

Combination Manual/Automated Cleaning Steps:

1. Completely submerge the instruments in enzyme solution and allow to soak for 10 minutes. Use a soft nylon-bristled brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon-bristled brush.

2. Remove devices from the enzyme solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.

3. Place instruments in a suitable washer/disinfectant basket and process through a standard washer/disinfectant instrument cycle.

i. Rinse 3 times using tap water for 30 seconds after wash using the enzymatic detergent in the ultrasound cleaner at 35-45°C for 3 minutes.

ii. Perform the ultrasound rinsing repeatedly subjected 3 times for 3 minutes using the purified water at 35-45°C.

iii. Dry at 100°C (±5°C) for 30 minutes.

Note: Use of a sonicator at 45-50kHz will aid in thorough cleaning of devices.

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas and closely mated surfaces.

INSPECTION

1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.

2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.

3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your CTL Medical representative for a replacement.

4. If corrosion is noted, do not use and contact customer service or your CTL Medical representative for a replacement.

CAUTION:

- Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.

- Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.

- Verify that the instruments are in operation condition.

Sterilization

All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field.

Sterilization: recommended method to achieve a degree of sterility equal to at least 10⁻⁶. The gravity displacement sterilization parameters we suggested comply with FDA recognized consensus standards such as "ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities" for details regarding the common steam sterilization parameters available on FDA cleared sterilizers used in health care facilities"

CTL Medical recommends the following parameters:

| METHOD | Steam | Steam |
|-------------|--------------|--------------|
| Cycle | Gravity | Pre-Vacuum |
| Temperature | 132°C(270°F) | 132°C(270°F) |
| Exposure | 15 minutes | 4 minutes |
| Dry time | 45 minutes* | 45 minutes* |

*15 Min Open Door Time + 30 Min Cool-Down Time)

It is important to note that an FDA-cleared sterilization wrap, package or sterilization container system should be used to enclose the case or tray in order to maintain sterility. Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be resterilized. Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CTL Medical implants and instruments.

CAUTION

Federal (USA) Law restricts this device to sale by or on the order of a physician.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or CTL Medical. Further, if any of the implanted spinal system component(s) ever malfunctions, (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately.

If any CTL Medical product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence.

When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use or surgical technique manual of this system are available at no charge upon request. If further information is needed or required, please contact CTL Medical.

SYMBOL TRANSLATION

| CATALOG NUMBER | LOT NUMBER | QUANTITY |
|----------------|------------|------------|
| REF | LOT | QTY |

NON-STERILE



SINGLE USE ONLY



See package insert for labeling limitation



Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician



MANUFACTURER



DATE OF MANUFACTURER



eIFU indicator



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