

Buonsanti Dual Hook

DEVICE DESCRIPTION

Buonsanti Dual Hook is a system with combination of both an Iris Retractor and a Capsular Bag supporting device (Capsule Hook).

Iris Retractor is made of a blue PP thread. The hook has a 'U' shaped bend on one end, which helps in engaging the iris and pulling it backwards to enlarge the pupil.

Capsule Hook is made of a black Nylon thread and is designed such that the hook is angled to be in the place of the anterior capsule with a bulb shaped tip which supports the capsular bag preventing any accidental damage to the peripheral capsule. Stem of the hook is bent at an angle from the end in order to make handling of both the hooks easy.

Both the hooks are combined together with an adjustable silicon lock which helps in retaining the hook in retracted position during the surgery.

A set of 5 Buonsanti Dual Hooks is packed & sealed in a blister and then in a medical grade peel open pouch before sterilization.

INTENDED USE / INDICATION FOR USE

A disposable set of sterile Buonsanti Dual Hook is used for providing temporary support to capsular bag and for temporary retraction (pupil enlargement) of the iris together without making too many incisions. It can be used in cases which have both zonular instability and small pupil size together.

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 silicon and plastic sensitivity.

INDICATION/INTENDED APPLICATION

Eyeball (Supporting devices for Ophthalmic Surgery).

MODE OF ACTION

Buonsanti Dual Hook is a system with combination of both an Iris Retractor and a Capsular Bag supporting device (Capsule Hook) which comes with an adjustable silicon lock. Dual Hook can be inserted together through the same incision reducing the number of incisions while providing benefits of both the hooks together. The silicon lock helps in retaining the hooks in position during the surgery. After the surgery, the lock can be again adjusted to release the hooks so that it comes back to its original position. Stem of the Capsule Hook is bent at an angle from the end in order to make handling of both the hooks easy.

- B. 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 slide up to the limbus to hold the retractor in place during surgery.

For Capsule Hook -

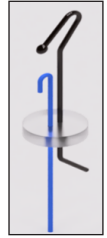
- A. The silicon lock is slide backwards away from the hook side and inserted into the anterior chamber with the help of a 'Y' pusher, going beyond the anterior chamber.
- B. The capsule hook is pulled towards the limbus till desired support of the bag is achieved. Holding the bag in desired position, the silicon rubber lock is slide up to the limbus to hold the bag in place during surgery.
3. Desired quantity of Dual Hooks are placed in position.
4. To remove the Dual Hook from the eye pull the silicon lock backwards, disengage the Iris Retractor from iris and Capsule Hook from the capsular bag. Pull it out using slight force. The hook becomes straight momentarily and comes out of the corneal wound without damaging the cornea.

EXPLICATION OF SYMBOLS:

Symbol	Meaning
	Caution/Warning
	Manufacturer
	Date of Manufacturing
	Do not resterilize
	Consult Instructions for Use
	Keep away from sunlight
	Do not Reuse
	This side up
	Do not use hook

HOW SUPPLIED

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



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: -
 - The used hooks might not have enough strength to perform the desired function and may not comply with the claim.
 - The U shape gets deformed after using and might not be in a position to be used again.
 - Re-use of device may lead to microbial contamination due to presence of Pseudomonas.
 - 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.

DIRECTIONS FOR USE

- Open the pouch of sterile set of Buonsanti Dual Hooks (BY AN UNSTERILE PERSON) and drop the inner blister with Dual Hooks on a sterile surface without touching it. Open the blister lid and take out one Dual Hook and wash it with saline water.
- Make four 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.

For Iris Retractor -

- The silicon lock is slide backwards away from the hook side and inserted into the anterior chamber with the help of a McPherson forceps, going beyond the pupil margin.

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/Lot Number
	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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