INSTRUCTIONS FOR RE-PROCESSING REUSABLE DEVICES

Manufacturer: BAILEY INSTRUMENTS LTD
Device(s): The following instructions are for all reusable medical devices supplied by (name of manufacturer), 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	• 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. • No part of the process shall exceed 140° C. • Some sensitive materials (e.g. Aluminium) are damaged by high alkaline solutions (pH >10). • Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning. **Note: When reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear.**
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.
INSTRUCTIONS	
FROM POINT OF USE	• Wherever possible, do not allow blood, debris or bodily fluids to dry on instruments. If they cannot be reprocessed immediately, place soiled instruments in an enzymatic solution immediately after use and prior to cleaning.
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.
CLEANING: AUTOMATED	• **Use only either CE marked or validated washer-disinfector machines and low-foaming, pH neutral cleaning agents, 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. • Ensure that soft, high purity water which is free from 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 stilette if provided) that reaches the depth of the feature.*
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 sink dedicated for instrument cleaning (not used for hand washing), rinse excess soil from instrument (water temp <35° C). 2. 3. Keeping the instrument submerged, with an autoclavable brush, apply CE marked cleaning solution to all surfaces. 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. 4. Rinse instruments thoroughly with soft, high purity water which is free from endotoxins, so that the water reaches all parts of the instrument, 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, holes and lumens for complete removal of soil and fluids. If any soil or fluids are still visible, return the instrument for repeat decontamination.
MAINTENANCE	• Apply surgical grade, non-silicon based lubricants to hinges, joints and moving parts as per the lubricant manufacturer's instructions.
INSPECTION AND FUNCTION TESTING	• 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 **Note:** *if an instrument is returned to the manufacturer / supplier, the instrument* ***must*** *be decontaminated and sterilised and be accompanied with the relevant documented evidence.*
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. If the instruments cannot be dried prior to sterilisation, then use distilled/de-ionised water in the final-rinse stage of cleaning.
STORAGE	• Ensure instruments are dry before storage, and stored in dry, clean conditions at an ambient room temperature.
ADDITIONAL INFORMATION	• Other forms of **cleaning** (ultrasonic, alkaline and neutral) and **sterilisation** (Low temperature steam and Formaldehyde, Ethyleneoxide 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.
MANUFACTURER	• See brochure for telephone and address of local representative or telephone 0161 872 8707

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.