

EN (English)

Vitrectomy Lens Set

DEVICE DESCRIPTION

This is a vitrectomy lens system comprising of a set of seven autoclavable glass lenses (with a concave contact surface to match the corneal curvature) and suturable stainless steel fixation rings to hold them in position during a vitreo-retina surgery. The lenses come in different specifications so as to view different areas during the surgery.

INTENDED USE / INDICATION FOR USE

A Vitrectomy Lens Set is used to visualize different area of the posterior segment during a vitreo-retina surgical procedure using a microscope.

CONTRAINDICATIONS

Not Known.

HOW SUPPLIED

Vitrectomy Lens Set is supplied un-sterile, in a silicon container. This silicon container is enclosed within an outer printed box. The overall packing contains Vitrectomy Lens Set and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTIONS

For External use only.

⚠ WARNING

1. Read all instructions before use.
2. This device is supplied in a non-sterile state and must be cleaned, disinfected and sterilized before first use and any subsequent use.
3. Proper cleaning and disinfection steps need to be followed to ensure that the sterilization steps are effective.
4. Using mechanical processes such as pre-cleaning and ultrasonic cleaning greatly increases the effectiveness of the cleaning process.
5. For effective reprocessing, the pre-cleaning should begin as soon as the surgery has been completed but no more than 30 minutes after the surgery.
6. The complete cleaning process must take place within the next two (2) hours of completing the pre-cleaning.
7. Follow instructions and warning as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.
8. Wherever possible avoid the use of abrasive materials for cleaning and drying.
9. Incorrect handling and care or misuse can lead to premature wear of these lenses.
10. Inspect these lenses carefully for damage, cracks or malfunctions before each use.
11. Do not use damaged lenses.
12. Use only approved disinfectant solutions (e.g., FDA, DGHM, CE Mark...).
13. Ensure cleaning and disinfection solutions fully contact all lenses surfaces and lumens.
14. Store lenses in a cleaned, disinfected and dry state.
15. Do not soak in Acetone or other Solvents.
16. Automated cleaning is not recommended.
17. Rapid cooling may damage the lenses.

PRE-CLEANING STEPS

1. All lenses, S.S. Rings & silicon container parts that have been used must be submerged into cold, de-ionized water (<40 Degree Celsius) immediately after use for removing large soiling.
2. All surfaces must be cleaned with a soft bristle toothbrush to remove macroscopic contaminants. Special attention is required for uneven surfaces to remove all macroscopic contaminants.
3. DO NOT use a fixating detergent or hot water (>40 Degree Celsius) – this may cause fixation of the residue on the lenses causing the reprocessing steps to fail. A fixating detergent contains aldehyde solution that may cause fixation of the blood contaminants on the device.

4. Soak the lenses in an enzymatic detergent with a pH level between 6-9 for 10 minutes at 40 Degree Celsius
5. The lenses must be rinsed with distilled or deionized water at least 3 times.

ULTRASONIC CLEANING

Some lenses may be heavily soiled during a surgery and require additional pre-cleaning using an ultrasonic bath. When ultrasonic cleaning is done, care must be taken that the exposure time and concentrations recommended by the manufacturers of the cleaning solution are observed, and cleaning and disinfection agents are compatible with devices.

1. The lenses must be placed on a silicone mat in the ultrasonic cleaner. DO NOT place lenses in contact with any metal surface on the ultrasonic cleaner.
2. To reduce or avoid endotoxin contamination, it is recommended to change the cleaning solution from the ultrasound cleaner after each and every use.
3. When using an enzymatic detergent, care must be taken to submerge the lenses completely in the cleaning solution.
4. Turn on the ultrasonic bath (38 KHz) for 10 minutes.
5. After the ultrasonic treatment, scrub the inside and outside of the lenses with a suitable soft bristled nylon brush until all visible soil is removed.
6. Flush with distilled or deionised water to remove the cleaning detergent. A free flow of water through the device is required.
7. Ensure that the ultrasonic bath is not contaminated before use. Contamination can increase the risk of corrosion and impairs the effective cleaning process. Criteria for contamination – visibly observe the water in the bath for contaminations, dirt, debris, or other coloration of the water. If contamination is observed, the water bath must be replaced with new distilled or deionised water.

DISINFECTION

1. Disinfectant Solutions (e.g., approved by FDA, CE mark etc) may be used in accordance with label instructions of the disinfectant manufacturer. Special attention needs to be paid to disinfectant manufacturers recommended concentrations and contact durations. Ensure that disinfectant solution makes complete contact with all device surface and lumens.
2. To avoid damage to the lenses, do not exceed recommended exposure time.
3. After manual disinfection, soak and rinse in cool water for 1 min and thoroughly flush all surfaces. Repeat this procedure 3 times with fresh rinse water to ensure complete removal of the disinfectant solution.
4. Dry the lenses carefully with lint free tissue or hospital grade compressed air and place it in a dry storage box.
5. After the cycle is finished, the lenses needs to be inspected for any damage, cracks or malfunctions.

STERILIZATION

1. Make sure that the lenses have been cleaned and inspected before sterilization.
2. Verify that the sterilizer is functioning properly on a regular basis.
3. Make sure that preventive maintenance, cleaning and inspection of the sterilizer is performed on a scheduled basis, according to the manufacturer's instructions.
 - a. By EO (Ethylene Oxide): Kindly follow EO sterilizer manufacturer's instructions and settings for sterilization of the lens. It is recommended to pack and seal the clean and disinfected lenses in medical grade peel open pouches before EO sterilization. Caution: Label the pouch with date of sterilization as per your SOP for labelling & handling in house sterilized devices.
 - b. By Steam autoclaving: It is recommended that lenses are sterilized using steam autoclaving procedure that is regularly used in hospitals and surgery center. The following table provides the suggested cycles based on recommended practices.

Steam Sterilization Cycle	Preparation	Exposure Time (Minimum Time)	Temperature	Drying Time (Minimum Time)
Gravity Displacement	Wrapped	15 Minutes	132° C /270° F	20 Minutes
Pre-Vacuum	Wrapped	4 Minutes	132° C /270° F	20 Minutes
Pre-Vacuum	Wrapped	3 Minutes	134° C /273° F	20 Minutes
Flash/ Immediate Use	Unwrapped	3 Minutes	132° C /270° F	N.A.

Note: Consult the manufacturer of your steam autoclave to confirm appropriate temperature and sterilization times. Other methods, times, and temperatures may also be used, but after validation of those methods.

PRECAUTION

- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR USE

1. Take the sterile vitrectomy lens set with lenses and rings in the silicon storage container provided with the set.
2. Fix the sterile stainless steel ring on the cornea with help of sutures.
3. Put some viscoelastic on the contact surface of the vitrectomy lens to be used and gently place it on the sutured ring over the patient's cornea.

EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution/Warning (Read instruction before use)
	Manufacturer Logo
	Date of Manufacturing
	Do not use hook
	Consult IFU
	Keep away from sunlight
	Re-Use
	Authorized European Representative
	This side up

Mfg. Facility: **MADHU INSTRUMENTS PVT. LTD.**

A 260, Okhla Industrial Area Phase-I, New Delhi-110020 India
MADHU INSTRUMENTS PVT. LTD.
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4. Change lenses as per requirement during the surgical procedure. Make sure that the sterile lenses are placed only on a sterile surface during the entire surgery.
5. Clean the lenses and rings as per instruction immediately after use and put them back in the silicon storage cum sterilization case.

RETURN OF DAMAGED PRODUCT

Note: Return the product in its original packing identified by the batch number, purchase information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected in nature, severity or incidence must be report to Madhu Instruments Pvt. Ltd.

DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance with the local regulatory requirements.

Symbol	Meaning
	Conformity of European Norm
	Batch/Lot Number
	Date of Expiry
	Temperature Limitation
	Do not use if package damaged
	Moisture Limitation
	Maximum stacking
	Handle with care

EC REP

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