

Cleaning Instructions:

Point of Use

- Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe.
- Place devices in a tray of distilled water or cover with damp towels.
- Instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
- Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

Preparation Before Cleaning

- Symbols or specific instructions etched on instruments or instrument trays and cases should be strictly followed.
- Where applicable, multi-component instruments should be disassembled for appropriate cleaning.
- Disassembly, where necessary is generally self-evident. Care should be exercised to avoid losing small screws and components.
- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.
- Note: Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Cleaning/Disinfection Options:

1. Manual - Enzymatic soak and scrub followed by sonication.
2. Combination Manual/Automated - Enzymatic soak and scrub followed by an automated washer/disinfect cycle.
3. Automated cycle - Not recommended without manual precleaning.

Note: If stainless steel instruments are stained or corroded, an acidic, anti-corrosion agent in an ultrasonic cleaner may be sufficient to remove surface deposits. Care must be taken to thoroughly rinse acid from devices. Acidic, anti-corrosion agents should only be used on an as needed basis.

Manual Cleaning Steps:

1. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. Scrub using a soft-bristled, nylon brush to gently clean the device until all visible soil has been removed. Note: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
2. Remove the device from the enzyme solution and rinse in tap water for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
3. Place prepared cleaning agents in sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes at 45-50kHz.
4. Rinse instrument in purified water thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream. Thoroughly and aggressively flush lumens, holes and other difficult to reach areas.
5. Repeat the sonication and rinse steps above.
6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.

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/disinfect basket and process through a standard washer/disinfect 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.

CAUTION:

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

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 a 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.

LIMITS ON REPROCESSING

Repeated processing cycles that include ultrasonic, mechanical wash-ing and sterilization have minimal effects on CTL Medical implants and instruments.

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.

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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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