PURPOSEFULLY DESIGNED

Aris®
Transobturator Kit

FEMALE STRESS URINARY INCONTINENCE
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.

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

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

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
- **Thinness**: About half as thin as others on the market: ≤ .40 mm
- **Density**: Lower than others on the market: 70 g/m²
- **Elasticity**: Low: 7.5%
- **Fiber size**: Lower than others on the market: .08 mm
- **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.

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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 counselled 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/deep healing, or other complications and adverse events.

References
1. Data on file at Coloplast.