

## **Virtue® Male Sling System**

### **BRIEF STATEMENT**

#### **Physician Facing**

#### **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](http://www.coloplast.com).

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

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