THE SINGLE INCISION SLING SYSTEM

THAT DELIVERS FOR YOU AND YOUR PATIENTS.

Altis®

Single Incision Sling System

Coloplast

Altis®

Single Incision Sling System

FEMALE STRESS URINARY INCONTINENCE

The Altis® Single Incision Sling System is a unique, minimally invasive solution purposefully designed to provide predictable placement and adjustable control. This makes the procedure straightforward, accurate and repeatable.

MORE EFFICIENT AND LESS INVASIVE FOR A BETTER PATIENT EXPERIENCE.

The Altis procedure is most often performed under local anesthesia in an outpatient setting. It involves fewer incisions and less tissue trauma than traditional full-length slings. This means patients can return to work or normal activity sooner.[2]

ALTIS® 522 STUDY

At 24 months, the Altis® single incision sling is comparable to full-length retropubic and transobturator slings. Altis is the only sling to have an IDE and 522 study, and is the most rigorously studied single incision sling available in the United States.

#1

In the U.S.
Single incision sling[4]

91.2%

Patient satisfaction
at 24 months[3]

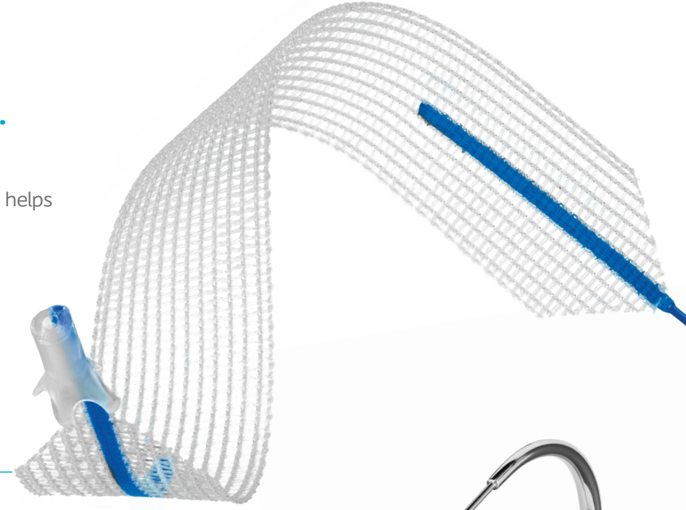
90.4%

Negative cough stress test
at 24 months[3]

3 standing +
3 supine tests

DESIGNED FOR PREDICTABLE PERFORMANCE AND CONTROL.

A combination of unique design features differentiate Altis® from other single incision mid-urethral slings and helps provide predictable placement and adjustable control.



STABLE SUPPORT
Patented, lightweight mesh is the thinnest and most flexible available, allowing better support of the urethra.[1]

REPRODUCIBLE INSERTION
Patented helical introducer makes the surgical procedure straightforward, accurate and reproducible.[1]

PRECISE TENSIONING
Place the device, then control the adjustable tensioning.[1]

COLOPLAST DELIVERS CONFIDENCE

It all started in 1954 with Elise Sorensen, a nurse who wanted to help her sister regain confidence and control. After having an ostomy operation, her sister was afraid to go out in public for fear of leakage. Elise worked with engineer Aage Louis-Hansen to develop the world's first adhesive ostomy bag for greater protection and control. Today, Coloplast is an environmentally conscious global leader in ostomy care, wound and skin care, and urology care products that improve lives for millions of people around the world.

To Order Call Toll-Free: 800.258.3476

This product may be ordered directly from Coloplast.

Product	Order Number
Altis® Single Incision Sling System	519650

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, 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 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.

References
1. Data on file.
2. Mostafa A, Lim CP, Hopper L, Madhurvata P, Abdel-Fattah M. Single-Incision Mini-Slings Versus Standard Midurethral Slings in Surgical Management of Female Stress Urinary Incontinence: An Updated Systematic Review and Meta-analysis of Effectiveness and Complications. *Euro Urology*. 2014;65(2):402-427. doi: 10.1016/j.eururo.2013.08.032.
3. Kocjancic E, Erickson T, Tu L, Gheiler E, Van Drie D. Two-year outcomes for the Altis® adjustable single incision sling system for treatment of stress urinary incontinence. *Neurourol and Urodyn*. 2016;36(6):1582-1587. doi: 10.1002/nau.23156.
4. IMS data.

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PM-16952 06.21