

## Virtue Male Sling for Post-Prostatectomy Stress Incontinence: A Prospective Evaluation and Mid-Term Outcomes

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### ABSTRACT

**Objective:** To evaluate the efficacy and safety of the Virtue® male sling (Coloplast, Humlebaek, Denmark) in a cohort of patients affected by post-prostatectomy stress urinary incontinence (SUI).

**Methods:** All 29 consecutive patients treated with a Virtue male sling at our Institution between July 2012 and October 2013 were included in the present prospective, non-randomized study. Patients were evaluated preoperatively and at 1, 3, 6, 12, 24 and 36 months after surgery using a 24-h pad weight test, the International Consultation on Incontinence short-form questionnaire (ICIQ-SF), Urinary Symptom Profile (USP) questionnaire, a bladder diary, uroflowmetry and the Patient Global Impression of Improvement (PGI-I) and Patient Global Impression of Severity questionnaires.

**Results:** The mean patient age was 65.5 years. A total of 72.4% of patients had preoperative mild incontinence (1–2 pads/day), while nine patients used 3–5 pads/day. There were a total of 17 complications, which occurred in 29 patients (58.6%); all were Clavien–Dindo grade I. At 12-month follow-up patients showed a significant improvement in 24-h pad test (128.6 vs 2.5 g), number of pads per day (2 vs 0), ICIQ-SF score (14.3 vs 0.9) and USP score for SUI (4 vs 0), and outcomes remained stable at 36 months. At last follow-up, the median score on the PGI-I questionnaire was 1 (very much better).

**Conclusion:** The Virtue male sling is an effective treatment option for low to moderate post-prostatectomy incontinence.

Figure 1: Mean 24-h pad weight over the 12 months of follow-up

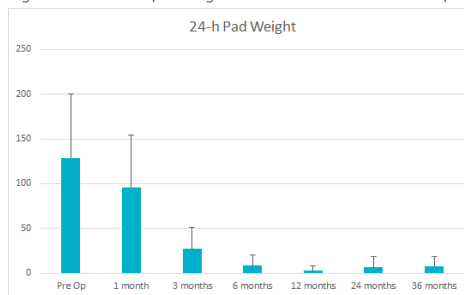


Figure 2: Mean number of pads/day over the 12 months of follow-up

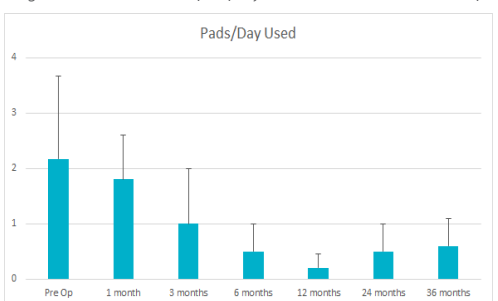
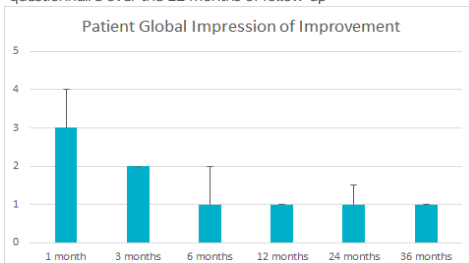


Figure 3: Results of the Patient's Global Impression of Improvement questionnaire over the 12 months of follow-up



At a mean (range) follow-up of 14.5 (12–22) months, the patients had considerable improvements in 24-h pad weight, numbers of pads/day, PGI-I scores (Figs 1–3).

## COLOPLAST KEY TAKEAWAYS

- 82.7% of patients in this study used 0 pads/day at 12 months post-operation with the Virtue® sling.
- At the 3-year follow-up, patient pad use was a maximum of 1 pad/day.
- 86.2% of patients reported their condition as very much better (PGI-I score 1) up to 3 years following their Virtue® sling placement.
- The Virtue® male sling has a reconstructive rather than merely obstructive role by providing bidirectional compression and elevation of the bulbous urethra.
- The goal of the Virtue® suburethral sling is to restore position and function of the pelvic floor through outflow obstruction and urethra repositioning.
- In this study, all complications were grade I on the Clavien-Dindo scale supporting Virtue® as a safe treatment for patients suffering from mild and moderate incontinence.

### 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](http://www.coloplast.us).

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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