Desara® and Desara® Blue

Sling for Female Stress Urinary Incontinence

Instructions For Use

Manufactured by:
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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.

Indication

Desara® and Desara® Blue 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.

CONTRAINDICATIONS

- Do not implant in patients with sensitivity or allergies to polypropylene products.
- 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, tissue necrosis or immune-compromised tissue or tissue connective disorders.
- Do not use this device in patients with any pathology which would compromise implant placement.
- Do not use in patient with prior incontinence surgery.

WARNINGS

- It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, 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.
- A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure
- The reuse, reprocessing or re-sterilization 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 re-sterilization of a single-use device can have ethical, legal and regulatory implications.
- 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. Users should be familiar with surgical procedures and techniques involving non-asorbable meshes.

- Users should have a good knowledge of pelvic anatomy and the correct use of the introducer needles to avoid damage to adjacent anatomical structure before implanting Desara® and Desara® Blue.
- Caldera Medical Desara® and Desara® Blue family of implants are designed for, and should be used only with a Caldera Medical introducer designed for the physician's implant technique. Before use, the introducer should be visually inspected. Defective introducers should not be used.
- 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® or Desara® Blue procedure through a separate incision in the anterior vaginal wall or as performed per the Physicians standard of care.
- Users should note the importance of placing the mesh tension free under the urethra. Ensure that the Implant is placed with minimal tension under the mid-urethra. As with other incontinence procedures, de novo detrusor instability may occur following a pubo-urethral procedure utilizing the the Desara® and Desara® Blue. To minimize this risk, make sure to place the Implant tension-free in the mid-urethral position.
- Since limited clinical information is available about pregnancy following pubo-urethral sling procedures with Desara® and Desara® Blue, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- 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.
- Polypropylene should not be placed in contact with bowel or visceral organs including the urinary bladder.
- Do not implant Desara® or Desara® Blue family of implants with any staples or clips as mechanical damage to the mesh may occur.
- Ensure that the mesh implant is positioned symmetrically to achieve desired results.
- To avoid device breakage or patient injury upon implantation, if high level of resistance is encountered, withdraw sling and reattempt placement.
- Do not remove the sleeves covering the mesh implant until the proper position and tensioning has been confirmed.
- Post-operatively, the patient should be advised to rest be advised to refrain from heavy lifting and/or exercise and from intercourse per the Physician's direction. The Physician should determine when it is suitable for each patient to return to normal activities.
- Do not perform this procedure if you think the surgical site may be infected or contaminated. Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Bleeding may occur postoperatively as with any sling procedure. Observe for any symptoms or signs before the patient is released from the hospital.
- Cystoscopy should be performed at the discretion of the surgeon to confirm bladder integrity and to recognize any inadvertent bladder or urethral injury or perforation.
- Should dysuria, bleeding, pain, discharge, signs of infection or other problems occur, the patient should be instructed to contact the surgeon immediately.
- 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 and additional surgeries may not always fully correct the complications.
- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an

appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.

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:

- As with all surgical procedures, patients with certain underlying conditions may be more susceptible to adverse reactions.
- Potential complications include, but are not limited to, abscess (acute or delayed), adhesion/scar formation, hypersensitivity or other immune reaction, bleeding (per- or post-op), 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), pelvic/urogenital pain, groin pain, hip pain (may be related to patient positioning) 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, 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, nausea, reaction to antibiotic, slight discomfort when returning to normal activities.
- As with all foreign bodies, Desara® and Desara® Blue family of implants may potentiate an existing infection.
- Allergic reaction may occur. Do not use if the patient is allergic to polypropylene or any other material that comprises the Desara® One implant and introducer.
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse. Pain with intercourse (dyspareunia), and loss of sexual function (apareunia), which may be ongoing and may not resolve in some patients.
- The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, suprapubic or transobturator) has been associated with cases of erosion. Erosion has been reported in the bladder, vagina, urethra, ureter, and bowel. Treatment of the erosion may require surgical removal.
- Desara® and Desara® Blue 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. Removal of the implant in whole or in part will not necessarily alleviate the patient's symptoms. Removal of part of the implant can be difficult. Surgery to remove the whole or part of an implant can result in further scarring and tissue damage which, in turn, may have adverse outcomes including severe chronic pain which may not be able to be satisfactorily treated. Surgery to remove the whole or part of the implant may also result in recurrence of SUI. Removal of the eroded mesh will not necessarily prevent further erosions or other adverse events.
- Over-correction, i.e., too much tension applied to the implant, may cause temporary or permanent lower urinary tract obstruction. If this occurs, this can lead to the need for prolonged foley catheter use and/or additional surgery to release the sling.
- Use of Desara® and Desara® Blue may lead to serious injury or even death.
- Surgical risks not associated directly with the use of the product, its function, or method of

implantation require understanding and consideration by a qualified surgeon who is knowledgeable of anatomy, medical treatments and procedures for conditions appropriately treated with this product. The information provided is not comprehensive with regard to product risks.

- The physician must determine the risks that should be included in the patient informed consent. 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.

PACKAGING

The sterile mesh is contained within a double sealed pouch. If the pouch is open or damaged do not use.

PACKAGING / PRODUCT LABELING SYMBOLS

Symbols utilized on Desara® and Desara® Blue labeling are in compliance with ISO 15223. A glossary of symbols can be accessed here: www.calderamedical.com. To request a printed copy, contact us at +1.818.879.6555, fax at +1.818.879.6556 or info@calderamedical.com.

Symbol	Title/ Meaning / Referent	Symbol	Title / Meaning / Referent
	**Manufacturer**		**Non-sterile**
	**Date of Manufacture**		**Keep Dry**
	**Use by Date**		**Do Not Re-use**
	**Batch Code**		**Consult Instructions for Use**
	**Catalogue number**	 [IFU URL]	**Consult Instructions for Use, or For Instructions for Use Refer to**
	**Sterilized Using Ethylene Oxide**		**Caution**
	**Do Not Re-sterilize**		**Packaging Unit**
	**Do Not Use If Package Is Damaged**	℞ ONLY	**Prescription Only**

PRODUCT TRACEABILITY

Traceability labels are enclosed with every Desara® and Desara® Blue implant, which identifies the type, size and lot number of the implant. 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® and Desara® Blue implants are provided sterile and labeled for single use only. Desara® and Desara® Blue implants are terminally sterilized by ethylene oxide (EO). Packaging should not be opened until time of use.

- Do not re-sterilize this product.
- Do not use if package is opened or damaged.
- Do not use after expiration date.

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.
- Do not use if the product packaging is damaged or open prior to use.

NATURAL RUBBER LATEX STATEMENT

The Desara® and Desara® Blue are not made with natural rubber latex. Manufacturing processes for Desara® and Desara® Blue do not contain natural rubber latex and are not manufactured in the presence of natural rubber latex.

MAGENTIC RESONANCE IMAGING (MRI) STATEMENT

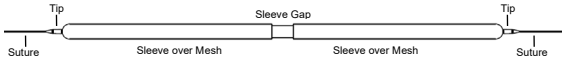
Desara® and Desara® Blue are designated MRI Safe.

Desara® and Desara® Blue
Guide for Use

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

Desara® – Item #CAL-DS01 and Desara® Blue – Item #CAL-DS01B Description

Monofilament polypropylene, warp knitted into a mesh.



SURGICAL IMPLANT TECHNIQUES

Note: The instructions provided are for general use of Desara® and Desara® Blue, it is not a comprehensive guide for surgical technique correcting stress urinary incontinence (SUI) and is not a substitute for appropriate SUI training and experience. Desara® and Desara® Blue are intended to be used only by surgeons trained in the surgical treatment of SUI and also trained in the use of Desara® and Desara® Blue. Adverse reactions may occur notwithstanding the training and experience of the surgeon. Variations in use may occur due to surgeon technique, patient anatomy and other surgical factors.

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 in the sub-urethral area.

A. Suprapubic Introducer (CAL-SP01)

1. Blunt and/or sharp paraurethral dissection is performed to allow the introducer tip to pass through the vaginal incision.
2. Two suprapubic stab incisions are created over the pubic symphysis approximately 1 cm lateral of midline.
3. Insert the Suprapubic Introducer (CAL-SP01) and move the handle cephalad so the tip of the introducer is directed to the posterior surface of the pubic symphysis.
4. Move the introducer down the superior side of the pubic bone through the Space of Retzius, avoiding the bladder. Maintain the introducer position close to the pubic bone to avoid any adverse events.
5. Using finger tip palpation, guide the introducer through the endopelvic fascia into the vaginal incision. Guidance of the introducer using finger palpation is recommended to avoid adverse events.
6. Perform steps 1-8 in section C. to complete the procedure.

B. Transobturator Introducers - Outside In (CAL-HL04, CAL-HR05, CAL-HR32, CAL-HR32, CAL-TB03, CAL-LHL01, CAL-LHR02, CAL-LHL32, CAL-LHR32)

1. Blunt and/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. Place the Helical, Hook, or Large Helical 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 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 until it exits through the vaginal incision. Maintain continuous finger palpation with the introducer tip passing close to the ischiopubic ramus to avoid any adverse events.
6. Perform steps 1-8 in section C. to complete the procedure.

C. Surgical Mesh Implantation for the Suprapubic and Transobturator Outside In Approach:

1. 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.
2. Remove the introducer from the suture loop.
3. Repeat steps 3-5 of section A. or B., as appropriate, on the contralateral side.
4. Place the sling in a tension free manner under the mid urethra.

Note: it is recommended that when tensioning the mesh:

- Remove any extra instrumentation near the vaginal opening that may distort tissue during the tensioning process.
- Leave enough space to allow easy placement, removal, and replacement of the spacer (using an in and out motion with the spacer between the mesh and urethra)
- Keep counter-traction on the sling when removing the sheath to avoid any tensioning rebound or overtightening.

5. Cystoscopy should be performed to rule out any bladder or urethral injuries or perforations.
6. Cut off the ends of the mesh assembly medial to the tip and suture connection system and pull off the sheath.
7. Trim the portion of the mesh that extends past the groin or suprapubic incisions just below the level of the skin.
8. Incisions are closed according to usual methods.

D. Transvaginal Introducer (CAL-TV02/TV32/ CAL-TV32T)

1. Blunt and/or sharp paraurethral dissection is performed to allow the Transvaginal Introducer to pass through the Space of Retzius. Hydrodissection in the sulci may also be performed.
2. Two stab incisions may be created over the pubic symphysis approximately 1 cm lateral of midline to demarcate introducer pathway. Conversely, stab incisions may be made over the introducer tip by: maintaining a pathway, aiming toward to the ipsilateral shoulder until the tip of the introducer is in the subcutaneous area just lateral to the midline and incise over the introducer tip
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 throughout passage of mesh through tissue On the contralateral side, confirm mesh is flat and untwisted along the entire length of placement.
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.

   Note: it is recommended that when tensioning the mesh:
   - Remove any extra instrumentation near the vaginal opening that may distort tissue during the tensioning process.
   - Leave enough space to allow easy placement, removal, and replacement of the spacer (using an in and out motion with the spacer between the mesh and urethra)
   - Keep counter-traction on the sling when removing the sheath to avoid any tensioning rebound or overtightening.
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. Palpate the sulcus to confirm proper placement.
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.

E. Transobturator Introducers- Inside Out (CAL-IO6, CAL-IO7, CAL-IOL32, CAL-IOR32)

1. Blunt and/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 5cm 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.

Note: it is recommended that when tensioning the mesh:

- Remove any extra instrumentation near the vaginal opening that may distort tissue during the tensioning process.
- Leave enough space to allow easy placement, removal, and replacement of the spacer (using an in and out motion with the spacer between the mesh and urethra)
- Keep counter-traction on the sling when removing the sheath to avoid any tensioning rebound or overtightening.

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 with estrogen or other fluid can be used at the discretion of the surgeon.
- Physician should determine post operative care plan and when it is suitable for each patient to return to normal activities.
- The patient should be instructed to contact the surgeon immediately should dysuria, bleeding, pain, discharge, signs of infection or other problems occur.
- For information on introducer care and handling, please refer to Caldera Medical's Guide for Cleaning, Sterilization and Storage of Reusable Introducers.

PRODUCT DISPOSAL

Discard any open and or used devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

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

To learn more about Desara® TV and Desara® Blue TV, other products for incontinence, and product evaluations and training, contact Caldera Medical at +1.818.879.6555 or visit our website at www.calderamedical.com.