

Reusable Instrumentation Instructions for Use

General Care & Handling

The Nextremity Solution Inc. Instruments that are provided non-sterile must be cleaned and sterilized prior to each use, using the following instructions.

The useable lifetime of any instrument is typically limited by normal wear and damage due to use. Instruments may be damaged by prolonged use, misuse, or improper handling. Always inspect instruments for signs of damage, cracking, deformation, wear or other signs of degradation prior to use. Do not use instruments in need of repair or replacement.

Use instruments only for the purpose for which they were designed and intended.

Do not attempt to reuse instruments labeled for single use.

Use caution when handling sharp instruments to avoid injury.

All users should be qualified personnel with documented evidence of training and competency. Training should include current applicable guidelines, standards and hospital policies.

Cleaning

Wear protective equipment, including gloves, an apron, safety goggles and a mask. Take care with sharp instruments to avoid injuries caused by penetration or cutting. Be particularly careful when removing debris from cannulae and cavities. Thoroughly wash all instruments and instrument case whether or not they were used or inadvertently came into contact with blood, other body fluids or saline solution.

Do not use highly acidic (pH<4) or highly alkaline (pH>10) products for cleaning, as these can corrode metal, causing discoloration or damage.

InCore Lapidus Disassembly Instructions

To disassemble the InCore Lapidus Targeting Guides for cleaning, insert the InCore Lapidus T10 Driver into the compression screw and rotate counterclockwise until the compression frame translates away from the guide. To reassemble, place compression screw back into compression frame, align with targeting guide, and rotate screw clockwise.



Manual Cleaning Instructions

The effectiveness of decontamination processes depends on first removing all visible debris, tissue and bone fragments from the instruments. Thoroughly scrub and rinse instruments for at least one minute in room temperature (23°C) tap water until visibly clean prior to their initial sterilization and as soon as possible after use. If cleaning must be delayed, place groups of instruments in a covered container with an appropriate, neutral pH detergent or enzymatic

cleaning solution (e.g. Enzol®), prepared according to the manufacturer's instructions, to delay drying. Do not allow soil to dry on the instruments.

Remove visible soil by soaking instruments in an ultrasonic bath of the enzymatic cleaning solution for a minimum of 20 minutes at room temperature. Use a soft bristle brush to remove all visible debris, paying close attention to textured surfaces, crevices, and hard-to-reach areas. Cannulas, lumens or holes should be scrubbed for their entire length with a tight fitting, soft, non-metallic bottle brush or pipe cleaner, using an in-out and twisting motion. Use a syringe filled with cleaning solution to flush hard-to-reach areas. Instruments with moving parts should be manipulated while in the solution to expose all surfaces. Do not use metal brushes or scouring pads during the manual cleaning process.

Referencing the rinsing instructions for the enzymatic cleaning solution, rinse the instruments thoroughly with tap water for a minimum of 1 minute, flushing all cannulas, lumens and holes. Instruments with moving parts should be manipulated during the rinse to rinse all surfaces. Distilled or deionized water should be used for a final rinse for at least one minute. Dry the instruments immediately after the final rinse, removing excess moisture with a clean, absorbent, non-shedding wipe, and using compressed air to dry hard-to-reach areas. Perform a final visual inspection for cleanliness to ensure that all visible soil is removed, paying close attention to hard to reach areas. If any visible soil is noted, repeat the cleaning procedure.

Visually inspect all instruments for damage or wear and to ensure complete removal of soil prior to sterilization. Damaged instruments (including instruments that are broken, cracked, visibly corroded or discoloured, and those with dulled cutting edges) must be set aside and replaced. Instruments that are not completely cleaned must be cleaned again.

Combination Cleaning and Disinfection Instructions*

1. Completely submerge the instruments in an enzyme or alkaline (pH \leq 12) solution and allow to soak and sonicate for 10 minutes at 45-50 kHz. If using enzymatic cleaning agents, 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 (i.e. pipe cleaner).

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

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

3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

Table 2. Typical U.S. Automated Washer/Disinfecter Cycle for Surgical Instruments

Step	Description
1	2 minute prewash with cold tap water
2	20 second enzyme spray with hot tap water
3	1 minute enzyme soak
4	15 second cold tap water rinse (X2)
5	2 minutes detergent wash with hot tap water (64-66 C/146-150 F)
6	15 second hot tap water rinse
7	2 minute thermal rinse (80-93 C/176-200 F)
8	10 second purified water rinse with optional lubricant (64-66 C/146-150 F)
9	7 to 30 minute hot air dry (116 C/240 F)

Note: The washer/disinfecter manufacturer’s instructions should be strictly adhered to. Use only cleaning agents recommended for the specific type of automated washer/disinfecter. A washer/disinfecter with approved efficacy (e.g. CE mark, FDA approval, and validation according to ISO 15883) should be used.

**Reference Zimmer Instructions for Care, Cleaning, Maintenance and Sterilization for Orthopaedic Reusable Devices – 97-5000-170-00 rev 6*

Inspection, Lubrication and Wrapping

After cleaning and decontamination, instruments must be put in their proper locations in the instrument tray. Inspect all instruments before sterilization to ensure that they function properly. Lubrication, if needed, should be performed after cleaning but before sterilization. Do not include any materials incompatible with steam sterilization within the sterilization load.

Instrument cases do not provide a sterile barrier and must be used in conjunction with a FDA cleared sterilization wrap to maintain sterility.

Sterilization

Instruments must be completely dry before being steam sterilized.

The following parameters are recommended and have been validated for a sterility assurance level (SAL) of 10⁻⁶. End users should re-validate these parameters on their own equipment to ensure that a SAL of 10⁻⁶ can be achieved. Flash sterilization is not recommended.

Cycle	Temperature	Minimum Exposure Time	Minimum Drying Time
Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

Do not stack trays during sterilization.

Storage

Sterile instruments should be stored in a limited access area that is well ventilated and provides protection from dust, moisture, insects and extremes in temperature and humidity.

Alternate Methods

The cleaning and sterilization instructions provided here have been validated by Nextremity Solutions. Other cleaning and sterilization methods may also be suitable, however, end users not using the methods recommended here are advised to validate any alternate methods using appropriate laboratory techniques.

Please contact Nextremity Solutions with any comments, questions or problems regarding the use or reprocessing of these products:



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