

EN (English)



Corneal Trephine

APPLICABLE FOR THE SIZES
1mm - 20mm

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.

MATERIALS USED

Stainless Steel, ABS Plastic.

TARGET AGE GROUP

Use 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 specified temperature and relative humidity (Temperature in between 10°C to 30°C and Relative humidity in between 45% to 65%).

CONTRAINDICATIONS

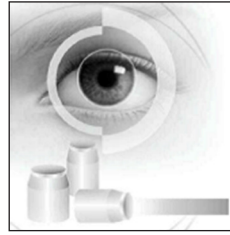
The device should not be used in patients who show hypersensitivity to any of the materials used in Manufacturing of the device.

HOW SUPPLIED

Corneal Trephine is individually packed and sealed in an inner blister and an outer pouch. Such packed 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.

CAUTION/WARNING

- Do not use if package is damaged and consult instructions for use.



- Do not use the device if the sterilized package is open or damaged.
The product is designed for single use only.
Do not re-use it may lead to cross contamination.
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.
Reusing the device may cause the transfer of contagious and communicable diseases to the patient and other serious problems to patients due to re-use of device such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
Store at specified temperature and humidity.
Keep out of reach of children.
Do not re-sterilize the device by any method. Madhu Instruments assumes no liability for the devices that have been re-sterilized.
Do not use the device after sterility expiry date.

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

- Check the package sealing integrity to ensure sterility.
Select the suitable size of Corneal trephine and inspect visually.
Open the inner blister, take out the corneal 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.

EXPIRATION DATE

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

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

EXPLICATION OF SYMBOLS:

Table with 2 columns: Symbol and Meaning. Includes symbols for Caution, Manufacturer, Date and Country of Manufacture, Consult instructions for use, Keep away from sunlight, Medical Device, Do not use hook, This side up, Temperature Limit, Humidity Limitation, Keep Out of reach of children, and Handle with care.

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

Table with 2 columns: Symbol and Meaning. Includes symbols for Maximum stacking, Batch Code, Use by date, Do not use if package is damaged and consult instructions for use, Do not re-use, Conformity of European Norm with Notified Body Number, Authorized Representative in European Community, Single Sterile Barrier System, and Unique device identifier.

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EC REP

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