


# ORION LARYNGOSCOPE BLADE REPROCESSING INSTRUCTIONS

These instructions are intended for use only by persons with the required specialist knowledge and training. **These reusable devices are supplied non-sterile and must be re-processed before first use and after each use.**

 <b>WARNINGS</b>	<ul style="list-style-type: none"> <li>The following instructions are for ORION laryngoscope blades only. Ensure devices are at minimum, cleaned and disinfected.</li> <li>The ORION bulb may be removed to allow thorough cleaning if required. Ensure that the bulb is securely attached onto the blade prior to any immersion, automated or sterilisation process.</li> <li>Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.</li> <li>Avoid use of mineral acids and harsh, abrasive agents.</li> <li>Do not use chemical sterilants with caustic ingredients such as: surgical scrub solutions, povidone-iodine solutions, bleach, peroxide solutions, Virox 3, Sporox and Cidex PA. Do not use garment or surface disinfectants.</li> <li>When reprocessing medical devices, handle with care, wearing protective clothing and face visors or goggles where appropriate.</li> </ul>
<b>LIMITATIONS ON REPROCESSING</b>	<ul style="list-style-type: none"> <li>Do not flash autoclave or use ultrasonic cleaning.</li> <li>VHP Sterilisation: Up to 230 cycles. Beyond these cycles, the device may continue to be used if inspected and determined to be in a safe and good condition for its intended use.</li> <li>Other Reprocessing Methods: As long as the device conforms to ISO 7376 requirements.</li> </ul>
<b>INSTRUCTIONS</b> <small>(* denotes parameter / equipment used in validation)</small>	
<b>AFTER POINT OF USE</b>	<ul style="list-style-type: none"> <li>It is recommended to transport the contaminated medical devices in a closed container.</li> <li>It is recommended to reprocess the medical devices immediately after use (*2 hours between soiling and pre-cleaning). A prolonged intermediate storage of medical devices used with impurities such as blood residues can lead to corrosion damage.</li> </ul>
<b>PREPARATION BEFORE CLEANING</b>	<ul style="list-style-type: none"> <li>Devices should be rinsed under cool running tap water (minimum drinking water quality), until all visible soil is removed (*1 minute).</li> <li>Rinse the hard-to-reach areas with a cleaning gun for at least 1 minute (*1 minute).</li> </ul>
<b>MANUAL CLEANING</b>	<p><b>Equipment:</b> Enzymatic Cleaner (*Neodisher MediZym, Dr. Weigert #404033), Cleaning Brush (*Interlock #09098), Tap water/flowing water (minimum drinking water quality) &amp; tank/basin for cleaning.</p> <ol style="list-style-type: none"> <li>Prepare the cleaner in accordance with the manufacturer's instructions (*Neodisher; 0.5% at 40°C).</li> <li>Soak the medical device completely in the cleaning solution.</li> <li>Brush the hard-to-reach areas with a soft brush for at least 1 minute (*1 minute). Pay attention to the critical hard-to-reach areas. Do not use a wire brush.</li> <li>Ensure that all surfaces are completely exposed to the cleaning solution for a length of time in accordance with manufacturer's instruction (*20 minutes).</li> <li>Remove the devices from the cleaning solution.</li> <li>Rinse thoroughly under clean water (minimum drinking water quality) for at least 1 minute (*1 minute) to remove the cleaning solution.</li> <li>Inspect the device for cleanliness. If any soiling remains, repeat the cleaning process.</li> </ol>
<b>MANUAL DISINFECTION</b>	<p><b>Equipment:</b> non-protein-fixing VAH-listed instrument disinfectant based on aldehydes (*Johnson &amp; Johnson, CIDEX OPA solution #20391 (active ingredient: ortho-Phtalaldehyde 0,55% / 100 g)), demineralized water (*demineralized water 20± 2°C), disinfectant tank, tank for demineralized water, lint free gauze &amp; medical compressed air.</p> <ol style="list-style-type: none"> <li>Fill the disinfectant solution in a disinfectant tank (*CIDEX OPA).</li> <li>Immerse the medical device completely in the disinfectant solution, ensuring all surfaces are exposed to the solution.</li> <li>Brush the hard-to-reach areas during the exposure time for at least 1 minute (*1 minute).</li> <li>Exposure time of the disinfectant solution in accordance with the manufacturer's instructions (*CIDEX OPA for 12 minutes).</li> </ol>

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	<ol style="list-style-type: none"> <li>5. Remove the products from the disinfectant solution.</li> <li>6. Place the instruments in a tank of demineralized water for at least 1 minute (*1 minute).</li> <li>7. Rinse with fresh demineralized water to remove the disinfectant solution completely.</li> <li>8. Wipe with a lint-free gauze and/or dry with medical compressed air.</li> </ol>
<p style="text-align: center;"><b>AUTOMATED CLEANING &amp; DISINFECTION</b></p>	<p><b>Equipment:</b> Washer disinfector with a validated process conformant to EN ISO 15883, enzymatic cleaner (*Neodisher MediZym, Dr. Weigert #404033), lint free gauze &amp; medical compressed air.</p> <ol style="list-style-type: none"> <li>1. Place the medical device in a suitable tray or place them on the load carrier that all inner and outer surfaces will be cleaned and disinfected.</li> <li>2. Pre-Rinse: Cold Water for at least 5 minutes.</li> <li>3. Cleaning: Deionised Water &amp; Enzymatic Cleaner in accordance with the manufacturer's instructions for concentration and temperature (*Neodisher; 0.2%, 5 minutes at 40°C).</li> <li>4. Rinse: Deionised water for at least 2 minutes.</li> <li>5. Thermal Disinfection: Recommended to use deionised Water at 90-95°C for at least 1 minute to achieve <math>A_0 &gt; 600</math> (*<math>A_0 &gt; 3000</math>; 90°C for 5 minutes).</li> <li>6. Drying: *15 minutes up to 120°C.</li> </ol> <ul style="list-style-type: none"> <li>• If devices are not dry, wipe with a lint-free gauze and/or dry with medical compressed air.</li> <li>• Inspect the device for cleanliness. If any soiling remains, manually clean the devices and repeat the automate cleaning &amp; disinfection process.</li> </ul>
<p style="text-align: center;"><b>PACKAGING</b></p>	<ul style="list-style-type: none"> <li>• All devices should to be packed following local protocol in accordance with BS standards.</li> </ul>
<p style="text-align: center;"><b>VHP STERILISATION</b></p>	<p><b>Equipment:</b> Steris Low Temperature Sterilisation System (V-PRO®1 Low, V-PRO® Plus Low, V-PRO® maX, V-PRO® maX 2, V-PRO® 60) &amp; VAPROX HC Sterilant.</p> <ol style="list-style-type: none"> <li>1. Ensure devices are clean prior to sterilisation. Repeat cleaning process if soiling is identified.</li> <li>2. Use the Standard, Lumen, Non-Lumen or Flexible Cycle. (*V-PRO maX; ½ Non-Lumen Cycle)</li> </ol>
<p style="text-align: center;"><b>STORAGE</b></p>	<ul style="list-style-type: none"> <li>• Ensure all devices are dry before storage, and stored in dry, clean conditions at an ambient room temperature.</li> </ul>
<p style="text-align: center;"><b>ADDITIONAL INFORMATION</b></p>	<ul style="list-style-type: none"> <li>• Follow cleaning and disinfection guidelines as per HTM 01-01.</li> <li>• Visually inspect and functionally check all devices. Dispose devices if damaged or if contaminants cannot be removed.</li> <li>• These instructions have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. 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.</li> </ul>

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