

## 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.

### TARGET AGE GROUP

Use All Age Groups

### DURATION OF USE

Transient Use (Less than 60 Minutes). It is recommended to withdraw the product after 60 minutes from the patient. The user is accountable for any type of problem taking place in case of use after 60 minutes of the same device.

### STORAGE CONDITIONS

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

### CONTRAINDICATIONS

Not Known

### NATURE OF BODY CONTACT

Skin

### MODE OF ACTION

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

### HOW SUPPLIED

Eye Shield is supplied sterile, packed in a peel open pouch. Such pouch is 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.

### MATERIALS USED

Eye Shield Clear: Polycarbonate

Eye Shield Blue and Eye Shield Green: Polypropylene

### CAUTIONS

Do not use the device if the sterilized package is open or damaged.

### ⚠ WARNING

- Madhu Instruments Pvt. Ltd. does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients are as under: -

### DEVICE LIFE

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date.

### 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         |
|        | 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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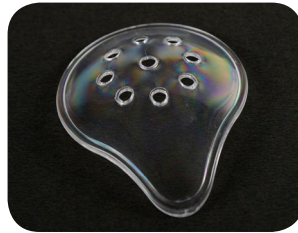
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- Re-use of device may lead to microbial contamination due to presence of Pseudomonas.
  - Contagious and communicable disease such as HIV, Hepatitis, contagion us diseases/communicable disease/undue diseases etc.
- Only qualified medical practitioner should use the device.
  - Do not use the device if the sterilized package is open or damaged.
  - Sterility is guaranteed only when the packing is neither opened nor damaged.
  - Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for devices that have been re-sterilized.
  - Do not reuse the device.
  - Read instruction before use.
  - Store at specified temperature and humidity.
  - The used Eye Shield and pouch should be disposed off in compliance with the local regulatory requirements.
  - Do not use the device after sterility expiry date.
  - For External use only.
  - Keep out of reach of children.

### PRECAUTIONS

- When handling the product care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments such as forceps etc.

### DIRECTION FOR USE

- Wash your hands
- Position the patient comfortably with head supported.
- Avoid distraction for yourself and the patient.
- Ensure good lighting.
- Always explain to the patient what you are going to do
- Place the eye shield over the eye with the curved side against 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

### 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.

| Symbol | Meaning  |
|--------|--|
|        | Maximum stacking   |
|        | Batch Code   |
|        | Use by date  |
|        | Do not use if package is damaged   |
|        | 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   |
|        | Model Number   |

**EC REP**

**Obelis s.a.**

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