

## Capsule Hooks

### DEVICE DESCRIPTION

A set of sterile disposable capsule hook is made of Nylon with an adjustable silicon lock. Capsule hook is designed such that the hook is angled to be in the place of the anterior capsule. As a result, it's easy to get a firm and reliable grip on the rim. Further the tip of the hook is rounded to prevent any accidental damage to the peripheral capsule while placing the hooks in the bag. The round tip also provides a larger support area per hook thereby reducing the number of hooks required in each surgery. The silicon lock helps in retaining the hook in retracted position during the surgery.

### INTENDED USE / INDICATION FOR USE

A disposable set of sterile capsule hook is used for temporary support of capsule bag 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

Capsule hooks are made of nylon with an adjustable silicon lock. They are designed such that the hook is angled to be in the place of the anterior capsule. Tip of the hook is rounded to prevent any accidental damage to the peripheral capsule while placing the hooks in the bag. Round tip also provides a larger support area per hook there by reducing the number of hooks required in each surgery  
Silicon lock helps in retaining the hook in retracted position during the surgery.

### HOW SUPPLIED

Capsule Hook is 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 capsule hook and medical literature insert, in an outer enclosing box, with external identification stickers.

### MATERIALS USED

Nylon, Silicon

### 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:-

- 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 slid up to the limbus to hold the bag in place during surgery.
- Each of the five hooks is placed in position as required.
- To remove the capsule hook from the eye pull the lock backwards, disengage the hook from the capsular bag 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.

### 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.

### EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Do not re-sterilize
	Consult instructions for use
	Keep away from sunlight
	Do not re-use
	Authorized Representative in European Community
	This side up
	Do not use hook
	Medical Device
	Unique device identifier



- The used Capsule hooks might not have enough strength to grip the rim.
  - The U shape gets deformed after using. The used Capsule Hooks might not be in a position to be used again due to this deformed shape.
  - Re-use of device may lead to microbial contamination due to presence of Pseudomonas.
  - Contagious and communicable disease such as HIV, Hepatitis, contagion disease/communicable disease/undue diseases etc.
- Only qualified medical practitioner should use the device.
  - Do not use the device if the sterilized package is open or damaged.
  - Sterility is guaranteed only when the packing is neither opened nor damaged. Do not re-sterilize the device by any method. Madhu Instruments 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 Capsule hook 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 capsule care (BY AN UNSTERILE PERSON) and drop the inner container with capsule hook on a sterile surface without touching it.
- Open the container cap and take out one capsule hook and wash it with saline water.
- Make incision as per number of hooks to be used and area to be supported. The incision sites are selected in such a position that it does not interfere with the surgical incision and maneuvers to follow.
- The silicon lock is slid backwards away from the hook side and inserted into the anterior chamber with the help of a 'Y' pusher, going beyond the anterior chamber.

### 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
	Conformity of European Norm with Notified Body Number
	Batch Code
	Use by date
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Single Sterile Barrier System, sterilized using Ethylene Oxide
	Handle with care
	Maximum stacking
	Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Catalogue Number
	Keep Out of reach of children

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