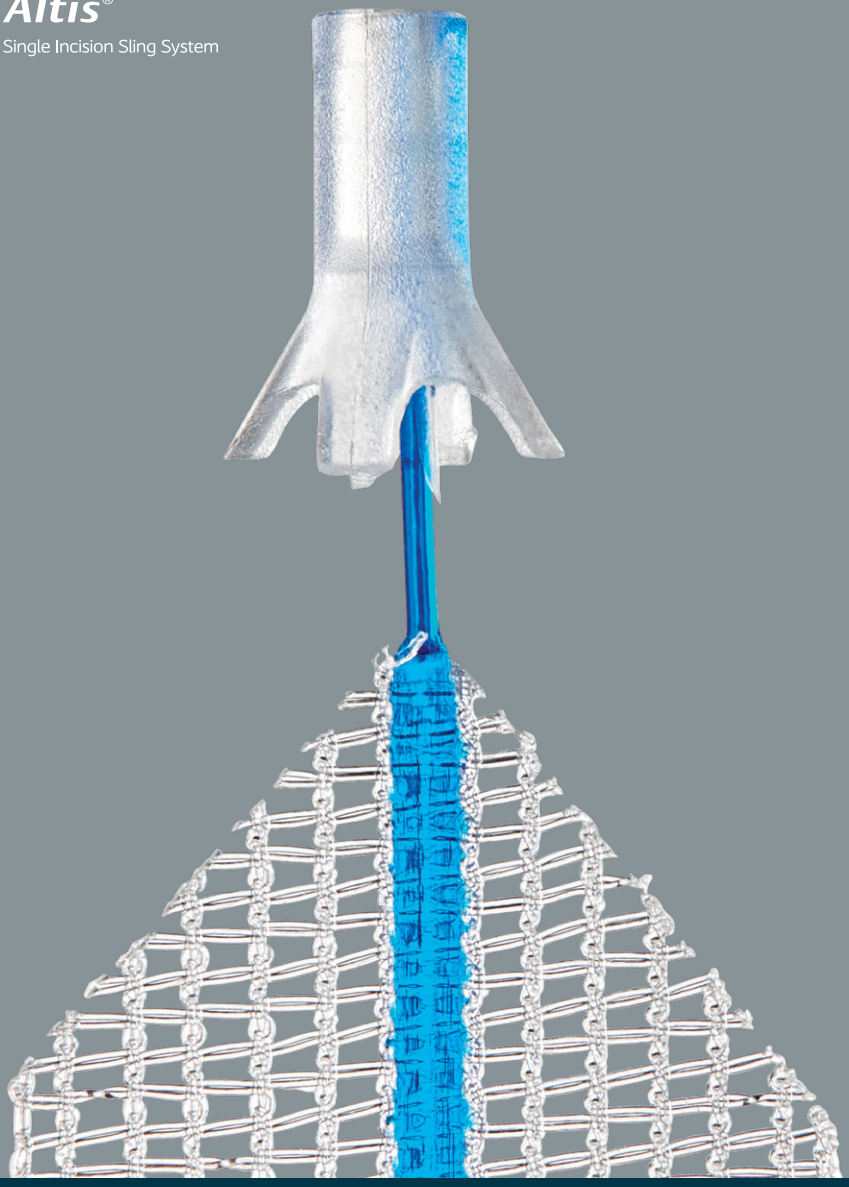
Altis®
Single Incision Sling System



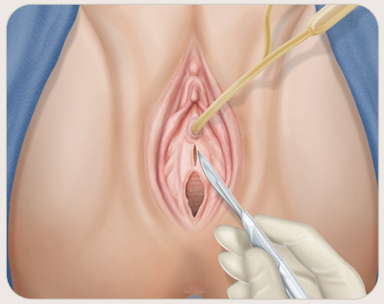
Altis® Single Incision Sling System

Procedural Technique

Coloplast

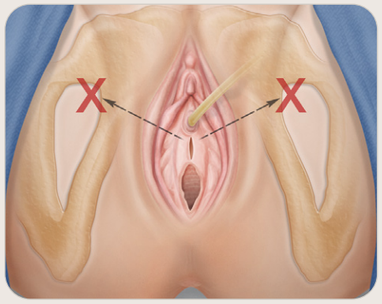
Procedural Technique

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.** The Altis® Single Incision Sling System 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, and maintain, adequate education and experience in the treatment of female SUI and potential associated complications.



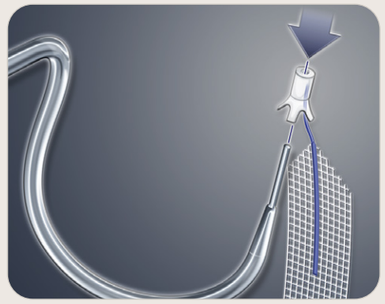
Steps 1-3

1. Remove sling assembly from plastic card, and slide dynamic anchor about two to three finger breadths from the end of the sling body to mobilize anchor.
2. Perform hydro-dissection with either local anesthetic or saline.
3. Make a 1.5 cm long midurethral full-thickness incision on the anterior vaginal wall approximately 1 cm proximal to the urethral meatus and continuing down towards the bladder neck.



Steps 4-5

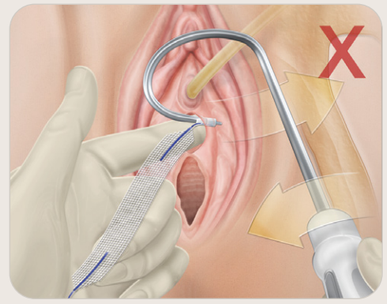
4. For a guide, consider drawing an "X" on the skin just below the adductor longus tendon insertion sites at the 10 and 2 o'clock position.
5. Insert the tip of the scissors through the vaginal incision and laterally spread the scissors 1.5 cm wide in the direction of the ipislateral ischiopubic ramus. Aim for the 10 and 2 o'clock positions marked by the "X." Further dissection may be carried out using finger dissection so that the width of the dissection is 1.5 cm, which is required for the sling to lie flat in the dissected plane. The dissected plane must extend to the obturator internus muscles bilaterally to allow the mesh to lie flat.



Step 6

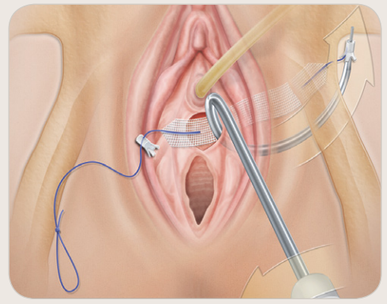
6. Place the static non-tensioning anchor on the appropriate introducer in preparation for an inside-out technique. Ensure the introducer tip exits the top of the anchor. This should be completed by pushing the anchor onto the introducer.

NOTE: *Some resistance may be felt when putting the anchor onto the introducer.*



Steps 7-9

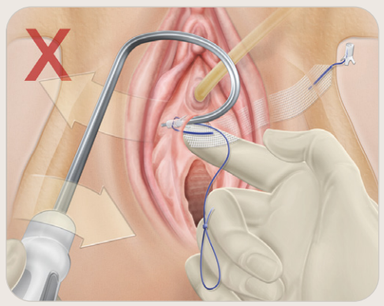
7. Place the introducer/sling into the midline vaginal incision using an inside-out technique and aim the tip of the introducer through the previously dissected periurethral site towards the ipsilateral "X" landmark. The shaft of the introducer should be parallel with the ipsilateral ischiopubic ramus.
8. With the aid of a finger transvaginally, pass the introducer/anchor tip to the medial border of the ischiopubic ramus.
9. Press the shaft of the introducer cephalad to allow the introducer tip to pass around the descending pubic ramus (cephalad drift).



Steps 10-12

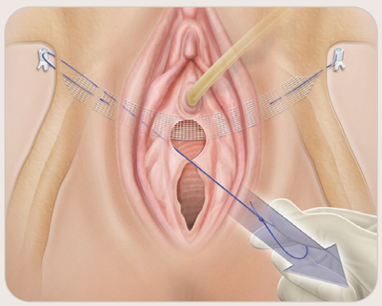
10. Press on the arc of the introducer to advance the introducer/static anchor tip through the obturator internus muscle and membrane until a "pop" is felt, protecting the vaginal sulcus.
11. Once the pop is felt, rotate the introducer handle approximately one quarter turn towards the patient's midline. Keep the introducer against the body and parallel with the ipsilateral ischiopubic ramus, advancing the anchor through the obturator membrane. The gray bar on the handle will be facing up.
12. Remove the introducer, leaving anchor in place, by rotating the introducer in the opposite direction from that used in placing the anchor.

NOTE: *The anchor is not designed to be retracted or advanced further after being placed into the tissue.*



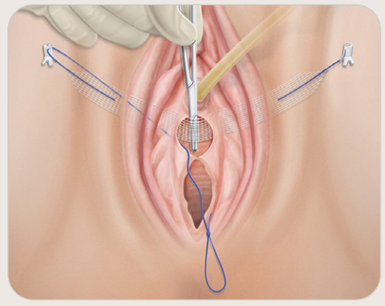
Step 13

13. Repeat steps 6-11 using the dynamic anchor on the contralateral side with the opposite introducer.



Steps 14-15

14. Ensure that the sling is lying flat under the urethra and is not folded or curled.
15. Adjust the sling by pulling the suture loop across the patient's midline until desired support is achieved. Sling should be placed under the urethra tension free. There should be no visible space between the sling and urethra.



Steps 16-19

16. If loosening of the sling is desired, use a blunt instrument between the sling and urethra and gently pull down on the sling.
17. Cystoscopy should be performed to confirm bladder integrity or to recognize bladder perforation.
18. After support is achieved, cut the tensioning suture as close to the pelvic sidewall as possible to avoid risk of vaginal suture exposure. Use caution to avoid damage to the sling or urethra when cutting the adjustment suture.
19. Close incision according to physician preference.

Altis® Single Incision Sling System
BRIEF STATEMENT

Indications:
The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Contraindications
It is the responsibility of the physician to advise the prospective patients prior to surgery, of the contraindications associated with the use of this product. The Altis Single Incision Sling System is contraindicated for use in patients with one or more of 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)
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Documented hypersensitivity or allergic reaction to polypropylene or polyurethane

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

The Altis Single Incision Sling System should only be used by physicians experienced in the surgical procedures involving transvaginal placement of non-absorbable, synthetic mesh slings. 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 prior to surgical intervention.

Obtain patient consent prior to surgery and ensure that the patient understands the postoperative risks and potential complications of transvaginal mesh sling surgery and that the Altis implant is permanent.

Serious mesh associated complications may result in one or more revision surgeries which may lead to partial or complete removal of the mesh. Complete removal of the mesh may not always be possible or advisable, and removal may not fully correct these complications. There may be unresolved pain with or without mesh explant. De novo complications and recurrence or worsening of SUI can occur.

Patient-Related Warnings
As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, mesh sling exposure or other complications and adverse events.

The risks and benefits of using Altis should be considered in patients with:

- Age-related underlying conditions
- Autoimmune disease
- Coagulation disorder
- Connective tissue disorder
- Debilitated or immunocompromised state
- Diabetes
- Pelvic radiation therapy or chemotherapy
- Physical characteristics (e.g., body mass index)
- Renal insufficiency
- Smoking-related underlying conditions
- Urinary tract anomalies

Future pregnancy could negate the benefits of this surgical procedure. Patients should report bleeding, pain, abnormal vaginal discharge or signs of infection at any time.

Potential Complications
Adverse events are known to occur with transvaginal synthetic sling procedures and implants and may include:

Abnormal vaginal discharge, abscess, adhesion, allergic reaction, hypersensitivity, or maladaptive immune response, bladder storage symptoms (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), bleeding/hemorrhage or hematoma, delayed/impaired/abnormal wound healing, dyspareunia, exposure, extrusion, or erosion of mesh sling or suture into the vagina or other structures and organs, fistula formation, granuloma/scar tissue formation, hispareunia (male partner pain with intercourse), infection, inflammation/irritation, necrosis, neuromuscular disorder, pain, palpable mesh (patient and/or partner), pelvic/urogenital pain, perforation or injury to adjacent muscles, nerves, vessels, structures, or organs (e.g., bone, bladder, urethra, ureters, bowel, vagina), scarring, seroma, sexual dysfunction, sling migration, tensioning suture exposure, ureteral obstruction, urinary tract infection, vaginal tightening/shortening, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, bladder outlet obstruction, straining, position-dependent voiding, slow stream) or wound dehiscence.

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.

Minneapolis, MN
PM-03363 04/2024

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