

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 [training videos](#).

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-1/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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