

Cellulose Absorbent Stick

DEVICE DESCRIPTION

Sterile compressed Cellulose Absorbent Stick packed in peel open pouches.

INTENDED USE/ INDICATION FOR USE

A Sterile Cellulose Absorbent Stick 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 cellulose.

NATURE OF BODY CONTACT

Eyeball

MODE OF ACTION

In the dry state, the Cellulose Absorbent Stick is used to manipulate ophthalmic tissue. When the compressed Cellulose Absorbent Stick is brought into contact with liquid (primarily saline) it rapidly absorbs the fluids to its full holding capacity. Due to the capillary action, the liquid from the operating field is absorbed into the Cellulose Absorbent Stick and the operating area becomes dry.

HOW SUPPLIED

Cellulose Absorbent Stick are supplied sterile, in a pack of 2. Fifty (50) such pouches are enclosed within an outer printed box. The overall packing contains Cellulose Absorbent Stick and IFU, in an outer enclosing box, with external identification stickers.

MATERIALS USED

Cellulose

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: -
 - The used Cellulose Absorbent Stick might not have sufficient soaking capacity and may not comply with the claim.

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

- The Cellulose Absorbent Stick gets deformed after wetting. The used Cellulose Absorbent Stick might not be able 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 diseases 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 packaging 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.
 - Read instructions before use.
 - Store at specified temperature and humidity.
 - 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

- Take the sterile cellulose absorbent stick pouch and peel it open (BY AN UNSTERILE PERSON) and drop the absorbent stick on to a sterile surface without touching it.
- The tip of the Stick is gently placed on the area from which the fluid is to be absorbed.
- The stick swells up on absorbing the fluid and ceases to absorb any more fluid after a point. The used Absorbent Stick shall not be reused and put back into the pouch and disposed off with other waste for incineration.
- In case the cellulose absorbent stick is to be used for corneal tissue manipulation, dip the tip of the absorbent stick in saline solution for few seconds. This will make the cellulose absorbent stick 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 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.

EXPLANATION 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
	This side up
	Do not use hook
	Medical Device
	Single Sterile Barrier System, Sterilised using Ethylene Oxide

Symbol	Meaning
	Batch Code
	Use by date
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Single Sterile Barrier System with protective packaging outside, Sterilised using Ethylene Oxide
	Model Number
	Handle with care
	Maximum stacking
	Catalogue Number

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