Ophthalmic Surgical Instruments

Guidelines for Cleaning and Reprocessing of OPTICO surgical instruments

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1. Guidelines

Please read these instructions carefully before you prepare, apply or put the instrument to use for the first time. These instructions should be read in conjunction with the Optico Guidelines for Cleaning and Reprocessing of OPTICO surgical instruments (Document CH-001) available to down-load from our website www.optico.org.uk.

These instructions do not replace the training, the care and the state of the art of the user/applier. The user must be familiar with the relevant legal regulations, standards and recommendations, and the devices should be monitored, controlled, handled, cleaned and processed by suitably trained and qualified personnel under an approved quality management system such as ISO 13485.

Follow Department of Health and MHRA Guidance where appropriate e.g. HTM 01-01, EN 556.

Thorough cleaning prior to disinfection or sterilization is important. If a medical device is not clean then the disinfection or sterilization process might be compromised.

⚠ **WARNING: Failure to process medical devices correctly and effectively can risk transmission of infectious agents**

2. Intended Use / Purpose

OPTICO instruments are supplied **NON-STERILE** and are hand-held reusable surgical instruments – non-powered and non-measuring. The instruments have been designed for use in the eye during surgical treatments. The instruments must only be used for their intended use/purpose i.e. holding, cutting, retracting, marking etc in the medical area of expertise and by appropriately trained and qualified personnel. Incorrect use could damage the instruments.
The instruments are for use by professional ophthalmic surgeons with the appropriate training, knowledge and experience of their use. It is the responsibility of the surgeon or treating clinician to choose the most appropriate instrument for the particular surgery being performed, based on his/her experience and expertise.

3. Materials and Material resistance

OPTICO instruments are manufactured with biocompatible materials in accordance with applicable regulations:-

- Stainless Steel in accordance with DIN EN ISO 7153-1
- Titanium alloy Ti6AL4V ELI (Grade 5)
- Medical Grade MT Peek
- Aluminium – used in caps on the end of some vitreoretinal and micro anterior instruments for colour coding purposes

⚠ **WARNING: Aluminium can be damaged by high alkaline solutions (pH>7)**
The products are thermostable, but must not be subjected to temperatures higher than 141°C (286°F)

4. Warranty

OPTICO LTD offers a 5-year warranty on all of its ophthalmic surgical instruments against defects in materials and workmanship. Any instrument returned to OPTICO LTD and proven to be defective in workmanship and/or materials will be repaired or replaced free of charge.

The responsibility for the proper handling, cleaning, disinfection and sterilization of OPTICO instruments lies with the owner and/or the product user. OPTICO excludes all warranty claims and will accept no liability for direct damage and consequential damage caused by:-

- Unintended use
- Improper use, application or handling
- Improper treatment and sterilization
- Improper maintenance and repairs
- Non-observance of these instructions

NOTE: Repairs may only be carried out by OPTICO and non-observance will void any warranty claim.

5. Warnings ⚠

- OPTICO instruments are delivered **NON-STERILE** and must be inspected, cleaned and sterilised before first use and before and after every re-use.
- Do not allow blood, medicines, viscoelastic, irrigating solutions (saline), or protein residue to dry on the instruments and always reprocess the instruments as soon as possible after use.
- Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid the use of mineral acids and harsh, abrasive agents.

- Follow instructions for use and warnings issued by the manufacturer of the ultrasonic/washer/disinfector.
- OPTICO instruments have delicate tips and must be handled with care and avoid the use of metal brushes, steel wool or abrasive powders/pads.
- Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning.
- Do not attempt to disassemble an instrument that is not designed to be disassembled. Instructions will be provided with any instruments designed to be disassembled.
- Follow hospital/facility approved Health & Safety procedures at all times. Wear protective clothes, gloves and eye wear as specified in your Health and Safety procedures.
- If an instrument is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the instrument cannot be reused and must be destroyed due to the inability to reprocess or sterilize and to eliminate the risk of cross-contamination. Consult WHO and local regulations for further information.
- Ensure instruments are dry before storage.

6. Combination with other products

Instructions will be provided with any instruments that require disassembling. When reassembly, the components must not be exchanged with parts from other manufacturers.

7. Limitations on Reprocessing

OPTICO instruments include delicate parts and precise components and must be handled with care in order to extend the life of the instrument. If these instructions are correctly followed, the instruments can be reprocessed many times. It is not therefore possible to give a precise number of cleaning-sterilisation processes that the instruments can withstand. End of life is normally determined before or after reprocessing takes places through the identification of wear and damage.

8. Inspecting and Preparing New Instruments

Although OPTICO makes every effort to ensure the instruments you receive are perfect, it is advisable that you inspect each new instrument under magnification, preferably a microscope, before use. Notify us immediately of any problems and do not use instruments that show signs of damage, defects or malfunction or attempt to repair an instrument that is damaged. Always return to manufacturer for repair. If your inspection of the new instrument confirms it is in perfect condition proceed with the cleaning and sterilising as provided in this document.

9. Preparation at Point of Use

- Following use, the instrument should be cleaned of excess soil using a disposable cloth/paper wipe and flushed or immersed in sterile water as soon as possible.
- Do not allow blood, debris, visco-elastic or bodily fluids to dry on the instruments and inside cannulas as this can damage the instruments.
- The instrument should be kept moist with sterile water to prevent soil from drying on the instrument

10. Containment and Transportation

- If supplied, ensure protection caps and guards are fitted to instruments.
- Safely store and transport the instruments in a closed container to the treatment location, in order to avoid damage to the instruments and contamination to people and the environment.
- Care must be taken to prevent unwanted contamination. Follow hospital/facility approved procedures using trained staff for transporting contaminated devices.

11. Preparation for Cleaning and Decontamination

- Reprocess all devices as soon as it is reasonably practical following use.
- Disassemble only where intended, without the use of tools unless specifically provided by the manufacturer. Where disassembly of instruments is required, instructions will be provided with the device.
- To remove all blood, debris or bodily fluids us a soft bristled brush, soft enough to avoid damaging delicate tips.

12. Ultrasonic Cleaning

Ultrasonic cleaners vary, so follow the instructions supplied by the manufacturer of your ultrasonic cleaner. The following guidelines should prove helpful:-

- To reduce or avoid endotoxin contamination, we strongly recommend that you dedicate an ultrasonic cleaner to be used only for eye surgery instruments. Mixing other surgical instruments and their debris, with eye instruments, could promote cross contamination.
- If a unit is used for other types of surgical instruments, we recommend it should be emptied, cleaned, rinsed and dried, in accordance with the manufacturer's directions, before use with ophthalmic instruments.

- Only use a cleaning solution that is recommended for titanium and stainless-steel surgical instruments and follow the guidelines set by the detergent manufacturer and ultrasonic cleaner manufacturer
- The instruments must be placed on a silicone mat in the ultrasonic cleaner. DO NOT put instruments in contact with metal surfaces.
- Ensure all locks, handles and jaws are in the open position, lumen and holes are set at an angle to drain and do not allow the instruments to touch each other.
- Ensure items are fully immersed and any air contained in the device is displaced.
- Ensure the instruments are given a final rinse in a clean bath of distilled or deionised water making sure to thoroughly flush instruments with lumens. Rinsing should provide a flow through and/or over instruments.
- Dry instruments using a hot air blower or a lint-free cloth. If necessary, use medical grade compressed air to dry any cannulated devices. Inspect and test prior to further processing.

13. Manual Cleaning

Manual cleaning is not recommended when an automated washer-disinfector is available. However, due to the nature of some medical devices it may be necessary to manually clean these before processing through the automated process.

- Use a double sink system dedicated only for cleaning instruments. Do not use a hand wash basin. Use a hospital/facility approved and CE marked detergent to the manufacturer's guidelines in the first sink and pure water, such as demineralised/distilled water in the second sink
- Rinse excess soil from device.
- Fully immerse devices into a hospital approved and CE marked detergent solution not exceeding 30°C.
- It is recommended that the device be cleaned as soon after use as possible, however where blood, tissue, saline or viscoelastic has been left to dry it is recommended that the device is left to soak for 30 minutes in the detergent solution.
- Keeping the device fully immersed in the solution, brush, wipe and agitate the item to dislodge any visible dirt. Pay particular attention to any serrations, teeth, ratchets, hinges or other difficult to clean areas. Ensure the instrument is thoroughly cleaned in both the open and closed position. Always brush away from the body to avoid splashing.
- It is important to ensure that no air is trapped inside devices with lumens or cannulations and that the detergent covers all surfaces. These devices should also be flushed through with a clean detergent solution for a minimum of 3 times.
- After manual cleaning, transfer items to the second sink and ensure device is fully immersed. Rinse thoroughly with demineralised/distilled water to remove all residues. Flush any lumen with demineralised/distilled water to ensure water flows freely. Ensure any blind holes are repeatedly filled and emptied.

14. Automated cleaning – Washer / Disinfector

- We recommend using a washer-disinfector meeting the requirements of ISO 15883 series.
- OPTICO surgical instruments are delicate and must be loaded carefully, ensuring all handles are in the open position and the delicate tips are not touching any hard surfaces
- Where available, use appropriate flushing adaptor attachments to flush inside devices with lumens or cannulations. Ensure lumens and cannulas have unobstructed flow prior to fitting flushing adaptors to ensure thorough cleaning and disinfection.
- Ensure that soft, freshly distilled or demineralised water, which is sterile or controlled for endotoxins is used in the final rinse stage.
- When removing instruments, check cannulations, holes etc. for complete removal of visible soil and if necessary, repeat cycle or repeat manual cleaning.
- After the cycle is finished, the instruments need to be inspected as per Inspection/Function Testing as outlined in section 17 of this document.

15. Manual Disinfection

Disinfection solution may be used in accordance with label instructions of the disinfectant manufacturer. After manual disinfection, rinse the device with freshly distilled or demineralised water for a minimum of 3 times. Ensure that running water passes through cannulations and blind holes are repeatedly filled and emptied. Re-do the entire manual cleaning and disinfection process if the last rinsing solution is not clear or if impurities are still visible on the device.

16. Drying

Drying can be achieved as part of an automated cleaning and disinfection process.
Products may be dried using filtered, compressed air.

17. Inspection / Function Testing / Disposal

- Visually inspect and check all instruments for damage and wear.
- Ensure all cutting edges are free of nicks and present a continuous edge and jaws and teeth align correctly.
- Check all articulated instruments have smooth movement without excess play, locking mechanisms fasten securely and close easily, long slender instruments are not distorted and any component parts fit and assemble correctly with mating components.
- Remove for repair or replacement any blunt, worn out, flaking, fractured or damaged instruments
- If an instrument fails the quality checks it should be segregated, identified accordingly and decontaminated. It should then be either returned to OPTICO for repair along with the signed Decontamination Certificate, or disposed of following hospital approved procedures i.e. Sharps Bin or Clinical Waste etc.

NOTE: If an instrument is returned to the manufacturer / supplier, it must be decontaminated and be accompanied by the relevant documented evidence. A repair form is available to download from the OPTICO website www.optico.org.uk.

18. Sterilisation

- Moist heat (steam) in autoclavable bags is the preferred method of sterilisation.
- Only use CE marked or validated vacuum autoclaves and always follow the instructions of the machine manufacturer.
- Ensure all instruments are thoroughly cleaned before sterilising and follow the guidelines in ISO 17665, HTM 2031 or the equivalent guidance document in your facility.
- For effective steam penetration, use perforated ophthalmic trays and open all ratchets and locks on the instruments.
- Protective caps provided with instruments are not suitable for high temperatures and should be removed before sterilisation.
- Ensure the autoclave has fully finished the cycle before opening the door.

We recommend you sterilize your Optico instruments using steam autoclave procedures that are regularly used in hospitals and surgery centres. The following table provides suggested cycles in accordance with Health Technical Memorandum 01:01: Part C: Steam sterilization. Other methods, times and temperatures may be used, however, the user should validate these methods.

High Temperature Steam		
Sterilization temperature	121°C	134°C
Maximum temperature	124°C	137°C
Minimum holding time	15 min	3 mins

19. Storage

Following sterilisation processing, packaged instruments may be stored in a clean area free of temperature and humidity extremes in accordance with your facility's policies.

20. Additional Information

Other forms of cleaning and sterilisation are available, but always follow the instructions for use as issued by the processing equipment manufacturer and always consult with them if in any doubt over the suitability of any process used.

Any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences. All cleaning and sterilisation processes require validation at the point of use.

OPTICO supplies sterilising trays that have been designed to hold our delicate micro incision instruments so please contact us for further information.

The instructions provided above have been validated as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed, using equipment, materials and personnel in the processing facility, achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

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