

WARNING:

- **Product must not be used on Brain, Meninges or Spinal Cord**
- **Intended for continuous use for less than 60 minutes.**

SF-37E V9 Jan 2021

Device(s): The following instructions are for all reusable medical devices supplied by Surgical Holdings, unless stated otherwise with the packaging of the product. These instructions are intended for use only by persons with the required specialist knowledge and training.

WARNINGS

Note when reprocessing medical devices, always handle with care, wearing protective clothing, gloves, and eyewear in accordance with local Health & Safety procedures.

- Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid the use of mineral acids and harsh, abrasive agents.
- No part of the process shall exceed 137° C.
- Some sensitive materials (e.g. Aluminium) are damaged by alkaline solutions (pH>10)
- Devices with long, narrow cannula, hinges, and blind holes require particular attention during cleaning.
- Prolonged instrument contact with saline solution leads to pitting, stress corrosion cracking and rust formation. If devices come into contact with saline during a procedure ensure they are thoroughly rinsed as soon as possible

LIMITATIONS ON REPROCESSING

- Repeated processing has minimal effect on these instruments.
- End of life is normally determined by wear and damage in use.
- Any specific limitations on the number of reprocessing cycles shall be made available with the instrument. For example, Diathermy and Bipolar leads

INSTRUCTIONS

FROM POINT OF USE

- Wherever possible, do not allow blood, debris or bodily fluids to dry on instruments; remove all coarse contamination (i.e. Saline) immediately after the procedure.
For best results, and to prolong the life of the medical device, reprocess immediately after use. If they cannot be reprocessed immediately, use an enzymatic foam spray cleaner to help protect soil from drying.

PREPARATION FOR DECONTAMINATION

- Reprocess all instruments as soon as it is reasonably practical following use.
- Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available through contacting Surgical Holdings.

CLEANING; AUTOMATED

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 routine cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.

- Instruments should be cleaned in washer disinfectors validated and maintained in accordance with HTM01-01/WHTM/SHTM
- Use only either CE marked or validated washer-disinfector machines and low-foaming, non-ionising cleaning agents and detergents following the manufacturers' instructions for use, warnings, concentrations and recommended cycles.
- Load instruments carefully, with any box joints and hinges open and so that any fenestrations in instruments can drain.
- Place heavy instruments with care in the bottom of containers, taking care not to overload wash baskets.
- Place instruments with concave surfaces facing down to prevent pooling of water.
- Where available, use appropriate attachments to flush inside reamers and devices with lumens or cannula.
- Ensure that soft, high purity water, which is controlled for bacterial endotoxins, is used in the final rinse stage.

Important instructions We recommend following our validated washer disinfectant cycles and drying processes for our reusable surgical instruments, as follows:
Do not use an alternative process unless you have a written concession for this or you will invalidate the warranty of your instruments.

These instructions have been validated using a water-disinfector cycle validated to include two cold rinses at 35°C, a detergent cycle and a rinse cycle both at 50°C, a disinfection cycle operating at a temperature of between 80°C and 90°C for a minimum holding time of 1 minute (actual holding time in excess of 2 minutes 50 seconds) and a 20 minute drying cycle. In accordance with HTM01-01 no residual water should be observed on any part of the instrument following drying. The detergent for validation used was a low foaming, non-ionising spray wash detergent cleaner (we recommend neutral pH) and the rinse aid a neutral pH low foaming, non-ionic surfactant with isopropyl alcohol.

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CLEANING: MANUAL

Note manual cleaning in NOT a disinfection process: when manual cleaning is used it may not be possible to disinfect the device prior to further handling

Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process

- 1 Use a double sink system (wash / rinse) dedicated for instruments cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35°C.
- 2 In the first sink, keeping the instrument 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 instruments are thoroughly cleaned in both open and closed positions. If cloths are used, they must be non-linting.
- 3 In the second sink, rinse instruments thoroughly with soft, high purity water which is controlled for bacterial endotoxins, so that the water reaches all parts of the instrument, then carefully hand dry or use a drying cabinet.

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 instrument for repeat decontamination.

MAINTENANCE

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

INSPECTION AND FUNCTION TESTING

Note if an instrument is returned to the manufacturer / supplier, the instrument must be decontaminated and sterilised and be accompanied by the relevant documented evidence

- Visually inspect and check; All instruments for damage and wear; cutting edges are free of nicks and present a continuous edge; jaws and teeth align correctly; all articulated instruments have a smooth movement without excess play; locking mechanisms (such as ratchets) fasten securely and close easily; long, slender instruments are not distorted; any component parts fit and assemble correctly with mating components.
- Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged instruments.

PACKAGING

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

STERILISATION

- Either CE marked or validated vacuum autoclave operating at 134-137°C 2.25 bar for a minimum holding time of 3 minutes – always following the instructions of the machine manufacturer.
- When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.
- Ensure instruments are dry before sterilisation

STORAGE

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

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 as issued by the manufacturer and always consult with them if in any doubt over the suitability of any process used.
- Cleaning and sterilising guidelines are available in HTM01-01/WHTM/SHTM

MANUFACTURER

SURGICAL HOLDINGS T:01702 602050 F:01702 460006 E: info@surgicalholdings.co.uk

NOTE IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING IS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY ACHIEVE THE DESIRED RESULTS. 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.