Metro Medical: Hand Instruments

Reprocessing Information

INTENDED USE

Manual dental and surgical instruments intended for grasping, cutting, shaping, retracting, measuring, or applying materials during diagnostic and therapeutic procedures in the oral cavity. Devices used to manipulate tissues, materials, or auxiliary devices. These are reusable devices.

All reuseable surgical/ dental instruments (list given Appendix) by Metro Medical, comprising fixed/ moveable assemblies and simple hinged assemblies, **excluding** those containing aluminium alloys.

REPROCESSING INSTRUCTIONS

The information in these instructions complies with the requirements of EN ISO 17664. Reprocessing must be carried out by qualified personnel only. The following procedure includes processes of cleaning, disinfection and sterilisation. All steps need to be performed together to obtain safe and effective reprocessing of the device. National directives, standards and specifications for the cleaning, disinfection and sterilisation of medical devices must be adhered to.

WARNING

- Device must be cleaned, disinfected and sterilised according to these processing instructions.
- Devices are supplied non-sterile and must be processed before first use, and after every re-use of the device. This is a risk of infection due to inadequate reprocessing. Thorough cleaning and disinfection are essential prerequisites for effective sterilisation.
- Reprocessing should be completed immediately after use to prevent contaminates drying out on device surfaces.
- All devices used in reprocessing must be subject to regular maintenance and inspections.

Limitations & Restrictions on Processing

- Only trained professionals can use, disinfect, clean and sterilise the devices. Always handle with care, wearing protective clothing, gloves, mask and eye protection.
- Do not use dry heat, radiation, formaldehyde, ethylene oxide or plasma sterilisation methods.
- Do not re-use devices with signs of degradation or damage. Degradation is indicated by damage to the surface, cracks, fractures and deformation.
- The device's service life cannot be precisely defined and depends on use, handling and reprocessing methods. It must be withdrawn from service if inspection or functional testing reveals or suspects any condition that could compromise safety or performance of the device.
- Do not re-use or reprocess devices after the treatment of a patient suspected of having a prion disease (e.g. Creutzfeldt-Jakob disease).Such devices must be disposed of after first use.

1. PREPARATION BEFORE PROCESSING

Perform visual inspection of the functionality of the device. Damage to the surface, bent parts, scratches, cracks, fractures, or deformation indicate the device is no longer suitable for use. If the device is connected to another instrument, it should be disassembled. One-part devices do not require any type of disassembly. Where disassembly is necessary, it should be self-evident.

2. CLEANING AND DISINFECTION

WARNING

- Do not use hot water (>30°C).
- Use only neutral detergents (pH=7). Aluminium based instruments may be damaged by alkaline detergents or solutions (pH>7). Stainless steel protective surface may be damaged by acidic detergents or solutions (pH<6).
- Always follow the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.
- Use only CE-marked cleaning and disinfectant agents validated for medical instruments.
- Ultrasonic cleaning is recommended as an effective method for cleaning dental and surgical instruments, particularly those with hinges, locks, or other removable parts.

2.1 PREPARATION FOR CLEANING

Remove surface contamination with a disposable cloth or paper wipe. Immediately after use, rinse the device under warm (not hot) running water. The device should be submerged in a solution of deionized or distilled water and neutral detergent for 10 minutes.

2.2 ULTRASONIC CLEANING

Instruments should be processed in the ultrasonic cleaner for the manufacturer's recommended cycle time. Place instruments with hinges, locks, or moving parts in the open position, ensuring sharp edges do not contact other instruments. Fully submerge all instruments in the cleaning solution. Do not mix instruments made of dissimilar metals in the same cycle. Replace the cleaning solution as frequently as recommended by the manufacturer. Rinse instruments thoroughly using deionized or distilled water only after ultrasonic cleaning to remove residual solution.

2.3 MANUAL CLEANING AND DISINFECTION

Accessories: disposable wipe or paper wipe, nylon brush, cleaning container, cleaning agent, disinfectant agent, disinfection bath, medical compressed air.

CLEANING

Prepare all accessories listed. Remove surface contamination with disposable cloth or paper wipe. Use a nylon brush to clean the device surface, until all visible residues have been removed. Thoroughly rinse the device under running water for a minimum of 3 minutes. Ensure that water flows through all cannulations, blind holes, and hinge areas, and rinse all external surfaces of the instruments.

WARNING

- Detergents used must be specifically designed to clean surgical instruments: washing-up liquid should not be used.
- If there is still visible contamination after the cleaning process, cleaning must be repeated.

DISINFECTION

Prepare an enzymatic or neutral-pH cleaning solution according to the detergent manufacturer's instructions.

Fully submerge the cleaned device in the disinfectant bath, ensuring that all surfaces are covered and no air pockets remain.
Allow the device to remain immersed for the recommended contact time (generally 5-10 minutes, depending on the disinfectant used).
After the contact time has elapsed, remove the device from the disinfection bath and rinse thoroughly with deionized or distilled water for at least 1 minute to remove any chemical residues.

DRYING
Immediately after cleaning and rinsing, instruments should be carefully dried. Dry at room temperature, using a lint-free cloth or medical compressed air. Ensure that difficult to reach areas have been dried.

2.4 AUTOMATED CLEANING AND DISINFECTION

WARNING

- Disinfection can be achieved by washing or rinsing devices in temperatures between 73°C and 90°C.
- Washer-disinfector drying temperatures must not exceed 100°C.

Accessories: washer-disinfector device (WD), basket insert, cleaning agent, disinfecting agent, lint-free cloth, medical compressed air.

Use only CE marked WD equipment validated under ISO 15883. Always follow the manufacturer's instructions for use. Place the device in a basket insert and load into the WD. Ensure device do not come in contact with each other. Fill the WD with cleaning / disinfectant agent and select the cleaning and disinfection programme according to the WD and agents manufacturer's instructions for use. After the programme has finished running, remove the device from the WD.

DRYING
If additional manual drying is required, this must be performed using a lint-free cloth or using medical compressed air. Ensure that difficult to reach areas have been dried.

3. INSPECTION AND MAINTENANCE

3.1 LUBRICATION

All instruments with hinges, locks, or other moving metal-to-metal parts, such as scissors, homeostatic, needle holders, extracting forceps etc. should be lubricated using only surgical-grade lubricants suitable for steam sterilisation. Apply a small amount of lubricant to the hinges, and discard any blunt or damaged instruments.

3.2 INSPECTION

- The device must be carefully inspected after processing. Repeat cleaning and disinfection processes if visual inspection indicates that the device is not yet clean.
- Visually inspect the device prior to each use for malfunction, stiffness, damage to the surface, corrosion, bent parts, scratches, cracks, breakage, loss of marking, fractures, or deformation, loose joints, dull cutting blade indicating the device is no longer suitable for use. Close attention must be paid to tips, closures, blades, cutting edges, notches, locks, catches, closures, all moving parts.
- Inspect the devices for proper functionality after each cleaning.
- The disassembled devices must be carefully checked for proper assembly, secure fitting of all parts and screws.
- Scissor blades should glide smoothly without looseness when closed. Cutting performance shall be verified using thin gauze or glove material, ensuring at least three quarters of the blade length cuts through to the tips without obstruction.
- Forceps tips must be properly aligned, with teeth meeting accurately and without catching.
- Hemostats and needle holders should close without light passing between the jaws when locked in the first ratchet position (a minor gap may be acceptable in hemostats midway from the tips). The locking mechanism must engage and release smoothly, joints should not be loose, and the jaw surfaces of needle holders must be inspected for wear.
- Biopsy punches shall produce a clean perforation in test material (e.g., tissue paper).
- Retractors must demonstrate proper function.
- Cutting instruments and knives shall have sharp, intact blades free from damage.
- Resharpen instruments if necessary. The cleaning, disinfection and sterilisation process must be repeated after re-sharpening.

Limitations

- The maximum number of usage cycles or reprocessing cannot be defined, as the durability of the devices depends on multiple factors, including method and frequency of use, handling and reprocessing.
- The device may continue to be used only if its condition has been confirmed to be adequate following inspection as described above.
- Use of damaged or contaminated instruments may pose a serious risk to patient safety, including the potential for severe injury or death. It is the responsibility of the user to ensure that only clean, intact and fully functional devices are used.
- Use of devices that are not properly inspected, maintained or that show signs of damage or contamination is at the sole risk of the user.

4. PACKAGING

4.2 INDIVIDUAL INSTRUMENTS

After processing, individually package the device in a disposable sterilisation pouch. Select appropriate size disposable sterilisation pouch for the device. Ensure the sealing is not under tension. Devices shall be packaged only after thorough cleaning and drying.

4.3 INSTRUMENT SETS

Instruments may be placed in sterilisation trays, ensuring that cutting edges are protected and the tray weight does not exceed 12 kg. Trays shall be properly wrapped prior to sterilisation.

5. STERILISATION

WARNING

- Sterilisation temperatures must not exceed 134°C.

- Only cleaned, disinfected and dry devices can be sterilised.
- Do not overload the autoclave chamber, as this may prevent adequate steam penetration.
- All instruments shall be unlocked and sterilised in the open position. When two layers are used, heavy instruments shall be placed at the bottom of the set.

Use only steam vacuum autoclaves which have been tested, validated and maintained in accordance with ISO 17665-1. Ensure that the manufacturers maximum load is not exceeded. Individual components must not contact to ensure the steam can circulate freely. Always follow the manufacturer's instructions for use of the autoclave.
Sterilise in a vacuum autoclave for a minimum of 5 minutes at 134 °C.

6. STORAGE

Packaged sterile devices must be protected against dust and moisture. Store in an environment between 5°C to 40°C. If the sterile packaging is compromised, the device must undergo reprocessing before use.

7. DISPOSAL

All devices, including sharp products, must be disposed in accordance with local and national laws, regulations, guidelines and standards. The contaminated devices must be reprocessed before disposal.

8. ADDITIONAL INFORMATION

The instructions provided have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. Any deviation from these instructions should be validated for effectiveness and potential adverse results. This requires verification and/or validation and routine monitoring of the process.

9. SYMBOLS

SYMBOL	DESCRIPTION
	Manufacturer
	Importer
	Distributor
EU REP	Authorised Representative in the European Community
MD	Indicates device is a medical device
CE	CE Marking, complaint with MDR 2017/745
134 °C	Sterilisable in a steam steriliser (autoclave) at temperature specified

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APPENDIX

List of reuseable surgical/ dental instruments

Amalgam Instruments
Anaesthesia Instruments
Articulators
Bone Instruments
Bone Instruments
Bracket Positioning Gauges
Cement Spatulas
Chisel and Gouges
Cotton Pliers
Cutting Instruments
Dressing Forceps
Elevators
Excavators – Explorers
Extracting Forceps
Filling Instruments
Haemostatic Forceps
Impression Trays
Matrix Retainers
Mirrors & Mirror Handles
Mouth Gags
Needle Holders
Operating Knives
Operative Instruments
Oral Instruments
Orthodontic Pliers
Periodontal Instruments
Probes
Retractors
Rubber Dam Instruments
Scalars / Implant Removers
Scalpel Handles
Scissors
Spatulas
Suture Instruments
Wax and Modeling Instruments
Wax Knives