

Tear Touch Blu

Schirmer Tear Test Strips with blue mark

DEVICE DESCRIPTION

A disposable whatman filter paper No 41 graduated strip (5mm width x 41mm length) with a least count of 1 mm. It's having a round blunt tip and a blue colour line in between tip to 5mm mark. Blue dye (FD & C Blue No.1) wicks up the scale to improve visibility in measuring tear production. This strip is packed individually in pouches before sterilization.

INTENDED USE / INDICATION FOR USE

A disposable sterile ophthalmic diagnostic Schirmer strip with blue mark (external use only) is used to measure the amount of tear secretion of the eye.

MATERIALS USED

Whatman Filter Paper

TARGET AGE GROUP

Can be used for all age groups.

INTENDED USER

Any of the registered medical doctor/medical professionals.

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. Schirmer Tear Test Strips with blue mark contraindicated in patients with ocular surface damage, inflammation or ulcers of cornea and conjunctiva.

HOW SUPPLIED

Schirmer tear test strips with blue mark are supplied sterile, in individual pouches. Such Packed pouches are enclosed within an outer printed box. The overall packing contains Schirmer tear test strips with blue mark 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.

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.

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

- Accuracy:** The printed scale of a Schirmer strips is a mm scale from 00 mm to 35 mm with a least count of 1 mm. The accuracy of the complete scale (0 to 35) mm is ± 1 mm which implies an accuracy of ± 0.028 mm between two graduated mm lines.

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- The product is designed for single use only.
- Do not re-use it may lead to cross contamination.
- The used strip might not have printed scale 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.
- 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 use of this product is restricted to a qualified doctor or medical practitioners.
- Store at specified temperature and humidity.
- 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.
- Do not use the device after sterility expiry date.

PRECAUTIONS

- Ensure before use that product/packaging is not tampered or damaged.
- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR USE

- Check the package sealing integrity to ensure sterility.
- Do not apply any topical medication to the eye or perform any manipulation of the eye before performing this test.
- Position patient in examining chair with head against a headrest.
- Examination room lights should be dimmed.
- Carefully open strips taking care not to touch the rounded end of the strip.
- While the patient looks up, carefully insert rounded end into the lower temporal lid margin of the eye, making sure the strip fits snugly.
- Wait for 5 minutes, remove the strip and record the length of the moistened area indicated by the distance travelled by the blue indicator dye.

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.

DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance with applicable local, state and country's laws and regulations.

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
	Authorized Representative in European Community
	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

EC REP

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