For surgical technique of introducers, please review the Instructions For Use package insert with each implant product.

1. INSTRUMENT DESCRIPTION

Caldera Medical surgical instruments are to be used in surgical procedures for the placement of implants from the Desara Product Family designed for the treatment of Genuine Stress Urinary Incontinence (SUI).

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

2. WARNINGS AND PRECAUTIONS

Warnings

- Universal precautions should be observed by all hospital personnel that work with contaminated or potentially contaminated medical devices.

- Personal protective equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipments. 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 instrument 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 instruments.

- 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 instruments over time.

- As with any surgical instrument, careful attention should be made to assure that excessive force is not placed on this instrument. Excessive force can result in failure.

- If the instrument does not function properly, 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. Do not sterilize by dry heat.

Aluminum based devices are damaged by high alkaline solution (pH > 10).

Precautions

- A surgeon should not begin clinical use of the introducer without reviewing the instructions for use. (It is imperative that appropriate personnel prior to surgery read all guideline materials. If the guidelines are not properly followed, the risk of complications to the patient increases.)
- When reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with applicable health and safety procedures.

3. MATERIALS

The introducer component materials are:

- stainless steel curved hook wire introducers secured into,
- anodized aluminum handles with a locking pin, and
- medical grade epoxy fill between wire shaft and handle.

4. LIMITATIONS AND RESTRICTIONS ON REPROCESSING

Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

5. INSPECTION, MAINTENANCE & TEST

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 instrument prior to and after cleaning for damage or wear. Discard instruments with damage or excessive wear.

The distal tip and slot features should be smooth without denting, cracks, burrs or fractured surfaces.

The handle and instrument 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 instrument wire should be firmly attached to the handle with no movement within the handle component.

Labeling should be legible.

6. PREPARATION FOR USE

The introducer is sold non-sterile and must be cleaned and sterilized prior to first use. The introducer can be re-used after appropriate cleaning and sterilization.

7. CLEANING

To prevent the drying of blood and tissue residues and growth of microorganisms, instruments 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.

**MANUAL**

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

1. Thoroughly rinse instrument under cool running tap water (~20°C) for at least 90 seconds to remove all gross soil and contaminants. Using a soft bristle brush, scrub in circular strokes until no soil is visible. A syringe to flush the lumen and hard to reach areas of the instrument is recommended.

2. Prepare enzymatic detergent, Enzol®, according to the manufacturer’s instructions of 1 oz/gallon using lukewarm (~33°C) tap water. Verify that cleaning solution expiration has not been exceeded. Verify facility processed water quality checks are current. Verify recommended splash, skin and inhalation protection measures are in place.

3. Fully immerse and soak instrument for a minimum of 10 minutes. No assembly or disassembly is required.

4. Remove from the Enzol® soak solution and perform cleaning under the water surface to limit aerosolization of the cleaning fluid and soil. Thoroughly clean all organic material from instruments. Scrub in circular strokes using soft bristle brushes for at least one (1) minute until all visible soil is removed. A syringe to flush the lumen and hard to reach areas of the instrument is recommended. Pay particular attention to all areas where soil could be embedded (such as grooves, crevices, or lumens).

5. After cleaning, thoroughly rinse instrument using running cold (~20°C) 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 lumen of the instrument is recommended.

6. Using warm (~38°C) tap water for at least one (1) minute, flush and rinse the instrument again. A syringe to flush the lumen of the instrument is recommended.

7. Rinse thoroughly for at least one (1) minute using cold (~20°C) processed water to remove any detergent residuals and to prevent water spots and corrosion. Drain.

8. Visually inspect the instrument for cleanliness. If any soil is detected, return to Step 1 and repeat the process. If no soil is detected, proceed to dry the instrument per Section 8. Drying.

8. **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 should be avoided.
9. **STERILIZATION**

Sterilization presumes that instruments are clean and residue free. Dry heat sterilization is not appropriate for this instrument as it is assembled with epoxy.

1. The introducer may be steam autoclaved.
2. Wrap individual introducer in two layers of one ply KC600 wrap.
3. The operator should 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
   - 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. If condensation is observed inside of the packs, the packs must be considered non-sterile and the instruments reprocessed.

10. **STORAGE**

Store wrapped introducer in a designated sterile supply area that protects sterile items and their packaging from damage.

11. **ADDITIONAL INFORMATION**

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

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 re-usable instruments 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 instruments must take particular precautions when handling instruments 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.

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.

This product and manual are subject to technical changes and modifications without notice.

References
These recommendations are developed using the following:

2. AAMI TIR12:2010 “Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.”

Note: All cleaning and sterilization procedures should be validated by the health care facility performing these operations.

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