

EN (English)

Fluorescein Sodium Ophthalmic Strip USP

DEVICE DESCRIPTION

A disposable Whatman filter paper No 1 round blunt tip (impregnated with Fluorescein Sodium dye-0.6mg) sandwiched between a sticker paper stick (overall length 60mm). 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.

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

Do not use with soft contact lenses fitting.

INDICATION/INTENDED APPLICATION

Eyeball

MODE OF ACTION

Fluorescein staining of the cornea is performed by first placing a drop of sterile saline on a sterile fluorescein strip. Touch conjunctiva or fornix as required with moistened tip. The patient blinks to distribute the dye, and the cobalt blue light is used to determine if there are any corneal epithelial defects.

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.

MATERIALS USED

Whatman Filter Paper no. 1, Fluorescein Sodium Powder

CAUTIONS

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

handling. Avoid crushing and crimping damage to the strip due to application of surgical instruments such as forceps etc.

DIRECTION FOR USE

- 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.

EXPLICATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date of Manufacture
	Do not sterilize
	Consult instructions for use
	Keep away from sunlight
	Do not re-use
	Authorized Representative in the European Community
	This side up
	Do not use hook

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



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 strip might not have adequate amount of Fluorescein Sodium Dye left to stain the cornea properly and may not comply with the claim.
 - 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.
 - Re use of device may lead to microbial contamination due to presence of Pseudomonas.
 - Contagious and communicable disease such as HIV, Hepatitis & undue diseases etc.
- This device is intended for the use of contact lens fitting (Hard and GP Lens) use only. Manufacturer does not hold any responsibility or claim of the device if used for any other purpose in ophthalmic procedure.
- Only qualified medical practitioner should use the device.
- 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 (Temperature in between 5°C to 55°C and Humidity in between 55RH to 75RH).
- Not to be used with soft contact lenses.
- The used strip 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.
- Keep away from sun light.

PRECAUTIONS

- When handling the Fluorescein Sodium ophthalmic strips care should be taken to avoid damage from

DEVICE LIFE / 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.

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 the local regulatory requirements.

Symbol	Meaning
	Conformity of European Norm with Notified Body Number
	Batch Code
	Use by date
	Temperature Limit
	Do not use if package is damaged
	Humidity Limitation
	Sterilized using Ethylene Oxide
	Handle with care
	Maximum stacking

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