

Canabrava Gupta Segment (Capsule Support Segment)

DEVICE DESCRIPTION

Canabrava Gupta Segment (Capsule Support Segment) is a partial ring of clear PMMA covering approximately one quadrant.

INTENDED USE / INDICATION FOR USE

A disposable piece of sterile capsule support segment is used for support of capsule bag during an ophthalmic surgical procedure.

TARGET AGE GROUP

Use All Age Groups

STORAGE CONDITIONS

- Store at specified temperature and humidity (Temperature in between 5°C to 55°C and Humidity in between 55% to 75%).

CONTRAINDICATIONS

The device is contraindicated for patients with known plastic sensitivity.

NATURE OF BODY CONTACT

Capsular Bag (Supporting devices for Ophthalmic Surgery)

MODE OF ACTION

The device is highly flexible 'C' shaped clear PMMA ring. Each end has a blunt tipped eyelet to aid in insertion of the ring. When positioned in the capsular bag, the ring exerts an outward force that redistributes tension from areas of intact zonules to strengthen areas of weak or missing zonules and support the capsular bag during an ophthalmic surgical procedure. An additional eyelet is used to suture the ring to scleral tissue for better stability of the capsular bag.

HOW SUPPLIED

The Capsule Support Segment is packed in a plastic container and then in a pouch, before sterilization. Such pouch is enclosed within an outer printed box. The overall packaging contains Capsule Support Segment and medical literature insert in an outer printed box, with external identification stickers.

MATERIALS USED

Clear PMMA

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. Re-use of device may lead to microbial contamination due to presence of Pseudomonas, etc.
- b. Might spread contagious and communicable diseases such as HIV, Hepatitis, etc.
- Only qualified medical practitioner should use the device.
- Do not use if the Capsule Support Segment is 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 Instructions for use.
- 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.

DIRECTION FOR USE

- Open the pouch of sterile piece of Capsule Support Segment (BYAN UNSTERILE PERSON) and drop the inner container with Capsule Support Segment on a sterile surface without touching it.
- Open the container cap and take out Capsule Support Segment and wash it with saline water.
- Continue with the fixation procedure.

DEVICE LIFE

The expiration date of the product is the sterility expiration date. The product should not be use 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 packaging material should be disposed of in compliance with the local regulatory requirements.

EXPLICATION OF SYMBOL:

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

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, Sterilised using Ethylene Oxide
	Handle with care
	Maximum stacking
	Single Sterile Barrier System with protective packaging outside, Sterilised using Ethylene Oxide
	Catalogue Number

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