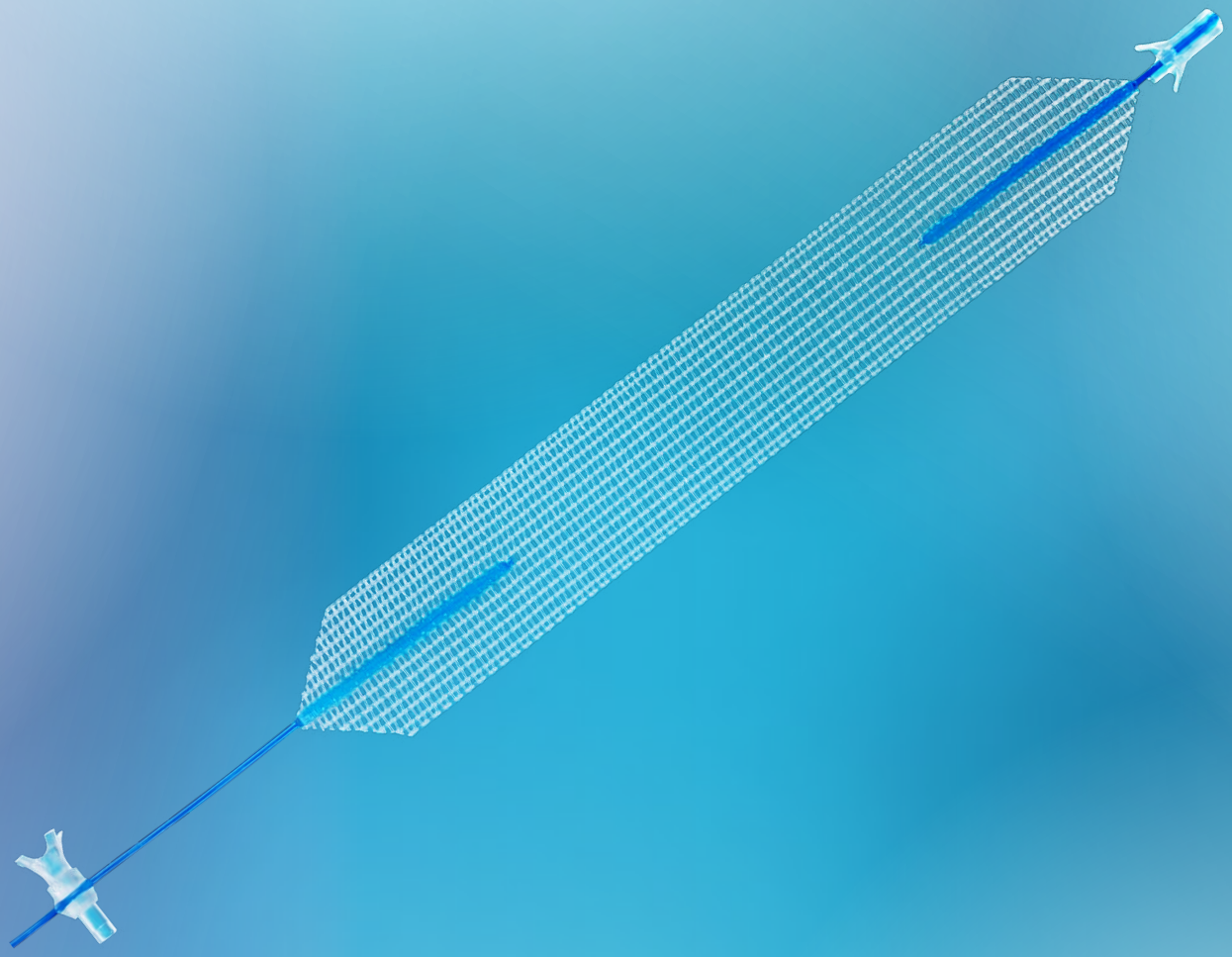


PURPOSEFULLY
DESIGNED

Altis®

Single Incision Sling System

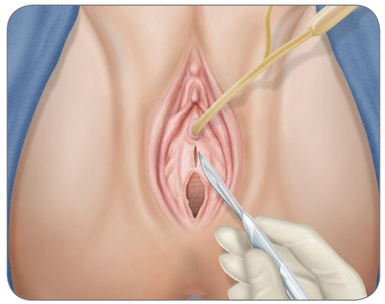
Altis® Procedural Technique

Coloplast

Altis®

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

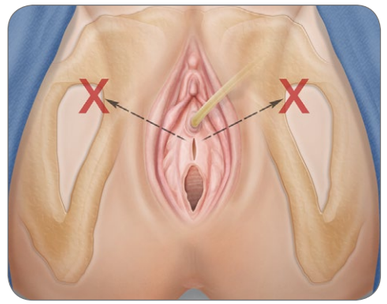


STEPS 1-3

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. Consider performing periurethral infiltration and/or hydro-dissection with either local anesthetic or saline.

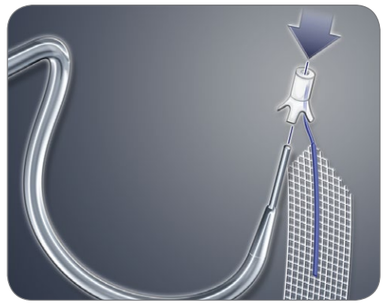
3. Make a 1.5 cm long midurethral incision on the anterior vaginal wall approximately 1 cm proximal to the urethral meatus and continuing down towards the bladder neck.



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.

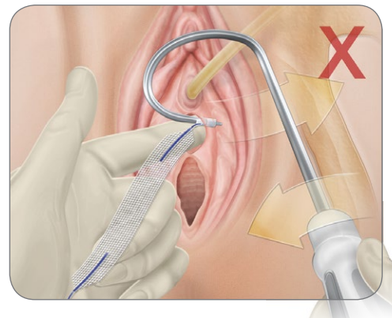
5. Insert the scissors into the vaginal incision and use a push spread technique (at least 1.5 cm wide) to dissect back to the ipsilateral ischiopubic ramus. Aim for the 10 and 2 o'clock positions marked by the "X". Further dissection may be carried out using finger dissection so that the width of the dissection is 1.5 cm, which allows the sling to lay flat in the dissected plane.



STEP 6

6. Take the sling and 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.

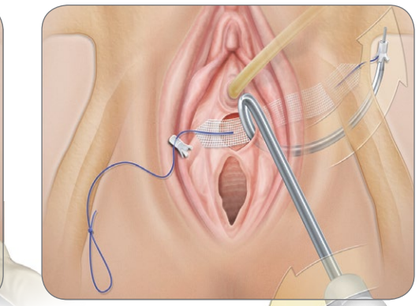
NOTE: *Some resistance may be felt when putting the anchor onto the introducer.*



STEPS 7-8

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 proximal to the cephalad posterior border of the ischiopubic ramus.



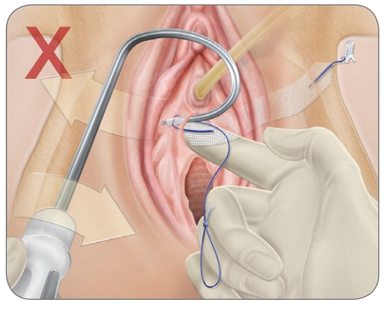
STEPS 9-11

9. By pressing on the arc of the introducer, advance the introducer/static anchor tip into the obturator internus, protecting the vaginal sulcus and avoiding a twisting motion.

10. Keeping the introducer against the body and parallel with the ipsilateral ischiopubic ramus, turn the introducer approximately one quarter turn towards the patient's midline to place the anchor through the obturator membrane (a "pop" may be felt). The gray bar on the handle will be facing vertical.

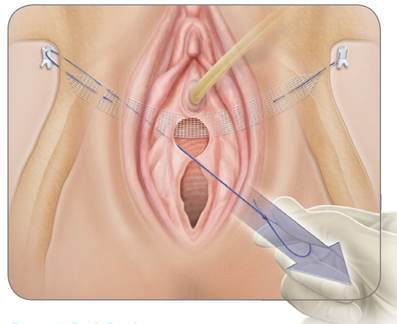
11. Remove the introducer, leaving anchor in place, by rotating the introducer in the opposite direction from that used in placing the anchor.

NOTE: *Once the anchor is placed into the tissue, anchor is not designed to be retracted or advanced further.*



STEP 12

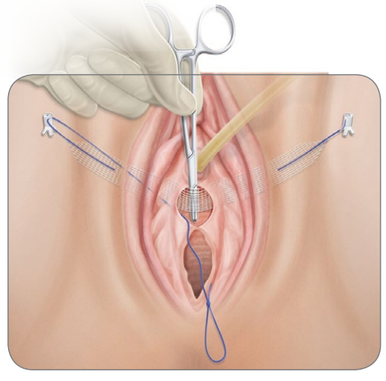
12. Repeat steps 6-11 using the dynamic anchor on the contralateral side with the opposite introducer.



STEPS 13-14

13. Ensure that the sling is lying flat under the urethra and is not folded or curled.

14. 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, such that a right angle instrument could fit easily between the sling and urethra.



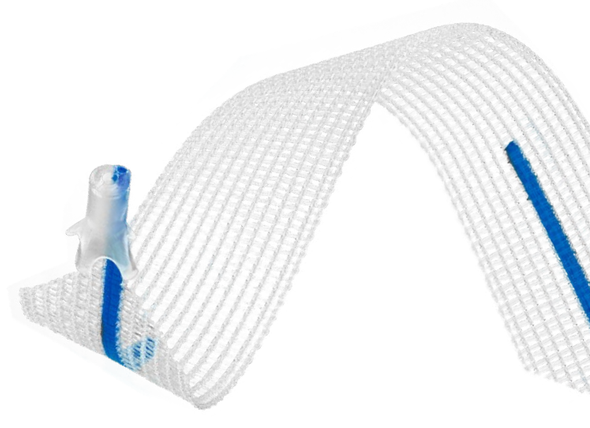
STEPS 15-18

15. If loosening of the sling is desired, use a blunt instrument between the sling and urethra and gently pull down on the sling.

16. Cystoscopy should be performed to confirm bladder integrity or to recognize bladder perforation.

17. Once desired support is achieved, cut the tensioning suture as close to the pelvic sidewall as possible without damaging the sling, bladder or urethra.

18. 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 or their representatives, 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 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/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 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 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 Altis 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 Altis 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 Altis sling during placement and adjustment to maintain sling integrity and to avoid compression of the urethra when tensioning.

Precautions: The Altis Sling and Altis 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 Altis sling come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the mesh, suture and anchors.

Potential Complications: Potential complications include mesh extrusion, pelvic/urogenital pain, groin pain, hip pain (may be related to patient positioning), urinary retention, bleeding, de novo urgency, delayed wound healing, dyspareunia, hip/groin pain, inflammation, nausea, overactive bladder, pain, pelvic hematoma, reaction to antibiotic, slight discomfort upon return to work, urinary tract infection, urine stream decreased, and voiding dysfunction. 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. Additional potential complications 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), 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, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, 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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