Women's Health

Product Catalog

Coloplast

The Coloplast History

It all started back in 1954. Nurse Elise Sorensen was concerned by the dramatic change in her sister's lifestyle following an ostomy operation. She came up with the idea of an ostomy bag with an adhesive ring, which would make it fit tightly to the skin. This would give her sister – and thousands of people like her – the chance to return to their normal life.

Today, Coloplast's business includes Ostomy Care, Continence Care, Wound and Skin Care and Interventional Urology. We work closely with people who have intimate healthcare needs and respond with products that help make their lives easier.

With a world class innovative spirit and the ultimate objective of always being able to make life easier,

Coloplast presents its latest dedicated Women's Health product catalog for:

- Stress Urinary Incontinence (SUI)
- Pelvic Organ Prolapse (POP)

Coloplast is proud to provide you with the highest level of services, products and support.

Our Customer Service and Sales Representatives are available whenever you need them to help you find the right solutions to your specific requirements.

To Order Call Toll-Free 800.258.3476
These products may be ordered directly from Coloplast.

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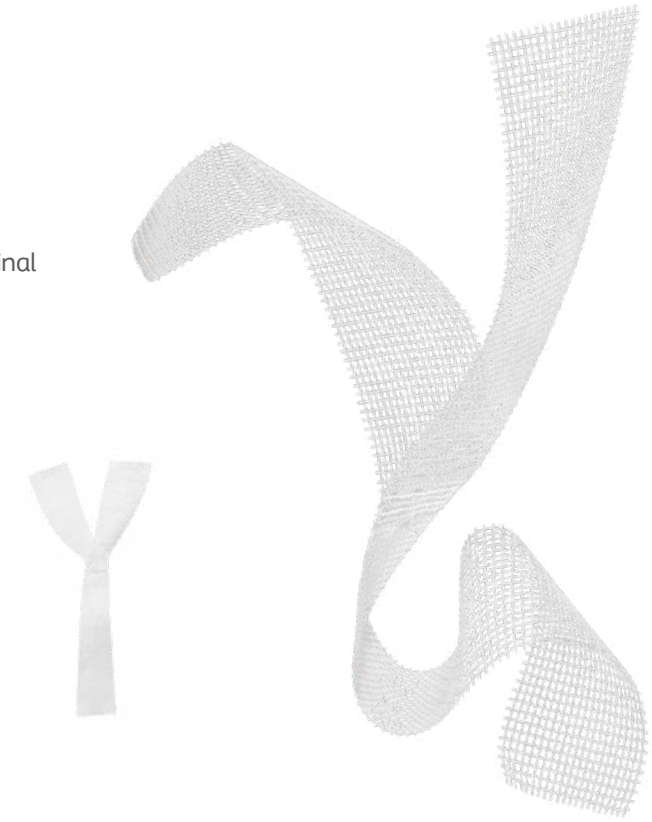
Pelvic Floor Reconstruction

Restorelle® Ultra Lightweight Mesh

Restorelle® mesh ***restores anatomy***, ***renews quality of life***, and ***redefines surgical outcomes***

A shaped or flat synthetic mesh indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (i.e., abdominal placement via laparotomy, laparoscopic, or robotic approach), where surgical treatment for vaginal prolapse is warranted.



Restorelle Y Mesh

Dimensions (cm)	Purchase UOM	Qty per UOM	Item
Restorelle Y			
24 x 4	EA	1	501420
27 x 4	EA	1	501430
Restorelle Y Contour			
24 x 3	EA	1	501520

Restorelle Flat Mesh

Dimensions (cm)	Purchase UOM	Qty per UOM	Item
Restorelle M			
15 x 10	EA	1	501320
Restorelle L			
24 x 8	EA	1	501440
Restorelle XL			
30 x 30	EA	1	501330

Restorelle Y Contour + Meridian Kit

Contains	Purchase UOM	Qty per UOM	Item
Restorelle Y Contour	EA	1	52081
Meridian VPS	EA	1	

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Images are not to scale and are for illustrative purposes only.

Saffron™ Fixation System

Designed for ***ease & reliability*** in prolapse repair

The Saffron Fixation System is indicated for attaching sutures to ligaments of the pelvic floor. It can be used with patients who are good surgical candidates for transvaginal surgical pelvic floor reconstruction. Saffron pairs consistent, reliable control and anchor deployment with ease of navigation, all while allowing surgeons to use their choice of suture and needles for POP repair. The design is intuitive, and easy to use, and surgeons report high satisfaction with the Saffron system.

Saffron™ Fixation System	Purchase UOM	Qty per UOM	Item
Saffron Fixation Tool	EA	1	520340
Saffron Anchor	Box	12	520350

Anchor detail

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Meridian® Vaginal Positioning System

A single-use device that is placed in the vagina to stabilize and aid in the identification of vaginal structures including the apex, fornices, anterior and posterior spaces during surgical procedures such as sacrocolpopexy. Intended for use in gynecological surgery to assist in the position and manipulation of the vagina.

Description	Purchase UOM	Qty per UOM	Item
Meridian® VPS	EA	1	52080

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Allografts

Axis™ Dermis and Suspend® Fascia Lata

The only allografts with the inclusion of POP repair and SUI in their Instructions for Use*

Axis™ Tutoplast® Processed Dermis and **Suspend® Tutoplast® Processed Fascia Lata** are regulated as a 361 human cell and tissue product (HCT/P) as defined in USFDA 21 CFR 1271 and are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional (e.g., physician). This includes supplemental support and reinforcement of soft tissue, such as suburethral graft placement in stress urinary incontinence procedures, and support and reinforcement of fascial structures in the pelvic floor in pelvic organ prolapse procedures. The implants are provided sterile and require rehydration prior to use.

Axis™ Dermis

Tutoplast® Processed Omni-directional Allografts

Dimensions (cm)	Purchase UOM	Qty per UOM	Item
4 x 7	EA	1	939247
6 x 8	EA	1	939268
6 x 12	EA	1	939612
6 x 16	EA	1	939616
8 x 12	EA	1	939812

Suspend® Fascia Lata

Tutoplast® Processed Uni-directional Allografts

Dimensions (cm)	Purchase UOM	Qty per UOM	Item
2 x 7	EA	1	937227
2 x 12	EA	1	937212
2 x 24	EA	1	937224
4 x 7	EA	1	937201
6 x 8	EA	1	937268

**Distributed by a market leader*

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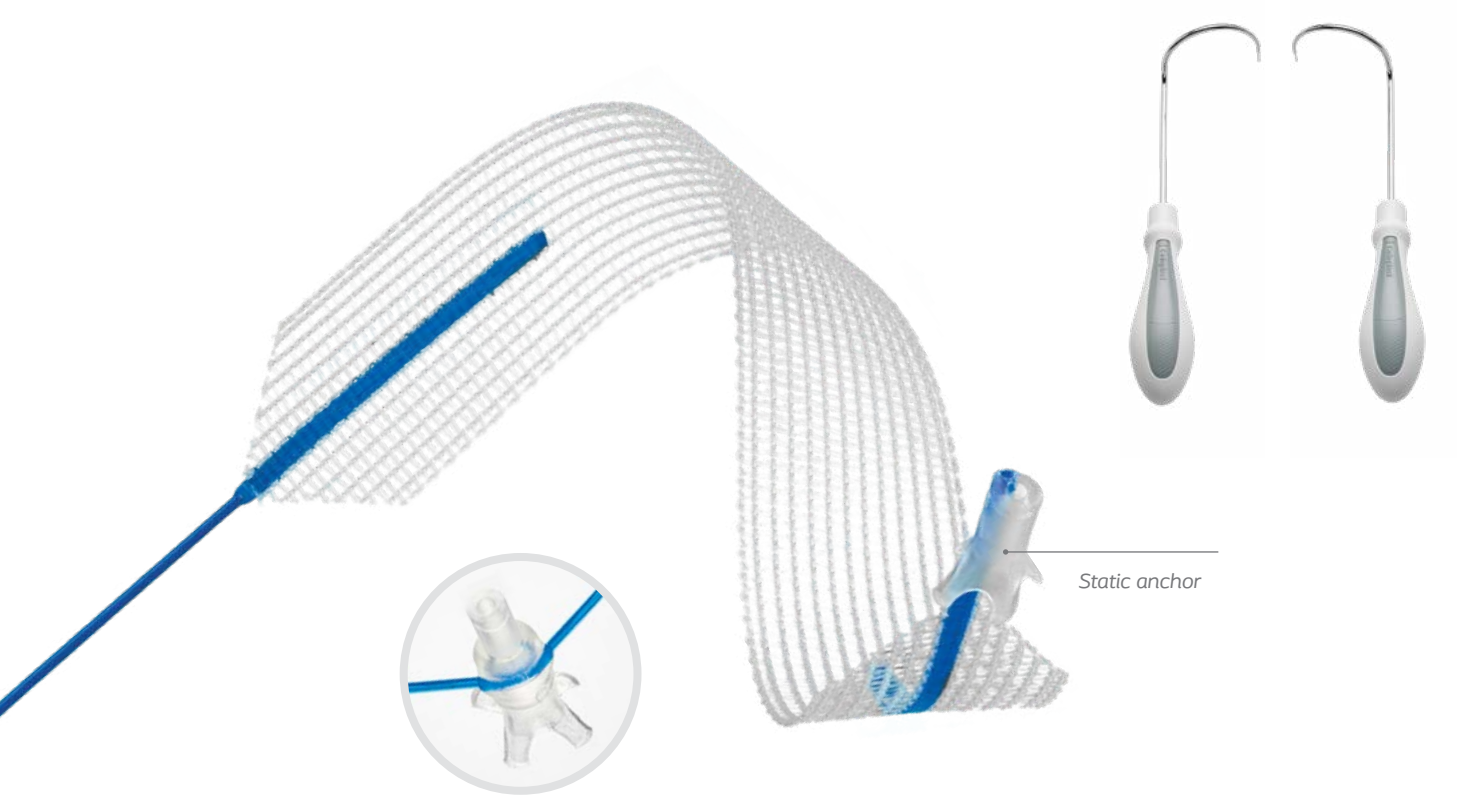
Altis® Single Incision Sling System

Designed for ***predictable performance and control***

A synthetic single incision sling indicated for the surgical treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD). It is made from a knitted, monofilament polypropylene.

Altis® Single Incision Sling System	Purchase UOM	Qty per UOM	Item
7.75 cm Sling	EA	1	519650
Helical Type Introducers	EA	2	



Adjustable anchor

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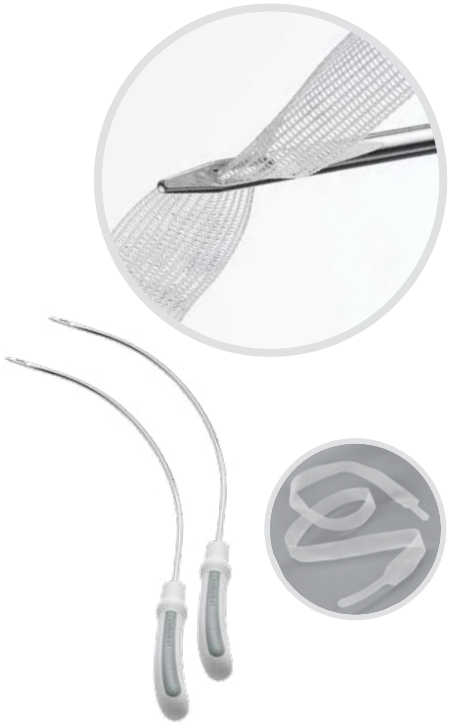
Female Continence

Supris® Retropubic Sling System

A midurethral sling placed retropubically and made from synthetic, knitted, low-elasticity monofilament polypropylene. It is indicated for the surgical treatment of female stress urinary incontinence (SUI), resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Supris® Retropubic Sling System	Purchase UOM	Qty per UOM	Item
60 cm Sling	EA	1	93-4450
Retropubic Introducers (top-down or bottom-up)	EA	2	



Aris® Transobturator Sling System

A midurethral sling made from synthetic, knitted, low-elasticity monofilament polypropylene intended to be placed via the transobturator approach. It is indicated for the surgical treatment of all types of stress urinary incontinence (SUI) and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Aris® Transobturator Sling System	Purchase UOM	Qty per UOM	Item
60 cm Sling	EA	1	93-4400
Flat Inducer	EA	1	
Helical Inducers	EA	2	

To Order Call Toll-Free 800.258.3476

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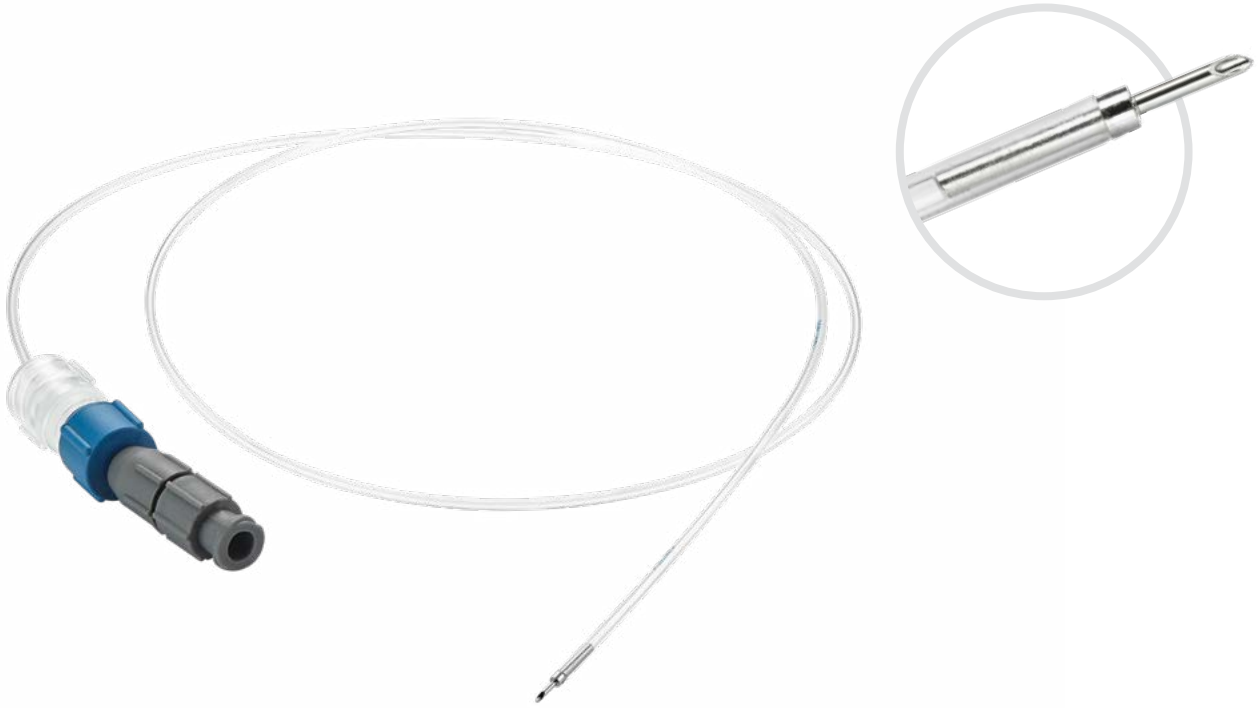
BoNee® Bladder Injection Needle

A single-use device used to deliver injectable materials (such as Botulinum Toxin) to the urinary bladder wall during transurethral endoscopic procedures.

Bonee® Bladder Injection Needle	Length (cm)	Purchase UOM	Qty per UOM	Item
Rigid Cystoscope Needle	35	EA	1	NB1035
Flexible or Rigid Cystoscope Needle	70	EA	1	NB1070



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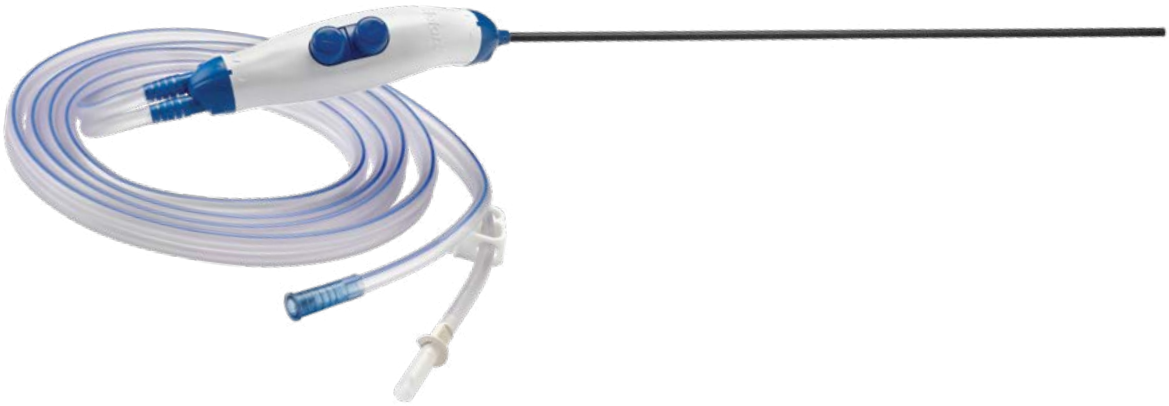
Elefant® Suction Irrigation Device

A device intended for use in laparoscopic procedures as an operating tool with irrigation and suction capabilities. It is a single-use device designed for introduction and use through a properly-sized trocar.

Cannula Diameter (cm)	Cannula Length (mm)	Purchase UOM	Qty per UOM	Item
Elefant without tubing				
5	35	Box	5	ASP145
10	35	Box	5	ASP150
5	45	Box	5	ASP180

	Diameter (cm)						
Cannula	Outside	Inside	Cannula Length (mm)	Tube (m)	Purchase UOM	Qty per UOM	Item
Elefant with tubing							
5	9.5	6.4	35	3	Box	10	ASP165
10	9.5	6.4	35	3	Box	10	ASP170
5	9.5	6.4	45	3	Box	10	ASP185



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Ordering Information

Coloplast Payment Policy

Terms: Net 30 days; all items priced F.O.B. shipping point. Prices and specifications subject to change without incurring obligation.

Returned Goods Policy

Authorization must be received from Coloplast prior to the return of merchandise. Merchandise returned must have all manufacturers' seals intact and be received within 30 days from date of invoice to be eligible for full credit or replacement. Please contact the Coloplast Urology Products Customer Service Department for details. To obtain a Return Authorization Number, call 800.258-3476, or fax 866.216.4161. Returned products may be subject to restocking charges.

Allograft Returns

1. Allografts must be stored in a clean and dry environment.
2. Temperature in storage area must be maintained in the range specified on the implant label.
3. Allografts must be kept out of direct sunlight.
4. All opened Allografts must be disposed of using Standard Practices for Handling and Disposal of Human Tissue, as determined by facility policy.
5. All Allografts must be shipped via overnight delivery.
6. No Allograft shall be shipped from Coloplast to facility or from facility to Coloplast on Friday with scheduled delivery of Monday.
7. Saturday and Holiday deliveries of Allografts may be purchased with no option for return or credit.
8. Facility must obtain a Returned Goods Authorization ("RGA") number from the Coloplast before returning any Allograft.
9. Allografts approved for return must be returned to Coloplast within 30 calendar days after receipt of the RGA number or no credit will be given.
10. No Allograft may be returned to Coloplast with less than a 1 month expiration date.
11. In order to return Allografts, facility must complete a Return Form and attest that all requirements in have been met.

Product Information Disclosure

Except for the limited warranty that all products identified in this product catalog will be free from defects in material and workmanship at time of delivery, subject to proper handling, transportation by a party other than Coloplast, storage, and use of such products, Coloplast excludes all warranties, whether written or oral, statutory, expressed or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability, fitness or design. Coloplast shall not be liable for any direct, incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. No representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or performance of the product shall be or be deemed to be a warranty by Coloplast for any purpose. Coloplast neither assumes nor authorizes any other or additional liability or responsibility in connection with this product.

Caution

Federal (USA) law restricts these devices to sale by or on the order of a physician.

Please refer to package insert provided with these products for complete Instructions for Use, Indications, Contraindications, Warnings, Precautions, Potential Complications, Adverse Effects, and Surgical Instructions prior to using these products.

Pricing

Coloplast reserves the right to change its prices without notice.

RESTORELLE® Y BRIEF STATEMENT
Polypropylene Mesh for Sacrocolposuspension/Sacrocolpopexy

Indications:
Restorelle Y is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (transabdominal placement via laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Contraindications:
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The Restorelle Y is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before placing the Restorelle Y mesh.
- Taking anti-coagulant therapy
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions:
It is the responsibility of the physician to advise the 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.

Warnings:
Restorelle Y mesh should only be used by physicians familiar with the surgical procedures and techniques involving non-absorbable mesh and who have adequate education and experience in the treatment of pelvic organ prolapse.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh procedure.

The patient should be counseled that alternative incontinence treatments may be appropriate, and the reason for choosing a mesh procedure should be explained.

Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transabdominal mesh surgery.

Patient counseling should include a discussion that the mesh to be implanted is a permanent implant and that some complications associated with the implanted mesh may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the mesh may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Restorelle Y should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Restorelle Y mesh requires good knowledge of pelvic anatomy.

Cystoscopy should be performed to confirm bladder and urethral integrity.

A digital rectal exam should be performed to detect possible rectal perforation.

Avoid placing excessive tension on the Restorelle Y mesh implant during placement and adjustment to maintain mesh integrity.

There should be an appropriate margin of mesh extending beyond the fixation points.

Inadequate fixation of the mesh material to the pelvic tissue may lead to failure of the repair and recurrence of the prolapse.

Precautions:
Restorelle Y mesh is provided sterile (ethylene oxide sterilization) and is for single-use only.

Use caution to prevent intraoperative injury to adjacent pelvic structures.

Do not let the Restorelle Y come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the mesh.

Potential Complications:
Adverse events are known to occur with transabdominal synthetic mesh procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent.

Potential complications include, but are not limited to, abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, bowel obstruction, constipation and/or defecatory dysfunction, fecal incontinence and/or anal sphincter incompetence, ileus, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, mesh migration, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., ligaments, muscles, nerves, vessels), structures, or organs (e.g., bowel, rectum, bladder, urethra, ureters, vagina), seroma, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), de novo or worsening prolapse in untreated compartment, granulation tissue formation, palpable mesh (patient and/or partner), recurrent prolapse, sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring, tightening, rigidity, shortening and/or contracture.

The occurrence of adverse events may require one or more revision surgeries, including removal of the mesh.

Complete removal of the mesh may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh explantation.

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

RESTORELLE® Y CONTOUR™

Polypropylene Mesh for Sacrocolposuspension/Sacrocolpopexy

Indications:
Restorelle Y Contour is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (transabdominal placement via laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Contraindications:

It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The Restorelle Y Contour is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before placing the Restorelle Y Contour mesh.
- Taking anti-coagulant therapy

• Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement

• Sensitivity/allergy to polypropylene

Warnings and Precautions:
It is the responsibility of the physician to advise the 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.

The effectiveness of Restorelle Y Contour has not been validated by a prospective, randomized clinical trial.

Warnings:
The Restorelle Y Contour mesh should only be used by physicians familiar with the surgical procedures and techniques involving non-absorbable mesh and who have adequate education and experience in the treatment of pelvic organ prolapse.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh procedure.

The patient should be counseled that alternative pelvic organ prolapse treatments may be appropriate, and the reason for choosing a mesh procedure should be explained.

Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transabdominal mesh surgery.

Patient counseling should include a discussion that the mesh to be implanted is a permanent implant and that some complications associated with the implanted mesh may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the mesh may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Restorelle Y Contour should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Restorelle Y Contour requires good knowledge of pelvic anatomy.

Cystoscopy should be performed to confirm bladder and urethral integrity.

A digital rectal exam should be performed to detect possible rectal perforation.

Avoid placing excessive tension on the Restorelle Y Contour mesh implant during placement and adjustment to maintain mesh integrity.

There should be an appropriate margin of mesh extending beyond the fixation points.

Inadequate fixation of the mesh material to the pelvic tissue may lead to failure of the repair and recurrence of the prolapse.

Precautions:
Restorelle Y Contour mesh is provided sterile (ethylene oxide sterilization) and is for single-use only.

Use caution to prevent intraoperative injury to adjacent pelvic structures.

Do not let the Restorelle Y Contour come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the mesh.

Potential Complications:
Adverse events are known to occur with transabdominal synthetic mesh procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent.

Potential complications include, but are not limited to, abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, bowel obstruction, constipation and/or defecatory dysfunction, fecal incontinence and/or anal sphincter incompetence, ileus, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, mesh migration, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., ligaments, muscles, nerves, vessels), structures, or organs (e.g., bowel, rectum, bladder, urethra, ureters, vagina), seroma, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), de novo or worsening prolapse in untreated compartment, granulation tissue formation, palpable mesh (patient and/or partner), recurrent prolapse, sexual dysfunction, vaginal discharge

(abnormal) and vaginal scarring, tightening, rigidity, shortening and/or contracture.

The occurrence of adverse events may require one or more revision surgeries, including removal of the mesh.

Complete removal of the mesh may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh explantation.

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.

RESTORELLE® M, L AND XL

Polypropylene Mesh for Sacrocolposuspension/Sacrocolpopexy

Indications:
Restorelle M, Restorelle L and Restorelle XL are indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (transabdominal placement via laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Contraindications:
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The Restorelle M, L and XL are contraindicated for use in patients with the following conditions:

• Pregnancy or desire for future pregnancy

• Potential for further growth (e.g., adolescents)

• Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before placing the Restorelle M, L or XL mesh.

• Taking anti-coagulant therapy

• Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement

• Sensitivity/allergy to polypropylene

Warnings and Precautions:
It is the responsibility of the physician to advise the 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.

Warnings:
The Restorelle M, L and XL mesh should only be used by physicians familiar with the surgical procedures and techniques involving non-absorbable mesh and who have adequate education and experience in the treatment of pelvic organ prolapse.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh procedure.

The patient should be counseled that alternative pelvic organ prolapse treatments may be appropriate, and the reason for choosing a surgical mesh procedure should be explained.

Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transabdominal mesh surgery.

Patient counseling should include a discussion that the mesh to be implanted is a permanent implant and that some complications associated with the implanted mesh may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the mesh may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Restorelle M, L or XL should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Restorelle M, L or XL requires good knowledge of pelvic anatomy.

Cystoscopy should be performed to confirm bladder and urethral integrity.

A digital rectal exam should be performed to detect possible rectal perforation.

Avoid placing excessive tension on the Restorelle M, L or XL mesh implant during placement and adjustment to maintain mesh integrity.

There should be an appropriate margin of mesh extending beyond the fixation points.

Inadequate fixation of the mesh material to the pelvic tissue may lead to failure of the repair and recurrence of the prolapse.

Precautions:
Restorelle M, L and XL mesh is provided sterile (ethylene oxide sterilization) and is for single-use only.

Use caution to prevent intraoperative injury to adjacent pelvic structures.

Do not let the Restorelle M, L or XL come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the mesh.

Potential Complications:
Adverse events are known to occur with transabdominal synthetic mesh procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent.

Potential complications include, but are not limited to, abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, bowel obstruction, constipation and/or defecatory dysfunction, fecal incontinence and/or anal sphincter incompetence, ileus, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, mesh migration, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., ligaments, muscles, nerves, vessels), structures, or organs (e.g., bowel, rectum, bladder, urethra, ureters, vagina), seroma, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), de novo or worsening prolapse in untreated compartment, granulation tissue formation, palpable mesh (patient and/or partner), recurrent prolapse, sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring, tightening, rigidity, shortening and/or contracture.

The occurrence of adverse events may require one or more revision surgeries, including removal of the mesh.

Complete removal of the mesh may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh explantation.

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.

SAFFRON™ FIXATION SYSTEM BRIEF STATEMENT

Indications:

The Saffron Fixation System is indicated for the attachment of suture to ligaments of the pelvic floor.

Contraindications:
The Saffron Fixation System is contraindicated in patients with one or more of the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Documented hypersensitivity or allergic reaction to polysulfone
- Active infection, including untreated urinary tract and/or infection in operative field
- Patients with untreated or serious anticoagulant disorders
- Autoimmune disease affecting connective tissue
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Applications requiring placement of suture into or through bone

Warnings:
It is the responsibility of the physician to advise prospective patients prior to surgery, of the warnings associated with the use of this product and the associated surgical risks.

- The Saffron Fixation System should only be used by physicians experienced in the surgical procedures and techniques involving transvaginal placement of permanent anchors.
- The risks and benefits of using the Saffron Fixation System should be considered in patients.
- As with all surgical procedures, patients with certain underlying conditions can be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.
- Patient counseling should include a discussion that Saffron Anchors are permanent.
- Future pregnancy could negate the benefits of this surgical procedure.
- Permanent anchor complications may result in one or more revision surgeries which may lead to removal of one or more Saffron Anchors.

Complete removal of the Saffron Anchor(s) may not always be possible, and removal may not fully correct these complications. There may be unresolved pain with or without anchor explant.

- Patients should be instructed to report bleeding, pain, abnormal vaginal discharge, or signs of infection at any time.

Precautions:
It is the responsibility of the physician to advise prospective patients prior to surgery, of the precautions associated with the use of this product and the associated surgical risks.

- Previous pelvic floor reconstruction may make the placement of Saffron Anchor(s) more difficult.

Potential Complications:
Adverse events are known to occur with transvaginal pelvic organ prolapse repair. Adverse events following pelvic organ prolapse surgery may be localized, systemic, de novo, worsening, acute, chronic, or permanent.

Adverse events may include but are not limited to: Anchor migration, exposure, extrusion into the vagina or other structures or organs, bladder storage symptoms (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), bleeding/hemorrhage/hematoma, delayed/impaired/abnormal wound healing, dyspareunia, fistula formation, infection, inflammation, irritation of surrounding tissue and/or foreign body reaction, pain, perforation or injury to adjacent muscles, nerves, vessels, structures or organs (e.g., bone, bladder, urethra, ureters, bowel, rectum, vagina), scarring, sexual dysfunction, and voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, bladder outlet obstruction, straining, position-dependent voiding, slow stream).

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.

MERIDIAN® VPS BRIEF STATEMENT

Indications:
The Meridian VPS is a single use device intended to assist in the position and manipulation of the vagina during gynecologic surgical procedures such as sacrocolpopexy.

Contraindications:
The Meridian VPS is contraindicated for use in patients with the following conditions:

- Pregnancy
- Intrauterine Device (IUD) present
- Physician deems use inadvisable

Warnings:
The procedure to insert the device requires a good knowledge of local anatomy and the correct use of the manipulator in order to avoid perioperative damage to adjacent anatomical structures.

Avoid using excessive force during vaginal insertion, manipulation and removal of the device.

Precautions:
Reuse of this single use product may create a potential harm to the physician, medical staff and/or patient.

To reduce the risk of perforation, if any resistance is felt when inserting the vaginal positioning system, do not force the vaginal positioning system against the resistance.

Potential Complications:
Adverse events may include, but are not limited to: adverse tissue reaction, bleeding, cramping or discomfort, damage to blood vessels, nerves, connective tissue and other adjacent structures, infection, muscle spasms, organ perforation and injury, pain, and tissue damage.

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.

AXIS™ DERMIS/SUSPEND® FASCIA LATA BRIEF STATEMENT

Description:
Axis Tutoplast® Processed Dermis and Suspend Tutoplast® Processed Fascia Lata are regulated as 361 human and cell tissue products and are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional. This includes supplemental support and reinforcement of soft tissue, such as suburethral graft placement in stress urinary incontinence procedures, and support and reinforcement of fascial structures in the pelvic floor in pelvic organ prolapse procedures.

Warnings:
The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. As with any human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant. Successful treatment is dependent upon the patient's host tissue response. Resorption of the implant and commensurate substitution with functional host tissue is required to restore function.

Precautions:
Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant., as such conditions may compromise outcomes. The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determined that the clinical circumstances require implantation in a site that is contaminated, or infected, appropriate local and/or systemic anti-infective measures should be taken. Appropriate placement and fixation of the implant are critical to success of the surgical procedure. The Suspend implant should be used with caution in sites where it is placed perpendicular to native tissue.

Tutoplast is a registered trademark of Tutogen Medical GmBH.

ALTIS® SINGLE INCISION SLING SYSTEM BRIEF STATEMENT

Indications:
The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

Contraindications:
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The Altis Single Incision Sling System is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Known active urinary tract infection and/or infection in operative field
- Taking anti-coagulant therapy
- Abnormal urethra (e.g., fistula, diverticulum)
- Intraoperative urethral injury
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions:
It is the responsibility of the physician to advise the 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.

Warnings:
The Altis Single Incision Sling System should only be used by physicians familiar with the surgical procedures and techniques involving transvaginal placement of non-absorbable, synthetic mesh slings and who have adequate education and experience in the treatment of female SUI.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure.

The patient should be counseled that alternative incontinence treatments may be appropriate, and the reason for choosing a mesh sling procedure should be explained.

Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transvaginal mesh sling surgery.

Patient counseling should include a discussion that the sling to be implanted is a permanent implant and that some complications associated with the implanted mesh sling may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the sling may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Altis should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

The procedure to insert the Altis sling requires good knowledge of pelvic anatomy and the correct use of the introducer needles in order to avoid damage to adjacent anatomical structures.

Cystoscopy should be performed to confirm bladder and urethral integrity.

Avoid placing excessive tension on the Altis sling during placement and adjustment to maintain sling integrity and to avoid compression of the urethra when tensioning.

Potential Complications
Potential complications include mesh extrusion, pelvic/urogenital pain, groin pain, hip pain (may be related to patient positioning), urinary retention, bleeding, de novo urgency, delayed wound healing, dyspareunia, hip/groin pain, inflammation, nausea, overactive bladder, pain, pelvic hematoma, reaction to antibiotic, slight discomfort upon return to work, urinary tract infection, urine stream decreased, and voiding dysfunction.

Adverse events are known to occur with transvaginal synthetic sling procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent.

Additional potential complications include, but are not limited to, abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh sling into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., muscles, nerves, vessels), structures, or organs (e.g., bone, bladder, urethra, ureters, vagina), seroma, sling migration, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), granulation tissue formation, palpable mesh (patient and/or partner), sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring or tightening.

The occurrence of these events may require one or more revision surgeries, including removal of the sling.

Complete removal of the sling may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh sling explanation.

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.

SUPRIS® RETROPUBIC KIT BRIEF STATEMENT

Indications:
The Supris Retropubic Kit consists of the Supris implantable midurethral support sling and disposable introducers for placement using a "top-down" or "bottom-up" retropubic surgical approach. The Supris sling and introducers are indicated for the surgical treatment of female stress urinary incontinence (SUI), resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Contraindications:
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The Supris Retropubic Kit is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Known active urinary tract infection and/or infection in operative field
- Taking anti-coagulant therapy
- Abnormal urethra (e.g., fistula, diverticulum)
- Intraoperative urethral injury
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions:
It is the responsibility of the physician to advise the 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.

Warnings:
The Supris Retropubic Kit should only be used by physicians familiar with the surgical procedures and techniques involving transvaginal placement of non-absorbable, synthetic mesh slings and who have adequate education and experience in the treatment of female SUI.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure.

The patient should be counseled that alternative incontinence treatments

may be appropriate, and the reason for choosing a mesh sling procedure should be explained.

Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transvaginal mesh sling surgery.

Patient counseling should include a discussion that the sling to be implanted is a permanent implant and that some complications associated with the implanted mesh sling may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the sling may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Supris should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Supris sling requires good knowledge of pelvic anatomy and the correct use of the introducer needles in order to avoid damage to adjacent anatomical structures.

Potential Complications:
Adverse events are known to occur with transvaginal synthetic sling procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent.

Adverse events may include but are not limited to: abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, bowel obstruction, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh sling into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., muscles, nerves, vessels), structures, or organs (e.g., bone, bladder, urethra, ureters, vagina), seroma, sling migration, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), granulation tissue formation, palpable mesh (patient and/or partner), sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring or tightening.

The occurrence of these events may require one or more revision surgeries, including removal of the sling.

Complete removal of the sling may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh sling explantation.

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.

ARIS® TRANSOBTURATOR KIT BRIEF STATEMENT

Indications:
The Aris Transobturator Kit consists of the Aris implantable midurethral support sling and disposable introducers. The Aris sling and introducers are indicated for the surgical treatment of all types of stress urinary incontinence (SUI) and for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The introducer is a surgical instrument designed to assist in correct placement of a sling.

Contraindications:
It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product. The Aris Transobturator Kit is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Known active urinary tract infection and/or infection in operative field
- Taking anti-coagulant therapy
- Abnormal urethra (e.g., fistula, diverticulum)
- Intraoperative urethral injury
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precaution:
It is the responsibility of the physician to advise the 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.

Warnings:
The Aris Transobturator Kit should only be used by physicians familiar with the surgical procedures and techniques involving transvaginal placement of non-absorbable, synthetic mesh slings and who have adequate education and experience in the treatment of female SUI.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure.

The patient should be counseled that alternative incontinence treatments may be appropriate, and the reason for choosing a mesh sling procedure should be explained.

Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transvaginal mesh sling surgery.

Patient counseling should include a discussion that the sling to be implanted is a permanent implant and that some complications associated with the implanted mesh sling may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the sling may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Aris should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Aris sling requires good knowledge of pelvic anatomy and the correct use of the introducer needles in order to avoid damage to adjacent anatomical structures.

Potential Complications:
Adverse events are known to occur with transvaginal synthetic sling procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent.

Adverse events may include but are not limited to: abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, dehiscence,

delayed wound healing, extrusion, erosion or exposure of mesh sling into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., muscles, nerves, vessels), structures, or organs (e.g., bone, bladder, urethra, ureters, vagina), seroma, sling migration, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), granulation tissue formation, palpable mesh (patient and/or partner), sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring or tightening.

The occurrence of these events may require one or more revision surgeries, including removal of the sling.

Complete removal of the sling may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh sling explantation.

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.

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BONEE® BRIEF STATEMENT

Indications:
The Bonee needle is used to deliver injectable materials, amongst other Botulinum toxin, into the urinary bladder wall during the transurethral endoscopic procedure.

Contraindications:
The Bonee needle is contraindicated for use in patients with the following conditions:

- coagulation disorders
- any known allergies to the medical device materials
- any contraindication related to cystoscopy or to the injected substance

Warnings:
Refer to the instructions for use of the injected substance and the clinical injection protocol.

Precautions:
The choice of the size of the needle is the responsibility of the physician.

This type of needle must only be used by trained and experienced professionals.

Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient.

Potential Complications:
Potential complications related to injection into the bladder wall include: bleeding, bladder wall perforation. Potential complications related to the passage of the cystoscope-needle unit into the bladder include: tears or perforation of the meatus and/or the urethra if the device is advanced with the needle protruding, pain, urinary tract infection. For injected substance related adverse effects, please refer to its instructions for use.

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.

ELEFANT® SUCTION IRRIGATION DEVICE BRIEF STATEMENT

Indications:
The Elefant suction/irrigation device is intended for use in laparoscopic procedures as an operating tool with irrigation and suction capabilities. It is a single use device designed for introduction and use through a properly-sized trocar.

Contraindications:
The Elefant Suction Irrigation Device is contraindicated for use in patients with the following conditions:

- Any existing contraindications to laparoscopic procedures
- The evaluation of the allergic background of a patient is the health care professional's responsibility

Precautions:
This type of device must only be used by trained professionals.

This device is not intended to generate high pressure. The maximal pressure tolerated for the Elefant suction/irrigation device is 0.6 bar.

Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient.

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.

Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare.

Our business includes Ostomy Care, Continence Care, Wound and Skin Care and Interventional Urology. We operate globally and employ about 14,000 employees.

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