Virtue®
Male Sling System

A Prospective 117 Patient Trial Over 36 Months

Virtue 3 Year Outcomes: *The European Trial for Urinary Incontinence after Prostatectomy*[1]

Authors: Madurga B, Elzevier H, Wagner L, Bottero D, Ferro M, Hegarty P, Shabbir M, Yiou R, Naumann C M, Arano P, Damm J, Everaert K, Chartier-Kastler E, Ryckebusch H and Roumeguère T.

Study included 14 different urology departments across 8 different countries

72% *of patients achieved* ***>50% decrease in 24 Hour (24H) Pad Weight Test (PWT) at 36 months***

No difference
per baseline incontinence severity, BMI or pads usage were found at **36 Months**

69%
of patients reported their condition as **much-very much improved** on the PGI-I scale

49%
of patients achieved results of **<8 grams during 24H PWT at 36 months**

Cure Rate
(<1.3 grams during 24H PWT)

39%
at **36 month follow-up**

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STUDY INFORMATION

Preoperative Incontinence Levels:

Incontinence Level	Definition	Study Patient Population
Mild	<100g	52 (46%)
Moderate	100-400g	47 (41%)
Severe	>400g	15 (13%)

Study Population and 36 Month Results

	Baseline	M3	M12	M36
Study population (n)	117	108	95	69
Mean urinary loss in PWT (g)	227	71	79	72
Median urinary loss in PWT (g)	113	10	14.5	7

Adverse Events

Postoperative Complication	Patient Population
Pain/Discomfort Requiring Analgesic Therapy	9 (7.7%)
Pain/Discomfort Requiring Revision	1 (0.8%)
Genital Paresthesia or Hypoesthesia	11 (9.4%)
Post Procedural Hematoma	4 (3.4%)
Transient Urinary Retention	9 (7.7%)
Micturition Urgency or Pollakiuria or Hypertonic Bladder	12 (10.2%)
Overall Revisions	1 (0.8%)*

* Revision due to patient discomfort

1. Madurga B, Elzevier H, Wagner L, Bottero D, Ferro M, Hegarty P, Shabbir M, Yiou R, Naumann C M, Arano P, Damm J, Everaert K, Chartier-Kastler E, Ryckebusch H and Roumeguère T. The Virtue European trial for urinary incontinence after prostatectomy: 3-year outcomes [abstract]. Paper presented at 49th Annual Scientific Meeting of International Continence Society. September 2019. Gothenburg, Sweden.

Virtue® Male Sling System Brief Statement

Indications: The Coloplast Virtue Male Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).
Contraindications: It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. This product is contraindicated for patients with urinary tract infections or urinary tract obstruction; blood coagulation disorders or prescribed anticoagulation therapy; obstructive uropathy; or, are under the age of 18.
Warnings and Precautions: It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the possible warnings associated with the use of this product.
Potential Complications: As with all foreign bodies, the Virtue sling system is likely to exacerbate any existing infection. Transitory local irritation at the wound site and a foreign body response may occur. The resulting response could lead to wound dehiscence, extrusion, erosion, inflammation or fistula formation. The following complications are known to occur with synthetic slings:
• urethral erosion
• infection
• bladder, urethra, vessel and nerve perforation
Known risks of incontinence surgical procedures include extrusion, erosion, infection, sling migration, pain, transient or permanent retention, bladder outlet obstruction, and, continued stress urinary incontinence and persistent or new overactive bladder symptoms.

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.

Ostomy Care / Continence Care / Wound & Skin Care / Interventional Urology

Coloplast

Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476
www.coloplast.us

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