

## Suction Trephine

### 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 silicon tube. Each suction trephine is individually packed and sealed in an inner pouch and outer pouch before sterilization.

### 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.

### 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 suction 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

Suction Trephine is supplied sterile, in individual pouches. This 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.

### MATERIALS USED

Stainless steel, ABS

- 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 on 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.
- 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.

### 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

Mfg. Facility: MADHU INSTRUMENTS PVT. LTD.

A 260, Okhla Industrial Area Phase-I, New Delhi-110020 India



MADHU INSTRUMENTS PVT. LTD.

F-90/3D, Okhla Industrial Area Phase-I, New Delhi-110020 India

Customer Care No. : 91-11-42701030, 42701031

Email: customercare@madhuinstruments.com

Website: www.madhuinstruments.com



### 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-
  - 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.
  - 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 suction 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 suction trephine of required size and open the outer pouch (BY AN UNSTERILE PERSON) and drop the inner sealed blister on to a sterile surface without touching it.
- 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 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.

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**

**Obelis s.a.**

Bd. Général Wahis 53

B-1030 Brussels, Belgium

Phone: 32.2.732.59.54, Fax: 32.2.732.60.03

E-mail: mail@obelis.net