

BrightMEM Preloaded[™] Corneal Allograft

Product Insert

BrightMEM is an innovative corneal allograft composed of Descemet's Membrane that promotes corneal re-epithelialization and functions as a robust basement membrane with natural long-term durability. 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 Preloaded allograft has been evaluated by Brightstar Therapeutics' manufacturing partner, Lions Gift of Sight, using the Medical Standards of the Eye Bank Association of America (EBAA). 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 for HIV-I/II, Hepatitis B, Hepatitis C and Syphilis. All post-mortem 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 are reported when available. FDA-approved tests for cadaveric blood were used where available and appropriate. Testing performed on pre-mortem blood on specimens no more than seven days prior to death may be reported in lieu of post-mortem testing. 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. The expiration term for BrightMEM tissue is fourteen days from preservation.

Prior to surgery, the transplanting surgeon should inspect the integrity of the tissue container and tamper-evident seal. IF THE STORAGE MEDIA IS LEAKING OR IF THE SEAL IS MISSING OR APPEARS TO HAVE BEEN TAMPERED WITH, 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.

If you are a surgeon or reporting on behalf of a surgeon regarding a product or procedural issue, please use the Surgeon Issue Report form available here: [Surgeon Issue Report Form](#). Once this form is submitted, the issue investigation and determination process will take place.

The following recommendations may reduce the risk of bacterial infection:

1. Each BrightMEM allograft is provided in a sterile container.
2. The BrightMEM allograft should be stored between 2°–8°C. DO NOT FREEZE. Warm the corneal storage solution to room temperature for a period of 1 hour prior to transplantation to maximize the effect of the antibiotic contained within it.
3. The storage solution contains phenol red pH indicator and should be a light rosy-orange color. DO NOT USE TISSUE IF COLOR HAS SHIFTED TO YELLOW OR DEEP RED. DO NOT USE TISSUE IF STORAGE SOLUTION APPEARS CLOUDY. 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 elect to perform surgical cultures. If culturing is performed by the surgeon, swab the corneal rim or other tissue remnants following donor graft manipulation. Prompt communication between lab and surgeon of any sign of growth can alert the surgeon to a possible infectious complication.

Brightstar Therapeutics
2501 Sandersville Road, Suite 120
Lexington, KY 40511
859-800-7147
info@brightstartx.com