

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 single use 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 exercise caution at all times when handling and using the trephine.

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

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

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 future alignment 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 Figure 2).

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 suction to 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 cut the tubing.

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

FIGURE 1

Note: One pin is longer than others for orientation.

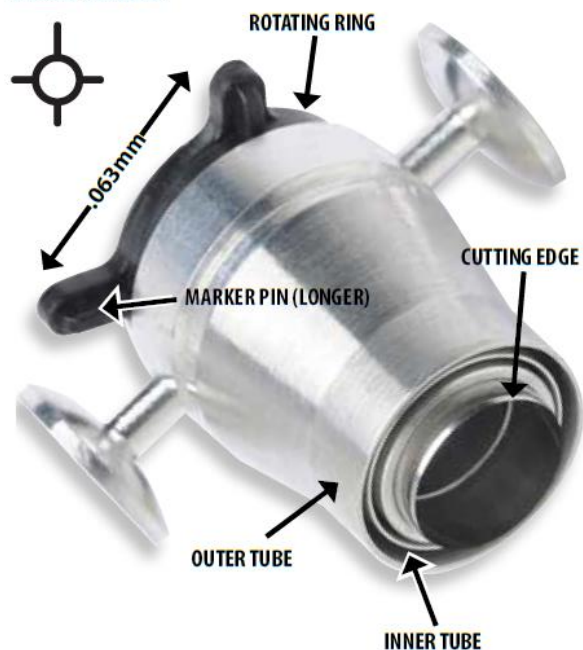


FIGURE 2

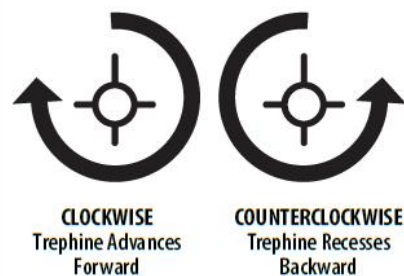
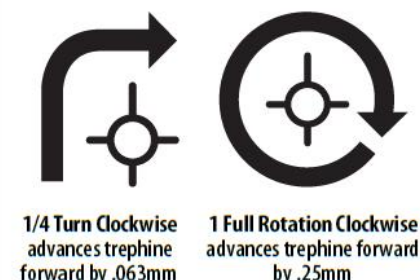


FIGURE 3



Surgistar™

The Cutting Edge of Tomorrow

INSTRUCTIONS FOR USE



VACUUM TREPHINE

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

- 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

STERILIZE

Do not re-sterilize

Rx only

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

For single patient use only

(possibility of infection)

CAUTION: Contains sharp objects

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