



## INSTRUCTIONS FOR RE-PROCESSING REUSABLE DEVICES

The following instructions are for all CRY02 and CRY03 devices supplied by Crytych unless stated otherwise with the packaging of the product.

<b>WARNINGS</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Always follow instructions and warnings as issued by manufacturers of devices, materials and equipment.</li><li><input type="checkbox"/> When reprocessing medical devices, handle with care, wearing protective clothing and face visors or goggles.</li><li><input type="checkbox"/> These instructions are intended for use only by persons with the appropriate specialist knowledge and training.</li></ul>
<b>LIMITATIONS ON REPROCESSING</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Repeated processing has minimal effect on these instruments.</li><li><input type="checkbox"/> End of life is normally determined by wear and damage in use.</li></ul>
<b>INSTRUCTIONS</b>	
<b>FROM POINT OF USE</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Soiled instruments should be placed in to a holding solution (combined disinfectant / enzymatic solution) immediately after use and prior to cleaning. If a holding solution is not readily available, covering the soiled instruments in a moistened towel or moistened absorbent material is recommended. It is important not to let the instrument soil completely dry out as this will worsen the challenge to the cleaning process.</li></ul>
<b>PREPARATION FOR DECONTAMINATION</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Reprocess all instruments as soon as it is reasonably practical following use.</li><li><input type="checkbox"/> Disassemble only where intended, without the use of tools unless specified by Crytych.</li></ul>
<b>CLEANING: AUTOMATED</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> <b>It is important to soak instruments in an enzymatic soak prior to the use of a washer-disinfector.</b></li><li><input type="checkbox"/> <b>Use only validated washer-disinfector machines and cleaning agents, following the manufacturer's instructions for use, warnings and recommended cycles.</b></li></ul> <ol style="list-style-type: none"><li>1. Using a sink dedicated to instrument cleaning (not used for hand-washing), perform an enzymatic soak with warm water (approximately 40 °C) as per the instructions provided by the manufacturer of the enzymatic solution. Soak the instruments for a minimum of 15 minutes. If cleaning a driver, use a brush to clean around the driver head. Change the solution often if grossly soiled.</li><li>2. Load instruments carefully into a wire basket, with any box joints and hinges open and so that fenestrations in instruments can drain.</li><li>3. Place heavy instruments into the bottom of the wire basket, taking care not to overload.</li><li>4. Place instruments with concave surfaces facing down to prevent pooling of water.</li><li>5. Place the wire basket containing all instruments in the washer-disinfector and run on the recommended cycle.</li></ol> <p><b>Note:</b> <i>Unless explicitly stated otherwise, all Crytych instruments, other than aluminium trays, can withstand high pH detergents.</i></p>
<b>CLEANING: MANUAL</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> <b>Manual cleaning is not advised if an automatic washer-disinfector is available. If an automatic washer-disinfector is not available, use the following process:</b></li></ul> <ol style="list-style-type: none"><li>1. Using a sink dedicated to instrument cleaning (not used for hand washing), perform an enzymatic soak with warm water (approximately 40°C) as per the instructions of the enzymatic solution manufacturer. Soak the instruments for a minimum of 15 minutes. Actuate any working mechanisms 3 times. Change the soak solution often if grossly soiled.</li><li>2. Keeping the instrument submerged in the soak solution, use a soft brush or a clean cloth to remove visible soil. Use an appropriate size cleaning brush to thoroughly brush the entire length of any lumens. Each lumen should be brushed through a minimum of 5 times.</li><li>3. After the enzymatic soak, rinse instruments thoroughly with clean, warm water, taking care to flush all lumens and crevices, for at least one minute each until the water runs clear.</li><li>4. Place all instruments in an ultrasonic bath containing fresh enzymatic detergent solution. Verify that all surfaces are in contact with the detergent solution. Actuate any working mechanisms 3 times. Sonicate the instruments for at least 15 minutes.</li><li>5. Rinse each instrument thoroughly for at least one minute with clean warm water, including the lumens, actuating any mechanisms 3 times. Rinse instruments again in de-ionised water. Repeat until all visible residues have been removed and the water runs clear. If instruments are not visibly clean, repeat cleaning steps 1-5.</li><li>6. Dry the instruments with a clean soft cloth and use clean compressed air or 70% isopropyl to dry the lumens.</li></ol> <p><b>Note:</b> <i>When manual cleaning is used it may not be possible to disinfect the device prior to further handling.</i></p>



## INSTRUCTIONS FOR RE-PROCESSING REUSABLE DEVICES

The following instructions are for all CRY02 and CRY03 devices supplied by Crytych unless stated otherwise with the packaging of the product.

<b>CLEANING: INSPECTION</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> After cleaning, check all surfaces, cannulations and lumens for complete removal of soil.</li><li><input type="checkbox"/> If any soil is still visible, return the instrument for complete decontamination.</li><li><input type="checkbox"/> If cleaning a driver, ensure that the driver head has not been damaged.</li></ul> <p><b>Note:</b> <i>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.</i></p>
<b>MAINTENANCE</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> This instrument does not require maintenance.</li></ul>
<b>INSPECTION AND FUNCTION TESTING</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Visually inspect and check:<ul style="list-style-type: none"><li>- All instruments for damage and wear</li><li>- Cutting edges are free of nicks and present a continuous edge</li><li>- Long, slender instruments are not distorted</li><li>- Any component part fit and assemble correctly with mating components</li></ul></li><li><input type="checkbox"/> Remove for repair or replacement any blunt, worn out, fractured or damaged instruments.</li></ul> <p><b>Note:</b> <i>If an instrument is returned to the manufacturer/supplier, the instrument <b>must</b> be decontaminated and sterilised, and be accompanied with appropriate documented evidence.</i></p>
<b>PACKAGING</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> All instruments are to be packaged following local protocol in accordance with National Standards.</li></ul>
<b>STERILISATION</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> <b>The following sterilisation procedure has been validated as effective for Crytych Instruments.</b><ul style="list-style-type: none"><li>- <b>Method: Moist-Heat Sterilisation</b></li><li>- <b>Vacuum Autoclave</b></li><li>- <b>Temperature: 134°C (273.2°F)</b></li><li>- <b>Exposure Time: 4 minutes</b></li><li>- <b>Dry-Time: 30 minutes (minimum, in chamber)</b></li><li>- <b>Cool-Time: 60 minutes (minimum, at room temperature)</b></li></ul></li><li><input type="checkbox"/> When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.</li><li><input type="checkbox"/> 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.</li></ul>
<b>STORAGE</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Ensure instruments are dry before storage, and stored in dry, clean conditions at ambient room temperature.</li></ul>
<b>ADDITIONAL INFORMATION</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Other forms of <b>cleaning</b> (ultrasonic, alkaline and neutral) and <b>sterilisation</b> (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.</li></ul>
<b>MANUFACTURER</b>	<ul style="list-style-type: none"><li><input type="checkbox"/> Crytych Pty Ltd. Suite 1502, 275 Alfred Street, North Sydney, NSW, 2060 Australia.</li><li><input type="checkbox"/> Tel +61 2 9959 5820.</li><li><input type="checkbox"/> <a href="http://www.vestech.com.au">www.vestech.com.au</a></li></ul>

**NOTE:**  
**IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT ALL REPROCESSING, AS ACTUALLY PERFORMED IN THE REPROCESSING FACILITY, ACHIEVES 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.**