

EN (English)



Four Mirror Goniolens

DEVICE DESCRIPTION

A Four Mirror Goniolens is a diagnostic glass lens having Four Mirror is inclined at an angle of 62 degrees each arranged at 90 degrees interval. The lens has a small front contact surface of 9 mm diameter (Hence requires no contact medium) with a curvature similar to that of the cornea. The anterior chamber angle is viewed on the mirrors through front contact surface. The lens is fixed in an aluminum ring with a detachable handle.

INTENDED USE/ INDICATION FOR USE

A Four Mirror Goniolens is a contact type diagnostic gonioscopy lens (requires no contact medium) having Four Mirror s inclined at an angle of 62 degrees each. This lens is used to observe all quadrants of the anterior chamber angle with the help of a slit lamp microscope.

MATERIALS USED

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

CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to any of the materials used in manufacturing of the device.

HOW SUPPLIED

Four Mirror Goniolens is supplied non-sterile in individual wooden box. This wooden box is enclosed within an outer printed box. The overall packing contains Four Mirror Goniolens and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTION/WARNING

- The use of this product is restricted to a qualified doctor or medical practitioners.

DISINFECTION

- 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.
- 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.
- 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.

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
	Handle with care



- The product is designed for single use only.
- Use only approved disinfectant solutions (e.g., FDA, DGHM, CE Mark...).
- Read instructions before use.
- Incorrect handling and care or misuse can lead to premature wear of these devices.
- Do not steam autoclave or boil this device.
- Do not soak in acetone or other solvents.
- For external use only.
- Keep out of reach of children.
- Rapid cooling may damage this device
- Automated cleaning is not recommended.

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 USE

- Take a Four Mirror 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 diagnostic procedure.
- Clean the lens as per given directions immediately after use and put the lens back in the case.

DIRECTION FOR CLEANING & DISINFECTION

- Immediately after removal from patient's eye, thoroughly rinse the lens in cool water to avoid viscoelastic or soil drying on surfaces.
- 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.
- Thoroughly rinse the lens in cool water and dry carefully with a non-linting tissue or hospital grade compressed air.
- 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.

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

Symbol	Meaning
	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



MADHU INSTRUMENTS PVT. LTD.
Mfg. Facility: A 260, Okhla Industrial Area Phase-I, New Delhi-110020 India.
Regd. Add.: F-90/3D, Okhla Industrial Area Phase-I, New Delhi-110020 India
Customer Care No.: +91-11-42701030, 42701031
Email: customercare@madhuinstruments.com
Website: www.madhuinstruments.com
M.L.: MFG/MD/2023/000843