

INSTRUCTIONS FOR RE-PROCESSING REUSABLE FIBRE OPTIC LARYNGOSCOPE BLADES & HANDLES

Manufacturer: TIMESCO OF LONDON.

Reference DECON/LARY/FIBRE/2 Dated 10/01/2006

Device(s): The following instructions are for all reusable Fibre Optic Laryngoscope Blades and Handles supplied by Timesco of London, 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	<ul style="list-style-type: none"> 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. 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. Do not autoclave with sub standard stainless steel surgical instruments as this may cause a reaction and lead to rust or discolourisation. No part of the process shall exceed 140° C. Ultrasonic cleaning is not permitted, as this will cause damage to the glass fibre optic bundle. Do not flash autoclave Timesco blades or handles, this will invalidate our guarantee. Current sterilisation techniques do not inactivate prions eg new variants of Creutzfeld-Jacob disease (CJD) <p>Note: When reprocessing medical devices, handle with care, wearing protective clothing and face visors or goggles. Batteries must be removed from the handles before reprocessing.</p>
LIMITATIONS ON REPROCESSING	<ul style="list-style-type: none"> Repeated autoclaving, especially for extended periods can affect the glass fibre bundle and so lead to a reduction in the light transmission from the blade. These reprocessing instructions will have a minimal effect on all other components of the blade and handle.
INSTRUCTIONS	
FROM POINT OF USE	<ul style="list-style-type: none"> If possible, soiled blades should be placed in a holding solution (combined disinfectant/enzyme solution) immediately after use and prior to cleaning.
PREPARATION FOR DECONTAMINATION	<ul style="list-style-type: none"> Reprocess all blades as soon as it is reasonably practical following use. Where necessary Optima Fibre Optic blades may be disassembled, by removing the fibre optic core in the block of the blade, please refer to instructions for use. Sirius blades do not need to be disassembled.
CLEANING: AUTOMATED	<ul style="list-style-type: none"> Use only either CE marked or validated washer-disinfector machines and cleaning agents, following the manufacturers' instructions for use, warnings and recommended cycles. <p>Load blades and handles carefully, ensure the fibre core ends are not liable to damage during loading procedure.</p>
CLEANING: MANUAL	<ul style="list-style-type: none"> If an automatic washer-disinfector is not available, manual cleaning will be necessary as follows: Using a sink dedicated for instrument cleaning (not used for hand washing), rinse excess soil from blades and handles (water temp <35° C). Keeping the blades submerged, with a brush, apply CE marked cleaning solution to all surfaces. Pay particular attention to underside of the blade and block. Always brushing away from the body. Do not use a wire brush. Take great care not to brush against the fibre ends in the blade to avoid scratching or damage. Rinse blades thoroughly with clean water, so that the water reaches all parts of the blade, then carefully hand dry or use a drying cabinet. <p>Note: when manual cleaning is used it may not be possible to disinfect the device prior to further handling.</p>
CLEANING: INSPECTION	<ul style="list-style-type: none"> After cleaning, check <i>all</i> surfaces for complete removal of soil. If any soil is still visible, return the blade for repeat decontamination. <p>Note: automated cleaning may not be suitable for oxyport blades, 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.</p>
REASSEMBLY	<ul style="list-style-type: none"> If the blades have been disassembled (as may be the case with Optima blades), reassemble as per instructions for use. Sirius blades do not require reassembly.
INSPECTION AND FUNCTION TESTING	<ul style="list-style-type: none"> Visually inspect and check: - all blades and fibre bundles for damage and wear. Remove for repair or replacement any damaged product. <p>Note: if a blade, handle or any other component is returned to Timesco, it <i>must</i> be decontaminated and sterilised and be accompanied with the relevant documented evidence.</p>
PACKAGING	<ul style="list-style-type: none"> All blades and handles should to be packed following local protocol in accordance with BS standards
STERILISATION	<ul style="list-style-type: none"> 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. When sterilising multiple instruments in one autoclave cycle, ensure that the steriliser manufacturer's stated maximum load is not exceeded. Ensure blades are dry before sterilisation. If the blades cannot be dried prior to sterilisation, then use distilled/de-ionised water in the final-rinse stage of cleaning.
STORAGE	<ul style="list-style-type: none"> Ensure blades are dry before storage, and stored in dry, clean conditions at an ambient room temperature.
ADDITIONAL INFORMATION	<ul style="list-style-type: none"> Other forms of cleaning (alkaline and neutral) and sterilisation (Cidex OPA, Ethylene oxide up to 65 degrees C for anaesthetic devices) <i>are permitted</i>. However, <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. Follow cleaning and sterilising guidelines as per HTM 2030 and HTM 2010.
MANUFACTURER	<ul style="list-style-type: none"> Timesco of London, 1 Knights Road, London E16 2AT, Tel 020 7511 9960, Fax 020 7511 7888, E-mail info@timesco.com, Website www.timesco.com

NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL 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.