

EN (English)



**PVA Sponge Spears**

**DEVICE DESCRIPTION**

GAMMA sterilized compressed PVA sponge spears mounted on Plastic 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.

**MATERIALS USED**

Polyvinyl Alcohol (PVA), K-resin

**TARGET AGE GROUP**

Use 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 relative humidity (Temperature in between 10°C to 30°C and relative 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 manufacture of the device.

**HOW SUPPLIED**

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

**CAUTION/ WARNING**

- Do not use if package is damaged and consult instructions for use.
- The used PVA Sponge Spears might not have sufficient soaking capacity and may not comply with the claim.
- Do not use the device if the sterilized package is open or damaged.
- The product is designed for single use only.

- Reusing the device may cause the transfer of contagious and communicable diseases to the patient and other serious problems to patients due to re-use of device such as HIV, Hepatitis, contagious diseases/ communicable disease/undue diseases etc.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- Store at specified temperature and humidity.
- 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**

- Before use, please make sure that the product or packaging has not been 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 spear from sterile packaging.
- 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.
- In case 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.

**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 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 applicable local, state and country's laws and regulations.

**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                |

| 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   |
|        | Conformity of European Norm with Notified Body Number   |
|        | Authorized Representative in European Community   |
|        | 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  |

**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.: +91-11-42701030, 42701031  
 Email: customercare@madhuinstruments.com  
 Website: www.madhuinstruments.com  
 M.L.: MFG/MD/2023/000843

**EC REP**

**Obelis s.a.**

Bd. Général Wahis 53  
 B-1030 Brussels, Belgium  
 Tel: +32.2.732.59.54, Fax: +32.2.732.60.03  
 E-mail: mail@obelis.net