

Trephine Punch- Vacuum

DEVICE DESCRIPTION

Nanoedge Trephine Punch (Vacuum) features an ultra sharp trephine blade mounted in a white nylon housing with four stainless steel guide pins. There is a cutting block base with four corresponding holes which helps in automatic centering of the trephine blade over the donor corneal tissue. A blue nylon spacer ring is provided to prevent trephine blade edge getting damaged during transportation and storage. A seating ring housing with four stainless steel guide pins are provided to make sure that the cornea is in complete contact with the cutting block base while creating a vacuum. A spring-based syringe system (to create the vacuum) is attached to the cutting block base through a silicon tubing. Each Nanoedge Trephine Punch (Vacuum) is individually packed and sealed in an inner blister and an outer pouch before EO sterilization.



INTENDED USE/ INDICATION FOR USE

A disposable sterile Nanoedge Trephine Punch (Vacuum) is used to take out a circular corneal button of predetermined diameter from the donor cornea in a corneal transplant procedure. This device uses vacuum to hold the donor cornea in place before cutting the corneal button.

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 55% to 75%).

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

The device contains a sharp blade which is used to cut corneal tissue of desired size and 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

Each Nanoedge Trephine Punch (Vacuum) is individually packed and sealed in an inner blister and an outer pouch before EO sterilization. The overall packing contains Nanoedge Trephine Punch (Vacuum) and IFU, in an outer enclosing box, with external identification labels.

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 Nanoedge Trephine Punch (Vacuum) might not have enough sharpness to properly cut the corneal tissue.

- Place the donor cornea, endothelial surface up, in the well of the cutting block. Centre the donor cornea in the well within fine-tooth forceps.
- Place the cutting block base on a solid, flat surface. Insert the four steel guide pins of the seating ring housing into the cutting block corresponding holes and press down gently.
- Release the plunger of the syringe abruptly.
- While holding the cutting block base with one hand, pull the seating ring housing upward with the other hand and discard.
- Place the cutting block base on a solid, flat surface. Insert the four steel guide pins of the trephine blade housing into corresponding holes in each corner of the cutting block base. Place thumb directly over the trephine blade and press down firmly.
- While holding the cutting block base with one hand, pull blade housing upward with the other to remove the trephine blade.
- Grasp the scleral rim with fine-tooth forceps and remove the rim from the cutting block. This releases the vacuum and leaves the donor cornea button in the well of the cutting block base.

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

- 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.
 - Re-use of device may lead to contagious and communicable diseases such as HIV, Hepatitis etc.
- Only qualified medical practitioner should use the device as per the intended use.
 - 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 Nanoedge Trephine Punch (Vacuum) 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 to the blade edge and guide pins.
- Avoid parts of the device falling on non sterile surface while handling them.

DIRECTION FOR USE

The Nanoedge Trephine Punch (Vacuum) should only be used by a qualified medical practitioner who is familiar with corneal transplant surgery and with the use of this device. The following instructions do not include all the procedural steps required to perform corneal transplant surgery.

- Verify the blade diameter, which is engraved on punch top and trephine blade.
- Hold the cutting block base with one hand and pull the trephine blade housing upward with the other hand, turn it over and place it on sterile tray. Discard the blue spacer ring.
- To mark the four quadrants on the epithelial side of the donor cornea, place the tip of the sterile surgical marking pen into each of the four holes in the well of the cutting block. Twist the pen until the sides of each hole are evenly coated with gentian violet.
- Push the plunger of the syringe all the way and hold.

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.

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
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged
	Do not re-use
	Conformity of European Norm with Notified Body Number
	Authorized Representative in European Community
	Single Sterile Barrier System, sterilized using Ethylene Oxide
	Single Sterile Barrier System with protective packaging outside, sterilized using Ethylene Oxide
	Do not re-sterilize
	Catalogue Number
	Unique device identifier
	Model Number

EC REP

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