

Endothelial Punch

DEVICE DESCRIPTION

- Universal** - Any size of trephine from 6 mm to 11 mm can be fitted.
- Precentered** - The trephine and the Teflon block are automatically centered for all sized trephines.
- Spring Recoil** - After completion of the cut, the trephine retracts back with inbuilt spring system.

INTENDED USE/ INDICATION FOR USE

This mechanical device gives an excellent donor corneal button punched out from the endothelial side of corneoscleral button.

MATERIALS USED

Stainless Steel

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 humidity (temperature in between 10°C to 30°C and humidity in between 45% to 65%).

CONTRAINDICATIONS

Not Known.

HOW SUPPLIED

Endothelial Punch is supplied un-sterile, in individual leather box. The overall packing contains Endothelial Punch and medical literature insert, in an outer leather box, with external identification stickers.

CAUTION/ WARNING

- The use of this product is restricted to a qualified doctor or medical practitioners.
- Read instruction before use.
- For External use only.
- Keep out of reach of children.

PRECAUTIONS

- Ensure before use that product/package is not tampered or damaged.

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's office regarding product return/exchange.

REPORTING

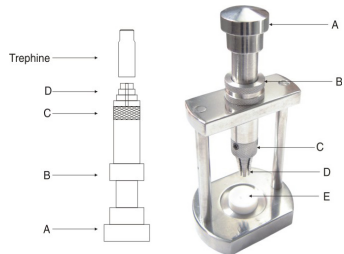
Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected

EXPLANATION OF SYMBOL:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
	Medical Device
	Temperature Limit
	Humidity Limitation
	Handle with care

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- When handling the product care should be taken to avoid damage from handling.

DIRECTION FOR USE

- Open the Endothelial Punch packaging and sterilize the device by using appropriate method.
- Unlock the piston by anticlockwise rotation at the knurled knob (B) and pull it out of the stand vertically upwards.
- Hold the piston at (C) with left thumb and forefinger and unscrew the knob (A) by 3-4 turns.
- Place the desired size disposable trephine on the appropriate step at the end (D) of the piston.
- Tighten the knob (A) by clockwise motion till the trephine is held firmly.
- Place the piston back in the cylinder carefully avoiding the trephine edge touching the sides of the cylinder.
- Lock the piston back by clockwise motion of the knob (B).
- Place the corneoscleral button on the Teflon block with endothelial side facing up.
- Place the Teflon block in the central round slot (E) made for it.
- By applying a firm and quick push on the piston with the palm, the corneal button is easily punched out.
- If the corneal button gets stuck in the trephine, remove the trephine from the piston and gently fill the trephine with saline or B.B.S. to push the corneal button out.

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 applicable local, state and country's laws and regulations.

REUSE OF DEVICE

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

Symbol	Meaning
	Maximum stacking
	Batch Code
	Do not use if package is damaged and consult instructions for use
	Re-Use
	Conformity of European Norm without Notified Body Number
	Authorized Representative in European Community
	Non-Sterile
	Catalogue Number
	Unique device identifier

EC REP

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