

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/disinfector basket and process through a standard washer/disinfector instrument

- 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.

Automated cleaning procedure

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be manual cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

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 thoroughly clean.
- Verify that the instruments are in visually clean.

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.

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 10⁶. The gravity displacement sterilization parameters we suggested comply with AAMI ST79. 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.

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.

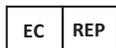
FURTHER INFORMATION

Recommended directions for use 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
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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