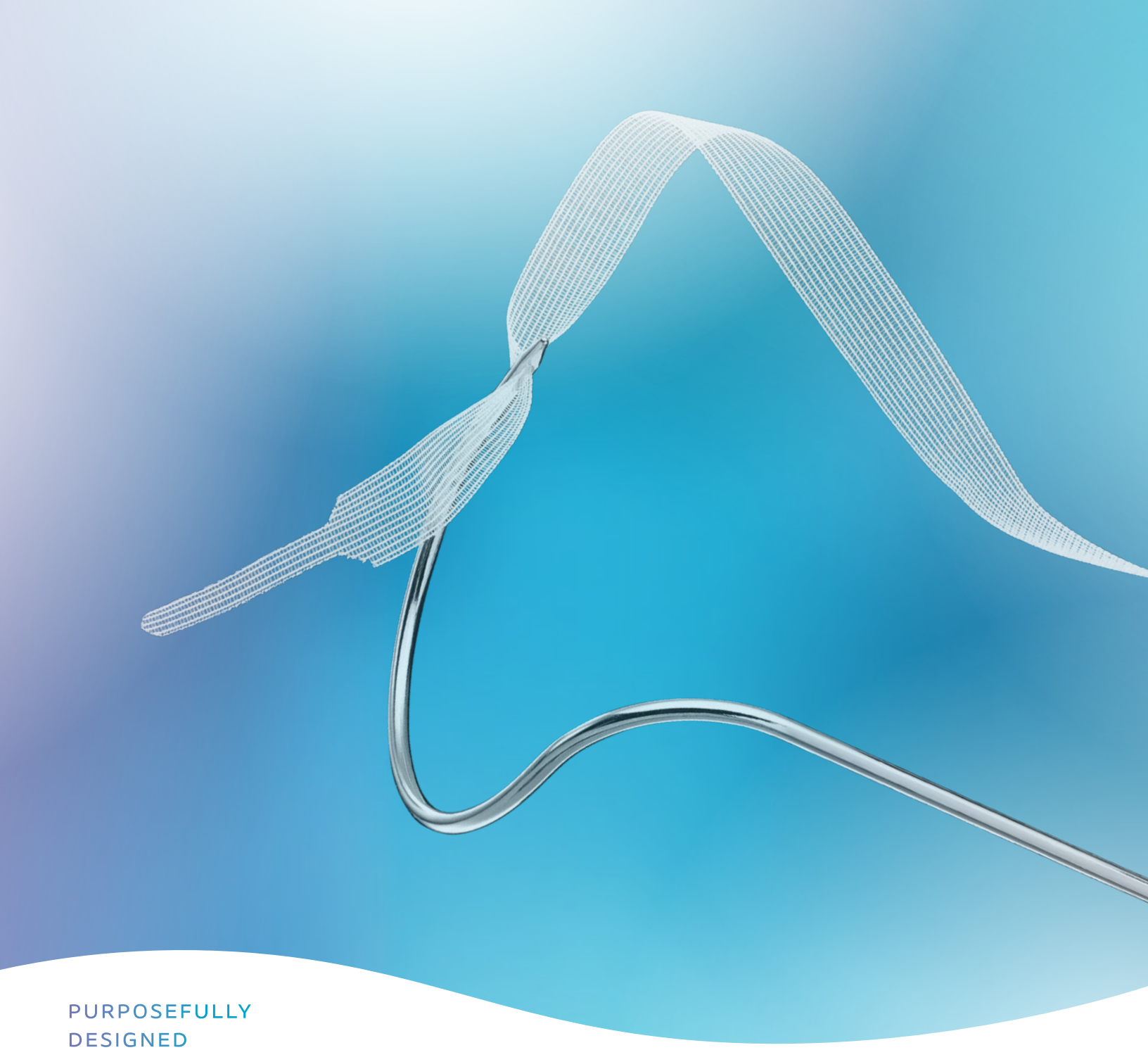


PURPOSEFULLY
DESIGNED

Aris®

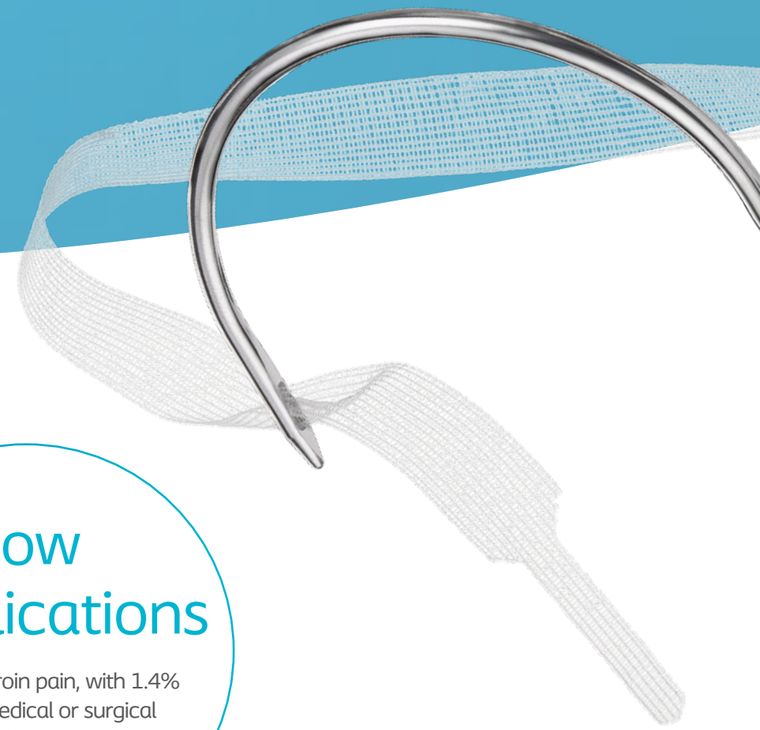
Transobturator Kit

FEMALE STRESS URINARY INCONTINENCE

Coloplast

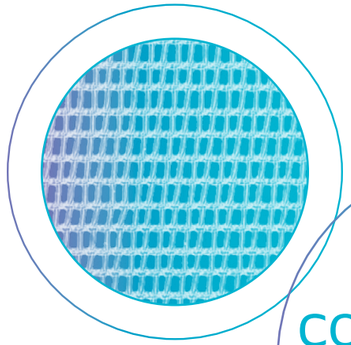
Aris®

Transobturator Kit



PURPOSEFULLY DESIGNED

Coloplast partnered with physicians to design the patented Aris® Transobturator Sling. Each Kit includes one flat curve and one set of helical introducers, providing physicians the option to choose their preferred transobturator (TO) approach for each patient.



9
year data*
341 patients

Largest, longest
randomized trial
of female TO slings[2]

Results stable beyond
3 years

- **71.6% of patients report very much improved,** 85.6% of patients report improved/very much improved[2,3]
- Outcomes at 3 years are most likely to be retained at 9 years and beyond[2]
- Data also suggest the **meshes used in the study** (Coloplast Aris® and Ethicon TVT®–O) have consistent results at year three and beyond[2]
- Authors also observed similar stability rates in other long-term studies utilizing midurethral slings[2, 3, 4, 5]

Low complications

4% Chronic groin pain, with 1.4% requiring medical or surgical treatment; 8% continence reoperation rate at 9-year follow-up[2]

Coloplast SUI Mesh

Thin, lightweight mesh features low elasticity and wide surface area designed to provide support for the urethra. It's easy to implant. It resists traction, and no sleeve or tensioning suture is required. It may look a little different but the reasons are purposefully clear:

Pore size **About 5x** the minimum	**Elasticity** **Low:** 7.5%
Thinness **About half as thin as others** on the market: ≤ .40 mm	**Fiber size** **Lower than others** on the market: .08 mm
Density **Lower than others** on the market: 70 g/m^2	**Total material/mass** **Low amount** of total material implanted

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
Aris® Transobturator Kit	93-4400

ARIS® TRANSOBTURATOR KIT

Indications:

The Aris Transobturator Kit consists of the Aris implantable midurethral support sling and disposable introducers. The Aris sling and introducers are indicated for the surgical treatment of all types of stress urinary incontinence (SUI) and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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 Aris Transobturator Kit 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 Aris Transobturator Kit 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 Aris 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 Aris 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 Aris sling during placement and adjustment to maintain sling integrity and to avoid compression of the urethra when tensioning.

Precautions:

The Aris sling and Aris 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 Aris sling come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the sling.

Potential Complications

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.

Adverse events may 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), pain (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, 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 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.

References
1. Data on file at Coloplast.
2. Karmakar D, Mostafa A, Abdel-Fattah M. Long-term outcomes of transobturator tapes in women with stress urinary incontinence: E-TOT randomised controlled trial. BJOG 2017;124:973–981.
3. Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013;24: 1265–9.
4. Ulrich D, Tammaa A, Holbfer S, Trutnovsky G, Bjelic-Radisic V, Tamussino K, et al. Ten-year followup after tension-free vaginal tape-obturator procedure for stress urinary incontinence. J Urol 2016;196:1201–6.
5. Serati M, Braga A, Athanasiou S, Tommaselli GA, Caccia G, Torella M, et al. Tension-free vaginal tape-obturator for treatment of pure urodynamic stress urinary incontinence: efficacy and adverse effects at 10-year follow up. Eur Urol 2016; DOI: 10.1016/j.eururo.2016.

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