

Fluoro Touch

Fluorescein Sodium Ophthalmic Strips USP

DEVICE DESCRIPTION

A disposable Whatman filter Paper No. 1 round blunt tip (impregnated with Fluorescein Sodium dye 1.0mg) sandwiched between a sticker paper stick (overall length 60 mm). Each strip is packed individually in pouches before sterilization.

INTENDED USE / INDICATION FOR USE

A disposable sterile ophthalmic diagnostic strip is used for evaluating contact lens fitting.

MATERIALS USED

Whatman Filter Paper No. 1, Fluorescein Sodium Powder

TARGET AGE GROUP

Can be used for all age groups.

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. Fluorescein Sodium Ophthalmic Strips USP contraindicated in patients with ocular surface damage, inflammation or ulcers of cornea and conjunctiva.

HOW SUPPLIED

Fluorescein Sodium Ophthalmic Strip USP are supplied sterile (ETO sterilized), in individual pouches. The overall packing contains Fluorescein Sodium Ophthalmic strips 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.
- The used strip might not have adequate amount of Fluorescein Sodium Dye left to stain the cornea properly and may not comply with the claim.
- 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.
- The filter paper tip gets deformed after wetting. The used strip might not be in a position to be used again due to this deformed shape.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- Store at specified temperature and humidity.
- For External use only.
- 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.
- Not to be used with soft contact lenses.
- Do not use the device after sterility expiry date.

PRECAUTIONS

- Ensure before use that product packaging is not tampered or damaged.
- When handling the Fluorescein Sodium ophthalmic strips care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the strip due to application of surgical instruments such as forceps etc.

DIRECTION FOR USE:

- Check the package sealing integrity to ensure sterility.
- To ensure full fluorescence and patient comfort, the Fluorescein Sodium impregnated tip should be moistened before application.
- One or two drops of sterile irrigating or saline solution should be used for this purpose.
- Touch conjunctiva or fornix as required with moistened tip.
- It is recommended that the patient blink several times after application.

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
	Single Sterile Barrier System, sterilized using Ethylene Oxide
	Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier

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