

INSTRUCTIONS FOR RE-PROCESSING TIMESCO REUSABLE SURGICAL INSTRUMENTS, LARYNGOSCOPES & PODIATRY INSTRUMENTS

Manufacturer: **TIMESCO HEALTHCARE LTD.**

Reference **I.C.001/9**

Date: **October 2020**

The following instructions are for all Timesco reusable surgical instruments, laryngoscopes and podiatry instruments manufactured by Timesco Healthcare, unless stated otherwise with the packaging of the product.

Additional instructions applicable to specific devices may be necessary and these are documented overleaf.

All reusable devices are supplied non sterile and should be cleaned and sterilised before first use and after each subsequent use.

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, this will invalidate our guarantee. When reprocessing medical devices, handle with care, wearing protective clothing and face visors or goggles where appropriate. Batteries must be removed from any battery operated devices before reprocessing.
LIMITATIONS ON REPROCESSING	<ul style="list-style-type: none"> These reprocessing instructions will have a minimal effect on all devices, but repeated autoclaving, especially for extended periods can affect certain devices, please see overleaf for specific guidance.
INSTRUCTIONS	
FROM POINT OF USE	<ul style="list-style-type: none"> If possible, soiled devices 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 devices as soon as it is reasonably practical to do so. Where necessary disassemble devices that require disassembly for adequate cleaning and reprocessing.
CLEANING: MANUAL	<ul style="list-style-type: none"> Some devices cannot be effectively cleaned by a washer-disinfector, those items should be manually cleaned as follows and then cleaned in a washer-disinfector as below: Using a sink dedicated for instrument cleaning (not used for hand washing), rinse excess soil from the device (water temp <35° C). Keeping the device submerged, with a brush, apply CE marked cleaning solution to all surfaces. Pay particular attention to underside and any jointed part of the device. Always brushing away from the body. Do not use a wire brush. Rinse the device thoroughly with clean water, so that the water reaches all parts of the device, then carefully hand dry or use a drying cabinet.
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. Load devices carefully, ensure any delicate parts of the device are not liable to damage during the loading procedure. <p>Timesco devices have been validated to the following automatic washer-disinfector cycle: Pre wash 28 °C for 4 minutes, Wash at 50 °C for 8 minutes, Rinse at 50°C for 4 minutes, Thermal Disinfection at 90°C – 95°C for 1 minute, Drying for 25 minutes. Validated detergents, Instro-Klenz, Enzycare, Olympic Spraydry 1000 and Sprayclean 2000.</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 device for repeat decontamination.
REASSEMBLY	<ul style="list-style-type: none"> If any devices have been disassembled, reassemble in accordance with any product specific instructions for use and test.
INSPECTION AND FUNCTION TESTING	<ul style="list-style-type: none"> Visually inspect and check all devices for damage and wear. Remove for repair or replacement any damaged product.
PACKAGING	<ul style="list-style-type: none"> All devices 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 all devices are dry before sterilisation. If the devices cannot be dried prior to sterilisation, then use distilled/de-ionised water in the final-rinse stage of cleaning. Timesco devices have been validated to the following steriliser cycle: Sterilising temperature 134 – 137°C, Sterilizing time 3 minutes, Normal drying time 5 minutes, Extended Drying time 15 minutes. Timesco reusable laryngoscopes have successfully passed all of the test criteria and are validated for reprocessing in the V-PRO® Low Temperature Sterilisers. Timesco recommend that you consult and follow all product labelling and instructions for use for the V-PRO® Steriliser using the operator manual for packaging and weight limitations.
STORAGE	<ul style="list-style-type: none"> Ensure all devices 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°C for anaesthetic devices) <i>are permitted</i>. However, <i>always</i> follow the instructions for use as issued by Timesco and <i>always</i> consult with us if in any doubt over the suitability of any process used. Follow cleaning and sterilising guidelines as per HTM 01-01.
MANUFACTURER	<p>Timesco Healthcare Ltd, Timesco House, 3 Carnival Park, Carnival Close, Basildon, Essex, SS14 3WN, England. E-mail info@timesco.com, Website www.timesco.com</p>

PRODUCT SPECIFIC INSTRUCTIONS FOR RE-PROCESSING TIMESCO REUSABLE DEVICES.

Additional instructions specific to certain devices may be necessary and these are documented below. Please note these instructions are in addition to the instructions listed overleaf.

REUSABLE LARYNGOSCOPE BLADES & HANDLES	
REUSABLE LARYNGOSCOPE BLADES	<ul style="list-style-type: none"> • OPTIMA and OPTIMA CLX blades have removable fibre optic cores. This core needs to be removed prior to cleaning in accordance with the supplied instructions for use. • For all Fibre Optic Blades, do not brush the ends of the fibre bundles with any abrasive brush or material as this will damage the fibre cores. • Orion Blades have a bulb in the blade which is autoclavable. The bulb does not need to be removed before reprocessing or autoclaving, but it is recommended to thoroughly clean around and behind the bulb to remove any deposits and debris. The bulb may be removed to allow thorough cleaning, but it is recommended that the bulb is refitted before the autoclave cycle. Please ensure that the bulb is tightly secured to the blade and the fit and performance is tested before use.
REUSABLE LARYNGOSCOPE HANDLES	<ul style="list-style-type: none"> • Optima, Optima XL, Sirius, XLED and Xenon Handles all contain a non-autoclavable bulb. The bulb must be removed before cleaning or autoclaving the handle. Bulbs should be manually cleaned by using an appropriate disinfectant. The area around the bulb housing and block assembly should be thoroughly cleaned during manual or automatic cleaning. Bulbs should be refitted to the handle after the handle has completed the full reprocessing and autoclaving cycle and the handle should be tested to ensure the bulb is fitted correctly and working. • Orion handles may develop deposits on the contacts with repeated reprocessing. We recommend the pin in the head block of the handle is cleaned with a cloth to remove any deposits which may affect reliable electrical contact with the blade. • We recommend the end cap is removed from all handles prior to washing and is refitted before the autoclave cycle. The end cap should be fitted so that it is not too tight on the handle during the autoclave cycle. • It is not necessary to remove the head block from the handle for cleaning or autoclaving unless it is necessary to remove a bulb.

REUSABLE ELECTROSURGERY INSTRUMENTS	
REUSABLE BIPOLAR AND MONOPOLAR FORCEPS AND CABLES.	<ul style="list-style-type: none"> • The coating on Timesco Bipolar and Monopolar forceps and cables is degraded by repeated autoclaving cycles. The Bipolar and Monopolar forceps are guaranteed to a minimum of 40 autoclave cycles or 24 months from date of purchase (whichever is sooner). The Bipolar and Monopolar cables are guaranteed to a minimum of 100 autoclave cycles or 24 months from date of purchase (whichever is sooner). • Visually inspect for <ul style="list-style-type: none"> ○ Cracked, broken or distorted plastic parts. ○ Broken or bent connector pins. ○ Cuts, punctures, nicks, abrasions, unusual bumps and significant discolouration. ○ Damage to tips including corrosion and misalignment. ○ On hand-switching forceps, check contacts for corrosion, discolouration and flatness. • Do not fully immerse or soak the forceps or cables. • These devices should be tested after each cycle to ensure the coating has not cracked or deteriorated and that there is no electrical leakage from the device.
PRODUCT GUARANTEE	<p>Timesco offer extensive guarantees across our range of reusable surgical products, users should refer to the specific guarantees provided with each product. These guarantees do not cover consumables or disposable items, fair wear and tear or any damage caused by misuse. Any alteration or marking of the product in any way will also invalidate these guarantees and the CE mark.</p>
RETURNING INSTRUMENTS TO TIMESCO	<p>Products returned to Timesco Healthcare Ltd must be accompanied by a decontamination certificate, which states that each instrument has been thoroughly cleaned and disinfected. Timesco reserve the right to immediately dispose of any products that are returned without evidence of adequate cleaning and disinfection. Please contact our customer services team for authorisation before returning any product as we may be able to resolve your query or arrange a replacement without the product having to be returned.</p>

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

V-PRO®, Virox 3, Sporox, Cidex PA, Instro-Klenz, EnzyCare, Olympic Spraydry 1000 and Sprayclean 2000 are trademarks of their respective companies.



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