

EN (English)



78D Aspheric Lens

DEVICE DESCRIPTION

A 78 D aspheric glass lens is a diagnostic lens with an aspheric surface on one side and a spherical surface on the other side fixed in an anodized aluminum ring with knurling for gripping the lens firmly.

INTENDED USE/ INDICATION FOR USE

A 78 D Aspheric diagnostic lens is used for general fundus examination with 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

HOW SUPPLIED

78 D Aspheric Lens is supplied non-sterile, in individual plastic box. This plastic box is enclosed within an outer printed box. The overall packing contains 78 D Aspheric Lens and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTION/ WARNING

- 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.

3. Caution:

- To avoid damage to the lens, do not exceed recommended exposure time.
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.

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

- 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.
- Keep out of reach of children.



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 78 D Aspheric lens and clean both the lens surface using soft tissue paper. Make sure that the lens surface is free from dust or other unwanted particles before examining each patient.
- Gently place the lens close to the patient's eye in front of the slit lamp.
- 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 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.

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.

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



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