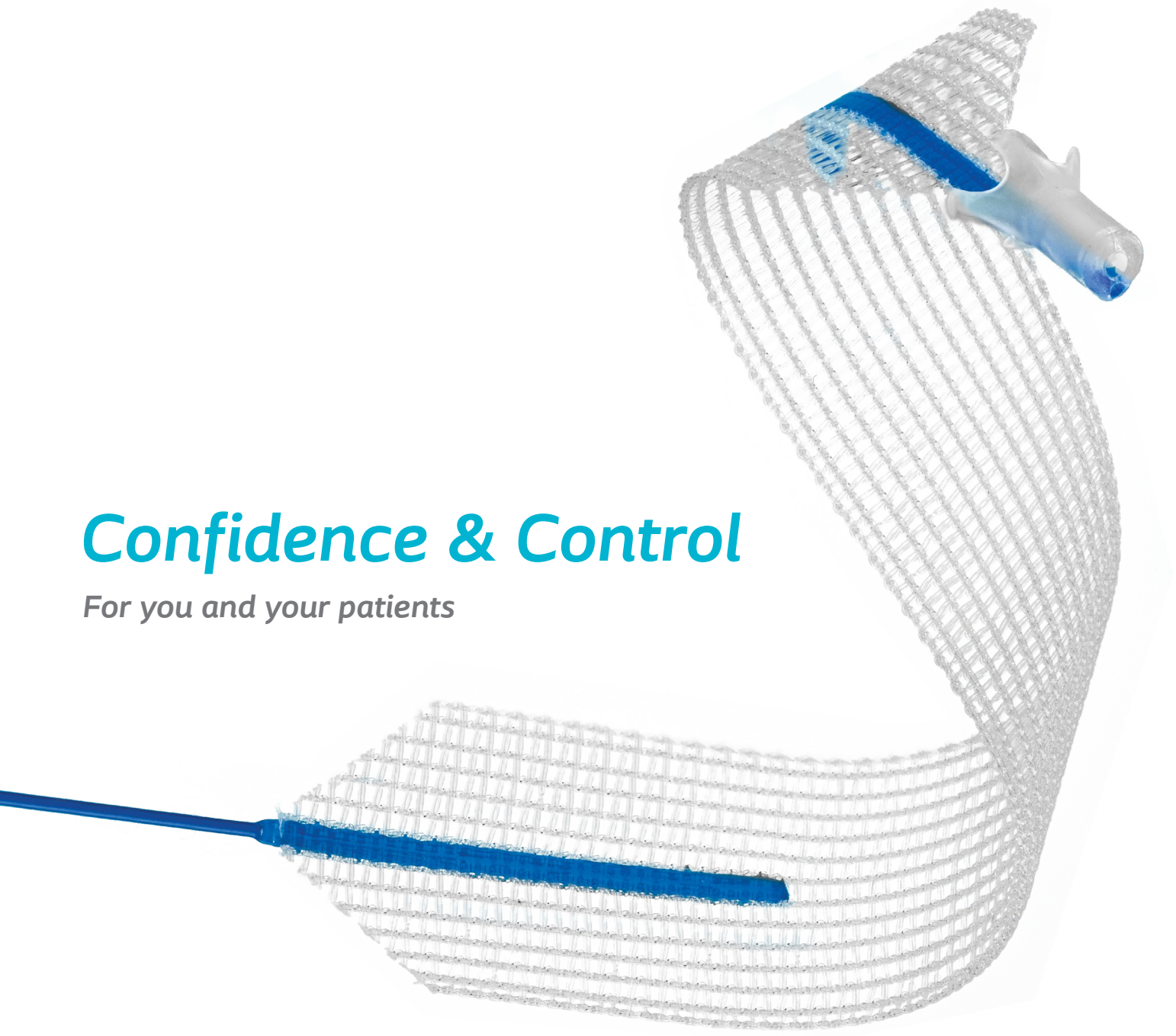
Altis®

Single Incision Sling System



Confidence & Control

For you and your patients

Coloplast

Altis®

Underreported.
Underdiagnosed.
Undertreated.

An estimated 53.6 million women in the U.S. suffer from stress urinary incontinence or mixed urinary incontinence.[1]

Some women feel too embarrassed or that their incontinence isn't severe enough to see a physician, while others aren't aware of their treatment options, meaning too many women aren't getting the life-changing help they need. **Less than 1% go onto have surgery,**[2] despite low quality of life, including depression and anxiety.[3]

More than an inconvenience

Urinary Incontinence can have profound impacts on a woman's life.

2/3
of women with SUI adopt **precautionary routines** to reduce the chance of leaking in public[4]

32.3%
of working-aged women with SUI **avoid sexual activity**[4]

25-50%
of women with SUI **experience anxiety or depression**[3,5]

Surgery
for SUI **decreased anxiety** by 1/2 and **depression** by 2/3[3]

Certain concerns may cause women to choose a less invasive option

Concerns with sling surgery:[6]

- Invasiveness: Concerns with incisions and anesthesia
- Risk/Safety
- Retreatment
- Recovery/Pain
- Setting
- Duration of Procedure

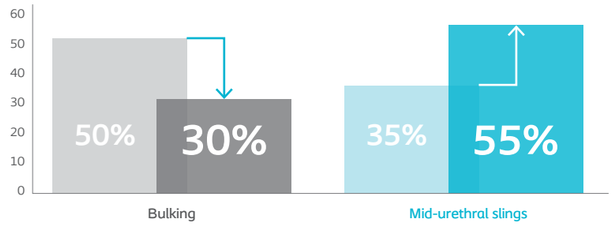
VS

Concerns with non-invasive SUI procedures:[6]

- Lack of efficacy

When initially being offered the option of bulking versus a mid-urethral sling (MUS), 50% of women preferred bulking vs. 35% to MUS.

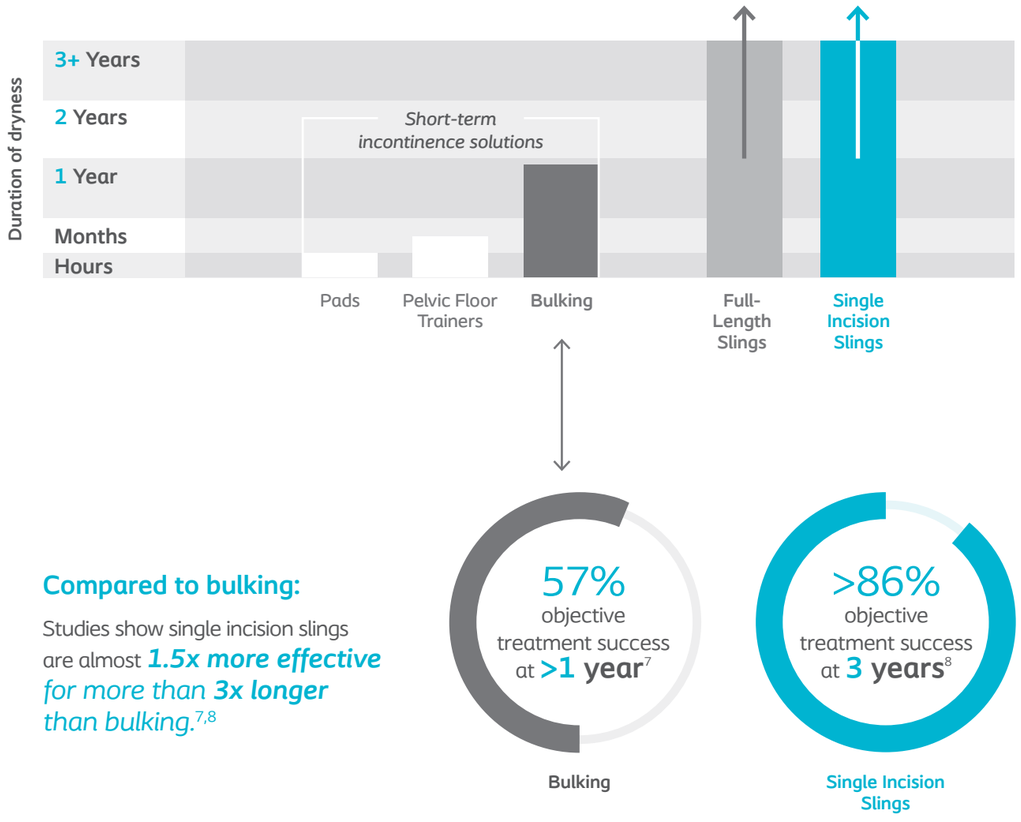
However, when they heard the difference in efficacy, 30% preferred bulking and **55% preferred MUS.**[6]



Altis®

The real-life advantages of single incision slings

Help your patients move beyond the limits of short-term solutions to experience long-term success with a better experience.

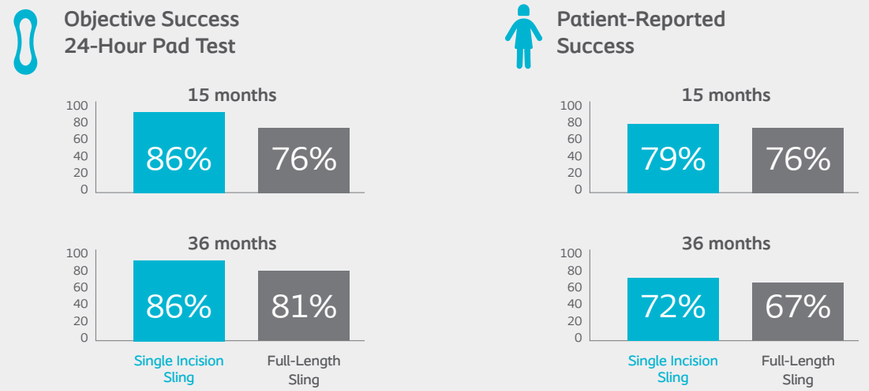


Compared to bulking:

Studies show single incision slings are almost ***1.5x more effective*** *for more than* ***3x longer*** *than bulking.*[7,8]

Same great results, better patient experience

According to the NEJM, single incision slings were found to have similar rates of objective success and patient-reported success to full-length slings.[8]



Compared to full-length slings:

Better Patient Experience

- Women with single incision slings had **less post-op pain** up to 14 days.[8]
- Compared to full-length slings, women receiving single incision slings were able to **return to normal activities** **on average 5 days sooner.**[9]
- **Minimally Invasive**
  Single incision slings involve **fewer incisions and less tissue** trauma than traditional full-length slings and can be implanted under local anesthesia in an outpatient setting.[9]
- **Sexual Function**
  Studies have shown there may be an **improvement in sexual function** for both single incision slings and full-length slings.[10]

Less Procedure & Hospital Time

- Single incision sling procedure patients are associated with **5% less procedure time and 26% less post-op recovery time.**[8]
- **Better Post-Op Voiding Results**
  Higher rates of postoperative voiding dysfunction are associated with retropubic slings.[8]

Safe

Single incision slings reported less bladder and urethral injury during surgery, with comparable results to full-length slings in number of post-operative serious adverse events.[8]

The control you need.
The confidence you want.
The choice your patients deserve.

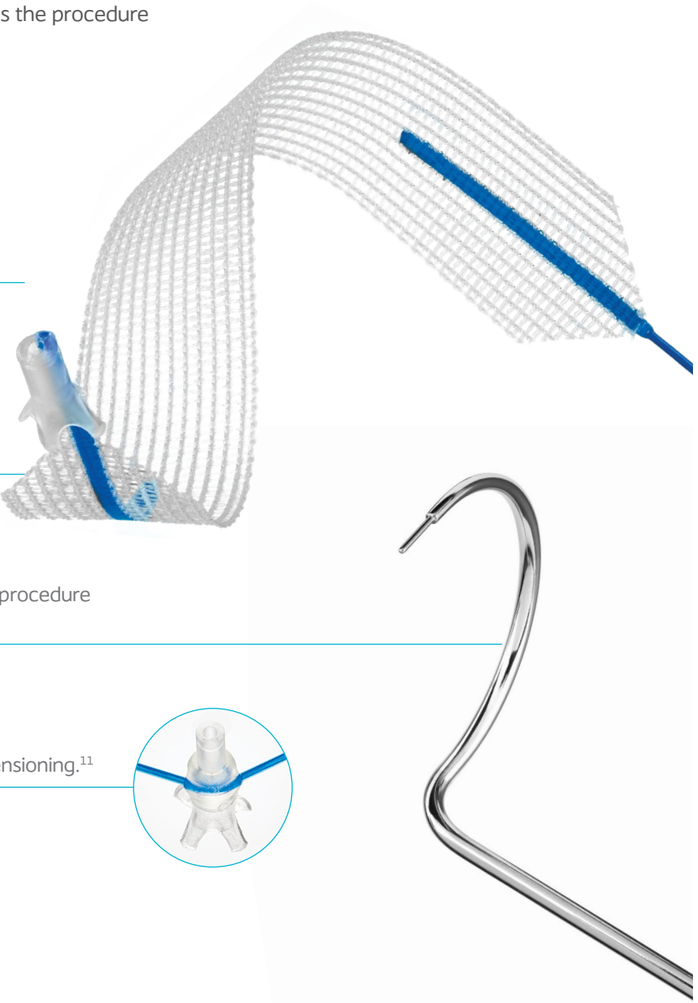
The Altis® Single Incision Sling System is a unique, minimally invasive solution purposefully designed to provide predictable placement and adjustable control. This makes the procedure straightforward, accurate and repeatable.

LESS INVASIVE
One incision. Less tissue trauma. Speed up procedure time and deliver a better patient experience.[9]

STABLE SUPPORT
Patented, lightweight mesh is the thinnest and most flexible available, allowing better support of the urethra.[11]

REPRODUCIBLE INSERTION
Patented helical introducer makes the surgical procedure straightforward, accurate and reproducible.[11]

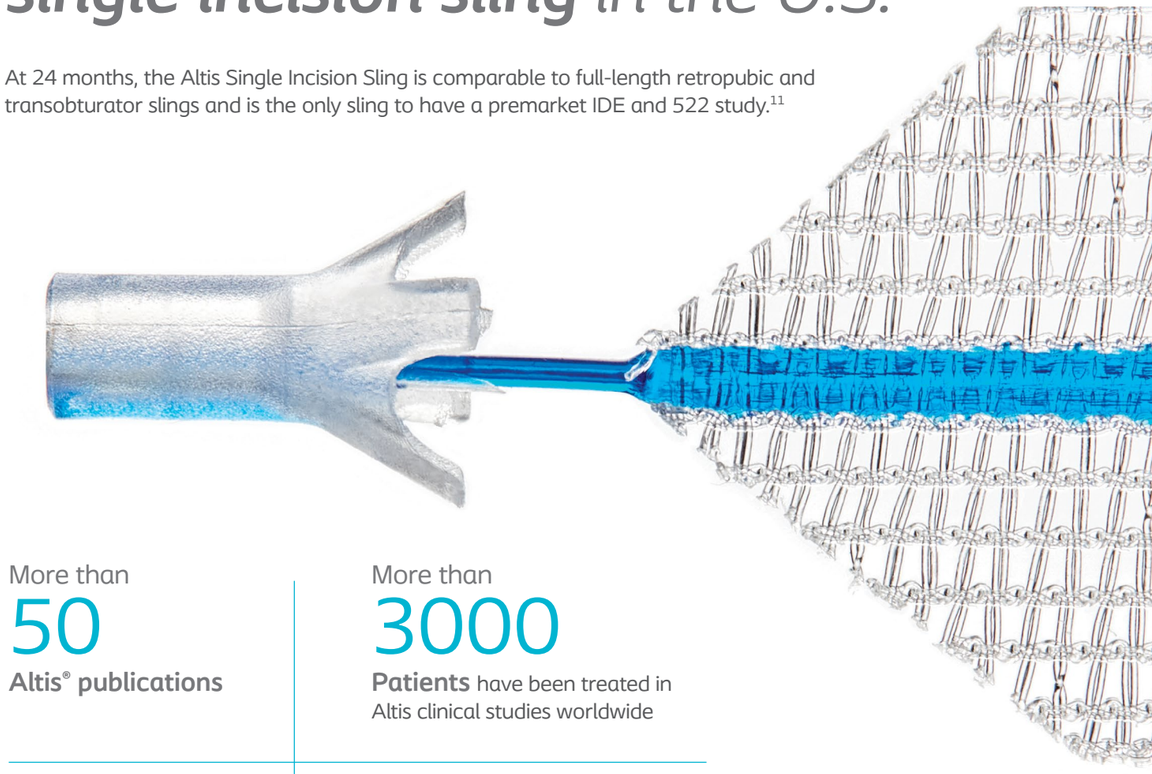
PRECISE TENSIONING
Place the device, then control the adjustable tensioning.[11]



Change perceptions. Change lives. Altis® is your alternative.

The most rigorously studied ***single incision sling*** *in the U.S.*

At 24 months, the Altis Single Incision Sling is comparable to full-length retropubic and transobturator slings and is the only sling to have a premarket IDE and 522 study.[11]



More than
50
Altis® publications

More than
3000
Patients have been treated in Altis clinical studies worldwide

#1
single incision sling
in the U.S.

FDA Reviewed
The only sling with prospective, multi-center clinical trial data reviewed by FDA to support market clearance

See the evidence

1. Patel UJ, Godecker AL, Giles DL, Brown HW. Updated Prevalence of Urinary Incontinence in Women: 2015-2018 National Population-Based Survey Data. *Female Pelvic Med Reconstr Surg.* 2022 Jan 12. **2.** Clarivate data accessed March 17, 2022. **3.** Kinjo M, Masuda K, Nakamura Y, Taguchi S, Tambo M, Okegawa T, Fukuhara H. Effects on Depression and Anxiety After Mid-Urethral Sling Surgery for Female Stress Urinary Incontinence. *Res Rep Urol.* 2020 Oct 19;12:495-501. doi: 10.2147/RRU.S270915. PMID: 33117749; PMCID:PMC7585269. **4.** St John W, Griffiths S, Wallis M, McKenzie S. Women's management of urinary incontinence in daily living. *J Wound Ostomy Continence Nurs.* 2013 Sep-Oct;40(5):524-32. doi: 10.1097/WON.0b013e3182a2198a. PMID: 24448621. **5.** Steibliene V, Aniuliene R, Aniulis P, Raskauskiene N, Adomaitiene V. Affective Symptoms and Health-Related Quality of Life Among Women with Stress Urinary Incontinence: Cross-Sectional Study. Neuropsychiatr Dis Treat. 2020 Feb 24;16:535-544. doi: 10.2147/NDT.S236234. PMID:32158213; PMCID: PMC7047965. **6.** Casteleijn, F.M., Zwolsman, S.E., Kowalik, C.R. et al. Patients' perspectives on urethral bulk injection therapy and mid-urethral sling surgery for stress urinary incontinence. *Int Urogynecol J* 29, 1249–1257 (2018). https://doi.org/10.1007/s00192-018-3644-0. **7.** Capobianco G, Saderi L, Dessole F, Petrillo M, Dessole M, Piana A, Cherchi PL, Dessole S, Sotgiu G. Efficacy and effectiveness of bulking agents in the treatment of stress and mixed urinary incontinence: A systematic review and meta-analysis. Maturitas. 2020 Mar;133:13-31. doi: 10.1016/j.maturitas.2019.12.007. Epub 2019 Dec 11. PMID: 32005420. **8.** Abdel-Fattah M, Cooper D, Davidson T, Kilonzo M, Hossain Md. Single-Incision Mini-Slings for Stress Urinary Incontinence in Women. *The New England Journal of Medicine.* 2022;386. 1230-1243. 10.1056/NEJMoa2111815. **9.** 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. **10.** Alwaal A, Tian X, Huang Y, Zhao L, Ma L, Lin G, Deng D. Female sexual function following mid-urethral slings for the treatment of stress urinary incontinence. Int J Impot Res. 2016 Jul;28(4):121-6. doi: 10.1038/ijir.2016.16. Epub 2016 May 5. PMID: 27146350. **11.** Data on file.

Making Life Easier _

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 Description	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 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.

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