CALDERA MEDICAL

Desara® Blue OV

Sling for Female Stress Urinary Incontinence

Instructions For Use

℞ Prescription Use only

Do not reuse

STERILE EO Sterilized using ethylene oxide

Manufactured by:
Caldera Medical, Inc.
5171 Clareton Drive
Agoura Hills, CA 91301
U.S. Toll Free: 866-4-CALDERA
Telephone: 818-879-6555
Fax: 818-879-6556
www.calderamedical.com

10-139-05 Rev B

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® Blue OV 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® Blue OV 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® Blue OV 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® Blue OV family of implants may potentiate an existing infection.
- Allergic reaction may occur.
- Desara® Blue OV 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® Blue OV implants 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. Do not use if the pouch is open or damaged.

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® Blue OV 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® Blue OV – Item #CAL-DS01BOV Description

Monofilament polypropylene, warp knitted into a mesh.

Indication

Desara® Blue OV 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
- Place the patient in lithotomy position
- Completely drain the bladder with a Foley catheter
- Optional – A rigid catheter guide may be used for retropubic approaches to shift the bladder position as an aid to avoid laceration or perforation of the bladder

Vaginal Dissection

- Local anesthetic may be used to anesthetize and hydrodissect the surgical site
- A midline longitudinal incision is made in the anterior wall of the vagina

Surgical Implant Techniques

A. Suprapubic Introducer (CAL-SP01)

17. A combination of appropriate sharp and blunt dissection is performed extending lateral to the urethra and toward the urogenital diaphragm and posterior surface of the pubis allowing the introducer tip to pass through the vaginal incision. This is performed bilaterally.
18. An area 1 cm above and 1-2 cm lateral to the midline of the pubis is marked with a sterile marking pen. This is performed bilaterally.
19. The subcutaneous tissue at these marks may be injected with local anesthetic.
20. Stab incisions are created over the marked areas.
21. The Suprapubic Introducer (CAL-SP01) is placed into the suprapubic incision.
22. The needle tip is placed straight through the Rectus fascia and Scarpa's fascia (this can be appreciated by two discernable pops).
23. The handle of the Suprapubic Introducer is moved cephalad, directing the tip of the introducer to the posterior surface of the pubis.

24. The introducer is advanced along the posterior surface of the pubis through the Space of Retzius and toward the ipsilateral vaginal paraurethral dissection. Maintenance of a position close to the pubis will reduce the risk of cystotomy and other adverse events.

25. Using fingertip palpation, guide the introducer through the ipsilateral urogenital diaphragm and vaginal dissection. Guidance of the introducer using fingertip palpation is recommended to avoid adverse events.

26. Repeat steps 5-9 on the contralateral side.

27. With both introducers in place, perform cystoscopy to rule out needle cystotomy or additional bladder/urethral injury.

28. Insert the suture loop from one side of the sling into the suture slot of one of the Suprapubic Introducers.

29. Guide the introducer and sling assembly through the vaginal incision and back out of the ipsilateral suprapubic skin incision.

30. Repeat step 13 on the contralateral side. Ensure the sling is not twisted with placement and lies completely flat under the urethra

31. Remove the introducer from the suture loop.

32. Adjust sling position under the midurethra in a supportive but tension-free manner.

33. Cut the ends of the mesh assembly medial to the tip and suture connection system and remove the sheath ensuring stable suburethral sling position.

34. Trim the portion of the mesh that extends past the groin or suprapubic incisions just below the level of the skin.

35. Incisions are closed according to usual methods.

B. Transobturator Introducers - Outside In (CAL-HL04, CAL-HR05, CAL-TB03, CAL-LHL01, CAL-LHR02)

1. Blunt or sharp paraurethral dissection is used to develop the existing plane inferior to the endopelvic fascia.

2. Palpate the medial border of the transobturator 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 (anterior medical notch), make a stab incision. Repeat on the contralateral side. The surgeon may elect to infiltrate the site with local anesthetic prior to incision.

3. Place the Helical, Hook, or Large Hook Transobturator introducer tip through the groin incision, perpendicular to the skin incision. The introducer handle should be held at a 45° angle from the introitus.

4. Insert the introducer straight through the skin incision until it perforates the transobturator membrane.

5. Using finger tip palpation, guide the tip of the introducer around the posterior surface of ischiopubic ramus and through the obtuator internus until it exits into the vaginal incision lateral to the periurethral tissue. Maintain continuous finger palpation with the introducer tip passing close to the ischiopubic ramus to avoid any adverse events.

6. Repeat steps 3-5 on the contralateral side, placing both introducers in the retropubic space. 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. Make sure

the mesh is lying flat under the urethra and is not twisted.

7. Remove the introducer from the suture loop.
8. Place the sling in a tension free manner under the mid urethra.
9. Cut off the ends of the mesh assembly medial to the tip and suture connection system and pull off the sheath ensuring the sling maintains its tension free suburethral position.
10. Trim the portion of the mesh that extends past the groin or suprapubic incisions just below the level of the skin.
11. Incisions are closed according to usual methods.

C. Transvaginal Introducer (CAL-TV02)

1. Blunt or sharp paraurethral dissection is performed to allow the Transvaginal Introducer to pass through the Space of Retzius.
2. Two stab incisions are created over the pubic symphysis approximately 1 cm lateral of midline.
3. Attach one side of the sling assembly suture to the suture slot of the Transvaginal Introducer.
4. Pass the Transvaginal Introducer through the vaginal incision up through the retropubic space close to the posterior surface of the pubic symphysis and through the suprapubic incision. Maintain the introducer position close to the pubic bone to avoid any adverse events.
5. Make sure the mesh is lying flat under the urethra and is not twisted.
6. Remove the suture loop from the Transvaginal Introducer. While grasping the suture loop, transverse the introducer back out through the vaginal incision.
7. Repeat on the contralateral side.
8. Place the sling in a tension free manner under the mid urethra.
9. Cystoscopy should be performed to rule out any bladder perforations.
10. Cut off the ends of the mesh assembly medial to the tip and suture connection system and pull off the sheath.
11. Trim the portion of the mesh that extends past the suprapubic incisions below the level of the skin.
12. Incisions are closed according to usual methods.

D. Transobturator Introducers- Inside Out (CAL-IO6, CAL-IO7)

1. Blunt or sharp paraurethral dissection is used to develop the existing plane inferior to the endopelvic fascia.
2. Palpate the medial border of the transobturator 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.
3. Perform blunt paraurethral dissection towards the ischiopubic ramus at approximately a 45 degree angle from the midline. Dissect to the medial surface of the pubic ramus, and avoid scything anterior to the pubic bone.
4. Perforate the transobturator membrane with the scissors, but do not dissect beyond this point. The dissection should not be more than 5 cm deep, and the dissection path should be re-evaluated if the membrane is not reached.

5. Insert the Winged Guide into the dissection with the open side of the guide facing the surgeon. The guide should be inserted until it passes through the opening in the transobturator membrane.
6. Attach one side of the sling assembly suture to the suture slot located at the tip of the Inside-Out Introducer.
7. Insert the introducer in the Winged Guide channel and move the introducer so that it remains close to the posterior surface of the ischiopubic ramus. The tip of the introducer should pass through the medial portion of the transobturator membrane, just lateral to the ischiopubic ramus, to avoid the obturator vessels.
8. Remove the Transobturator Winged Guide. Keep it sterile for the patient's other side.
9. Complete the introducer passage so that the tip of the shaft exits at the groin incision. To achieve this passage, the introducer handle should be rotated and moved to midline. Make sure the sling is lying flat under the urethra and is not twisted.
10. Remove the suture loop from the Transobturator Introducer. While grasping the suture loop, withdraw the introducer back out through the vaginal incision.
11. Repeat steps 5-10 on the contralateral side.
12. Place the sling in a tension free manner under the mid urethra.
13. Cystoscopy should be performed to rule out any bladder perforations.
14. Cut off the ends of the mesh assembly medial to the tip and suture connection system and pull off the plastic sheath.
15. Trim the portion of the mesh that extends past the groin incisions below the level of the skin.
16. Incisions are closed according to usual methods.

Post Operative Care

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

For information on introducer care and handling, please refer to Caldera Medical's Guide for Cleaning, Sterilization and Storage of Reusable Introducers.

To learn more about Desara® Blue OV, other products for incontinence, product evaluations or training, contact Caldera Medical at 866.422.5337 or visit our website at www.calderamedical.com.

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