

Issue Number 1.

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Reprocessing Instructions

Black Belt Retractor

The following 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)

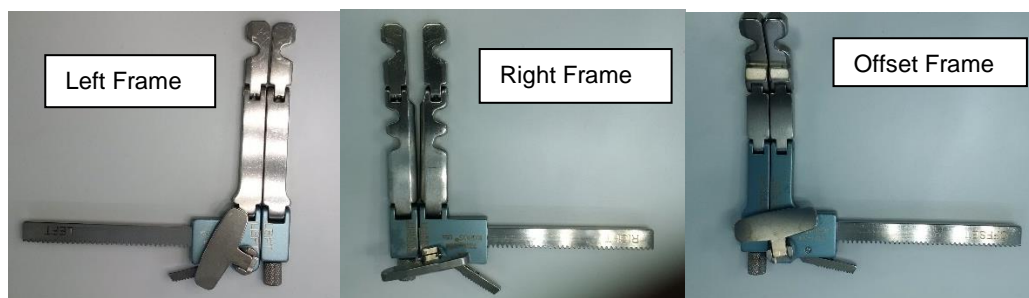
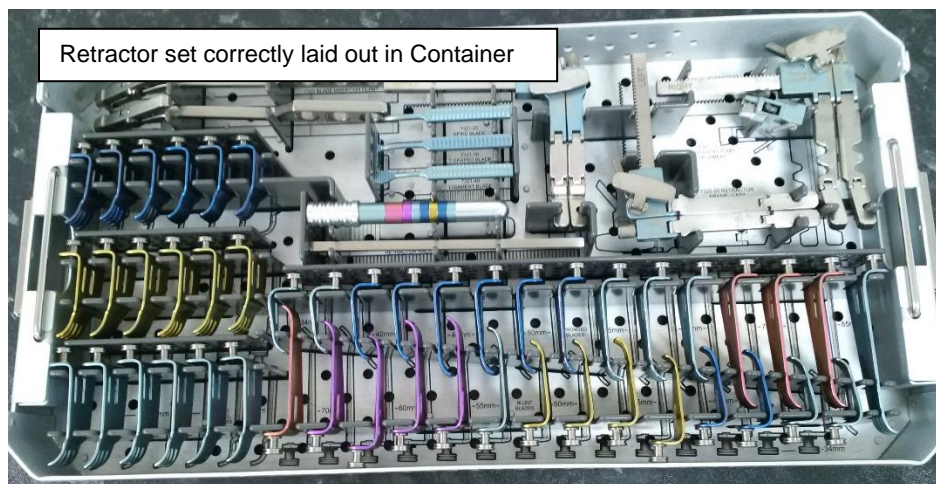
These instructions are intended for use only by persons with the required specialist knowledge and training.

Precautions;

- Follow instructions and warnings as issued by manufacturer of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.
- Components may be damaged by high alkaline detergents pH > 11. As per HTM 0101 1.138 alkaline detergents in the pH range 8.0–11.0 are preferred

Limitations on Reprocessing:

- Repeated processing has minimal effect on these devices.
- End of life is 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 components. For best results, and to prolong the life of the device, reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help prevent soil from drying.

Preparation for Decontamination

- Give particular attention to the grub screws on the retractor frames to ensure they are all firmly secured.

1. 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 15883-2:2016 *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

- Load devices carefully, with any box joints and hinges open so that any crevices in devices can drain.
- Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage.

Cleaning - Manual

- **Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, 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 components 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, cannulations, ratchets, joints, holes 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.

Inspection & Function Testing

- Visually inspect and check all components for damage.

Note: *if the Retractor 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.

2. 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.
 - 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

- 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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