Surgistar Non-Vacuum Trephine Punch Instructions for Use

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.

Product Details and Cautions:
The unit is supplied sterile and ready to use for single use only. Do not resterilize 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, resterilized and/or reused.

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 trephine portion 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.

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