

Corneal Trephine

DEVICE DESCRIPTION

EO gas sterilized single use circular blade of different diameters mounted on a plastic handle (see through for proper centering of cornea). Each piece is individually packed and sealed in a pouch before sterilization. The pouch is then packed in a printed outer cardboard box and labeled.

INTENDED USE/ INDICATION FOR USE

A disposable sterile circular blade used to take out a circular corneal button of predetermined diameter from the donor or recipient cornea in a corneal transplant (Keratoplasty) procedure.

TARGET AGE GROUP

Use All Age Groups

DURATION OF USE

Transient Use (Less than 60 Minutes). It is recommended to withdraw the product after 60 minutes from the patient. The user is accountable for any type of problem taking place in case of use after 60 minutes of the same device.

STORAGE CONDITIONS

- Store at specified temperature and humidity (Temperature in between 5°C to 55°C and Humidity in between 55RH to 75RH).

CONTRAINDICATIONS

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

INDICATION/INTENDED APPLICATION

Eyeball (Supporting devices for Ophthalmic Surgery)

MODE OF ACTION

A corneal trephine consists of an ultra-sharp blade mounted on a handle. The cutting action can be supported by a vacuum attachment for better stability during cutting of the corneal tissue. Corneal trephines of various diameters help in cutting the desired size of the corneal tissue.

HOW SUPPLIED

Corneal Trephine is supplied sterile, in individual pouches. This pouch is enclosed within an outer printed box. The overall packing contains Corneal Trephine 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 are as under: -

DEVICE LIFE

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.

EXPLICATION OF SYMBOLS:

Symbol	Meaning
	Caution/Warning (Read instruction before use)
	Manufacturer Logo
	Date of Manufacturing
	Do not re-sterilize
	Consult IFU
	Keep away from sunlight
	Don't re-use
	Authorized European Representative
	This side up
	Do not use hook

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- The used Corneal Trephine might not have enough sharpness and may not comply with the claim.
 - The blade gets deformed after cutting. The used blade might not be in a position to be used again due to this deformed shape.
 - Re-use of device may lead to microbial contamination due to presence of Pseudomonas.
 - Contagious and communicable disease such as HIV, Hepatitis, contagious disease/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. Madhu Instruments Pvt. 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.
 - The used trephine and pouch should be disposed off in compliance with the local regulatory requirements.
 - Do not use the device after sterility expiry date.
 - The device is not for implant.
 - 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

- Take the sterile trephine of required size out of the box and open the outer pouch (BY AN UNSTERILE PERSON) and drop the inner sealed blister pack on to a sterile surface without touching it.
- Open the blister and take out the trephine from the holder taking care not to touch the blade to any surface.
- Take out the corneal button either by using an endothelial punch or directly from the recipient cornea manually.
- Put back the used trephine in the blister and dispose in compliance with local regulation.

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.

Symbol	Meaning
	Conformity of European Norm with Notified Body Number
	Batch/Lot Number
	Date of Expiry
	Temperature Limitation
	Do not use if package damaged
	Moisture Limitation
	EO Sterile Product/Device
	Handle with care
	Maximum stacking

EC REP

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