

**Dholakia Iris Hooks**

**DEVICE DESCRIPTION**

Dholakia Iris Hooks is a set of disposable iris retractors made of black nylon thread with an adjustable silicone lock. The hook has a 'U' shaped bend on one end, which helps in engaging the iris and pulling it backwards to enlarge the pupil. The hook is designed in such a way that the hook is angled to be in the plane of the anterior capsule. The silicone lock helps in retaining the hook in retracted position during the surgery. After the surgery, the lock can be adjusted to release the iris so that it comes back to its original position.

**INTENDED USE / INDICATION FOR USE**

A disposable set of sterile Dholakia Iris Hooks is used for temporary retraction (pupil enlargement) of the iris where dilation can not be achieved pharmacologically 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 45RH to 65RH).

**CONTRAINDICATIONS**

The device should not be used in patients with known silicone and plastic sensitivity.

**NATURE OF BODY CONTACT**

Eyeball (Supporting devices for Ophthalmic Surgery).

**MODE OF ACTION**

Dholakia Iris Hooks is a set of disposable iris retractors. The "U" shaped hook is designed in such a way that the hook lies in the plane of anterior capsule. This hook's unique design provides comfort to the iris while retraction. Silicone lock helps in retaining the position of the hooks once they are engaged and the pupil is enlarged. After the surgery, the lock can be adjusted to release the hooks so that the iris comes back to its original position.

**HOW SUPPLIED**

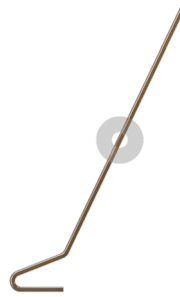
Dholakia Iris Hooks are supplied sterile, in set of 5, packed in a plastic container and then in a medical grade peel open pouch. Such pouch is enclosed within an outer printed box. The overall packing contains Dholakia Iris Hooks and medical literature insert, in an outer enclosing box, with external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

**DIRECTIONS FOR USE**

1. Open the pouch of sterile set of Dholakia Iris Hooks (BY AN UNSTERILE PERSON) and drop the inner plastic container with Dholakia Iris Hooks on a sterile surface without touching it. Open the plastic container and take out one hook and wash it with saline water.
2. Make four 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.
3. 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.
4. The retractor is pulled towards the limbus till desired dilation of the pupil is achieved. Holding the retractor in desired position, the silicone lock is slid up to the limbus to hold the retractor in place during surgery.
5. Desired quantity of hooks is placed in position.
6. To remove a Dholakia Iris Hook from the eye, pull the silicone lock backwards, disengage the iris retractor from iris. Pull it out using slight force. The hook becomes straight momentarily and comes out of the corneal wound without damaging the cornea.

**EXPLANATION OF SYMBOLS:**

Symbol	Meaning
	Caution
	Manufacturer
	Date of Manufacture
	Do not re-sterilize
	Consult instructions for use
	Keep away from sunlight
	Do not re-use
	This side up
	Do not use hook



**CAUTIONS**

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

**WARNING**

- Do not reuse the device. Madhu Instruments Pvt. Ltd does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients such as: -
  - a. The used hooks might not have enough strength to perform the desired function and may not comply with the claim.
  - b. The U shape gets deformed after using and might not be in a position to be used again.
  - c. Re-use of device may lead to microbial contamination due to presence of Pseudomonas, etc.
  - d. Contagious and communicable diseases such as HIV, Hepatitis, etc. may spread.
- Only qualified medical practitioner should use the device.
- Do not use if the hooks are broken or damaged.
- Do not re-sterilize the device by any method. Madhu Instruments Pvt. Ltd. assumes no liability for devices that have been re-sterilized.
- Read Directions for Use before using the product.
- Store at specified temperature and humidity.
- Do not use the device after sterility expiry date.
- 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.

**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 reported to Madhu Instruments Pvt. Ltd.

**DISPOSAL OF THE USED DEVICE**

The used device should be disposed of in compliance with the local regulatory requirements.

Symbol	Meaning
	Batch Code
	Use by date
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Sterilized using Ethylene Oxide
	Handle with care
	Maximum stacking

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