

INSTRUCTIONS FOR USE

BARRON RADIAL VACUUM TREPHINE WITH CROSS HAIRS

A single-use trephine
for lamellar and penetrating keratoplasty

SURGICAL TECHNIQUE

The Barron Radial Vacuum Trephine 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) Dry the anterior corneal surface with a cellulose sponge. Mark the visual axis of the recipient cornea with a sterile gentian violet marking pen. **2)** Verify the blade diameter that is stamped into the white plastic spoked rim. Examine the trephine under the operating microscope and turn the white plastic spokes on top of the blade assembly clockwise until the edge of the blade is aligned with the inner wall of the vacuum chamber; this is the zero position. **3)** Retract the blade by turning the spokes of the blade assembly one full rotation (4 spokes) counterclockwise. **If the blade is not retracted, vacuum will not be obtained.** **4)** Moisten the anterior corneal surface with balanced salt solution. **5)** Push the plunger of the syringe all the way in and hold. **6)** Grasp the white plastic finger grips with thumb and index finger of the non-dominant hand, look through the center of the trephine with the operating microscope, and align the cross hairs with the visual axis mark on the recipient cornea. **7)** Press the trephine evenly on the anterior corneal surface and **release the plunger of the syringe abruptly.** Test if vacuum has been obtained and is adequately holding the trephine to the cornea.

Note: If vacuum is not obtained, check the following: **a)** Make sure the blade was retracted one complete revolution as outlined in step # 3 above. **b)** A slightly uneven cornea can prevent the trephine vacuum chamber from making complete contact with the cornea. A small amount of viscoelastic applied to the cornea usually improves surface contact. **c)** Loose epithelium can also prevent the trephine vacuum chamber from making complete contact with the cornea. Remove any loose epithelium and moisten the anterior corneal surface with Balanced Salt Solution. **d)** Remember to release the syringe plunger abruptly. Grasping the syringe with your full hand and placing your thumb on the plunger will make a quick release easy. **8)** Once vacuum has been obtained, confirm that the trephine is in the correct position and wait approximately 30 seconds. **9)** Stabilize the trephine by gently holding it with the thumb and index finger of the non-dominant hand. Do not squeeze or tilt the trephine, excessive pressure on the finger grips may prevent the blade from rotating freely. **10)** With the index finger of the dominant hand, turn the spokes of the blade assembly one full rotation(4 spokes) clockwise. This will return the blade to the zero position.

11) To start cutting, advance the blade by turning the spokes of the blade assembly clockwise. For each complete rotation (4 spokes), the blade is lowered 0.25mm. **12)** When the desired depth of cut has been reached, release the vacuum by pushing in the plunger of the syringe and remove the trephine from the cornea. **13)** For even suture placement, dry the anterior corneal surface with a cellulose sponge and mark the 16 radial impressions made by the trephine with a sterile gentian violet marking pen.

CAUTION: Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the use of this instrument. Once the cornea is perforated, do not advance the blade any further. Remove the trephine from the eye immediately.

IMPORTANT: This trephine has been EtO gas sterilized. It is a disposable unit designed for single-use and should not be resterilized or reused. To prevent blade damage, **do not disassemble the trephine.** Each trephine is tested before packaging and is ready for use when you receive it. Technique video available upon request.

**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.

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