

ClearSHIELD

Eye Shield

DEVICE DESCRIPTION

Eye Shield is made of high impact resistant plastic and it is used over the eye pad dressing that is applied after cataract surgery or other procedures.

INTENDED USE / INDICATION FOR USE

Eye shield is used for a short duration to protect the patient's eye from accidental injury or rubbing after a cataract surgery.

MATERIALS USED

Eye Shield Clear: Polycarbonate

Eye Shield Blue and Eye Shield Green: Polypropylene

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 specified temperature and Relative humidity (Temperature in between 10°C to 30°C and Relative Humidity in between 45% to 65%).

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

Eye Shield is supplied sterile, packed in a peel open pouch. Such Packed pouches are enclosed within an outer printed box. The overall packing contains Eye Shield and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTION/ WARNING

- Do not use if package is damaged and consult Instructions for use.
- Do not use the device if the sterilized package is open or damaged.
- The product is designed for single use only.
- Do not re-use it may lead to cross contamination.

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.

EXPLANATION OF SYMBOLS:

| Symbol | Meaning |
|--------|---------------------------------|
| | Caution |
| | Manufacturer |
| | Date and Country of Manufacture |
| | Consult instructions for use |
| | Keep away from sunlight |
| | Medical Device |
| | Do not use hook |
| | This side up |
| | Temperature Limit |
| | Humidity Limitation |
| | Keep Out of reach of children |
| | Handle with care |



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- The use of this product is restricted to a qualified doctor or medical practitioners.
- Store at specified temperature and humidity.
- Keep out of reach of children.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
- Do not use the device after sterility expiry date.

PRECAUTIONS

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

DIRECTION FOR USE

- Wash/Disinfect your hands.
- Position the patient comfortably with head supported.
- Check the package sealing integrity to ensure sterility.
- Ensure good lighting.
- Place the eye shield over the eye with the curved side against the nose.
- Put the shield in place with tape across the top of the shield. The tape should go from the middle of forehead to the middle of ear.
- Apply a second and third piece of tape to ensure the shield lies firmly.

EXPIRATION DATE

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

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.

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 |
| | Use by date |
| | Do not use if package is damaged and consult Instructions for use |
| | Do not re-use |
| | Conformity of European Norm with Notified Body Number |
| | Authorized Representative in European Community |
| | Single Sterile Barrier System, sterilized using Ethylene Oxide |
| | Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide |
| | Do not re-sterilize |
| | Catalogue Number |
| | Unique device identifier |

EC REP

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