

Reprocessing Instructions

These instructions are applicable for all reusable medical devices supplied by Mercian, unless stated otherwise with the packaging of the product.

These instructions conform to the Medical Directive 93/42/EEC (Annex 1 section 13)

Conforming to Health Technical Memorandum 01-01: *Management and decontamination of surgical instruments*. Part C: Steam sterilization and Part D: Washer-disinfectors.

These instructions are intended for use only by persons with the required specialist knowledge and training.

These instructions are relevant for reprocessing of the following devices:

1. **Reusable Surgical Instruments**
2. **Lumbar, Cervical and Spinal Instrument set**
3. **McCulloch Lumbar Retractor set**
4. **Black Belt Cervical Retractor set**
5. **Caspar Lumbar Retractor set**
6. **Super-Slide Retractor set**
7. **Caspar Distractor set**
8. **Micro Instruments**
9. **Bipolar Forceps**

Further instructions relating to the above sets can be found by following this link:

<https://www.merciansurgical.com/reprocessing-instructions>



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Reprocessing Instructions applicable to Mercian Reusable Devices;

Treatment of new Instruments:

- It is recommended new instruments are processed 3 times prior to first use, to protect the surface of the Instruments.

Precautions:

- Follow instructions and warnings by manufacturers of any decontaminants, disinfectants and cleaning agents used.
- Wherever possible avoid use of mineral acids and harsh, abrasive cleaning agents.
- Do not use saline to clean instruments in Theatres, use sterile water.
- Ensure Instruments are processed following use within 3 hours.
- Instruments may be damaged by high alkaline detergents.
- As per HTM 0101 1.138 alkaline detergents in the pH range 8.0–11.0 are preferred.
- Racks, jaws and hinges require particular attention during cleaning.

Limitations on Reprocessing:

- Repeated processing has minimal effect on these devices.
- End of life is normally determined by wear and damage in use.

INSTRUCTIONS

From Point of Use:

- Wherever possible, do not allow blood, debris or bodily fluids to dry on devices. To prolong the life of the device, reprocess as soon as possible after use and within 3 hours of use.
If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to prevent protein's from drying on the surface.

Preparation for Decontamination:

- Disassemble Instrument only if intended, without the use of tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available with the device.

Cleaning - Automated washer-disinfector machines:

Our Instruments are suitable to be processed through automated washer-disinfector machines which are CE marked and validated to:

- ISO 15883-2:2024 Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments.
 - Adhering to: HTM 01-01: Management and decontamination of surgical instruments:
Part D - Washer-disinfectors
1. Load devices carefully, with any box joints and hinges open and so that any fenestrations in devices can drain.
 2. Place heavy devices with care in the bottom of containers, taking care not to overload wash baskets.
 3. Place devices with concave surfaces (e.g. curettes) facing down to prevent pooling of water.
 4. Where required use a soft brush to remove debris and blood from Racks, Ronguer and Kerrison jaws.
 5. Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage.

Cleaning parameters:

Process:	Parameters:
Washer Disinfector (Thermal)	90°C (-0°C +5°C) for a minimum of 1 minute
Autoclaving	Refer to the Sterilization section of these instructions.
Final rise	Tap water/Reverse osmosis water is acceptable

Note: Automated cleaning may not be suitable for all devices, in which case clean manually with a water jet gun, if available, and an appropriate brush that reaches the crevices. After manually cleaning, pass all devices through an automated cleaning cycle to achieve disinfection.

Cleaning - Manual:

- **Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is unavailable, use the following process:**
 1. Using a double sink system (wash / rinse) dedicated for device cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35°C.
 2. In the first sink, keeping the device submerged, with an autoclavable brush, apply CE marked cleaning solution to all surfaces until all soil has been removed. Pay particular attention to serrations, teeth, ratchets and hinges, always brushing away from the body and avoiding splashing. Ensure rongeurs and hinged devices are thoroughly cleaned in both open and closed positions.
 3. In the second sink, rinse the device thoroughly with soft, high purity water which is controlled for bacterial endotoxins, so that the water reaches all parts of the device, then carefully hand dry or use a drying cabinet.

Note: *Manual cleaning is NOT a disinfection process. When manual cleaning is used it may not be possible to disinfect the device prior to further handling.*

Cleaning - Inspection:

- After cleaning, visually inspect all surfaces, ratchets, joints, jaws and lumens for complete removal of soil and fluids. If any soil or fluid is still visible, return the device for repeat decontamination.

Maintenance:

- Apply surgical grade lubricants to hinges, joints and moving parts as per the lubricant manufacturer's instructions.

Inspection & Function Testing:

- Visually inspect and check the function of all devices for damage.
- Check the jaws of the Kerrison Ronguers, Disc Ronguers and Bone Ronguers to ensure they are clear of debris.

Note: *If a Set is returned to Mercian it must be decontaminated and sterilized and be accompanied by the relevant documented evidence.*

Packaging:

- All devices are to be packed following local protocol in accordance with BS standards.
- Instruments to be placed into their correct brackets in the trays.

Sterilization:

- Sterilize in a steam autoclave conforming to BS EN 285:2015+A1:2021 at a holding temperature of **134°C to 137°C for between 3 to 3.5 minutes.**
- > Validated to the following standard EN ISO 17665:2024
- > Adhering to: Health Technical Memorandum 01-01: Management and decontamination of surgical instruments. Part C: Steam sterilization

Storage:

- Ensure devices are dry before storage, and stored in dry, clean conditions at an ambient temperature.

Cleaning and sterilizing guidelines are detailed in:

Health Technical Memorandum 01-01: *Management and decontamination of surgical instruments.*

Part C: Steam sterilization Part D: Washer-disinfectors.

<https://www.gov.uk/government/publications/management-and-decontamination-of-surgical-instruments-used-in-acute-care>

Note: *It is the responsibility of the reprocessor to ensure that the reprocessing as actually performed using equipment, materials and personnel in the reprocessing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.*

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