

EN (English)

PVA Segment

DEVICE DESCRIPTION

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

INTENDED USE

A sterile PVA Segment is used to absorb excess fluids from the corneal / scleral surface or to manipulate tissue during an ophthalmic surgical procedure.

INDICATION FOR USE

A sterile PVA Segment is indicated for use during ophthalmic surgical procedures, including cataract surgery, for the absorption of excess fluids.

MATERIALS USED

Polyvinyl Alcohol.

TARGET AGE GROUP

Suitable for use on all age groups.

INTENDED USER

Any of the registered medical doctor/medical professionals.

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.

OPERATING PRINCIPLE

The PVA Segment is composed of polyvinyl alcohol, highly absorbent material. Upon contact with liquid, it rapidly absorbs fluid and expands to its full capacity. When applied to the corneal or scleral surface, it helps absorb and retain excess fluids during ophthalmic procedures. The absorbed fluid may be gradually released, assisting in maintaining a controlled surgical field

HOW SUPPLIED

PVA Segments are supplied sterile, in a peel open pouch. These 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.

CAUTIONS / WARNING

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

EXPIRATION DATE

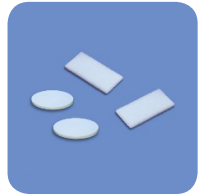
The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

RETURN OF DAMAGED PRODUCT

Return the product in its original packing identified by the batch number, purchase

EXPLICATION 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
	Handle with care



- 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

- Ensure before use that product/packaging is not tempered or damaged.
- 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.

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.

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 device and all associated items should be disposed of in accordance with applicable local, state, and country laws and regulations.

Symbol	Meaning
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged and consult Instructions for use
	Do not re-use
	Single Sterile Barrier System, sterilized using Irradiation
	Single Sterile Barrier System with protective packaging outside, sterilized using Irradiation
	Do not re-sterilize
	Catalogue Number
	Unique device identifier
	Model Number
	Keep Dry

MADHU INSTRUMENTS PVT. LTD.

Mfg. Facility: A 260, Okhla Industrial Area Phase-I, New Delhi-110020 India.
 Regd. Add.: F-90/3D, Okhla Industrial Area Phase-I, New Delhi-110020 India
 Customer Care No.: 011-42701030, 42701031
 Email: customercare@madhuinstruments.com
 Website: www.madhuinstruments.com
 M.L.: MFG/MD/2023/000843

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