SURGICAL TECHNIQUE

Single Incision POP Repair System

Calistar S

SINGLE INCISION POP REPAIR SYSTEM

DESCRIPTION

This publication describes detailed recommended procedures for using Calistar S.

This brochure must be read and understood prior to first Calistar S implantation.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

Further training material is available at Promedon's online platform: www.promedon-urologypf.com.

In case of doubt with regard to the surgical technique, we recommend participation in a workshop prior to first surgery. Please contact your local Promedon representative or distributor for further information.

TABLE OF CONTENTS

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

INDICATIONS, PRECAUTIONS AND WARNINGS

INTENDED USE

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

INDICATIONS

Calistar S is indicated for the treatment of anterior pelvic organ prolapse in non-fertile women[1] with or without apical vaginal wall involvement in both,

- recurrent pelvic organ prolapse and
- primary pelvic organ prolapse, when other surgical procedures are expected to fail (i.e. complex primary prolapse) defined by the presence of at least two risk factors:
  - levator avulsion injury
  - family history of pelvic organ prolapse
  - enlarged genital hiatus
  - advanced stage POP (≥POP-Q stage 3)
  - pelvic floor muscle weakness
  - multiparity
  - younger age (<60 years of age)
  - collagen deficiency
  - co-morbidities which increase the intraabdominal pressure such as:
    - high body mass index
    - chronic obstructive pulmonary disease
    - chronic asthma
    - chronic constipation.

CONTRAINDICATIONS

Calistar S must not be used in:

- Fertile women
- 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 Calistar S 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:

- Calistar S must ONLY be used by surgeons experienced in transvaginal pelvic floor reconstruction.
- The surgical technique brochure (B-90-42)[2] must be read and understood PRIOR to first implantation of Calistar S.

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.
- Calistar S 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 Calistar S simultaneously with any other transvaginal mesh for pelvic organ prolapse repair or midurethral sling for treatment of stress urinary incontinence because this may increase the risk for mesh exposure or extrusion.
- There might be an increased risk for mesh complication if subsequent midurethral sling for stress urinary incontinence is performed.

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 surgical technique brochure 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 vaginal wall dissection increases the risk for mesh exposure and 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 and AAA with the insertion guides in order to ensure the integrity of the anchors.
- Avoid excessive pressure in the wrong direction during TAS and AAA placement.

General aspects

- DO NOT use the product if the package is open or damaged, as Calistar S components are supplied sterile.
- Polypropylene may cause inflammatory reaction.
- Calistar S 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-urologypf.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 Calistar S 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 discharg
- 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 Calistar S kit and must be created by the physician.

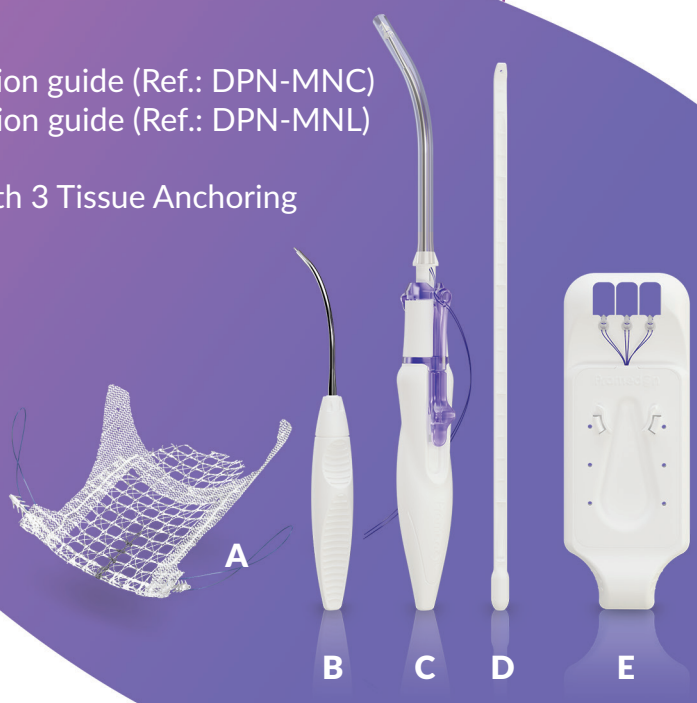
CALISTAR S KIT

The mesh kit contains:

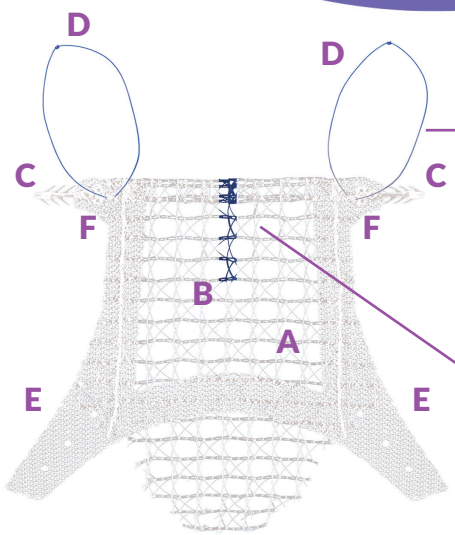
- 1 Calistar S implant.
- 1 Dispenser Unit with 3 Tissue Anchoring Systems (Ref.: TAS) attached with polypropylene sutures
- 1 Retractable insertion guide (Ref.: DPN-MNL), disposable, designed for the placement of the Tissue Anchoring System and provided with a tube in order to protect surrounding tissues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

NOTE:
1 TAS is provided additionally if required.

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



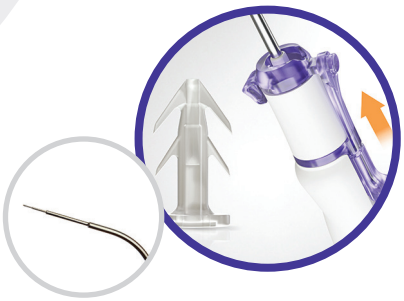
A Central mesh
B Central mark
C Anchor of the anterior attachment arms (AAA)
D Polypropylene sutures
E Posterior mesh arms
F Anterior attachment Arm (AAA)



NOTE:
The looped sutures of the anterior attachment arms are provided in case of necessity for removal of the anchor. Pull firmly on the loop in order to release the anchor from its position.

NOTE:
The Calistar S implant has a black, vertical, anterior middle line. This feature is provided for orientation purposes and indicates the anterior centre of the implant.

FUNCTIONALITY OF THE RETRACTABLE INSERTION GUIDES

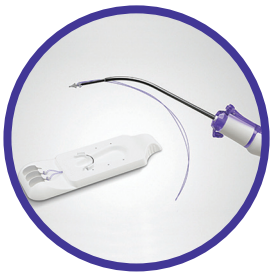


01

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 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

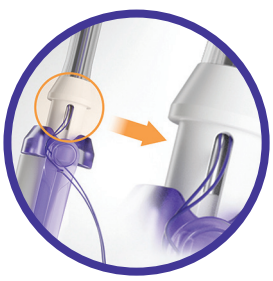
Place the suture ends around the fixation point on the handle.

05

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

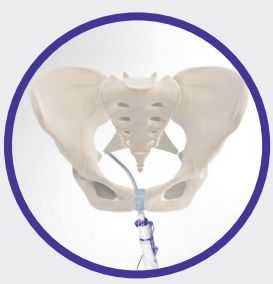
06

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

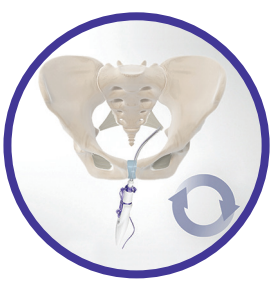
For TAS implantation, guide the RIG to the sacrospinous ligament as described in this brochure.

09

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

10

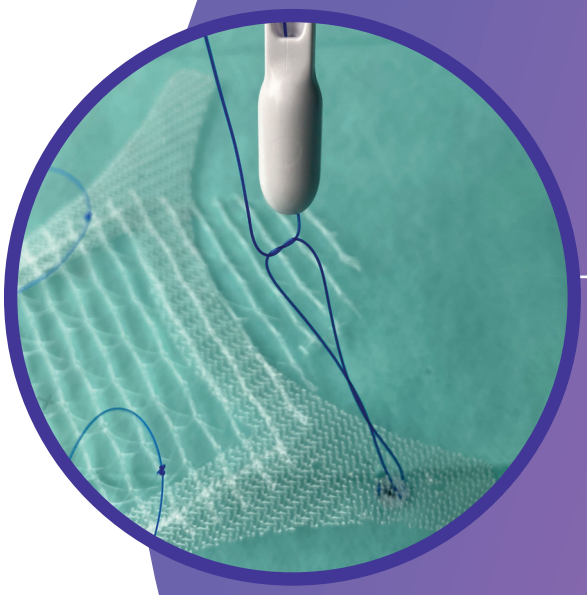
Release the anchor by shifting the RIG switch on the handle downwards. The RIG can then be safely removed.



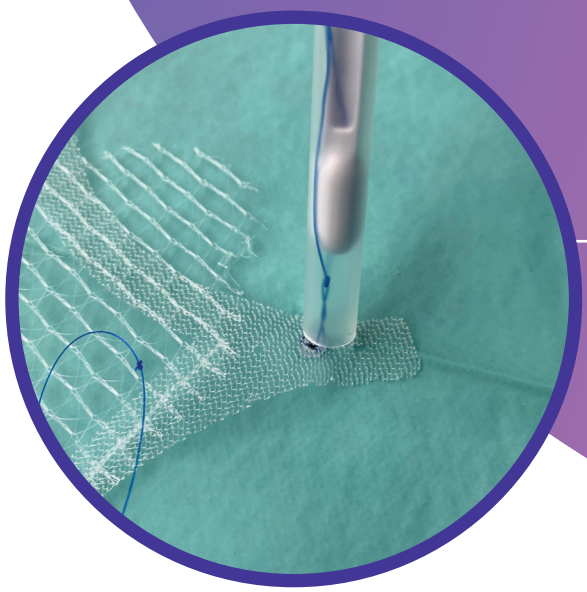
11

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

FUNCTIONALITY OF THE KNOT PUSHER



The Knot Pusher is an optional instrument to facilitate the knotting of the posterior 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 Calistar S 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 Calistar S prior to the operation. Prepare the patient for surgery according local standard procedures and requirements for transvaginal POP repair. Calistar S is implanted under general or regional anesthesia.

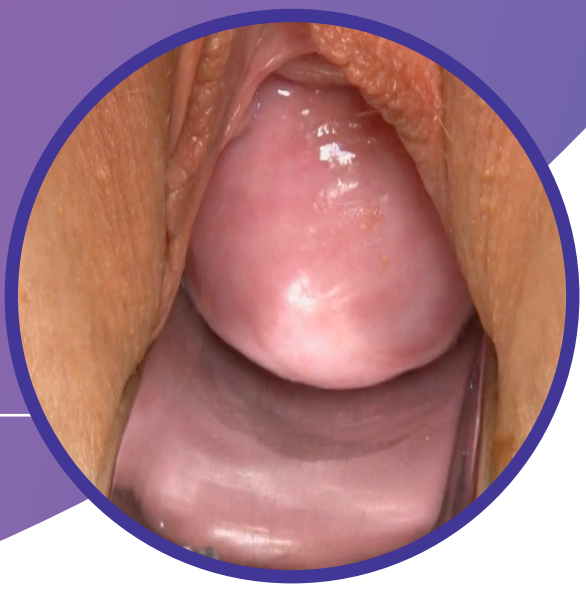
TIP:
Gert Naumann, M.D.
If atrophy of the vagina is identified, use topical oestrogens for four weeks prior to the operation unless contraindicated.

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.

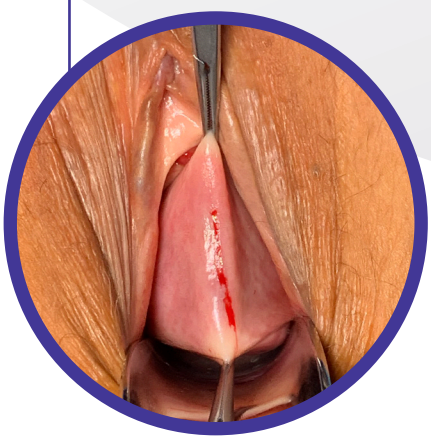


Surgical Steps

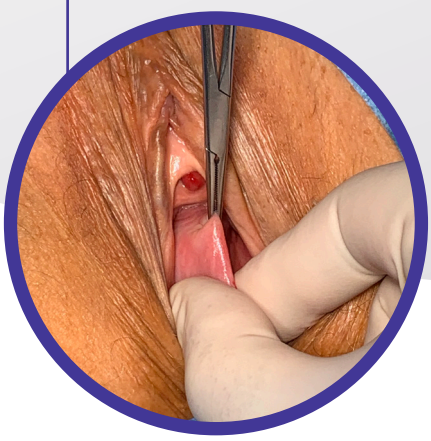
Ensure the bladder is empty prior to starting the operation. Use a urinary catheter as appropriate.

SECTION I:
Full thickness vaginal wall dissection

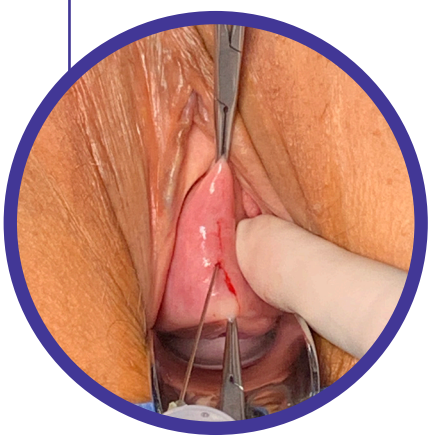
01 Place two Allis clamps vertically on the vaginal wall for the midline incision.

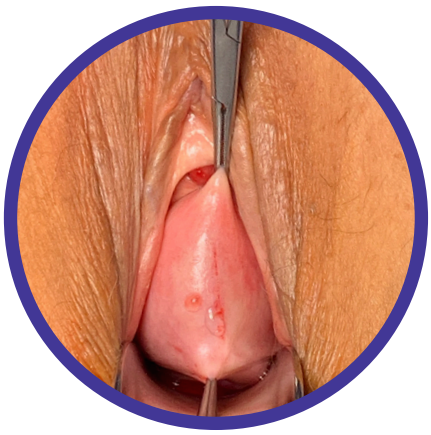


02 Milk the bladder away from the vaginal wall with the thumb and index finger to develop the vesicovaginal space.



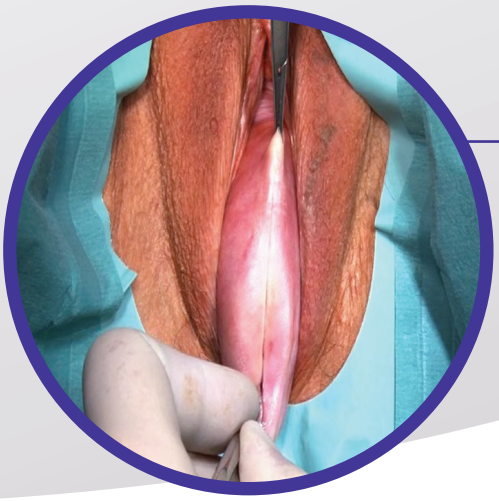
03 Perform a hydrodissection with injectable saline prior to incision to create a space between the vaginal wall and the underlying structures.





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

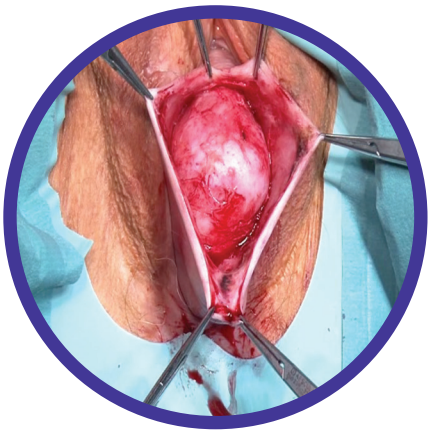
TIP:
Gert Naumann, M.D.
Adding a vasoconstrictive agent minimises bleeding during the procedure, e.g. 1 mg epinephrine (1:1000) diluted in 100 cc of injectable saline.



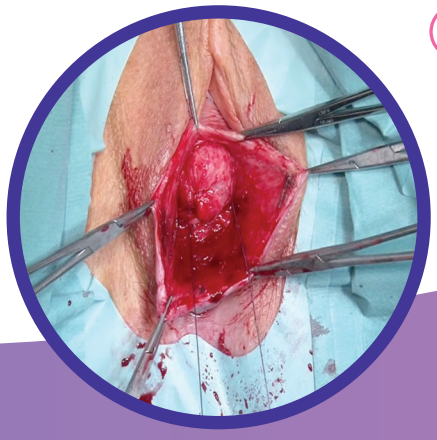
04 Perform a midline incision of the anterior vaginal wall with the scalpel. Place an elasticated retractor if desired.

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

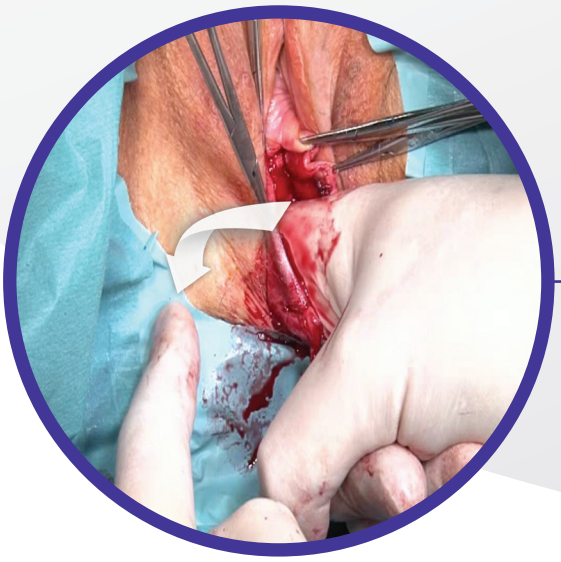
NOTE:
Limit the use of electrocautery to prevent the disruption of blood flow.



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

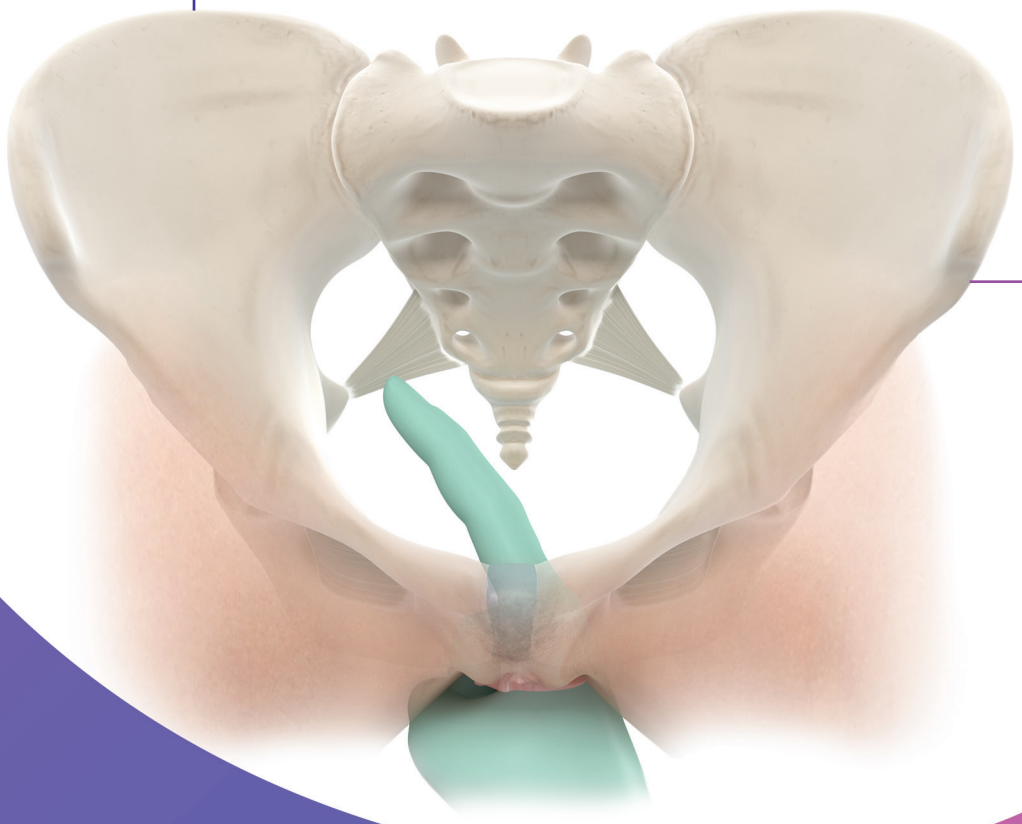


TIP:
Gert Naumann, M.D.
A colporrhaphy may also be performed to facilitate mesh implantation.



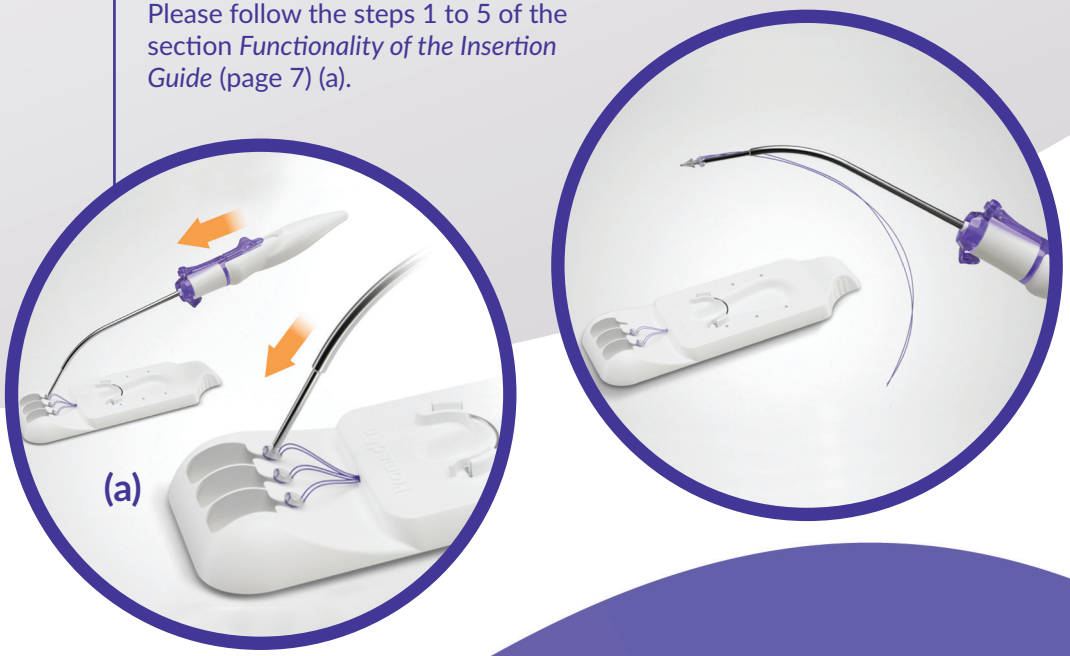
06 Develop the rectovaginal space by sharp and blunt dissection as appropriate.
Subsequently, enter the pararectal space using blunt finger dissection to identify the ischial spine with the index finger.

07 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.

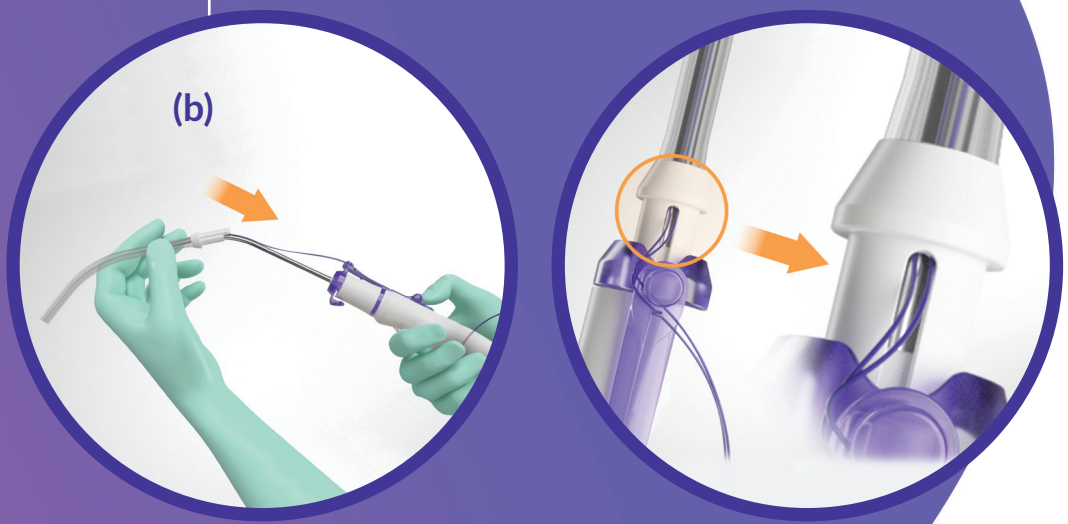


NOTE:
The final position of the anchor is recommended to be approx. 2 cm medially from the ischial spine in the sacrospinous ligament. Surrounding tissue should be minimised at the intended position of the anchor.

08 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).

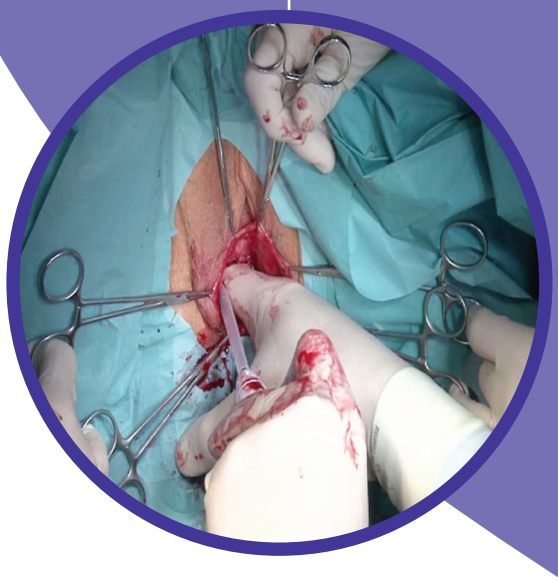


Then, the protection tube is pulled over the RIG (please refer to section *Funcionality of the Insertion Guide*, steps 6 and 7, page 7) (b).



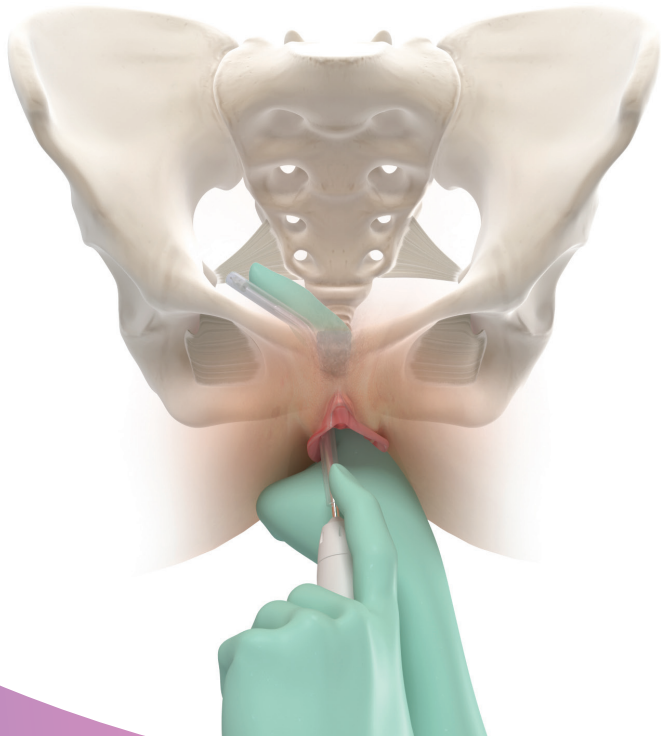
NOTE:
The protection tube closes with the tip of the Retractable Insertion Guide to prevent it from becoming stuck or injuring surrounding tissue due to the anchor's barbed hooks.

09 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.

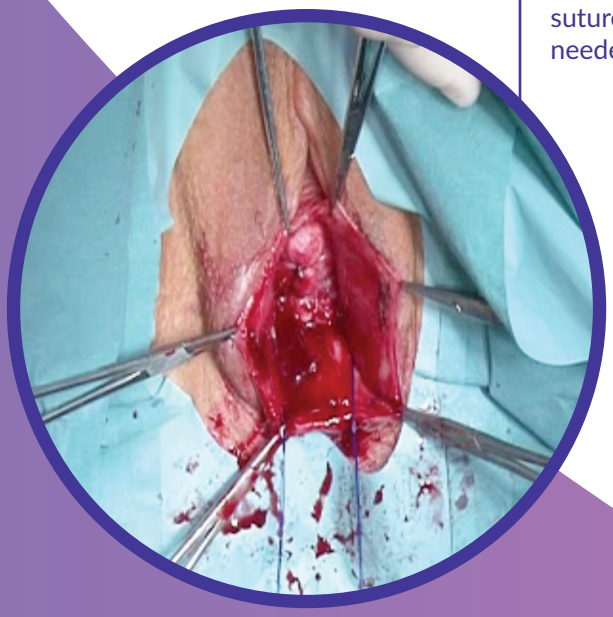


Unlock the protective tube lock and release mechanism

Release the anchor



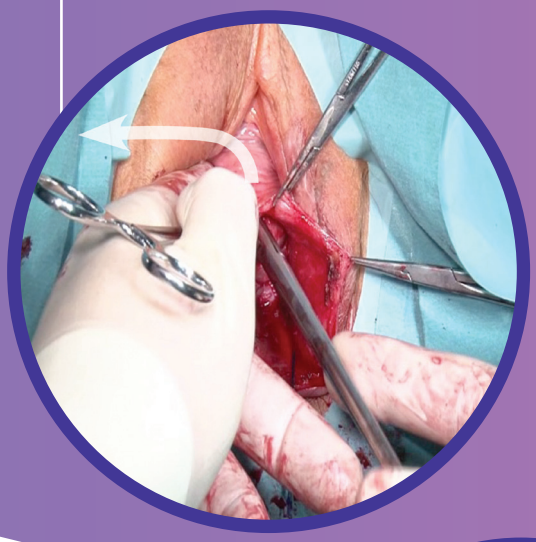
10 Perform the procedure accordingly on the contralateral site by using the left hand for guidance and the right hand for pushing. The sutures are left hanging out of the introitus until needed.

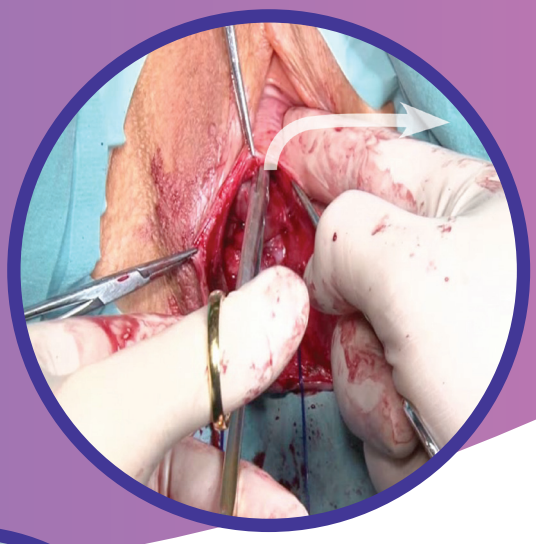


NOTE:
Rectal examination may be required in case of suspected bowel perforation.

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

11 Perform a sharp and blunt dissection towards the obturatum foramen horizontally to the bladder neck on the right side. For this purpose, put the left index finger in the angle between the labium majus and minus pudendi, slightly below the commissura labiorum anterior, on the right side and take the corresponding clamp in the same hand. The sharp and blunt dissection is performed by the right hand. The instruments and directions are palpated by the index finger of the left hand. Perform the dissection of the contralateral side accordingly by putting the right index finger in the angle while using the left hand for dissection.



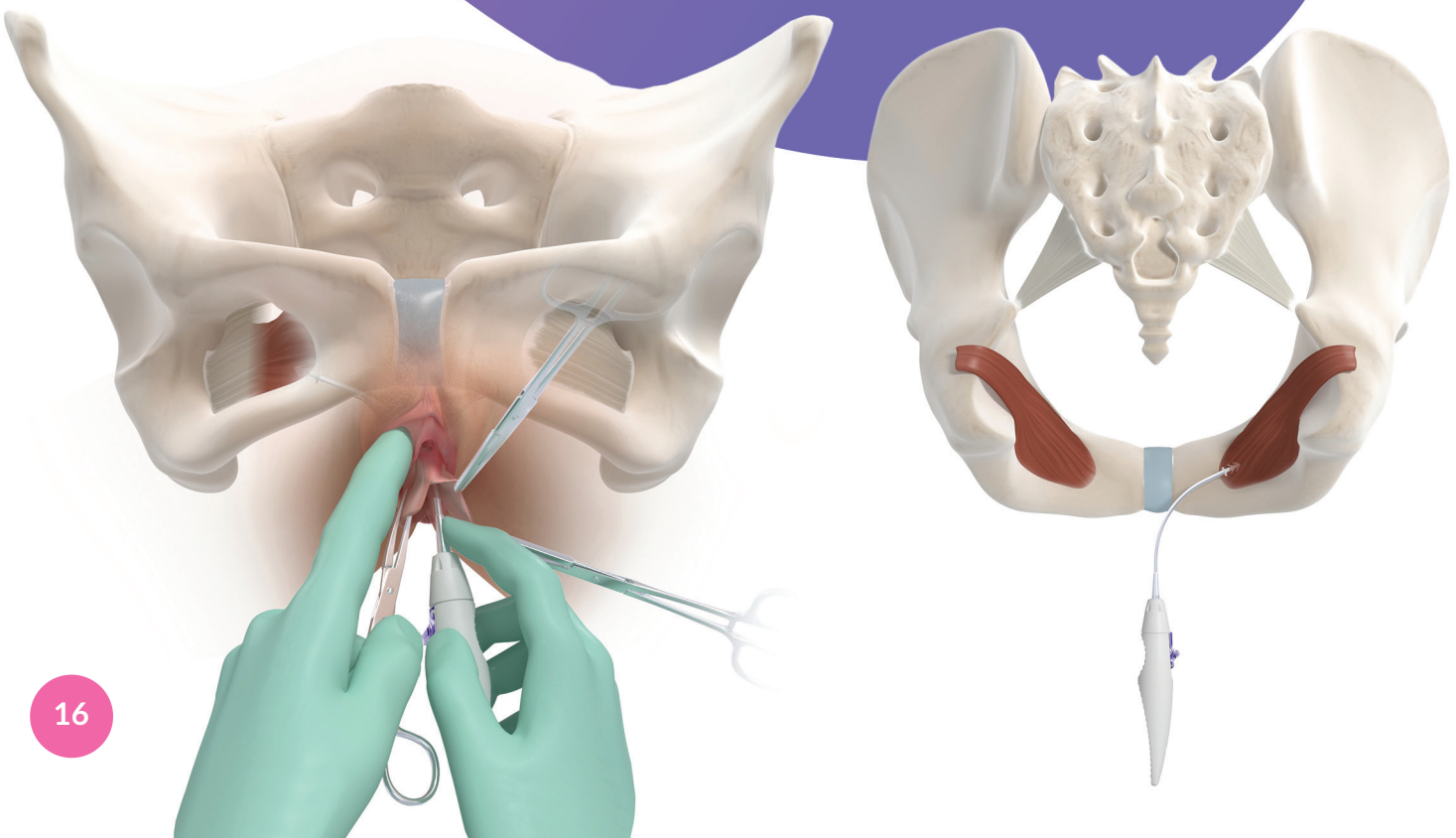


12 Put the anchor of the Anterior Attachment Arm (AAA) on the RIG (Ref: DPN-MNC).

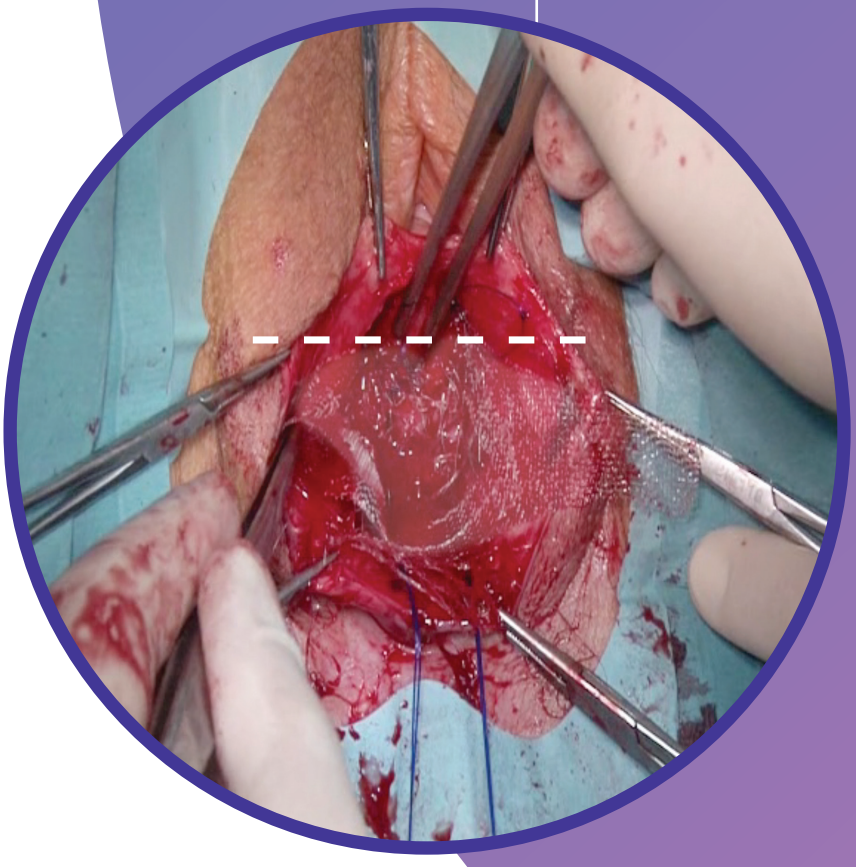
13 The RIG is guided by the right hand to the right internal obturator muscle by pushing the RIG parallel to the obturator membrane into the bulge of the internal obturator muscle. For this purpose, the left index finger is put in the angle between the labium majus and minus pudendi, slightly below the commissura labiorum anterior, on the right side. The RIG is palpated and guided in this position by the left index finger, while the RIG is pushed by the right hand parallel to the obturator membrane. The anchor is fixed into the internal obturator muscle.

NOTE:
DO NOT rotate the RIG since the intended position of the anchor is NOT the obturator membrane.

Release the RIG by pulling the switch of the handle down. Perform the procedure accordingly on the contralateral site by using the left hand for pushing the RIG and the right index finger for palpating the RIGs direction.



14 Ensure that the AAA is firmly attached to internal obturator muscle by gently pulling on the AAA's looped sutures. The sutures can subsequenty be cut and removed once the final position of the anchors and mesh are confirmed.



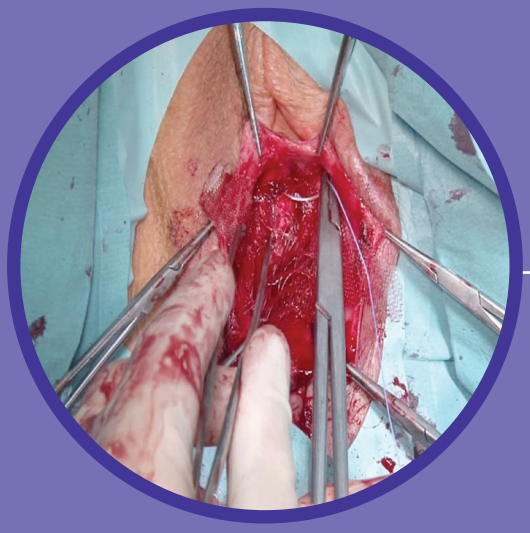
NOTE:
Ensure that the mesh is not twisted and positioned horizontal to the bladder neck.

NOTE:
Ensure a tension-free implantation technique. If required, the AAA arms can be loosened or released by firmly pulling on the AAA's looped sutures.

NOTE:
A cystoscopy may be required if bladder perforation is suspected.

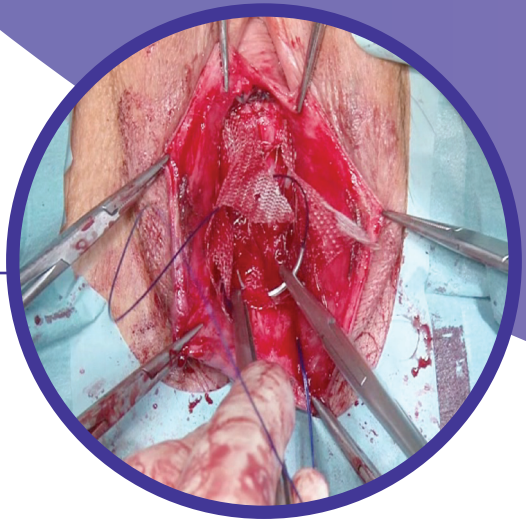
TIP:
Gert Naumann, M.D.
Putting the second anchor of the AAA on the RIG can be facilitated by grabbing the anchor with a blunt instrument (e.g. mosquito clamp)

TIP:
A pair of Metzenbaum scissors may be inserted between the bladder neck and the implant in order to ensure it is implanted without tension.

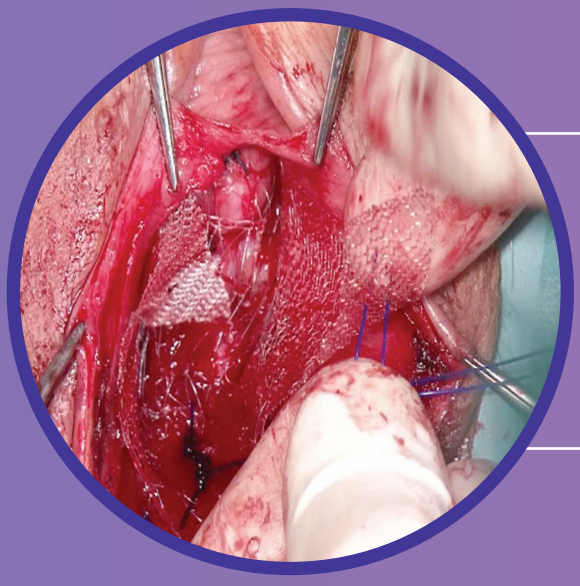


15 The central part of the mesh is attached by two absorbable sutures close to the bladder neck to prevent displacement.

15.2 Option In patients with uterus, the posterior semicircle of the central mesh part should be cut away with scissors. The safety and performance of the implant are not affected by this procedure.

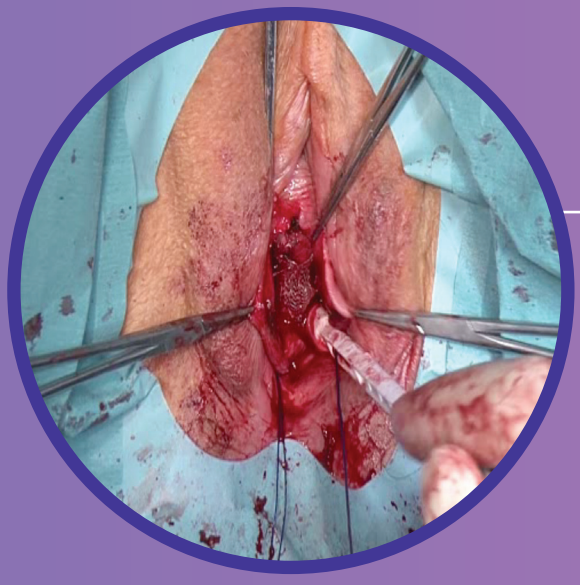


16 The posterior central part of the mesh is attached with two non-absorbable sutures to the pericervical ring, or in case of hysterectomy, to the remnants of the cardinal ligaments.



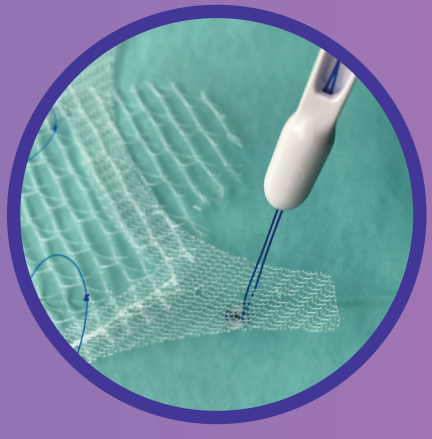
17 The TAS suture ends are led through the pores of the corresponding posterior mesh arms. For this purpose, select the outer distal part of the mesh arm in order to ensure a tension free implantation of the mesh. Since the sutures are already attached to the sacrospinous ligament by the anchors, ensure that the suture ends are guided from the posterior to the anterior aspect of the mesh arm.

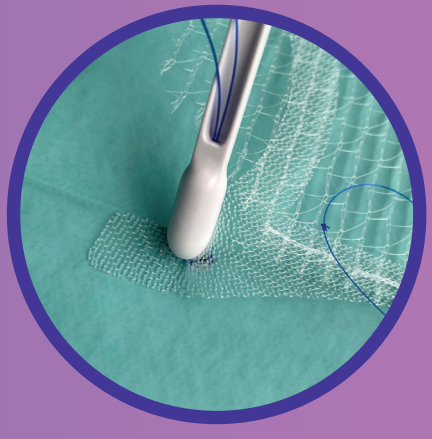
NOTE:
Ensure that the mesh (arm) is not twisted.

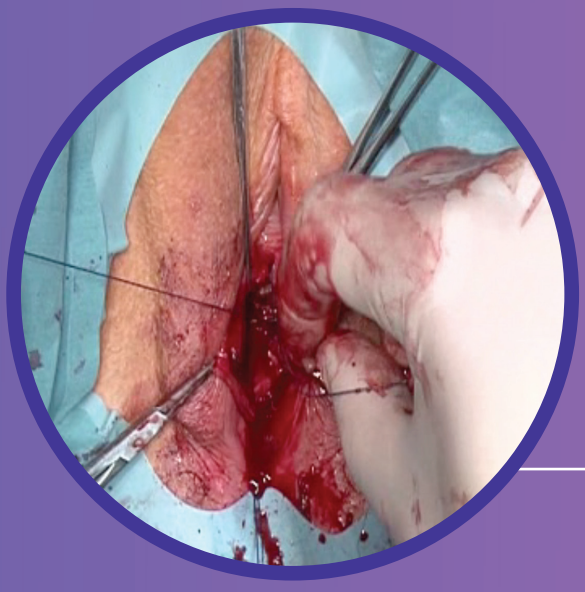


18 Slide the posterior mesh arm to the sacrospinous ligament bilaterally. Hold on to the end of the TAS suture during this procedure.

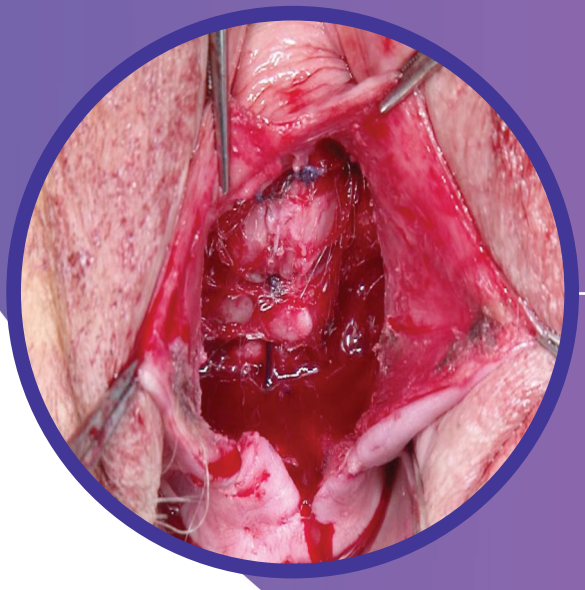
TIP:
Gert Naumann, M.D.
Using the knot pusher for guidance of the posterior mesh arms to the sacrospinous ligament facilitates this step. Lead both suture ends from one side through the tip of the Knot Pusher and push the mesh with the Knot Pusher to the sacrospinous ligament.



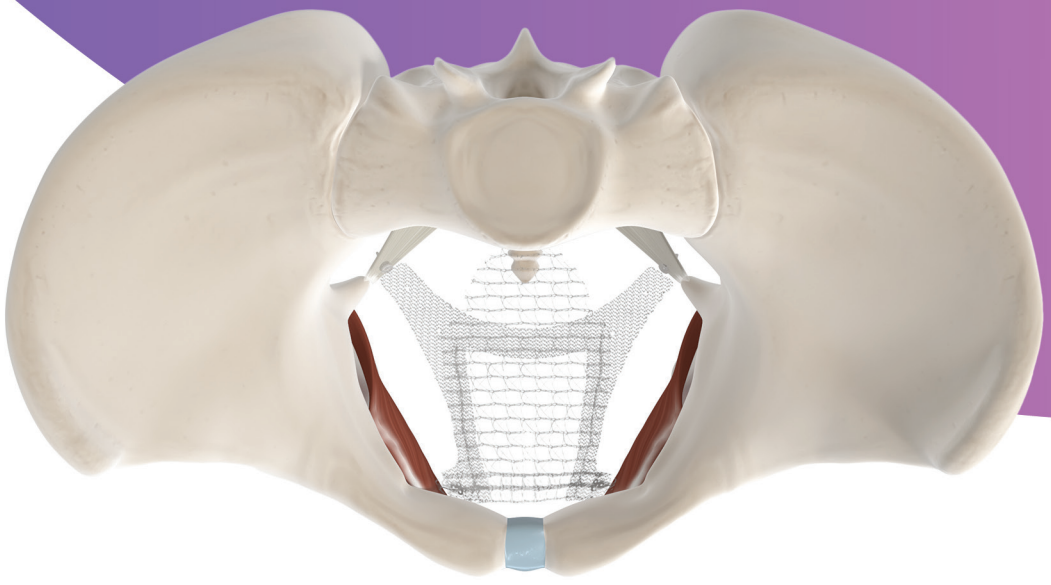




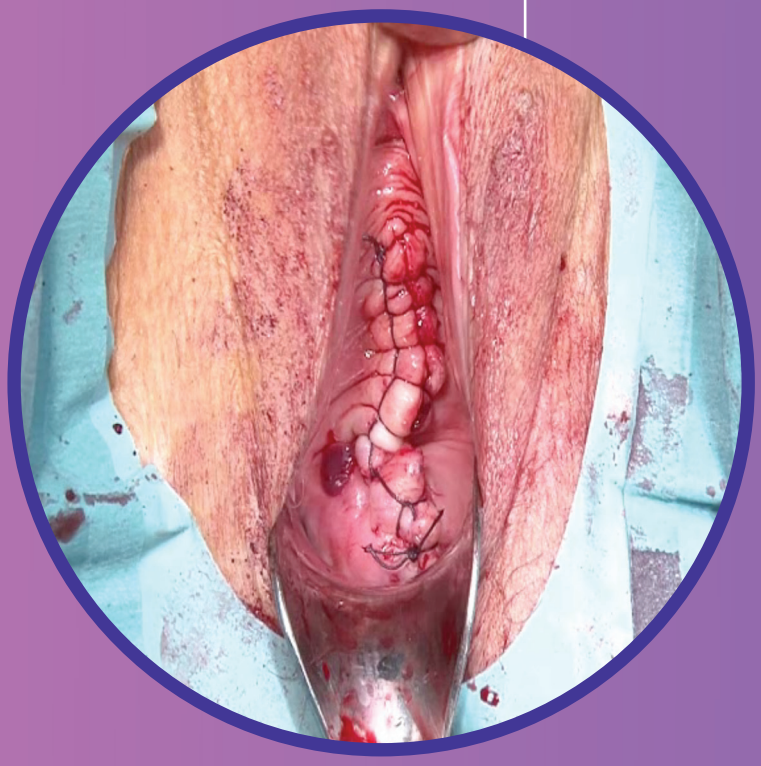
19 Knot the posterior mesh arms to the sacrospinous ligament with the corresponding sutures on both sides respectively. The Knot Pusher can be utilised for this step as and when required.



✓ Final mesh appearances after the completed implantation procedure.



20 Closure of the vagina according to the surgeon's standard procedure. Vaginal packing for app. 24h is recommended.



NOTE:
Limit the trimming of the vaginal epithelium in order to minimise the risk of vaginal stricture formation (i.e. contraction) since this may cause dyspareunia and pain.

NOTES

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Urology and Pelvic Floor

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