Surgical Technique

POP Tissue Anchoring System

Splentis

POP TISSUE ANCHORING SYSTEM

TABLE OF CONTENTS

Acknowledgments:
Promedon acknowledges the following surgeons for his support in the development of this surgical technique guide: Priv.-Doz. Dr. med. habil. Gert Naumann

INDICATIONS, PRECAUTIONS AND WARNINGS

• INTENDED PURPOSE

Splentis is intended for transvaginal reestablishment and reinforcement of the physiologic anatomy of the female pelvic floor in the defined patient population.

• INDICATIONS

Splentis is indicated for the transvaginal repair of apical pelvic organ prolapse in non-fertile women[1] with
- descent of the uterus
- descent of the uterine cervix after subtotal (supracervical) hysterectomy

• CONTRAINDICATIONS

Splentis must not be used in:

- Fertile women
- Women with post-total hysterectomy vaginal vault prolapse
- Patients with an active or latent infection of the vagina, cervix or uterus
- Patients with previous or current vaginal, cervical or uterine cancer
- Previous, current or planned pelvic radiation therapy
- Known allergy to polypropylene.

[1] Non-fertile women are defined as women who have gone through the menopause (def: absence of menstruation for at least one year) or those who are not fertile for iatrogenic reasons (e.g. subtotal hysterectomy, sterilization), which permanently prevent women from becoming pregnant.

WARNINGS AND PRECAUTIONS

The implantation of Splentis should be based on a thorough patient assessment as well as the patient's individual characteristics and preferences. Please consider the following warnings and precautions in the decision for surgery, clinical aspects, during the surgical procedure or handling of the device to avoid complications:

- Splentis must ONLY be used by surgeons experienced in transvaginal pelvic floor reconstruction and capable of recognising, diagnosing, and treating potential mesh-related complications associated with the procedure.
- Splentis must be used in sterile conditions in a surgical theatre.
- This surgical technique brochure[2] must be read and understood PRIOR to first implantation of Splentis.

Clinical aspects and decision to perform surgery

- Tobacco use, poorly controlled diabetes mellitus, genital atrophy, Body-Mass-Index > 30, and concomitant hysterectomy increases the risk of impaired wound healing and mesh exposure.
- Splentis must be used with care in patients with:
  - immunodeficiency
  - autoimmune disorders
- Risks can be minimised by using imaging methods before the procedure if appropriate and by inserting the retractable insertion guide correctly.
- DO NOT use Splentis simultaneously with any other transvaginal mesh for pelvic organ prolapse repair because this may increase the risk of mesh exposure or extrusion.
- Polypropylene mesh integrates with patient's tissue, hence complete removal may be difficult or unfeasible. The risk for organ injury caused by mesh removal may be higher than the benefits resulting from this removal. Adverse events (e.g. pain) may be persistent even after successful removal of the mesh. A decision on each case should therefore be made individually at the surgeon's discretion.

Surgical procedure and aftercare

- DO NOT deviate from the implantation procedure as described in the section SURGICAL TECHNIQUE of the IfU and consider patients' individual anatomical variations since aberrations can cause perforation or injury to the surrounding tissue and organs, e.g. blood vessels, nerves, ureters, urethra, bladder or bowel to avoid complications, such as revision surgery.
- DO perform full thickness vaginal wall dissection since split thickness vaginal wall dissection increases the risk for mesh exposure and extrusion.
- Attachment of Splentis to the posterior cervix may be associated with a risk of lower performance since the mesh may rip out and the physiologic axis of the vagina may not be maintained.
- DO NOT attach Splentis to the vaginal vault (i.e. colpopexy) due to the increased risk of mesh exposure or extrusion.
- Tension free implantation technique is mandatory to avoid urinary obstruction, lower urinary tract symptoms, pain, mesh exposure or extrusion.
- DO limit trimming of the vaginal epithelium in order to minimize the risk of vaginal stricture formation (i.e. contraction) since this may cause dyspareunia and pain.
- The surgical procedure must be carried out carefully, avoiding damage to the surrounding organs and tissues, e.g. blood vessels, nerves, bladder, or bowel.
- Check carefully before discharging the patient from hospital.

Clinical Benefits

Splentis improves the apical prolapse by means of reestablishing and reinforcing the physiological anatomy of the female pelvic floor.

Splentis has an expected lifetime of 10 years based on the available preclinical tests, chemical and biological tests performed, literature data and post-market surveillance data. To achieve this, all the sections in the Instructions for Use shall be considered and the product shall be implanted following the steps stated in the Surgical Steps in this Instructions for Use. There are no reasons to explant the product if there are no complications after the specified lifetime. However, each case should be assessed and a decision made at the surgeon's discretion.

Magnetic Resonance (MR) Environment

There are no concerns about a patient with a Splentis implant undergoing a magnetic resonance study. The implant is considered to be safe in this environment.

Radiation associated with diagnostic procedures

There are no concerns for patients with Splentis implants who undergo:
- Ultrasound examinations
- X-rays examinations.

CAUTION: All exams using ionising radiation should be performed only when necessary to answer a medical question, treat a disease or guide a procedure.

[2] The Surgical Technique Brochure is also available at https://www.promedon-urologypf.com/ and is supplied by the distributor to hospitals/health institutions.
[3]NICE: Urinary Incontinence and pelvic organ prolapse in women: management. NICE Guideline. 2019.

PATIENT INFORMATION AND AFTERCARE

The surgeon is responsible for thorough counselling and assessment of the patient as well as for requesting informed consent from the patient prior to implantation of the mesh. In particular, alternative conservative and surgical treatment options must be adequately discussed with the patient. The surgeon must counsel the patient regarding potential adverse events, including the advantages and disadvantages of urogynecological surgical mesh.

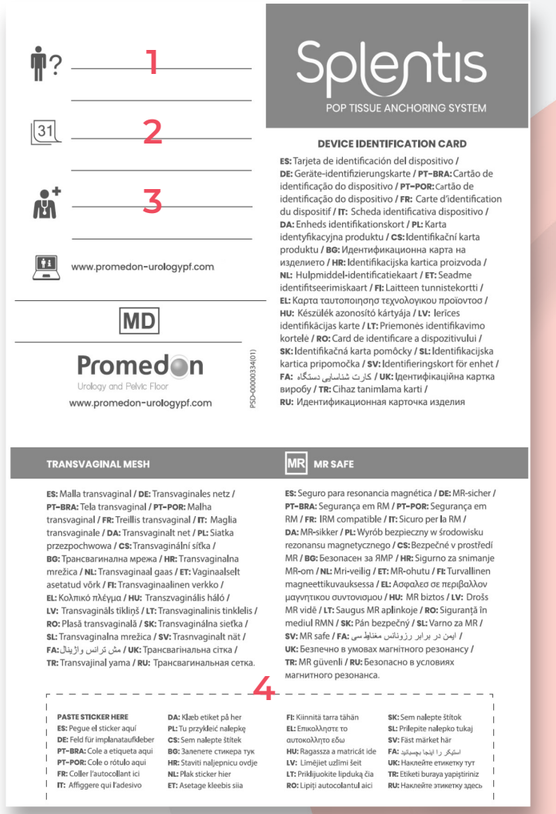
The patient should be advised that Splentis is a permanent implant, and any complication associated with the implant may require further surgery. The patient should contact the surgeon immediately in the event of signs for implant infections or other complications, such as:

- Purulent or bloody vaginal discharge
- Severe Pain
- Fever.

The patient should avoid heavy lifting, excessive physical exercise and sexual intercourse or other vaginal insertions for at least six weeks after surgery.

Topical oestrogens may be considered for vaginal exposure smaller than 1 cm^2 and no other symptoms for approximately 6 weeks after the operation if there are no contraindications[3].

DEVICE IDENTIFICATION CARD



According to Figure 1, complete the following information:

1. Name of the patient or patient ID. To be filled by the healthcare institution.

2. Date of implantation. To be filled by the healthcare institution.

3. Name and address of the healthcare institution. To be filled by the healthcare institution.

4. Product information. Stick the product's label which is attached to the Instructions for Use.

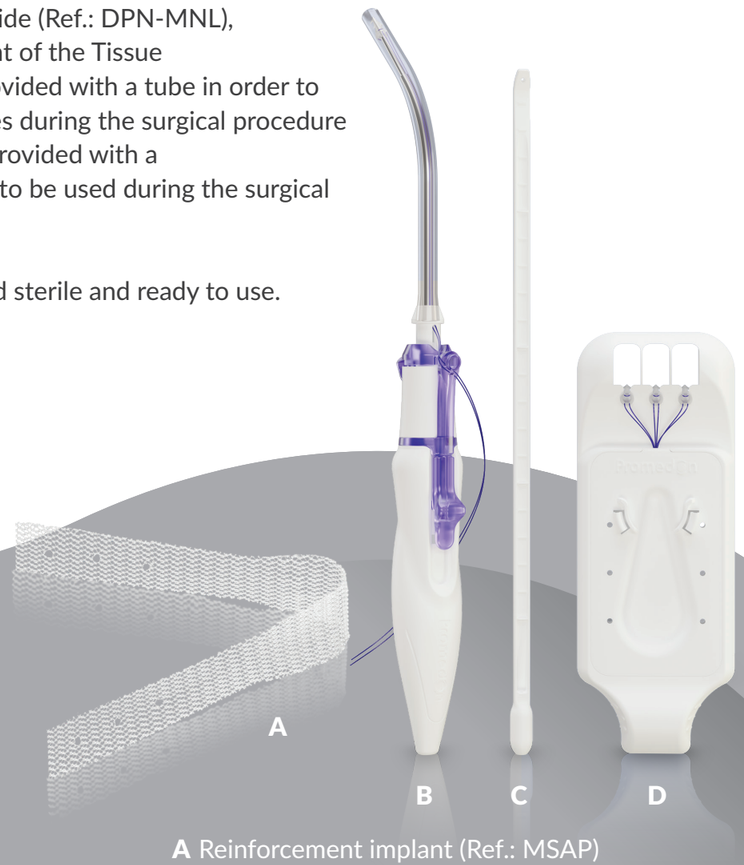
This implant card must be provided to the patient once it has been completed.

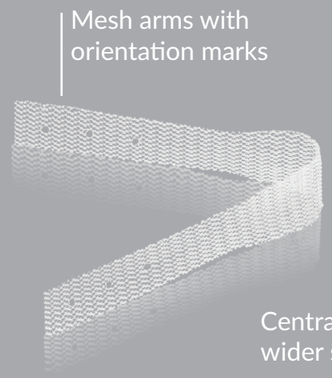
GENERAL INFORMATION

SPLENTIS KIT

- 1 Reinforcement implant (Ref.: MSAP)
- 1 Dispenser Unit with 3 Tissue Anchoring Systems (Ref: TAS) attached with polypropylene sutures
- 1 Retractable insertion guide (Ref.: DPN-MNL), designed for the placement of the Tissue Anchoring System and provided with a tube in order to protect surrounding tissues during the surgical procedure
- 1 Knot Pusher (Ref: KP), provided with a protective tube, designed to be used during the surgical procedure if necessary.

All components are supplied sterile and ready to use.

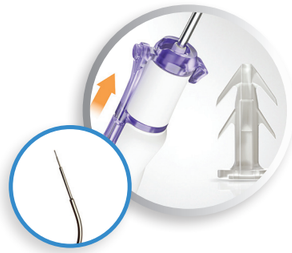




A Reinforcement implant (Ref.: MSAP)
B Retractable insertion guide (Ref.: DPN-MNL)
C Knot Pusher (Ref.: KP)
D Dispenser Unit with 3 Tissue Anchoring Systems (Ref.: TAS)

NOTE:
1 TAS is provided additionally if required

FUNCTIONALITY OF THE RETRACTABLE INSERTION GUIDES

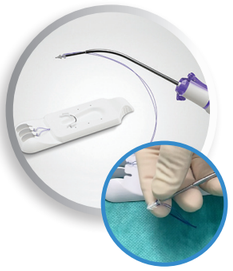


01

The TAS Anchors have a hole that can be placed on the tip of the RIG. Ensure that the switch on the RIG's handle has been pushed into the upper position to extend the RIG's tip before putting on the TAS Anchor.

02

Pick up a TAS from the Dispenser Unit by placing the extended RIG Tip into the TAS and pushing downwards. Once there is a "click", the anchor is attached to the RIG.



03

The TAS can now be safely removed from the Dispenser Unit. Ensure that the anchor is firmly attached to the RIG tip.

04

Place the suture ends around the fixation point on the handle.

05

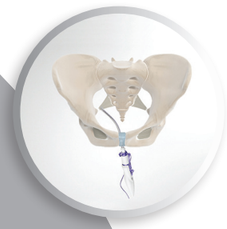
Ensure that the protective tube lock and release mechanism is in a pushed back, locking position.

06

The protective tube is pulled over the RIG until there is a "click". The protective tube is now securely attached to the RIG.

07

Ensure that the suture ends are passed through the slot on the bottom of the protective tube.



08

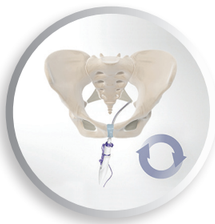
TAS implantation. For TAS implantation, guide the RIG to the sacrospinous ligament as described in this brochure.

09

Once the anchor is placed in its final position, the protective tube must be released by pushing the protective tube lock and release mechanism in its unlocked position. Subsequently, the TAS can be inserted into the sacrospinous ligament using firm pressure.

10

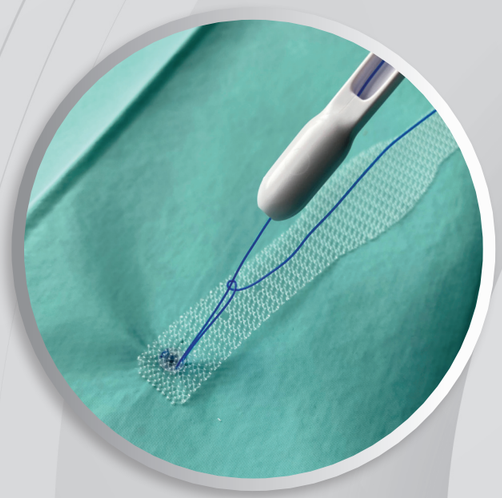
Release the anchor by shifting the RIG switch on the handle downwards. The RIG can then be safely removed.



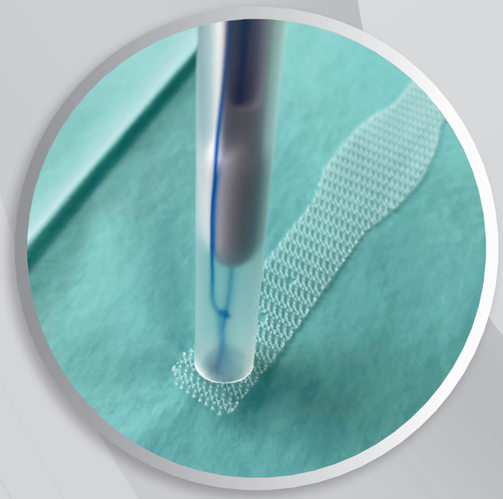
11

Remove the protective tube from the RIG to start implanting the second TAS on the contralateral side. Start the process from step 1.

FUNCTIONALITY OF THE KNOT PUSHER



The Knot Pusher is an optional instrument to facilitate the knotting of the mesh arm with the sacrospinous ligament.
The Knot Pusher has a hole at its tip and an indentation on one side.
For facilitation of the knotting procedure to the sacrospinous ligament, make the first knot as usual with one suture end.
This suture end is consecutively led through the hole in the Knot Pusher.



Pull the protection tube over the Knot Pusher, including both suture ends.
Push the Knot Pusher to the sacrospinous ligament.

SURGICAL TECHNIQUE

Preoperative considerations

The implantation of the Splentis should be based on a thorough patient assessment as well as the patient's individual characteristics and preferences. Please consider the indications, contraindications, warnings and precautions of using the Splentis prior to the operation. Prepare the patient for surgery according to local standard procedures and requirements for transvaginal POP repair. Splentis is implanted under general or local anesthesia.

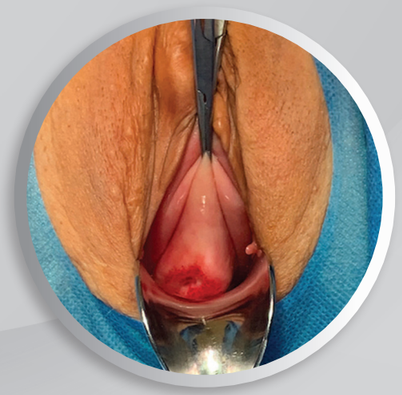
TIP:
Gert Naumann, M.D.
If atrophy of the vagina is identified, use topical oestrogens for four weeks prior to the operation unless contraindicated.

NOTE:
Remove a vaginal pessary four weeks prior to the operation to avoid preoperative injuries to the vaginal epithelium, such as erosions or ulcerations.

Positioning

Use a standard or high lithotomy position according to the surgeon's standard procedure.

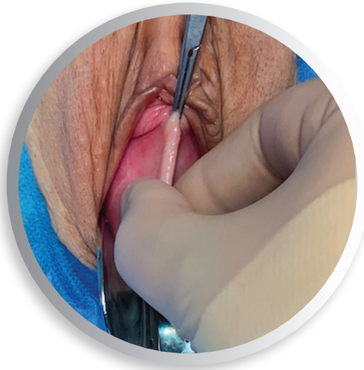
NOTE:
Lower limb nerve injury and compartment syndrome may occur with lithotomy positioning of the patient. Limit the risk by avoiding excessive hip flexion and hip abduction and reducing the operation time.



Surgical Steps

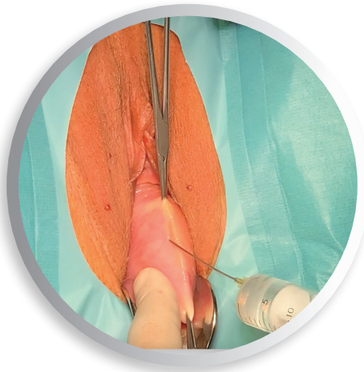
Ensure the bladder is empty prior to starting the operation. Use a urinary catheter as appropriate.

SECTION I:
Full thickness vaginal wall dissection



01

Place two Allis clamps vertically on the vaginal wall for the midline incision. Milk the bladder away from the vaginal wall with the thumb and index finger to develop the vesicovaginal space.

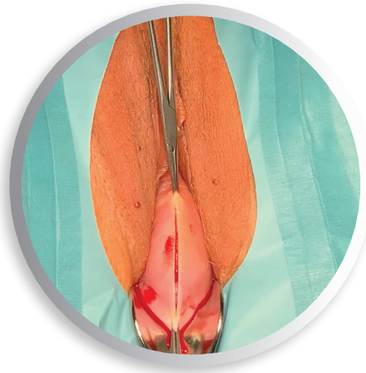


02

Perform a hydrodissection using injectable saline prior to the first incision to create a space between the vaginal wall and the underlying structures.

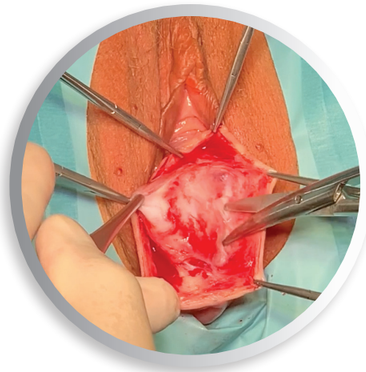
TIP:
Gert Naumann, M.D.
Adding a vasoconstrictive agent minimises bleeding during the procedure, e.g. 1 mg epinephrine (1:1000) diluted in 100 cc of injectable saline.

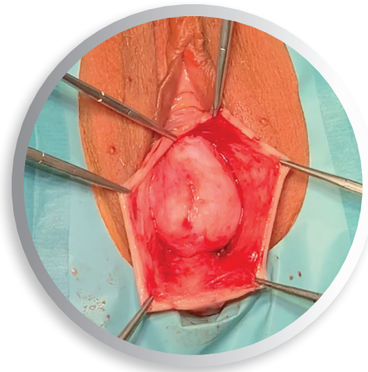
NOTE:
A blunt needle gives tactile feedback by reducing resistance at the entry of the vesicovaginal space.



03

Perform a midline anterior colpotomy with the scalpel, at the level of the bladder neck up to 1 cm before the cervix.





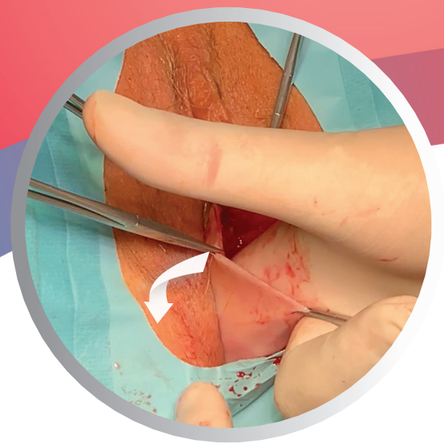
04

Perform a full-thickness vaginal wall dissection for entry of the vesicovaginal space by sharp and blunt preparation.

NOTE:
Limit the use of electrocauterization to prevent disruption to the blood flow.

NOTE:
A partial-thickness dissection may disrupt the blood supply to the vaginal mucosa and increases the risk of mesh exposure.

SECTION II:
Mesh and TAS Implantation



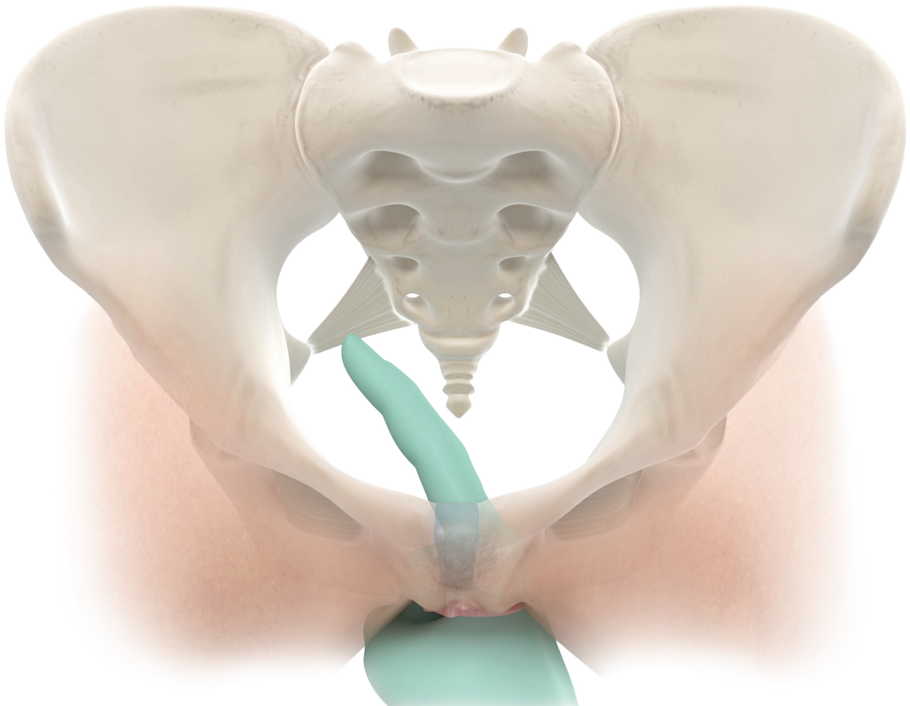
05

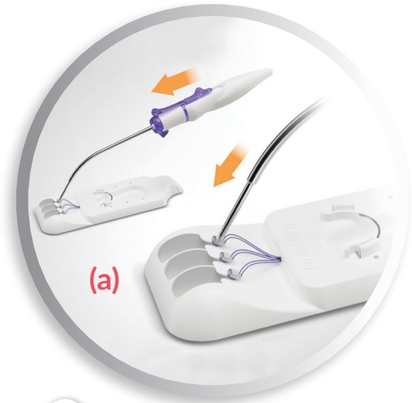
Develop the vesicovaginal space by sharp and blunt dissection as appropriate. Then enter the pararectal space using blunt finger dissection to identify the ischial spine with the index finger.

06

The ischial spine and sacrospinous ligament are identified by palpation. The surrounding tissue of the sacrospinous ligament is wiped away carefully from the ischial spine along the ligament using the index finger. Perform Steps 5 and 6 bilaterally.

NOTE:
The final position of the anchor is recommended to be approx. 2 cm medial to the ischial spine in the sacrospinous ligament. Surrounding tissue should be minimized at the intended position of the anchor.

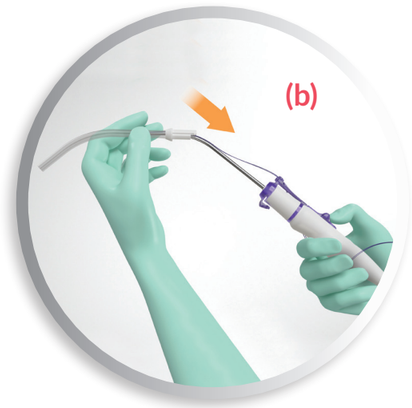




07

Then, the TAS has to be attached to the retractable insertion guide (Ref.: DPN-MNL).
Please follow the steps 1 to 5 of the section *Functionality of the Insertion Guide* (page 7) **(a)**.

NOTE:
Ensure that the anchor is firmly attached to the RIG tip.

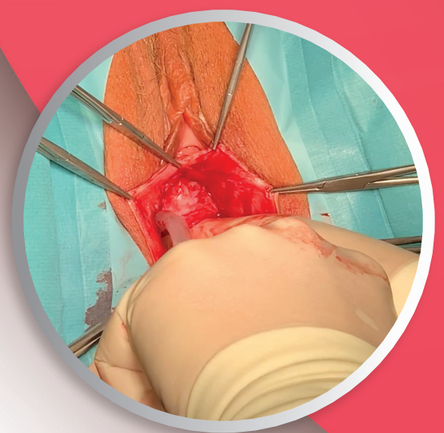


Then, the protection tube is pulled over the RIG (please refer to section *Funcionality of the Insertion Guide*, steps 6 and 7, page 7). **(b)**.

NOTE:
The protection tube is closed with the tip of the Retractable Insertion Guide to prevent it from becoming stuck or injuring the surrounding tissue as a result of the anchor's barbed hooks.

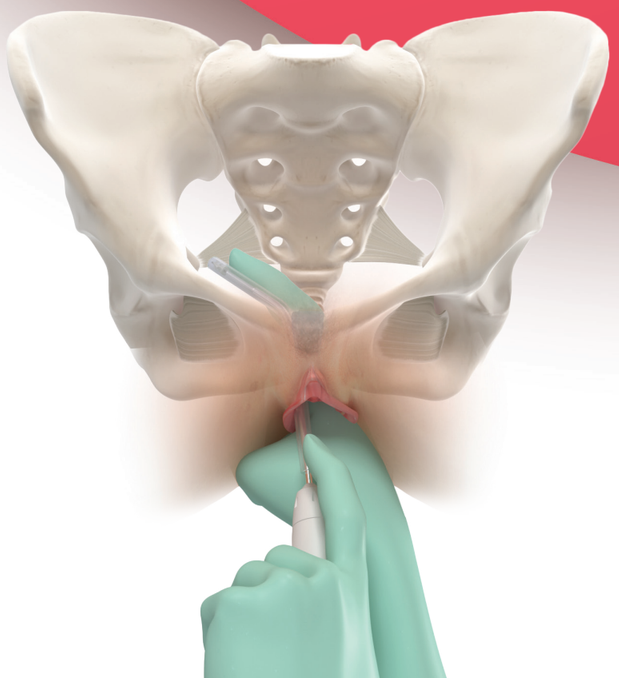
SECTION II:
Mesh and TAS Implantation

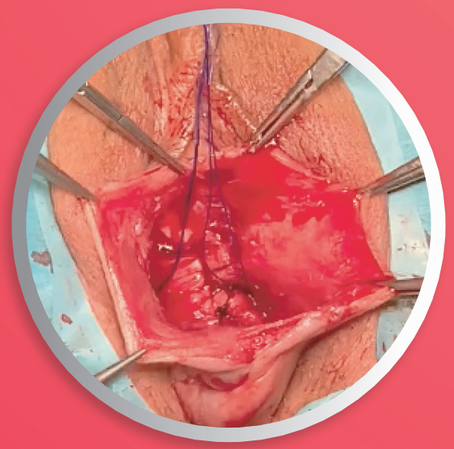
08 The TAS is fixed to the right sacrospinous ligament by the left hand. Firstly, the right index finger identifies the ischial spine and sacrospinous ligament. The rectum is gently pulled in a medial direction. The right hand remains in this position in order to guide the TAS to the sacrospinous ligament. The RIG is subsequently pushed forward to the sacrospinous ligament using the left hand along the right hand for guidance. The final position of the TAS should be approximately 2 cm medial to the ischial spine on the sacrospinous ligament. Hold the RIG firmly and straight when pushing the RIG onto sacrospinous ligament in its final position. Then, the protective tube must then be released by pushing the protective tube lock and release mechanism into its unlocked position. The TAS can then be inserted into the sacrospinous ligament using firm pressure. Release the anchor by shifting the switch on the handle downwards. The RIG and protective tube can then be safely removed.



Unlock the protective tube lock and release mechanism.

Release the anchor.

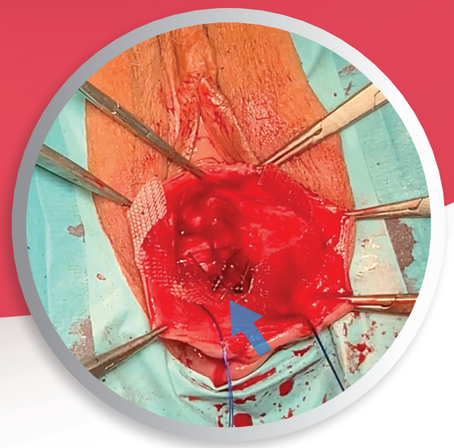




09 Perform the procedure accordingly on the contralateral site by using the left hand for guidance and the right hand to push. The sutures are left hanging out of the introitus until needed.

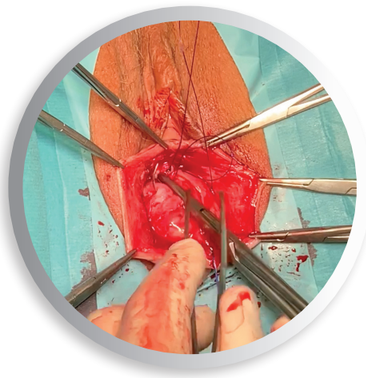
NOTE:
Rectal examination may be required in case of suspected bowel perforation.

NOTE:
Ensure that the TAS are firmly attached to sacrospinous ligament by gently pulling on the TAS suture.

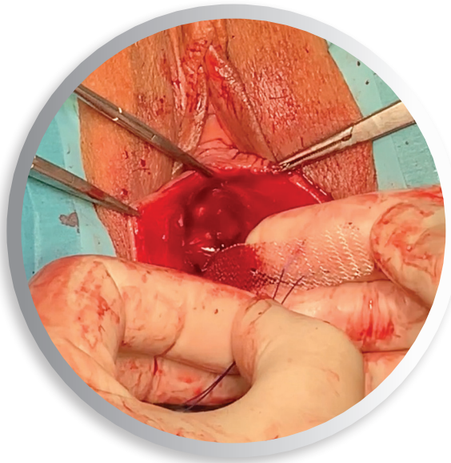


10 Positioning of the mesh to the anterior supravaginal portion of the cervix. Fixation of the mesh with three non-absorbable sutures.

TIP:
Gert Naumann, M.D.
Ensure that the mesh is fixed to the supravaginal portion of the cervix, which should be at least 1 cm distal from the incision line proximal to cervix orificium.



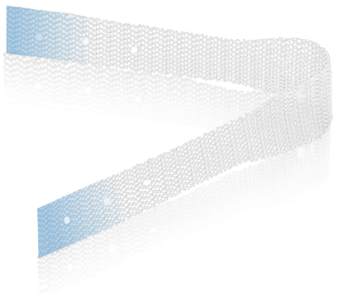
SECTION II:
Mesh and TAS Implantation



11

The TAS suture ends are then guided through the holes of the corresponding mesh arms.

TIP:
Gert Naumann, M.D.
Using the most distal part of the arm is usually adequate to suspend the uterus in a tension-free technique.

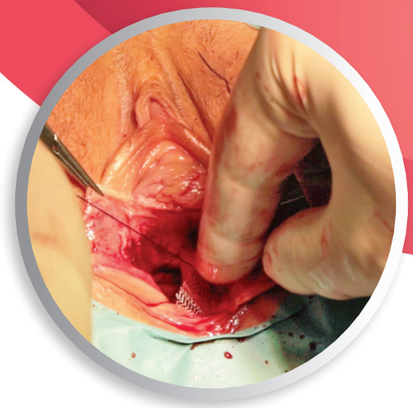


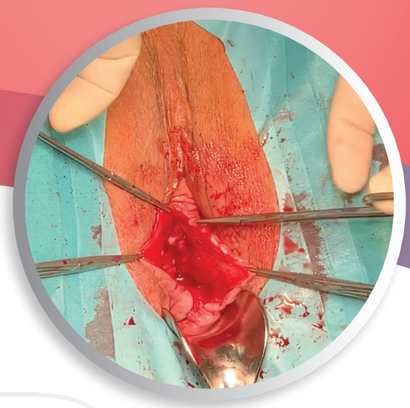
12

Since the sutures are already attached to the sacrospinous ligament by the anchors, ensure that the suture ends are guided without twisting the mesh arm.

NOTE:
Ensure that the mesh (arm) is not twisted.

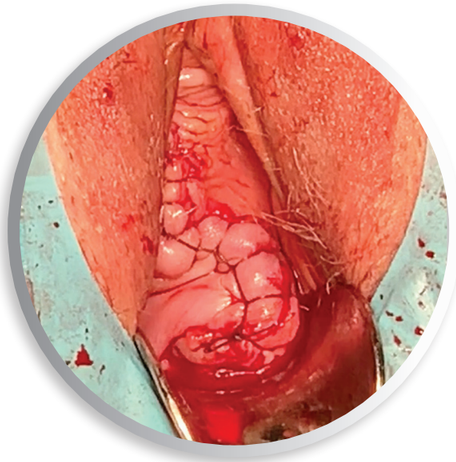
NOTE:
Ensure a tension-free implantation technique.





13

Slide the mesh arm onto the sacrospinous ligament bilaterally. Hold on to the end of the TAS suture during this procedure. Then knot the sutures to the sacrospinous ligament with the corresponding mesh arms on both sides and cut the excess portion of suture as close to the mesh as possible.

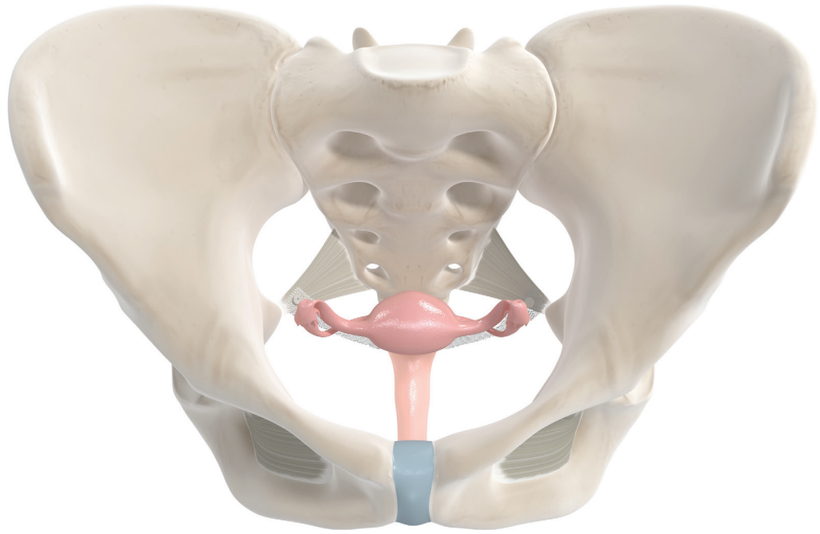


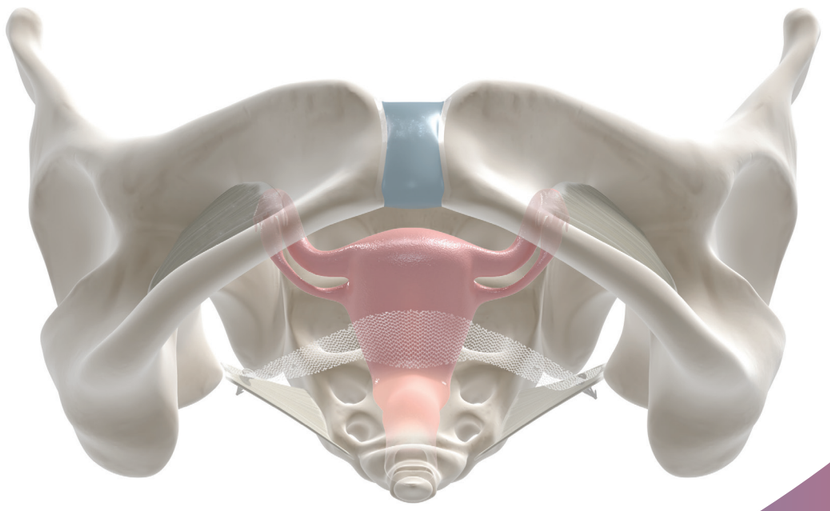
14

An anterior colporrhaphy may be performed simultaneously. Close the vaginal wall using absorbable sutures according to the standard surgical procedure. Vaginal packing for approx. 24h is recommended.

TIP:
Gert Naumann, M.D.
Since anterior and apical prolapse are frequently caused reciprocally, perform an anterior colporrhaphy in addition.

SECTION II:
Mesh and TAS Implantation





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