Surgistar™
The Cutting Edge of Tomorrow

INSTRUCTIONS FOR USE



VACUUM TREPHINE PUNCH

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UK CA 0086 CE 2797 FDA Registration No. 2028661

BSI REGISTERED
ISO 13485:2016
FM 702438

These Instructions Apply to the Following Devices

REF	Description
360600	6.00 mm Vacuum Trephine Punch
360625	6.25 mm Vacuum Trephine Punch
360650	6.50 mm Vacuum Trephine Punch
360675	6.75 mm Vacuum Trephine Punch
360700	7.00 mm Vacuum Trephine Punch
360725	7.25 mm Vacuum Trephine Punch
360750	7.50 mm Vacuum Trephine Punch
360775	7.75 mm Vacuum Trephine Punch
360785	7.85 mm Vacuum Trephine Punch
360800	8.00 mm Vacuum Trephine Punch
360825	8.25 mm Vacuum Trephine Punch
360850	8.50 mm Vacuum Trephine Punch
360875	8.75 mm Vacuum Trephine Punch
360900	9.00 mm Vacuum Trephine Punch
360925	9.25 mm Vacuum Trephine Punch
360950	9.50 mm Vacuum Trephine Punch

STERILE R — Sterilized via gamma radiation

CAUTION: Contains sharp objects

For single patient use only
(possibility of infection)

Rx only — CAUTION: U.S. Federal law restricts the use of this device to sale by or on the order of a physician

Do not re-sterilize

Surgistar, Inc.

MFG of Single-Use Ophthalmic, ENT, and Other Surgical Cutting Instruments

An ISO 13485 and CE certified company

CE 2797

Vacuum Trephine Punch
Instructions for Use

IMPORTANT NOTICE

It is highly recommended that the surgeon adhere to the warnings 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 gradesilicone
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.

Warning/Contraindications/caution

- The trephine blade is exceptionally sharp. Avoid contact between the blade edge and any surfaces prior to use to avoid injury or damage.
- Do not use on patients who are sensitive or allergic to metals
- 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.
- To avoid infection, microbial hazard or physical hazard from sharp blade, please discard the knife into an approved sharps container after use.

- 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 man ufacturer and the competent authority of the Member State in which the user and/or patient is established.

- METHOD OF STERILIZATION

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, dry place at room temperature, 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.

Manufacturing Date

The manufacturing date is lot number indicated on the packaging.

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(gentianviolet) 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.

RELEASE VACUUM AND REMOVAL OF DONOR CORNEA

Pull trephine portion straight and evenly off the tissue. Depress the syringe plunger to release the vacuum. Using fine-tooth forceps, remove the scleral rim. Any remaining vacuum will be 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

EN			
LOT	Lot Code	REF	Product Code
STERILE R	Gamma		Use by date
	Do not use if package is damaged		Manufacturer
2	Do not reuse	Rx Only	CAUTION: Federal (USA) law restricts this device to sale and use by, or on the order of a Physician
	Consult instructions for use		

Do Not Resterilize

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EC REP

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