INSTRUCTIONS FOR RE-PROCESSING REUSABLE DEVICES

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

WARNINGS	Always follow instructions and warnings as issued by manufacturers of devices, materials and equipment. When reprocessing medical devices, handle with care, wearing protective clothing and face visors or goggles. These instructions are intended for use only by persons with the appropriate specialist knowledge and training.
LIMITATIONS ON REPROCESSING	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage in use.

INSTRUCTIONS

INITIAL TREATMENT AT POINT OF USE	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, cover the soiled instruments in a moistened towel or moistened absorbent material. It is important not to let the instrument soil completely dry out as this will worsen the challenge to the cleaning process.
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 specified by Cryptych.
CLEANING: AUTOMATED	**Equipment required:** **Validated washer-disinfector in compliance to ISO 15883-1 and -2.** **Alkali detergent intended for use in washer-disinfector. Do not exceed the concentration and temperature recommended by the detergent manufacturer.** **Purified water is to be used for washer-disinfector.** **IMPORTANT:** **Soak instruments in an enzymatic solution for minimum 15mins prior to the use of a washer-disinfector** 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. 2. Load instruments carefully into a wire basket, with any box joints and hinges open and so that fenestrations in instruments can drain. 3. Place heavy instruments into the bottom of the wire basket, taking care not to overload. 4. Place instruments with concave surfaces facing down to prevent pooling of water. 5. Place the wire basket containing all instruments in the washer-disinfector. 6. Using an alkali detergent at the concentration recommended by the alkali manufacturer, run the recommended cycle. An example washer-disinfector cycle is detailed below: a) Cleaning: Clean using alkali detergent at the recommended concentration for 45 minutes b) Disinfection: Disinfect at 90°C for 1 minute (i.e., a disinfection cycle with an A_0 of at least 600) c) Rinsing: Rinse with purified water d) Drying: Dry at 80°C for 10 minutes **Note:** *Unless explicitly stated otherwise, all Cryptych instruments can withstand high pH detergents.*
INSPECTION	After cleaning, check all surfaces, cannulations and lumens for complete removal of soil. If any soil is still visible, return the instrument for complete decontamination including repeating cleaning cycle. If cleaning a driver, ensure that the driver head has not been damaged.
MAINTENANCE	This instrument does not require maintenance.

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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 - Long, slender instruments are not distorted - Any component part fit and assemble correctly with mating components - Ensure instruments are dry before sterilization, paying special attention to crevices and lumens. **Note:** *If the instruments cannot be dried prior to sterilisation, then use distilled/de-ionised water in the final-rinse stage of cleaning.* ☐ Remove for repair or replacement any blunt, worn out, 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 appropriate documented evidence.*
PACKAGING	☐ All instruments are to be packaged following local protocol in accordance with National Standards.
STERILISATION	☐ **The following sterilisation procedure has been validated as effective for Cryptych Instruments.** - **Method: Moist-Heat Sterilisation** - **Vacuum Autoclave** - **Temperature: 134°C (273.2°F)** - **Exposure Time: 4 minutes** - **Dry-Time: 30 minutes (minimum, in chamber)** - **Cool-Time: 60 minutes (minimum, at room temperature)** ☐ When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded.
STORAGE	☐ Ensure instruments are dry before storage, and stored in dry, clean conditions at ambient room temperature.
ADDITIONAL INFORMATION	☐ Other forms of cleaning (ultrasonic, and neutral detergent) and sterilisation (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. Note: Cryptych Pty Ltd has not validated these alternative cleaning and sterilisation methods and cannot guarantee instruments are compatible with these methods, and will be adequately cleaned and/or sterilised. ☐ If the device could have caused or contributed to the death or serious injury of a patient, user, or other persons, or a serious public health threat, Cryptych must be notified immediately. These serious incidents must also be reported to the Competent Authority of the European Member State or, when applicable, the equivalent regulatory authority, where the user and/or patient is established. The Competent Authority for each Member State can be found at: https://ec europa eu/health/md_sector/contact_en
MANUFACTURER	☐ Cryptych Pty Ltd. Suite 1502, 275 Alfred Street, North Sydney, NSW, 2060 Australia ☐ Tel: +61 2 9959 5820. ☐ Website: https://cryptych net | Complaint Email: ComplaintManagement@vestech.com.au
EC REP **AUTHORISED REPRESENTATIVE**	☐ Emergo Europe ☐ Prinsessegracht 20, 2514 AP, The Hague, The Netherlands

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.

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