

Reprocessing Instructions

Surgical Handpieces & Micro Motors

The following instructions are applicable for Surgical Hand Pieces and Micro Motors supplied by Mercian. These instructions conform to the Medical Directive 93/42/EEC (Annex 1 section 13). These instructions are intended for use only by persons with the required specialist knowledge and training. Conforming to Health Technical Memorandum 01-01: *Management and decontamination of surgical instruments*. Part C: Steam sterilization Part D: Washer-disinfectors.

Precautions:

- The Handpiece must be allowed to cool to ambient conditions before being used.
- Hand Pieces must be tested prior to every procedure to ensure they are rotating freely to prevent them overheating during surgery.
- If any unusual noise or overheating is noticed withdraw from use immediately and return for servicing.
- Do not cover up Micro Motor Air-vents with tape, this will result in overheating.
- Return for service to Mercian Annually.
- As per HTM 0101 1.138 alkaline detergents in the pH range 8.0 to 10.0 are preferred.

Limitations on Reprocessing:

- Repeated processing has minimal effect on these devices.
- End of life is normally determined by wear and damage in use.
- No specific limitations on the number of reprocessing cycles for the device.

Manual cleaning of Handpieces or Micro Motors:

- Clean & disinfect the exterior of the Handpiece/Micro Motor with a clean damp cloth and suitable disinfection solution.

Note; Products containing acetone, chlorine, and bleach are not recommended as disinfectants.

- Visually inspect the Handpiece & Micro Motor for any remaining debris or damage.

N.B; Hand Pieces are not suitable for cleaning in an ultrasonic bath.

1. Cleaning - Automated washer-disinfector machines

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

ISO 15883-2:2016 *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. Place the Handpiece or Micro Motor in the appropriate basket.
 2. Pre-rinse with mains water.
 3. Wash with mains water at 60°C with alkaline detergent with a pH of no more than 11 in dilution.
 4. Rinse with warm mains water at 50°C.
 5. Final rinse with reverse osmosis water at 90°C.
 6. Hot air drying.
- Remove the Handpiece & Micro Motor immediately from the Washer/Disinfector and lubricate with the indicated Intra Spray can prior to sterilisation.

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

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

2. Lubrication of Handpieces & Micro Motor

- Always Lubricate before each sterilisation.
- Always use Mercian Lubrifluid oil spray order code; 1600064-006

Handpiece



Procedure Lubricating Hand Pieces;

1. Remove Bur from Handpiece chuck.
2. Open chuck up.
3. Hold the Handpiece in a cloth to catch any debris or foreign matter expelled by the jet.
4. Remove the protective cap from the can and insert nozzle into the back of the instrument sleeve.
5. Spray for 1 second.

After lubrication, always stand the Handpiece upright, for 5 minutes

Micro Motor



Procedure Lubricating Micro Motors;

1. Use pointed finer nozzle of Lubrifluid.
2. Hold the Micro Motor in a cloth.
3. Remove the protective cap from the can, and insert nozzle into the open end of the Micro Motor.
4. Spray for less than 1 second.

3. Sterilisation

- Sterilize in a steam autoclave conforming to; BS EN 285:2015 at a holding temperature of 134° to 137° for between 3 to 3.5 minutes
 - o Validated to the following standard; EN 17665-1;2006
 - o Adhering to: Health Technical Memorandum 01-01: *Management and decontamination of surgical instruments*. Part C: Steam sterilization

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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MERCIAN
Surgical Instruments of Excellence

Mercian Surgical Supply Co Limited

10 Topaz Business Park, Topaz Way, Bromsgrove, Worcestershire, B61 0GD. UK



Tel: +44 (0) 844 879 1133
Email: info@merciansurgical.com