



Trephine Punch- Vacuum

APPLICABLE FOR THE MODELS

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

DEVICE DESCRIPTION

Nanoedge Trephine Punch (Vacuum) features ultra sharp trephine blade mounted in a white plastic 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 plastic spacer ring is provided to prevent the trephine blade edge getting damaged during transportation and storage. A tissue holder housing with four stainless steel guide pins is provided to make sure that the cornea is in complete contact with the cutting block base during vacuum creation. A spring-based syringe system (to create the vacuum) is attached to the cutting block base through silicone tubing.

INTENDED USE

A disposable sterile Nanoedge Trephine Punch (Vacuum) is used to take out a circular corneal piece 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 cornea.

INDICATION FOR USE

The Trephine Punch (Vacuum) is indicated for use in corneal transplantation procedures to trephine donor and/or recipient corneal tissue and create a circular corneal button of a predetermined diameter. The device incorporates vacuum-assisted fixation to stabilize the corneal tissue during trephination.

MATERIALS USED

Stainless Steel, Thermoplastic polymers, Silicone.

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.

OPERATING PRINCIPLE

The Trephine Punch (Vacuum) uses a vacuum system to securely hold the corneal tissue in place during trephination. An ultra-sharp circular blade is then guided and manually advanced through the tissue to create a corneal button of the predetermined diameter with accurate centering.

- Release the plunger of the syringe abruptly
- While holding the cutting block Base with one hand, pull the Tissue Holder 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 required donor cornea cut piece in the well of the cutting block base.

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



HOW SUPPLIED

Each Nanoedge Trephine Punch (Vacuum) 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 Nanoedge Trephine Punch (Vacuum) and medical literature inserted in an outer enclosing box, with external identification labels.

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 Nanoedge Trephine Punch (Vacuum) might not have enough sharpness to properly cut the corneal tissue.
- The blade gets deformed after cutting. The used blade might not be in a position to be used again due to this deformed shape.
- 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

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.

- Check the package sealing integrity to ensure sterility.
- Select the suitable size of Trephine Punch (Vacuum) and inspect visually.
- Verify the blade diameter, which is engraved on Punch Top, base and blade shell.
- 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.
- Place the donor cornea, endothelial surface up, in the well of the cutting block. Centre the donor cornea in the well with fine-tooth forceps.
- Place the cutting block Base on a solid, flat surface. Insert the four steel guide pins of the Tissue Holder housing into the cutting block corresponding holes and press down gently.

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 device and all associated items should be disposed of in accordance with applicable local, state and country 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 the Union
	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



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