

EN (English)

PVA Instrument Wipe

DEVICE DESCRIPTION

Gamma sterilized PVA Instrument Wipe is packed in a peel open pouch.

INTENDED USE

PVA Instrument Wipe is used to absorb excess fluids from the corneal / scleral surface or to manipulate tissue during an ophthalmic surgical procedure

INDICATION FOR USE

Indicated for use during ophthalmic surgical procedures to absorb excess fluid from the corneal and scleral surface and to assist in atraumatic manipulation of ocular tissues

MATERIALS USED

Polyvinyl Alcohol (PVA)

TARGET AGE GROUP

Can be used for 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 any of the materials used in manufacturing of the device.

OPERATING PRINCIPLE

The PVA Instrument Wipe works by absorbing fluids through its porous structure. When it comes in contact with fluid, it swells and retains the fluid. When moistened, it becomes soft and can be used for gentle handling or manipulation of ocular tissue.

HOW SUPPLIED

PVA Instrument Wipes are supplied sterile, in a peel open pouch. Ten Such packed pouches are enclosed within an outer printed box. The overall packing contains PVA Instrument Wipes and medical literature inserted in an outer enclosing box, with external identification stickers.

CAUTION/WARNING

- Do not use the product if the package is damaged or open consult for instructions for use.

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.

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

- Do not use the device if the sterilized package is open or damaged.
- The product is designed for single use only.
- Do not re-use it may lead to cross contamination. Reusing the device may cause transfer Contagious and communicable disease such as HIV, Hepatitis etc.
- If re use it may lead to cross contamination.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- Keep out of reach of children.
- Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
- Do not use the device after sterility expiry date.
- For External use only.



PRECAUTIONS

- Ensure before use that product/packaging is not tampered or damaged.
- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR USE

- Check the package sealing integrity to ensure sterility. Remove the Instrument Wipe from sterile packaging.
- The Instrument Wipe is gently placed on the area from which the fluid is to be absorbed.
- The sponge swells up on absorbing the fluid and ceases to absorb any more fluid after a point. The used Instrument Wipe should not be reused and put back into the pouch and disposed off with other waste for incineration.
- In case the PVA Instrument Wipe is to be used for corneal tissue manipulation, dip the tip of the sponge in saline solution for few seconds. This will make the PVA Instrument Wipe very soft and suitable for corneal tissue manipulation.

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 information, your reference and reason for return. Please contact your local distributor's office regarding product return/exchange.

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

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