Desara® One

Single Incision Sling for female stress urinary incontinence

Instructions for Use

Manufactured by:
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10-395 Rev C

Instructions for Use
Desara® One

CAUTION: Federal Law restricts use of this device to physicians trained in performing mid-urethral 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

- Do not implant in patients with known sensitivity or allergy to polypropylene products.
- Should not be implanted in patients while on anticoagulants, aspirin, non-steroidal anti-inflammatory agents, or in those with blood coagulation disorders.
- It should not be utilized in patients with future growth potential, including women with plans for future pregnancies or those currently pregnant.
- Do not use this 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 the implant.
- Do not use this device in patients with active or latent urinary tract infections, infections in the operative field, tissue necrosis or immuno-compromised tissue or connective tissue disorders.
- Do not use this device in patients with any pathology which would compromise implant placement.
- Do not use this device in patients with prior incontinence surgery.

WARNINGS AND PRECAUTIONS

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician. Training on the use of Desara® One is recommended and available. Contact your company sales representative to arrange for this training. Physicians should have experience in the transvaginal placement of non-absorbable implants for the treatment of female SUI including the management of potential complications resulting from transvaginal placement of surgical implants.

- Desara® One is provided by Caldera Medical as a sterile product. It is intended for single-use only. Do not re-sterilize. If packaging is opened or damaged it is no longer considered sterile and should not be used clinically. Discard any unused product. 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 for 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. Implantation of Desara® One requires good knowledge of pelvic anatomy and the correct use of the introducers in order to avoid damage to adjacent anatomical structures.

- A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh sling procedure.
- The patient should be counseled that alternative incontinence treatments may be appropriate, and the reason for choosing a mesh sling procedure should be explained. Patient consent should be obtained prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transvaginal mesh sling surgery.
- 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 physician must determine the risks that should be included in the patient informed consent.
- Caldera Medical Desara® One implant is designed for, and should be used only with, a Caldera Medical Desara® One introducer designed for Single Incision Implant technique.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires cystocelle repair, it should be done prior to the Desara® One procedure through a separate incision in the anterior vaginal wall.
- Cystoscopy is recommended and may be performed at the discretion of the surgeon to confirm bladder integrity and to recognize any inadvertent bladder perforation.
- Bleeding may occur postoperatively as with any sling procedure. Observe for any symptoms or signs before the patient is released from the hospital.
- Users should note the importance of placing the implant under the appropriate tension in the mid portion of the urethra. Avoid placing excessive tension on Desara® One during placement and adjustment to maintain sling integrity and to avoid compression of the urethra when tensioning.
- Do not implant Desara® One with any staples or clips as mechanical damage to the mesh may occur.
- If excessive resistance is encountered during insertion, stop and evaluate prior to proceeding because the introducer tip may be in contact with the posterior edge of the ischiopubic ramus.
- Duration of catheter use or vaginal pack should be minimized after implantation of Desara® One.
- Polypropylene implant should not be placed in contact with bowel or visceral organs including the urinary bladder.
- As with all sling procedures, the patient should be counseled that future pregnancies may alter the effects of the Desara® One procedure and the patient may again become incontinent.
- Patients should be counseled on abstaining from heavy lifting, exercise and intercourse for a minimum of 4 weeks. The patient can return to other normal daily activities at the physician’s discretion.
- Patients should be counseled to report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.
- Patient counseling should include a discussion that the sling to be implanted is a permanent implant and that some complications associated with the implant mesh sling may require additional surgery; repeat surgery may not resolve these complications and/or symptoms. Complete removal of the sling may not always be possible, and additional surgeries may not always fully correct the complications. Patients may experience varying degrees of scarring.
- The Desara® One is a single incision and minimally invasive synthetic implant sling for vaginal repair of stress urinary incontinence (SUI). Compared to multi-incision retropubic and transobturator mid-urethral slings for SUI, there is relatively less published data on the safety and effectiveness of single incision slings. Single incision slings may have a lower cure rate compared with standard length mid-urethral slings. There are no clinical performance data published in peer-reviewed journals on the Desara® One.

ADVERSE REACTIONS

Potential adverse reactions are similar to those associated with other surgically implanted polypropylene implant. 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.
- 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® One implant is a permanent implant that integrates into the tissue 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® One 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 device is contained within a sealed tray. If any part of the tray, including the seal, is damaged or unsealed, **do not use**.

PRODUCT LABELING SYMBOLS

Symbols utilized on Desara® One labeling is 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 Resterilize**		**Packaging Unit**
	**Do Not Use If Package Is Damaged**		**Prescription Only**

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 used so patients can be notified in the event of a product recall.

STERILIZATION

Desara® One devices are provided sterile and labeled for single use only. Desara® One devices 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

Desara® One is not made with natural rubber latex. Manufacturing processes for Desara® One does not contain natural rubber latex and is not manufactured in the presence of natural rubber latex.

MAGNETIC RESONANCE IMAGING (MRI) STATEMENT

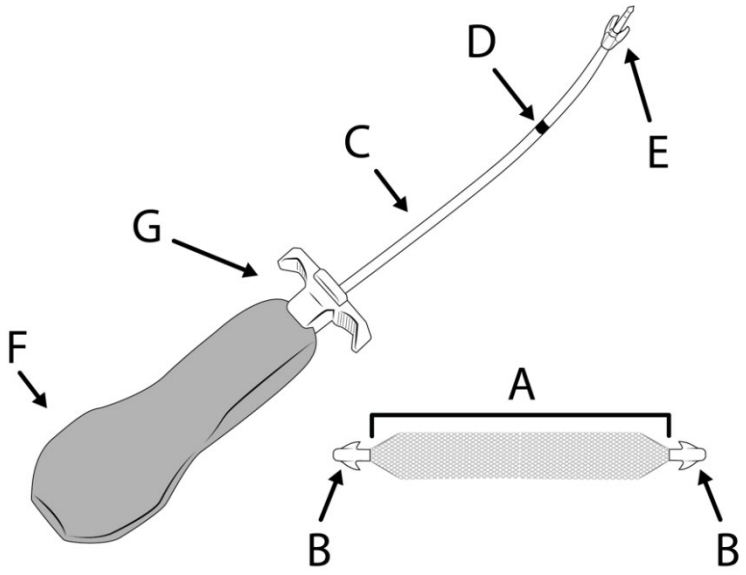
Desara® One is designated as MRI Safe.

Desara® One Guide for Use

DESCRIPTION

The Desara® One system is shown below in Figure 1 and consists of one (1) monofilament polypropylene warp-knit implant and one (1) single incision introducer to place the implant. The sling is comprised of a strip of polypropylene (A) with polypropylene anchors located bilaterally (B). The introducer is comprised of an introducer wire (C), a midline marker (D), an introducer tip with disengagement wings (E) designed to mate with the implant's anchors, a handle (F), and two anchor release buttons (G).

Figure 1 Desara® One Introducer and Implant Components



INDICATIONS FOR USE

The Desara® One mid-urethral mesh implant is intended for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

The Desara® One introducer is intended for the placement of the Desara® One single incision mesh implant.

PATIENT PREPARATION

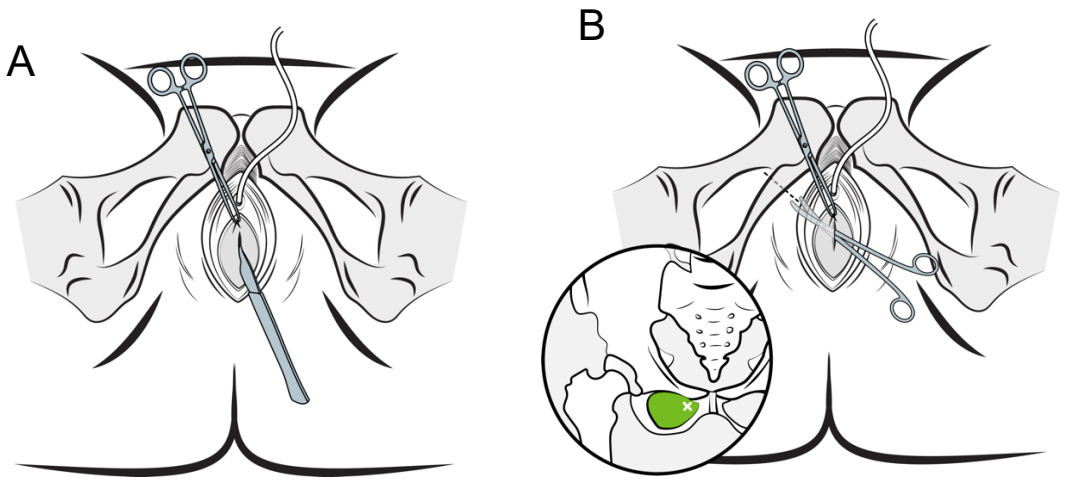
- Use appropriate local, spinal or general anesthesia.
- Place the patient in a modified dorsal lithotomy position with the hips flexed, legs elevated in stirrups, and buttocks even with or slightly extending beyond the edge of table.
- Patient should be thoroughly prepped using an antiseptic solution and properly draped.
- Completely drain the bladder prior to beginning the dissection with a Foley catheter.

INCISE AND DISSECT PATIENT USING STANDARD TECHNIQUES

Perform a full thickness vertical incision at the level of the mid-urethra, wide enough to accommodate at least the width of the sling. **See Figure 2A**

- It is recommended to hold the vaginal epithelium taut during placement. Local anesthetic may be used to anesthetize and hydrodissect the surgical site.
- Perform a full thickness paraurethral dissection towards the ischiopubic ramus from the midline bilaterally. Dissect laterally toward the obturator internus muscle until under the ipsilateral ischiopubic ramus, creating a peri-urethral space for the sling. **See Figure 2B**
- Dissecting to the obturator internus muscle improves ease and proper anchor placement.

Figure 2: Incision and Dissection



Warning: Desara® One should only be implanted after confirming absence of urethral injury via visual inspection of the urethral surface with a Foley catheter in place.

- The Desara® One package can now be opened.
- Be certain that the package integrity has not been compromised in shipping and verify that the expiration date is valid relative to the date of the surgery.
- Ensure that the tray is oriented upright before fully peeling the package open. While holding the tray steady, remove the inner tray lid, and then the introducer and sling.

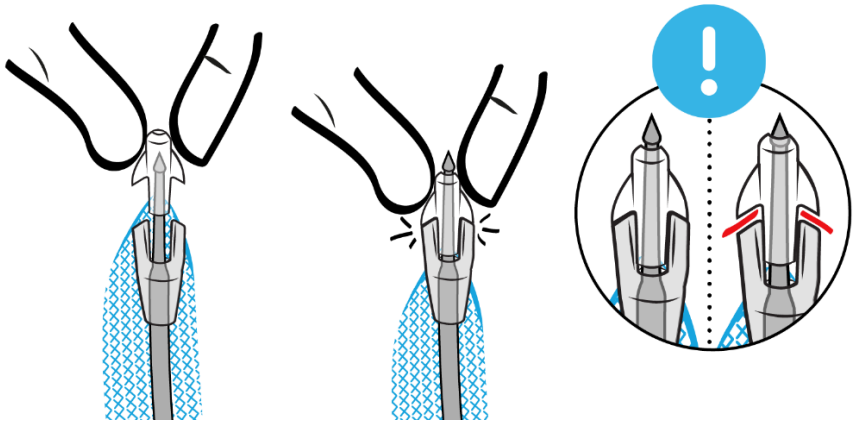
Preparing Device for Surgery. See Figure 3

NOTES:

- Be certain that the entire implant stays within the sterile field during passage through the tissues.
- Care should be used when handling the implant around sharp objects; implant damage may occur.
- The introducer tip is keyed to the anchors to prevent rotation during placement.
- The anchors snaps onto the introducer tip to prevent disengagement during placement.
- Avoid pulling on the implant while loading the anchors onto the introducer tip; implant damage may occur.

1. Load Desara® One onto the introducer, ensuring that the anchor is oriented such that the implant wraps along the outside of the introducer.
2. Press the implant's anchor onto the introducer tip until it is securely affixed to the introducer. A "click" should be felt.
3. Make sure anchor is completely engaged with no significant gap between the anchor and the disengagement wings.

Figure 3: Tip Attachment



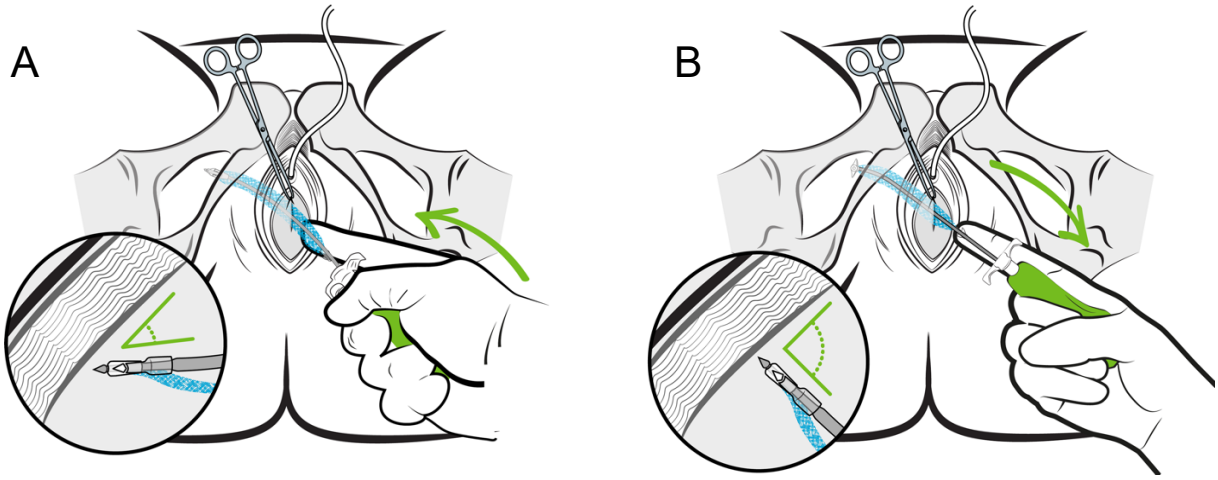
CAUTION: Use care when handling the implant to avoid possible glove puncture.

SURGICAL IMPLANT PROCEDURE

1. Advance the introducer through the previous dissection aiming for the medial edge of the obturator foramen. An index finger may help guide the introducer tip during placement. **See Figure 4A.**
2. Once beyond the ischiopubic ramus, orientate the tip so the anchor is advancing into the obturator internus muscle at a perpendicular angle. **See Figure 4B.**

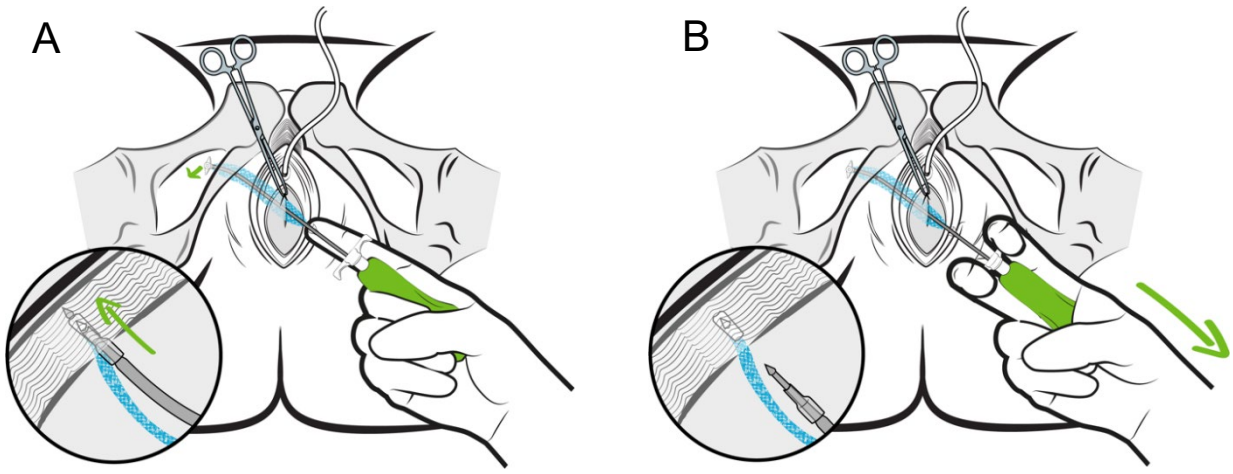
Warning: If a high level of resistance is encountered, as may happen if pressing against the pubic bone, withdraw the introducer and anchor tip, reassess implant trajectory and reattempt placement.

Figure 4: Tip Approach and Orientation



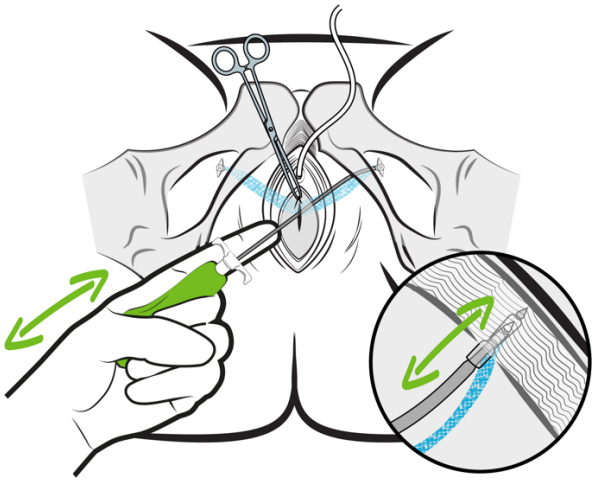
3. Insert the tip perpendicularly into the obturator internus muscle until the introducer's mid-line mark is aligned with the midline of the urethra. Avoid pulling back on the release buttons during anchor insertion. **See Figure 5A.**
4. Once satisfied with the location of the tip, deploy the first anchor by pressing down on the introducer release buttons. Keep pressing the release buttons, while removing the introducer back. **See Figure 5B.**

Figure 5: Tip Insertion and Anchor Release



5. Load the contralateral anchor ensuring that the implant is not twisted.

Figure 6: Second Tip Placement

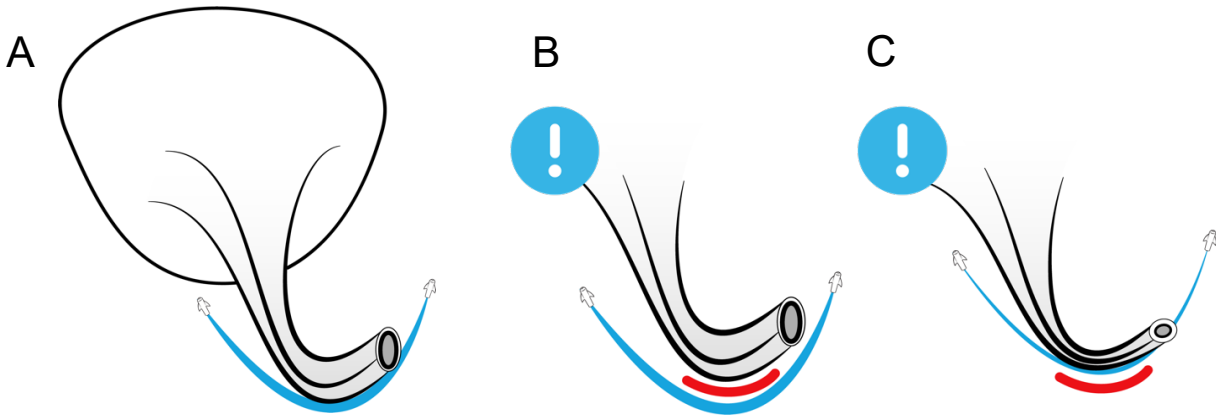


6. Use the previous steps to place the second anchor.
7. Adjust the tension if needed. **Do not release the anchor until the correct tensioning is achieved.**

ADJUSTING SURGICAL IMPLANT TENSION

1. Anchor location is adjustable bidirectionally prior to deployment.
2. Tension such that the implant lies directly up and flat against the urethra. **See Figure 7A.**
3. There should be no space between the mesh and the urethra. **See Figure 7B.**
4. Avoid excessive tension that visually depresses the urethra or significantly narrows the implant under the urethra. **See Figure 7C.**

Figure 7: Adjusting Surgical Implant Tension



A Cystoscopy may be performed to rule out any bladder or urethral perforations.

- **Caution: Avoid pulling back on the Release Buttons during anchor insertion.**

POST-OPERATIVE CARE

- A catheter and vaginal packing with estrogen can be used at the discretion of the surgeon.
- The ability of the patient to empty the bladder should be confirmed post-procedure.
- Post-procedure antibiotic can be administered at the physician's discretion.
- If dysuria, bleeding, severe pain, inability to empty the bladder, or other problems occur, the patient should be instructed to call the physician immediately.

PRODUCT DISPOSAL

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

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