

**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.

**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 5°C to 55°C and Humidity in between 55RH to 75RH).

**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 cellulose sponge spear is used to manipulate ophthalmic tissue.

When the compressed cellulose 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 cellulose sponge spear and the operating area becomes dry.

**HOW SUPPLIED**

Cellulose sponge spears are supplied sterile, in pack of 5. Fifty (50) such 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.

**MATERIALS USED**

Cellulose, PP

**CAUTIONS**

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

**DIRECTION FOR USE**

- Take the sterile cellulose 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 product should be store at Temperature 5°-55°C and Humidity 55-75 RH.
- Mishandling or improper transport can cause damage to the device or packaging.

**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.

**EXPLICATION OF SYMBOLS:**

Symbol	Meaning
	Caution/Warning (Read instruction before use)
	Manufacturer Logo
	Date of Manufacturing
	Do not re-sterilize
	Consult IFU
	Keep away from sunlight
	Don't re-use
	Authorized European Representative
	This side up
	Do not use hook



**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 Cellulose Sponge Spears might not have sufficient soaking capacity and may not comply with the claim.
  - The Cellulose Sponge Spears gets deformed after wetting. The used Cellulose 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 Cellulose 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.

**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/Lot Number
	Date of Expiry
	Temperature Limitation
	Do not use if package damaged
	Moisture Limitation
	Radiation Sterile Product/Device
	Handle with care
	Maximum stacking

**Mfg. Facility: MADHU INSTRUMENTS PVT. LTD.**

A 260, Okhla Industrial Area Phase-I, New Delhi-110020 India

**MADHU INSTRUMENTS PVT. LTD.**

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

**EC REP**

**Obelis s.a.**

Bd. Général Wahis 53

B-1030 Brussels, Belgium

Phone: 32.2.732.59.54, Fax: 32.2.732.60.03

E-mail: mail@obelis.net