

Temporary Keratoprosthesis

DEVICE DESCRIPTION

This PMMA Lens has a central viewing area and has six suture holes around its peripheral edge. Once the sutures are placed, the lens/cornea interface acts as a seal and provide a closed system for a vitrectomy

INTENDED USE / INDICATION FOR USE

This is a surgical lens which is used to facilitate viewing of the peripheral retina and the posterior pole during vitrectomy and corneal transplant surgery procedure.

CONTRAINDICATIONS

Not Known.

HOW SUPPLIED

Temporary keratoprosthesis is supplied sterile, packed in a peel open pouch. Such pouch is enclosed within an outer printed box. The overall packing contains Temporary keratoprosthesis and medical literature insert, in an outer enclosing box, with external identification stickers.

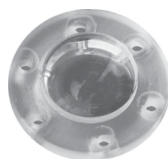
CAUTIONS

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

⚠ WARNING

- Madhu Instruments Pvt. Ltd does not hold any responsibility if the device is reused. Reusing the device may cause serious problems to patients as under:-
 - a. Optical part might not very clear, check the lens for optical clarity
 - b. All suture tying holes should be intact.
 - c. Contagious and communicable disease such as HIV, Hepatitis, contagious disease/communicable disease/undue diseases etc.
- Only qualified medical practitioner should use the device.
- Do not use the device if the sterilized package is open or damaged.

- Sterility is guaranteed only when the packing is neither opened nor damaged.



- Do not re-sterilize the device by any method. Madhu Instruments 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.
- The used Temporary Keratoprosthesis and pouch should be disposed off in compliance with the local regulatory requirements.
- Do not use the device after sterility expiry date.
- Keep out of reach of children.

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

- 1) A disposable corneal trephine is used to remove corneal button.
- 2) The Temporary Keratoprosthesis (0.5mm bigger than the button) is placed through the opening and rotated down into the cornea.
- 3) The Keratoprosthesis is sutured to the cornea using 8.0 nylon suture.
- 4) The corneal lens provides a wide field view of the posterior retina and permits clear visualization.
- 5) At the conclusion of the pars plana vitrectomy, the sutures holding the keratoprosthesis are removed.
- 6) The donor button is sutured in place.

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 Madhu Instruments Pvt. Ltd.

DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance with the local regulatory requirements.

EXPLICATION OF SYMBOLS

Symbol	Meaning
	Caution
	Manufacturer
	Date of Manufacturing
	Do not re-sterilize
	Consult instructions for use
	Keep away from sunlight
	Do not re-use
	This side up
	Do not use hook

Symbol	Meaning
	Batch/Lot Number
	Use by date
	Temperature Limit
	Do not use if package damaged
	Humidity Limitation
	Sterilized using Ethylene Oxide
	Handle with care
	Maximum stacking

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