

PVA Sponge Spears

DEVICE DESCRIPTION

GAMMA sterilized compressed PVA sponge spears mounted on PP sticks packed in peel open pouches.

INTENDED USE/ INDICATION FOR USE

A sterile compressed PVA sponge spear is used to absorb excess fluids from the corneal / scleral surface or to manipulate tissue during an ophthalmic surgical procedure. A PVA sponge is particularly preferred in the LASIK laser surgery due to a very soft cell structure when wet.

TARGET AGE GROUP

Use All Age Groups

DURATION OF USE

Transient Use (Less than 60 Minutes). It is recommended to withdraw the product after 60 minutes from the patient. The user is accountable for any type of problem taking place in case of use after 60 minutes of the same device.

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 components of the preparation.

INDICATION/INTENDED APPLICATION

Eyeball

MODE OF ACTION

In the dry state, the PVA sponge spear is used to manipulate ophthalmic tissue. When the compressed PVA sponge spear 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 sponge spear and the operating area becomes dry.

HOW SUPPLIED

PVA sponge spears are supplied sterile, in pack of 2, 3 or 5. Fifty (50) such pouches are enclosed within an outer printed box. The overall packing contains PVA sponge spears and medical literature insert, in an outer enclosing box, with external identification stickers.

MATERIALS USED

PVA, K-resin

CAUTIONS

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

DIRECTION FOR USE

- Take the sterile PVA sponge spear pouch and peel it open (BY AN UNSTERILE PERSON) and drop the sponge spears on to a sterile surface without touching it.
- The tip of the spear 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 sponge spear should not be reused and put back into the pouch and disposed off with other waste for incineration.
- Incase the PVA spear 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 sponge very soft and suitable for corneal tissue manipulation.
- The product should be store at Temperature 10°-30°C and Humidity 45%-65%.
- Mishandling or improper transport can cause damage to the device or packaging.

EXPLICATION OF SYMBOLS:

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

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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 patients are as under:-
 - The used PVA Sponge Spears might not have sufficient soaking capacity and may not comply with the claim.
 - The PVA Sponge Spears gets deformed after wetting. The used PVA Sponge Spears 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 practitioner 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 instruction before use.
- Store at specified temperature and humidity.
- The used PVA sponge spears 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.

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.

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 used device should be disposed off in compliance with the local regulatory requirements.

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, sterilized using Irradiation
	Handle with care
	Maximum stacking
	Single Sterile Barrier System with protective packaging outside, sterilized using irradiation
	Catalogue Number
	Keep Out of reach of children

EC REP

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