Incus
SURGICAL LTD

The Vital Link

# Re-processing Instructions (re-usable medical devices)

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In accordance with MDD 93/42/EEC, MDR745:2017 and ISO 17664:2017

**Manufacturer:** Incus Surgical Limited, Mabrook House, Bocking End, Braintree, Essex, CM7 9AA

**Symbol:**

CE

EC REP International Associates Auditing & Certification Limited,
The Black Church, St Mary's Place, Dublin 7, DO7 P4AX, Ireland

**Device(s):** the following instructions are for Class 1 Re-usable surgical Instruments supplied by Incus Surgical Limited, unless stated otherwise with the packaging of the product.

Our range of reusable surgical instruments comprise the following families of devices:

Associated Medical Devices, Chisels & Osteotomes, Clamping Instruments, Cutting Instruments, Elevators & Levers, Endoscopes, Forceps, Gouges, Hard Edge Instruments, Holloware, Hospital Furniture, Mallets, Micro Instruments, Needles, Probes, Retractors, Scissors, Speculums and Suction Instruments.

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

It is the responsibility of the re-processor to ensure that the reprocessing is performed using validated equipment, materials, and personnel in the reprocessing facility to achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the re-processor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

**Note:** *Dimensions stated in our catalogue and labels are for guidance only and may change without notice.*

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

| WARNINGS | • **HIGH ALKALINE SOLUTIONS Ph 10 AND ABOVE CAN DAMAGE THE FOLLOWING PRODUCTS: ALUMINIUM, RUBBER, INSULATED AND FIBRE LIGHT DEVICES AND BLACKENED INSTRUMENTS.**<br>• **HIGH ALKALINE SOLUTIONS Ph 10 AND ABOVE CAN LEAVE A RESIDUE OR STAIN ON INSTRUMENTS IF NOT RINSED CORRECTLY.**<br>• 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. |
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| | • No part of the process shall exceed 140°<br>• Devices with long, narrow cannula, hinges and blind holes require special attention during cleaning.<br>• Care must be taken when handling thin sections such as wire and needle electrodes.<br>• Do not use metallic or abrasive cleaning agents on insulated coatings.<br>• Do not permit sharp instruments or edges to contact insulation coating or cable covers.<br>• When handling fibre optic light cables do not allow them to be bent in a tight radius. |
| **Limitations on processing** | • Non-insulated stainless-steel instruments - Repeated processing has minimal effect on these instruments.<br>• Insulated instruments – Repeated processing of these instruments may cause deterioration of the insulation over a prolonged period.<br>• Devices made of plastic – Repeated processing may degrade the material over a long period.<br>• End of life is normally determined by wear and damage in use.<br>• Any specific limitations on the number of reprocessing cycles shall be made available with the device. |

| **INSTRUCTIONS** | |
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| **Pre-treatment at point of use before processing:** | • 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.<br>• 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.<br>• 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).<br>• To ensure the safe collection, handling, and transportation of contaminated equipment from the clinical setting to the Central Service Facility in a safe manner, trained CSSD personnel shall transport instruments for reprocessing using puncture proof and leak resistant trolleys with removable bins, and dedicated instrument trolleys. Protective attire: i.e., clothing, masks, gloves, eye protection, safety footwear should be worn. |
| **Preparation before Cleaning:** | • Reprocess all devices as soon as it is reasonably practical following use.<br>• 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.<br>• 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 / disinfector as they are particularly difficult for automated cleaning. |

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| | • Burnt on deposits may have to be removed before automated cleaning.<br>• Use suitable cleaning apparatus / brushes to clean Diathermy Quivers. Brushes must be long enough to clean right down to the base of the quivers. |
| **Cleaning** | **Automated:**<br><br>• **Use only either CE marked or validated washer-disinfector machines that comply with ISO 15883.**<br>• **Use Low foaming, non-ionising cleaning agents and detergents, following the manufacturer's instructions for use, warnings, and recommended cycles.**<br><br>1. Load devices carefully, with any box joints and hinges open and so that any fenestrations in devices can drain.<br>2. Care must be taken when loading the instruments to prevent damage to fine needles, wires, and delicate instruments.<br>3. Place heavy devices with care in the bottom of containers, taking care not to overload wash baskets.<br>4. Place devices with concave surfaces (e.g., curettes) facing down to prevent pooling of water.<br>5. Where available, use appropriate attachments to flush inside reamers and devices with lumens or cannula.<br>6. Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage.<br><br>**Automated Wash Process:**<br>• **Automatic Washing/disinfection 90-95 Degree C for a minimum of 1 minute.**<br>• **PH Neutral Detergent**<br>• **Steam Sterilisation @134-137 Degree C for 3 to 3.5 minutes.**<br><br>**Manual:**<br><br>• **Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following process:**<br><br>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.<br>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 special 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.<br>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. |

**Disinfection:**

**Automated:**

- **Use only either CE marked or validated washer-disinfector machines that comply with ISO 15883.**

  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.

| Disinfection temperature (°C) | Maximum allowable temperature (°C) | Exposure time period |
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| 70 | 75 | 100 minutes |
| 80 | 85 | 10 minutes |
| 90 | 95 | 1 minute |

**Manual:**

**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.

**Disinfection (AO 3000)** **1 min @ 90-93°C**

**Drying:**

Final rinsing and drying must be performed under conditions that rule out the re-contamination of disinfected surgical instruments. The use of medical compressed air for drying is therefore recommended, as it is fast-acting and effective. Other drying methods may comprise wiping or using an autoclave oven.

**Drying** **15 min @ 120°C**

**Inspection, maintenance, and functionality testing:**

**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.

**Inspection & Functionality Testing:**

- Visually inspect and check all devices for damage and wear – including but limited to:
  - 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.

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| | • Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged devices.<br>• Remove from service any device or electrosurgical cable where there is any doubt as to the integrity of the insulation.<br>• 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<br>**Note:** If an instrument is returned to the manufacturer, the instrument MUST be decontaminated and sterilised and accompanied by the relevant documented evidence. |
| **Packaging:** | We recommend that **Incus Surgical Limited** re-usable surgical instruments are processed using stainless steel washing and instrument baskets, produced in line with all industry standard sizes. Trinket and small wire baskets hold small items, therefore containing them during wash cycle and minimising movement.<br>**Note:** Packaging can influence the attainment of sterilization conditions; Guidance on packaging for specific processes is provided in ISO 17665-1, ISO/TS 16775, and ISO 11607-1. |
| **Sterilisation:** | • **Either CE marked or validated vacuum autoclave machines that comply with ISO 17665-1:2006 should be used.**<br>• **They should operate at 134-137°c / 2.25 bar for a minimum holding time of 3 to 3.5 minutes – always following the instructions of the machine manufacturer.**<br>• When sterilising multiple devices in one autoclave cycle, ensure that the steriliser manufacturers stated maximum load is not exceeded.<br>• Ensure devices are dry before sterilisation.<br>• Please refer to the following standards for:<br>➢ Moist Heat - ISO 17665 (and steam penetration tests ISO 17665-2).<br>➢ Low temperature steam and formaldehyde - ISO 25424<br>➢ Ethylene oxide - ISO 11135<br>➢ Dry heat - ISO 20857<br>• Post sterilisation activities include, but are not limited to:<br>➢ Allowing autoclave and packs to cool before handling.<br>➢ Not touching packs until completely cooled.<br>➢ Not touching hot racks without heat resistant gloves.<br>➢ Once cooled, checking for wet packs, tears, indicator changes etc.<br>➢ Storing according to policy |
| **Storage:** | Reprocessed surgical instruments that are used in a sterile state must completely dry before storing, always be packaged and stored in a dust-proof, clean, dry, and vermin-proof area at ambient room temperature. Ideally reprocessed instruments should be returned to the relevant ward/theatre as soon as possible following reprocessing, to avoid missing planned procedures. |
| **Transportation:** | **Transportation Method(s) needed for protection of the medical device, environment, and health care personnel:**<br>• Place in puncture proof container.<br>• Use of tip guards, holders, and brackets to secure items<br>• Pay attention to specific containment or labelling requirements<br>• Use the facilities transportation trolleys where possible to prevent dropping and damaging the instruments<br>• Always refer to the in-house transportation procedures. |

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| **Manufacturer Contact:** | Additional Information can be obtained from:<br>Geoff.dowsett@incus-surgical.com |
| **Validation:** | **Pre-Market Validation – Manual and Automated Cleaning**<br>Our range of reusable surgical instruments have been exposed to artificial test soils to simulate clinical soils and were allowed to dry for 2 hours prior to cleaning. After manual/automated cleaning, they were visually inspected for any sign of remaining soil test residual protein and total organic carbon (TOC) to an acceptable level.<br>**Incubation:** The dishes treated with the Test Extract, with the positive and negative control, and with the Extraction solvent control are incubated for 48h @ 37± 1°C in a 5% $CO_2$ atmosphere.<br>**Apparatus:**<br>• Incubator, which maintains the culture at 37°C, 5% $CO_2$<br>• Microscope, with inverted phase contrast optics<br>• Water Bath<br>• Laminar flow Cabinet<br>• Sterile disposable<br>• Tissue Culture dishes<br>• Ultrasonic Unit<br>**Detergents:**<br>• Neutral pH soap<br>• Water solution with neutral pH (7) detergent<br>• Distilled (demineralised) water<br>• ASAHI TRICHLOR AL Chemicals<br>Full reports are on file.<br>**Post-Market Validation:**<br>Incus Surgical Instruments are routinely reprocessed at a leading London Hospital CSSD Department. Independent Instrument Reprocessing Validation reports, in support of this document are on file. |

| Additional Information: References | **ISO 17664:2017**<br>Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices<br>**ISO 15883-1:2006**<br>Washer-disinfectors — Part 1: General requirements, terms and definitions and tests<br>**ISO 17665-1:2006**<br>Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices<br>**ISO 11607-1:2019**<br>Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems<br>**ISO/TS 17665-2:2009**<br>Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1<br>**ISO TS 17665-2**<br>Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1<br>**ISO 25424:2018**<br>Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation, and routine control of a sterilization process for medical devices<br>**ISO 11135:2014**<br>Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices<br>**ISO 20857:2010**<br>Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices |
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The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for re-use, as per the requirements of ISO 17664:2017.

**It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials, and personnel in the processing facility, achieves the desired result.**

This requires verification and/or validation and routine monitoring of the process.

Date issued: 13.06.22

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