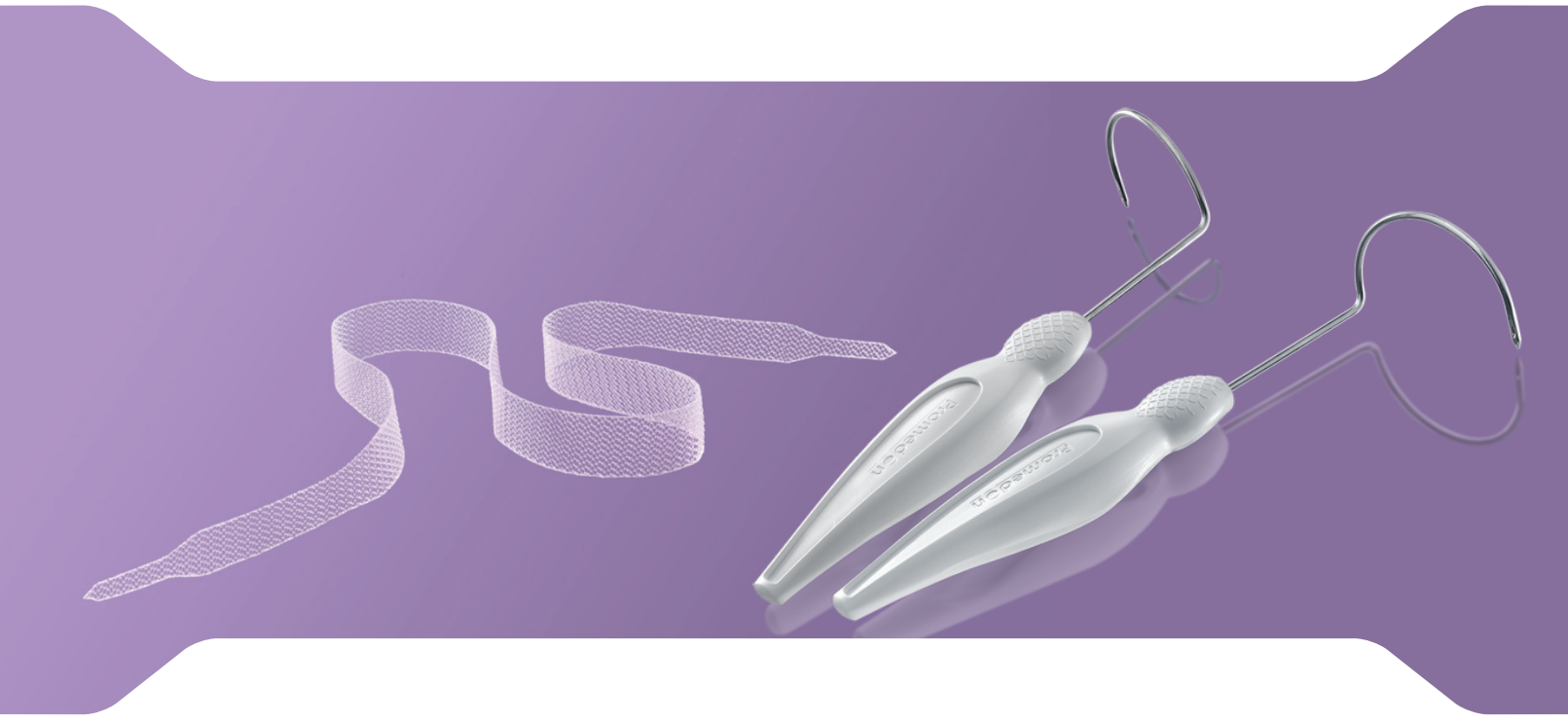
Surgical Technique

SUBURETHRAL SLING



Unitape tplus

TABLE OF CONTENTS

INDICATIONS, PRECAUTIONS AND WARNINGS

• INTENDED PURPOSE

UNITAPE T PLUS is a suburethral sling intended to restore continence in adult female patients with stress urinary incontinence caused by urethral hypermobility or intrinsic sphincter deficiency by means of tissue reinforcement and stabilization of the soft tissues of the female pelvic floor.

• INDICATIONS

UNITAPE T PLUS has been developed to restore continence in adult female patients with stress urinary incontinence caused by urethral hypermobility or intrinsic sphincter deficiency.

• CONTRAINDICATIONS

UNITAPE T PLUS cannot be prescribed if there is any kind of untreated acute urinary tract infection, active infection at the surgical sites or systemic infections (sepsis).

UNITAPE T PLUS must not be used in patients:

- who have soft tissues pathologies in the site intended for implant placement
- during pregnancy,
- with known sensitivity or allergy to polypropylene products,

WARNINGS AND PRECAUTIONS

WARNING AND PRECAUTIONS

The implantation of UNITAPE T PLUS 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:

- Surgeons performing these procedures should be adequately trained in stress urinary incontinence (SUI) surgery and capable of recognizing, diagnosing, and treating potential mesh-related complications associated with the procedure[1].
- UNITAPE T PLUS must be used in sterile conditions in a surgical theatre.
- This surgical technique brochure must be read and understood PRIOR to first implantation of UNITAPE T PLUS.

To the best of Promedon knowledge, based on the detected extractable chemicals no carcinogenic, mutagenic or toxic to reproduction (CMR) substance of Category 1A or 1B or listed as SVHC (e.g., endocrine disrupting properties) exceeded the stated limit of mass fraction according to the specifications in MDR Annex I, Chapter II, Section 10.4.

After use, discard the excess of the mesh, surgical instruments and packaging according to institutional, administrative, or local government procedure. To avoid the risk of puncturing, cover the tip of the needles T Plus with handles (DPN-HAS) with the provided protective tubes before their disposal.

CLINICAL ASPECTS AND DECISION FOR SURGERY

- Diabetes and vascular diseases have been reported to increase the risk of sepsis, pulmonary failure, thromboembolic events, and myocardial infarction during surgical procedure[2].
- Diabetic women planning to undergo sling surgery should be counselled regarding their higher risk for mesh erosion and reduced effectiveness compared with their non-diabetic counterparts[3].
- Obesity (BMI major or equal to 35 kg/m2) might increase technical difficulty and complication rates[4].
- Surgical treatment of SUI should be deferred until after childbearing is complete in patients planning pregnancies[3]. After pregnancy, it is recommended to wait at least 6 months before implant the product. The doctor should determine when is appropriate according to the patient's conditions.
- Risk factors determined for failure of TOT sling can be the presence of urgency, patients age and previous surgery[4].
- UNITAPE T PLUS must be used with care in patients with:
- immunodeficiency
- autoimmune disorders or any pathology, related to blood supply limitations that would compromise wound healing (for example patients undergoing anticoagulant therapy, etc
- Polypropylene may cause inflammatory reaction. DO NOT use UNITAPE T PLUS simultaneously with any other product.
- Polypropylene mesh integrates with patient's tissue, hence complete removal may be difficult or unfeasible. The risk for 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.
- In women undergoing surgery for SUI with mid-urethral slings, coital incontinence is likely to improve (clinical evidence level 3)[5].
- UNITAPE T PLUS should not be used in patients undergoing concomitant urethral diverticulectomy, repair of urethrovaginal fistula, or urethral mesh excision and concurrently stress incontinence surgery. Any procedure in which the urethra is opened in proximity to the sling position could affect wound healing.[3]

SURGICAL PROCEDURE

- DO NOT deviate from the implantation procedure as described in the section SURGICAL TECHNIQUE of this STB and consider patients' 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.
- Tension free implantation technique is mandatory to avoid urinary obstruction, lower urinary tract symptoms, pain, mesh exposure or extrusion.
- 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
- For patients who choose surgical treatment for stress urinary incontinence, intraoperative cystoscopy should be performed to confirm the integrity of the lower urinary tract and the absence of a foreign body within the bladder or urethra[3].

CLINICAL BENEFITS

UNITAPE T PLUS restores the continence in adult female women by means of tissue reinforcement and stabilization of the soft tissues of the female pelvic floor.

UNITAPE T PLUS 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, the product shall be implanted following the different clauses stated in these 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.

POTENTIAL ADVERSE EVENTS AND SAFETY RELEVANT TOPICS

The possible complications associated with the use of the sling should be discussed with the patient prior to the surgery. The use of this sling may result in complications related to the surgical procedure. There may also exist complications associated with the patient's reaction or degree of intolerance to any foreign material implanted in her body. Infections not responding to antibiotic treatment require the partial or total removal of the implant. The occurrence of some adverse events, in particular exposure or extrusion, may require partial or complete removal of the mesh. Complete removal of the mesh may not be feasible and/or adverse event may be persistent even after successful removal (e.g. pain). Also, performance of multiple surgeries does not ensure the total repair of complications. Some patients may experience groin or vaginal pain during the initial postoperative period. Treatment with ANALGESICS and ANTIINFLAMMATORIES may be enough to relieve the pain. Other complications reported with this, or other slings include:

- Purulent, serous or bloody discharge
- Discomfort and/or acute or chronic pain in the groin, thigh, leg, pelvic, vaginal and/or abdominal area
- Mesh extrusion (i.e. passage gradually out of a body structure or tissue
- Mesh exposure (i.e. a condition of meshdisplaying, revealing, exhibiting, or making accessible)
- Overactive bladder symptoms including De Novo urgency
- Voiding dysfunctions (abnormally slow and/or incomplete micturition, or severe voiding dysfunction such as urinary retention or obstruction)
- Wound, local or device infection
- Urinary tract infections
- Dysuria.
- Dyspareunia
- Hemorrage
- Hematoma/ecchymosis
- Vaginal scarring[6]
- Persistent or recurrent SUI
- Organ perforation, laceration or damage (bladder, vaginal, urethral, bowel)
- Injuries to blood vessels or nerves
- Other sporadic complications found for other slings such as ileus or constipation, impaired wound healing, hematuria or abscess.

The postoperative formation of a fibrous tissue capsule around the sling is a normal physiological response to the implantation of a foreign body. Promedon requires surgeons to report any complication associated with the use of Unitape T plus to the Company or the Distributor.

1 As recommended in the review of scientific societies statements by Ugianskiene A. (Ugianskiene A. "FIGO review statements on the use of synthetic mesh for pelvic organ prolapse and stress urinary incontinence". Int J Gynecol Obstet (2019) 147: 147– 155)
2 Constantini E. "Managing complications after midurethral sling for stress urinary incontinence". EAU-EBU Update series 5 (2007) 232–240.
3 Kobashi KC, Albo ME, Dmochowski RR et al: Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline. J Urol 2017; 198: 875.
4 a. EAU Guidelines on Urinary Incontinence in Adults. European Association of Urology 2020. b. Diniz M.B. "Five-year Follow-ip of transobturator sling: 152 cases with the same surgeon" Rev. Bras. Ginecol. Obstet. (2018) 40:614–619. c. Pradhan A. "Effectiveness of midurethral slings in recurrent stress urinary incontinence: a systematic review and meta-analysis" Int. Urogynecol. J. (2012) 23:831-841.

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 UNITAPE T PLUS 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, serous or bloody vaginal discharge
- Vaginal Pain
- Fever
- Hemorrhages
- Vaginal exteriorization of the mesh

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 approximately 6 weeks after the operation if there are no contraindications for vaginal exposure smaller than 1 cm² and no other symptoms[7].

DEVICE IDENTIFICATION CARD

According to Figure 1, complete the following information:

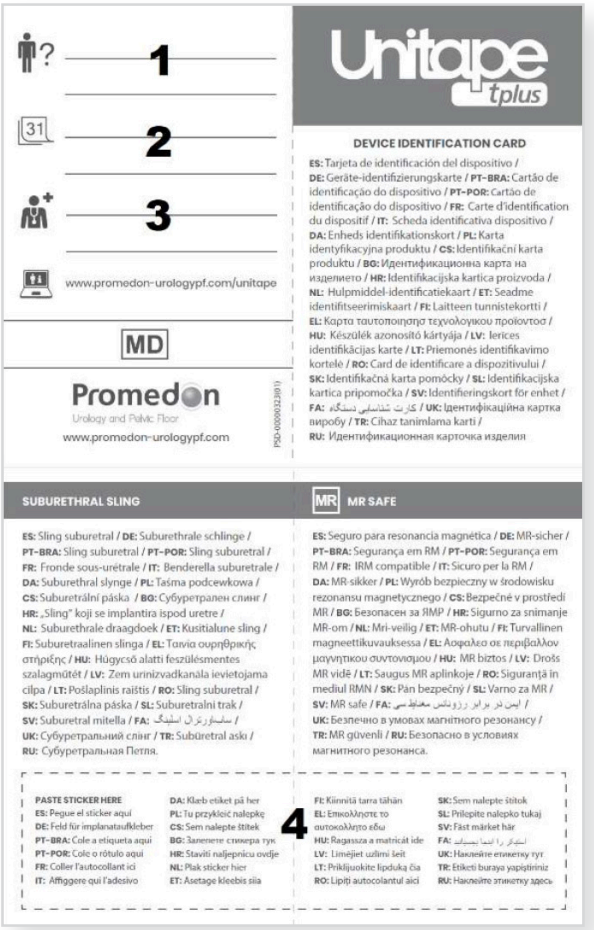
1. Name of the patient or patient ID.
To be filled by the healthcare institution.

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 annexed in these Instructions for Use.

This implant card must be provided to the patient after its completion.



5 EAU Guidelines on Management of Non- Neurogenic Female Lower Urinary Tract Symptoms. Edn. presented at the EAU Annual Congress Amsterdam March 2022. ISBN 978-94-92671-16-5
6 "Considerations about Surgical Mesh for SUI". FDA 2019. URL: https://www.fda.gov/medicaldevices/urogynecologic-surgical-mesh-implants/considerations-about-surgical-meshsui.
7 NICE: Urinary Incontinence and pelvic organ prolapse in women: management. NICE Guideline. 2019.

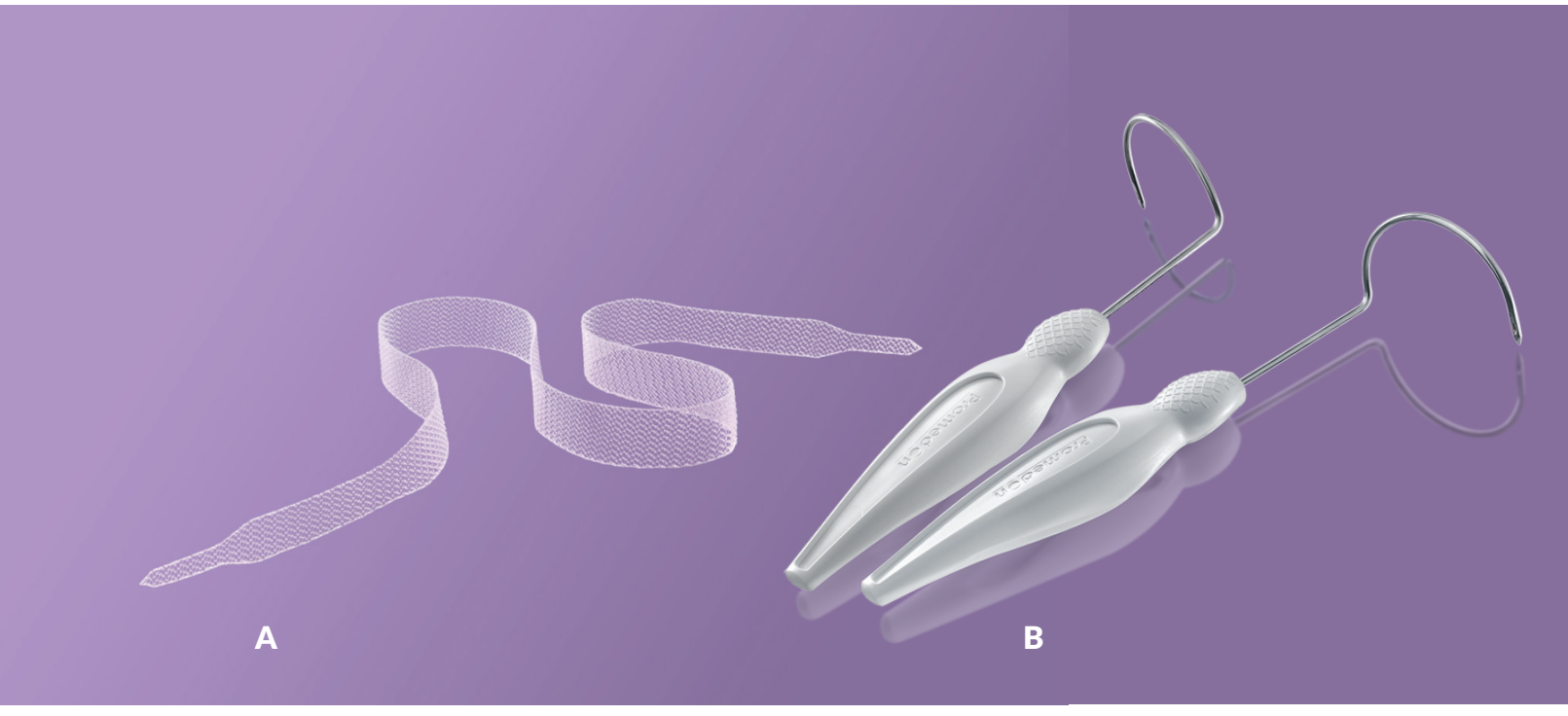
GENERAL INFORMATION

Unitape T Plus is a permanent implant composed of biocompatible type 1, monofilamentous and macroporous (117-861 µm), lightweight (55-69 g/m2) polypropylene mesh with two mesh arms.

UNITAPE T PLUS KIT
(Ref.: KIT-UNITAPE-T PLUS)

1 Sling Unitape (Ref.: SL-100-L)
2 Needles T Plus with handles (Ref.: DPN-HAS)

All components are supplied sterile and ready to use.



A Sling Unitape (Ref.: SL-100-L)
B Needles T Plus with handles (Ref.: DPN-HAS)

SURGICAL TECHNIQUE

UNITAPE T PLUS can be implanted by two different approaches, the OUT-IN and the IN-OUT transobturator approach. The decision on the approach is up to the surgeons preference.

Preoperative Care

The implantation of UNITAPE T PLUS should be based on a thorough patient assessment as well as the patient's characteristics and preferences. Please consider the indications, contraindications, warnings, and precautions of using the UNITAPE T PLUS prior to the operation. Prepare the patient for surgery according to local standard procedures and requirements for transvaginal surgeries. UNITAPE T PLUS can be implanted under general or regional anesthesia. Prepare the patient for surgery following the usual procedures and insert a Foley catheter into the urethra. The administration of prophylactic therapy with antibiotics should be considered, according to the procedure approved by the hospital.

WARNING: DO NOT handle the implant with pointed, serrated, or sharp objects since any damage, perforation, or tearing can cause device damage and or deficiency.

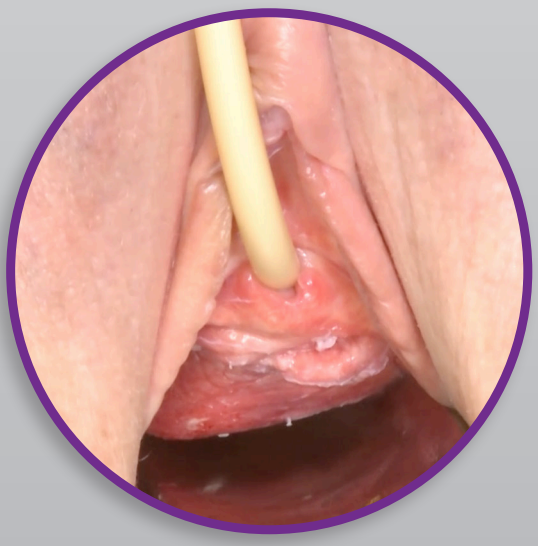
WARNING: The implantation of the sling must be performed with the needles provided in the UNITAPE T PLUS kit.

Inner pouches of the components must be manipulated only by surgeon assistants and/or surgeons in order to maintain the sterile conditions of the product.

Positioning

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

NOTE:
The administration of prophylactic therapy with antibiotics should be considered, according to the procedure approved by the hospital.



PRE-SURGICAL STEPS CATHETERIZATION

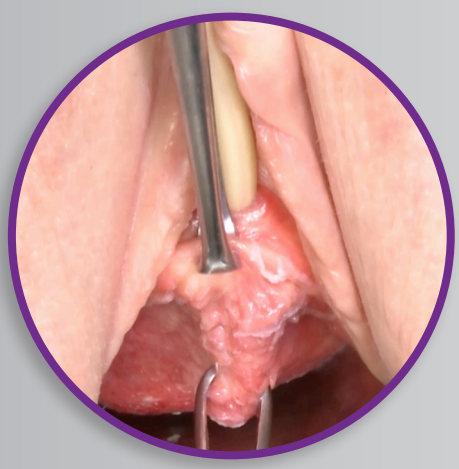
Ensure the bladder is empty prior to starting the operation. Use a urinary catheter as appropriate.

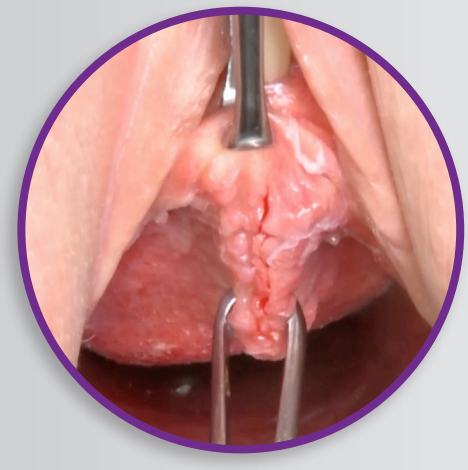
01

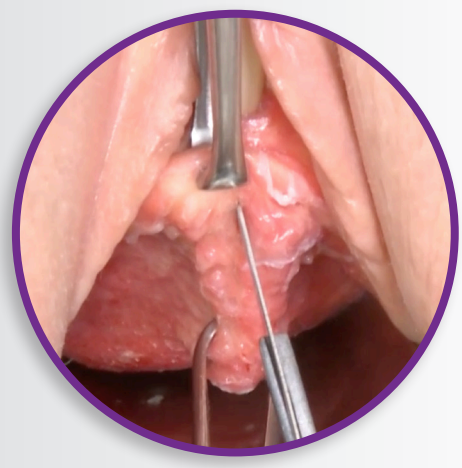
Remove the protecting tube and place both instrumentals on the table with each tip pointing to opposite sides. The needle on the left will be 'A' and the other one 'B'.

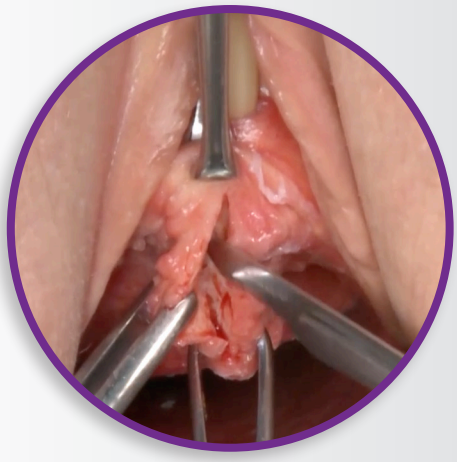
02

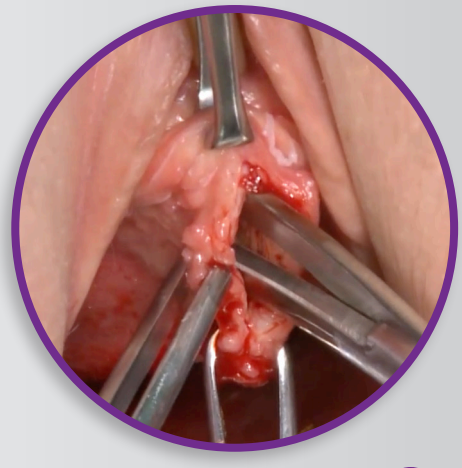
Midline Colpotomy: Perform a sagittal incision of 1.5 cm long, starting about 1 cm from the lower edge of the urethral meatus.

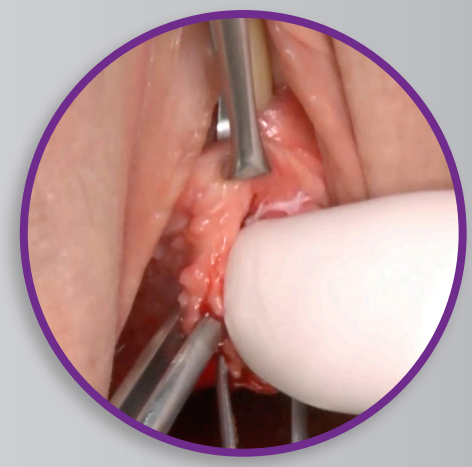












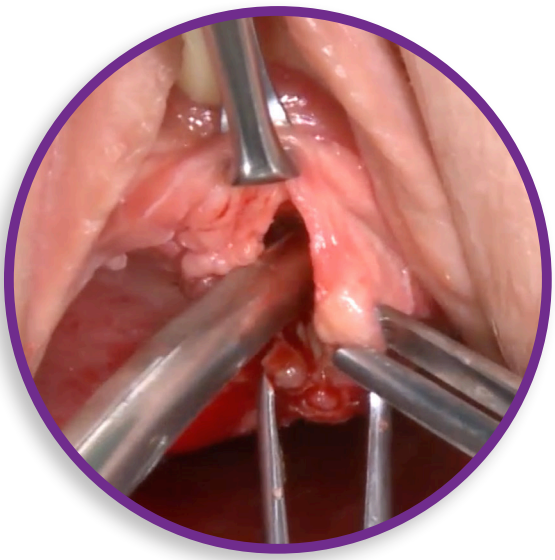
NOTE:
Take care not to injure the vaginal mucosa. Perform a minimal vaginal dissection to form a tunnel that will allow the passage of the transobturator needle.

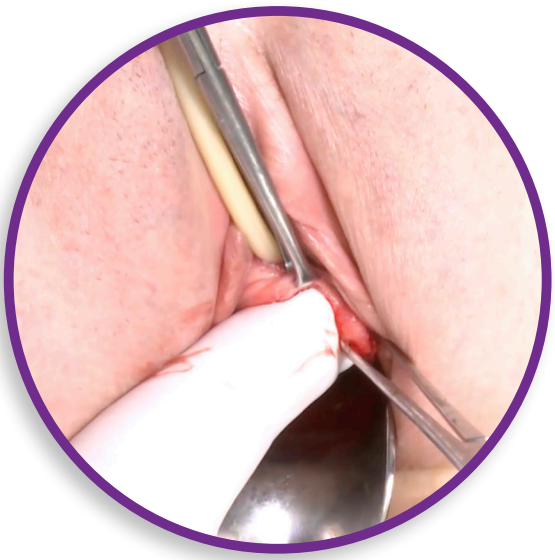
03

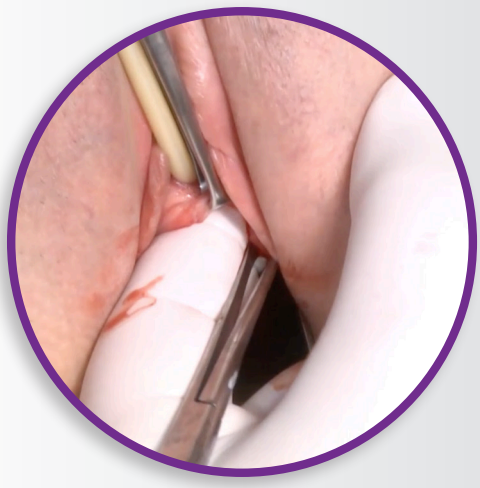
Paraurethral Dissection: Perform a dissection at a 45° angle from the incision at the urethral axis towards the obturator foramen in the paraurethral space.

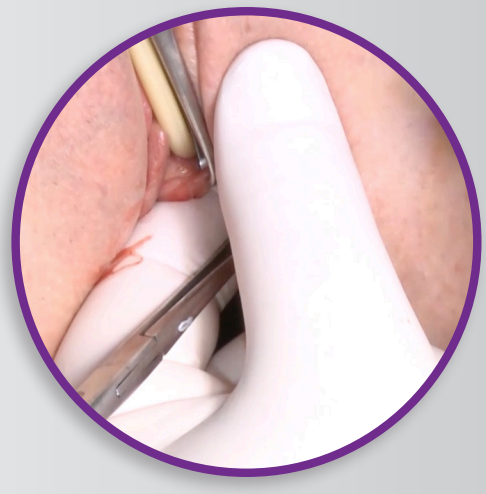
04

Repeat the process on the other side.



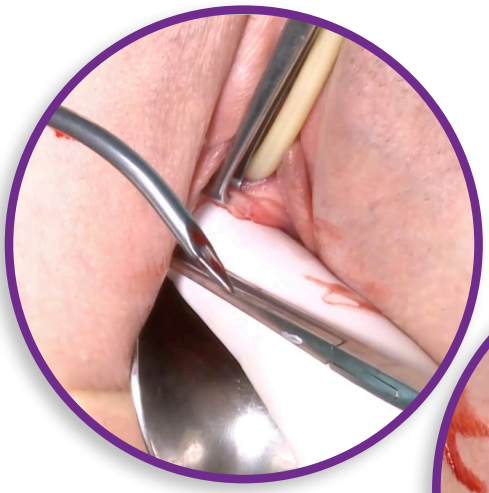


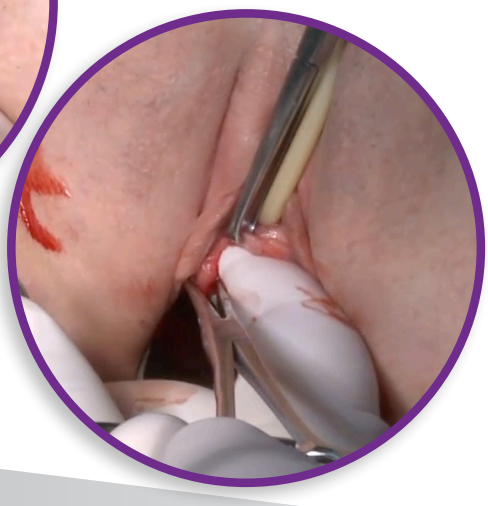




05

Sling placement: Make a punctiform incision about 2cm above the urethra, on the same horizontal line, in the genitofemoral fold on the right side.





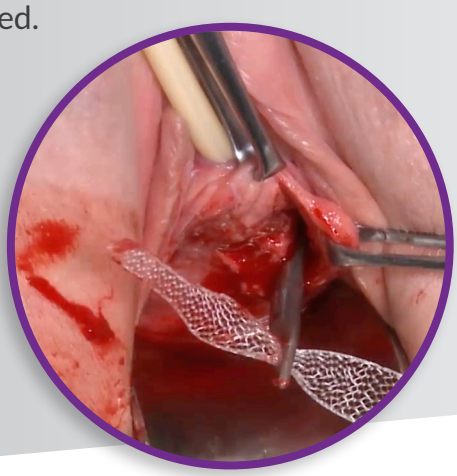
06

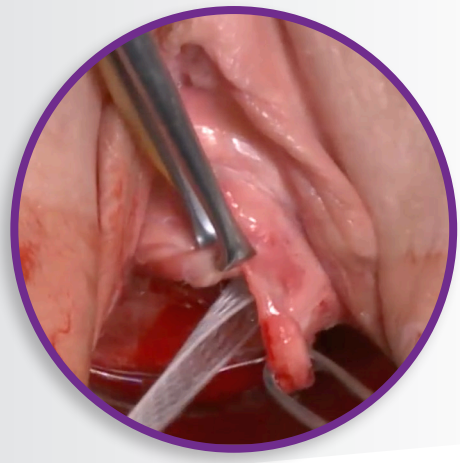
The needle A enters in the left incision site towards the obturator foramen, bordering the ischiopubic branch until it reaches the vaginal incision

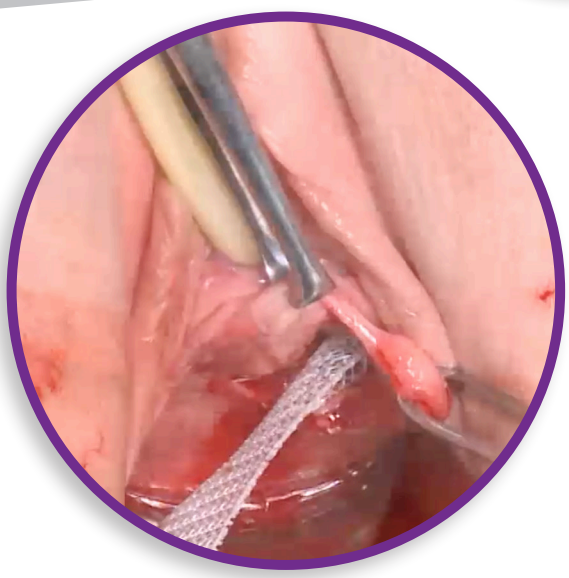
NOTE:
The surgeon should guide the exteriorization process by touching his index finger to avoid urethral and vaginal mucosa injuries.

07

Pull the sling through the eyelet of the needle tip until the width becomes constant. Then pull back the needle to pass the sling through the tunnel previously opened.





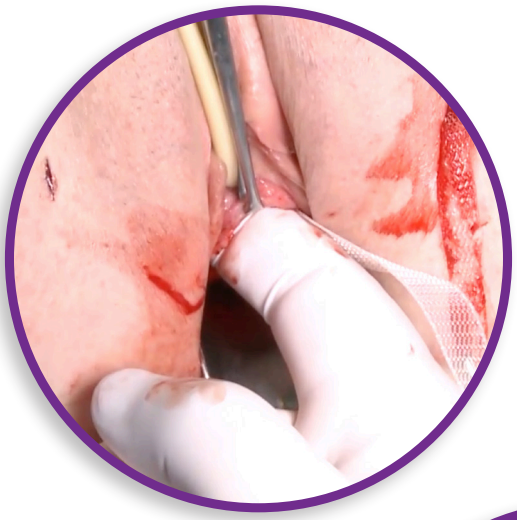


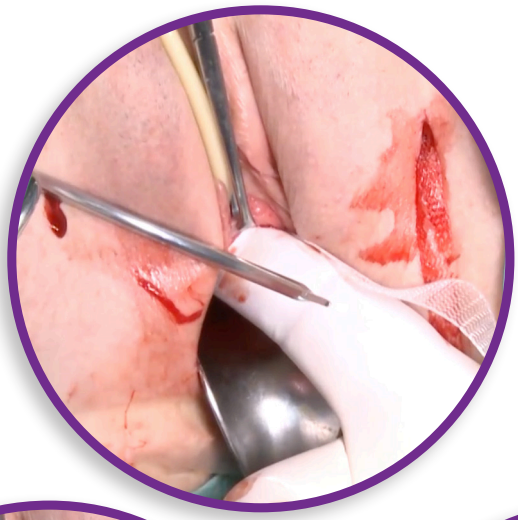
08

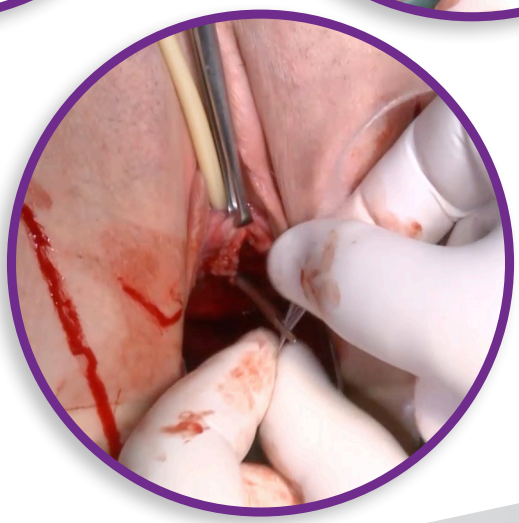
Release the sling tip from the needle tip.

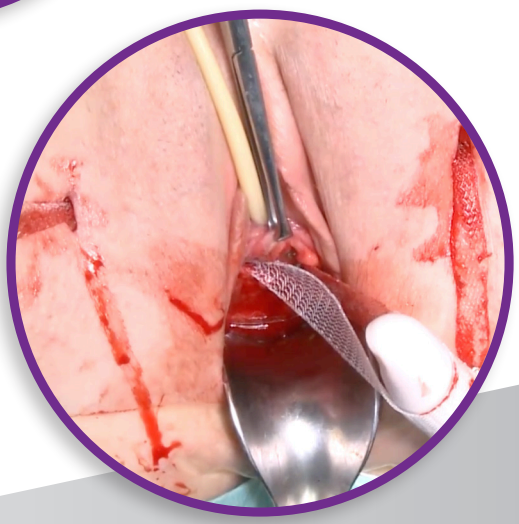
09

Repeat the procedure from Step 5 on the other side with needle B.



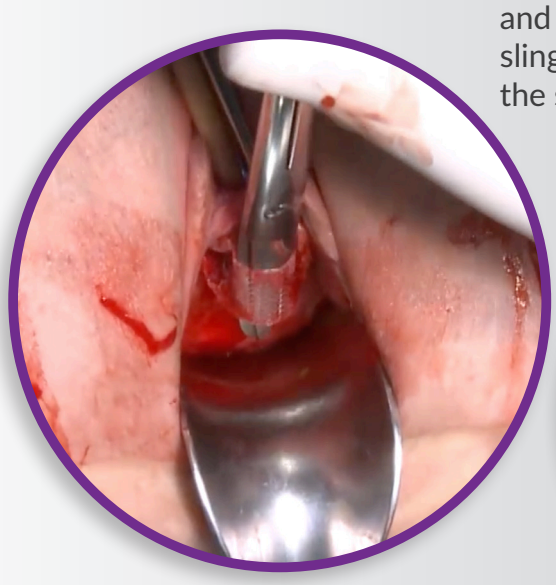


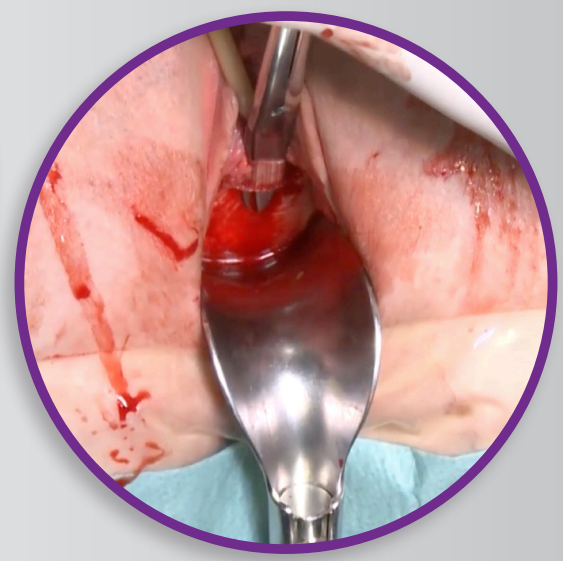


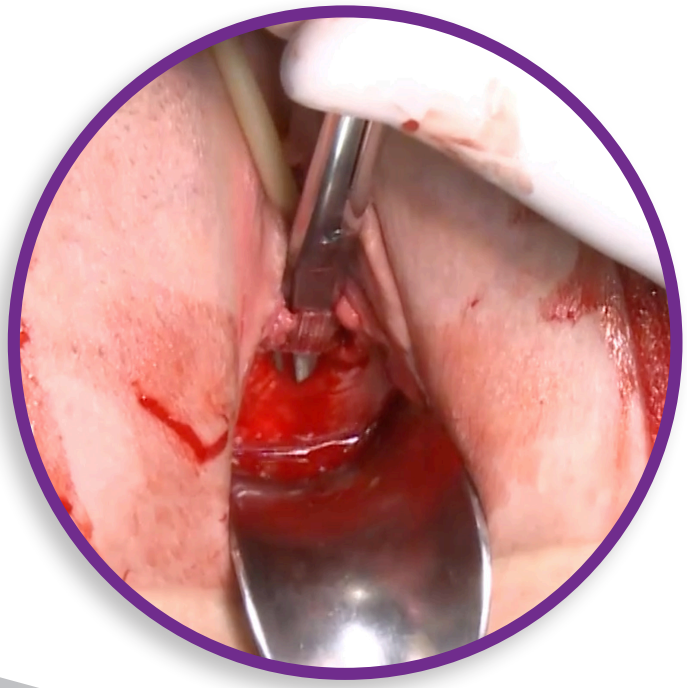


10

Tension-free fixation:
Place an 18 cm Metzenbaum scissors between the urethra and the sling. Then, pull the sling ends, making sure the sling is located under the urethra without tension. Prevent the sling from folding.





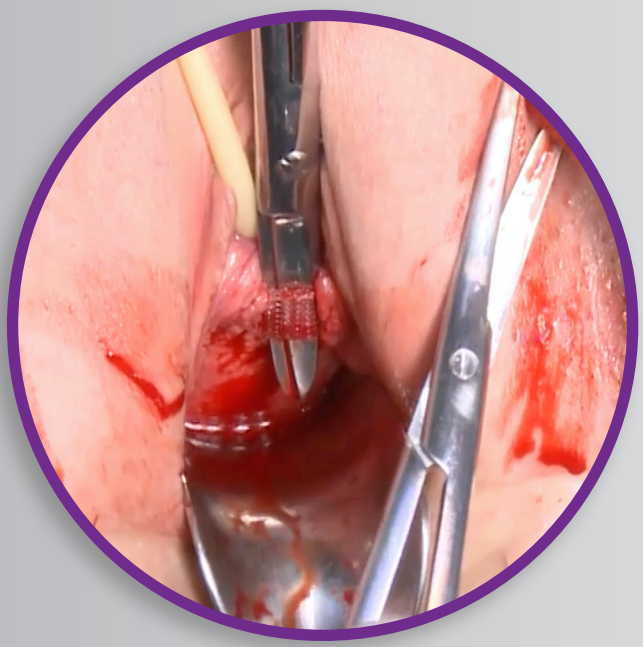


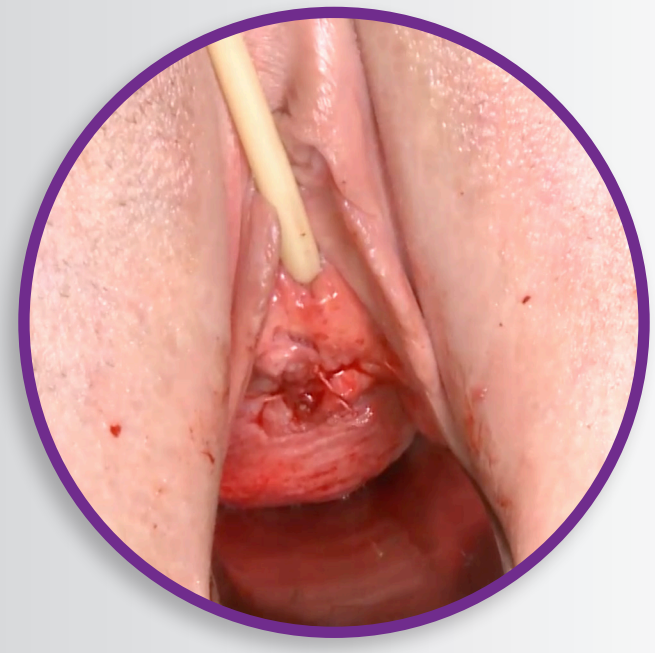
11

Pull the ends of the meshsling until it contacts the scissors.

12

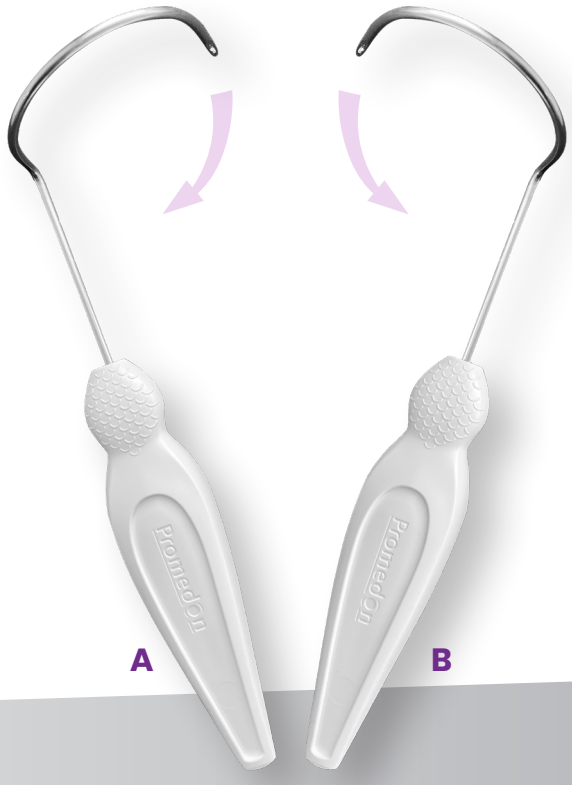
Cut the excess of the mesh above the incision of the skin, remove the Metzenbaum scissors and close the incisions.





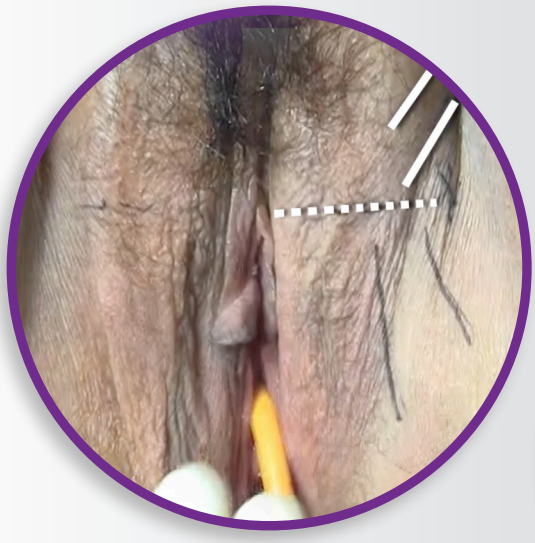
01

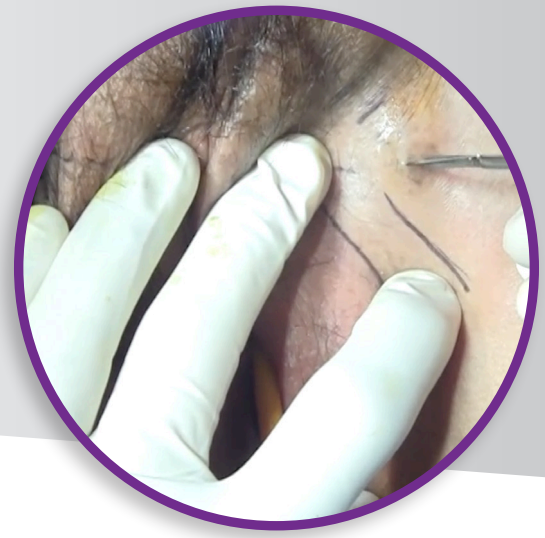
Remove the protecting tube and place both instrumentals on the table with each tip pointing to the same side. The needle on the left will be 'A' and the other one 'B'

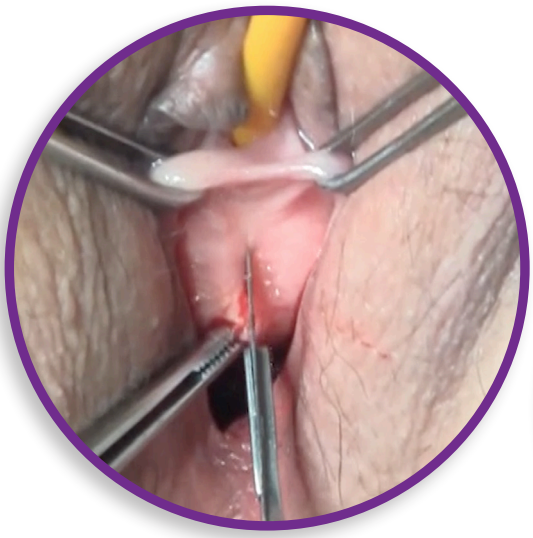


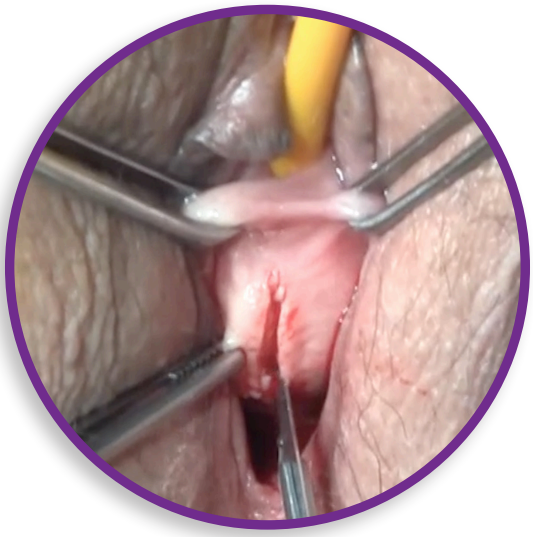
02

Make a punctiform incision about 2cm above the urethra, on the same horizontal line, in the genitofemoral fold on both sides.



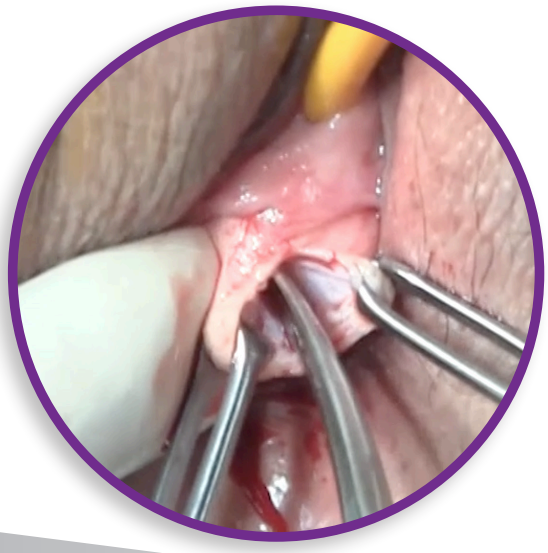






03

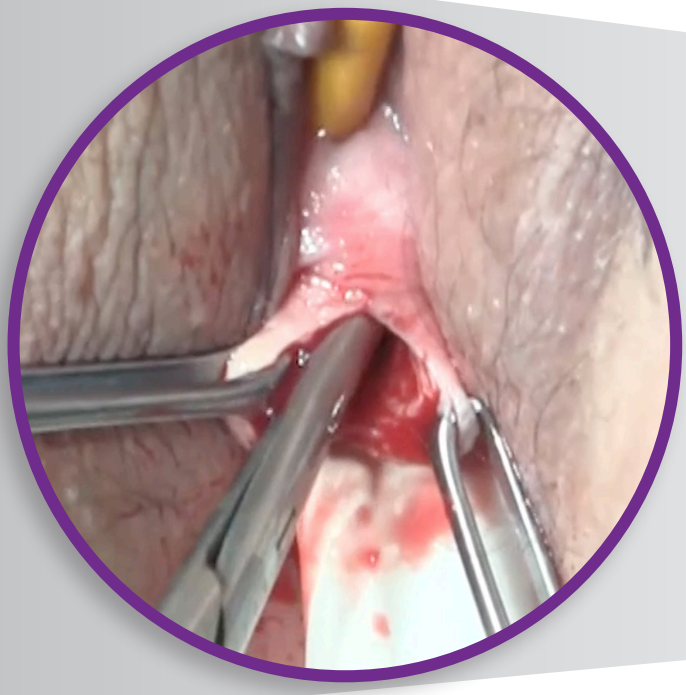
Midline Colpotomy: Perform a sagittal incision, 1.5 cm long, starting about 1 cm from the lower edge of the urethral meatus



04

Paraurethral Dissection: Perform a dissection at a 45° angle from the incision at the urethral axis towards the obturator foramen in the paraurethral space

NOTE:
Take care not to injure the vaginal mucosa. Perform a minimal vaginal dissection to form a tunnel that will allow the passage of the transobturator needle.

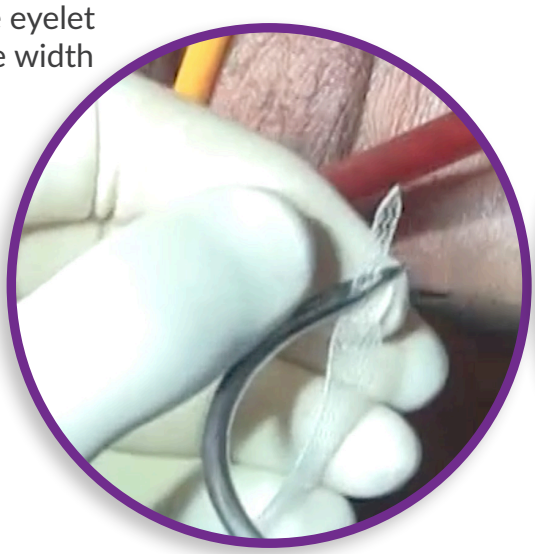


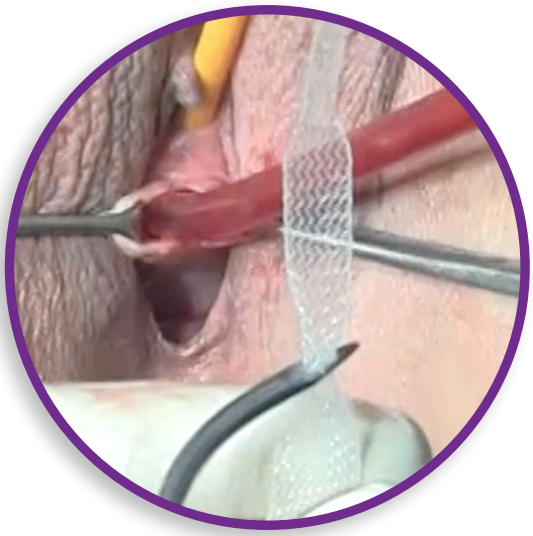
05

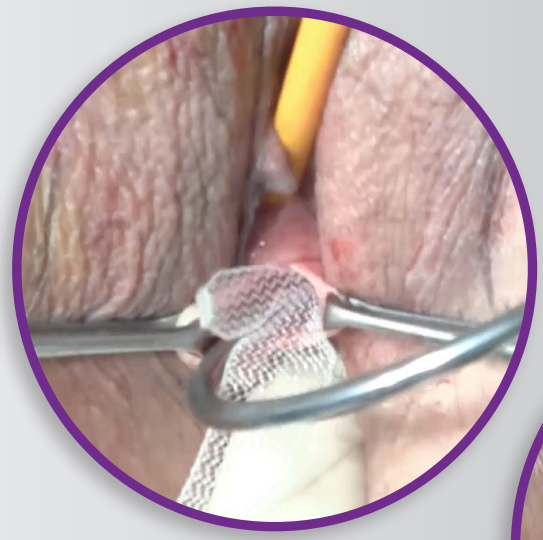
Repeat Step 4 on the other side.

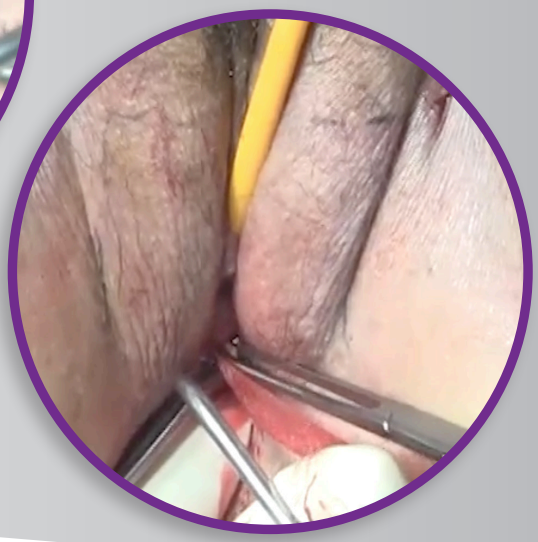
06

Pull the sling through the eyelet of the needle tip until the width becomes constant.



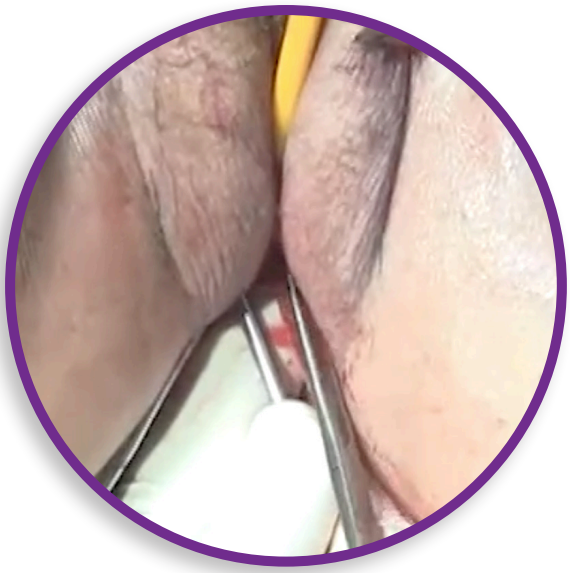






07

Enter needle A into the dissected area and push the needle forward, slightly passing through and penetrating the obturator membrane.

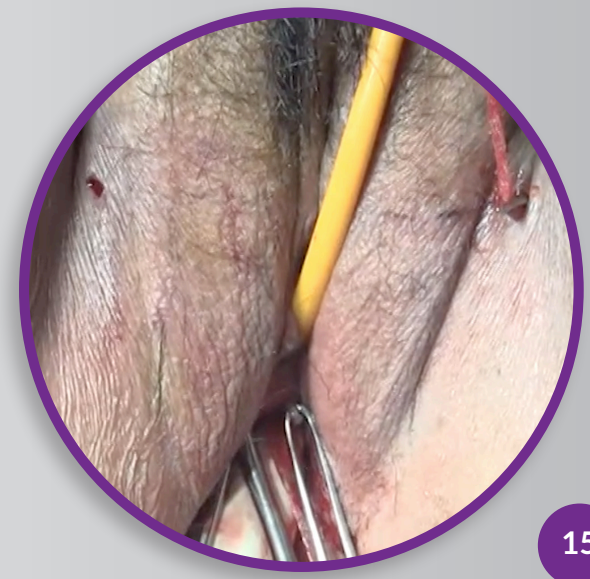


08

Rotate the instrument on the ischiopubic branch until the needle appears at the incision at the genitofemoral fold, previously performed.

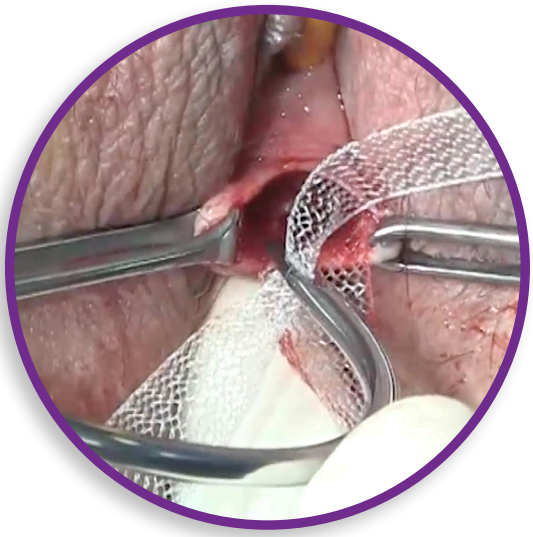
09

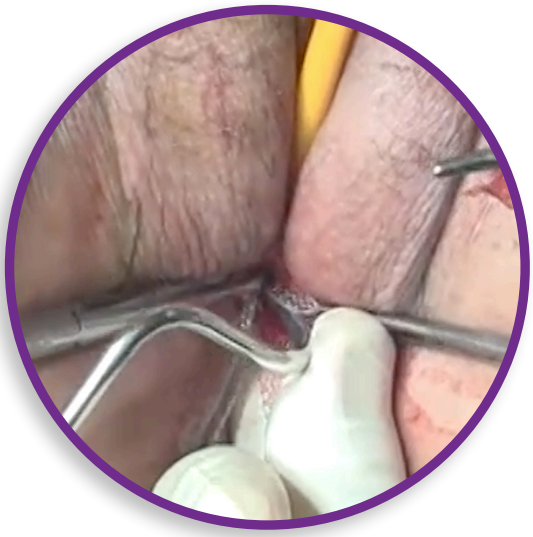
When the tip of the needle and the sling tip appears at the opening of the skin, release the mesh from the needle, clamp it with a forceps and remove the needle, rotating the handle in the opposite direction.

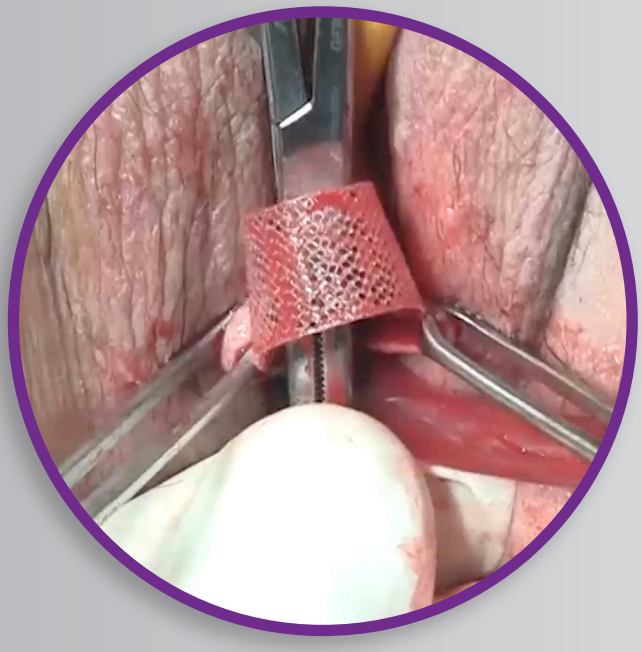


10

Repeat the process from Step 6 on the other side of the patient with needle B.

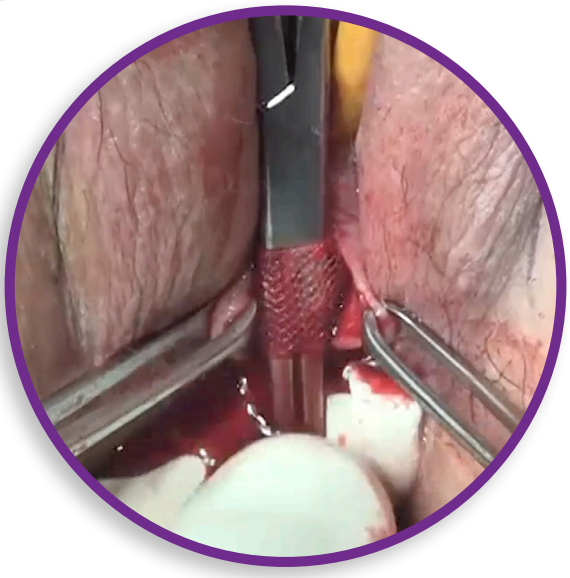






11

Tension-free fixation:
Locate the sling without tension under the mid-urethra by placing an 18 cm Metzenbaum scissors between the sling and the urethra to perform tension regulation easier and prevent the sling from bending.

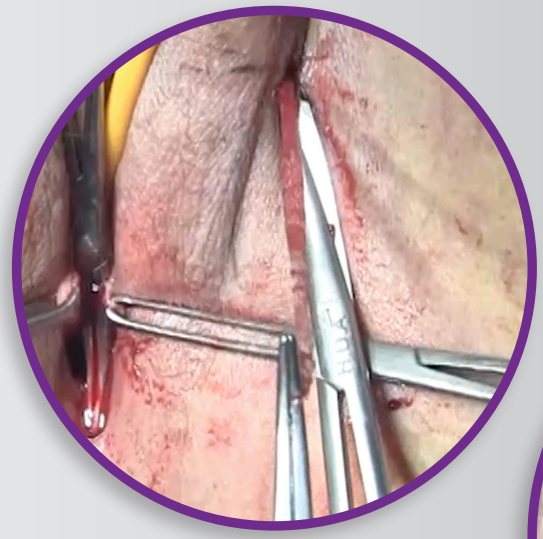


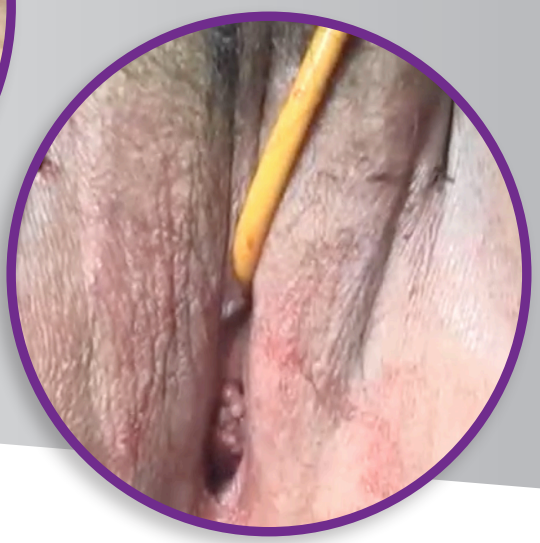
12

Pull the ends of the mesh until it contacts the scissors.

13

Cut the excess of the mesh above the incision of the skin, remove the Metzenbaum scissors and close the incisions.





POSTOPERATIVE CARE

Postoperative care and therapy are at the surgeon´s discretion. The patient should avoid activities such as sexual intercourse, strenuous exercise, and heavy lifting.

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Urology and Pelvic Floor

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