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LIONS WORLD VISION INSTITUTE™

BRIGHTSTAR™ THERAPEUTICS

BrightMEM Corneal Allograft

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Introductory Packet for Physicians

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BRIGHTSTAR THERAPEUTICS

BrightMEM™ Corneal Allograft

Product Insert

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 procedure overview document and/or visit our website for additional information

The enclosed BrightMEM allograft has been evaluated by Brightstar Therapeutics' manufacturing partner, Lions Gift of Sight, using the Medical Standards of the Eye Bank Association of America. These standards are approved by the American Academy of Ophthalmology and have been developed to standardize procedures in the procurement, preservation, storage, and use of eye tissue for transplantation.

This tissue is delivered with no warranty as to the merchantability or fitness for a particular purpose, and the recipient waives all claims it may have for breach of warranty either express or limited. The final responsibility for determining the suitability of the tissue for transplantation rests with the surgeon.

This tissue was non-reactive when tested by the Eye Bank for HIV-I/II, Hepatitis B, Hepatitis C and Syphilis. Infectious disease testing was performed at a CLIA-certified and FDA-registered laboratory. If the donor was also an extra-ocular tissue donor, then additional test results not required for ocular tissue may be reported when available. The U.S. Food and Drug Administration (FDA) and EBAA have approved the kits used for this testing, some of which are approved for pre-mortem blood. FDA approved tests for cadaveric blood were used where available. Test results are documented on the enclosed Donor Tissue Detail Form sent with the tissue.

This tissue is for single patient use only. The tissue label indicates an expiration date. DO NOT USE THIS TISSUE BEYOND THE EXPIRATION DATE.

Prior to surgery, the transplanting surgeon should inspect the integrity of the tissue container. IF THE STORAGE MEDIA IS LEAKING, DO NOT USE THE TISSUE FOR TRANSPLANT. Contact Lions Gift of Sight immediately at 612-624-0433. Press 0 if you reach voicemail.

The consignee is responsible for tracking the tissue recipient's name, unique identification number, age and/or date of birth, diagnosis, date of surgery, location of surgery, type of surgery, the name of the transplanting surgeon when the tissue is transplanted, and the ISBT 128 tissue identifier. This information is required to track the tissue from the donor to the consignee and the consignee to the recipient.

The following recommendations may reduce the risk of bacterial infection:

1. Each BrightMEM allograft is provided in a sterile vial.
2. The BrightMEM allograft should be stored between 2°–8°C. DO NOT FREEZE. Warm the corneal storage media to room temperature for a period of 1 hour prior to transplantation to maximize the effect of the antibiotic contained within it.
3. The medium should be a light rosy-orange color. DO NOT USE CORNEA IF COLOR RANGE HAS SHIFTED TO YELLOW OR DEEP RED. DO NOT USE CORNEA IF STORAGE SOLUTION HAS PARTICULATES OR APPEARS CLOUDY. In this case, the tissue should not be used. Make a report immediately to Lions Gift of Sight at 612-624-0433. Press 0 if voicemail.
4. No pre-surgical cultures were performed on the BrightMEM allograft. The transplanting surgeon may want but is not required to culture the corneo-scleral rim in a liquid microbiologic culture media following excision or punching of the donor button. Prompt communication between lab and surgeon of any sign of growth can alert the surgeon to a possible infectious complication.

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BRIGHTSTAR THERAPEUTICS

BrightMEM™ Anterior Keratoplasty (BMAK)

Surgical Instructions

Description:

BrightMEM is a novel corneal allograft that promotes the 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 the 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 refer to the product insert for more information.

Before performing the procedure, we encourage all surgeons to watch the training video and to review the "Surgical Pearls" document for additional surgical advice from users found on our website at www.lwvi.org/sterile-tissue-services/brightmem-corneal-allograft/

Usage Instructions:

BrightMEM Allograft Preparation

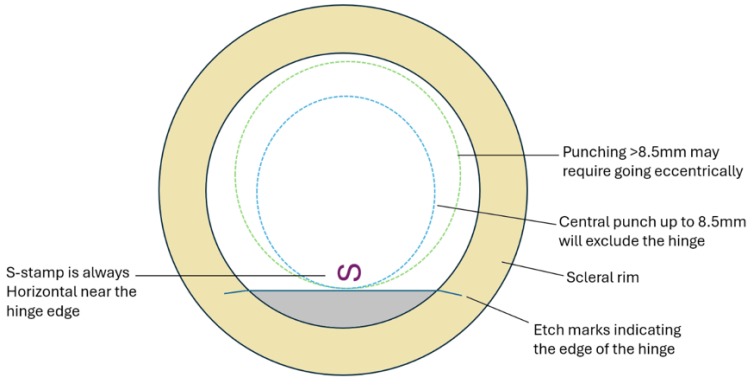
- Allow the tissue to warm to room temperature (20°C–25°C) in its unopened, tissue chamber for 1 hour prior to use.
- Open the plastic tissue chamber. Note: The interior of the container, the storage solution, and the tissue are considered sterile, while the exterior of the container is considered non-sterile.
- When removing the tissue from the chamber, grasp the tissue by the scleral rim on the hinge side, closest to where the S-stamp is. Gravity helps keep the graft flat as you lift it out of the Optisol while transferring to the Teflon block. Once on the Teflon block of the **vacuum trephine**, if the graft appears wrinkled or partially scrolled, add a few drops of Optisol to the well. **Hold the graft by the scleral rim closest to where the S-stamp is and gently wick out fluid by dabbing the scleral rim inferiorly, allowing the graft to lay back down in place.**
- 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. 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.

Preparing the Patient's Eye

- 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.
- It is critical that the stromal surface is completely dry after the superficial keratectomy to remove scar/pannus.

BrightMEM Allograft Trephination

- Descemet's membrane has been peeled from the stroma up to the shaded hinged area, and the S-stamp is located close to the hinge as shown here:



- 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 re-stain the allograft with Vision Blue In a small dish for 30-60 seconds.

Securing the BrightMEM Allograft

- Place the trephined corneal button with the Descemet's membrane side down onto the corneal surface, staying within the margins of the epithelial debridement.
- Allow the corneal button to dry in place for 1-2 minutes. 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 an 'S' orientation mark ('Z' indicates the graft is upside down).
- If there are wrinkles in the BrightMEM allograft, use a 27 or 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 for 2-3 minutes.
- Place a thin layer of tissue fibrin glue. We recommend two drops of component 1 and then one drop of component 2 over the BrightMEM allograft. Place two drops of glue at the 3 and 9 o'clock positions and spread circumferentially as much as possible. Add more glue if desired.
- The reason to use Tisseel / fibrin glue is to ensure the BrightMEM allograft edges adhere well to stroma and to prevent epithelium growing under (rather than on top of) the allograft.
- 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. A flat base curve is preferable, as air bubbles can interfere with adhesion.
- Carefully remove the lid speculum without dislodging the contact lens.

Post-operative instructions

- Leave the bandage contact lens in place for 1 month before disturbing it in patients with severe or near-total LSCD. It can be removed earlier in patients with mild to moderate LSCD (<50% of limbus involved) but should stay in place for at least two weeks.
- Use antibiotics QID for at least one week and hypertonic saline 5% QID until the bandage contact lens comes off and the membrane is noted to be epithelialized. Corticosteroids should be used as appropriate for each patient (some need higher dosing) but you can use a standard QID, TID, BID, daily pred taper over several weeks.
- Aggressive lubrication recommended with preservative-free artificial tears or autologous serum tears.
- Avoid ocular ointments while the contact lens is in place.