Surgistar™
*The Cutting Edge of Tomorrow*

# INSTRUCTIONS FOR USE



## NON-VACUUM TREPHINE PUNCH


**Surgistar, Inc.**

2310 La Mirada Drive
Vista, California USA
92081

Telephone: (760) 598-2480
Facsimile: (760) 598-2481

Visit us online: www.surgistar.com
E-mail us: customerservice@surgistar.com


UK CA 0086 | CE 2797 | FDA Registration No. 2028661

BSI REGISTERED
ISO 13485:2016
FM 702438

STERILE R — Sterilized via gamma radiation

CAUTION: Contains sharp objects

For single patient use only
(possibility of infection)

℞ 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

**These Instructions Apply to the Following Devices**

| REF | Description |
|---|---|
| 340600 | 6.00 mm Non-Vacuum Trephine Punch |
| 340625 | 6.25 mm Non-Vacuum Trephine Punch |
| 340650 | 6.50 mm Non-Vacuum Trephine Punch |
| 340675 | 6.75 mm Non-Vacuum Trephine Punch |
| 340700 | 7.00 mm Non-Vacuum Trephine Punch |
| 340725 | 7.25 mm Non-Vacuum Trephine Punch |
| 340750 | 7.50 mm Non-Vacuum Trephine Punch |
| 340775 | 7.75 mm Non-Vacuum Trephine Punch |
| 340785 | 7.85 mm Non-Vacuum Trephine Punch |
| 340800 | 8.00 mm Non-Vacuum Trephine Punch |
| 340825 | 8.25 mm Non-Vacuum Trephine Punch |
| 340850 | 8.50 mm Non-Vacuum Trephine Punch |
| 340875 | 8.75 mm Non-Vacuum Trephine Punch |
| 340900 | 9.00 mm Non-Vacuum Trephine Punch |
| 340925 | 9.25 mm Non-Vacuum Trephine Punch |
| 340950 | 9.50 mm Non-Vacuum Trephine Punch |
| 341000 | 10.00 mm Non-Vacuum Trephine Punch |

Surgistar™
The Cutting Edge of Tomorrow™

CE
2797

.

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

## An ISO 13485 and CE certified company

# Non-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 non-vacuum trephine punches are standard ophthalmic devices consisting of a stainless steel blade, a plastic holder and four stainless steel guide pins. They are delivered sterile to the end user and are intended for single patient use.

Materials
- Blade: stainless steel
- Holder: plastic
- Guide Pins: stainless steel

### INTENDED USE
The Surgistar non-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 non-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 non-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
Surgistar's non-non-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 non-vacuum trephine punch held after the expiration date should not be used.

### RETURN GOODS POLICY
Surgistar accepts returned non-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 two pieces - the trephine portion (top) and the well portion (bottom).

Remove the packaging band that holds the two pieces of 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.

### CUTTING THE DONOR CORNEA
Place donor cornea in the well portion with the endothelial side facing up. Cut away all sclera tissue extending beyond the well portion.

Center the tissue with fine tooth forceps before cutting.

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

Press down firmly on the flat surface of the trephine portion using your thumb.

### REMOVAL OF DONOR CORNEA
Pull top of trephine punch straight and evenly off the tissue.

The Donor button typically will remain in the well portion, while the peripheral tissue will pull away with the trephine portion.

Should the button pull away with the trephine portion and not remain in the well portion, it may be dislodged with Balanced Salt Solution or Viscoelastic from the rear (endothelial) side, which is through the center of trephine.

### SYMBOLS

| | | | |
|---|---|---|---|
| EN | | | |
| LOT | Lot Code | REF | Product Code |
| STERILE R | Sterilized using 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 | | |

STERILE R Gamma

Do Not Resterilize

Surgistar, Inc.
2310 La Mirada Drive
Vista, California 92081 USA
Telephone: (760) 598-2480
Fax: (760) 598-2481
Email: customerservice@surgistar.com
www.surgistar.com

EC REP

Wellkang Ltd
Enterprise Hub, NW Business Complex,
1 Beraghmore Rd, Derry, BT48 8SE
Northern Ireland