

CAPSULE HOOK

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 anterior capsule. As a result, its 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 hook 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

A disposable set of sterile capsule hook is used for temporary support of capsule bag during an ophthalmic surgical procedure.

Contraindications

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

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.

Cautions

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

Warning

Tarun Enterprises does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients are as under ;

- The used Capsule hook might not have enough strength to grip the rim.
 - The U shape gets deformed after using. The used capsule hook might not be in a position to be used again due to this deformed shape.
 - Re-use of the device may lead to microbial contamination due to the presence of Pseudomonas.
 - Contagious and communicable diseases such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
- Only qualified medical practitioner should use the device as per the intended use .
 - Sterility is guaranteed only when the packing is neither opened nor damaged.
 - Do not re-sterilize the device by any method. Tarun Enterprises assumes no liability for devices that have been re-sterilized.
 - Do not re use the device
 - Read instruction before use
 - The used Capsule hook and pouch should be disposed off in compliance with local regulatory requirements.
 - Do not use the device after sterility expiry date
 - For external use only
 - Keep out of reach of children

Precautions

While handling the product care should be taken to void damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments .

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Direction for use

1. open the pouch of sterile capsule care (BY AN UNSTERILE PERSON) and drop the inner container with capsule hook on to the sterile surface without touching it.
2. Open the container cap and take out one capsule hook and wash it with saline water.
3. 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.
4. 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.
5. The capsule hook is pulled towards the limbus till desired support of the bag is acheived. The silicon rubber lock is slid up to the limbus to hold the bag in place during surgery.
6. Each of the five hooks is placed in position as required.
7. 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 eyes

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.

Explication of Symbol:

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

Symbol	Meaning
	Maximum Stacking
	Batch Code
	Use by date
	Do not use if package is damaged
	Do not re-use
	Peel Open
	Keep DRY
	Single Sterile Barrier System, sterilized using Ethylene Oxide
	Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Do not re-sterilize
	Distributor



TARUN ENTERPRISES

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TE/ART/2021-22/01 L. Rev No .02 Dated 05th Sep 2024

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