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CE UK CA

Empire

Reprocessing Instructions

Microsurgery Instruments

The following instructions are applicable for Microsurgery Instruments supplied by Empire Medical, unless stated otherwise with the packaging of the product.

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.

Precautions:

- Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.
- **Do not** clean Micro Instruments in Theatres with **saline**, use sterile water.
- As per HTM 01-01 Part D 1.138 - alkaline detergents in the pH range **8.0–11.0** are preferred.
- Handle Micro Instruments with care as most damage occurs during the reprocessing process.
- The use of an Instrument container with silicone matting ensures the instruments held securely during reprocessing and transportation.

Limitations on Reprocessing:

- Repeated processing has minimal effect on these devices.
- End of life is normally determined by wear and damage in use.
- Any specific limitations on the number of reprocessing cycles are indicated in the IFU for the device.

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 Instrument, reprocess as soon as possible after use and within 6 hours of use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.

Preparation for Decontamination:

- To avoid damage process Micro Instruments within their own designated Container.

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 15883-2:2009 *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 Micro Instruments carefully within their designated container, with any joints and hinges open.
2. Avoid mixing heavy Instruments with Micro Instruments, Don't overload wash baskets.
3. 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	Please refer to the 'Sterilisation' section of these instructions.
Final rise	Tap water / Reverse osmosis water is acceptable

Note: *Automated cleaning may not be suitable for all lumens and cannula, in which case clean manually with a water jet gun, if available, and an appropriate brush (and stilette if provided) that reaches the depth of the feature. 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 Instrument 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 Acland Clamps 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, 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 all devices for damage.

Note: I*f a device is returned to the manufacturer/supplier, the device MUST be decontaminated and sterilised and be accompanied by the relevant documented evidence.*

Packaging:

- All devices are to be packed following local protocol in accordance with BS standards.

Sterilisation:

- Sterilize in a steam autoclave conforming to BS EN 285:2015 at a holding temperature of 134°C to 137°C for between 3 to 3.5 minutes.
    - Validated to the following standard EN 17665-1:2006
    - 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 room temperature.

Additional Information:

- Other forms of cleaning (i.e., ultrasonic) and sterilisation (i.e., low temperature steam and formaldehyde, ethylene oxide and gas plasma) are available. However, always follow the instructions for use issued by the manufacturer and always consult with them if in any doubt over the suitability of any process used.

- 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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