Time After Time

Altis® Delivers_

The most rigorously studied single incision sling, now supported by even more clinical research.

Altis 522 post-market surveillance study

Altis
Single Incision Sling

(n=184)
56.2 years (11.4)
30.0 BMI (5.8)

Baseline incontinence diagnosis:

39.7%	60.3%	35.3%
SUI	MUI	ISD

Comparator: Full length retropubic (RP) and transobturator (TOT) slings

(n=85 retropubic; n=86 transobturator)
53.3 years (12.3)
31.8 BMI (7.6)

Baseline incontinence diagnosis:

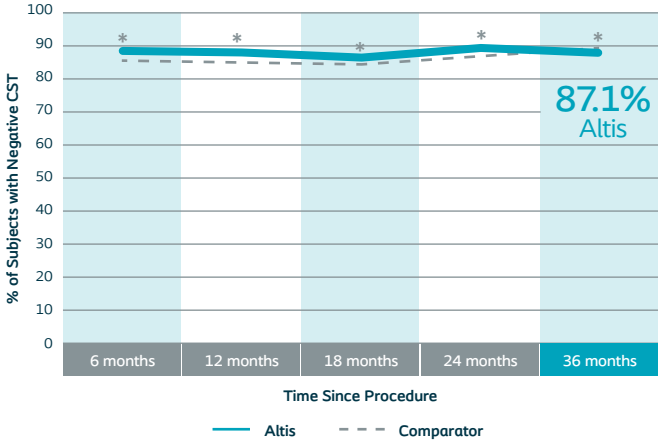
17.5%	82.5%	29.8%
SUI	MUI	ISD

Convincing results time after time_

At 36 months, Altis performs similarly to full length retropubic and transobturator slings in safety and efficacy.

Proven Effectiveness

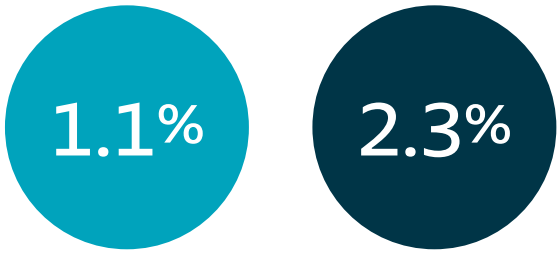
CST demonstrated Altis is similar to full length retropubic and transobturator slings (p<0.001)



Altis performed similarly to the Comparator arm at every study visit and rates of negative cough stress test (CST) remained **above 80%** for both groups.

Proven Safety

Serious Device and/or Procedure-Related Adverse Events (SAE) Through 36 Months



Altis

Full length slings

Altis had primary safety endpoint results similar to full length retropubic and transobturator slings, and **zero cases** of mesh exposure, extrusion or erosion.

Data for the treated population are presented as the number of subjects (%)

Coloplast

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 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 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 post- operative 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.

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.

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, 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 explanation.

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 www.coloplast.com.

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

PM-03363 01/2021

1. Tu LM, Gheiler E, Hanson CE, Jalkut M, McCrery R, Parekh M, Parva M, Erickson T. Management of female stress urinary incontinence with single-incision mini-sling (Altis®): 36 month multicenter outcomes. *Neurourol Urodyn*. 2023 Aug 9. doi: 10.1002/nau.25256. Epub ahead of print. PMID: 37555436.

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