Desara® SL and Desara® Blue SL

Sling for Female Stress Urinary Incontinence

Instructions For Use

℞ Prescription Use only

Do not reuse

STERILE EO Sterilized using ethylene oxide

Manufactured by:
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10-222 Rev. E

Instructions for Use

CAUTION: Federal Law restricts use of this device to physicians trained in performing suburethral sling procedures for treating stress urinary incontinence.

CAUTION: Read all Information contained in this product label including, Indications, Contraindications, Warnings, Precautions, Adverse Reactions, Instructions for Use, etc., prior to using this product.

Contraindications

- Should not be implanted in patients while on anticoagulants, aspirin, non-steroidal anti-inflammatory agents, or in those with bleeding disorders.
- It should not be utilized in patients with future growth potential, including women with plans for future pregnancies or currently pregnant.
- Do not use product for treatment of vaginal vault or pelvic organ prolapse.
- Do not use this device in contaminated wounds as subsequent infection may require removal of mesh.
- Do not use this device in patients with active or latent urinary tract infections, infections in the operative field.
- Do not use this device in patients with any pathology which would compromise implant placement.

Warnings

1. The reuse, reprocessing or resterilization of a single-use device (SUD) can potentially lead to injury, illness or death of a patient. Inadequate cleaning and disinfection may lead to cross-contamination (infection) of patient and/or user; residuals from cleaning agents may lead to biological responses; impairment or failure of functional product use as the device may not function to its intended purpose; impairment or failure of product integrity as the device material may become fatigued and weakened. In addition, the reuse, reprocessing or resterilization of a single-use device can have ethical, legal and regulatory implications.
2. Polypropylene should not be placed in contact with bowel or visceral organs including the urinary bladder.
3. Please review surgical guide for further details before use. This guide is provided for reference only and is not intended to replace proper surgical training and technique. Before utilizing this product, the surgeon should be trained and must be familiar with surgical techniques for incontinence procedures.
4. Caldera Medical Desara® SL and Desara® Blue SL family of implants are designed for, and should be used only with a Caldera Medical introducer designed for the physician's implant technique.
5. Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires cystocele repair, it should be done prior to the Desara® SL or Desara® Blue SL procedure through a separate incision in the anterior vaginal wall.
6. Users should note the importance of placing the mesh tension free under the urethra.
7. Bleeding may occur postoperatively as with any sling procedure. Observe for any symptoms or signs before the patient is released from the hospital.

8. Cystoscopy is recommended and may be performed at the discretion of the surgeon to confirm bladder integrity and to recognize any inadvertent bladder perforation.
9. As with all sling procedures, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
10. Do not implant Desara® SL or Desara® Blue SL family of implants with any staples or clips as mechanical damage to the mesh may occur.
11. Ensure that the mesh implant is positioned symmetrically to achieve desired results.
12. This product must not be utilized in patients with known allergies to polypropylene.
13. To avoid device breakage or patient injury upon implantation, if high level of resistance is encountered, withdraw sling and reattempt placement.
14. Before implanting this device, inspect quality of the mesh edge for any fraying prior to implantation. In the event that mesh edge is frayed, please discard and open new unit.
15. Post-operatively, the patient should be advised to rest for the first 24 to 48 hours. Further, the patient should be advised to refrain from heavy lifting and/or exercise for at least three to four weeks and from intercourse for one month. The patient can usually return to other normal activity after two weeks.
16. Mesh is considered a permanent implant. Multiple surgeries may be required to remove or correct mesh related to complications. Complete removal of mesh may not be possible.

Adverse Reactions

Potential adverse reactions are similar to those associated with other surgically implanted meshes. Adverse reactions include but are not limited to the following:

- Potential for infection, inflammation, adhesions, fistula formation, device migration, scarring/scar contracture and mesh extrusion, exposure or erosion.
- Injury to vessels, nerves, bladder, ureter, urethra, and bowel, and may occur during passage of any needles and may require open surgical repair.
- Potential for hemorrhage resulting in hematoma formation, seroma, and wound infection.
- De Novo development of postop urge incontinence, urinary frequency, voiding dysfunction, retention, atypical vaginal discharge, acute and/or chronic pain (including groin pain), and dyspareunia.
- As with all foreign bodies, Desara® SL and Desara® Blue SL family of implants may potentiate an existing infection.
- Allergic reaction may occur.
- Desara® SL and Desara® Blue SL mesh family is considered a permanent implant and the occurrence of these events may require removal in part or whole which may require significant dissection.
- May lead to serious injury or even death.

Product Traceability

Traceability labels are enclosed with every prosthesis box, which identifies the type, size and lot number of the prosthesis. This label should be affixed to the patient's permanent medical record to clearly identify the device which was implanted so patients can be notified in the event of a product recall.

Sterilization

Desara® SL and Desara® Blue SL® are sterilized by ethylene oxide. Do not re-sterilize this product. Do not use if package is opened or damaged. Do not use after expiration date.

Packaging

The sterile mesh is put in a sealed pouch. If the pouch is open or damaged do not use.

Storage

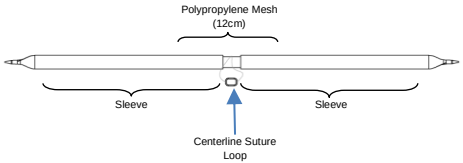
This product must be stored at room temperature in a clean dry place. Do not expose product to direct sunlight, humid environments or extreme temperatures. Do not use after the expiration date.

Desara® SL and Desara® Blue SL Guide for Use of Surgical Introducers

The following instruction is meant as a guideline only and does not replace proper surgical technique, clinical judgment and surgical training.

Desara® SL – Item # CAL-DS01SL and Desara® Blue SL – Item # CAL-DS01BSL Description

The Desara® SL and Desara® Blue SL sling for female stress urinary incontinence is a sterile, single-use sling used to provide mid-urethral support. The device is manufactured out of large pore, monofilament polypropylene yarn, which is knitted into a 12 cm long mesh. The device has a centerline suture loop and integral sleeves and sutures to assist the surgeon in placement of the device. The sleeve and sutures are removed after placement of the device with only the 12 cm portion of mesh remaining implanted.



Indication

Desara® SL and Desara® Blue SL are intended to be used in females to position a mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

Preparation

- Use appropriate local, spinal or general anesthesia.
- Correctly place the patient in the dorsal lithotomy position.
- Completely drain the bladder with a Foley catheter.

Vaginal Dissection

- Local anesthetic may be used to anesthetize and hydrodissect the surgical site.
- A 1-3 cm. long midline longitudinal incision is made in the anterior wall of the vagina at the point of the mid-urethra. Use Allis clamps for tissue traction and perform sharp and/or blunt dissection to develop the existing plane inferior to the endopelvic fascia.
- Continue the dissection just past the inferior pubic ramus to the obturator internus muscle.

Surgical Procedure Techniques

Desara® SL and Desara® Blue SL are intended for transobturator placement only. Caldera Medical surgical instruments are to be used with Caldera Medical implants only. Desara® SL and Desara® Blue SL have been validated for use with the following Caldera Medical Introducers:

Surgical Approach		Caldera Medical Instrument
Transobturator	Outside-In	Helical (CAL-HL04/CAL-HR05, CAL-HL32/CAL-HR32) Large Helical (CAL-LHL1/CAL-LHR2, CAL-LHL32/CAL-LHR32) Hook (CAL-TB03)
	Inside-Out	Inside-out (CAL-IO6/CAL-IO7 or CAL-IOR32/CAL-IOL32) with Winged Guide Accessory (CAL-WI)

For more information on the use, care and handling of Caldera Medical Introducers, please review the Instructions for Use (IFU) for these poducts.

Do not attempt to implant Desara® SL and Desara® Blue SL using a retropubic technique.

Transobturator - Outside In (Utilizes Caldera Medical Helical, Large Helical, or Hook Introducers)

1. Palpate the medial border of the obturator foramen. Locate the base of the adductor longus tendon, at the level of the clitoris. At this location, just inferior to the tendon, and just lateral to the bone and away from the obturator vessels, make a stab incision. Repeat on the contralateral side.
2. Place the helical or hook transobturator introducer tip through the groin incision, perpendicular to the skin incision. The introducer handle should be held at a 45º angle from the introitus.
3. Insert the introducer through the skin incision until it perforates the obturator membrane.
4. Using finger tip palpation, guide the tip of the introducer around the posterior surface of ischiopubic ramus until it exits through the vaginal incision. Maintain continuous finger palpation with the introducer tip passing close to the ischiopubic ramus to avoid button holing and any other adverse events.
5. Insert the suture loop from one side of the sling into the suture slot at the tip of the introducer. Guide the introducer back through the incision and out of the body, pulling the end of the mesh assembly through the skin incision.
6. Place the mesh portion of the sling such that it is lying flat with the centerline suture loop approximately aligned with the urethra.
7. Remove the introducer from the suture loop.
8. Repeat steps 3-5 on the contralateral side.
9. Pull gently on both ends of the sling until the centerline suture loop is aligned with the mid-urethra, placing the sling in a tension free manner.
10. Perform cystoscopy to rule out any bladder perforations.
11. Cut off the ends of the mesh assembly medial to the tip and suture connection system and pull off the sleeves only, leaving the green sutures in place. A blunt instrument (e.g., forceps or male dilator) may be used between the urethra and the mesh sling to maintain tension free placement while removing the plastic sleeves. **Be careful not to remove the green sutures at this point.**

12. Make final adjustments in placement as necessary using the green sutures. If the mesh sling should be loosened, use a blunt instrument to pull on the mesh.
13. Once the mesh position is finalized, pull on one end of the green suture from each of the bilateral incisions, completely removing the suture.
14. While grasping the green pendant on the centerline suture loop away from the sling, carefully cut one end of the suture loop closest to the pendant. Slowly remove the cut suture loop from the sling by pulling the green pendant.
15. Incisions are closed according to usual methods.

Transobturator- Inside Out (Utilizes Caldera Medical Inside-Out Introducers & Winged Guide)

1. Insert the winged guide into the dissection with the open side of the guide facing the surgeon. The guide should be inserted until it reaches the obturator internus muscle.
2. Attach one side of the sling assembly suture to the suture slot located at the tip of the Inside-Out introducer.
3. Insert the introducer in the winged guide channel and move the introducer so that it slides in the winged guide channel and remains close to the posterior surface of the ischiopubic ramus with rotation. The tip of the introducer should pass through the medial portion of the obturator membrane, just lateral to the ischiopubic ramus and ≤2 cm lateral to the groin fold to avoid the obturator vessels.
4. Remove the Winged Guide. Keep it sterile for the patient's other side.
5. Complete the introducer passage so that the tip of the introducer shaft exits ≤2 cm lateral to the groin fold. To achieve this passage, the introducer handle should be rotated and moved to midline.
6. Remove the suture loop from the Inside Out Introducer. While grasping the suture loop, withdraw the introducer back out through the vaginal incision.
7. Place the mesh portion of the sling such that it is lying flat with the centerline suture loop approximately aligned with the urethra.
8. Repeat steps 1-7 on the contralateral side.
9. Pull gently on both ends of the sling until the centerline suture loop is aligned with the mid-urethra, placing the sling in a tension free manner.
10. Perform cystoscopy to rule out any bladder perforations.
11. Cut off the ends of the mesh assembly medial to the tip and suture connection system and pull off the sleeves only, leaving the green sutures in place. A blunt instrument (e.g., forceps or male dilator) may be used between the urethra and the mesh sling to maintain tension free placement while removing the plastic sleeves. **Be careful not to remove the green sutures at this point.**
12. Make final adjustments in placement as necessary using the green sutures. If the mesh sling should be loosened, use a blunt instrument to pull on the mesh.
13. Once the mesh position is finalized, pull on one end of the green suture from each of the bilateral incisions, completely removing the suture.
14. While grasping the green pendant on the centerline suture loop away from the sling, carefully cut one end of the suture loop closest to the pendant. Slowly remove the cut suture loop from the sling by pulling green pendant.
15. Incisions are closed according to usual methods.

Post Operative Care

A catheter and vaginal packing with estrogen can be used at the discretion of the surgeon.

To learn more about Desara® SL and Desara® Blue SL, other products for incontinence, a glossary of terms/symbols, product evaluations and training, contact Caldera Medical at 866.422.5337 or visit our website at www.calderamedical.com.

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