24 MONTH IDE PREMARKET STUDY OUTCOMES

Altis®
Single Incision Sling System

PURPOSEFULLY STUDIED

ALTIS® IS THE ONLY SLING WITH A PREMARKET IDE STUDY

Trial results include first implant experience with Altis for all investigators

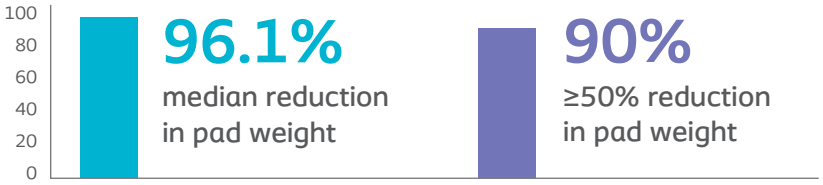
Kocjancic E, Erickson T, Tu L-M, Gheiler E, Van Drie D. Two-Year Outcomes for the Altis® Adjustable Single Incision Sling System for Treatment of Stress Urinary Incontinence. Neurourol Urodyn. Released electronically October 29, 2016.

PATIENT IMPROVEMENT*

90.4%
very much better or much better

87.9%
negative CST

PAD WEIGHT REDUCTION*



96.1%
median reduction in pad weight

90%
≥50% reduction in pad weight

RIGOROUS TESTING METHODS

Cough Stress Test (CST)

CST performed **10 times in two different positions**

10x

x 5 in lithotomy

x 5 standing

COMMON METHODS

clinicians often use **one CST in a single position**

1x

1 in lithotomy

Pad Weight Testing

evaluated effectiveness using **24-hour pad weight testing**

24 hr

clinicians often use **one-hour pad weight testing**

1 hr

*Post-op assessment at 24 months compared to baseline.

Coloplast

Altis®

Single Incision Sling System

Study Characteristics

N=113 at Baseline N=94 at 24 Months

Age (years)	BMI (kg/m2)
54.5 ± 14. at Baseline	31.2 ± 6.8 at Baseline
56.6 ± 13.7 at 24 Months	30.8 ± 6.2 at 24 Months

Study Adverse Events

Adverse Event	Events (%)
Non-pelvic pain (other)	8.0
Mesh extrusion	3.5
Pelvic/urogenital pain	3.5
Urinary retention	1.8
Other – Bleeding	1.8

De novo urgency and Dyspareunia occurred at a rate of 0.9% in this study.
See the IFU for a complete list of adverse events.

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.

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 / Continence Care / Wound & Skin Care / Interventional Urology

Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476
www.coloplast.us

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