

EN (English)

PEROPERATIVE KERATOSCOPE

DEVICE DESCRIPTION

This is a mechanical device made of anodized aluminum tube. The inner wall of the tube has alternate black and white rings of different thickness. The reflection of these rings on the patient's cornea helps in analyzing the astigmatism induced due to tight and loose sutures. This device can be autoclaved and used during a surgical procedure.

INTENDED USE/ INDICATION FOR USE

This is an ophthalmic device used during an ophthalmic surgical procedure to judge the astigmatism induced in the cornea while putting sutures.

MATERIALS USED

Aluminium

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 room temperature.

CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to any of the materials used in manufacturing of the device.

HOW SUPPLIED

Preoperative Keratoscope is supplied non-sterile, in individual printed box. The overall packing contains Preoperative Keratoscope and medical literature insert, in an outer printed box, with external identification stickers.

CAUTION/ WARNING

- Read instructions before use.

- Inspect these devices carefully for damage, cracks or malfunctions before each use.
- Do not use damaged devices.
- Each device requires cleaning and disinfection prior to its first use and before any subsequent use.
- Store devices in a cleaned, disinfected and dry state.
- For External use only.
- Only qualified medical practitioners should use the device.
- Keep out of reach of children.



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

- Sterile the device prior to the surgery by ETO or steam sterilization.
- Once the sutures have been put in the cornea, remove all other instruments from the eye.
- Switch on the microscope light and position it directly above the cornea.
- Place the preoperative keratoscope under microscope light just above the patient's cornea (Without touching the cornea)
- A reflection of alternate black & white concentric rings would form on the patient's cornea.
- Study the patterns of these concentric circles and analyze the astigmatism.

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 reported to Madhu Instruments Pvt. Ltd.

EXPLANATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
	This side up
	Keep out of reach of children
	Medical Device
	Handle with care

Symbol	Meaning
	Maximum stacking
	Batch Code
	Do not use if package is damaged and consult instructions for use
	Re-use
	Do not use hook
	Catalogue Number
	Unique device identifier
	Non-Sterile

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