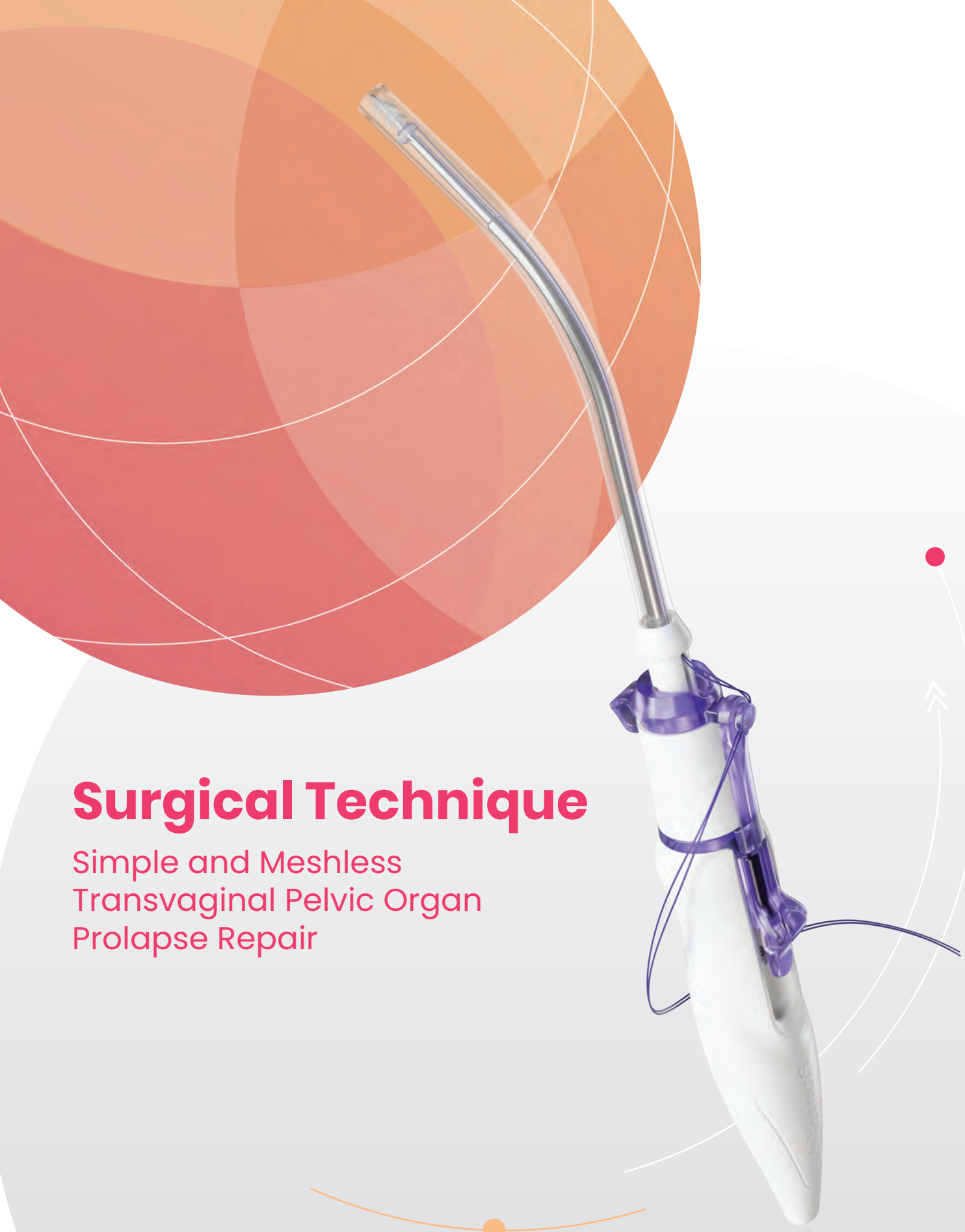


Surgical Technique

Simple and Meshless Transvaginal Pelvic Organ Prolapse Repair

ANCORIS

POP REPAIR 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 USE

ANCORIS POP Repair Sytem is indicated for surgical treatment of apical prolapse

INDICATIONS

Ancoris is indicated for the transvaginal repair of apical pelvic organ prolapse in women older than 18 years, with

- descent of the uterus
- descent of the uterine cervix after subtotal (supracervical) hysterectomy
- descent of the vaginal vault after total hysterectomy

CONTRAINDICATIONS

ANCORIS POP Repair System must not be used in patients:

- Undergoing anticoagulation therapy
- During pregnancy
- 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.

WARNINGS AND PRECAUTIONS

The implantation of ANCORIS 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:

- ANCORIS must ONLY be used by surgeons experienced in transvaginal pelvic floor reconstruction.
- This surgical technique brochure[2] must be read and understood PRIOR to first implantation of ANCORIS.

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.

- Ancoris must be used with care in patients with:
  - Coagulation difficulties
  - Obstruction of the upper urinary tract
  - Renal insufficiency
  - Autoimmune disease affecting connective tissue
- Risks can be minimized by utilization of imaging methods before the procedure if appropriate and by inserting the retractable insertion guide correctly.
- The patient must be warned that future pregnancies could invalidate the surgical effects of the implant.

Surgical procedure and aftercare

- DO NOT deviate from the implantation procedure as described in the section SURGICAL PROCEDURE of this brochure and the 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.
- Tension-free repositioning technique is mandatory to avoid urinary obstruction, lower urinary tract symptoms and pain.
- 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 the 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

- The implant must not be handled with pointed, serrated, or sharp objects since any damage, or tearing can cause subsequent complications.
- 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 Ancoris components are supplied sterile.
- Polypropylene may cause an inflammatory reaction.
- Ancoris 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 counseling and assessment of the patient as well as for requesting informed consent from the patient prior to 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.

The patient should be advised that ANCORIS 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:

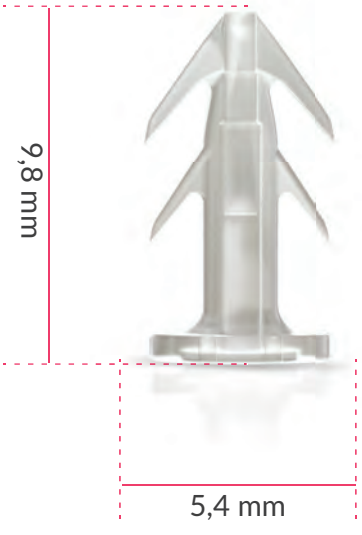
- Device name
- Device type
- Serial and lot number or unique device identifier as appropriate
- Manufacturer's name, address and website
- Name of the patient or patient ID
- Name and address of the healthcare institution which performed the implantation
- Date of implantation/explantation
- Warnings,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

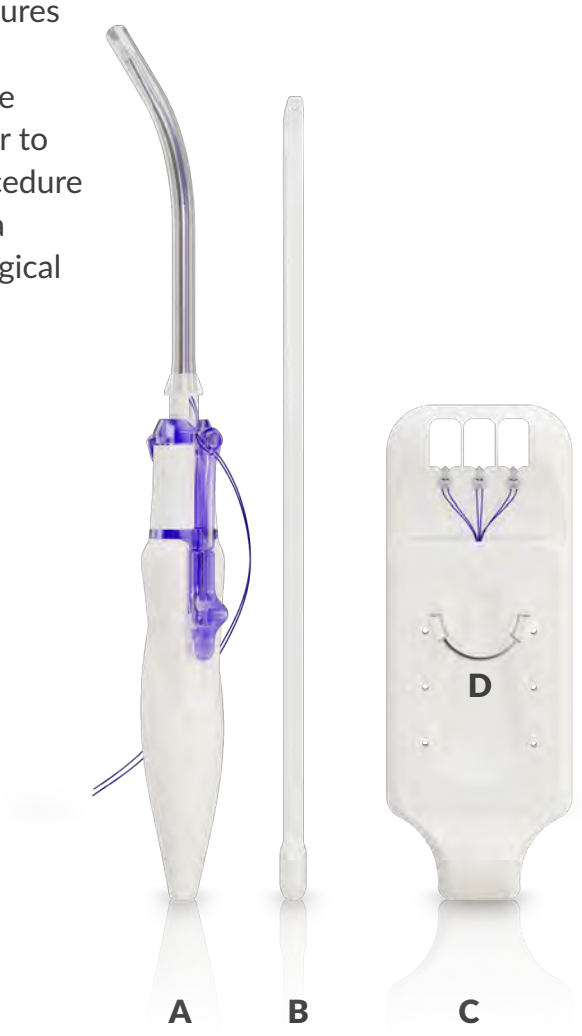
GENERAL INFORMATION

ANCORIS KIT

- 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.
- 1 Half circle surgical eye needle (Ref.: ESN)

All components are supplied sterile and ready to use.





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

NOTE:
1-2 TAS are 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 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

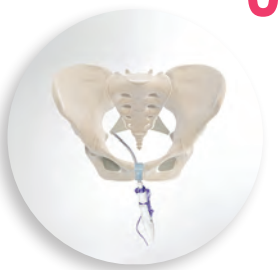
Ensure that the protective tube lock and release mechanism is in a pushed back, locking position.

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.

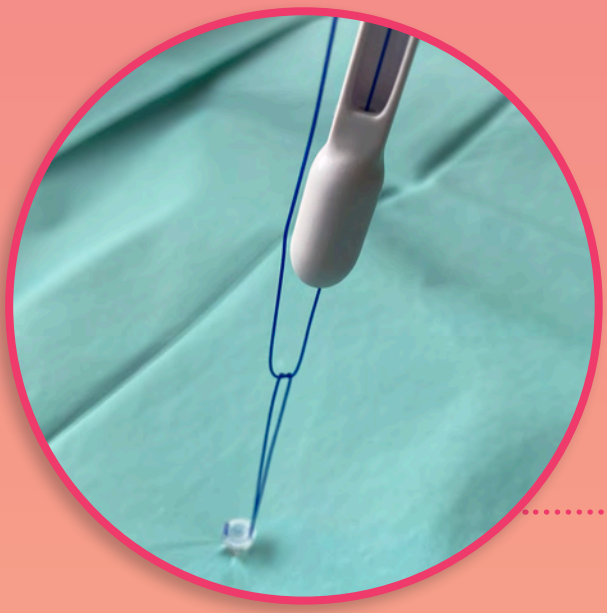
10

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

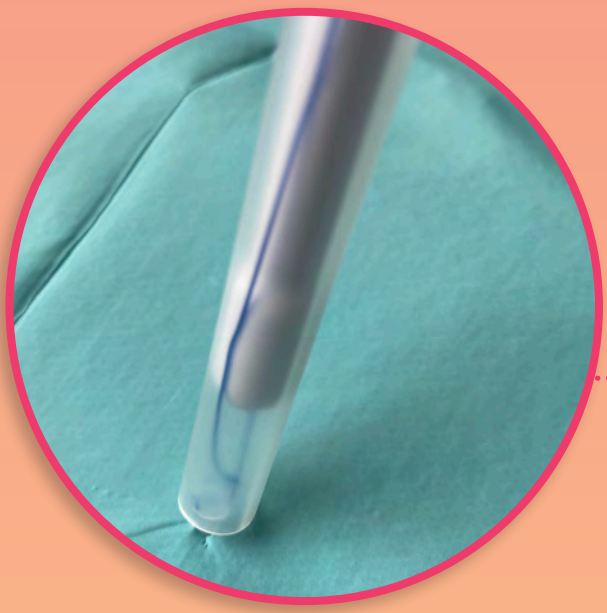
11

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 down to 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

ANCORIS POP Repair System can be implanted by two different approaches, the anterior (paravesical) and the posterior (pararectal) approach. The decision of which approach is to be preferred depends on the preconditioning of the patient and type of pelvic floor defect:

- In case of a uterine preservation the anterior (paravesical) approach is recommended.
- In case of absence of uterus the approach depends on the type of concurrent defect.
  - In case that an anterior wall repair needs to be performed in the same surgery, it is recommended to implant ANCORIS POP Repair System also via the anterior (paravesical) approach.
  - In case that a posterior wall repair needs to be performed in the same surgery, it is recommended to implant ANCORIS POP Repair System also via the posterior (pararectal) approach.

Preoperative considerations

The implantation of the Ancoris 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 Ancoris prior to the operation. Prepare the patient for surgery according local standard procedures and requirements for transvaginal POP repair. Ancoris is implanted under general or regional anesthesia.

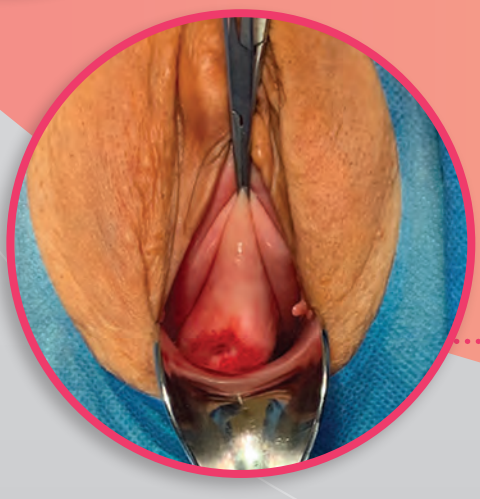
TIP:
Gert Naumann, M.D.
If atrophy of the vagina is identified, use topical oestrogens for four weeks prior to the operation unless contraindicated.

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.

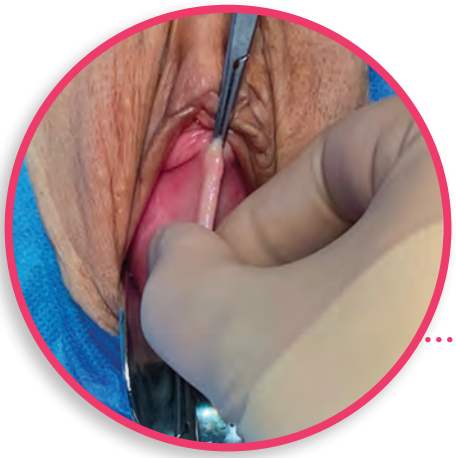
NOTE:
Lower extremity nerve injury and compartment syndrome may occur with lithotomy positioning of the patient. Limit the risk by avoiding excessive hip flexion and hip abduction and reducing the operation time.



Catheterization

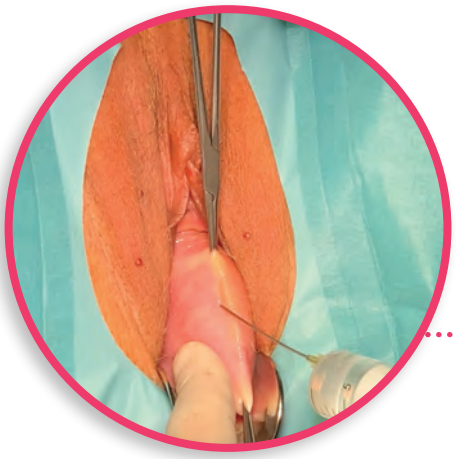
Ensure the bladder is empty prior to starting the operation. Use a urinary catheter as appropriate.

SECTION I: Anterior 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.

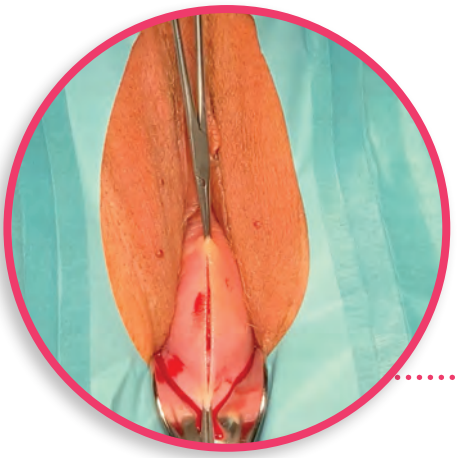


02

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

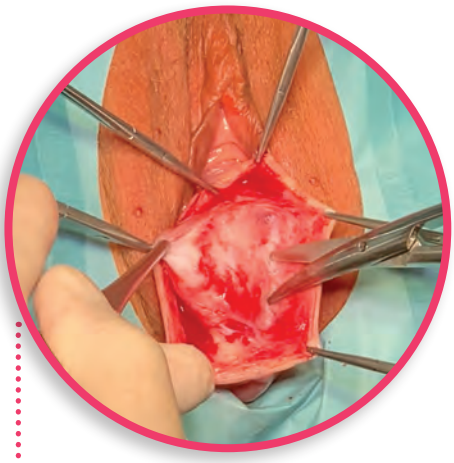
TIP:
Gert Naumann, M.D.
Adding a vasoconstrictive agent minimizes bleeding during the procedure, e.g. 1 mg epinephrine (1:1000) diluted in 100 cc of injectable saline.

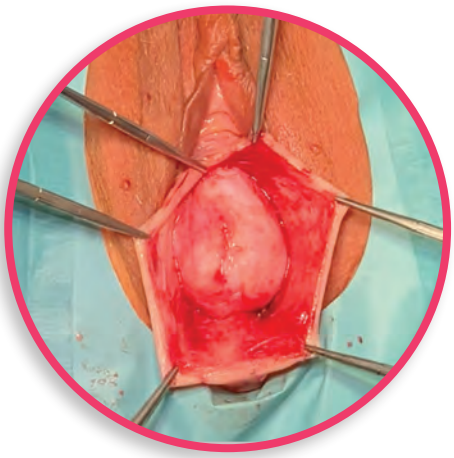
NOTE:
A blunt needle gives tactile feedback by reducing resistance at the entry of the vesicovaginal space.



03

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



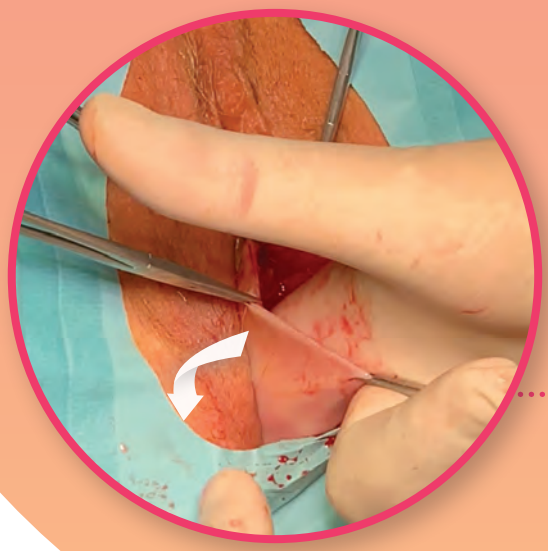


04

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

NOTE:
A split-thickness dissection may disrupt the blood supply to the vaginal mucosa.

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



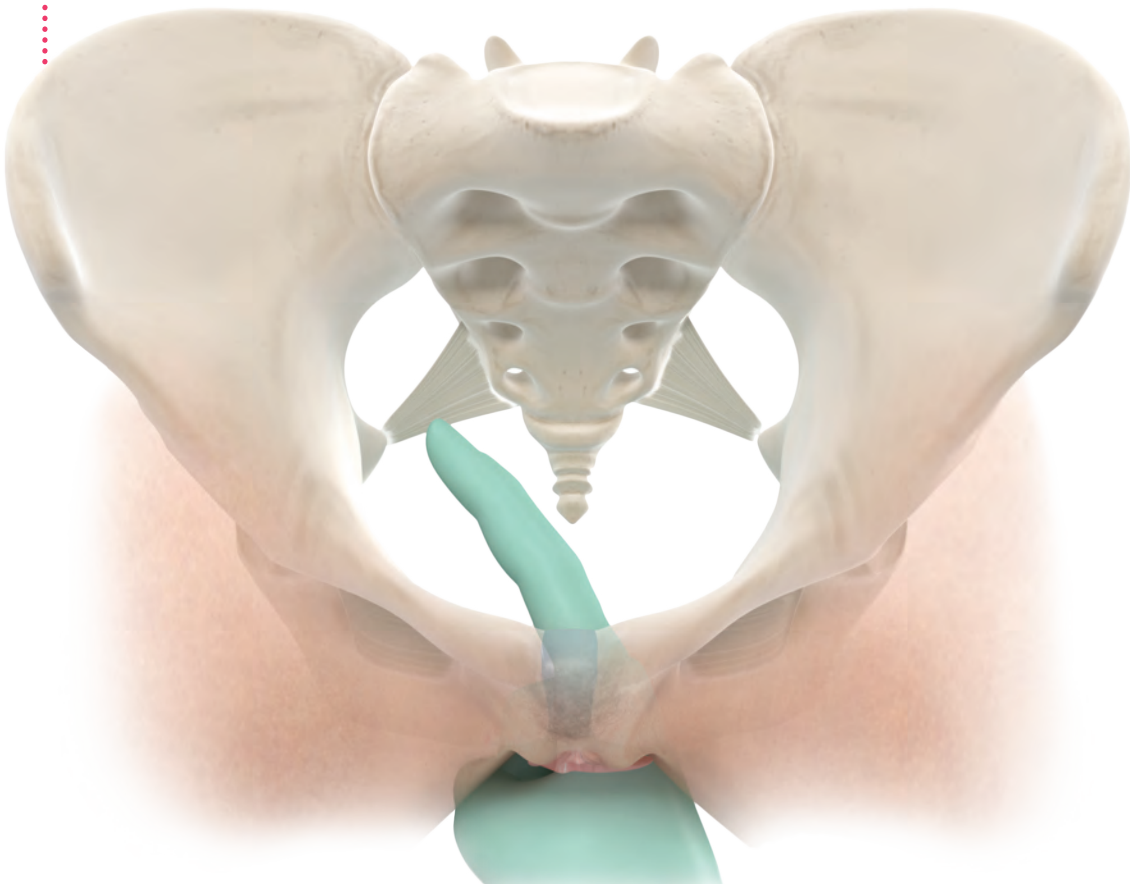
05

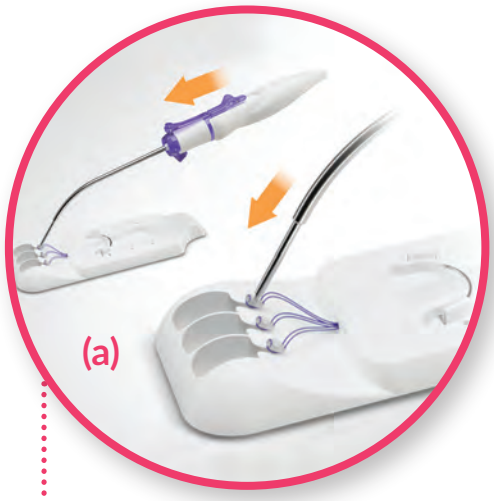
Develop the vesicovaginal space by sharp and blunt dissection as appropriate. Subsequently, enter the pararectal space using blunt finger dissection to identify the ischial spine with the index finger.

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 minimized at the intended position of the anchor.

06

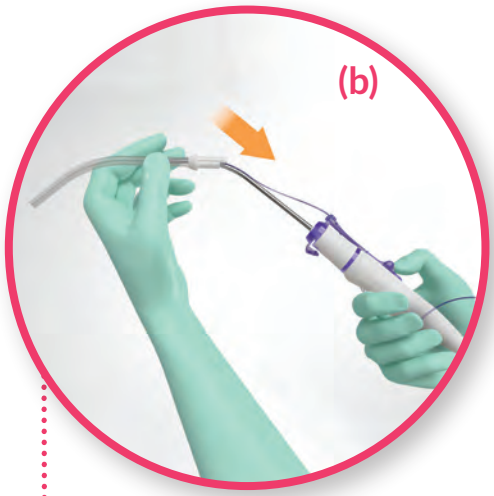
The ischial spine and sacrospinous ligament are identified by palpation. The surrounding tissue of the sacrospinous ligament is wiped away carefully from the ischial spine along the sacrospinous ligament using the index finger. If a bilateral fixation is planned, steps 5 and 6 are performed on both sides.





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)**.



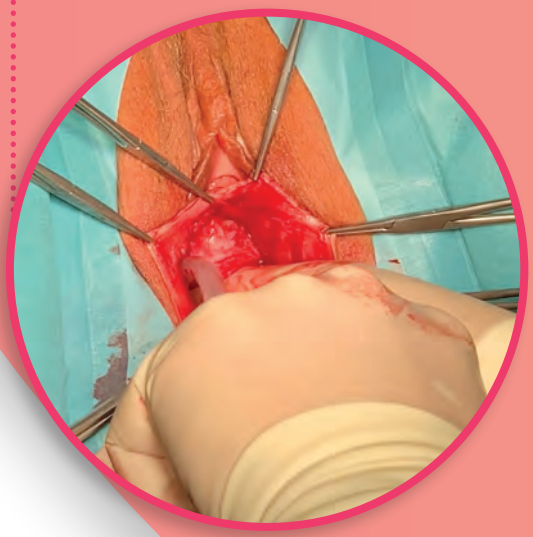
Then, the protection tube is pulled over the RIG (please refer to section *Functionality of the Insertion Guide*, steps 6 and 7, page 7). **(b)**.

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: TAS Implantation via the Anterior Approach

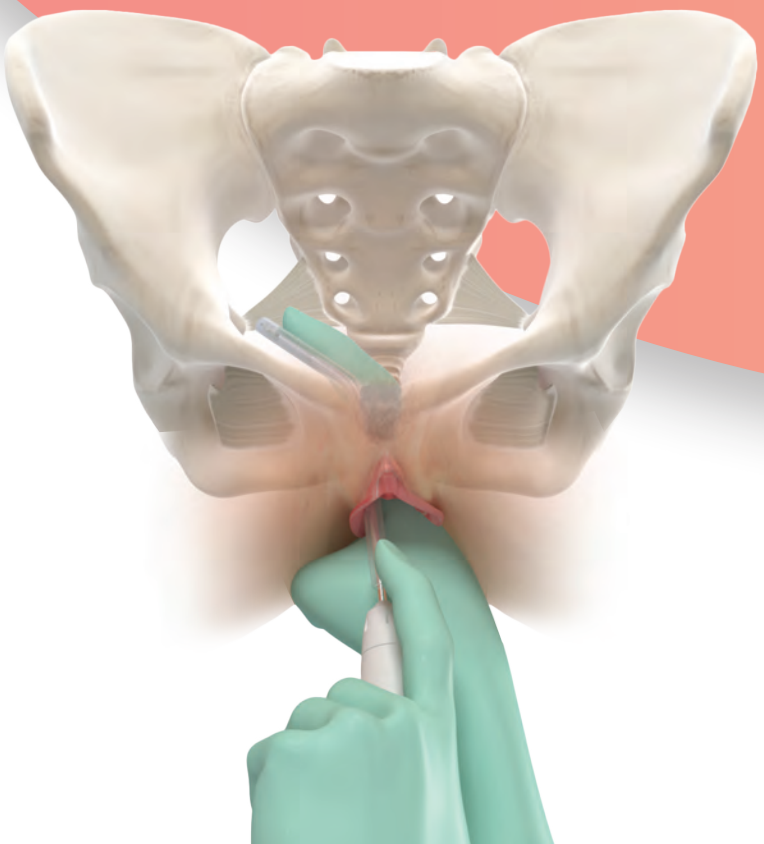
08

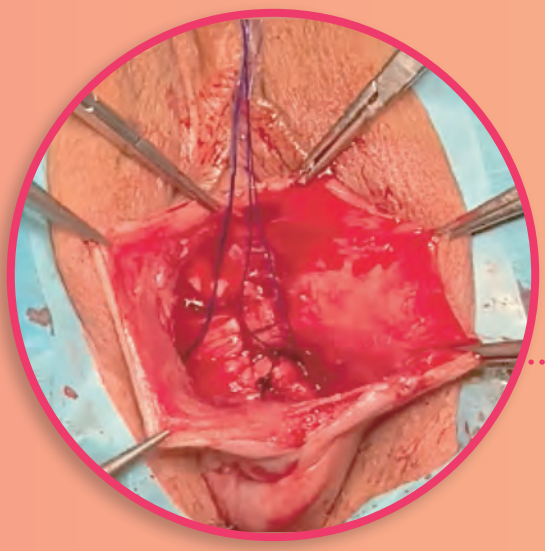
The TAS is fixed to the right sacrospinous ligament by the left hand. Firstly, the right index finger identifies the ischial spine and sacrospinous ligament. The rectum is gently pulled medially. The right hand remains in this position in order to guide the TAS to the sacrospinous ligament. The RIG is 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.





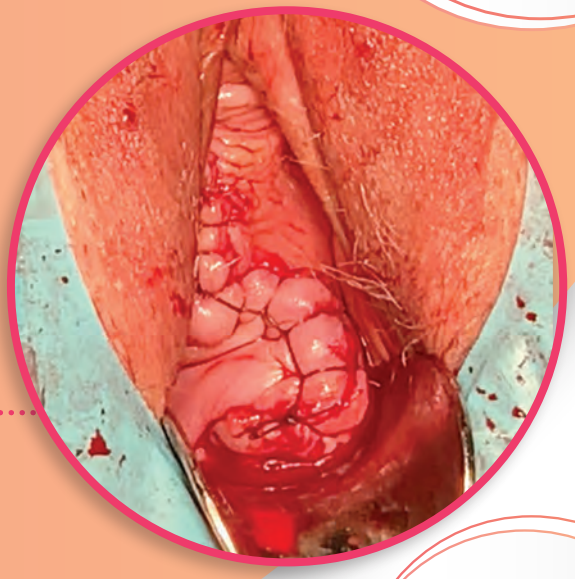
09

For a bilateral fixation, perform the procedure accordingly on the contralateral side 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:
In case of an unilateral fixation, only one TAS anchor is needed. Ensure that the TAS is / are firmly attached to sacrospinous ligament by gently pulling on the TAS suture.

10

The repositioning of the uterus, respectively the vaginal apex by suturing to the sacrospinous ligament is performed according to the surgeon's preference / standard procedure or the local clinical institution. The half-circle surgical eye needle, which is provided with the Ancoris Kit, can be used for this step.



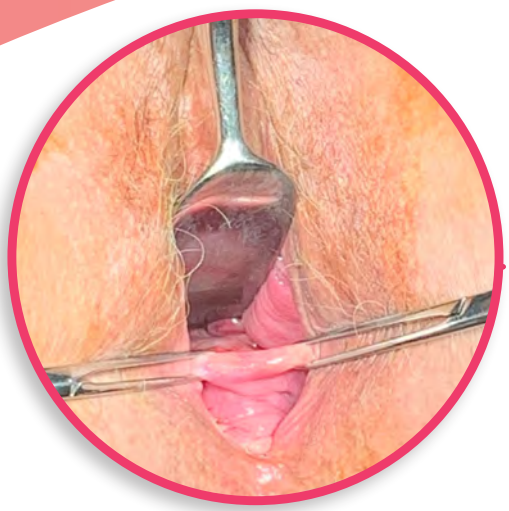
TIP:
Gert Naumann, M.D.
Since anterior and apical prolapse are frequently caused reciprocally, perform an anterior colporrhaphy in addition.

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

11

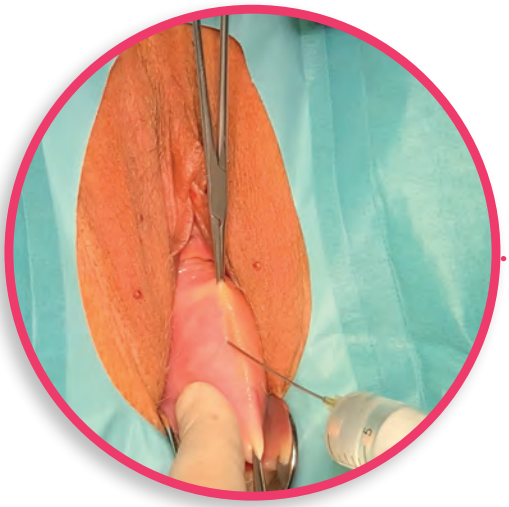
An anterior and/or posterior colporrhaphy may be performed simultaneously. Closure of the vagina according to the surgeon's standard procedure. Vaginal packing for app. 24h is recommended.

SECTION III: Posterior full-thickness vaginal wall dissection



01

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

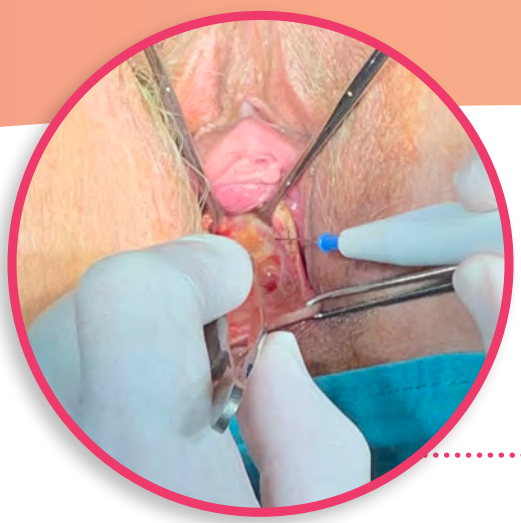


02

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 minimizes bleeding during the procedure, e.g. 1 mg epinephrine (1:1000) diluted in 100 cc of injectable saline.

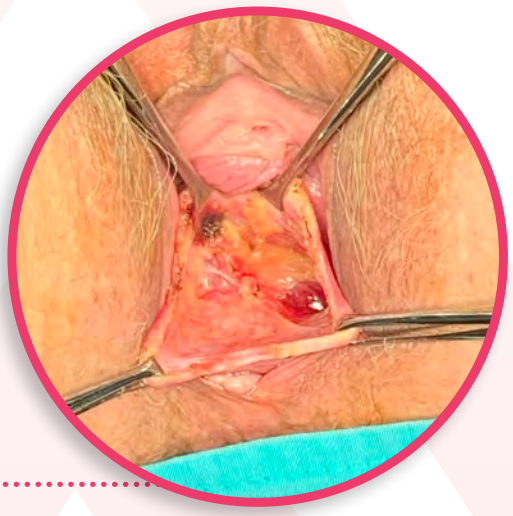
NOTE:
A blunt needle gives tactile feedback by reducing resistance at the entry of the rectovaginal space.



03

Perform a posterior colpotomy with the scalpel or electrocautery. Place an elasticated retractor if desired.

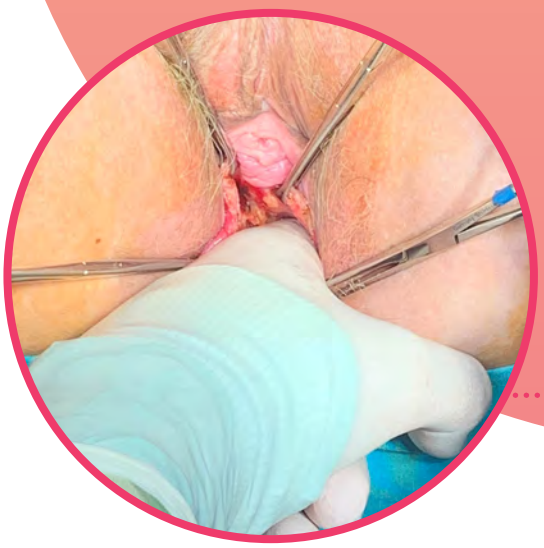
NOTE:
Limit the use of electrocautery to prevent the disruption of blood flow.



04

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

NOTE:
A split-thickness dissection may disrupt the blood supply to the vaginal mucosa.



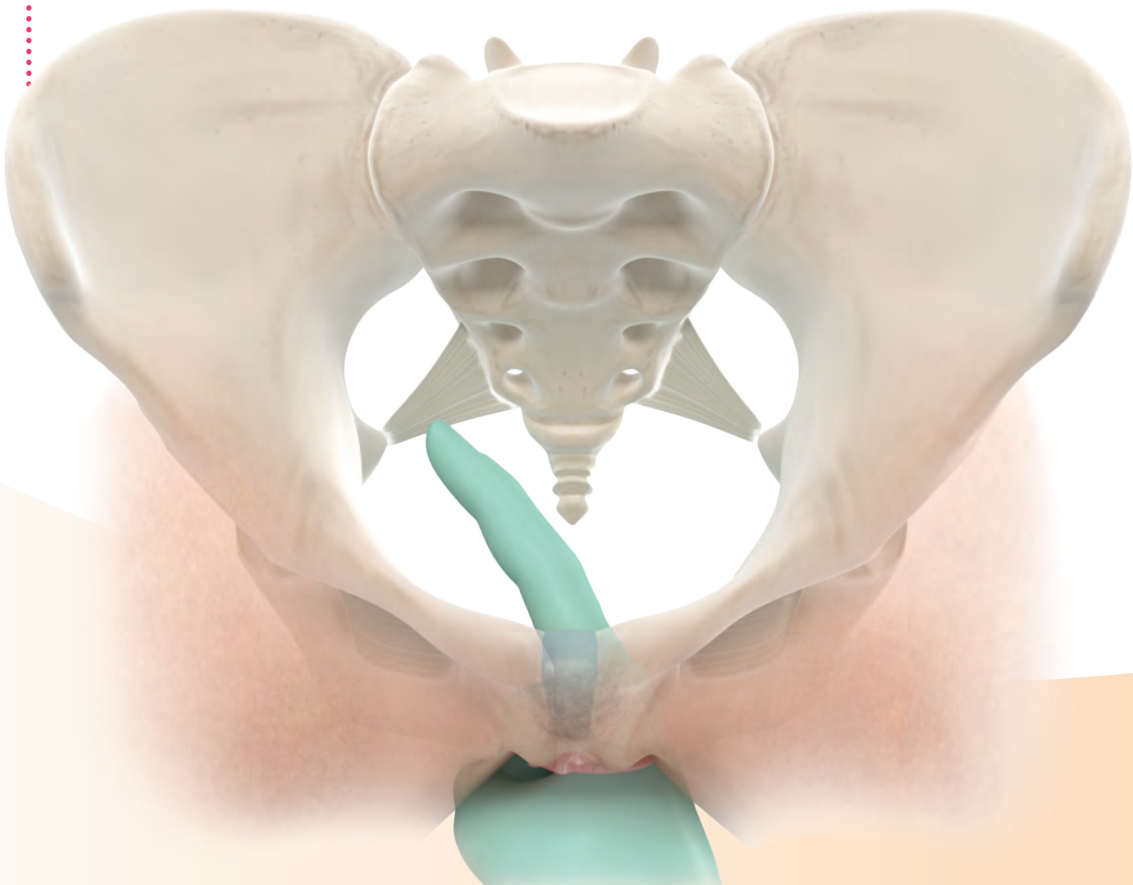
05

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.

The ischial spine, the coccygeal muscle 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. If a bilateral fixation is planned, steps 5 and 6 are performed on both sides.

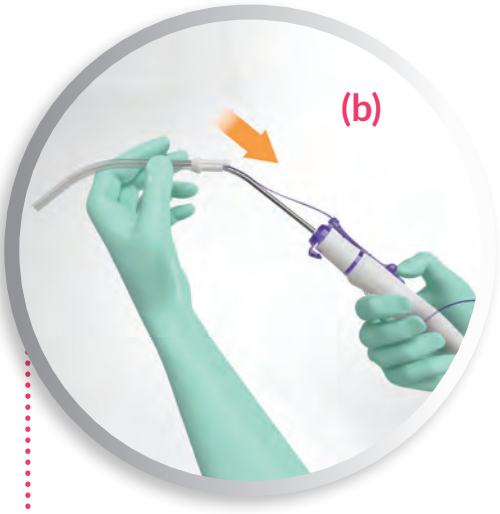
NOTE:
The final position of the anchor is recommended to be approx. 2 cm medially from the ischial spine in the sacrospinous ligament. Surrounding tissue should be minimized at the intended position of the anchor.

06



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)**.



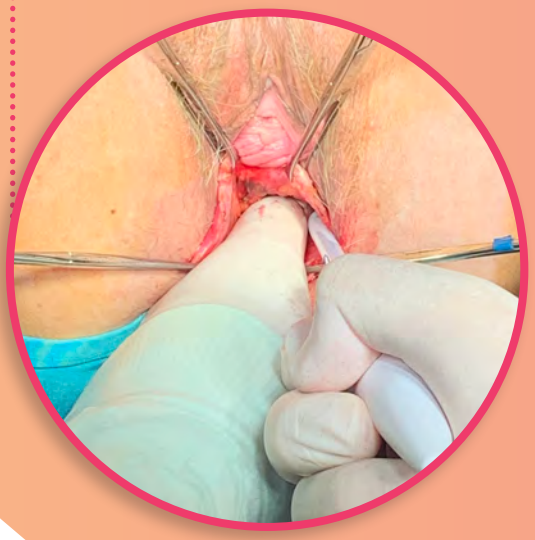
Then, the protection tube is pulled over the RIG (please refer to section *Functionality of the Insertion Guide*, steps 6 and 7, page 7). **(b)**.

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 IV: TAS Implantation via the Posterior Approach

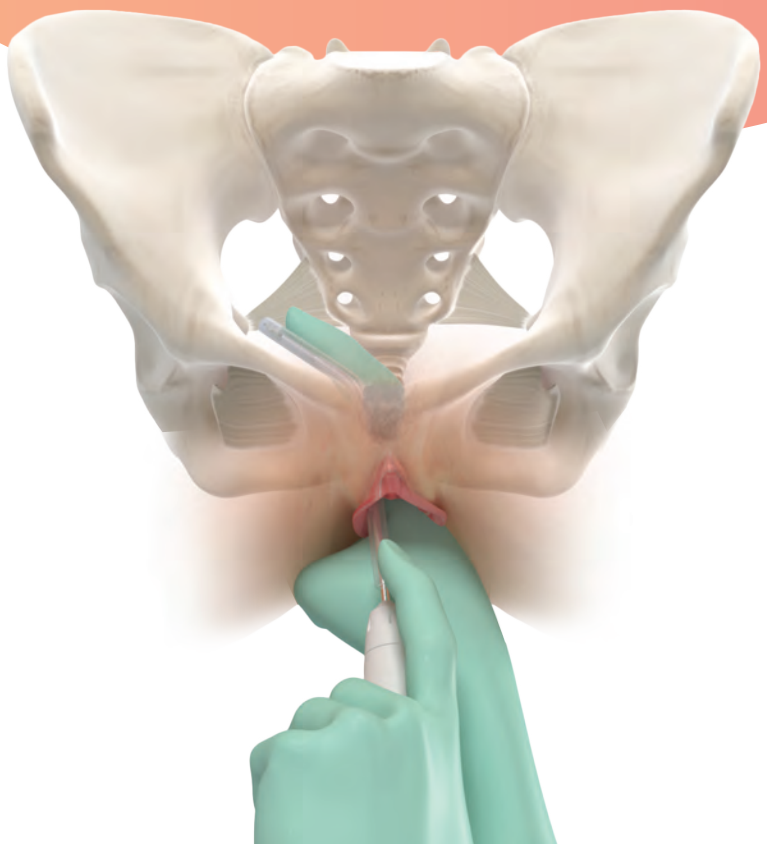
08

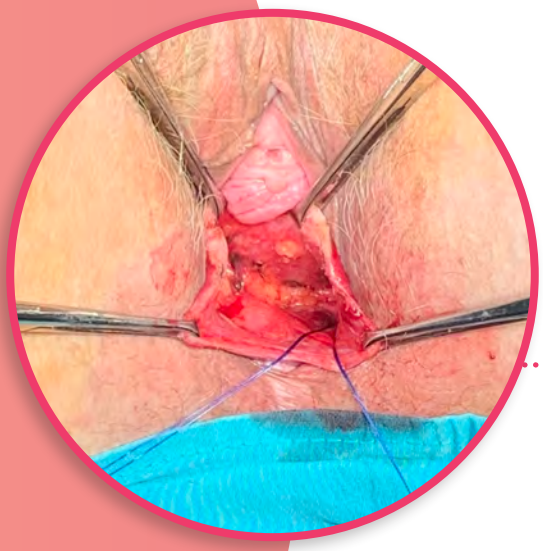
The TAS is fixed to the right sacrospinous ligament by the left hand. Firstly, the right index finger identifies the ischial spine and sacrospinous ligament. The rectum is gently pulled medially. The right hand remains in this position in order to guide the TAS to the sacrospinous ligament. The RIG is 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.





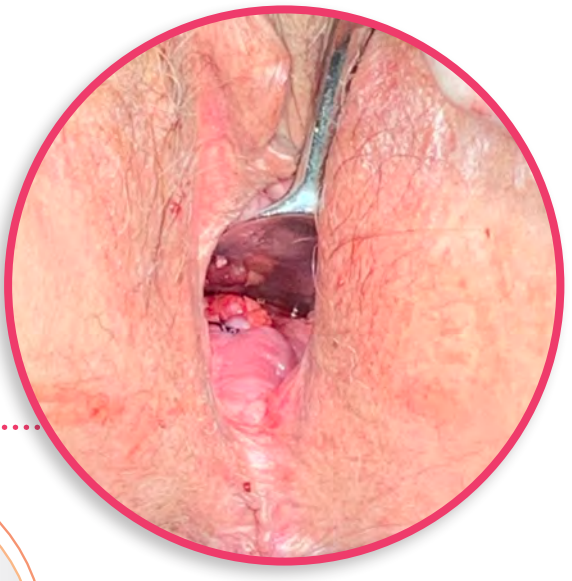
09

For a bilateral fixation, perform the procedure accordingly on the contralateral side 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:
In case of an unilateral fixation, only one TAS anchor is needed. Ensure that the TAS is / are firmly attached to the sacrospinous ligament by gently pulling on the TAS suture.

10

The repositioning of the uterus, respectively the vaginal apex by suturing to the sacrospinous ligament is performed according to the surgeon's preference / standard procedure or the local clinical institution. The half-circle surgical eye needle, which is provided with the Ancoris Kit, can be used for this step.



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

11

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

NOTES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POP REPAIR SYSTEM

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Promedon

Urology and Pelvic Floor

CE 0197

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