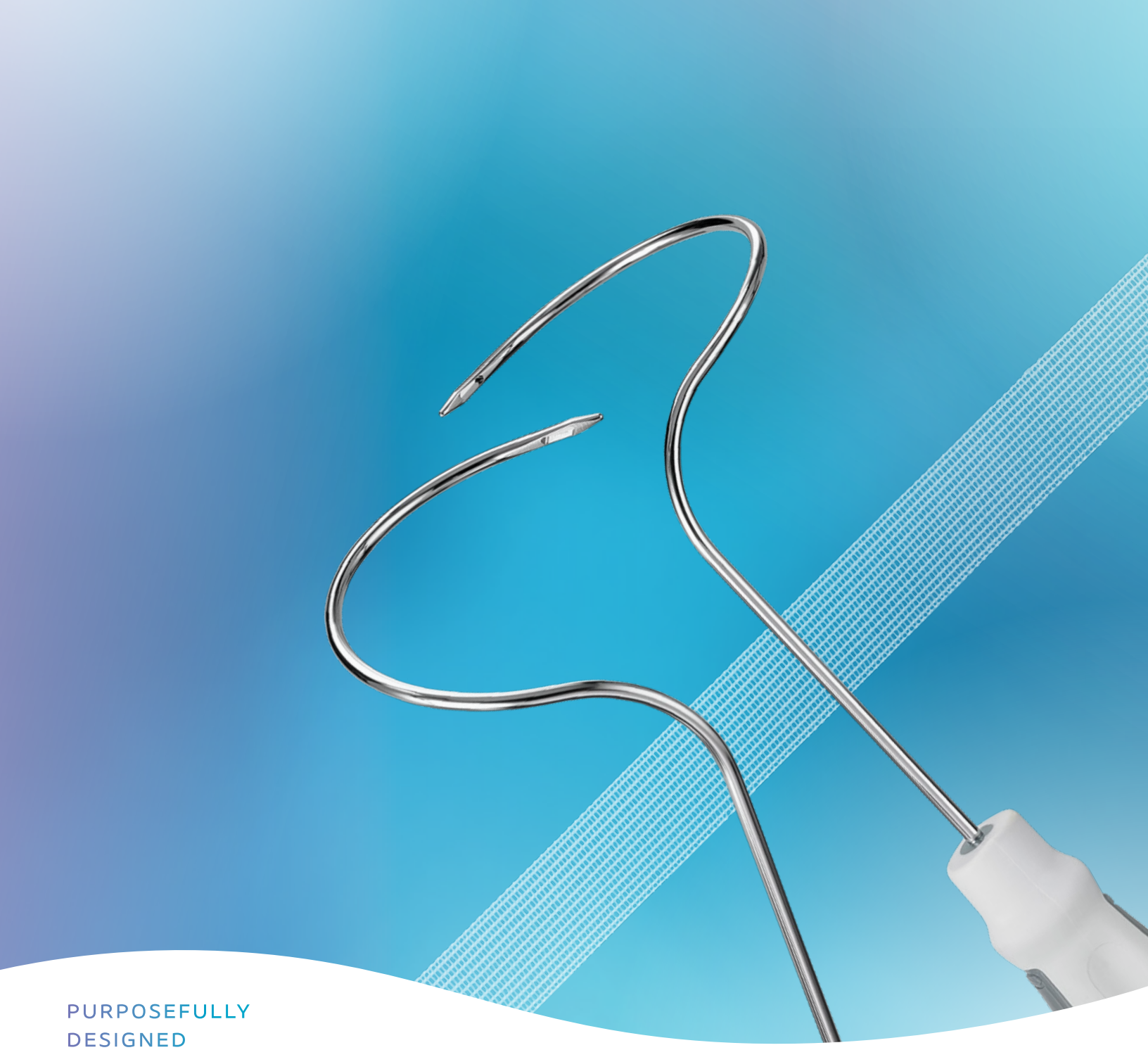


PURPOSEFULLY
DESIGNED

Aris®

Transobturator Kit

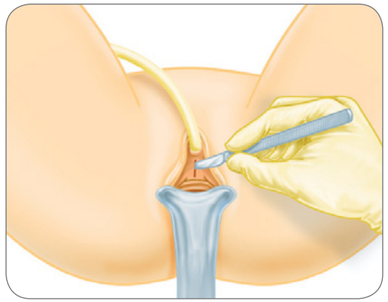
Aris® Procedural Technique

Coloplast

Aris®

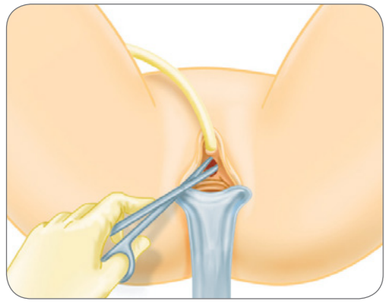
Aris® Procedural Technique

These illustrations are recommended for the general use of these devices in the treatment of stress urinary incontinence. These illustrations are not intended to replace the instructions in the IFU. Aris® Transobturator Kit should only be used by physicians who have received surgical instruction on pelvic floor reconstruction in general, and specifically with the Aris® mesh. Variations in use may occur due to individual technique and patient anatomy.



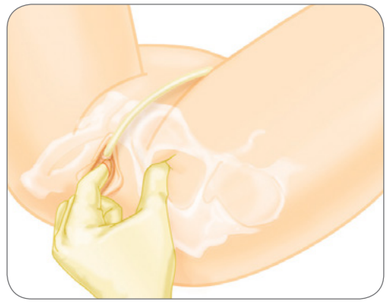
STEP 1

1. Make a full thickness incision on the anterior vaginal wall at the midurethra.



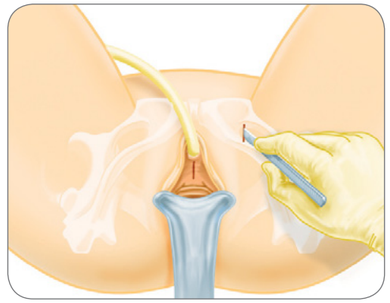
STEP 2

2. Perform sharp and blunt periurethral full thickness dissection anterolateral to the medial border of the descending ischiopubic rami. Width of dissection should be 1.5 cm to allow the sling to lay flat in the dissected plane.



STEP 3

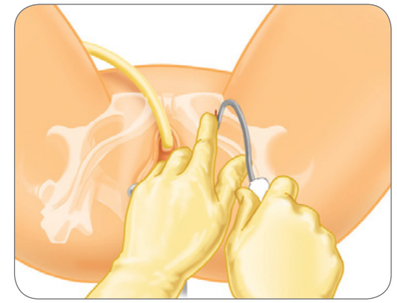
3. Manually confirm the introducer insertion point by putting a finger in the vaginal incision and a thumb on the inner surface of the thigh. Press them together to feel the anticipated needle path through the obturator foramen and around the ischiopubic ramus.



STEP 4-5

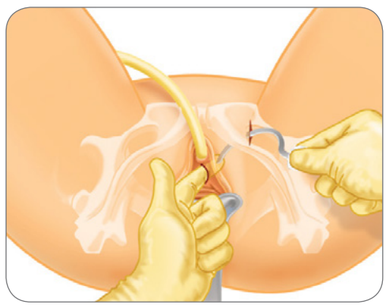
4. Make a small vertical skin incision directly above the medial portion of the obturator foramen and adjacent to the lateral border of the ischiopubic ramus. The entry point of the introducer should be on a horizontal line passing through the clitoris and adjacent to the lateral border of the ischiopubic ramus.

5. Repeat steps 3-4 on contralateral side.



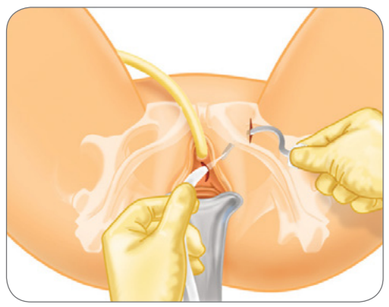
STEP 6

6. Insert the introducer through the skin incision until it perforates the obturator membrane.



STEP 7

7. Rotate the introducer around the posterior surface of the ischiopubic ramus, perforating the obturator internus muscle, while an index finger is placed in the vaginal incision for guidance and urethral protection. Confirm that the introducer has not pierced the vaginal sulcus.

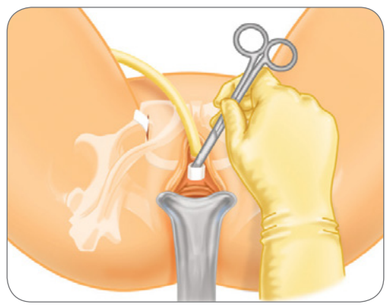


STEP 8-10

8. Attach Aris sling to the introducer by threading the sling through the eye of the introducer. Pull the sling through the eyelet about 3-4 centimeters. Reverse the introducer through the incision tunnel to place the sling.

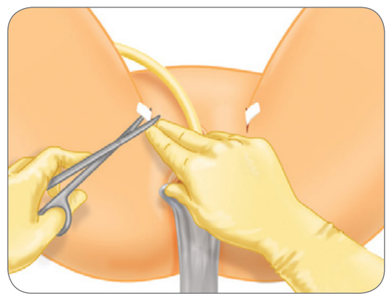
9. Repeat steps 6-8 on the contralateral side.

10. Cystoscopy should be performed after the passing of the introducers to confirm bladder integrity or to recognize bladder perforation.



STEP 11

11. Vaginal retraction should be removed prior to tensioning. To prevent over-tensioning, the sling should be placed under the urethra tension free, such that a right angle instrument could fit easily between the sling and urethra. Ensure that the sling is lying flat under the urethra and is not folded or curled.



STEP 12-13

12. Push the skin down without pulling on the sling, and cut off excess sling at the obturator incisions. Make sure that the ends of the Aris sling are below the level of the skin.

13. Close all incisions according to physician preference.

ARIS® TRANSOBTURATOR KIT BRIEF STATEMENT

Indications:
The Aris Transobturator Kit consists of the Aris implantable midurethral support sling and disposable introducers. The Aris sling and introducers are indicated for the surgical treatment of all types of stress urinary incontinence (SUI) and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Contraindications:
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The Aris Transobturator Kit is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Known active urinary tract infection and/or infection in operative field
- Taking anti-coagulant therapy
- Abnormal urethra (e.g., fistula, diverticulum)
- Intraoperative urethral injury
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions:
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the warnings and precautions associated with the use of this product and the associated surgical risks.

Warnings:
The Aris Transobturator Kit should only be used by physicians familiar with the surgical procedures and techniques involving transvaginal placement of non-absorbable, synthetic mesh slings and who have adequate education and experience in the treatment of female SUI. A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure. The patient should be counseled that alternative incontinence treatments may be appropriate, and the reason for choosing a mesh sling procedure should be explained. Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transvaginal mesh sling surgery. Patient counseling should include a discussion that the sling to be implanted is a permanent implant and that some complications associated with the implanted mesh sling may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the sling may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring. As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.
The risks and benefits of using Aris should be considered in patients. Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time. Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised. The procedure to insert the Aris sling requires good knowledge of pelvic anatomy and the correct use of the introducer needles in order to avoid damage to adjacent anatomical structures. Cystoscopy should be performed to confirm bladder and urethral integrity. Avoid placing excessive tension on the Aris sling during placement and adjustment to maintain sling integrity and to avoid compression of the urethra when tensioning.

Precautions:
The Aris sling and Aris introducers are provided sterile (ethylene oxide sterilization) and are for single-use only. Use caution to prevent intraoperative injury to adjacent pelvic structures. Do not let the Aris sling come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the sling.

Potential Complications:
Adverse events are known to occur with transvaginal synthetic sling procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent. Adverse events may include but are not limited to: abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh sling into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., muscles, nerves, vessels), structures, or organs (e.g., bone, bladder, urethra, ureters, vagina), seroma, sling migration, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), granulation tissue formation, palpable mesh (patient and/or partner), sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring or tightening. The occurrence of these events may require one or more revision surgeries, including removal of the sling. Complete removal of the sling may not always be possible, and additional surgeries may not always fully correct the complications. There may be unresolved pain with or without mesh sling explantation. The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.us.

Caution:
Federal law (USA) restricts this device to sale by or on the order of a physician.

Ostomy Care
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