

Suction Trephine

APPLICABLE FOR THE MODELS

(7.00mm, 7.25mm, 7.50mm, 7.75mm, 8.00mm, 8.25mm, 8.50mm, 8.75mm, 9.00mm)

DEVICE DESCRIPTION

EO gas sterilized single use circular blade of different diameters fixed on a stainless-steel handle (see through for proper centering of cornea). Each piece is then mounted on a plastic suction apparatus such that it can be moved forward or backward by screwing and unscrewing action. The suction apparatus consists of a cavity where the suction is created by using a spring-loaded disposable syringe connected to the suction apparatus through a silicone tube.

INTENDED USE/ INDICATION FOR USE

A disposable sterile circular blade used to take out a circular corneal button of predetermined diameter from the recipient cornea in a corneal transplant (Keratoplasty) procedure. The cutting action of the circular blade is assisted by a manual suction mechanism which holds the recipient cornea firmly while the cutting is being performed.

MATERIALS USED

Stainless Steel, ABS Plastic, Silicone, Rubber

TARGET AGE GROUP

Can be used for 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

Suction 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 Suction 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.

- Keep rotating the blade till it cuts through the cornea. This is confirmed by release of aqueous in the blade cavity (visible through the microscope) as well as by break suction grip of the apparatus.
- Gently remove the blade with suction apparatus and complete the cut in the cornea by using corneal scissors. Never put the suction trephine back again even if suction breaks in between before completing the cut.
- Put back the used trephine in the blister and dispose off 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.

EXPLICATION OF SYMBOLS:

Symbol	Meaning
	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
	Handle with care



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- The product is designed for single use only.
- Do not re-use it may lead to cross contamination.
- The used suction 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.
- Contagious and communicable disease such as HIV, Hepatitis, contagious diseases/communicable diseases/undue diseases etc.
- The use of this product is restricted to a qualified doctor or medical practitioners.
- 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.
- The device is not for implant.

PRECAUTIONS

- Ensure before use that product/package 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 suction trephine and inspect visually.
- Open the inner blister, take out the suction trephine and withdraw the blade approximately 2mm from the contact point so that corneal surface is not damaged by extended blade while adjusting the suction apparatus.
- Put some viscoelastic over the corneal surface and make a reference mark for centering the trephine.
- Compress the plunger of the disposable syringe thereby removing all the air from the syringe and place it over the cornea while holding the plunger compressed. Now release the plunger thereby creating suction by the withdrawing plunger due to spring action.
- Check the grip of the suction apparatus on the cornea by gently moving the apparatus sideways. Once the suction is established, start rotating the blade in the clockwise direction while observing through the microscope.

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

Symbol	Meaning
	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, with inside protective packaging sterilized using Ethylene Oxide
	Single Sterile Barrier System with inside and outside protective packaging, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier

EC REP

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