



## Cellulose Sponge Spears

### DEVICE DESCRIPTION

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

### INTENDED USE/ INDICATION FOR USE

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

### MATERIALS USED

Cellulose, Polypropylene

### 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 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 of the preparation.

### HOW SUPPLIED

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

### CAUTION/ WARNING

- Do not use if package is damaged and consult Instructions for use.
- 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 the transfer of contagious and communicable disease 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.

### 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.

### 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



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- 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

- Ensure before use that product/package 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.
- Take the sterile cellulose sponge spear pouch and peel it open 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.
- Mishandling or improper transport can cause damage to the device or packaging.

### 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.

### DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance with applicable local, state and country's laws and regulations.

Symbol	Meaning
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged and consult instruction 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
	UDI

**EC REP**

**Obelis s.a.**

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