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 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 one or more of 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)
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Documented hypersensitivity or allergic reaction to polypropylene or polyurethane

Warnings
It is the responsibility of the physician to advise prospective patients prior to surgery, of the warnings associated with the use of this product and the associated surgical risks.

The Altis Single Incision Sling System should only be used by physicians experienced in the surgical procedures involving transvaginal placement of non-absorbable, synthetic mesh slings. 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 prior to surgical intervention.

Obtain patient consent prior to surgery and ensure that the patient understands the postoperative risks and potential complications of transvaginal mesh sling surgery and that the Altis implant is permanent.

Serious mesh associated complications may result in one or more revision surgeries which may lead to partial or complete removal of the mesh. Complete removal of the mesh may not always be possible or advisable, and removal may not fully correct these complications. There may be unresolved pain with or without mesh explant. De novo complications and recurrence or worsening of SUI can occur.

Patient-Related Warnings
As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, mesh sling exposure or other complications and adverse events.

The risks and benefits of using Altis should be considered in patients with:

- Age-related underlying conditions
- Autoimmune disease
- Coagulation disorder
- Connective tissue disorder
- Debilitated or immunocompromised state
- Diabetes
- Pelvic radiation therapy or chemotherapy
- Physical characteristics (e.g., body mass index)
- Renal insufficiency
- Smoking-related underlying conditions
- Urinary tract anomalies

Future pregnancy could negate the benefits of this surgical procedure. Patients should report bleeding, pain, abnormal vaginal discharge or signs of infection at any time.

Potential Complications
Adverse events are known to occur with transvaginal synthetic sling procedures and implants and may include:

Abnormal vaginal discharge, abscess, adhesion, allergic reaction, hypersensitivity, or maladaptive immune response, bladder storage symptoms (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), bleeding/hemorrhage or hematoma, delayed/impaired/abnormal wound healing, dyspareunia, exposure, extrusion, or erosion of mesh sling or suture into the vagina or other structures and organs, fistula formation, granuloma/scar tissue formation, hispareunia (male partner pain with intercourse), infection, inflammation/irritation, necrosis, neuromuscular disorder, pain, palpable mesh (patient and/or partner), pelvic/urogenital pain, perforation or injury to adjacent muscles, nerves, vessels, structures, or organs (e.g., bone, bladder, urethra, ureters, bowel, vagina), scarring, seroma, sexual dysfunction, sling migration, tensioning suture exposure, ureteral obstruction, urinary tract infection, vaginal tightening/shortening, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, bladder outlet obstruction, straining, position-dependent voiding, slow stream) or wound dehiscence.

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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