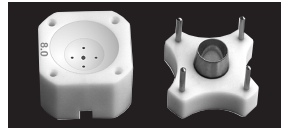


INSTRUCTIONS FOR USE
BARRON
DONOR CORNEA PUNCH

for corneal transplants

A disposable, ready to use punch
for the donor cornea.



Cutting Block

Trephine Blade

SURGICAL TECHNIQUE

The Barron Donor Cornea Punch should only be used by a licensed physician who is familiar with corneal transplant surgery and with the use of this instrument. The following instructions do not include all of the procedural steps required to perform corneal transplant surgery.

- 1) Verify blade diameter that is stamped on top of punch, and remove elastic band from punch unit.
- 2) While holding base of punch with one hand, use other hand to pull top of punch straight upward and place on the sterile tray. Discard white spacer ring.
- 3) To mark the four quadrants on the epithelial side of the donor cornea, place the tip of the sterile surgical marking pen into each of the four holes in the well of the cutting block. Twist the pen until the sides of each hole are evenly coated with gentian violet.
- 4) Place donor cornea in the base with endothelial side facing up. Remove all scleral tissue protruding beyond the cutting block well. Center the graft in the cutting block using a fine tooth forceps.
- 5) With the cutting block base on a solid, flat surface, insert the four steel guide posts of the trephine blade housing into corresponding holes in each corner of the cutting block base. Place thumb directly over the trephine blade and press down firmly.
- 6) Remove trephine blade by pulling the blade housing upward. The corneal button will usually remain in the well of the block, while the peripheral corneoscleral rim remains on the blade. If the button remains in the blade, it may be dislodged by dripping Balanced Salt Solution (BSS), or viscoelastic substance, on the endothelial side of the button, through the center of the trephine blade.

CAUTION:

Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the use of this instrument.

IMPORTANT:

This donor cornea punch has been EtO gas

sterilized. It is a disposable unit designed for single-use and should not be resterilized or reused.

This donor cornea punch has been carefully checked before packaging and is ready for use when you receive it.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Limited Product Warranty

This product is warranted to be free of defects in materials and workmanship until the expiration date as indicated on the product packaging. Should this device fail by reason of such defects during the warranty period, the seller will, at its option, repair or replace the device with the same model or, if the same model is no longer in production, a model of equivalent kind, function and performance. ALL OTHER WARRANTIES OF ANY KIND OR NATURE, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS ARE EXPRESSLY DISCLAIMED. OTHER THAN THE COST OF REPAIR OR REPLACEMENT UNDER THE TERMS OF THIS WARRANTY, THE SELLER SHALL NOT BE RESPONSIBLE FOR ANY LOSS, CONSEQUENTIAL DAMAGE, EXPENSE OR LIABILITY INCURRED BY THE PURCHASER AS A CONSEQUENCE OF THE USE, MISUSE OR NON-USE OF THIS PRODUCT. Any provision of this disclaimer found to be unenforceable as written shall be deemed amended or stricken only as necessary so as to preserve the enforceability of the balance hereof.

The purchaser acknowledges that this product is intended for use only by trained persons, possessing the requisite skill and experience to use this device in accordance with the prevailing standards of medical practice, and in accordance with the instructions included with this device. By using this product purchaser agrees to release, indemnify and hold the seller harmless for any loss, damage, expense or liability incurred by the purchaser due to any failure by the purchaser or others under purchaser's control to use this product in a proper manner.