

Stress Urinary Incontinence: Underreported. Underdiagnosed. Undertreated.

Addressing safety, efficacy and patient experience with Altis®, the next generation single incision mini-sling.

For the 53.6 million women in the U.S. who suffer from stress urinary incontinence (SUI) or mixed urinary incontinence,¹ it's more than an inconvenience.

More than an inconvenience:

The high impact of urinary incontinence

- 32.3% of working-aged women with SUI avoid sexual activity²
- 2/3 women with SUI adopt precautionary routines to reduce the chance of leaking in public²
- 25-50% of women with SUI experience anxiety or depression^{3,4}

Still, some women feel too embarrassed about their condition or that their incontinence isn't severe enough to seek help, while others are unaware of potentially life-changing treatment options. In fact, less than 1% go on to have surgery⁵ despite evidence that shows how surgical interventions for SUI can lead to an improved quality of life (QoL).³

Understanding patient preferences around SUI treatments

There are a variety of treatment options available for patients suffering from SUI, ranging from lifestyle changes and medical devices to surgery.⁶ Each provides varying degrees of efficacy that can span from hours to years of "dryness".⁷

Typical first-line incontinence solutions include pads, vaginal pessaries, pelvic floor therapy and peri-urethral bulk injection therapy (bulking).⁸ While less invasive than other solutions, these may only provide short-term incontinence results. For example, pads need to be changed every few hours, and the treatment success of pelvic floor therapy heavily depends on continuous patient compliance and requires multiple doctor visits a month.⁷ Additionally, treatment success of bulking is relatively limited. According to a recent meta-analysis that included studies from 11 different bulking agents, bulking demonstrated only 57% effectiveness at one year.⁹ On the other hand, surgical interventions in which slings are placed under the urethra have been shown to provide long-lasting efficacy of at least 3 years.^{10,11}

Still, when considering treatment for SUI women may opt for a less invasive option due to concerns related to the invasiveness of surgery or concerns regarding their

recovery.¹² However, when they compare the efficacy of surgical interventions with that of less invasive options, a majority of patients will choose surgical options over their concerns.¹²

Certain concerns may cause women to choose a less invasive option¹²

Concerns with sling surgery¹²

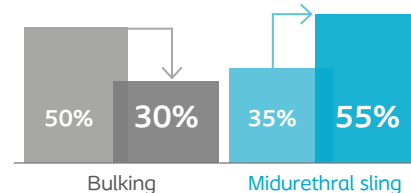
- Invasiveness: concerns with incisions and anesthesia
- Risk/Safety
- Retreatment
- Recovery/Pain
- Setting
- Duration of procedure



Concerns with non-invasive SUI procedures¹²

- Lack of efficacy

When initially being offered the option of bulking versus a midurethral 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**.¹²



Created from: Casteleijn FM et al. 2018.

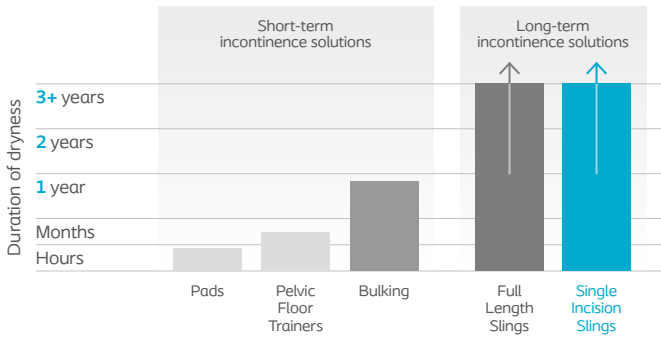
Closing the gap: balancing efficacy, safety and cost-efficiency

So, besides efficacy, how can clinicians substantiate the surgical route when deciding on treatments with their SUI patients? Here, the cost-efficiency of surgery may be a strong argument. When breaking down the various costs associated with each treatment, sling surgeries may prove to be the more cost-efficient route as it demonstrates the high effectiveness as measured in quality-adjusted life-years.⁷

This means that although short-term incontinence solutions typically have lower upfront costs, the need for multiple retreatments and the continued cost of managing symptoms can bring on higher costs over time.⁷

Moreover, studies indicate that surgical incontinence solutions can positively impact patients' mental health: surgery for SUI has shown to decrease anxiety by 1/2 and depression by 2/3 as these improvements correlate with improvements in symptoms of incontinence.³

There are various incontinence solutions on the market. How cost-efficient are they?*,13



Created from: Chang OH et al. 2021.

- **Pads and diapers:** \$1,400-3,000, factoring in frequent changes averaging as many as 6/day⁷
- **Pelvic floor therapy:** \$1,250, may have a low probability of treatment success due to patient compliance⁷
- **Bulking:** \$8,800, considering cost of treatment, re-treatment and symptom management over time**⁷
- **Full-length sling surgery:** \$5,800, considering costs of treatment, re-treatment and complications over time⁷
- **Single-incision sling surgery:** \$4,900, considering costs of treatment, re-treatment and complications over time¹³

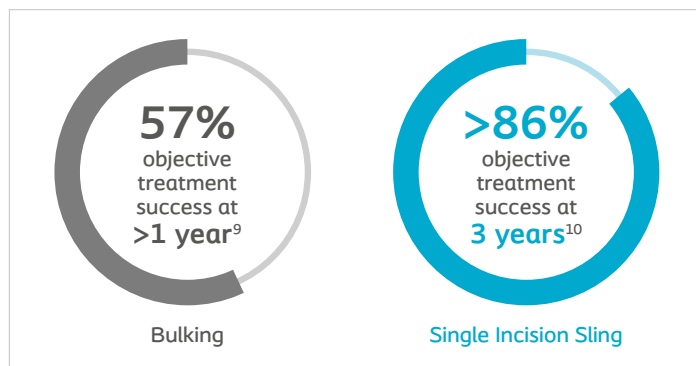
* Cost of non-surgical and surgical treatments over 2 years, based on Chang OH et al. 2021 and Boyers D et al. 2013.

** Assuming rate of re-treatment as 2.5, every 3-6 months.

The single incision sling: the latest generation of surgical SUI therapies

Over the last two decades, surgical treatments for SUI have evolved towards safer, more effective and ambulatory surgical procedures, with the full length mid-urethral sling (MUS) remaining the mainstay of surgical SUI therapy.¹³

However, many surgeons have turned their attention to the latest generation of MUS: the single incision mini-sling (SIS).¹⁴ While similarly efficacious to traditional MUS,^{10,14} SIS has helped transform the patient experience by addressing many of the initial concerns that women have raised about sling surgery.¹⁰





MUS vs. SIS:

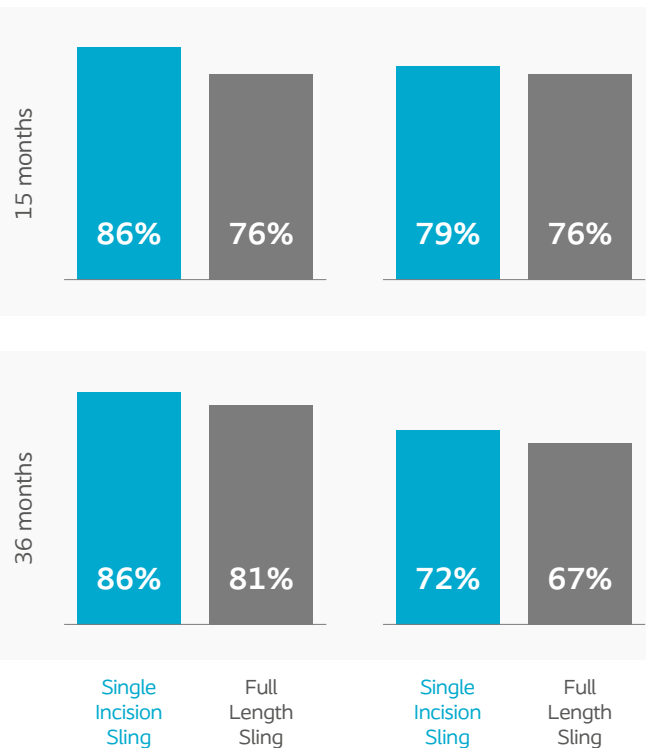
How Altis® transforms the patient experience

With both sling types demonstrating similar efficacy in the short- and long-term,^{10,14,15} SIS can provide the additional benefits of less post-operative pain and a shorter recovery time (both in the PACU and at home) until return-to-normal compared to MUS.^{10,14}

Similar results, better patient experience

 Objective success 24-hour-pad test

 Patient-reported success



Adapted from: Abdel-Fattah M et al. 2022.

According to a recent study published in *NEJM*, SIS were found to have similar rates of objective success and patient-reported success to full length slings.¹⁰

Specifically, SIS demonstrated better post-operative voiding without intervention as well as less post-op pain for up to 14 days,¹⁰ allowing patients to leave the PACU sooner, and return to normal activities quicker following surgery – providing a quicker recovery both in the facility and at home. In addition, women treated with SIS were able to return to normal activities on average 5 days sooner than those treated with MUS.¹⁴

SIS vs. MUS: The patient experience



Better patient experience

Patients receiving SIS experience less pain 2-weeks post-surgery compared to those receiving full-length slings.^{10,14}



Minimally invasive

SIS implantation involves fewer incisions and consequently less tissue trauma. It can be implanted in an outpatient setting.¹⁴



Less procedure & hospital time

Patients receiving SIS spend on average 5% less time in the OR and 26% less time in post-op recovery (PACU), including better post-op voiding without intervention and less post-op pain.¹⁰



Faster return to normal activities

Women treated with SIS returned to normal activities (including work) on average 5 days earlier than women treated with MUS.¹⁴



Cost savings

Cost savings with SIS is driven by improved recovery time both in PACU and during the days following surgery, including improved voiding without intervention.^{10,13,14}

Coloplast's Altis® Single Incision Sling System allows for less invasive placement with fewer implantation steps required and simplicity of the procedure – thus reducing time in the OR and time to recovery to provide a durable improvement in the patient experience.

Changing the game with innovative single incision sling technology

With only 1% of SUI patients who decide on surgical interventions for their condition,² it is clear that there are widespread misconceptions around this course of treatment. But an ever-growing compendium of clinical evidence for SIS options like Altis may empower more women suffering with SUI to find the effective treatment option that they need.

By providing similar efficacy and safety as other traditional sling options on the market while addressing many concerns that have led patients to stay with shorter-term solutions, Altis can help ensure your SUI patients are able to secure long-lasting continence results and a better patient experience.^{14,15}

Abbreviations:

MUS, full-length mid-urethral sling; OR, operation room; PACU, post-op recovery unit; QoL, quality of life; SIS, single-incision mini-sling; SUI, stress urinary incontinence.

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Brief statement

Altis® Single Incision Sling System

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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