

EN (English)



Surgical Lenses

Irrigating Vitrectomy Lens Set

DEVICE DESCRIPTION

This Irrigating vitrectomy lens Set system comprises of a set of three glass lenses (with a concave contact surface to match the corneal curvature) fixed in a stainless-steel ring attached to a hollow steel handle. This hollow handle helps the user to hold the lens in position as well as allows irrigation fluid (through a silicone tube attached at the rear part of the handle) to reach the lens and corneal surface throughout the vitreo-retina surgery. The lenses come in different specifications so as to view different areas during the surgery.

INTENDED USE/ INDICATION FOR USE

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

MATERIALS USED

Stainless Steel, Aluminium, Glass

TARGET AGE GROUP

Can be used for all age groups.

INTENDED USER

Any of the registered medical doctor/medical professionals.

DURATION OF USE

Transient use (Less than 60 minutes).

STORAGE CONDITIONS

Store at Room Temperature

HOW SUPPLIED

Irrigating Vitrectomy Lens Set is supplied non-sterile, in a plastic box. The overall packing contains Irrigating Vitrectomy Lens Set and medical literature insert, in an outer box, with external identification stickers.

CAUTION/ 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.

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.

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.

DIRECTION FOR USE:

1. Take the sterile Irrigating Vitrectomy lens set and attach the infusion line to the rear end connector.
2. Put some viscoelastic on the contact surface of the Irrigating Lens to be used and gently place it over the patient's cornea.

EXPLICATION OF SYMBOLS:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
	This side up
	Keep Out of reach of children
	Medical Device



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.

PRECAUTIONS

- Ensure before use that product/packaging is not tampered or damaged.
- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR CLEANING & 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.

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. 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.
4. Clean the lenses as per work instruction immediately after use and put them back in the storage cum sterilization case.

RETURN OF DAMAGED PRODUCT

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 applicable local, state and country's laws and regulations.

REUSE OF DEVICE

The device should undergo a detailed multi step process of cleaning & sterilization before reuse.

Symbol	Meaning
	Handle with care
	Maximum stacking
	Batch Code
	Do not use if package is damaged and consult instructions for use
	Re-use
	Catalogue Number
	Unique device identifier
	Non-Sterile

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M.L.: MFG/MD/2023/000843

DOC No. MIPL/L2/IFU/01, Rev. No.: 00, Rev. Date: 23.01.2025