

PVA Instrument Wipe

DEVICE DESCRIPTION

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

INTENDED USE/ INDICATION FOR USE

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

TARGET AGE GROUP

Use 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

In the dry state, the PVA Instrument Wipe is used to manipulate ophthalmic tissue. When the compressed PVA Instrument Wipe is brought into contact with liquid (primarily saline) it rapidly absorbs and expands to its full holding capacity. Due to this expansion, the liquid from the operating field is absorbed into the PVA Instrument Wipe and the operating area becomes dry.

HOW SUPPLIED

PVA Instrument Wipes are supplied sterile, in a peel open pouch. Ten (10) such pouches are enclosed within an outer printed box. The overall packing contains PVA Instrument Wipes 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.

⚠ WARNING

- Madhu Instruments Pvt. Ltd. does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients as under: -

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.

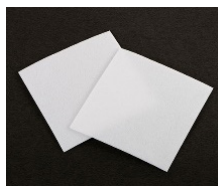
REPORTING

Adverse events and/or potentially sight-threatening complications that may

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
	Handle with care

a. The used PVA Instrument Wipes might not have sufficient soaking capacity and may not comply with the claim.



- b. The PVA Instrument Wipes gets deformed after wetting. The used PVA Instrument Wipes might not be in a position to be used again due to this deformed shape.
- c. Re-use of device may lead to microbial contamination due to presence of Pseudomonas.
- d. 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.
- Do not reuse the device.
- Read instructions before use.

Store at specified temperature and humidity.

- The used PVA Instrument Wipes 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.

DIRECTION FOR USE

1. Take the sterile PVA Instrument Wipe pouch and peel it open (BY AN UNSTERILE PERSON) and drop the Instrument Wipes on to a sterile surface without touching it.
2. The Instrument Wipe is gently placed on the area from which the fluid is to be absorbed.
3. 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.
4. 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.

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.

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
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged
	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

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