

Because moderate matters.

Moderate stress incontinence deserves a precise solution

The Virtue Male Sling's dual mode of action¹ fills the gap between standard slings and invasive treatments like the AUS.² With its innovative four-arm design, the Virtue sling offers anatomical support³ to improve continence outcomes.⁴

The Virtue sling difference

Prepubic arms

provide urethral **compression** for increased resistance⁶

Transobturator arms

provide proximal relocation through **elevation** of the bulbous urethra⁶

Anatomical fit³ for those in-between²

Its dual adjustment modes and four-arm design provide an anatomical fit³ that addresses the needs of moderate incontinence patients.² Our innovative quadratic design provides optimal support while reducing complications.⁴

Anatomical fit³ for ongoing sling support⁶

- 2 Dual tension adjustments¹ contributing to patient's continence
- 4 Quadratic fixation⁶ limits sling loosening and/or movement

Minimally invasive for fast recovery^{*,4}

The Virtue sling allows your patients to return to their lifestyles fast^{*,7} with its minimally invasive approach.⁴

- Strategic alternative to more invasive intervention like the AUS
- Increased quality of life⁴
- Safe and effective for all levels of incontinence²

Ordering Information

Coloplast Interventional Urology Service Support **800-258-3476**

Virtue® Male Sling System

Product	Order number
Virtue Male Sling System with Alexis® Retractor	50020
Contains:	
1 - Alexis Retractor	
1 - Virtue Sling	
1 - Single-use Introducer	



Virtue® Male Sling System Brief Statement

Indications

The Virtue Male Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

Contraindications

The Virtue Male Sling is contraindicated in patients with one or more of the following conditions: Documented hypersensitivity or allergic reaction to polypropylene. Active infection, including untreated urinary tract and/or infection in the operative field. Patients with untreated or serious blood coagulation disorders. Patients with obstructive uropathy. Patients under the age of 18.

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 Virtue Male Sling should only be implanted by physicians experienced in the surgical procedures and techniques involving placement of stress urinary incontinence slings.

A thorough assessment of each patient should be conducted, based on current medical practice guidelines, to determine the suitability of a sling procedure. Patients should be counseled that the Virtue Male Sling is permanent.

It is recommended that sling candidates are evaluated for overactive bladder syndrome and post-void residual. Residual sphincteric function should be considered prior to sling surgery.

It is recommended that sling candidates are evaluated for the presence of bladder neck contracture or urethral strictures prior to sling surgery.

The patient should be counseled to consider conservative incontinence treatments as well as other treatments.

Sling associated complications may result in one or more revision surgeries which may lead to partial or complete removal of the sling. Complete removal of the sling may not always be possible, and removal may not fully correct these complications. De novo complications may occur.

The additional risks versus benefits of Virtue Male Sling should be considered in patients with one or more of the following conditions: auto-immune disease, coagulation disorder, connective tissue disease, debilitated or immunocompromised state, diabetes, pelvic radiation therapy, physical characteristics (e.g., body mass index), renal insufficiency, smoking related underlying conditions.

Potential Complications

Adverse events are known to occur with sling procedures and implants. Adverse events following sling implantation may be immediate or delayed, localized or systemic, de novo or worsening, acute or chronic, transient or permanent.

Adverse events may include but are not limited to: allergic reaction, hypersensitivity; autoinflammatory /autoimmunity syndrome; bladder storage symptoms (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence); bleeding/hemorrhage or hematoma, delayed/impaired/abnormal wound healing; exposure, extrusion or erosion of sling into other structures or organs; fistula formation; foreign body granuloma/scar tissue formation; genital paresthesia; infection; inflammation/irritation; male dyspareunia; necrosis; neuromuscular disorder; palpable mesh; pain; perforation or injury to adjacent muscles, nerves, vessels, structures, or organs (e.g., bone, bladder, urethra, ureters, bowel); seroma; sexual dysfunction; sling migration; urinary tract infection, urinary tract obstruction; voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, bladder outlet obstruction, straining, position-dependent voiding, slow stream).

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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*Postoperative care is determined by the treating physician and standard postoperative protocols should be followed.

References

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2. Comiter CV, Dobberfuhr AD. The artificial urinary sphincter and male sling for postprostatectomy incontinence: Which patient should get which procedure? *Investigative Clinical Urology*. 2016;57(1):3-13. doi: 10.4111/icu.2016.57.1.3
3. Data on File with Coloplast
4. Shridharani A, Rhee E. Virtue Chapter. In: Martins FE, Kulkarni SB, Köhler TS (eds.) *Textbook of Male Genitourinary Reconstruction*. Springer, Cham; 2020. p. 823-838. doi: 10.1007/978-3-030-21447-0_63
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6. Comiter, Craig V. et al. The Virtue Sling—A New Quadratic Sling for Postprostatectomy Incontinence—Results of a Multinational Clinical Trial. *Urology*, Volume 84, Issue 2, 433 - 439
7. Welkand BK, Herschorn S. The male sling for post-prostatectomy urinary incontinence: a review of contemporary sling designs and outcomes. *Am J Mens Health*. 2012;6(3):166-175

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