

Iris Retractor

DEVICE DESCRIPTION

A set of sterile disposable iris retractors is made of a blue Nylon / PP hook with an adjustable silicon 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 silicon 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.

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

The device is contraindicated for patients with known silicon and plastic sensitivity.

INDICATION/INTENDED APPLICATION

Eyeball (Supporting devices for Ophthalmic Surgery)

MODE OF ACTION

An iris retractor is made of a blue PP hook with an adjustable silicon lock. The 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 silicon 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.

HOW SUPPLIED

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

MATERIALS USED

Nylon / PP monofilament fiber, Silicone

- The silicon 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 retractor is pulled towards the limbus till desired dilation of the pupil is achieved. Holding the retractor in desired position, the silicon rubber lock is slid up to the limbus to hold the retractor in place during surgery.
- Each of the four hooks is placed in position one by one.
- To remove the retractor 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.
- The product should be store at Temperature 10°C-30°C and Humidity 45%-65%.
- Mishandling or improper transport can cause damage to the device or packaging.

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

MADHU INSTRUMENTS PVT. LTD.

Mfg. Facility: A 260, Okhla Industrial Area Phase-I, New Delhi-110020 India.
 Regd. Add.: F-90/3D, Okhla Industrial Area Phase-I, New Delhi-110020 India
 Customer Care No.: 011-42701030, 42701031
 Email: customercare@madhuinstruments.com
 Website: www.madhuinstruments.com



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:
 - a. The used Iris Retractors might not have enough strength to pull & hold the Iris and may not comply with the claim.
 - b. The U shape gets deformed after using. The used Iris Retractor might not be in a position to be used again due to this deformed shape.
 - c. Re-use of device may lead to microbial contamination due to presence of Pseudomonas.
 - d. Contagious and communicable diseases such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
- Only qualified medical practitioner should use the device.
- Sterility is guaranteed only when the packing is neither opened nor damaged.
- Do not re-sterilize the device by any method. Madhu Instruments Pvt. Ltd. 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 Iris Retractors and pouch should be disposed off in compliance with the local regulatory requirements
- Do not use the device after sterility expiry date
- The device is not for implant
- 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

- Open the pouch of sterile set of iris retractors (BY AN UNSTERILE PERSON) and drop the inner container with iris retractors on a sterile surface without touching it.
- Open the container cap and take out one iris retractor and wash it with saline water.
- Make four 20G incisions at approximately 90 degree apart. The incision sites are selected in such a position that it does not interfere with the surgical incision and maneuvers to follow.

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.

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.

Bd. Général Wahis 53
 B-1030 Brussels, Belgium
 Phone: 32.2.732.59.54, Fax: 32.2.732.60.03
 E-mail: mail@obelis.net