

Vacuum Trephine Punch
Instructions for Use

IMPORTANT NOTICE

It is highly recommended that the surgeon adhere to the cautions outlined in these instructions.

DEVICE DESCRIPTION

Surgistar's vacuum trephine punches are standard ophthalmic devices consisting of a stainless steel blade, a plastic holder, a silicone tube and a hand-held polypropylene syringe with a stainless steel spring used to create a vacuum during corneal procedures. They are delivered sterile to the end user and are intended for single patient use.

Materials

- Blade: stainless steel
- Holder: plastic
- Tube: medical grade silicone
- Syringe: polypropylene
- Spring: stainless steel

INTENDED USE

The Surgistar vacuum trephine punch is a disposable system designed for use in Corneal Transplant Surgery, particularly for preparing the donor cornea.

CAUTION

- The trephine blade is exceptionally sharp. Avoid contact between the blade edge and any surfaces prior to use to avoid injury or damage.
- Care should be taken at all times to avoid unintentional sticks to healthcare providers or patient. If unintentional stick occurs, do not use the device.
- Do not use excessive force, or use with inappropriate equipment.
- Surgistar's vacuum trephine punches are sold sterile. Sterility is guaranteed unless opened or damaged. Do not use if the sterile pack has been opened or damaged.
- Do not re-sterilize or reuse. Surgistar, Inc. assumes no liability for devices that have been altered, dismantled, reassembled, re-sterilized or reused.
- Please use Surgistar's vacuum trephine punches responsibly and remember to dispose of in a safe and environmentally friendly manner.
- Federal (USA) law restricts this device to sale by, or on the order of a physician.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

METHOD OF STERILIZATION

STERILE R

Surgistar's vacuum trephine punches are gamma sterilized to SAL 10⁻⁶ and must be opened under aseptic conditions.

CONDITIONS OF STORAGE

Surgistar's vacuum trephine punches should be stored in a cool (60°F – 70°F), dry place, away from sources of heat or sunlight, and possible contamination from biohazards and water damage.

EXPIRATION DATE

The expiration date is clearly indicated on the packaging. Any vacuum trephine punch held after the expiration date should not be used.

RETURN GOODS POLICY

Surgistar accepts returned vacuum trephine punches for exchanges or account credit only. No cash refunds will be issued. To return these devices, you must first obtain a return authorization number from our customer service department. No returned goods will be accepted without proper authorization number. Returned goods should be shipped by traceable method. No credit will be given for lost or damaged devices in shipment. Devices will be replaced or your account credited as long as they are returned within six months of their original invoice date.

PREPARATION

Remove unit from box and verify the blade diameter indicated on the top of the punch.

The unit consists of three pieces - the trephine portion (top), the well portion with suction syringe (bottom) and the seating ring.

Remove the packaging band that holds the unit together.

Pull trephine portion straight and evenly off the unit and place both pieces on procedural field with the flat side down. Discard the protective ring surrounding the trephine and the packaging band.

MARKING THE DONOR CORNEA

In order to mark the four quadrants on the epithelial side of the donor cornea, place the tip of a sterile surgical marking pen (gentian violet) into the four holes located in the well portion.

Evenly coat each hole by twisting the pen.

ATTAINING SUCTION

Depress the syringe plunger completely and hold. Ideally this is with the aid of a surgical assistant.

Place donor cornea in the well portion with the endothelial side facing up. Center the tissue with fine tooth forceps.

Insert the four posts of the seating ring into the holes of the well portion and gently press down. Abruptly release the syringe plunger. Pull the seating ring off the well and discard it.

CUTTING THE DONOR CORNEA

Next, insert the four pins of the trephine portion into the four holes located in the corners of the well portion.

IMPORTANT: Press down firmly on the flat surface of the punch and hold for 5 to 10 seconds to ensure trephine blade cuts completely through the donor tissue.

REMOVAL OF DONOR CORNEA

Pull trephine portion straight and evenly off the tissue. Using a fine tooth forceps, remove the scleral rim. The vacuum is released and the Donor button will remain in the well portion.

Leaving the button undisturbed in the well until needed allows maximum contact with the ink, enhancing the epithelial marks. A few drops of the corneal storage medium on the button prevents desiccation.



SYMBOLS



Lot Code

REF

Product Code



Sterilized using Ethylene Oxide



Use by date



Do not use if package is damaged



Manufacturer



Do not reuse



CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of a Physician



Consult instructions for use



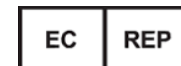
gamma



Do Not Resterilize



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