

Title: Instrument Cleaning & Reprocessing Guidelines

1. Guidelines

These instructions are recommended for the care, cleaning, maintenance and sterilisation of reusable Optico surgical instruments. This document is intended to assist health care personnel in safe handling practices, effective reprocessing, inspection and maintenance of Optico reusable instruments.

2. Instruments

These instructions for use are suitable for all Optico Ltd instruments.

3. Intended Use / Purpose

Re-useable surgical instruments used by qualified healthcare personnel to perform invasive surgical procedures in Ophthalmic Surgery.



4. Warnings

- Instruments are delivered NON-STERILE and must be inspected, cleaned and sterilised before first use and before and after every re-use.
- We recommend that you inspect each new instrument under magnification before use. Do not use instruments that show signs of damage, defects or malfunction or attempt to repair an instrument that is damaged.
- Do not allow blood, medicines, OVD's, 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.
- Instruments have delicate tips and must be handled with care, do not use metal brushes, steel wool or abrasive powders/pads.
- Follow instructions for use and warnings issued by the manufacturer of the ultrasonic/washer/disinfectant equipment.

- Instruments with long, narrow lumen, hinges, grooves 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.
- 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.
- 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)
- Any serious incident that has occurred in relation to the instrument should be reported to the manufacturer and the competent authority in which the user and/or patient is established.
- Follow hospital/facility approved, Health & Safety procedures.
 - Wear protective clothes, gloves and eye wear as specified in your Health and Safety procedures.

5. Limitations on Reprocessing

Repeated processing has minimal effect on these instruments. End of life is determined by wear and tear and damage in use. Any specific limitations on the number of reprocessing cycles shall be made available with the instrument.

6. Preparation at Point of Use

Following use, the instrument should be cleaned of excess soil using a disposable fibre free wipe cloth/paper wipe and flushed or immersed in demineralised/sterile water (not saline) as soon as possible.

- Do not allow blood, debris, OVD's or bodily fluids to dry on the instruments and inside lumen as this can damage the instruments.
- The instrument should be kept moist with demineralised/sterile water (not saline) to prevent soil from drying on the instrument

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7. Containment and Transportation

- Safely store and transport the instruments in a closed container to the treatment location, 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 instruments.

8. Preparation for Cleaning and Decontamination

- Reprocess all instruments 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 instrument.
- To remove all blood, debris or bodily fluids use a soft bristled brush to avoid damaging delicate tips.

9. Ultrasonic Cleaning

Ultrasonic cleaning is used as a preparation before automated cleaning

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

- Submerge the instruments in an ultrasonic bath filled with 5 mL per litre detergent and distilled water to be processed for 10 minutes.
- 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 instrument is displaced.
- Instrument can now be cleaned and disinfected see section 10

10. Automated cleaning – Washer / Disinfector

- We recommend using a washer-disinfector meeting the requirements of ISO 15883 series.
- Optico Ltd 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 instruments with lumens. Ensure lumen has unobstructed flow prior to fitting flushing adaptors to ensure thorough cleaning and disinfection.
- Ensure that the automated washer / disinfector is connected to a water supply of the quality as recommended by its manufacturer.
- Use preservative-free solutions.
- When removing instruments, check for complete removal of soil, and if necessary, repeat cycle.
- After the cycle is finished, the instruments need to be inspected as per Inspection/Function Testing as outlined in section 12 of this document.
- The following ultrasonic/washer/disinfector settings are recommended

Cleaning step	Description
Sonication	As preparation before automated cleaning, submerge the instruments in an ultrasonic bath filled with 5 mL per litre detergent and distilled water to be processed for 10 minutes.  Warning: Do not allow the instruments to rest on the bottom of the ultrasonic cleaner.
Pre-wash	Flush the inner lumens or channels (if applicable) of all visible soil using cold water for at least 10 seconds. One pre-wash stage at <40 °C for 1 minute, using cold water.
Wash	One wash stage at >50 °C for 4 minutes, using cold water and 0.4% Triple-Zyme enzymatic detergent or equivalent.

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Rinse	One rinse cycle at >40 °C for 1 minute, using cold water.
Disinfection	One disinfection cycle at 90 °C for 1 minute, using purified water.

11. Drying

- Drying can be achieved as part of an automated cleaning and disinfection process.
- Ensure instruments are dry before storage.

12. Inspection/Function Testing/Disposal

- Visually inspect and check all instruments for damage and wear.
- Ensure all cutting edges are free of nicks, burrs and present a continuous edge
- Ensure 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 matching components.
- Remove for repair or replacement any instruments that are blunt, worn out, flaking, fractured, burred or damaged.
- If an instrument fails the quality checks it should be segregated, identified accordingly and decontaminated. It should then be either returned to Optico Ltd for repair along with the signed Decontamination Certificate, or disposed of following hospital approved procedures i.e. Sharps Bin or Clinical Waste etc.

13. Sterilisation

- Reprocess in autoclavable bags is the preferred method of sterilisation.
- Only use CE marked or competent authority 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.
- Ensure the autoclave has fully finished the cycle before opening the door.

We recommend you sterilise your Optico Ltd 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 sterilisation. Other methods, times and temperatures may be used; however, the user should validate these methods.

High Temperature Steam		
Sterilisation temperature	121°C/250°F	134°C/273°F
Maximum temperature	124°C/255°F	137°C/279°F
Minimum holding time	15 min	3 mins

14. 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.



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