

I-DEW Tearstrips Schirmer Strips

ERC/OS/A/01



INSTRUCTION FOR USE & WARNING:

Schirmer Tear Test Strips

DEVICE DESCRIPTION

A disposable whatman filter paper No 41 graduated strip (5mm width x 41mm length) with a least count of 1 mm, having a round blunt tip and is packed individually in pouches before sterilization.

INTENDED USE / INDICATION FOR USE

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

CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to any of the components of the preparation. Schirmer Tear Test Strips contraindicated in patients with ocular surface damage, inflammation or ulcers of cornea and conjunctiva.

HOW SUPPLIED

Schirmer tear test strips are supplied sterile, in individual pouches. 100 such pouches are enclosed within an outer printed box. The overall packing contains schirmer tear test strips and medical literature insert, in an outer enclosing box, with external identification stickers.

CAUTIONS

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

WARNING

- Entod Research Cell (UK) Ltd. does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
- 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. Entod Research Cell (UK) 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 product care should be taken to avoid damage from handling. Avoid crushing and crimping damage to the product due to application of surgical instruments such as forceps etc.

DIRECTION FOR USE

- 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.

Expected group of Patients for I Dew Tear Strips :

Children above the age of 5 years, adults & geriatric population, who are affected by dry eyes (such as soreness, burning, irritation or dryness) or dry eye syndrome or Sjögren's syndrome to measure the amount of tear production.

Dry eye syndrome, also known as chronic dry eye, is characterised by a reduced ability to form tears or a reduction in the quality of those tears.

Sjögren's syndrome is a chronic autoimmune disease in which the body's white blood cells destroy the exocrine glands, specifically the salivary and lacrimal glands, that produce saliva and tears, respectively.

Do not use if pregnant or breast-feeding.

EXPIRATION DATE

The expiration date of the product is the sterility expiration date. The product should not be use 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.

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 Entod Research Cell (UK) Ltd.

STERILE EO

Sterilized using Ethylene Oxide



Do not re use



Caution



Do not re-sterilize



Keep away from sunlight



Consult instructions for use



Temperature Limitation



Humidity Limitation



Do not use if package damaged

100 Sterile Strips

EC REP

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