



**TREPHINE PUNCH – NON-VACUUM**

**DEVICE DESCRIPTION**

Trephine Punch (Non-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 the trephine blade edge getting damaged during transportation and storage.

Each Nanoedge Trephine Punch (Non-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 (Non-Vacuum) is used to take out a circular corneal button of predetermined diameter from the donor cornea in a corneal transplant procedure.

**MATERIALS USED**

Stainless Steel, Nylon

**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 material used in Manufacturing of the device.

**HOW SUPPLIED**

Each nanoedge trephine punch (Non-Vacuum) is individually packed and sealed in an inner blister and an outer pouch. Such a packed pouch is enclosed within an outer printed box. The overall packing contains nanoedge trephine punch (Non-Vacuum Design) 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.

- 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.

**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.
- Read instructions before use.
- Do not re-use it may lead to cross contamination.
- The used nanoedge trephine punch (Non-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.
- Contagious and communicable disease such as HIV, Hepatitis, contagious diseases/communicable disease/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.

**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 (Non-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 suction trephine and inspect visually.
- 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.
- 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.

**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**

**Obelis s.a.**

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