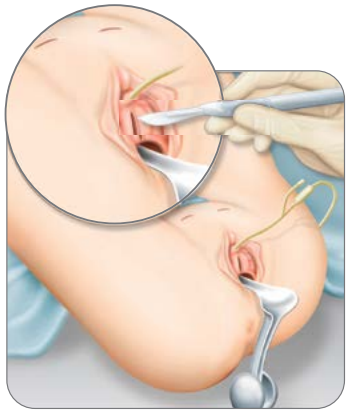
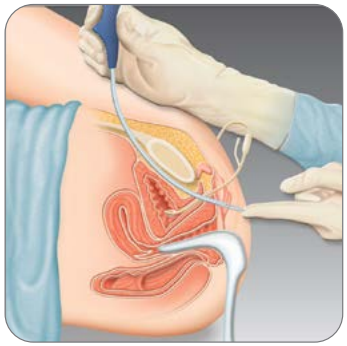
# **Retropubic** (Bottom-up) Procedural Technique

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. Supris® Retropubic Kit should only be used by physicians who have received surgical instruction on pelvic floor reconstruction in general, and specifically with the Supris® mesh. Variations in use may occur due to individual technique and patient anatomy.



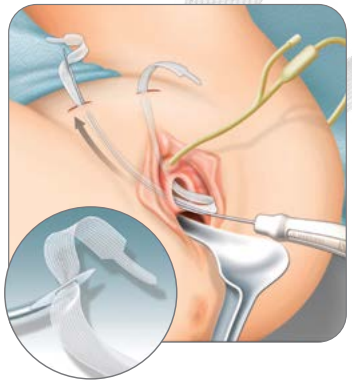
## Steps 1-3

1. Make a full thickness vertical incision on the anterior vaginal wall at the midurethra.
2. Perform a paraurethral dissection. Develop a paraurethral tunnel on both sides of the urethra up to the pelvic diaphragm by scissors and/or blunt dissection. Vaginal dissection should be 1.5 cm wide to allow sling to lay flat under the urethra.
3. Make two abdominal skin incisions approximately 1 cm in length and 2 cm from the midline or one finger breadth above and lateral to the pubic symphysis. Avoid incisions that may go too far laterally.



## Steps 4-7

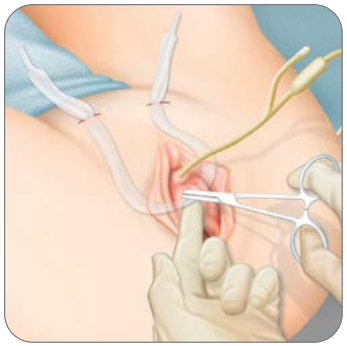
4. Attach Supris sling to the introducer by threading the sling through the eye of the introducer. Pull the sling through the eyelet about 3-4 centimeters.
5. Insert the introducer into the vaginal incision. Pass the introducer into the paraurethral tunnel, staying close to the inferior pubic ramus, penetrating the pelvic diaphragm, passing through the retropubic space and then the rectus muscle complex to exit the skin just above the pubic tubercle approximately 2 cm from the midline. Avoid passing introducer too far medially or laterally.
6. Cystoscopy should be performed after the passing of each introducer to confirm bladder integrity or to recognize bladder perforation.
7. Remove sling from eye of introducer, and reverse the introducer through the incision tunnel.



## Steps 8-10

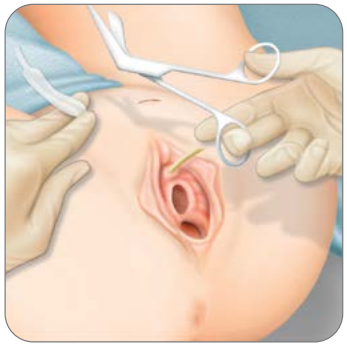
8. Repeat steps 4 and 5 on the contralateral side with the second introducer.
9. Cystoscopy should again be performed after the passing of the second introducer to confirm bladder integrity or to recognize bladder perforation.
10. Remove sling from eye of introducer, and reverse the introducer through the incision tunnel.

*Additional steps on back side*



## 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.



## Steps 12-13

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

**13.** Close all incisions according to physician preference.

---

**SUPRIS® RETROPUBIC KIT BRIEF STATEMENT**

**Indications:**
The Supris Retropubic Kit consists of the Supris implantable midurethral support sling and disposable introducers for placement using a "top-down" or "bottom-up" retropubic surgical approach. The Supris sling and introducers are indicated for the surgical treatment of female stress urinary incontinence (SUI), 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 Supris Retropubic 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 Supris Retropubic 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 Supris 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 Supris sling requires good knowledge of pelvic anatomy and the correct use of the introducer needles in order to avoid damage to adjacent anatomical structures.

**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, bowel obstruction, 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.com.

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

PM-04431 04/2021



Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476



Coloplast