

DEVICE DESCRIPTION

A set of sterile disposable iris retractors is made of a blue Nylon / PP hook with an adjustable silicone lock. The Nylon / PP hook has a 'U' shaped bend on one end, which helps in engaging the iris and pulling it backwards to enlarge the pupil. The silicone lock helps in retaining the hook in retracted position during the surgery. After the surgery, the lock can be again adjusted to release the iris so that it comes back to its original position. Four such retractors at different position are used to enlarge the pupil completely. A set of iris retractors is individually packed & sealed in a pouch before sterilization.

INTENDED USE / INDICATION FOR USE

A disposable set of sterile iris retractors is used for temporary retraction (pupil enlargement) of the iris during an ophthalmic surgical procedure.

MATERIALS USED

Polypropylene, Nylon, Silicone

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 construction of the device.

HOW SUPPLIED

Iris Retractors are supplied sterile, in set of 5, packed in container and then pack in a peel open pouch. Such packed pouch is enclosed within an outer printed box. The overall packing contains Iris Retractors and medical literature inserted in an outer enclosing box, with external identification stickers.

CAUTION/WARNING

- Do not use the product if the package is damaged or open and consult instructions for use.

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.

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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- Do not use the device if the sterilized package is open or damaged.
- The product is designed for single use only.
- If re use it may lead to cross contamination.
- 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.
- The device is not for implant.
- Mishandling or improper transport can cause damage to the device or packaging

PRECAUTIONS

- Before use, please make sure that the product or packaging has not been tampered or damaged.
- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR USE

- Check the package sealing integrity to ensure sterility.
- Open the pouch of sterile set of iris retractors drop the inner container with iris retractors on a sterile surface without touching it.
- Open the container cap and take out one iris retractors and wash it with saline water.
- Make four 20G incisions at approximately 90 degrees apart. The incision sites are selected in such a position that it does not interfere with the surgical incision and maneuvers to follow.
- The silicone lock is slid backwards away from the hook side and inserted into the anterior chamber with the help of a Mcpherson forceps, going beyond the pupil margin.
- The retractors is pulled towards the limbus till desired dilation of the pupil is achieved. Holding the retractors in desired position, the silicone rubber lock is slid up to the limbus to hold the retractors in place during surgery.
- Each of the four hooks is placed in position one by one.
- To remove the retractors from the eye pull the lock backwards, disengage the hook from the iris and pull it out using slight force. The hook becomes straight momentarily and comes out of the corneal wound without damaging the cornea. The hooks regain its 'U' shape immediately after removing from the eye.

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
	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, with inside protective packaging sterilized using Ethylene Oxide
	Single Sterile Barrier System with inside and outside protective packaging, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier

EC REP

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