BrightMEM™ Anterior Keratoplasty (BMAK)

Surgical Instructions

Description:

BrightMEM is a novel corneal allograft that promotes regeneration of the corneal epithelium. It is made from Descemet's Membrane, which serves as an optimized substrate for protecting the stroma from degradation and promoting regeneration of the corneal epithelium.

The product is aseptically processed from tissues obtained from donated human tissue (corneas) according to the current Good Tissue Practices (cGTP) regulations established by the US Food & Drug Administration (FDA). Please see the product insert for more information.

Before performing the procedure, we encourage all surgeons to watch the training video found on our website at www.brightstartx.com/surgeontraining.

Usage Instructions:

Prior to surgery

- Allow the tissue to warm to room temperature (20°C–25°C) in its unopened, tissue chamber for 1 hour prior to use.
- Open the plastic tissue chamber. Note: The interior of the container, the storage solution, and the tissue are considered sterile, while the exterior of the container is considered non-sterile.

Surgical procedure

- It is recommended that the lid margins be scrubbed with 5% betadine and the ocular surface be prepped with 5% betadine for 5 minutes prior to the procedure to mitigate risk of infection.
- Place a speculum in the patient's eye and debride the epithelium or pannus over the cornea out to a 0.5mm clearance on all edges.
- Remove the tissue from the tissue chamber by grasping the corneoscleral rim with toothed forceps. Avoid touching the clear cornea with toothed instruments.
- **Using an operating microscope, check that the allograft is 100% flat and not partially folded**. If there is a small fold, try:
    - 1. A few drops of BSS to float the edge free or
    - 2. A nontoothed (tying) forceps to unfold it.
- Using a Weck-Cel sponge, wick excess fluid from under the BrightMEM allograft by dabbing 360° on the peripheral posterior surface of the donor cornea. Avoid touching the BrightMEM allograft directly with the Weck-Cel sponge.
- Trephine the tissue to the desired size allowing for 0.5mm clearance on all edges. If there seems to be Insufficient blue color present in the allograft, you can restain the allograft with Vision Blue In a small dish for 30-60 seconds.
- Dry the anterior stromal bed thoroughly with a Weck-Cel sponge.
- Place the trephined corneal button with Descemet's membrane side down onto the cornea surface, staying within the margins of the epithelial debridement.
- Allow the corneal button to dry in place for 60 seconds. To facilitate adhesion of the allograft to the corneal stroma, wick fluid out by dabbing peripherally 360° with a Weck-Cel sponge.
- Remove the corneal button by grasping at the anterior stromal edge with tooth forceps (do not grasp the full thickness of the corneal button) and lifting it off. The BrightMEM allograft should remain attached to the patient's cornea. If the BrightMEM allograft does not separate readily from the carrier corneal button, gently insert a pair of forceps or a

spatula between the corneal button and the BrightMEM allograft and hold the allograft down on the recipient bed as you lift off the corneal button.
- Confirm proper orientation of the BrightMEM allograft based on the presence of a 'S' orientation mark ('Z' indicates the graft is upside down).
- If there are wrinkles in the BrightMEM allograft, use a 30g cannula to gently sweep over or under the graft to smooth it out. Re-wetting the graft with a few drops of BSS can facilitate this process.
- After the BrightMEM allograft is completely smooth and orientation is confirmed, wick residual interface fluid out by gently dabbing 360° around the periphery of the graft edge using a Weck-Cel sponge.
- Place a thin layer of tissue fibrin glue. Recommend two drops of component 1 and the one drop of component 2 over the BrightMEM allograft, ensuring complete coverage of the edges. Add more glue if desired.
- Allow the glue to dry for approximately 30-45 seconds before applying the bandage contact lens.
- Place a bandage contact lens over the glue, removing any excess glue that may have leaked out.
- Carefully remove the lid speculum without dislodging the contact lens.

Post-operative instructions

- Administer topical antibiotics until the epithelium is healed and the contact is removed. Hypertonic solution (NaCl 5%) QID is recommended to facilitate allograft adhesion. Steroid drops may be used at surgeon discretion.
- Aggressive lubrication recommended with preservative-free artificial tears or autologous serum tears.
- Avoid ocular ointments while the contact lens is in place. Plan to keep the contact lens in place for at least two weeks.

BMAK Tips

- Warm the tissue for an hour before trephination to prevent premature separation from stroma.
- Position the BrightMEM allograft membrane side down in the debrided area. Use either a Paton spatula, 0.12 forceps. Note that some practitioners prefer the precision of 0.12 forceps over the Paton spatula.
- Ensure you have created an epithelial defect that is at least 0.5mm greater on all edges than the expected allograft diameter to prevent graft overlap with remaining epithelium/pannus. Using a zone marker or trephine allows for a continuous circular edge, that may facilitate healing.
- Once the allograft is correctly positioned and smooth, dry its edges with Weck Cel spears for 60-90 seconds. Be aware: if the graft is too wet, it might hide minor wrinkles.
- If wrinkles appear, avoid moving the BrightMEM allograft. Instead, apply a few drops of BSS on top and smooth with a 30G cannula tip. If wrinkles remain, introduce BSS slowly under the graft to adjust it.
- If you can't place a bandage contact lens on the eye due to issues like symblepharon, create a smaller diameter lens by punching the original lens using a trephine.
- If the graft becomes dislodged or folds post-operation, it can be gently removed at the slit lamp using jeweler forceps. However, repositioning or replacing the membrane in the clinic is discouraged and has a low success rate.

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