**Patient Preparation:**
- Conduct proper anatomical evaluation of the patient.
- Procedure can be performed under local, regional or general anesthesia.
- Place patient in the modified lithotomy position with hips flexed, legs elevated in stirrups and buttocks slightly off the edge of the table.
- Insert Foley catheter in urethra and ensure bladder is empty.
- Use suitable vaginal retraction, if desired.

**Procedural Steps**

1. Consider periurethral infiltration and/or hydro-dissection with local anesthetic. Locate and make a 1.5 cm mid-urethral incision in the anterior vaginal wall, approximately 1 cm proximal to the urethral meatus and continuing down towards the bladder neck.

2. For a guide, draw an X on the skin just below the adductor longus tendon insertion sites at the 10 and 2 o'clock position. Insert scissors into the vaginal incision and use a push spread technique (at least 1.5cm wide) to dissect back to the ipsilateral ischiopubic ramus. Aiming for the 10 and 2 o'clock positions marked by the “X”. Further dissection may be carried out using finger dissection. Gently free the urethra from the anterior vaginal wall to allow for the sling to lay flat at the mid urethra.

3. Remove sling assembly from plastic card. Slide dynamic anchor about two-three finger breadths from end of the sling body to mobilize anchor.

4. Take the sling and place the static non-tensioning anchor on the appropriate introducer. Ensure the introducer tip exits the top of the anchor. NOTE: Some resistance may be felt when putting the anchor onto the introducer.

5. Place the introducer/sling assembly into the midline vaginal incision using inside-out technique and aim the tip of the introducer through the previously dissected peri-urethral sites towards the “X” landmarks. The shaft of the introducer should be parallel with the ipsilateral ischiopubic ramus. Insert finger transvaginally to aid in passing the introducer, with introducer/anchor tip posterior to the ischiopubic ramus.
To loosen the sling, use a blunt instrument between the sling and the urethra and gently pull down on the sling. Cystoscopy should now be performed.

Once desired support is achieved, cut the tensioning suture as close to the pelvic sidewall as possible. Caution should be used to ensure damage to the sling, bladder or urethra does not occur when cutting the tensioning suture.

Close vaginal incision according to usual methods.

Postoperative Care:

- Standard post-operative protocols should be followed.
- General antibiotics should be administered at the physician’s discretion.
- A catheter and/or vaginal pack should be used at the discretion of the physician.
- Proper surgical practice should be followed for post-operative management of contaminated or infected wounds.
- Physical strain, sexual intercourse and heavy lifting should be avoided for six weeks after surgery, but the patient may resume other normal activities after two weeks or at the physician’s discretion.
- Patient should be instructed to immediately report any onset of bleeding, pain, vaginal discharge or sign of infection that occurs at any time.
- If infection occurs, partial or full sling removal or revision may be necessary, per physician’s discretion.

SINGLE INCISION SLING 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 surgeon to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of the Altis sling.

Warnings and Precautions:
It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the possible warnings and precautions associated with the use of this product and the associated surgical risks. The Altis Sling System should only be used by surgeons who are qualified to perform this type of surgery, have experience in the surgical treatment of SUI and who are familiar with the use of non-absorbable mesh and the specific insertion technique. The patient should be informed that any future pregnancy may negate the benefits of this surgical procedure and the patient may become incontinent again. Patients should immediately report any onset of bleeding, pain, vaginal discharge or sign of infection that occurs at any time.

Adverse Effects:
Potential adverse reactions are those associated with surgery using implantable synthetic mesh materials. As with all foreign bodies, the Altis sling is likely to exacerbate any existing infection. Transitory local irritation at the wound site and a foreign body response may occur. There is also the risk of complete failure of the procedure resulting in continued incontinence due to incomplete support or overactive bladder. The occurrence of these events may require partial or complete removal of the sling. Patients should be monitored regularly after the device has been implanted for immediate treatment of any adverse reaction.

See the device manual for detailed information regarding the implant procedure, warnings /precautions, adverse reactions, prior to using this product.

For further information, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.us.com

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