

EN (English)

PVA Segment

DEVICE DESCRIPTION

EO sterilized rectangular or round shaped PVA Segments, packed in peel open pouches.

INTENDED USE/ INDICATION FOR USE

A sterile PVA Segment is used for controlled application of Mitomycin C on the corneal tissue.

TARGET AGE GROUP

Suitable for use on all age groups.

DURATION OF USE

Transient Use (Less than 60 Minutes).

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 should not be used in patients who show hypersensitivity to PVA material.

INDICATION/INTENDED APPLICATION

Eyeball

MODE OF ACTION

When the dry PVA Segment is brought into contact with liquid (Mitomycin C) it rapidly absorbs to its full holding capacity. This soaked PVA segment is put on the corneal surface for slow release of the Mitomycin C from the PVA segment to the corneal surface.

HOW SUPPLIED

PVA Segments are supplied sterile, in a peel open pouch. Ten (10) such pouches are enclosed within an outer printed box. The overall packing contains PVA Segments and medical literature insert, in an outer enclosing box, with external identification stickers.

MATERIALS USED

PVA

CAUTIONS

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

DIRECTION FOR USE

- Take the sterile PVA Segment pouch and peel it open (BY AN UNSTERILE PERSON) and drop the Segments on to a sterile surface without touching it.
- The Segment is gently placed on a flat surface and Mitomycin C drops are poured drop by drop on the segment till it is completely wet.
- The sponge swells up on absorbing the fluid and ceases to absorb any more fluid after a point.
- Gently place the wet PVA segment on the corneal surface and wait for it to slowly release Mitomycin C on the cornea. The time duration and further surgical steps are to be followed as per the SOP of desired surgical procedure.

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.

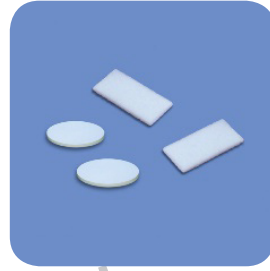
EXPLANATION OF SYMBOLS:

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



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WARNING

- Madhu Instruments Pvt. Ltd. does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patient as under: -
 - The used PVA Segments might not have sufficient soaking capacity and may not comply with the claim.
 - The PVA Segments gets deformed after wetting. The used PVA Segments 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, contagious disease/communicable disease/undue diseases etc.
- Only qualified medical practitioners 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. Madhu Instruments Pvt. Ltd. assumes no liability for devices that have been re-sterilized.
- Read instructions before use.
- Store at specified temperature and humidity.
- The used PVA Segments and pouch should be disposed off in compliance with the local regulatory requirements.
- Do not use the device after sterility expiry date.
- For External use only.
- 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.

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's 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 off in compliance with the local regulatory requirements.

Symbol	Meaning
	Handle with care
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged
	Do not re-use
	Single Sterile Barrier System, sterilized using Ethylene Oxide
	Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier
	Model Number