NANO edge
Ophthalmic Blades

Trephine Punch- Vacuum

APPLICABLE FOR THE MODELS
(6.50-8.00mm,7.00mm,7.25mm,7.50mm,7.75mm,7.75-8.75mm,8.00mm,8.00mm-9.50mm, 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/ INDICATION FOR 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.

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 10ºC to 30ºC 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
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.
- Do not re-use it may lead to contagious and communicable disease such as HIV, Hepatitis etc.
- 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/packaging 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.
1. Check the package sealing integrity to ensure sterility.
2. Select the suitable size of Trephine Punch (Vacuum) and inspect visually.
3. Verify the blade diameter, which is engraved on Punch Top, base and blade shell.
4. 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.
5. 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.
6. Push the plunger of the syringe all the way and hold.
7. 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.
8. 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.
9. Release the plunger of the syringe abruptly.

10. While holding the cutting block Base with one hand, pull the Tissue Holder housing upward with the other hand and discard.
11. 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.
12. While holding the cutting block Base with one hand, pull blade housing upward with the other to remove the trephine blade.
13. 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.

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.

EXPLICATION OF SYMBOLS:

Symbol	Meaning
⚠	Caution
🏭	Manufacturer
📅	Date and Country of Manufacture
📖	Consult instructions for use
☀	Keep away from sunlight
MD	Medical Device
⊗	Do not use hook
⬆⬆	This side up
10°C — 30°C	Temperature Limit
45% — 65%	Humidity Limitation
👶	Keep Out of reach of children
☂	Handle with care

Symbol	Meaning
4	Maximum stacking
LOT	Batch Code
⧖	Use by date
⊘	Do not use if package is damaged and consult Instructions for use
⊗	Do not re-use
CE 2460	Conformity of European Norm with Notified Body Number
EC REP	Authorized Representative in European Community
STERILE EO	Single Sterile Barrier System, with inside protective packaging sterilized using Ethylene Oxide
STERILE EO	Single Sterile Barrier System with inside and outside protective packaging, sterilized using Ethylene Oxide
STERILIZE ⊘	Do not re-sterilize
REF	Catalogue Number
UDI	Unique device identifier

🏭 **MADHU INSTRUMENTS PVT. LTD.**
Mfg. Facility: A-260, Okhla Industrial Area Phase-I, New Delhi-110020 India.
Regd. Add.: 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
M.L.: MFG/MD/2023/000843

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