



# OPHMED INSTRUMENT CARE GUIDE

## General Remarks

- The following are instrument care instructions for all reusable medical devices supplied by OPHMED, unless stated otherwise with the packaging of the product.
- Our instruments are designed for use by surgeons with a good knowledge of their features and how they should be used.
- The following instructions have been validated. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the facility achieve the desired results. This requires validation and routine monitoring of the process.

## Warnings

- The utmost care must be taken at all times when handling OPHMED precision surgical instruments to avoid possible damage.
- Vitreo-Retinal instruments, IOL Cutters & Diamond Knives require special care, therefore please refer to the section of additional information.
- Prior to sterilization, please remove the protective caps provided with OPHMED instruments, as there is a possibility that the cap may melt.
- 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.
- Devices with long, narrow cannula, hinges and blind holes require particular attention during cleaning.
- No part of the process shall exceed 170°C.
- Instruments must be used for their intended purposes, an incorrect use could damage instrument.
- Please note that blue surface of titanium instruments and other silver instruments are subject to tarnishing and discoloration after many times of sterilization. This will in no way affect the performance of the instrument.

Note: when reprocessing medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health & Safety procedures



### Limitations on Reprocessing

- Repeated processing has minimal effect on these devices.
- End of life is normally determined by wear and damage due to use.

### New Instruments

- OPHMED makes every effort to offer you the perfect instruments.
- Carefully move them out of their boxes and examine them under magnifier or microscope.
- If a problem is found, inform OPHMED immediately by email [info@ophmed.com](mailto:info@ophmed.com) or via Contact Us page in [www.ophmed.com](http://www.ophmed.com).
- Once the instruments have been examined and accepted, they should be cleaned before placing them in sterilization trays.

### Do . . .

- Handle instruments carefully
- Hand instruments one at a time or in small numbers
- Protect the tips of instruments, especially from other instruments
- Wipe blood off instrument immediately after use - Allowed to dry, blood causes deterioration, corrosion and pitting
- Leave instruments in solutions if necessary, for as brief a time as possible; rinsing them thoroughly with demineralized, distilled water

### Don't . . .

- Toss or drop instruments onto one another or weigh them down by stacking them on top of one another
- Throw sharp and delicate instruments in basins
- Rinse or soak instruments in saline or bleach, prolonged exposure can lead to pitting and corrosion
- Permit stainless steel to come in contact with strong solutions such as any chloride, any acid, disinfectants, salts of any kind, phenol, potassium, mercury, iodine, bleach
- Use abrasive cleaners when cleaning microsurgical instruments which can damage or scar finishes.
- Put delicate microsurgical instruments in mechanical washer unless it has a delicate cycle.



### Preparation for Cleaning

- Rinse and clean all instruments immediately after use.
- Wherever possible, do not allow blood and debris to dry on instruments.
- If cleaning cannot be done immediately, place instrument sets in a basin of sterile water, or use an enzymatic foam spray cleaner to help prevent soil from drying, removing excess soil with disposable cloth/paper wipe.
- Use a bristled brush so soft not to damage delicate tips, remove all blood, debris or bodily fluids.
- Disassemble microsurgical instruments with removable parts and open the hinged microsurgical instruments.
- Distilled, demineralized water used for flushing should be cool to avoid coagulation of proteinaceous material.
- All cannulated instruments, handpieces, suction tubes, cannula and other instruments with lumens (i.e. Vitreoretinal instruments) should be flushed thoroughly with distilled water immediately after use, to prevent caking and obstruction.

### Cleaning - Ultrasonic

- Ultrasonic cleaners utilize high frequency sound waves which create mechanical vibrations which pull soil from the instrument.
- Ultrasound penetrates areas that a brush or mechanical washer cannot reach.
- Care must be taken, as not all the OPHMED range is compatible with this method of cleaning, instruments with delicate tips, in particular some Hooks, Probes and Diamond Knives are not recommended for an ultrasonic cycle.
- Ultrasonic cleaning for 5-10 minutes with a neutral pH ultrasonic detergent is recommended.
- Prevent ion transfer by separating instruments according to their metallic composition, i.e. do not mix Titanium and Stainless steel surgical instruments in one ultrasonic cleaning cycle.
- Rinse instrument thoroughly with distilled water after the cycle to remove residue and particles from surfaces and to prevent staining
- Check screws on instruments, as vibration may loosen screws
- Instruments should be air dried
- Protect fine tips and edges which can be damaged by contact with gauze or towels
- If drying can only be accomplished with a towel, the towel must be lint-free
- The ultrasonic tank should be drained and cleaned/disinfected frequently based upon the volume of usage. This can be as frequently as every 1-2 hours.



### **Cleaning - Automated**

- Mechanical machine washing (except the open style tunnel washer) is suitable for almost all OPHMED ophthalmic instruments (with exception of Diamond Knives).
- Use only either CE marked or validated washer-disinfector machines and low-foaming, non-ionising cleaning agents and detergents following the manufacturer's instructions for use, warnings, concentrations and recommended cycles.
- It is recommended to disinfect thermally (at least 10 minutes at 93°C) to reduce the risk of disinfectant residuals.
- Disinfectant solution may be used in accordance with label instructions of the disinfectant manufacturer.
- When preparing the devices for cleaning, ensure that they do not touch each other and the instruments are relaxed (locks unlocked, hinges open etc).
- Instruments should be secured in recommended *OPHMED™* Ophthalmic Trays with silicone matting to prevent movement.
- Place devices with concave surfaces (e.g. currettes) facing down to prevent pooling of water.
- 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 deionised water which is sterile is used in the final rinse stage.

Note: automated cleaning may not be suitable for all lumens and cannulations, in which case clean manually with a water jet gun, if available, and an appropriate brush that reaches the depth of the feature. After manually cleaning, pass all devices through an automated cleaning cycle to achieve disinfection.

Note: these instructions have been validated using a washer-disinfector cycle validated to include a cold rinses at 30°C, a detergent cycle and a rinse cycle, a disinfection cycle operating at a temperature of 93°C for a minimum holding time of 10 minutes and a 20 minute drying cycle. The detergent used was a Lancerzyme, a cleaning agent for metallic surgical devices and rinsed with sterile water.

### **Cleaning - Manual**

- Care must be taken not to damage delicate tips on OPHMED instruments by the use of hard brushes, scouring agents or by excessive force.
- Manual cleaning is not advised if an automatic washer-disinfector is available. If this equipment is not available, use the following processes:



## OPHMED INSTRUMENT CARE GUIDE

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1. Rinse excess soil from instruments.
2. Fully immerse instruments into a detergent solution not exceeding 30°C.
3. 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.
4. Using a brush, wash and scrub vigorously applying detergent solution to all surfaces ensuring that hinged instruments are cleaned in both open and closed positions.
5. It is important to ensure that no air is trapped inside the devices with lumens or cannulations and that the detergent covers all surfaces. These instruments should also be flushed through with a clean detergent solution for a minimum of 3 times.
6. After manual cleaning, rinse the instruments for a minimum of 3 times. Ensure that running water passes through cannulations, and blind holes are repeatedly filled and emptied.

### **Disinfection - Manual**

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

### **Drying**

- When drying is achieved as part of a washer disinfector cycle, do not exceed 170°C.
- Instruments may be dried using filtered compressed air.

### **Lubrication**

- Ophthalmic surgical instruments do not normally require lubricating baths
- Apply a small amount of surgical grade lubrication oil to hinges, joints and moving parts to prevent staining, rusting corrosion and wear
- Traces of prior lubrication will be removed during ultrasonic cleaning



### Inspection & Testing

- Crucial step in the processing of instruments
- Use of an appropriate magnifier or microscope is recommended due to the delicate and precise nature of ophthalmic microsurgical instruments
- Visual and mechanical inspection is imperative
  - Check hinged instruments mechanically to assure that each is functioning properly
  - There should be no stiffness
  - There should be an absence of dull spots, dents, nicks or chips
  - Joints should work smoothly
  - Pins and screws should be intact
  - Jaws should be in alignment
  - Teeth should meet perfectly
- Critically inspect every instrument for misalignment function, pits, cracks, corrosion, bad edges, nicks, bent tips, loose screws or other damage
- Sharp instruments, such as scissors, trephines, cystotomes, knives, chisels and curettes should be tested for sharpness
- If a problem is observed or suspected, label the instrument and set aside for evaluation
- Remove for repair or replacement any blunt, worn out, fractured or damaged instruments
- Reprocess incompletely cleaned instruments
- Do not further process a suspect instrument

### Packaging

- Instruments are recommended to be secured in *OPHMED™* Ophthalmic Trays with silicone matting to prevent movement.
- Do not let instruments touch the sides of a tray.
- Curved jaws or tips should be protected by pointing them in the same direction.
- Wrap the trays using appropriate method.
- Ensure that cutting edges are protected, if the supplied protective caps are fitted to delicate tips, and diamond blades are retracted into their handle.

### Sterilization

- Only sterilize a clean instrument.
- The preferred method of sterilization is moist heat (steam) in autoclave at a temperature of 132 to 137degrees Celsius for a minimum hold time of 3 to 4 minutes.
- Use either CE marked or validated vacuum autoclave - always following the instructions of the machine manufacturer.



## OPHMED INSTRUMENT CARE GUIDE

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- When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded.
- Ensure instruments are dry before sterilization.
- Do not exceed 170 degrees Celsius.
- For effective steam penetration, recommend to use perforated *OPHMED™* Ophthalmic Trays and open all ratchets and locks on instruments.
- Instruments should not be taken from the Sterile Services Department until properly cooled down, as rapid lowering of temperature will cause condensation and may cause corrosion.
- Delicate tips of sharp hooks, etc. may be protected during steam sterilization by using tip protectors that have been validated for use in steam sterilization cycles.

### Storage

- Ensure instruments are completely free of moisture before storage.
- Store in a dry, clean condition at an ambient room temperature.

### Vitreo-Retinal Instruments

- OPHMED VR Instruments have a delicate working mechanism.
- Intraocular fluids may enter this mechanism, and if not cleaned out immediately after use, may lead to the instrument malfunctioning due to corrosion.
- In addition, protein may coagulate inside the mechanism if it is not flushed out prior to sterilization. This could eventually lead to the working mechanism becoming damaged.
- Through cleaning of the VR instruments immediately after use is essential.
  - Soak the instruments in an enzymatic detergent with a pH level between 6-9 for 10 minutes at 40°C (source: lab test data.)
  - If a disinfection solution is used, ensure that it is aldehyde-free. After using an aldehyde-free solution, the instrument must be rinsed with distilled or deionized water at least 3 times.
  - A syringe with the silicone tubing can be used to flush OPHMED VR Instruments.
  - Place the silicone tubing attached to the syringe (50ml or more) over the tip of the instrument and push it over the front part of the handle.
  - Flush the sterile distilled, demineralised water through the front part of the instrument.
  - Gently press the piston of the syringe, some pressure will be required to enter the mechanism.
  - Remove the demineralised water by flushing through with 100% alcohol.
  - To remove the majority of the alcohol, blow through the instrument with one or two syringes of air.



## Stains & Suggestion

Color of Stain	Reason	Suggestion
Dark brown	Dried blood and debris	Clean instruments thoroughly before sterilization.
Blue-black	Dissimilar metals being autoclaved together	Separate instruments by metal type before sterilization.
Black	Acid reaction	Remove with pencil eraser. Use a neutral detergent in the future.
Purple-black	Detergent used contains ammonia	Rinse instruments thoroughly. Avoid detergents with ammonia.
Brown-orange	Phosphate deposits from detergent used	Try removing with pencil eraser. If stain does not come off, use a neutral detergent. Rinse instruments thoroughly with distilled water.
	Rust in water used in autoclave	

## Additional Information

Other forms of sterilization (i.e. low temperature steam and formaldehyde, ethyleneoxide and gas plasma) are available. However, always follow the instructions for use as issued by the processing equipment manufacturer and always consult with them if in any doubt about 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 sterilization processes require validation at the point of use.

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