Desara® TV and Desara® Blue TV

Sling for Female Stress Urinary Incontinence

Instructions For Use

℞	Prescription Use only
	Do not reuse
STERILE	Sterilized using ethylene oxide
	Available Electronically

Manufactured by:
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10-139-06 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® 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.
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® TV or Desara® Blue TV 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® TV or Desara® Blue TV 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® TV and Desara® Blue TV family of implants may potentiate an existing infection.
- Allergic reaction may occur.
- 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.
- 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® TV and Desara® Blue TV 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. If the pouch is open or damaged do not use.

Storage

This product must be stored at room temperature in a clean dry place.

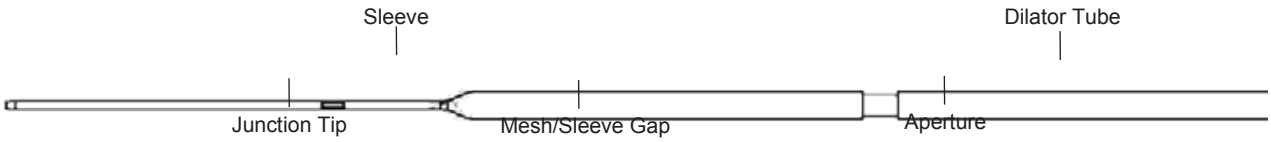
- Do not expose product to direct sunlight, humid environments or extreme temperatures.
- Do not use after the expiration date.

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

Monofilament polypropylene, warp knitted into a mesh.



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.

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.

Surgical Implant Technique

Using the Caldera Medical Transvaginal Introducer (CAL-TV32):

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 1-2 cm lateral of midline.
3. Locate the aperture on the dilator tube, and place one dilator tube assembly over the Transvaginal 3.2 mm Introducer.
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.
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. Cut off the ends of the mesh assembly medial to the tip and dilator tube and pull off the sleeve.
12. Trim the excess mesh that extends beyond the suprapubic incisions so the mesh lies below the skin.
13. 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.

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® TV and Desara® Blue TV, other products for incontinence, and product evaluations and training, contact Caldera Medical at 866.422.5337 or visit our website at www.calderamedical.com.

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