EN (English)

YAG Iridectomy Lens

DEVICE DESCRIPTION
An Iridectomy lens consists of a modified Goldman type fundus glass lens with a 7.50 mm diameter Plano-convex lens bonded on the anterior surface of the lens. These combined lenses are fixed in an anodized aluminum ring with knurling for gripping the lens firmly.

INTENDED USE/ INDICATION FOR USE
An Iridotomy Lens is a contact type lens used for carrying out iridectomy procedures with YAG laser. The lens is used to increase the power density of the YAG Laser by up to 2.5 times as compared with using no lens. It also helps stabilize the patient's eye and retains the eyelids.

CONTRAINDICATIONS
Not Known.

HOW SUPPLIED
YAG Iridotomy Lens is supplied un-sterile, in individual plastic box. This plastic box is enclosed within an outer printed box. The overall packing contains YAG Iridotomy Lens and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTIONS
For External use only.

⚠ WARNING
- Read all instructions before use.
- Follow instructions and warning as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used.
- Wherever possible avoid the use of abrasive materials for cleaning and drying.
- Incorrect handling and care or misuse can lead to premature wear of these devices.
- Inspect these devices carefully for damage, cracks or malfunctions before each use.
- Do not use damaged devices.
- Use only approved disinfectant solutions (e.g., FDA, DGHM, CE Mark…).
- Each device requires cleaning and disinfection before its first use and any subsequent use.
- Ensure cleaning and disinfection solutions fully contact all device surfaces and lumens.
- Store devices in a cleaned, disinfected and dry state.
- Do not Steam Autoclave or boil this device.
- Do not soak in Acetone or other Solvents.
- Rapid Cooling may damage this device
- Automated cleaning is not recommended.

DIRECTION FOR USE
- Take an Iridectomy Lens and clean the front contact surface using IPA (Iso Propyl Alcohol). Make sure that the lens surface is free from dust or other unwanted particles before examining each patient.
- Gently place the lens on the patient's anaesthetized cornea.
- Hold the lens in position with one hand and with the other, adjust the slit lamp setting so as to start the Laser procedure.
- Clean the lens as per given directions immediately after use and put the lens back in the case.

DIRECTION FOR CLEANING & DISINFECTION
1. Immediately after removal from patient's eye, thoroughly rinse the lens in cool water to avoid viscoelastic or soil drying on surfaces.
2. Put a few drops of mild soap (i.e. neutral pH (7.0) detergent formulated for medical instruments) on a moistened cotton ball and gently clean the lens surface in a circular motion.
3. Thoroughly rinse the lens in cool water and dry carefully with a non-linting tissue or hospital grade compressed air.
4. Visually inspect all surfaces, joints, crevices, holes and lumens for complete removal of soil. If any soil is visible, then repeat cleaning.

STERILIZATION
By EO (Ethylene Oxide) only. 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 lens in medical grade peel open pouches before EO sterilization.
Caution: Label the pouch with date of sterilization as per your SOP for labelling & handling inhouse sterilized devices.

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. After manual disinfection, soak and rinse in cool water for 1 min and thoroughly flush lumens. Repeat this procedure 3 times with fresh rinse water to ensure complete removal of the disinfectant solution.
3. Caution:
   - To avoid damage to the lens, do not exceed recommended exposure time.
   - If lens is to be used on an ulcerated cornea, lens must be sterilized before next procedure.
4. Dry the lens carefully with lint free tissue or hospital grade compressed air and place it in a dry storage box.

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 the local regulatory requirements.

EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date of Manufacture
	Keep away from sunlight
	Consult instructions for use
	Re-use
EC REP	Authorized Representative in the European Community
	This side up
	Do not use hook

Symbol	Meaning
CE	Conformity of European Norm
LOT	Batch Code
-5°C 55°C	Temperature Limit
	Do not use if package is damaged
75RH 55 RH	Humidity Limitation
	Handle with care
4	Maximum stacking
MD	Medical Device
NON STERILE	Non-Sterile

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