

Reprocessing instructions for re-usable instruments and non-sterile implants

Warnings:

- Do not exceed 140 °C during reprocessing steps
- Complex devices such as those with cannulations or lumens, hinges, retractable features, matted surfaces and textured surface finishes require special attention during cleaning
- Manual pre-cleaning of such device features may be required prior to automated cleaning processing
- Avoid exposure to sodium hypochlorite solutions (bleach), which will promote corrosion

Limitations on Reprocessing:

- Repeated processing has minimal effects on the instruments
- End of useful life is generally determined by wear or damage
- Damaged instruments should be replaced to prevent patient injury. Return damaged instruments to Osteotec

Preparation at the Point of Use:

- Remove excess soil with a disposable wipe
- Immerse instruments in a detergent solution or water after surgical use to prevent drying and encrustation of biological soil. If soil is allowed to dry onto the instrument, effective cleaning may be impaired. Avoid prolonged exposure to saline to minimize potential corrosion

Containment and Transportation:

- Instruments should be processed as soon as reasonable after use
- Precautions for handling bio-hazardous materials should be observed

Preparation for Cleaning:

- Disassemble instruments that require disassembly for cleaning

Manual Cleaning:

- Delicate instruments should be cleaned separately from other instruments
- Prepare an enzymatic cleaning solution per the manufacturer's instructions
- Soak soiled instruments in the enzymatic solution
- All instruments - Use a soft bristle brush to remove all traces of blood and debris, paying close attention to any hard to reach areas and textured surfaces or crevice locations
- Rinse the instruments thoroughly in clean water
- Instruments with cannulations, lumen or holes – use a tight fitting, non-metallic cleaning brush or pipe cleaner to scrub cannula, lumen or hole. Push in and out using a twisting motion to remove debris. Use a syringe filled with enzymatic cleaning solution to flush hard to reach internal areas. Thoroughly rinse the cannulations, lumens, or holes with warm water
- Articulated instruments – Immerse instruments in the cleaning solution to avoid aerosol generation and brush with a soft, non-metallic bristle brush to remove all traces of blood and debris, paying close attention to threads, crevices, seams and any hard to reach areas. Actuate any moveable mechanisms such as hinged joints to free trapped blood and debris. If the components of the instruments can be retracted, retract or open the part while cleaning these areas. Rinse the instruments thoroughly in clean water, paying particular attention to internal areas and moving

parts. Actuate moving parts while rinsing. If the components of the instruments can be retracted, retract or open the part while rinsing these areas

- Alternatively, ultrasonically clean instruments in a validated machine for 10 minutes, in neutral pH detergent, prepared in accordance with the manufacturer’s instructions

Automated Cleaning:

- Clean instruments in neutral pH detergent at a temperature at or below 35°C. Mild alkaline detergents in the pH range 8.0 – 11.0 can lead to staining. The use of demineralized water prevents staining and corrosion.
- This is followed by a hot water disinfectant rinse at 90°C for 1 minute
- The manufacturer’s instructions should be followed on the use of an automated washer/disinfector equipment
- Cleaning/Disinfection can also be carried out in accordance with **HTM 01-01 Part D**

Cleaning Inspection:

- Inspect *all* instruments prior to sterilization or storage to ensure complete removal of soil from surfaces, cannulations, movable mechanisms and lumens
- If soil is still visible, re-clean and reprocess through the washer/disinfector

Inspection and Function Testing:

- Visually inspect and check for damage and wear
- Cutting edges should be free from nicks and have a continuous edge
- Jaws and teeth should align properly
- All articulated instruments should have a smooth movement without excess play
- Locking mechanisms should fasten securely and close easily
- Check long thin instruments for bending and distortion

Packaging:

- Instruments that are provided in sets may be loaded into dedicated instrument trays and processed in accordance with local procedures using standard wrapping

Sterilisation:

- Sterilise with steam sterilization according to **HTM 01-01 Part C**
- The following steam sterilisation cycles are suggested based upon validation of a single, wrapped, multiple insert instrument case, within a properly maintained autoclave. It is critical that process parameters be validated for each type of sterilization equipment and product load configuration

TRAYS	CYCLE	TEMPERATURE	EXPOSURE TIME
Single & Dual Level Trays	Pre-vacuum	134°C – 137°C	minimum 3 minutes

Suggested drying times:	Metal or metal/poly trays	20 minutes
	All poly trays	45 minutes

Storage:

- Sterile, packaged instruments should be stored in a manner that provides protection from dust, moisture, insects, vermin and extremes of temperature and humidity