Surgistar Vacuum Trephine Instructions for Use

Intended Use:
The Surgistar Vacuum Trephine is a disposable system designed for use in Corneal Transplant Surgery.

Product Details and Cautions:
The unit is supplied sterile and ready to use for singleuse only. Do not re-sterilize or reuse.

Carefully inspect the packaging. Do not use if the package has been opened or damaged.

After opening the package, please always exercise caution when handling and using the trephine.

The trephine blade is exceptionally sharp. Avoid contact between the blade edge and any surfaces priorto use, to avoid injury or damage.

Surgistar, Inc. assumes no liability for devices that havebeen altered, dismantled, reassembled, re-sterilized and/or reused.

To avoid infection, microbial or physical hazard, please discard the knife into an approved sharps container after use.

Manufacturing Date: The manufacturing date is lot number indicated on the packaging.

Using the System *(see Figure 1)*
Under the microscope, align the trephine cutting edge with that of the inner tube by rotating the ring. For futurealignment reference, take note of the position of the LONG marker pin on the ring.

From this position, make two complete counterclockwise rotations, recessing the trephine deeper into the inner tube, thus providing a more effective vacuum *(see Figure2)*.

Looking through the lumen and centering the crosshairs, carefully position and press the unit down on the cornea.

Fully depress the suction syringe plunger and hold.

Release and wait about 10 seconds for adequate suctionto develop.

Test suction by gently lifting the unit. Then permit the cornea to return to its normal shape before the next step.

Advance the trephine blade forward by rotating the ring clockwise two full turns. This once again aligns the trephine edge with the edge of the inner tube.

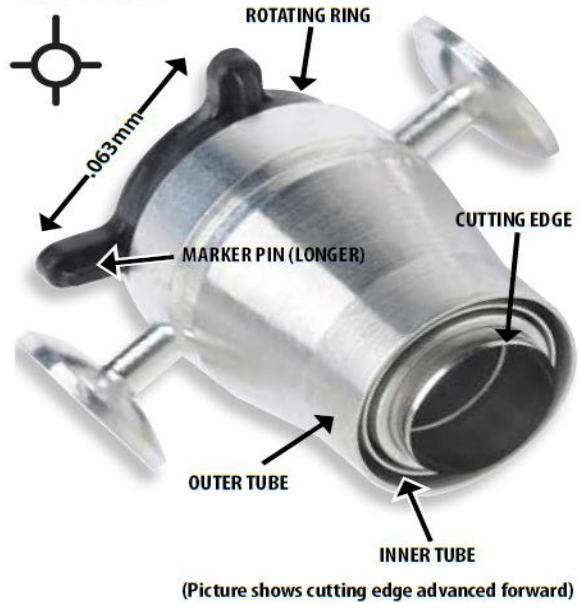
Cutting is now achieved via clockwise rotation of the ring.Each quarter-rotation advances the cutting surface downward by .063 mm (for a total of .25 mm per one complete rotation) *(see Figure 3)*.

Rotate slowly and carefully, using the pins for greater control. Discontinue cutting at the first sign of aqueous.

To release the suction, either depress the plunger or cutthe tubing.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

FIGURE 1



(Picture shows cutting edge advanced forward)

FIGURE 2

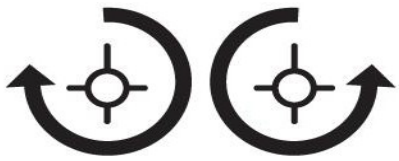
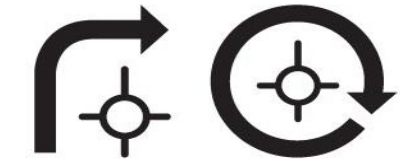


FIGURE 3



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

ISO 13485:2016
FM 702438

2797

Registration No.
2028661

EC REP

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

UK CA 0086

UK Responsible Person:
M.L.S.S Ophthalmicskill
3 Ryder Court, Saxon Way East
Oakley Hay Industrial Estate
Corby, Northamptonshire
NN18 9NX United Kingdom

VACUUM TREPHINE

INSTRUCTIONS FOR USE

Surgistar™
The Cutting Edge of Tomorrow

CONTRAINDICATIONS AND PROHIBITIONS

- Do not use on patients who are sensitive or allergic to metals.
- Do not use for any other purpose than ophthalmic surgery.
- Do not use if the blade has been hit against or been in contact with anything other than the eye, as the blade's sharpness might be compromised.
- Do not reuse or re-sterilize. Reuse or re-sterilization could seriously compromise the structural integrity and / or might lead to damage or infection to patients. As far as the safety knife is concerned, re-sterilization may lead to the deformation or breakage of the handle, which would result in a change of the length of the blade.

WARNINGS

- The user must be fully acquainted with surgical procedures and techniques.
- Select the appropriate type of knife for each surgical purpose. Use in accordance with normal surgical procedures.
- Do not use if its packaging is damaged or if there is evidence of any other abnormalities.
- 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.

These Instructions Apply to the Following Devices

REF	Description
370600	6.00 mm Advanced Radial Vacuum Trephine
370650	6.50 mm Advanced Radial Vacuum Trephine
370700	7.00 mm Advanced Radial Vacuum Trephine
370725	7.25 mm Advanced Radial Vacuum Trephine
370750	7.50 mm Advanced Radial Vacuum Trephine
370775	7.75 mm Advanced Radial Vacuum Trephine
370800	8.00 mm Advanced Radial Vacuum Trephine
370825	8.25 mm Advanced Radial Vacuum Trephine
370850	8.50 mm Advanced Radial Vacuum Trephine
370875	8.75 mm Advanced Radial Vacuum Trephine
370900	9.00 mm Advanced Radial Vacuum Trephine

STERILE R

CAUTION: Contains sharp objects

For single patient use only
(possibility of infection)

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