Guide for Cleaning, Sterilization and Storage of Instruments for Desara® Product Family of Implants

Manufacturer by:
Caldera Medical, Inc.
4360 Park Terrace Drive, Suite 140
Westlake Village, CA 91361
Telephone: 818-879-6555
Fax: 818-879-6556
www.calderamedical.com

1. INDICATIONS FOR USE

The Caldera Medical surgical mesh instruments are intended to be used in surgical procedures for the insertion and placement of Desara® surgical mesh indicated for treatment of Genuine Stress Urinary Incontinence (SUI) and mixed incontinence.

For Indications for Use for each Caldera Medical Desara® implant (sling) product, please review their respective Instructions For Use (IFU).

2. INSTRUMENTS DESCRIPTION

The Caldera Medical Reusable Surgical Introducers and Winged Guide Accessory are referred to collectively as "Instruments". The Reusable Introducers may commonly be referred to as instruments, trocars and/or needles. The Winged Guide Accessory may be referred to as the winged guide or guide and is for use with the Caldera Medical Inside-Out introducers only.

Caldera Medical surgical instruments are to be used with Caldera Medical implants only. The instruments have been validated for use with the following Desara® implants only:

For surgical technique of instruments, please review the Instructions For Use (IFU) for each Caldera Medical Desara® implant (sling) product.

Surgical Approach		Caldera Medical Implant (sling)	Caldera Medical Implant IFU	Caldera Medical Instrument Catalog Codes
Transobturator	Outside-In (Helical or Hook)	Desara® (CAL-DS01) Desara® Blue (CAL-DS01B) Desara® OV (CAL-DS01OV) Desara® Blue OV (CAL-DS01BOV) Desara® SL (CAL-DS01SL) Desara® Blue SL (CAL-DS01BSL) Desara® SS (CAL-DS01SS) Desara® Blue SS (CAL-DS01BS)	10-139-03 10-139-05 10-122 10-139-04	CAL-HL04/CAL-HR05 CAL-HL32/CAL-HR32 CAL-LHL1/CAL-LHR2 CAL-LHL32/CAL-LHR32 CAL-TB03
	Inside-Out	Desara® (CAL-DS01) Desara® Blue (CAL-DS01B) Desara® OV (CAL-DS01OV) Desara® Blue OV (CAL-DS01BOV) Desara® SL (CAL-DS01SL) Desara® Blue SL (CAL-DS01BSL) Desara® SS (CAL-DS01SS) Desara® Blue SS (CAL-DS01BS)	10-139-03 10-139-05 10-122 10-139-04	CAL-IO6/CAL-IO7 CAL-IOR32/CAL-IOL32 with Winged Guide Accessory CAL-WI
Retropubic	Suprapubic	Desara® (CAL-DS01) Desara® Blue (CAL-DS01B) Desara® OV (CAL-DS01OV) Desara® Blue OV (CAL-DS01BOV) Desara® SS (CAL-DS01SS) Desara® Blue SS (CAL-DS01BS)	10-139-03 10-139-05 10-139-04	Suprapubic (CAL-SP01)
	Transvaginal	Desara® (CAL-DS01) Desara® Blue (CAL-DS01B) Desara® Blue OV (CAL-DS01BOV) Desara® TV (CAL-DS01TV)* Desara® Blue TV (CAL(DS01BTV)*	10-139-03 10-139-03 10-139-05 10-139-06 10-139-06	Transvaginal (CAL-TV02) Transvaginal (CAL-TV32) Transvaginal 32T (CAL-TV32T) *Can only be used with CAL-TV32 or CAL-TV32T

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

3. WARNINGS AND PRECAUTIONS

Warnings

- Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices. Always handle with care.
- Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment in accordance with applicable health and safety procedures. 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 instruments 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 introducers.
- 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 introducers over time.
- As with any surgical instruments, careful attention should be made to assure that excessive force is not placed on any instruments. Excessive force can result in failure.
- If the instrument does not function properly or does not meet the inspection criteria specified in Section 5 and 6, 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 solutions (pH > 10).
- If all debris is not removed from the suture slot of the introducer wire through proper cleaning, the suture slot may not function as intended and/or increase risk of patient harm.
- Introducers should not be modified in any way. Modifications to introducers may result in product failure, patient and/or user harm.

Precautions

- A surgeon should not begin clinical use of the instruments without reviewing the implant product Instructions For Use. (Refer to *Instruments Description* on Section 2). It is imperative that appropriate personnel read all guideline materials prior to surgery. If the guidelines are not properly followed, the risk of complications to the patient increases.

- 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 reusable introducers 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 introducers must take particular precautions when handling introducers 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.

4. MATERIALS

The reusable introducer component materials are:

- Stainless steel wire / needle
- Anodized aluminum handle
- Medical grade epoxy
- Stainless steel locking pin

The winged guide introducer accessory material is:

- Stainless steel

5. REUSE / SHELF-LIFE

For the Reusable Surgical Introducers, end of life is normally determined by wear and damage due to use. Refer to Section 6 for further information.

The Winged Guides are disposable and single use only.

6. INSPECTION AND MAINTENANCE OF REUSABLE INTRODUCERS

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 introducers prior to and after cleaning for damage, excessive wear and/or corrosion. Do not use any introducers with any evidence of damage or excessive wear or corrosion and contact Caldera Medical.
- Visually inspect the wire-to-handle connection or joint. The connection between the wire and handle should be entirely sealed and not have any divots, partially filled rings or open spaces.
- The distal tip and slot features should be smooth without denting, bending, cracks, burrs or fractured surfaces. The slot should be free and clear of any debris.
- The handle and introducer 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 introducer wire should be firmly attached to the handle and not disengage. Shake the introducer handle. If the wire feels or sounds loose and/or disengages, do not use. Firmly grip the wire and handle and pull in opposite directions. If the wire feels loose and/or disengages, do not use.
- Labeling should be legible.
- If any defects are observed, contact Caldera Medical. Refer to contact information on the final page of this IFU.

7. PREPARATION FOR USE

All instruments, including single-use Winged Guides, are sold non-sterile and must be cleaned and sterilized prior to first use. Introducers labeled as reusable can be re-used after appropriate cleaning and sterilization as per this guidance.

8. MANUAL CLEANING

For all instruments

Warning: *Prior to initiating cleaning, remove packaging, such as protective wire tips.*

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

Note For reusable introducers: To prevent the drying of blood and tissue residues and growth of microorganisms, introducers 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.

1. Thoroughly rinse instruments under cool running tap water (~20°C/68°F) for at least 90 seconds to remove all gross soil and contaminants. Using a soft bristle brush, scrub in circular strokes until no soil and contaminants are visible. Ensure that all debris is removed from the suture slot of reusable introducers. A syringe to flush the suture slot opening and hard to reach areas of the introducers is recommended.
2. Prepare mild, proteolytic (pH) enzymatic detergent, according to the manufacturer's instructions using lukewarm (~33°C/91°F) tap water. Verify that detergent expiration has not been exceeded. Verify facility processed water quality checks are current. Verify recommended splash, skin and inhalation protection IPPE) measures are in place.
3. Fully immerse and soak instruments for a minimum of 10 minutes. No assembly or disassembly is required.
4. Remove from the detergent soak solution and perform cleaning under a water surface to limit aerosolization of the cleaning fluid and soil. Thoroughly clean all organic and contaminant material from instruments. Scrub in circular strokes using soft bristle brushes for at least one (1) minute until all visible soil and contaminants are removed. A syringe to flush the suture slot opening and hard to reach areas of the introducers is recommended. Pay particular attention to all areas where soil and contaminants could be embedded (such as grooves, crevices, or suture slot opening).
5. After cleaning, thoroughly rinse instruments using running cold (~20°C/68°F) tap water for at least one (1) minute. During this rinse, flush the instrument crevices and gently scrub in circular strokes using a soft bristle brush. A syringe to flush the suture slot opening of the introducers is recommended.
6. Using warm (~38°C/100°F) tap water for at least one (1) minute, flush and rinse the instruments again. A syringe to flush the suture slot opening of the introducers is recommended.
7. Rinse thoroughly for at least one (1) minute using cold (~20°C/68°F) reverse osmosis / deionized water to remove any detergent residuals and to prevent water spots and corrosion. Drain.
8. Visually inspect the instruments for cleanliness. If any soil is detected, return to Step 1 and repeat the process. If no soil is detected, proceed to dry the instruments per Section 9. Drying.

9. 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 after drying should be avoided.

10. STERILIZATION

For all instruments - Sterilization presumes that the instruments are clean and residue free. Dry heat sterilization is not appropriate for introducers, which are assembled with epoxy.

1. The instruments may be steam autoclaved.
2. Wrap individual instruments in two layers of one-ply FDA-cleared wrap.
3. 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/270°F
   Exposure Time: 4 minutes
   Dry Time: 30 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. After opening the packs, if condensation is observed on the inside of the packs, the packs must be considered non-sterile and the introducers reprocessed. Refer to section 9 Drying for additional information.

11. STORAGE

Store wrapped instruments in a designated sterile supply area that protects sterile items and their packaging from damage. This area should be clean, dry and free of contaminants or items that may damage the instruments.

12. ADDITIONAL INFORMATION

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

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.

The products referenced herein and the contents of this manual are subject to technical changes and modifications without notice. Please refer to www.calderamedical.com for the most up-to-date manual.

13. CLINICAL EVALUATION

Results from simulated use testing with end-users, benchtop model, biocompatibility, cadaver and performance validation testing demonstrate that the instruments perform to their intended use in terms of device function and mechanical performance.

14. REFERENCES

These recommendations are developed using the following:

1. **ANSI/AAMI ST79** "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities".

2. **AAMI TIR12** "Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers."

3. **U.S. FDA** "Guidance for Industry and Food and Drug Administration Staff: Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

The most current version of the Guide for Cleaning, Sterilization and Storage of Instruments is available for viewing or download here:
www.calderamedical.com – physical portal – IFU links

All Caldera Medical IFU documents are available in print form at no additional cost upon request. If you would like to request a copy please contact us at 818.879.6555, fax 818.879.6556 or email info@calderamedical.com.

To learn more about our products or for additional information about the reprocessing procedures, contact Caldera Medical at 818.879.6555 or visit our website at www.calderamedical.com.