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.

CONTRAINDICATIONS
Not Known.

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

CAUTIONS
For External use only.

⚠ WARNING
- Only qualified medical practitioner should use the device.
- Read instruction before use.
- Store at room temperature.
- For External use only.
- Keep out of reach of children.

PRECAUTIONS
- 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 from 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 report to Madhu Instruments Pvt. Ltd.

DISPOSAL OF THE USED DEVICE
The used device should be disposed off in compliance with the local regulatory requirements.

REUSE OF DEVICE
The device should undergo a detailed multi step process of cleaning & sterilization before reuse.

EXPLICATION OF SYMBOL:

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

Symbol	Meaning
CE	Conformity of European Norm
LOT	Batch Code
10°C 30°C	Temperature Limit
	Do not use if package is damaged
45RH 65RH	Humidity Limitation
	Handle with care
4	Maximum stacking
MD	Medical Device
NON STERILE	Non-Sterile

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Doc No. MIPL/IFU/N 5/02, Issue No .01, Issue Date: 01.03.14, Rev. No.: 03, Rev. Date: 01.01.2022