Surgical Technique

POP Tissue Anchoring System

Splentis

POP TISSUE ANCHORING SYSTEM

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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 USE

Splentis is intended for transvaginal reestablishment and reinforcement of the physiologic anatomy of the female pelvic floor concomitantly with Anterior Colporrhaphy, 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 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 in menopause (def: absence of menstruation for at least one year) or iatrogenic causes (e.g. hysterectomy, sterilization) which exclude women permanently 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.
- This surgical technique brochure must be read and understood PRIOR to first implantation of Splentis.

Clinical aspects and decision for 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 minimized by utilization of 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 for 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. Therefore, each case should be decided individually at the surgeon's discretion.

Surgical procedure and aftercare

- DO NOT deviate from the implantation procedure as described in the section SURGICAL PROCEDURE of this IfU and consider patients' individual anatomical variations since aberrations can cause perforation or injury of 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 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 surrounding organs and tissues, e.g. blood vessels, nerves, bladder, or bowel.
- Check carefully before releasing the patient from hospital.
- The patient should avoid heavy lifting, excessive physical exercise and sexual intercourse or other vaginal insertions for at least six weeks after surgery.

Handling of the device

- DO NOT handle the implant with pointed, serrated, or sharp objects since any damage, perforation, or tearing can cause device damage and or deficiency.
- Avoid excessive tension of the implant.
- Maximum precautionary measures must be taken when connecting the TAS with the insertion guide in order to ensure the integrity of the anchors.
- Avoid excessive pressure in the wrong direction during TAS placement.

General aspects

- DO NOT use the product if the package is open or damaged, as Splentis components are supplied sterile.
- Polypropylene may cause inflammatory reaction.
- Splentis components are designed for SINGLE use only.
- Ensure that the product is discarded according to the local rules and be aware of the risks of contamination of the environment, patients and personal.
- DO NOT reuse or resterilize since this could decrease the performance of the device and increase the risk of improper sterilization and cross-contamination.
- Maximum precaution must be taken to avoid contamination. Operating room conditions must meet hospital, administrative and/or local governmental requirements.

[2] The Surgical Technique Brochure is also available at http://www.promedon-upf.com/ and is supplied by the distributor to hospitals/health institutions.

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 mesh implantation. 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 regarding 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 e.g.:

- 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 estrogens may be considered for approximately 6 weeks after the operation if there are no contraindications.

IMPLANT CARD

The patient must be provided with an implant card including:

- Device name
- Device type
- Serial and lot number or unique device identifier as appropriate
- Manufacture's name, address and website
- Name of the patient or patient ID
- Name and address of the healthcare institution which performed the implantation
- Date of implantation/explantation
- Warnings, precautions or measures to be taken by the patient
- Expected lifetime of the device and mandatory follow-ups
- Any other information to ensure safe use of the device by the patient.

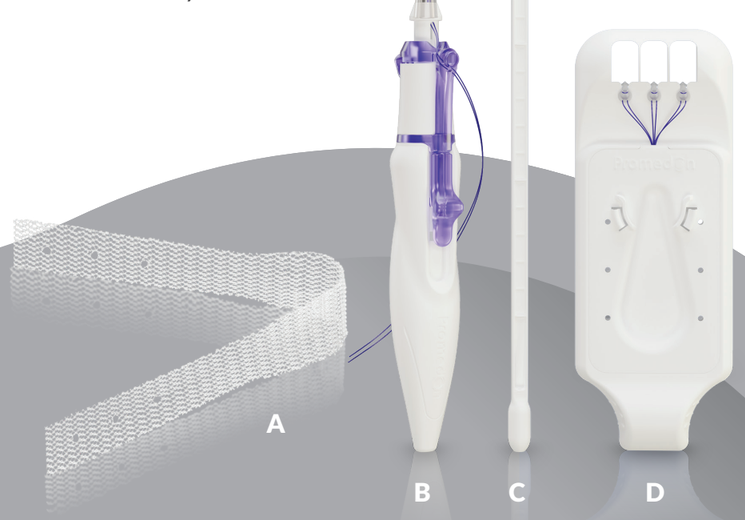
The implant card is NOT included in the Splentis kit and must be created by the physician.

GENERAL INFORMATION

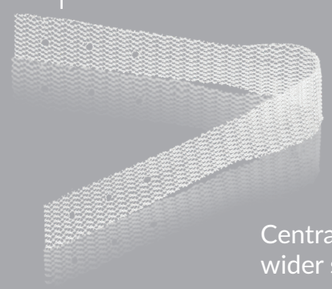
SPLENTIS KIT

- 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), disposable, 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), disposable, provided with a protective tube, designed to be used during the surgical procedure if necessary.

All components are supplied sterile and ready to use.



Mesh arms with orientation marks

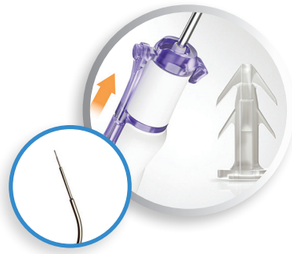


Central mesh with wider surface

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 GUIDE



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 and place the anchor on the extended RIG tip. Once there is a "click", the anchor is attached to the RIG.

03

The TAS can now be safely removed from the Dispenser Unit.

04

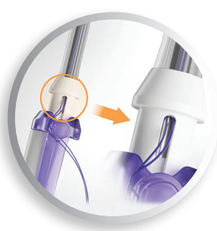
Place the suture ends around the fixation point on the handle.

05

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

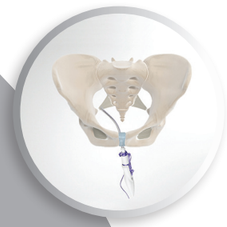
06

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

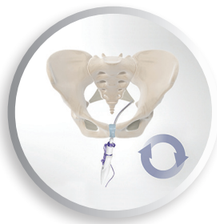
TAS implantation. For TAS implantation, guide the RIG to the sacrospinous ligament as described in this brochure.

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

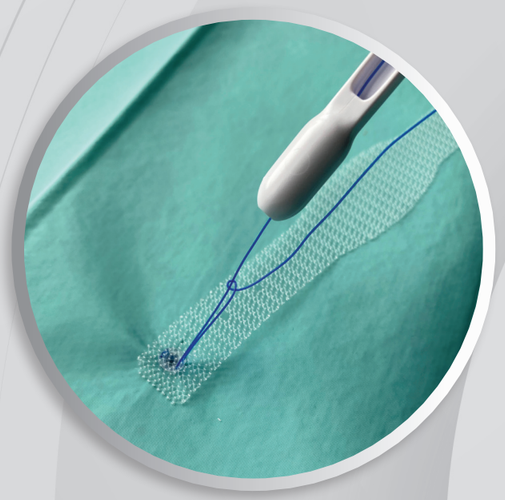
Release the anchor by shifting the RIG switch on the handle downwards. The RIG can then be safely removed.



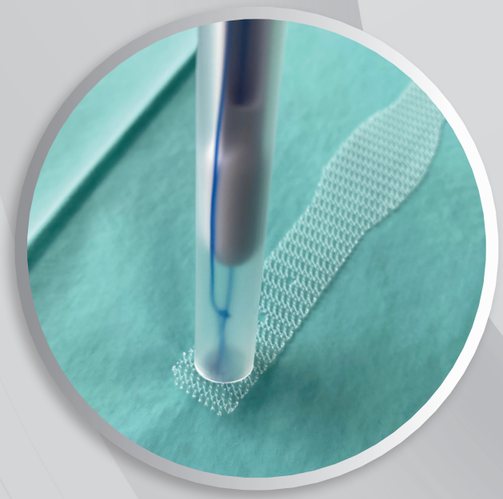
11

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 local standard procedures and requirements for transvaginal POP repair. Splentis is implanted under general or regional anesthesia.

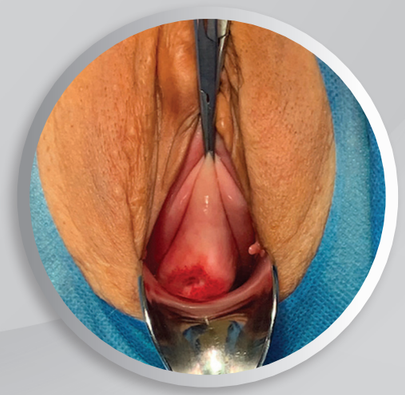
TIP:
Gert Naumann, M.D.
If atrophy of the vagina is identified, use topical oestrogens for four weeks prior to the operation unless contraindicated.

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

Positioning

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

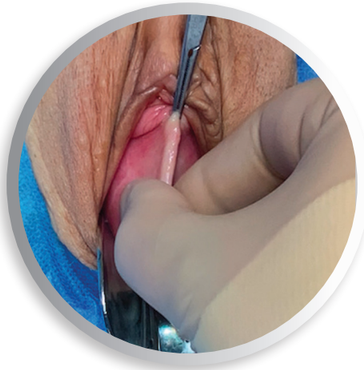
NOTE:
Lower extremity nerve injury and compartment syndrome may occur with lithotomy positioning of the patient. Limit the risk by avoiding excessive hip flexion and hip abduction and reducing the operation time.



Surgical Steps

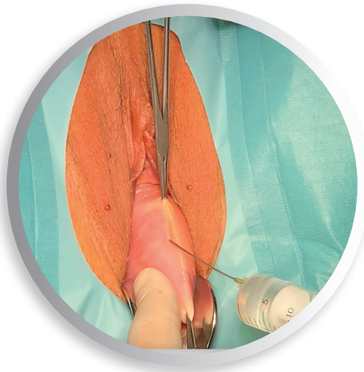
Ensure the bladder is empty prior to starting the operation. Use a urinary catheter as appropriate.

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.

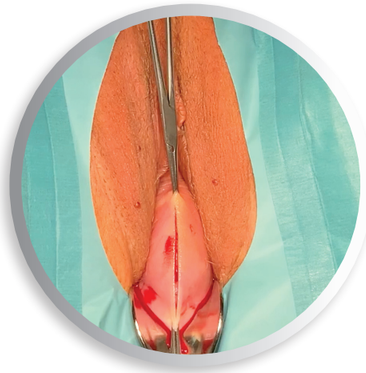


02

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

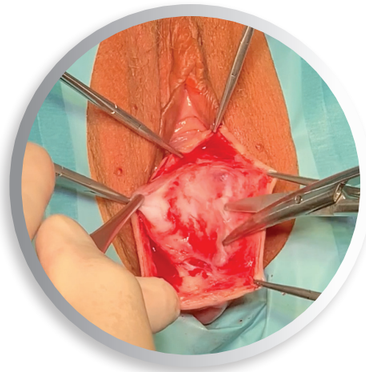
TIP:
Gert Naumann, M.D.
Adding a vasoconstrictive agent minimises bleeding during the procedure, e.g. 1 mg epinephrine (1:1000) diluted in 100 cc of injectable saline.

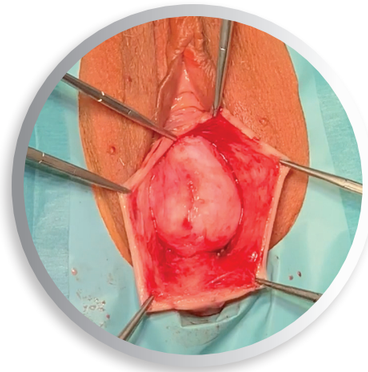
NOTE:
A blunt needle gives tactile feedback by reducing resistance at the entry of the vesicovaginal space.



03

Perform a midline incision of the anterior vaginal wall with the scalpel. Place an elasticated retractor if desired.





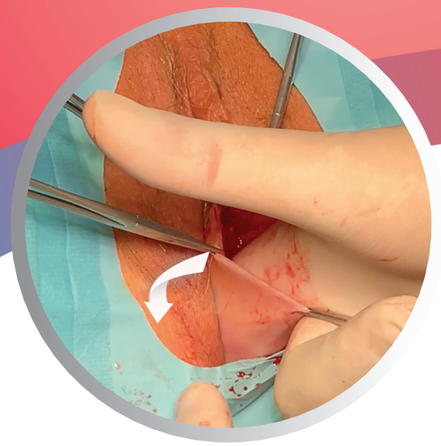
04

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

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

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

SECTION II:
Mesh Implantation



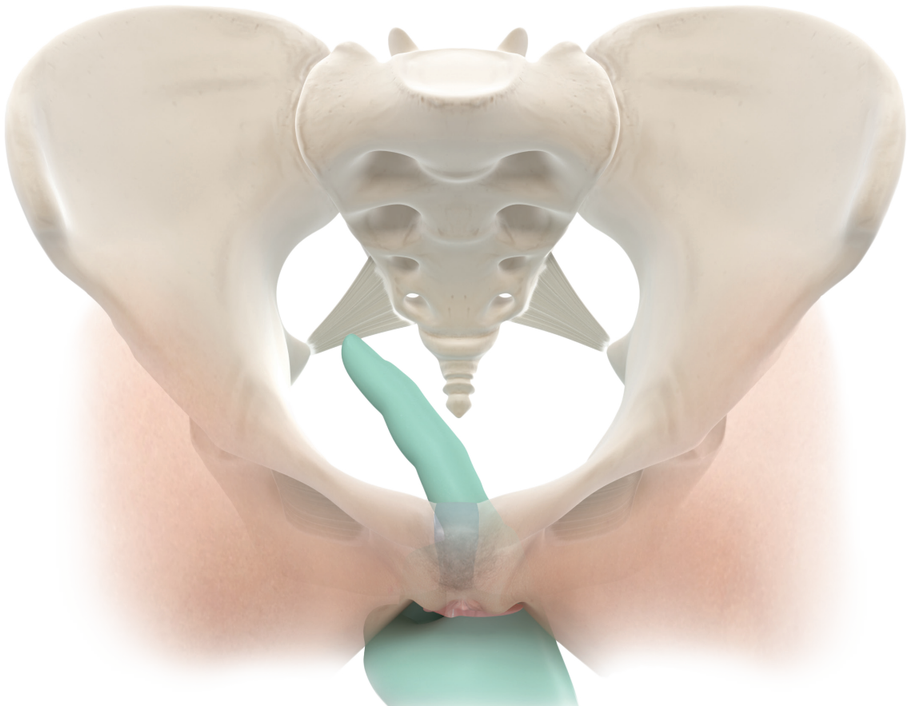
05

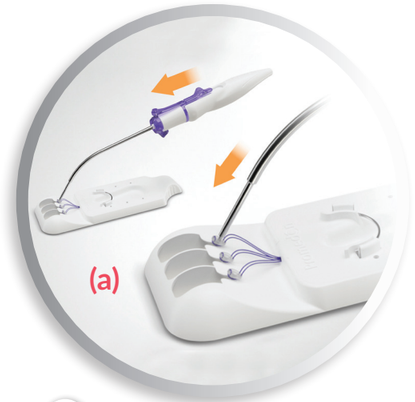
Develop the vesicovaginal space by sharp and blunt dissection as appropriate. Subsequently, enter the pararectal space using blunt finger dissection to identify the ischial spine with the index finger.

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 sacrospinous ligament using the index finger.
Perform Steps 6 and 7 bilaterally.

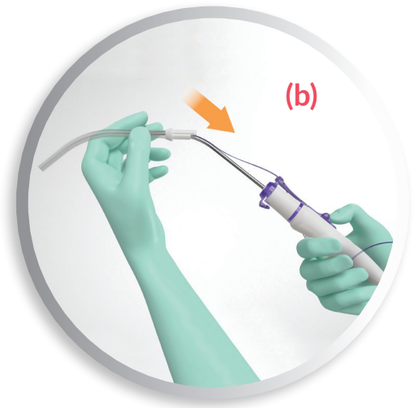
NOTE:
The final position of the anchor is recommended to be approx. 2 cm medially from the ischial spine in the sacrospinous ligament. Surrounding tissue should be minimised at the intended position of the anchor.





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)**.

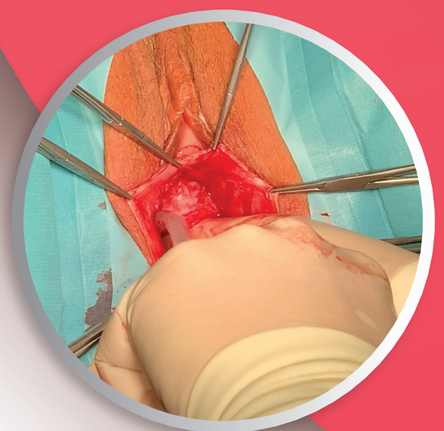


Then, the protection tube is pulled over the RIG (please refer to section *Funcionality of the Insertion Guide*, steps 6 and 7, page 7). **(b)**.

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

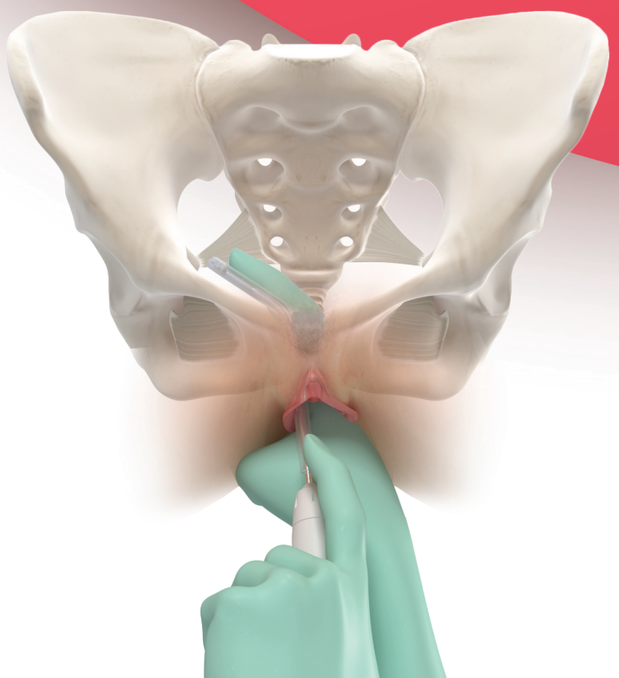
SECTION II:
Mesh Implantation

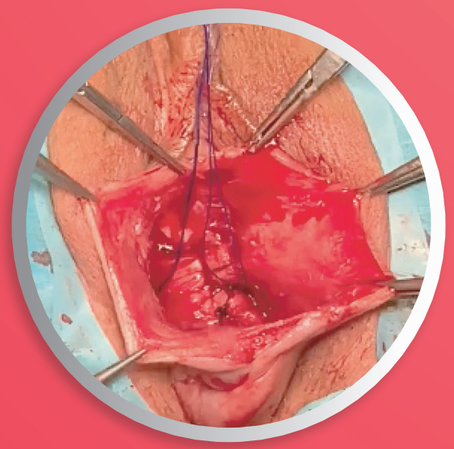
08 The TAS is fixed to the right sacrospinous ligament by the left hand. Firstly, the right index finger identifies the ischial spine and sacrospinous ligament. The rectum is gently pulled medially. The right hand remains in this position in order to guide the TAS to the sacrospinous ligament. The RIG is subsequently pushed forward with the left hand along the right hand for guidance to the sacrospinous ligament. The final position for the TAS should be located approximately 2 cm medially from the ischial spine on the sacrospinous ligament. Hold the RIG firmly and straight when pushing the RIG on the sacrospinous ligament at its final position. Then, 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. Release the anchor by shifting the switch on the handle downwards. The RIG can then be safely removed.



Unlock the protective tube lock and release mechanism.

Release the anchor.

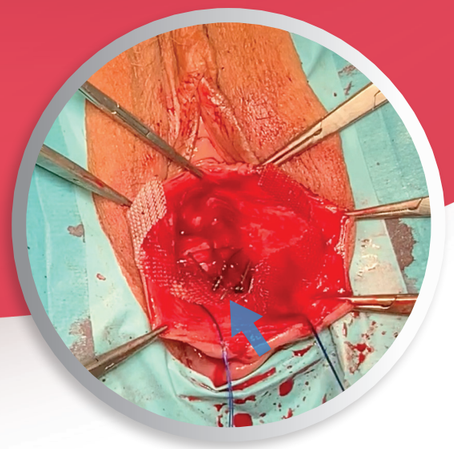




09 Perform the procedure accordingly on the contralateral site by using the left hand for guidance and the right hand for pushing. The sutures are left hanging out of the introitus until needed.

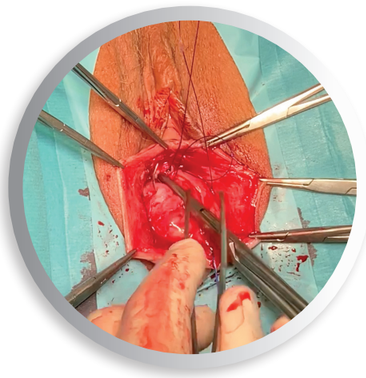
NOTE:
Rectal examination may be required in case of suspected bowel perforation.

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

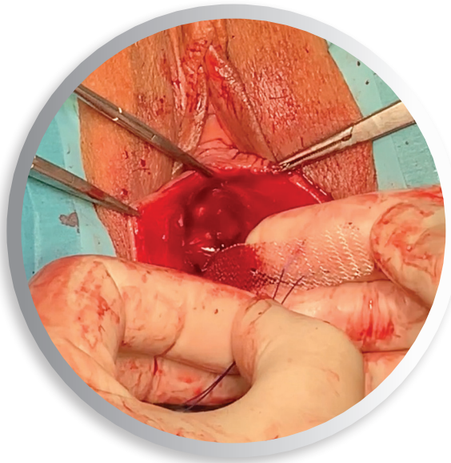


10 Positioning of the mesh to the anterior supravaginal portion of the cervix. Fixation of the mesh with three non-absorbable sutures.

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.



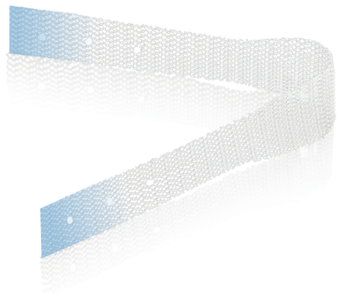
SECTION II:
Mesh Implantation



11

Then, the TAS suture ends are led through the pores of the corresponding mesh arms. For this purpose, select the outer distal part of the mesh arm in order to ensure a tension free implantation of the mesh.

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.

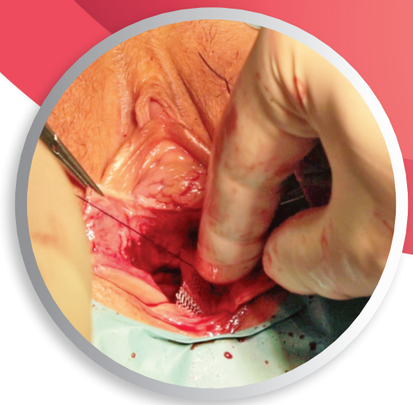


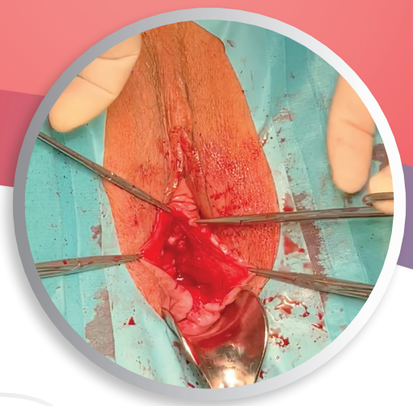
12

Since the sutures are already attached to the sacrospinous ligament by the anchors, ensure that the suture ends are guided from the posterior to the anterior aspect of the mesh arm.

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

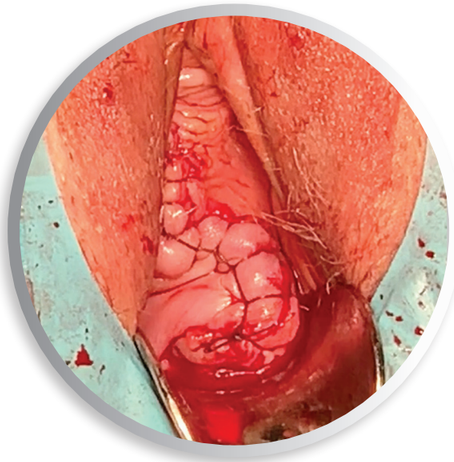
NOTE:
Ensure a tension-free implantation technique.





13

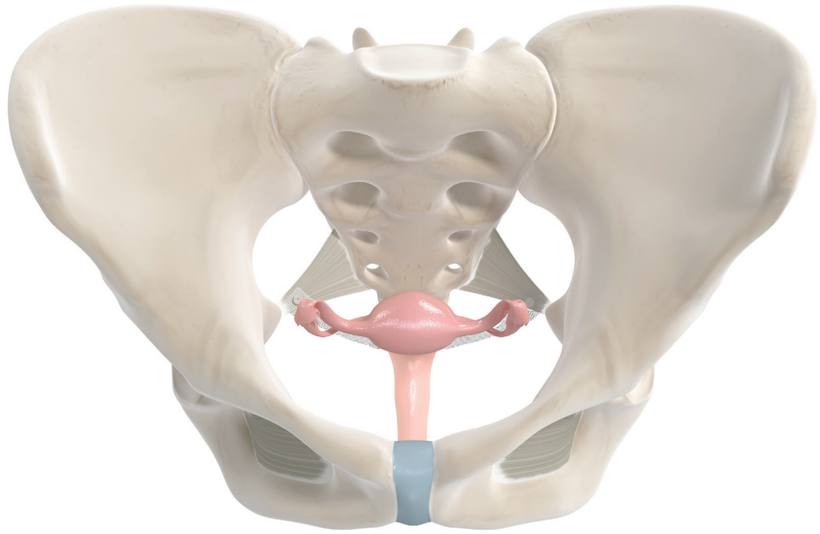
Slide the mesh arm to the sacrospinous ligament bilaterally. Hold on to the end of the TAS suture during this procedure. Subsequently, knot the mesh arms to the sacrospinous ligament with the corresponding sutures on both sides respectively.

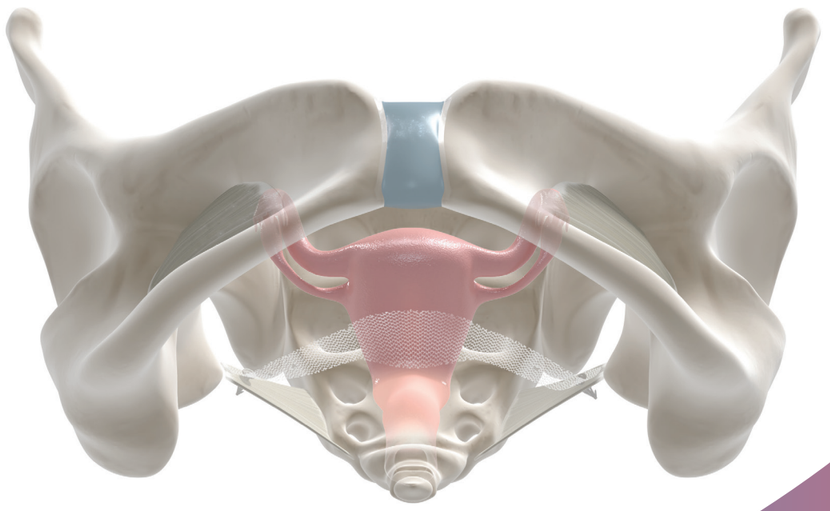


14

An anterior colporrhaphy shall be performed simultaneously. Closure of the vagina according to the surgeon's standard procedure. Vaginal packing for app. 24h is recommended.

SECTION II:
Mesh Implantation





Splentis

POP TISSUE ANCHORING SYSTEM

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Content ID: PSD-00000161 (03) / MAR-2024

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CE 0197

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