MINISLINGSYSTEM

Minimal Invasive Stress Urinary Incontinence Treatment

Ophira®
MINISLINGSYSTEM

DESCRIPTION

This publication describes detailed recommended procedures for using Ophira. This brochure must be read and understood prior to the first Ophira 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-upf.com. In case of doubt with regard to the surgical technique, we recommend participation in a workshop prior to the first surgery. Please contact your local Promedon representative or distributor for further information.

TABLE OF CONTENT

INDICATIONS, PRECAUTIONS AND WARNINGS

INTENDED PURPOSE

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

INDICATIONS

OPHIRA has been developed to be used for the treatment of female stress urinary incontinence caused by urethral hypermobility or intrinsic sphincter deficiency.

CONTRAINDICATIONS

OPHIRA must not be prescribed if untreated urinary tract infection, active infection at the surgical site or systemic infection (sepsis) is present.

OPHIRA must not be used in patients, who

- have a soft tissue pathology
- are pregnant
- have known sensitivity or allergy to polypropylene products.

WARNINGS AND PRECAUTIONS

WARNINGS AND PRECAUTIONS

The decision to use the OPHIRA mini sling should be based on a thorough assessment of the patient as well as on the patient's individual characteristics and preferences. In order to avoid complications, please consider the following warnings and precautions concerning the decision whether to perform surgery, the related clinical aspects, the surgical procedure and handling of the device:

- Surgeons performing these procedures should be appropriately trained in stress urinary incontinence (SUI) surgery and capable of recognizing, diagnosing, and treating potential mesh-related complications associated with the procedure (1).
- OPHIRA must be used in sterile conditions in a surgical theatre.
- This surgical technique brochure must be read and understood BEFORE implanting OPHIRA for the first time.

CLINICAL ASPECTS AND DECISION FOR SURGERY

- 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 (2).
- Obesity (BMI greater than or equal to 35 kg/m^2) might increase the technical difficulty and complication rates (3).
- Surgical treatment of SUI should be deferred until after childbearing is complete in patients planning pregnancies (2). After pregnancy, it is recommended to wait at least 6 months before implanting the product. The doctor should determine the appropriate time in accordance with the patient's condition.
- Identified potential risk factors for failure of the single incision mini sling procedures include the presence of persistent or de novo urgency, prolonged urinary retention, recurrent urinary incontinence, dyspareunia, age and previous surgery (4).

OPHIRA must be used with caution in patients with:

- Immunodeficiency
- Autoimmune disorders or any factors that could compromise wound healing (for example, patients on anticoagulant therapy, following radiation therapy, presence of significant scarring, poor tissue quality, etc.)(2)
- Polypropylene may cause an inflammatory reaction.
- DO NOT use OPHIRA simultaneously with any other product.
- The polypropylene mesh integrates with the patient's tissue, hence complete removal may be difficult or unfeasible. The risk of injury caused by mesh removal may be higher than the benefits resulting from this removal. Adverse events (e.g. pain) may persist 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, coital incontinence is likely to improve (clinical evidence level 3) (5).
- OPHIRA should not be used in patients undergoing concomitant urethral diverticulectomy, repair of an urethrovaginal fistula, or urethral mesh excision with concurrent stress incontinence surgery. Any procedure in which the urethra is opened close to the mini sling position could affect wound healing (2).

SURGICAL PROCEDURE

- DO NOT deviate from the implantation procedure as described in the section SURGICAL STEPS of the IFU. In order to avoid complications such as revision surgery, take individual anatomical variations into account, since aberrations can cause perforation or injury of surrounding tissue and organs, e.g. blood vessels, nerves, urethra or bladder.
- A 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 or bladder.
- The patient should be carefully followed-up before being discharged from hospital.

CLINICAL BENEFITS

OPHIRA restores continence in adult women by means of tissue reinforcement and stabilization of the soft tissues of the female pelvic floor.
On the basis of the available preclinical, chemical and biological tests that have been performed, and data from the literature and from postmarket surveillance, the expected lifetime of OPHIRA is 10 years. In order to achieve this, it is necessary to take into account all the sections in the Instruction for Use and to implant the product as described in the Surgical Steps in the Instructions for Use and/or this surgical technique brochure. There are no reasons to explant the product if there are no complications after the specified lifetime. However, each case should be assessed and a decision made at the surgeon's discretion.

MAGNETIC RESONANCE (MR) ENVIRONMENT

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

GENERAL ASPECTS

- DO NOT use the product if the package is open or damaged, as Ophira components are supplied sterile.
- Ophira 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 precautions must be taken to avoid contamination. Operating room conditions must meet hospital, administrative and/or local governmental requirements.

References:

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: Kobashi KC, Albo ME, Dmochowski RR et al: Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline. J Urol 2017; 198: 875-883.

3: a. Oliveira R, Botelho F, Silva P, et al. Single-incision sling system as primary treatment of female stress urinary incontinence: prospective 12 months data from a single institution. BJU Int. 2011;108(10):1616-1621.
b. EAU Guidelines on Urinary Incontinence in Adults. European Association of Urology 2020.

4: a. Maturana AP, Palos CC, Ghersel FR, Fernandes CE, Oliveira E. Randomized controlled trial comparing mini-sling with transobturator sling for the treatment of stress urinary incontinence. Int Urogynecol J. 2020;31(9):1925-1931.
b. Mira Gon L, Zanettini Riccetto CL, Citatini de Campos CC, Iamashita Voris BR, Reis LO, Rodrigues Palma PC. Mini-Sling Ophira at 8 Years Follow-Up: Does It Sustain Results?. Urol Int. 2019;102(3):326-330.
c. Golbasi C, Taner CE, Golbasi H. Long-term outcomes and quality of life effects of single incision mini sling procedure in stress urinary incontinence patients. Eur J Obstet Gynecol Reprod Biol. 2019;234:10-13.
d. Yildiz G, Batur AF, Akand M, Kiliç Ö, Şahin MO. Comparison of Two Single-Incision Mini-Slings for the Treatment of Incontinence. Med Princ Pract. 2021;30(1):85-91.

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: NICE guideline 2019: Urinary Incontinence and pelvic organ prolapse in women: management. https://www.nice.org.uk/Guidance/NG123

PATIENT INFORMATION AND AFTERCARE

The surgeon is responsible for the thorough counselling and assessment of the patient as well as for requesting informed consent from the patient before implanting the mesh. In particular, alternative conservative and surgical treatment options must be sufficiently discussed with the patient. The surgeon must inform the patient about potential adverse events, including the advantages and disadvantages of urogynaecological surgical mesh.

The patient should be advised that OPHIRA 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 of implant infection or other complications, such as:

- Purulent, serous or bloody vaginal discharge; bleeding
- Severe Pain
- Fever

Topical oestrogens, if not otherwise contraindicated, may be considered approximately for 6 weeks after the procedure for a single area of mesh exposure smaller than 1 cm^2, if no other symptoms are present (6).

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

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.

GENERAL INFORMATION

OPHIRA is a permanent implant (mini sling) made of a biocompatible, lightweight (55 – 69 g/m2)(7) polypropylene mesh, which is classified as type 1 (macroporous [pore size 117 – 861 µm] monofilament) according to the Amid classification (8).

OPHIRA SYSTEM

- 1 Ophira mini sling (Ref: S-38-AF)
- 1 Retractable Insertion Guide (Ref: DPN-MN),

designed to be used together with the sling for implantation.

All components are supplied sterile and ready to use.

Ophira®
MINISLINGSYSTEM

A OPHIRA mini sling (Ref: S-38-AF)
B Retractable Insertion Guide (Ref: DPN-MN)

A B

References:
7: Coda A, Lamberti R, Martorana S. "Classification of prosthetics used in hernia repair based on weight and biomaterial." Hernia (2012). 16(1):9 - 20.
8: PK Amid. "Classification of biomaterials and their related complications in abdominal wall hernia surgery". Hernia (1997). 1: 15 - 21.

SURGICAL TECHNIQUE

OPHIRA is implanted under regional or local anaesthesia via a vaginal approach using a single vaginal incision and is anchored to the obturator internus muscle at a point near the arcus tendineus.

Preoperative Care

Prepare the patient for surgery according to local standard procedures and requirements for transvaginal surgery. OPHIRA can be implanted under general or local anaesthesia. Use the standard or high lithotomy position according to the surgeon's standard procedure.
Administration of prophylactic antibiotic therapy should be considered in accordance with the procedure approved by the hospital.

WARNING: DO NOT handle the implant with pointed, serrated or sharp objects since any damage, perforation or tearing could damage or impair the device.

WARNING: The Retractable Insertion Guide (RIG) provided in the OPHIRA system must be used to implant the mini sling.

NOTE: All the components provided in the system must be handled only by surgeon assistants and/or surgeons in order to maintain the sterile conditions of the product.

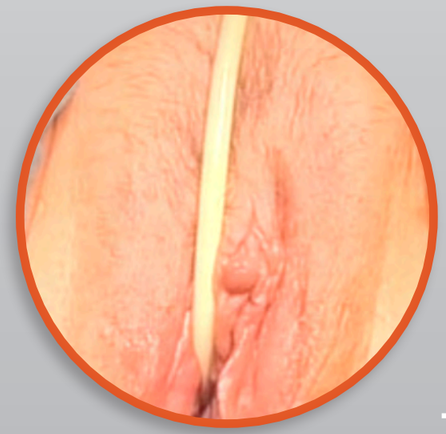
POSITIONING

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

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

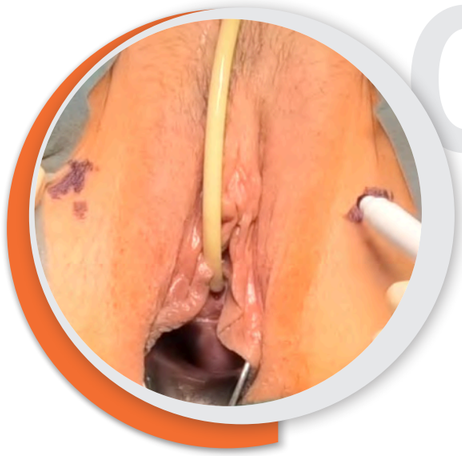
PRE-SURGICAL STEPS
CATHETERIZATION

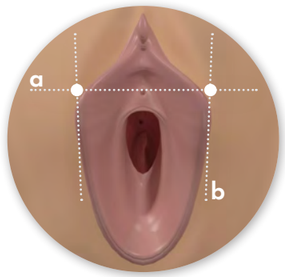
Ensure the bladder is empty prior to starting the operation. Use a urinary catheter as appropriate.



SURGICAL STEPS

01



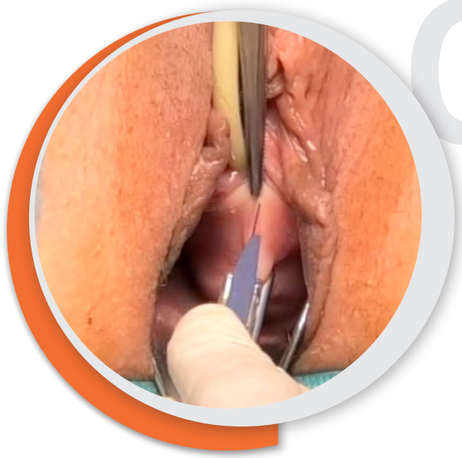


References direction point:
intersection with genito femoral fold

ORIENTATION MARKS

For optimal positioning of the implant, make orientation marks to define an intersection point as follows:
a. A horizontal line at a point located halfway between the urinary meatus and the clitoris.
b. A vertical line in the genitofemoral fold.

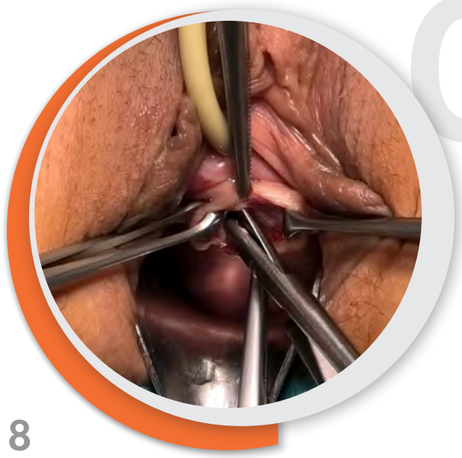
02



MIDLINE COLPOTOMY

Make a sagittal incision 1.5 cm long, starting 1 cm from the urinary meatus.

03



PARAURETHRAL DISSECTION

Starting at the incision, dissect the paraurethral space to the inferior ramus of the pubic bone in the direction of the homolateral shoulder, without perforating the endopelvic fascia.

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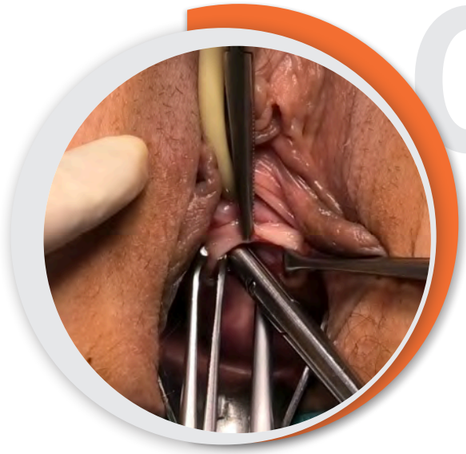
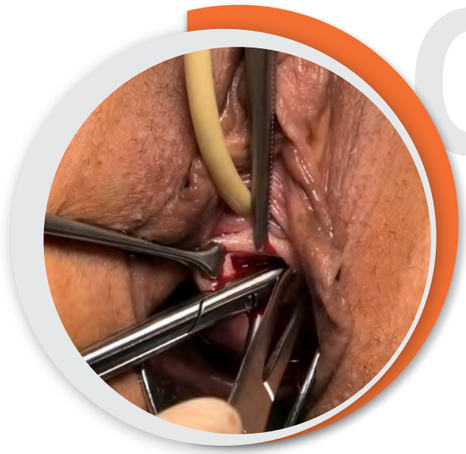


Perform a minimal dissection, in order to form a tunnel that will permit the passage of the retractable insertion guide.

05



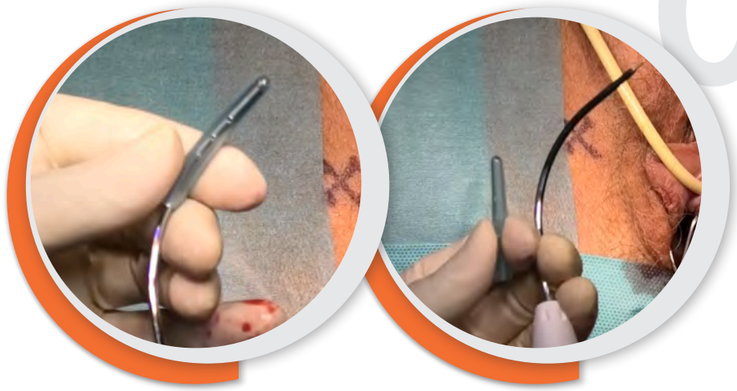
Repeat this step on the contralateral side.

REPEAT

SURGICAL STEPS

PLACEMENT OF THE MINI SLING

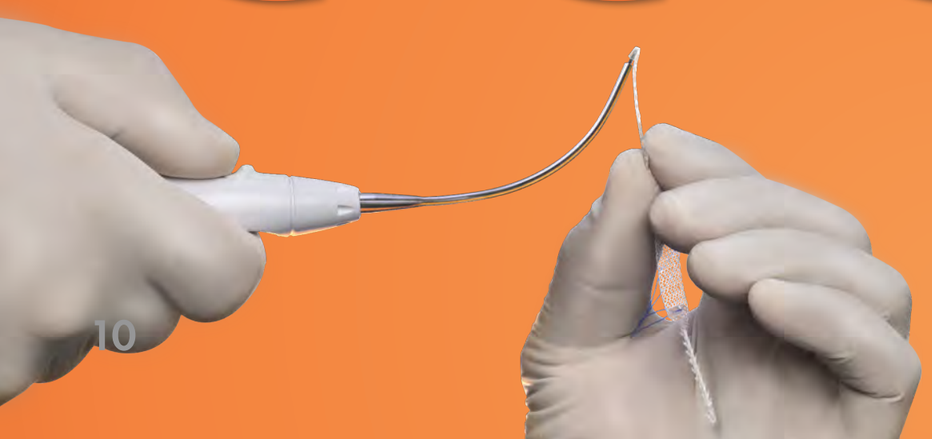
06



Remove the protective cap of the retractable insertion guide (RIG) and ensure that the switch on the handle of the RIG has been pushed into the upper position to extend the tip of the RIG.

07

Hold of the OPHIRA implant and insert the extended tip of the RIG into the hole of the anchor by pulling on the anchor. Ensure that the anchor is completely attached to the RIG.



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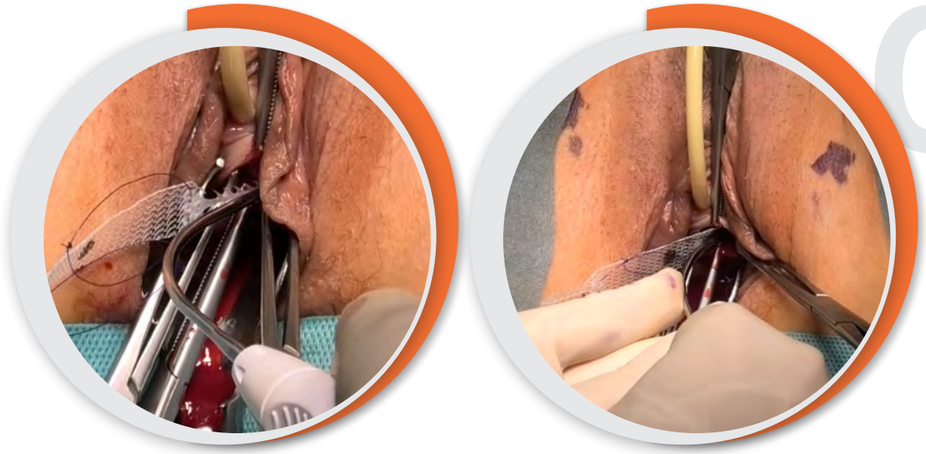
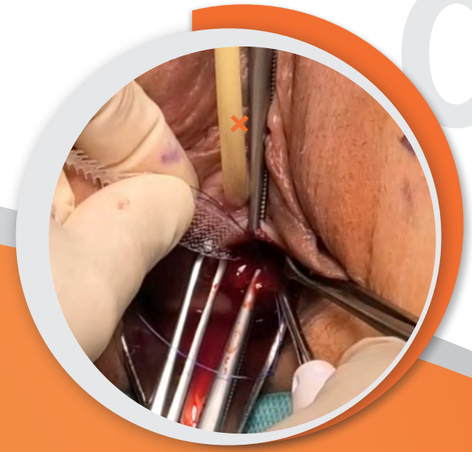


Insert the implant attached to the RIG through the vaginal incision in direction of the previously made orientation marks.
Guide the implant towards the paraurethral dissection and up to the inferior ramus of pubic bone until the perineal membrane is perforated.

09

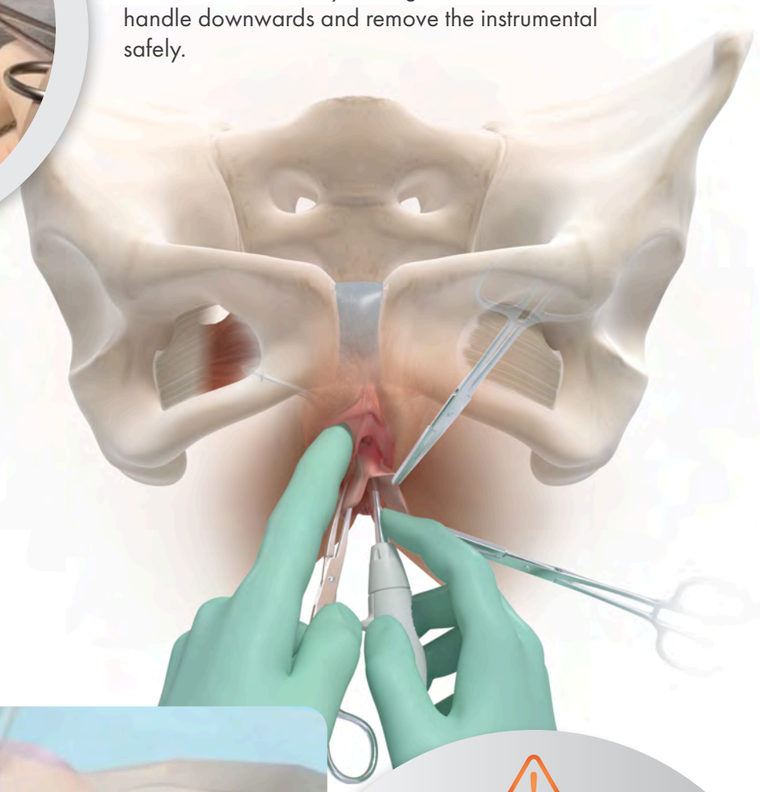


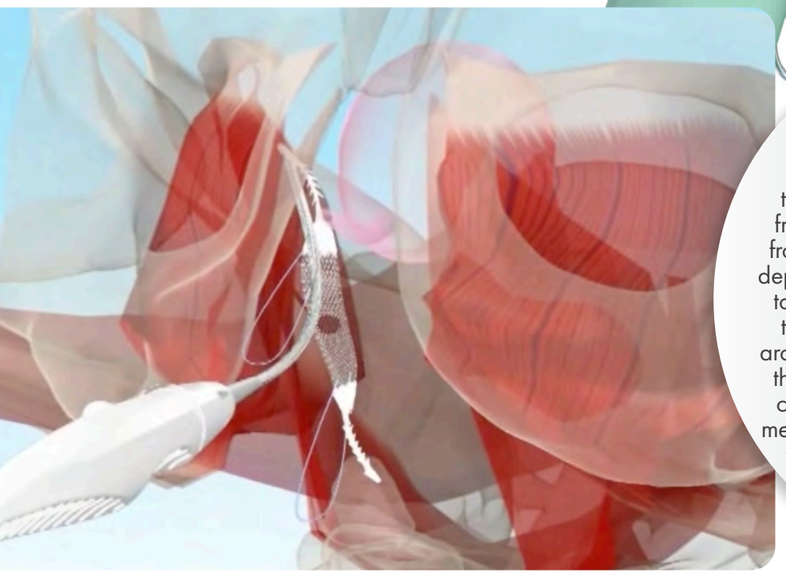
Insert and fix the anchor to the obturator internus muscle in a parallel direction to the obturator membrane at the level of the arcus tendinous. Ensure that the central mark of the implant is located under the urethra.

10

WARNING:
While these manoeuvres are being performed, use the index finger to protect the vagina from perforation.

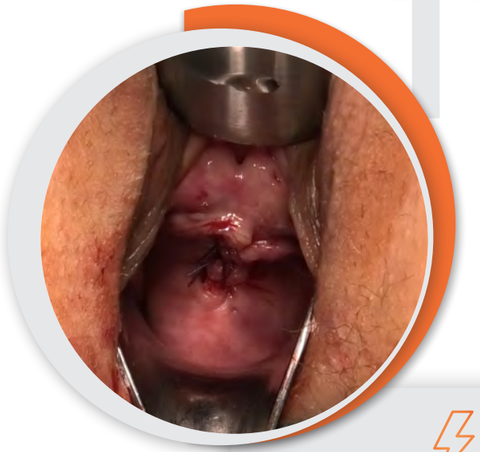
Release the anchor by shifting the switch of the handle downwards and remove the instrumental safely.





WARNING:
Avoid inserting the RIG along a higher trajectory since it will encounter resistance from the pubic bone and thus be prevented from reaching the recommended anchorage depth. The implant anchors should be attached to the obturator internus muscles, parallel to the obturator membrane at the level of the arcus tendineus. The correct insertion depth for the first anchor is reached once the surgeon can see the central mark on the suburethral mesh, which has already been inserted below the ipsilateral side of the vaginal incision.

11



Repeat steps 7 to 10 on the contralateral side. The insertion depth of the second anchor is defined by means of a stress test or tension-free fixation.

Stress test

Holding the RIG in place, fill the bladder with 200 ml of saline solution. If the patient continues losing urine, keep pressing the RIG into the muscle to insert the anchor further.

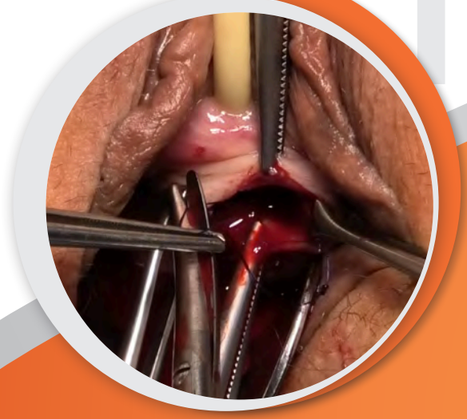
Tension-free fixation

Place 18 cm Metzenbaum scissors between the urethra and the implant. Then fix the anchor, making sure the implant is located under the urethra without tension.
If it is necessary to adjust or release the tension of the implant, pull carefully on the blue thread-loops that are attached to each arm of the implant.

12

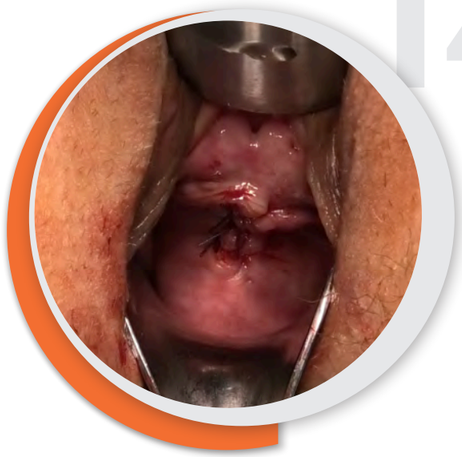
After making the adjustment, remove the RIG by retracting the switch of the handle to release the anchor.

13



Remove the two blue threads-loops attached to the implant.

14



NOTE:
Vaginal packing and catheterization to the next day is recommended.

Close the vaginal incision so as to completely cover the polypropylene mesh with sufficient epithelial tissue to minimize the risk of the mesh becoming exposed.

POSTOPERATIVE CARE

The patient should avoid heavy lifting, excessive physical exercise, sexual intercourse and the use of any vaginal insertions for at least four to six weeks after surgery. The doctor should determine, on an individual basis, when such activities can be resumed.

4 WEEKS

NOTES

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her professional clinical judgment when deciding whether to use a product for the treatment of patients. Promedon does not dispense medical advice. A surgeon must always refer to the package content, product label, and/or instructions for use, before using any Promedon product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Promedon representative if you have questions about the availability of Promedon products in your area. Ophira is CE marked.

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Urology and Pelvic Floor

CE 0197

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