. Hook loop of the pulling suture (2) in the tip of the helical tunneller (TVA 5140).
5. Place the helical tunneller (TOA5140) into the vaginal incision and pass it with a

circular motion behind the ischipubis ramus maintaining close contact with it until its tip passes just beyond the ramus. Proceed to perforate the obturator membrane and the tip of the helical tunneller must exit through the subcutaneous tissue of the thigh, where previously marked.

6. When the tunneller tip exits the subcutaneous tissue, grasp the pulling suture and secure it by placing a clamp on it, thus securing it extra-cutaneously. Detach the pulling suture from the tunneller and retract the tunneller.
7. Repeat on the contralateral side.
8. **When implanting the sensiTVT-A adjustable sling:** pull on both vaginal adjustment sutures (4) (SensiTVT-A) with the use of the pre-attached sutures 1 cm lateral to the vaginal skin incision from the back of the vagina wall - through to the front of the vaginal wall by taking up with the needle provided.



Warning! Vaginal adjustment sutures (4) must be placed symmetric to the urethra. Sling (7) lies evenly and completely centrally under the urethra

9. Tension the mesh by pulling upwards on both pulling sutures.
10. When the appropriate tension is achieved, cut the sling at position 10 (bilaterally) and remove the protective sleeve by pulling upwards on both sides simultaneously. Fix the adjusted sling in place by holding on to vaginal adjustment sutures.



NOTE: the sling can be adjusted via adjustment sutures up to 5 days postoperatively. After postoperative adjustment, remove all adjustment sutures by cutting one of the suture pair, and pull on the other for complete removal.

11. Cut the protruding mesh below skin level, leaving the adjustment sutures in place.
12. Cut the provided needles from the adjustment suture on both sides.
13. Close the incisions in the usual manner.
14. Cover the protruding vaginal and suprapubic adjustment sutures (4, 5) with sterile dressing.
15. **When implanting sensiTVT non-adjustable sling** follow the next steps to conclude the procedure:
When the appropriate tension is achieved, cut the sling at position 10 (bilaterally) and remove the protective sleeve by pulling upwards on both sides simultaneously. Fix the sling in position to avoid sling tightening.

16. Close the incisions in the usual manner.

Make sure sufficient and qualified aftercare measures as well as an appropriate follow-up examination is in place.

Postoperative adjustment of the SensiTVT-A, if indicated:

1. Perform sling adjustment at the 1st up to the 5th postoperative day.
2. Cranial adjustment for sling tightening, use supra-pubic adjustment sutures (5).
3. Caudal adjustment for sling loosening, use vaginal adjustment sutures (4).
4. Cut and remove all adjustment sutures (4, 5)

14. Explantation of the product

Patient information

Transvaginal sling removal is a technically complex surgical procedure that requires qualified surgeons with appropriate experience and skill in surgery and knowledge in pelvic anatomy.

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

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

Due to tissue growth into and around the sling, removing the sling 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. 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 sling implants 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.

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 sling removal.

Sharp dissection around the affected area depending on the size of the erosion. Remove the part of the sling as required by cutting the sling material with a scissor.

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 mesh arm.

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 the event of mesh erosion into the bladder or urethra, referral to a specialist familiar with reconstructive techniques is warranted.

16. Partial resection of SUI slings due to incorrect sling position



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- Especially the removal of sling implants 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.

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 sling removal.

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

Dissect the sling paraurethrally with surgical scissors close to the sling on both patient sides up to a distance of approximately 3 cm to Ramus ischiopubicus.

Remove the sling as much as possible by cutting the sling material on both patient sides with scissors.

Reconstruct the defect and close the incision with sufficient overlap of vaginal tissue.

In regard to a sling release for outlet obstruction a small incision is made in the previous incision site or an anterior vaginal sulcus, the full width of the sling is isolated completely, an instrument is placed beneath the sling, and the sling is transected.

Ensure at all times that structures / organs are unimpaired. Depending on the surgical site, potentially use cystoscopy, urethroscopy and / or rectoscopy.

17. Total resection of SUI slings due to e.g. pain.



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 sling implants 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.

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

Dissect the sling paraurethrally with surgical scissors close to the sling on both patient sides up to a distance of approximately 3 cm to Ramus ischiopubicus.

Remove the sling as much as possible by cutting the sling material on both patient sides with scissors. 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.

If there is a need to remove the mesh arms the surgeon should go on with an abdominal approach in regard to a retropubic tape (via laparotomy or laparoscopy) or an access lateral to the descending pubic bone with dissection of the adductor muscles in regard to a transobturator tape.

Consider a multidisciplinary approach, including working with specialists in urology, female pelvic medicine and reconstructive surgery.

18. 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.

19. 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:	+10°C - +25°C
Rel. humidity:	20-60%

20. 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.

RETURNS:

Returns will only be accepted if all components have been previously cleaned and sterilized. Contaminated components must be marked accordingly upon returns.

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

REPAIRS:

You may not carry out any product repairs on your own accord. This could endanger the user, patient or third parties and cause the warranty to become invalid.

21. 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 sling implantation perform the surgery.







A.M.I. GmbH recommends that pelvic reconstructive surgery incl. sling 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.

22. 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

Symbol	Description
	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 (low – high)
	Humidity limitation
	This product is compatible with MRI with magnetic field strengths of up to 3 Tesla

23. Specifications

Sling specifications	
Material mesh	Polypropylene
Length of implant	450mm
Width of implant	15mm
Length of central part	35mm
Thickness of mesh	0,62mm
Pore size	>40mm ²
Grammage	95g/m ²
Porosity	>75%

24. Materials

Material	Mass, surface area etc.	Type of contact
Polypropylene	Max. 0,5g	Long-term (> 30 days)

25. Conformity

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

CE 0297