



Desara[®] SL

Slings for Female Stress Urinary Incontinence


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.

STERILE Sterilized using ethylene oxide

② Do not reuse

R Prescription Use only

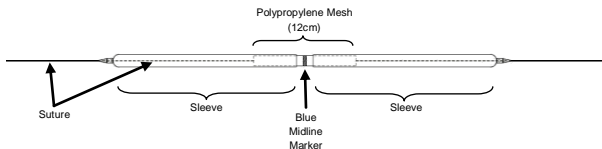
 Manufactured by:
Caldera Medical, Inc.
5171 Clareton Drive
Agoura Hills, CA 91301
U.S. Toll Free: 866-4-CALDERA
Telephone: 818-879-6555
Fax: 818-879-6556
www.calderamedical.com

10-222 Rev. B

Instructions for Use

Description

The Desara 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 blue midline marker 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 is 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.

Adverse reactions

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

- Potential for infection, inflammation, adhesions, fistula formation and mesh extrusion erosion, hematoma, urinary incontinence, voiding dysfunction, pain, dyspareunia and wound dehiscence.
- Perforations or lacerations of vessels, nerves, bladder, urethra, bowel, and uterus may occur during passage of any needles and may require open surgical repair.
- As with all foreign bodies, the Desara SL sling may potentiate an existing infection.
- Over-correction, i.e., too much tension applied to the mesh sling, may cause temporary or permanent lower urinary tract obstruction.

Contraindications

1. As with any suspension procedure, this device must not be implanted in patients while on anticoagulants, aspirin, non-steroidal anti-inflammatory agents, or in those with bleeding disorders.
2. This mesh will not stretch significantly; therefore, it must not be utilized in patients with future growth potential, including women with plans for future pregnancies.
3. Do not use this device in contaminated wounds as subsequent infection may require removal of mesh.

Warnings and Precautions

1. The reuse, reprocessing or resterilization of a single-use (SUD) device 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. Before utilizing this product, the surgeon must be familiar with transobturator surgical techniques for incontinence procedures. Please review surgical guide for further details before use.
4. Bleeding may occur postoperatively as with any sling procedure. Observe for any symptoms or signs before the patient is released from the hospital.
5. Cystoscopy may be performed at the discretion of the surgeon to confirm bladder integrity and to recognize any inadvertent bladder perforation.
6. 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.
7. Do not sling Desara SL with any staples or clips as mechanical damage to the mesh may occur.
8. Ensure that the mesh sling is positioned symmetrically to achieve desired results.
9. This product must not be utilized in patients with known allergies to polypropylene.
10. To avoid suture breakage upon implantation, if high level of resistance is encountered, withdraw sling and reattempt placement.
11. In the event that a suture breaks during mesh placement, before suture has passed through the external skin incision, remove sling and tie ends of suture together to form a loop. Re-attach suture to the instrument and resume procedure. In the event that suture breaks during mesh placement, after suture has exited the external skin incision, grasp ends of suture and pull device manually to complete placement. Visually inspect area to ensure that no suture material remains in operative site.
12. Before implanting this device, inspect quality of the mesh edge for any fraying. In the event that mesh edge is frayed, please discard and open new unit.
13. Please reference the Guide for Use of Surgical Introducers for additional instructions regarding proper use of instruments during mesh placement.
14. 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.

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 is 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 Guide for Use

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 is intended for transobturator placement only. **Do not attempt to implant Desara 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 45° 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 blue midline marker 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 blue midline marker 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. 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 blue midline marker 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 blue midline marker 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. 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.

Guide for Cleaning, Sterilization, and Storage of Reusable Introducers

Caldera Medical surgical instruments are for use with Caldera Medical products only.

Instrument Description

Caldera Medical surgical instruments are to be used in surgical procedures for the placement of devices for the treatment of Genuine Stress Urinary Incontinence (SUI).

Note: New and used instruments must be thoroughly processed according to these instructions prior to use to attain sterility.

Warnings

- Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices.
- Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipments. PPE includes gown, mask, goggles or face shield, gloves and shoe covers.
- Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft-bristled, nylon brushes and pipe cleaners should be used.
- Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution. Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent formation of aerosols and splashing which may spread contaminants. Cleaning agents must be easily and completely rinsed from device surfaces to prevent accumulation of detergent residue.
- Do not allow contaminated devices to dry prior to reprocessing. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluid, tissue debris, saline, or disinfectants to dry on used instruments.
- Saline and cleaning/disinfecting agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used, instruments must not be placed or soaked in Ringers Solution.
- Descaling agents that include morpholine should not be used in steam sterilizers. These agents leave residue which can damage polymer instruments over time.
- As with any surgical instrument, careful attention should be made to assure that excessive force is not placed on this instrument. Excessive force can result in failure.
- If the instrument does not function properly, immediately discontinue use and contact a Caldera Medical representative.
- Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants, and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.
- No part of the process shall exceed 145 °C (293 °F). Do not sterilize by dry heat.
- Aluminum based devices are damaged by high alkaline solution (pH > 10).

Precautions

- A surgeon should not begin clinical use of the introducer without reviewing the instructions for use. (It is imperative that appropriate personnel prior to surgery read all guideline materials. If the guidelines are not properly followed, the risk of complications to the patient increases.)
- When reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with applicable health and safety procedures.

Materials

The introducer component materials are:

- stainless steel curved hook wire introducers secured into,
- anodized aluminum handles with a locking pin, and
- medical grade epoxy fill between wire shaft and handle

Limitations and Restrictions on Reprocessing

Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

Inspection, Maintenance & Test

- Proper care and maintenance is important for the efficient and safe operation of sophisticated medical/surgical equipment. We recommend careful inspection of all equipment upon receipt and prior to each use, as a safeguard against possible injury to patient and/or operator.
- Visually inspect the instrument prior to and after cleaning for damage or wear. Discard instruments with damage or excessive wear.
- The distal tip and slot features should be smooth without denting, cracks, burrs or fractured surfaces.
- The handle and instrument wire surfaces and edges should be uniform and smooth, without corrosion and dents, sharp edges or points. Minor surface hazing and scratches on the wire are acceptable. The instrument wire should be firmly attached to the handle with no movement within the handle component.
- Labeling should be legible.

Preparation for Use

The introducer is sold non-sterile and must be cleaned and sterilized prior to first use. The introducer can be re-used after appropriate cleaning and sterilization.

Cleaning

To prevent the drying of blood and tissue residues and growth of microorganisms, instruments should be immersed as soon as possible after each procedure in an aqueous solution and preferably a combined neutral or enzymatic cleaning and/or disinfectant solution prepared and maintained per solution manufacturer instruction. Reprocess as soon as reasonably practical following use.

❖ Manual

It is necessary to rinse and/or remove visible tissue and blood debris from all instruments thoroughly as detergents and bodily fluids can compromise sterilization.

1. Thoroughly rinse instrument under running luke warm tap water (~32°C) for at least 90 seconds to remove all gross soil and contaminants. Using disposable wipes dampened with cleaning solution and/or soft bristle brushes scrub in circular strokes until no soil is visible. A syringe to flush the lumen and hard to reach areas of the instrument is recommended.
2. Prepare enzymatic detergent, Enzo[®], according to the manufacturer's instructions of 1 oz/gallon using lukewarm (~31.6°C) tap water. Verify that cleaning solution expiration has not been exceeded. Verify facility processed water quality checks are current. Verify recommended splash, skin and inhalation protection measures are in place.
3. Fully immerse and soak instrument for a minimum of 10 minutes. No assembly or disassembly is required.
4. Remove from the Enzo[®] soak solution and perform cleaning under the water surface to limit aerosolization of the cleaning fluid and soil. Thoroughly clean all organic material from instruments. Scrub in circular strokes using soft bristle brushes for at least one (1) minute until all visible soil is removed. A syringe to flush the lumen and hard to reach areas of the instrument is recommended. Pay particular attention to all areas where soil could be embedded (i.e. grooves).
5. After cleaning, use running cold (~22°C) tap water for at least one (1) minute, then warm (~38°C) tap water for at least one (1) minute, to flush and rinse the instrument.
6. Rinse thoroughly for at least one (1) minute using cold (~23°C) processed water to remove any detergent residuals and to prevent water spots and corrosion. A syringe to flush the lumen of the instrument is recommended. Drain.

Drying

Instruments must be dried as soon as possible after cleaning in a protected or clean environment to minimize new contamination. The use of a swab or pressurized air in and on all surfaces and channels to dry is recommended. After drying inspect for condensation and if any is found repeat the drying process until no condensation is observed, then proceed with sterilization. To limit recontamination of the instruments, delays in sterilizing should be avoided.

Sterilization

Sterilization presumes that instruments are clean and residue free. Dry heat sterilization is not appropriate for this instrument as it is assembled with epoxy.

1. The introducer may be steam autoclaved.
2. Wrap individual introducer in two layers of one ply KC600 wrap.
3. The operator should follow the sterilizer manufacturer's instructions for steam sterilization cycle parameters. The following sterilization times and temperatures have been validated for Dynamic air removal/Pre-vacuum Sterilization:

3 preconditioning pulses

Exposure Temperature: 132° C (274° F)

Exposure Time: 4 minutes

Dry Time: 20 minutes

4. Remove instruments from steam sterilization chamber and allow packs to cool before use. Instruments, packs and chamber walls are hot immediately after steam sterilization cycle completion. Use thermal protection when unloading sterilizers.
5. Verify or process sterilization monitors or indicators.
6. Sterilized packs must be dry. If condensation is observed inside of the packs, the packs must be considered non-sterile and the instruments reprocessed.

Storage

Store wrapped introducer in a designated sterile supply area that protects sterile items and their packaging from damage.

Additional Information

When in doubt to proper care and maintenance procedures, please contact your local Caldera Medical sales representative.

Precautions regarding transmission of Creutzfeldt-Jacob disease (CJD):

- CJD is the human transmissible spongiform encephalopathy (TSE) variant agent which is recognized as resistant to the normal disinfection and sterilization procedures.
- The intended use for the Caldera Medical re-usable instruments are recognized as low risk procedures for the transmission of CJD. Deactivation of the CJD agent is being actively researched at this time and is beyond the scope of these instructions.
- Facilities reprocessing surgical instruments must take particular precautions when handling instruments used on patients at high risk for CJD to not only deactivate the CJD agent but also to reduce cross contamination during the transportation and cleaning processes.

Caldera Medical, Inc. as a manufacturer and seller of the instruments, which are the subject of this manual, is not responsible for any direct or indirect damages resulting from improper or incorrect use, care, or servicing of these instruments, or from the failure to follow the guidelines contained in this manual.

If non-authorized persons perform any repairs or modifications of this product, Caldera Medical, Inc. does not accept any liability and the warranty becomes void. Components influencing safety may only be replaced with original replacement parts.

This product and manual are subject to technical changes and modifications without notice.

References

These recommendations are developed using the following:

1. ANSI/AAMI ST79:2006 "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities".
2. AAMI TIR12:2010 "Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers."

Note: All cleaning and sterilization procedures should be validated by the health care facility performing these operations.

This page intentionally left blank.

 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