

Package Insert Section

Advancing Sight Global is an accredited member of the Eye Bank Association of America. Advancing Sight Global supplies the following information to assist surgeons in the evaluation of eye tissue for transplantation. The enclosed eye tissue has been evaluated by the Source Eye Bank and by Advancing Sight Global using the Eye Bank Association of America (EBAA) Medical Standards and Food and Drug Administration (FDA) regulations.

Current regulations require infectious disease testing for the following diseases: HIV 1, HIV 2, HBV, HCV, and Syphilis. All infectious disease tests were performed by CLIA certified (42 U.S.C. 263a and 42 CFR Part 493) and FDA registered laboratories. FDA approved screening tests were used for infectious disease testing as required by the FDA and EBAA where available. The results shall be non-reactive or negative before tissue is distributed for transplantation and are documented on the tissue information form. Certain other non-required tests may be reactive, but the tissue is still considered safe for transplant.

The Source Eye Bank is responsible for determining whether the donor is eligible or ineligible to donate for transplantation, in accordance with FDA, EBAA, and Source Eye Bank guidelines. Advancing Sight Global shall not determine donor eligibility. In order to assess donor eligibility, the following is a summary of donor-related examinations performed by the Source Eye Bank: 1) examination of medical records, including infusion/transfusion records, at the healthcare facility where the donor died or was treated prior to death, 2) consultation with medical personnel having specific medical knowledge of the donor, when necessary, 3) medical/social history interview with the next-of-kin or other relative, primary treating physician, or person with an affinity relationship with the donor, 4) donor body physical assessment, 5) slit-lamp microscopic evaluation, 6) specular microscopic evaluation, 7) examination of gross physical autopsy results (if applicable), 8) death investigation report (if applicable), and 9) consultation with an eye bank Medical Director or infectious disease specialist (if applicable).

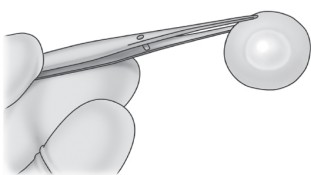
This tissue is delivered with no warranty as to merchantability or fitness for a particular purpose, and the recipient waives all claims he or she may have for breach of warranty, either expressed or implied. The final responsibility for determining the suitability of the tissue for transplantation rests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

This corneal tissue is preserved in glycerol, a long-term corneal storage medium, is stored at room temperature and expires on the date the glycerol expires (see tissue label). The vial should be free of debris and /or cloudiness. Any change in the appearance may indicate contamination, in which case the tissue should not be used and Advancing Sight Global should be immediately notified. A slight pink or blue discoloration of clear glycerol is normal and acceptable, due to either residual phenol red indicator from the prior intermediate-term corneal storage media or residual trypan blue from prior DMEK preparation. **DO NOT REFRIGERATE OR FREEZE!** A glycerol preserved cornea may be rehydrated as shown below.

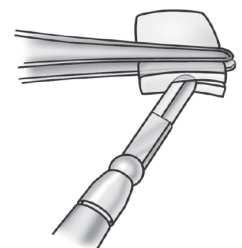
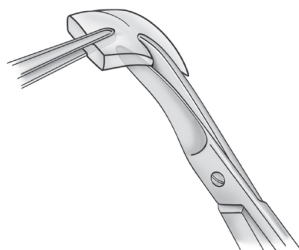
Shrink seals are applied to GlycerolPlus Cornea vials in the Advancing Sight Global laboratory post-processing to prevent tampering. The surgeon or his/her designee should always check for integrity of the seal. If the seal is compromised and/or any evidence of possible tampering is observed, Advancing Sight Global should be immediately notified.

GlycerolPlus Corneas are recovered and processed aseptically but are not considered sterile. Advancing Sight Global does not perform pre-surgical microbiologic cultures. It cannot be assumed that the storage medium is bactericidal. Culturing the medium or the corneoscleral rim at the time of surgery is at the discretion of the surgeon. Half GlycerolPlus Cornea is approximately 5mm x 11mm.

Notify Advancing Sight Global immediately if a recipient experiences an adverse reaction related to the donor tissue.



GlycerolPlus Corneas from Global Sight Network™ should be rehydrated, de-epithelized, and trimmed before use.



1. Prepare rehydrating solution: Gentamicin (0.75 mL of 80 mg / 2 mL solution) + Balanced Salt Solution (30 cc)
2. Place cornea into the rehydrating solution for ~ 20 minutes. Cornea will become thicker and cloudy.

3. Remove GlycerolPlus Cornea from hydrating solution. Trim to desired size and remove scleral rim.

4. De-epithelize by scraping the anterior surface with a Tooke knife, other blade, or surgical sponge.

5. To reduce tissue thickness for smoother coverage by conjunctiva, grasp corneal segment with forceps and pass a blade horizontally to produce two thin pieces. Tissue is for single-patient use only. Discard remainders appropriately.