Desara® TV and Desara® Blue TV

Sling for Female Stress Urinary Incontinence

Instructions For Use

Manufactured by:
Caldera Medical, Inc.
4360 Park Terrace Drive
Westlake Village, CA 91361
Telephone: +1.818.879.6555
Fax: +1.818.879.6556
www.calderamedical.com

10-139-06 Rev D

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® TV and Desara® Blue TV 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 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.
- 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 nonabsorbable 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® TV and Desara® Blue TV 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® TV or Desara® Blue TV 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® TV and Desara® Blue TV. 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® TV and Desara® Blue TV, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- 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.
- 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® TV or Desara® Blue TV 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, advised to refrain from heavy lifting and/or exercise and from intercourseper the Physicians direction.. The Physician should determine when it is suitable for each patient to return to normal activities.
- 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 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 surgiers 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® TV and Desara® Blue TV 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® TV and Desara® Blue TV or 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® TV and Desara® Blue TV 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® TV and Desara® Blue TV 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® TV or Desara® Blue TV labeling are in compliance with ISO 15223. A glossary of symbols can be accessed here: www.calderamedical.com. To request a printed copy, please 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 Resterilize**		**Packaging Unit**
	**Do Not Use If Package Is Damaged**		**Prescription Only**

PRODUCT TRACEABILITY

Traceability labels are enclosed with every Desara® TV or Desara® Blue TV 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® TV and Desara® Blue TV implants are provided sterile and labeled as single use only. Desara® TV and Desara® Blue TV 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

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

MAGENTIC RESONANCE IMAGING (MRI) STATEMENT

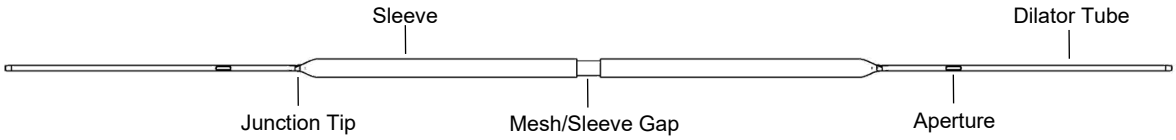
Desara® TV or Desara® Blue TV are designated as MRI Safe.

Desara® TV and Desara® Blue TV
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® TV – Item #CAL-DS01TV and Desara® Blue TV– Item #CAL-DS01BTV Description

Monofilament polypropylene, warp knitted into a mesh.



SURGICAL IMPLANT TECHNIQUE

Note: The instructions provided are for general use of Desara® TV and Desara® Blue TV, 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® TV and Desara® Blue TV are intended to be used only by surgeons trained in the surgical treatment of SUI and also trained in the use of Desara® TV and Desara® Blue TV. 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 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 at the level of the mid-urethra.

<u>Using the Caldera Medical Transvaginal Introducer (CAL-TV32/CAL-TV32T):</u>

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. Locate the aperture on the dilator tube, and place one dilator tube assembly over the Transvaginal 3.2 mm Introducer.
3. Two stab incisions may becreated over the pubic symphysis approximately 1-2 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
4. Pass the Transvaginal Introducer and dilator tube assembly through the vaginal incision up

through the retropubic space adjacent 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 the mesh through the tissue.
6. While Desara TV is in place, grasp the dilator tube at the junction with the sleeve where colored green, and slowly withdraw the rigid introducer out of the dilator tube through the vaginal incision. Alternatively, you can grasp the dilator tube tip at the suprapubic exit point while withdrawing the introducer.
7. Once the introducer is removed, place a clamp on the dilator tube tip to hold it in place prior to placing the opposite side.
8. Repeat steps 3 - 7 on the contralateral side.
9. Cystoscopy should be performed to rule out any bladder perforations.
10. Place the sling in a tension free manner under the mid urethra.
11. Place the sling in a tension free manner under the mid urethra.
    a. Note: it is recommended that when tensioning the mesh:
12. Remove any extra instrumentation near the vaginal opening that may distort tissue during the tensioning process.
13. 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)
14. Keep counter-traction on the sling when removing the sheath to avoid any tensioing rebound or overtightening.
15. Palpate the sulcus to confirm proper placement.
16. Cut off the ends of the mesh assembly medial to the tip and dilator tube and pull off the sleeve.
17. Trim the excess mesh that extends beyond the suprapubic incisions so the mesh lies below the skin.
18. 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.