

## **INSTRUCTIONS FOR RE-PROCESSING REUSABLE DEVICES**

**Manufacturer:** Seward Thackray

**Device(s):** All re-usable surgical instruments supplied by (Seward Thackray). Specific instructions are made available with any exceptional instruments supplied.

<b>WARNINGS</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• No part of the process shall exceed 140° C.</li> <li>• Some sensitive material (e.g. aluminium) are damaged by high alkaline solutions (pH &gt;10).</li> <li>• Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning.</li> </ul> <p><b>Note:</b> when reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear.</p>
<b>Limitations on Reprocessing</b>	<ul style="list-style-type: none"> <li>• Repeated processing has minimal effect on these instruments.</li> <li>• End of life is normally determined by wear and damage in use.</li> <li>• Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.</li> </ul>
<b>Instructions</b>	
<b>From Point of Use</b>	<ul style="list-style-type: none"> <li>• Wherever possible, do not allow, 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.</li> </ul>
<b>Preparation for Decontamination</b>	<ul style="list-style-type: none"> <li>• Reprocess all instruments as soon as it is reasonably practical following use.</li> <li>• Disassemble only where intended, without use of tools unless specifically provided by the manufacture. Where instructions for disassembly are required these will be supplied with the product.</li> </ul>
<b>Cleaning: Automated</b>	<ul style="list-style-type: none"> <li>• <b>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, warning s, concentrations and recommended cycles.</b></li> <li>• Load instruments carefully, with any box joints and hinges open so that any fenestrations in the instruments can drain.</li> <li>• Place heavy instruments with care in the bottom of containers, taking care not to overload wash baskets.</li> <li>• Place instruments with concave surfaces facing down to prevent pooling of water.</li> <li>• Where available, use appropriate attachments to flush inside reamers and devices with lumens or cannula.</li> <li>• Ensure that soft, high purity water which is controlled for bacterial endotoxins is used in the final rinse stage.</li> </ul> <p><b>Note:</b> automated cleaning may not 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</p>

	<p>through an automatic cleaning cycle to achieve disinfection.</p> <p><b>Note:</b> these instructions have been validated using a washer-disinfector cycle validated to include two cold rinses at &lt;35°C, a detergent cycle and a rinse cycle both at &gt;50°C, a disinfection cycle operating at a temperature of between 80° C and 87°C for a minimum holding time of 1 minute and a 20 minute drying cycle. The detergent used was a 12 pH low foaming spray wash detergent cleaner and the rinse aid a neutral pH low foaming, non-ionic surfactant with isopropyl alcohol.</p>
<b>Cleaning: Inspection</b>	<ul style="list-style-type: none"> <li>• <b>After cleaning, visually inspect <i>all</i> 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.</b></li> </ul>
<b>Maintenance</b>	<ul style="list-style-type: none"> <li>• Apply surgical grade lubrication oil to hinges, joints and moving parts as per the lubrication oil manufacturer's instructions</li> </ul>
<b>Inspection and Function Testing</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged instruments.</li> </ul> <p><b>Note:</b> if an instrument is returned to the manufacturer / supplier, the instrument <b>must</b> be decontaminated and sterilised and be accompanied with the relevant documented evidence</p>
<b>Packaging</b>	<ul style="list-style-type: none"> <li>• All instruments to be packed following local protocol in accordance to BS standards.</li> </ul>
<b>Sterilisation</b>	<ul style="list-style-type: none"> <li>• <b>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.</b></li> <li>• When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.</li> <li>• Ensure instruments are dry before sterilisation.</li> </ul>
<b>Storage</b>	<ul style="list-style-type: none"> <li>• Ensure instruments are dry before storage, and stored in dry, clean conditions at an ambient room temperature and away from direct sunlight.</li> </ul>
<b>Additional Information</b>	<ul style="list-style-type: none"> <li>• Other forms of <b>cleaning</b> (i.e. ultrasonic) and <b>sterilisation</b> (i.e. Low temperature steam, Formaldehyde, Ethylene Oxide and Gas Plasma) <i>are</i> available. <i>Always</i> follow the instructions for use as issued by the manufacturer and <i>always</i> consult with them if in any doubt over the suitability of any process used.</li> <li>• Cleaning and sterilising guidelines are available in HTM 2010 and HTM 2030. Contact: The NHS Estate Stationary Office Publication Centre for details at <a href="http://www.tsonline.gov.uk">www.tsonline.gov.uk</a>. For further information contact: NHS Estates Information Centre, Department Of Health, 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE, England or visit <a href="http://www.nhsestates.gov.uk">www.nhsestates.gov.uk</a>.</li> </ul>
<b>Manufacturer Contact</b>	See brochure for telephone and address or telephone (00 44 (0)1685 844 983)

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 normally requires validation and routine monitoring of the process. Likewise any deviation by the reprocessor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.