



## **INSTRUCTIONS FOR RE-USE OF CLASS I MEDICAL DEVICES** **Manufactured by Incus Surgical Ltd**

The following instructions are for all reusable medical devices manufactured by Incus Surgical Ltd, unless stated otherwise with the packaging of the product. These instructions are intended for use by persons with the required specialist knowledge and training. **Please note that dimensions stated in our catalogue and labels are for guidance only and may change without notice.**

### **WARNINGS**

- Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of the mineral acids and harsh, abrasive agents.
- No part of the process shall exceed 140°C.
- Aluminium based products are damaged by high alkaline solutions (pH>10).
- Rubber, Plastic, Blackened, Insulated and Fibre light devices are damaged by high alkaline solutions (pH>10).
- Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning.
- Care must be taken when handling thin sections such as wire and needle electrodes.
- Do not use metallic or abrasive cleaning agents on insulated coatings.
- Do not permit sharp instruments or edges to contact insulation coating or cable covers.
- When handling fibre optic light cables do not allow them to be bent in a tight radius.

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

### **LIMITATIONS ON REPROCESSING**

- Non-insulated stainless steel instruments - Repeated processing has minimal effect on these instruments.
- Insulated instruments – Repeated processing of these instruments may cause deterioration of the insulation over a prolonged period.
- Devices made of plastic – Repeated processing may degrade the material over a long period
- 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 device.

## **INSTRUCTIONS**

### **From Point Of Use**

- Wherever possible, do not allow blood, debris or bodily fluids to dry on devices. 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.
- It is important that thin tubes and lumens and difficult to access areas are cleaned after use before the debris had adhered to the surfaces otherwise it may not be possible to obtain a satisfactory degree of cleanliness prior to sterilisation.
- Where deposits are burnt on the device i.e. electrosurgical electrodes, these should be removed as soon as possible using a light abrasive agent(see also Warnings above)

### **Preparation for Decontamination**

- Reprocess all devices as soon as it is reasonably practical following use.
- Disassemble only where intended, without the use of the tools unless specifically provided by the manufacturer. Where instructions for disassembly are required, these are available with the device.
- Use suitable autoclavable pipe cleaning apparatus to clean small bore tubes and fine lumens. These areas should be thoroughly flushed through before being placed in the washer / disinfectant as they are particularly difficult for automated cleaning
- Burnt on deposits may have to be removed before automated cleaning.

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## **Cleaning – Automated**

- **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 and recommended cycles.**
- Load devices carefully, with any box joints and hinges open and so that any fenestrations in devices can drain.
- Care must be taken when loading the instruments to prevent damage to fine needles, wires and delicate instruments.
- Place heavy devices with care in the bottom of containers, taking care not to overload wash baskets.
- Place devices with concave surfaces (e.g. curettes) 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.

**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 stiletto if provided) that reaches the depth of the feature. After manually cleaning, pass all devices through an automated cleaning cycle to achieve disinfection.*

**Note:** *these instructions have been validated using a washer-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 87 °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. The detergent used was a low-foaming, non-ionising spray wash detergent cleaner (max 12pH) and the rinse aid a neutral pH low-foaming, non-ionic surfactant with isopropyl alcohol.*

## **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 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, cannulations, ratchets, joints, holes and lumens for complete removal of soil and fluids. Visually inspect active devices for signs of burnt on debris. 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.

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## **Inspection and Function Testing**

- Visually inspect and check:
  - All devices for damage and wear.
  - Cutting edges are free of nicks and present a continuous edge.
  - Jaws and teeth align correctly.
  - All articulated devices have a smooth movement without excess play.
  - Locking mechanisms (such as ratchets) fasten securely and close easily.
  - Long, slender devices 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 devices.
- Remove from service any device or electrosurgical cable where there is any doubt as to the integrity of the insulation.
- The dielectric strength of the insulation may be tested using suitable equipment and with reference to BS EN 60601-1:1990, BS EN 60601-1-1:2001 and BS 5724:section 2.2:1992

**Note:** *if 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**

- **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 devices in one autoclave cycle, ensure that the steriliser manufacturers stated maximum load is not exceeded.
- Ensure devices are dry before sterilisation

## **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 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 HTM 2030 and HTM 2010. Contact: The Stationary Office for details at [www.tso.co.uk](http://www.tso.co.uk). For further information contact: NHS Estates Information Centre, Department of Health, 1 Trevelyan Square, Boar Lane, Leeds, LS1 5AE, or visit [www.nhsestates.gov.uk](http://www.nhsestates.gov.uk)

**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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