Note: Certain cleaning solutions such as those containing bleach or formalin may damage some devices and they must not be used.
All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.
Sterilization Procedures
Following is the recommended method to achieve a degree of sterility equal to at least 10^{-6}

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 give 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 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.

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 sytsem should be used to enclose the case or tray in order to maintain sterility. This pre-vacuum sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizer and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Because of the potential risk of transmission of Creutzfeldt Jakob disease, some Health Care Authorities recommend sterilization according to these parameters, especially for surgical instruments that could come into contact with the central nervous system. Remove all packaging materials pri-or to sterilization. Use only sterile products in the operative field.

LIMITS ON REPROCESSING
Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CTL Medical implants and instruments.

Recall
The guarantee is only applicable if the device is used in accordance with normal conditions
as defined in these instructions and in conformity with the recommended surgical technique.

Guarantee
The guarantee is only applicable if the device is used in accordance with normal conditions, as defined in these instructions and in conformity with the recommended surgical technique

SYMBOL TRANSLATION

CATALOG NUMBER

LOT NUMBER

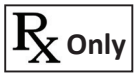
QUANTITY

NON-STERILE

SINGLE USE ONLY

See package insert for labeling limitation

Fedral 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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