

Virtue™

Ventral Urethral Elevation Sling System



STERILE EO	Sterilized using Ethylene Oxide
	Do not reuse
	Do not use if package is damaged
	Do not re-sterilize
	Caution: consult accompanying documents
	Batch code
	Date of Manufacture
	Use by

Manufacturer:
Coloplast A/S
3050 Denmark

Distributor:
Coloplast Corp.
Minneapolis, MN 55411
USA

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Virtue™
Ventral Urethral Elevation Sling System

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

Device Description
The Coloplast **Virtue** Ventral Urethral Elevation Sling System is a permanent, synthetic suburethral sling. It is designed for the surgical treatment of male stress urinary incontinence (SUI). The **Virtue** sling is made from knitted, monofilament polypropylene. This structure gives the **Virtue** sling resistance to traction, allows tissue in-growth and facilitates proper positioning during surgery. An introducer is supplied with the **Virtue** sling system and is intended to facilitate the placement of the sling according to the surgeon's preferred technique.

The Coloplast **Virtue** sling and introducer system is provided sterile and is for single-use only. The seal on the component packaging must be intact. Damage to the packaging could compromise sling and introducer sterility. Do not use devices with damaged packaging. The Coloplast **Virtue** Ventral Urethral Elevation Sling System is sterilized by ethylene oxide.

Indications for Use
The Coloplast **Virtue** Ventral Urethral Elevation Sling System is an implantable, suburethral support sling indicated for the treatment of male stress urinary incontinence (SUI).

Surgical Procedure
Patient Preparation
1. Place patient in dorsal lithotomy position with legs positioned at 90 degrees in allen stirrups.
2. Place a 14 French catheter.

3. Make a vertical perineal incision in the midline, dissecting to eventually isolate the ventral bulbous urethra and the pubic rami ensuring the bulbospongiosus muscle is intact. Expose the bulbospongiosus muscle and take it off the perineal body (do not open muscle) to allow ventral urethral elevation and compression by the trans-obturator portion of the sling.

Inside-Out Trans-Obturator (TO) Procedure:
4. Attach inferior extension (TO arm) of the sling to the distal slot of the introducer. Pass the TO introducer via the perineal incision from medial to lateral through the upper aspect of the obturator foramen as an "inside – out" maneuver. The angle of the introducer should be at the 10 o'clock (patient's right side) and 2 o'clock (patient's left side) position when passing through the obturator foramen.
5. Detach the suture from the introducer and pull the sling through the tissue. Repeat on the contralateral side.

Outside-In Pubic Arm Procedure:
6. Make an incision 2cm above the pubic symphysis and lateral to the midline on either side.
7. Pass the introducer from above, through the pubic incision.
8. Pass the introducer in front of the pubic bone (prepubic) out through the perineal incision lateral to the urethra.
9. Attach the superior sling arm to the proximal slot of the introducer and pull up through the incision.
10. Detach the suture from the introducer and pull the sling through the tissue. Repeat on the contralateral side.
11. Remove the suture tips and poly sleeves from the mesh device such that only mesh is remaining in contact with tissue.

Tensioning Arms
12. Firmly tension the TO arms laterally, by simultaneously pulling on the ends of the sling, to elevate the bulbous urethra.
13. Tension the pubic arms superiorly in the same manner.
14. Inspect the device to verify placement and proper tension. The sling should be tensioned over the urethra (with an indwelling 14F catheter) so that a small hemostat may still be passed between the sling and the urethra without difficulty.

To loosen the Sling:
Place an instrument between the sling and the urethra. Use the instrument to pull down and loosen the sling as desired.

To tighten the Sling:
Clamp a device such as a hemostat across the sling, at the lateral incision. Be sure that the complete width of the sling is captured within the clamp to improve the grip. Pull up to tighten the sling as desired. If needed this can be repeated on the contralateral side and pubic incisions.

15. Remove the plastic sheath from the sling and discard. Confirm the correct tension of the sling after the sheath has been removed.
16. Trim the sling at the level of the subcutaneous tissue.
17. Complete a multi-layer closure of the perineal incision and the skin incisions.

End of Procedure
18. Leave the indwelling catheter in place for 2 days.
19. Instruct participant to refrain from lifting (nothing heavier than gallon of milk), running, walking fast, squatting, riding bikes, swimming, rollerblading, or any other form of exercise and sexual intercourse for 6 weeks, but can resume normal activities after 4 weeks.
20. Patient may shower in 2 days.

Post-Operative Care:
1. Standard post-operative protocols should be followed.
2. Antibiotic prophylaxis should be administered.
3. A catheter should be used at the discretion of the surgeon.
4. Patients should also be advised to avoid physical strain, sexual intercourse and lifting for 6 weeks, but can resume normal activities after 4 weeks.
5. Patients should be instructed to immediately report to the surgeon any onset of bleeding, pain, dysuria or sign of infection that occurs at any time.

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. The product is contraindicated for the following patients:
• Patients with urinary tract infections or urinary tract obstruction.
• Patients with blood coagulation disorders or prescribed anticoagulation therapy.
• Patients with obstructive uropathy.
• Patients 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.

General
• Good surgical practice should be followed for management of contaminated or infected wounds.
• This product should only be used by surgeons who are qualified to perform this type of surgery, and who are familiar with the use of non-absorbable mesh and the specific insertion technique for **Virtue**.
• This product should only be used by surgeons who have been trained in the use of **Virtue**.
• This product is sold sterile for single-use only, and should never be re-sterilized. No portion of this procedure kit is reusable. In the event the product becomes contaminated prior to use, the product should be discarded.
• Product with damaged packaging should not be used, as sterility may be compromised.
• Each device should be carefully examined prior to surgery and continuously monitored throughout the surgical procedure to ensure that the structural integrity and sterility of the device have not been compromised in any way. A device which has been damaged or on which repairs have been attempted should not be implanted.
• Non-functional instruments should not be used and should be returned to Coloplast.
• Do not use product beyond the indicated expiration date.
• The implantation of this device should only be considered in patients whom the physician determines are appropriate surgical candidates.
• Good surgical practice must be complied with during implantation of the **Virtue** sling.
• Persistence of de novo incontinence should be carefully considered before a sling implant is conducted.
• It is recommended that good bladder function be demonstrated by candidates for a male sling.
• It is recommended that the presence of bladder neck or urethral strictures be evaluated for male sling candidates.

- The patient should not have an active lower urinary tract infection at the time of implantation.
- It is recommended that low volume detrusor overactivity be assessed for male sling candidates.
- A 6-month period of non-invasive treatment (e.g. behavior modification, bladder exercises, biofeedback, pelvic floor exercises, or drug therapy) is recommended before a sling implant is considered for males with stress urinary incontinence.

Patient-Related
• The risks and benefits of using **Virtue** in patients with blood coagulation disorders should be carefully considered.
• The risks and benefits of using **Virtue** in patients with renal insufficiency due to urinary tract obstruction should be carefully considered.
• The risks and benefits of using **Virtue** in patients with compromised immune systems or any other conditions that affect healing should be carefully considered.

Procedural
• Bleeding and pelvic organ dysfunction due to intra-operative vessel or nerve damage associated with anomalous location, during introducer passage through the medial area of the obturator foramen membrane, should be checked.
• The proper tension and placement of the sling should be verified prior to closure.
• The plastic sheath and sutures on **Virtue** should not be removed until the sling is in its desired position.
• Vessel and organ (urethra, bladder, bowel, etc) perforation should be carefully avoided. The patient should be observed for any signs of retropubic or periurethral bleeding.
• Cytoscopy can be performed to confirm bladder integrity or to recognize bladder perforation if suspected.

Post-Procedure
• Standard post-operative protocols should be followed.
• Patients should be advised to avoid physical strain, sexual intercourse and heavy lifting for 6 weeks, but can resume other normal activities after 4 weeks.
• Patients should be instructed to see their surgeon immediately to report any unusual bleeding, pain, dysuria or sign of infection that occurs at any time.
• Proper surgical practice should be followed for management of contaminated or infected wounds.
• If infection occurs, a portion of the entire mesh may have to be removed or revised.
• If the product is removed, it should be handled as biologically hazardous.

Adverse Reactions
No undesirable effects that could be directly attributed to the polypropylene fibers/materials have been reported in the literature. 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

Patients should be monitored regularly after the device has been implanted.

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 occurrence of these responses may require operative intervention with removal of part or all of the sling. No undesirable effects directly attributed to materials used in the introducers have been reported in the literature.

Product Evaluation
Coloplast requests physicians to notify the company of any complications which may develop with the use of this device, and requests return of any explanted devices or components. For safe handling during shipment and upon receipt, Coloplast requests that devices be decontaminated prior to shipment. This is requested even though Coloplast will autoclave-sterilize any opened product returned. Alteration for the purposes of venting to prevent additional damage will be performed as required. If explantation is necessary, Coloplast may analyse the explanted device, and the patient and physician may be asked to allow Coloplast to perform tests that might alter the condition of the device.

Any complications from the use of this device should be brought to the immediate attention of your local sales representative's office. Contact information is located at the front of this booklet or by contacting: Quality Assurance, Product Evaluations Department, Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free telephone (800) 338-7908 in USA; or outside USA: (612) 337-7800; or fax (612) 287-4203.

Returned Good Authorization
Authorization must be received from Coloplast prior to the return of merchandise. Merchandise returned must have all manufacturer's seals intact and be returned within 30 days from date of invoice to be eligible for credit or replacement. Please contact the Coloplast Customer Service Department for details. To obtain a Return Authorization number, see contact information located at the front of this booklet or by contacting: (800) 258-3476 or outside USA: (612) 337-7800; or fax (866) 216-4161 or outside USA: (612) 337-7803. Returned products may be subject to restocking charges.

Product Order Information
To order, please contact your local sales representative or Coloplast Customer Service Department at Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free telephone: (800) 258-3476; or outside USA: (612) 337-7800; or fax (866) 216-4161 or outside USA: (612) 337-7803.

References
Literature references are available upon request from your local sales representative or:
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