Anterior Procedural Steps

These instructions are recommended for general use of these devices in the treatment of pelvic organ prolapse. The Restorelle® DirectFix and Digitex® should only be used by physicians that have received surgical instruction on pelvic floor reconstruction in general and specifically with the Restorelle DirectFix synthetic grafts. Variations in use may occur due to individual technique and patient anatomy.

Procedure and technique overview

- Using sterile technique, open the Restorelle DirectFix, Digitex Suture Delivery Device and suture cartridge(s) packaging and transfer into the sterile field.
- The DirectFix mesh is used as an inlay to support fascial defects. Care should be taken to properly size the body of the mesh graft to appropriately fit the patient and vaginal dimensions. Trim proximal tail as needed to approximate appropriate support based on individual patient anatomy.
- Sutures or other means may be used to fixate the mesh in place. Coloplast offers the Digitex Suture Delivery Device to secure DirectFix mesh to anatomical landmarks.
- Patient placement should be in lithotomy position according to standard operating procedure.
- Failure to follow instructions properly may lead to improper functioning of the devices and result in injury to the patient.

1. Perform precise hydro-dissection with saline, dilute anesthetic and/or vasoactive solution.

2. Make a transverse or sagittal incision beginning at the vesicourethral junction. A full thickness dissection of the pubocervical fascia, through all of histological layers, is necessary to allow for the complete placement of the mesh in the appropriate compartment. Use a combination of blunt and sharp dissection lateral to the arcus tendineus at the level of the vesicourethral junction. Dissect posteriorly and laterally to expose the ischial spine.
Bring the head of the loaded Digitex Suture Delivery Device to the proximal suture placement 1-2 finger breadths medially from the ischial spine on the sacrospinous ligament. Ensure that the locking knob is in an unlocked position. Rock the body of the device toward the floor to engage the ligament. Apply pressure at Digitex neck to prevent device movement during deployment. Pull device trigger to capture suture within the sacrospinous ligament. Release the trigger and slowly remove the device from the incision. Clamp suture and rotate the locking knob back to locked position to release the carrier bullet. Repeat steps 3-5 on contralateral side and to arcus tendineous for distal anterior fixation.

Load the Digitex Suture Delivery Device with your preference of preferred size and type of preloaded suture cartridge. Place carrier cap in the head of the device ensuring that the cap is flush with the head of the device. Place suture cartridge on the top of the body of the device with the grey “BOTTOM” side facing down.

Expose the sacrospinous ligament and sweep medially, exposing the sacrospinous ligament and deflect the rectum away from the operative field. Verify that no soft tissue remains over the sacrospinous ligament.
Once DirectFix mesh is in place and suture knots made, ensure mesh is tension free and lies flat under the anterior compartment. Close incision with your preferred method with caution to not strangulate epithelial margins.

Cystoscopy should be performed to confirm bladder integrity.

For arcus tendoneous fixation, the Digitex shaft has a malleable portion that allows the device head to be repositioned 15° in any direction. To place suture for distal end of mesh, rotate the body of the device horizontally to the floor to reach the arcus tendoneous, obturator internus fixation point.

Once all sutures are placed and clamped, proceed to thread suture through reinforced proximal arms of DirectFix to sacrospinous ligament. Position for anatomical support. Ensure that mesh lays flat and tension free against the vesicourethral junction. Trim central mesh as necessary to ensure there is no folding or rolling. Stabilize apical mesh to cervix or apex prior to tying arms to sacrospinous ligament. Stabilize the mesh to the bladder neck and laterally to avoid rolling or bunching of mesh.
Postoperative Care

- Standard post-operative protocols should be followed.
- Option to place a catheter and/or vaginal gauze pack at physician’s discretion.
- General antibiotics should be administered at the physician’s discretion.
- Proper surgical practice should be followed for post-operative management of contaminated or infected wounds.
- Physical strain, sexual intercourse and heavy lifting should be avoided for six weeks after surgery, but physician should determine when it is suitable for each patient to return to normal activity.
- Patient should be instructed to immediately report any onset of bleeding, pain, vaginal discharge or sign of infection that occurs at any time.
- If infection occurs, partial or full mesh removal or revision may be necessary, per physician’s discretion.

RESTORELLE DIRECTFIX BRIEF STATEMENT

Indications
Restorelle DirectFix transvaginal mesh is indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor in vaginal wall prolapse, where surgical treatment is intended, either as a mechanical support or a bridging material for the fascial defects. The Digitex Suture Delivery System is intended to place suture with or without direct visualization. It is indicated in a variety of obstetric-gynecologic, transvaginal surgical procedures including correction of pelvic organ prolapse. The Digitex Suture Cartridges intended for use with the Digitex Suture Delivery Device hold sterile suture indicated for soft tissue approximation.

Contraindications
Restorelle DirectFix transvaginal mesh should not be used in pregnant women, or in women planning future pregnancies or any patient with potential for future growth. Restorelle transvaginal products should not be used in those who are taking anticoagulant therapy, have a sensitivity to polypropylene, have a pre-existing local or systemic infection, or women that have a known or suspected pathology which would compromise implant or implant placement. The use of The Digitex System is contraindicated in patients who are not candidates for surgical procedures. The Digitex is NOT to be used in applications requiring placement of suture into bone.

Warnings and Precautions
It is the responsibility of the surgeon to advise prospective patients or their representatives, prior to surgery, of the warnings and precautions associated with the use of this product and the associated surgical risks. Restorelle mesh should only be used by surgeons familiar with the surgical procedures and techniques involving non-absorbable meshes and who have adequate education and experience in the treatment of pelvic organ prolapse. Based on physician experience and education, a thorough assessment of each patient should be made to determine the suitability of a synthetic mesh procedure. Patients should be counseled that there are alternative non-mesh prolapse surgeries, and the reason for choosing a mesh procedure should be explained. Physician should also obtain patient consent to surgery with an understanding of the post-operative risks and potential complications of mesh surgery. The Digitex Suture Delivery System and Digitex Suture are intended for use only by physicians with adequate training and experience. The physician should be aware of techniques, complications and hazards associated with the intended procedures. As anatomy of individual patients may vary greatly, it is important that the intended locations for suture placement are planned for each procedure and each individual patient. Adequate knot security requires the accepted surgical technique of flat, squared ties as warranted by surgical circumstance and experience of the surgeon.

Adverse Effects
Potential adverse events are those associated with surgery using implantable synthetic mesh materials. As with all foreign bodies, Restorelle DirectFix mesh is likely to exacerbate any existing infection. Local irritation at the wound site and/or a foreign body response may occur. There is also the risk of complete failure of the procedure resulting in recurrent prolapse. The following complications are known to occur with synthetic mesh implantation: mesh erosion (e.g., vaginal, bladder), mesh extrusion, mesh exposure, infection, pain (acute or chronic), and bladder, bowel, urethra, vagina, vesicle, and/or nerve perforation/injury. Serious adverse tissue responses or infection may require removal of mesh. See the device instructions for use for detailed information regarding the implant procedure, warnings/precautions, and adverse reactions prior to using this product. As with any instrument used for surgery, the potential complications associated with the use of the Digitex SDS to place sutures include bleeding, hematoma, infection; injury to vessels, nerves, internal organs and/or tissue; inflammatory reaction, dehiscence, erosion, extrusion, infection to abdominal wall, peritonitis.

Digitec Suture Fixation Device BRIEF STATEMENT

Indications
The Digitex Suture Delivery System is intended to place suture with or without direct visualization. It is indicated in a variety of obstetric-gynecologic, transvaginal surgical procedures including correction of pelvic organ prolapse. The Digitex Suture Cartridges intended for use with the Digitex Suture Delivery Device hold sterile suture indicated for soft tissue approximation.

Contraindications
The use of the Digitex System is contraindicated in patients who are not candidates for surgical procedures. The Digitex is NOT to be used in applications requiring placement of suture into bone. The Digitex Suture Cartridge is contraindicated in patients with known sensitivities or allergies to its components.

Warnings and Precautions
The Digitex Suture Delivery System and Digitex Suture are intended for use only by physicians with adequate training and experience. The physician should be aware of techniques, complications and hazards associated with the intended procedures. As anatomy of individual patients may vary greatly, it is important that the intended locations for suture placement are planned for each procedure and each individual patient. Adequate knot security requires the accepted surgical technique of flat, squared ties as warranted by surgical circumstance and experience of the surgeon.

Adverse Effects
As with any instrument used for surgery, the potential complications associated with the use of the Digitex SDS to place sutures include bleeding, hematoma, infection; injury to vessels, nerves, internal organs and/or tissue; inflammatory reaction, dehiscence, erosion, extrusion, injury to abdominal wall, peritonitis.

For further information, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.us.com

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