Instructions for Reprocessing of Reusable Devices

The following instructions are for all reusable medical devices supplied by Platts & Nisbett Ltd, 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 the manufacturers of any decontaminants, disinfectants and cleaning agents. Wherever possible avoid use of mineral acids and harsh, abrasive agents. • No part of the process shall exceed 140ºC. • 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 in accordance with local Health & Safety procedures.***
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. 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 prevent 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 with the device.
CLEANING: AUTOMATED	• **Use only either CE marked or validated washer-disinfector machines and low foaming, non-ionising cleaning agents and detergents following the manufacturer's 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. ***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 manually cleaning, pass all devices through an automatic cleaning cycle to achieve disinfection.* ***Note**: These instruments have been validated using a washer-disinfector cycle validated to include two cold rinses at <35ºC, a detergent cycle and a rinse cycle both at >50ºC, a disinfection cycle operating at a temperature of between 80ºC and 90ºC 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 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 the equipment is not available, use the following process:-** **1. Use a double sink system (wash/rinse) dedicated for instrument cleaning (not used for hand washing). Ensure that the water temperature does not exceed 35ºC.** **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.** **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.** **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 instrument for repeat decontamination.**
MAINTENANCE	• Apply surgical grade lubricant to hinges, joints and moving parts as per the lubricant manufacturers instructions.
INSPECTION AND FUNCTIONAL TESTING	• Visually inspect and check:- all instruments for damage and wear; cutting edges are free from 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 ISO 11607-1 or AAMI/CSR technique
STERILISATION (USA)	• **Autoclaves should comply with the requirements of, and be validated and maintained in accordance with ANSI/AAMI ST79** • **Pre-Vacuum Moist heat sterilisation operating at temperature 132°C bar for a minimum holding time of 4 minutes – always following the instructions of the machine manufacturer.** • When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturers stated maximum load is not exceeded. • Ensure instruments are dry before sterilisation.
STERILISATION (Outside USA)	• **Autoclaves should comply with the requirements of, and be validated and maintained in accordance with EN 285, EN 13060, ENISO 17665** • **Either CE marked or validated vacuum autoclave operating at 134-137ºC 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 manufacturers stated maximum load is not exceeded. • Ensure instruments are dry before sterilisation.
STORAGE	• Ensure instruments 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 NHS Estates Stationers Office Publications Centre for details at www.tsonline.gov.uk. For further information contact: NHS Estates Information Centre, Department of Health, 1 Trevelyan Square, Boar Lane, Leeds, LS1 6AE, UK or visit 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.