

CLINICAL ARTICLE SUMMARY

The Virtue Sling—A New Quadratic Sling for Postprostatectomy Incontinence—Results of a Multinational Clinical Trial

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The study evaluates initial clinical results of a novel fixation mechanism used to prevent early sling loosening. It reports the 1-year results of the fixated quadratic sling and compares it with those of an unfixated device.

ABSTRACT

Introduction: To successfully perform male sling surgery, and the surgery must achieve proximal urethral relocation and/or bulbar urethral compression. The Virtue quadratic sling is a novel device that incorporates both mechanisms of action.

Aim: To report the 1-year results of the Virtue sling with fixation and compare it with the results of the initial “unfixated” sling trial.

Methods: A prospective trial was performed to assess the efficacy and safety of the Virtue sling. Objective success was predefined as >50% decrease in 24-hour pad weight and subjective success as a score of “much” or “very much” better on the Patient Global Impression of Improvement. Subgroups were analyzed by baseline incontinence: mild (<100 g), moderate (100-400 g), and severe (>400 g). After analysis of the 1-year data, a second clinical trial incorporating a novel “fixation” technique was performed, with similar outcome measures.

Results: In the initial cohort, subjective and objective successes were achieved in 41.9% at 12 months. Median pad weight reduction was 51.1% at 12 months and varied with the degree of baseline leakage. In the fixation cohort, subjective and objective successes were 70.9% and 79.2%, median pad weight reduction was 88.3% at 12 months, and efficacy was similar regardless of baseline incontinence. There were no cases of prolonged retention and no severe adverse events.

Conclusion: The Virtue sling with fixation is a safe and efficacious treatment for postprostatectomy incontinence. Superior 12-month results compared with the unfixated device demonstrate that fixation prevents early sling loosening.

COLOPLAST KEY TAKEAWAYS

- The Virtue® fixation sling is the only male incontinence device that has reported significant improvement in 24-hour pad weight up to 1-year postoperatively.
- The combined mechanisms of compression and proximal urethral relocation increase urethral resistance more than a purely transobturator sling.
- Fixation of the Virtue® sling is a crucial step in the surgical technique leading to improved patient outcomes at the 1-year postoperative follow-up mark.
- 80% of mild incontinence patients, 83% of moderate incontinence patients, and 71% of severe incontinence patients realized a 50% or greater reduction in pad weight at 1-year post-operation with quadratic sling fixation in this study.
- With proper fixation of the Virtue® male sling, 46% of patients in this study were considered cured at the 1-year postoperative mark.

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.com.

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

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