

Eyeball Stand with Fixation Head

DEVICE DESCRIPTION

An Eyeball Stand with Fixation Head consists of a stainless steel Eye Holder fixed inside a plastic Fixation Head to give a more natural feel of the human face to the user. The Eye Holder has a cavity for keeping the eyeball in place whereas one of the two Eye Rings of diameter 19.00 mm and 21.00 mm is used to fix the eyeball firmly and regulate the intraocular pressure. Eye Ring is chosen depending upon the size of the eyeball being used.

INTENDED USE

Eyeball Stand with Fixation Head is used for securely fixing human / animal eye during micro-surgical training.

CONTRAINDICATIONS

Not Known.

HOW SUPPLIED

Eyeball Stand with Fixation Head is supplied un-sterile, in a corrugated box, packed properly to provide adequate protection. The overall packing contains Eyeball Stand with Fixation Head and IFU with external identification stickers.

CAUTION

For External use only.

⚠ WARNING

- Only qualified medical practitioner should use the device.
- Read instruction before use.
- Store at room temperature.
- For External use only.
- Keep out of reach of children.

PRECAUTIONS

- When handling the product, care should be taken to avoid damage from handling.

DIRECTION FOR USE

1. Loosen the Side Screw Knob, pull out the Eye Ring and keep it aside.

2. Place the eyeball into the Eye Holder with cornea facing upwards.



3. Select the Eye Ring of appropriate size according to the eyeball and insert the Eye Ring Pins into the holes adjacent to the Eye Holder.
4. After centering the cornea, further press the Eye Ring to get the desired Intraocular Pressure (IOP) and lock using the Side Screw Knob.
5. Once the eyeball is properly fixed and desired IOP is achieved, proceed with intended surgical/training procedure.

REUSE OF DEVICE

The device should undergo a detailed multi step process of cleaning before reuse.

DIRECTIONS FOR CLEANING

1. Remove all the attached foreign substances like tissues, cotton gauges, etc. by using forceps or wiping the surface by using a moistened cotton ball.
2. Rinse the device and used Eye Rings with cool fresh water.
3. Soak in mild soap water for 1 minute.
4. Thoroughly rinse the device and used Eye Rings with cool fresh water to completely remove the soap and dry carefully by wiping with a non-linting tissue, cloth or sponge or using hospital grade compressed air.
5. Visually inspect all surfaces, joints, crevices and holes for proper cleaning. Repeat the process, if device is not cleaned properly.
6. Keep the device and Eye Rings in a dry storage box.
7. Before use, wipe the device with a dry non-linting tissue.

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 and Country of Manufacture |
| | Keep away from sunlight |
| | Consult instructions for use |
| | Re-use |
| | This side up |
| | Do not use hook |
| | Model Number |

| Symbol | Meaning |
|--------|----------------------------------|
| | Batch Code |
| | Temperature Limit |
| | Do not use if package is damaged |
| | Humidity Limitation |
| | Handle with care |
| | Maximum stacking |
| | Medical Device |
| | Non-Sterile |
| | Catalogue Number |

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