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 40°C and Humidity in between 35 % to 65 %).

CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to cellulose.

NATURE OF BODY CONTACT

Eveball

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.

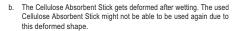
- Tarun Enterprises does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients as under: -
 - The used Cellulose Absorbent Stick might not have sufficient soaking capacity and may not comply with the claim.

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



- 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. Tarun Enterprises 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.

Mfg. Facility:

Regd. Office: 8/8, Strachy Road, Allahabad-211001, Uttar Pradesh, India Works: Shed No. E 20, NSIC Campus, Mirzapur Road, Naini, Prayagraj-211009, UP, India Ref. No. TE/IFU/22, Issue No .01, Issue Date: 12.12.22, Rev. No.: 00, Rev. Date: Nill

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AWARNING

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

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Adverse events and/or potentially sight-threatening complications that may



- b. 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.
- d. 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
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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 Tarun Enterprises

DISPOSAL OF THE USED DEVICE

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

EXPLICATION OF SYMBOLS:

Symbol	Meaning
\triangle	Caution
***	Manufacturer
m ^r	Date and Country of Manufacture
	Do not resterilize
(Ii	Consult instructions for use
淤	Keep away from sunlight
2	Do not re-use
<u> 11</u>	This side up
S. Constitution	Do not use hook
MD	Medical Device
STEPLE	Single Sterile Barrier System, Sterilised using Ethylene Oxide

Symbol	Meaning
LOT	Batch/Lot Number
\geq	Date of Expiry
	Temperature Limitation
8	Do not use if package damaged
201 - SON	Moisture Limitation
	Single Sterile Barrier System with protective packaging outside, Sterilised using Ethylene Oxide
62	Handle with care
8	Maximum stacking

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STIFILE	Single Sterile Barrier System, Sterilised using Ethylene Oxide

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®	Do not use if package damaged
260 t	Moisture Limitation
	Single Sterile Barrier System with protective packaging outside, Sterilised using Ethylene Oxide
3	Handle with care
<u>8</u>	Maximum stacking