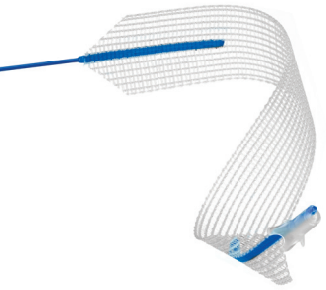

CLINICAL ARTICLE SUMMARY

Management of female stress urinary incontinence with single-incision mini sling (Altis®): 36 month multicenter outcomes[1]

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Purpose: To assess noninferiority of the safety and effectiveness of the Altis® Single Incision Sling (SIS) with standard midurethral transobturator and/or retropubic slings through 36 months in a prospective, longitudinal, nonrandomized US FDA 522 cohort study.

Materials and Methods: Adult females with confirmed predominant stress urinary incontinence (UI) through cough stress test (CST) or urodynamics and failed two noninvasive incontinence therapies. Effectiveness endpoints included objective dryness, negative CST, adverse events, and revision/resurgery through 36 months. The primary effectiveness endpoint was reduction from baseline in 24-hour pad weight of ≥50% at 6 months, as requested by the FDA, and is included as a study point in this paper. Primary safety endpoint was rate of related serious adverse events (SAE) through 36 months. Noninferiority margins of 15% and 10% were prespecified for the effectiveness and safety endpoints. Due to the observational nature of the cohort study, a propensity methodology was conducted to assess the effect of potential confounding variables on the primary endpoints between groups.

Results: Three hundred fifty-five women underwent the sling procedure (n=184 Altis; n=171 Comparator). One hundred forty (76%) Altis subjects and 101 (59%) Comparator subjects completed follow-up through 36 months. At 36 months, for the effectiveness endpoint, the difference in proportions of -0.005 for Altis versus Comparator (95% confidence interval [CI]:–0.102 to 0.092) was statistically significant (p=0.002), supporting the hypothesis that Altis is noninferior to Comparator. Furthermore, both groups demonstrated high objective efficacy; in the Altis arm n=99 (81.8%) subjects were a success, and in the Comparator arm, n=79 (82.3%) subjects were a success. Additionally, regarding the CST, Altis was found to be noninferior to the Comparator at every study visit, and the rate of negative CST remained above 80% for both groups (p<0.001). At 36 months, Altis (n=2; 1.1%) and Comparator (n=4; 2.3%) subjects experienced a device and/or procedure-related SAE. The difference in proportions of 0.013 for Altis versus Comparator (95% CI:–0.023 to 0.048) was statistically significant (p<0.001), demonstrating that Altis is noninferior to Comparator with respect to the primary safety endpoint throughout the study. There were 62 (36.3%) retropubic midurethral slings (RMUS), 96 (56.1%) transobturator midurethral slings (TMUS), and 13 (7.6%) SIS slings in the Comparator group. For the 36 month effectiveness endpoint, assessing the noninferiority of Altis versus RMUS and Altis versus TMUS, 99 (81.8%) Altis and 37 (90.2%) RMUS were a success, trending toward statistical significance, however, it cannot be determined to be noninferior (p=0.092).
Ninty-nine (81.8%) Altis and 33 (71.7%) TMUS were a success; this was statistically significant (p<0.001), demonstrating Altis was noninferior to TMUS. Rates of negative CST were 122 (87.1%) Altis, 40 (93.0%) RMUS (p<0.001), and 44 (91.7%) TMUS (p<0.001). CST demonstrated that Altis was noninferior to RMUS and Altis was noninferior to TMUS at 36 months.

Conclusions: Altis single-incision sling was noninferior to standard midurethral sling for treatment of stress UI, throughout the study and at 36 months. Furthermore, adverse event rates were low.

COLOPLAST KEY TAKEAWAYS

- Altis® is the first and only peer reviewed published 522 study to compare a single incision sling to full length retropubic and transobturator slings (Comparator).
- At 36 months, Altis performed similarly to full length retropubic and transobturator slings in safety and efficacy:
- *Safety*
    - Altis and the Comparator had low rates of serious device and/or procedure-related adverse events (1.1% Altis vs 2.3% Comparator).
    - Altis had zero cases of mesh exposure, extrusion or erosion.
- *Efficacy*
    - 87.1% negative CST for Altis; CST demonstrated Altis was similar to both retropubic and transobturator slings (p<0.001).
    - The rate of Altis patients with dry pad weight was similar to patients in the Comparator arm.
- Altis is the most rigorously studied single incision sling in the US — the 36 month results from the Altis 522 study add to the wealth of data confirming the safety and efficacy of the Altis Single Incision Sling to treat women with stress UI.

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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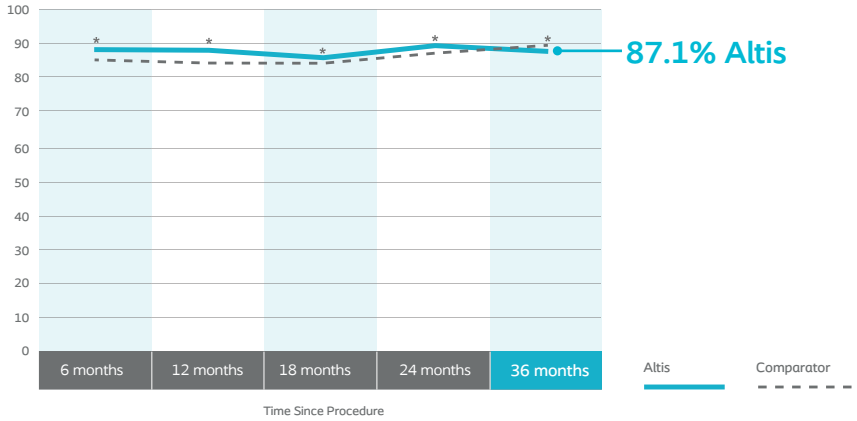
Negative Cough Stress Test (CST) through 36 Months

Data for the treated population are presented as percent of subjects. Significance p≤0.050.



**p-value for categorical variables is a difference in proportions non inferiority test between groups with a non inferiority margin of 0.15.*

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 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.

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, 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 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.

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