CLEANING, DISINFECTION & STERILISATION

BUSINESSMED INSTRUMENTS

Reprocessing Guide for Reusable Stainless-Steel Hand Instruments

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1. Purpose and responsibility

This guide describes how to reprocess BusinessMed Instruments reusable hand instruments so they are safe for the next patient and stay in good condition. It applies to the instruments listed in BMI-IFU-G01. Where a product has its own reprocessing instructions, those take priority.

> The parameters below are the ones recommended by BusinessMed Instruments. The healthcare facility is responsible for ensuring that its washer-disinfectors, sterilisers, detergents, packaging and loading patterns are validated, maintained and operated by trained staff in line with national standards (for example EN ISO 15883, EN ISO 17665-1, EN 285 / EN 13060, ANSI/AAMI ST79, HTM 01-01 or AS/NZS 5369). Any deviation from these instructions must be assessed and validated by the facility.

2. Overview of the cycle

#	Step	Key point
1	Point of use	Remove gross soil; do not let blood or tissue dry
2	Containment and transport	Closed container; keep moist; start cleaning within 2 hours
3	Preparation	Open, unlock and take apart; separate delicate and dissimilar instruments
4	Cleaning and disinfection	Automated washer-disinfector (preferred) or manual + ultrasonic cleaning
5	Drying	Completely dry, including joints and lumens
6	Inspection and function test	Clean, intact, aligned, sharp, working
7	Lubrication	Water-soluble, steam-permeable lubricant on moving parts
8	Packaging	Sterile barrier system to ISO 11607; ratchets open
9	Sterilisation	Steam, pre-vacuum, 134 °C (maximum 137 °C)
10	Storage	Clean, dry, protected

3. Limits on reprocessing

- Repeated reprocessing according to this guide has little effect on stainless-steel instruments. Their end of life is decided by wear and damage found at inspection.
- **New instruments** must go through the complete cycle before first use; they are supplied non-sterile and may carry manufacturing residues.
- Instruments with **aluminium, titanium, anodised or coloured parts** must not be put in an ultrasonic bath or exposed to alkaline detergents or dry heat; use detergents approved for these materials.
- Instruments with **plastic, silicone or wooden parts** must not be dry-heat sterilised.

4. Point of use, containment and transport

1. Immediately after use, wipe off blood and tissue with a lint-free cloth moistened with water. Flush lumens (for example cannulas and suction tubes) with water.
2. Do not put instruments in saline, and do not leave them to dry. Dried soil is much harder to remove and promotes corrosion.
3. If cleaning cannot start soon, keep the instruments moist: cover them with a damp cloth, or use a pre-cleaning foam or gel compatible with stainless steel.
4. Transport them in a closed, puncture-resistant container. Start cleaning within **2 hours** of use where possible.
5. Do not leave instruments soaking in any solution longer than the detergent maker specifies, and never overnight or over a weekend.

5. Preparation for cleaning

- Open all hinged instruments (scissors, forceps, needle holders, clamps) and release ratchets.
- Take apart instruments that are designed to be dismantled (for example cannulas with separate handles, retractors with removable blades). Keep the parts together.
- Do not dismantle joints or screws that are not meant to be dismantled.
- Separate microsurgical and fine-tipped instruments, and keep instruments of different metals or with coatings apart from stainless steel.

6. Cleaning and disinfection

Automated cleaning in a washer-disinfector is preferred because it can be validated and is reproducible. Manual cleaning is acceptable where no washer-disinfector is available, and is recommended for delicate microsurgical instruments.

6.1 Automated cleaning and thermal disinfection (preferred)

Use a washer-disinfector that meets EN ISO 15883, with racks or connectors suited to the instruments. Load instruments open, without overlapping, and connect cannulated instruments to the rinsing ports. A typical validated cycle is:

Phase	Conditions	Notes
Pre-rinse	Cold tap water (< 40 °C), at least 2 minutes	Cold water avoids fixing proteins to the surface
Cleaning	45–55 °C, at least 5 minutes	Neutral or mildly alkaline detergent, at the detergent maker's dose
Neutralisation (if alkaline detergent used)	Warm water with neutraliser, about 2 minutes	As specified by the detergent maker
Intermediate rinse	Warm water, about 1–2 minutes	Demineralised water recommended
Thermal disinfection	90–93 °C for at least 5 minutes ($A_0 \geq 3000$)	Final rinse in demineralised (purified) water
Drying	Hot air, not above 110 °C	Check joints and lumens are dry afterwards

6.2 Manual cleaning

1. **Pre-rinse:** rinse each opened instrument under cold running tap water (< 40 °C) for at least 1 minute.

2. **Soak:** fully immerse the instruments in a freshly prepared **enzymatic or neutral detergent** (pH about 7 to 8.5) at the concentration, temperature and contact time given by the detergent maker (typically 5–10 minutes).
3. **Brush:** while the instrument is under the surface of the solution, clean all surfaces with a soft nylon brush. Pay attention to serrations, teeth, box locks, ratchets, hinges and the inside of jaws. Work hinged instruments open and closed several times.
4. **Lumens:** brush cannulas and tubes with a brush of matching diameter along their full length, then flush with detergent solution using a syringe or water jet.
5. **Rinse:** rinse thoroughly under running water for at least 1 minute, flushing lumens and moving the joints.
6. **Ultrasonic cleaning (recommended for joints, serrations and lumens):** place the opened instruments in a mesh basket, fully immersed in fresh detergent solution. Run the bath at 35–45 kHz for 5–10 minutes, at no more than 40 °C. Do not overload the basket and do not let instruments touch each other. Do not use ultrasound for microsurgical instruments with very fine tips, or for aluminium, titanium, anodised or plated parts.
7. **Final rinse:** rinse in **demineralised or reverse-osmosis water** to avoid mineral spots and chloride residues.
8. **Disinfection:** if no thermal disinfection follows, disinfect with an instrument disinfectant that is compatible with stainless steel and approved in your country, following its instructions, then rinse again with demineralised water.

> **Do not use:** steel wool, wire brushes, scouring powder or pads, bleach (sodium hypochlorite), iodine solutions, hydrochloric or other strong acids, or strongly alkaline cleaners not intended for medical instruments. These damage the protective passive layer of stainless steel and cause pitting and corrosion.

7. Drying

Dry instruments straight after the final rinse with a clean, lint-free cloth or with filtered, oil-free medical compressed air. Blow out lumens, joints and box locks. Residual moisture causes water spots and corrosion and can prevent effective sterilisation.

8. Inspection and function testing

Inspect every instrument after cleaning, under good light. Magnification (a lamp with a magnifier) is recommended for fine tips, serrations and joints. Any instrument that is still soiled must be cleaned again. Any instrument that is damaged must be removed from use.

Instrument type	What to check
All instruments	No visible residues, stains, corrosion, pitting or cracks (especially at box locks and joints); markings legible; no burrs or bent tips.
Scissors	Blades close smoothly from the joint to the tip without catching. The blades cut cleanly along their whole length through a suitable test material (for example a thin latex or test sheet) without folding or tearing it. Tips meet.
Forceps, haemostats, clamps, needle holders	Jaws and teeth meet exactly with no overlap. Ratchets engage on every tooth and hold securely when the closed instrument is lightly tapped. Joints move freely without wobble. Tungsten carbide inserts are complete and not chipped.
Retractors, hooks, skin hooks	Blades, prongs and tips are straight and undamaged; sharp hooks are still sharp; self-retaining mechanisms lock and release correctly.
Elevators, osteotomes, chisels, curettes, scalers	Working edges are free of nicks, rolled edges and flattening; cutting edges are sharp; handles are firmly attached.
Rongeurs, bone cutters, punches	Springs work; jaws close completely and bite cleanly; no play in the joints.
Cannulas, suction tubes	Lumen is clear (look through it against the light or flush with water); openings are free of burrs; threads and connectors are undamaged.
Measuring instruments	Scales are legible; jaws or points close to zero; moving parts are not loose.

9. Lubrication

Apply a **water-soluble, steam-permeable instrument lubricant** ("instrument milk" or spray) to joints, box locks, ratchets and other moving parts after inspection and before packaging. Work the joint a few times to spread it and wipe off the excess. Do not use mineral oil, silicone oil or general-purpose machine oil: they block steam and hold soil.

10. Packaging

- Use a sterile barrier system that meets EN ISO 11607 and is suitable for the chosen sterilisation method: sterilisation pouches, double wrap, or rigid containers with filters.
- Pack hinged instruments open, or closed on the first ratchet tooth only.
- Protect sharp and fine tips with steam-permeable tip protectors.
- In trays, place heavy instruments at the bottom and do not overload. Pack only dry instruments.

11. Sterilisation

Recommended method: moist heat (steam) sterilisation in a steam steriliser that meets EN 285 or EN 13060, using a process validated to EN ISO 17665-1.

Cycle	Temperature	Holding (exposure) time	Drying time
Pre-vacuum (fractionated vacuum) – recommended	134 °C (273 °F), approx. 2.1 bar	3–7 minutes	at least 20–30 minutes
Pre-vacuum (dynamic air removal) – USA	132 °C (270 °F)	4 minutes	at least 20–30 minutes
Gravity displacement – alternative	121 °C (250 °F)	30 minutes	at least 20–30 minutes

- **Never exceed 137 °C.** Higher temperatures can affect the hardness and edge of the steel.
- Drying time depends on the steriliser and load. Packs must leave the steriliser dry; wet packs are not sterile and cause corrosion.
- Check the process parameters and chemical indicators after each cycle before releasing the load.
- Allow instruments to cool to room temperature in their packaging before use or storage.
- Where national guidance requires extended cycles (for example 18 minutes at 134 °C for prion risk), follow that guidance and contact us for advice on the instruments concerned.
- Use steam of good quality (EN 285 limits). Water with high chloride or mineral content causes stains and corrosion.

11.1 Dry heat (only where steam sterilisation is not available)

Solid all-metal stainless-steel instruments may be sterilised by dry heat at **170 °C for at least 60 minutes** or **160 °C for at least 120 minutes**, in a validated hot-air steriliser. Never exceed 177 °C, as it can soften cutting edges and discolour the steel. Dry heat is not suitable for instruments with plastic, silicone, wooden, aluminium, titanium or coated parts.

11.2 Other methods

Low-temperature methods (ethylene oxide, hydrogen peroxide plasma, formaldehyde) and liquid chemical sterilants are not covered by this guide. If you plan to use them, contact BusinessMed Instruments first. Flash or immediate-use steam sterilisation should not be used as a routine method.

12. Storage

Store sterile packs in a clean, dry, dust-free and well-ventilated area, at room temperature and away from direct sunlight and chemicals. Handle packs carefully so the sterile barrier is not damaged. Before use, check that each pack is intact, dry and within the shelf life defined by your facility.

13. Troubleshooting: stains and corrosion

What you see	Likely cause	What to do
White or grey spots, chalky film	Minerals (calcium, silica) from tap water in the final rinse or steam	Final rinse in demineralised water; check steam and water quality. Remove with a suitable acid-based instrument cleaner, then rinse well.
Brown to orange deposits that rub off	Rust carried over from corroded instruments or from pipework and steam, or dried blood	Remove the corroded instruments from the cycle; check the water and steam system. Clean the affected instruments.
Rust spots that do not rub off, pitting (small holes)	Chlorides: saline, dried blood, bleach, unsuitable disinfectants, residues left too long	Take the instrument out of service and send it for assessment. Avoid saline contact and long soaking; rinse thoroughly.
Black or dark discoloration	Acidic or ammonia-containing products, or unsuitable detergents	Check detergent compatibility and concentration; rinse thoroughly.
Rainbow or blue-gold heat tint	Overheating, for example dry heat above the limit or too-hot drying	Usually cosmetic; check the temperature settings. Instruments with overheated cutting edges should be checked for sharpness.
Stiff joints	Soil in the joint, or no lubrication	Clean again with ultrasound, then lubricate.
Cracks at the box lock	Stress corrosion, often from instruments sterilised fully closed or overloaded	Remove from use. Sterilise ratcheted instruments open or on the first tooth only.

14. Manufacturer and contact

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Made in Pakistan

Questions about reprocessing, stains or repairs: send photos and the product reference by email or WhatsApp.