



MEDICAL ADVISORY

The following changes were made at the October 16, 2025, meeting of the Medical Advisory Board and will become effective on **January 16, 2026**.

E1.200 Processing and Preservation

Aseptic processing shall be performed in a certified and qualified bacteriologically and climate-controlled environment, such as an ISO 5/Class 100 laminar airflow hood or clean room. The processing shall be performed by qualified, trained, and competent staff using validated methods to prevent contamination and cross-contamination and to maintain tissue quality for its intended use.

Eye banks shall establish and maintain policies, processes, and procedures designed to minimize contamination of the tissue. The following shall be addressed:

1. Environmental controls and monitoring
2. Process controls
3. Staff training in aseptic technique
4. Attire, gowning, and use of personal protective equipment
5. Workflow movement and movement of personnel through workspaces
6. Prevention of cross-contamination and labeling mix-ups (e.g., tissue from different donors may not be processed simultaneously).

E1.210 Whole Eye

Eye banks that preserve and store whole eyes for lamellar or refractive keratoplasty may use preservation methods such as moist chamber at 2-8 degrees Celsius, freezing below zero degrees Celsius, or some other validated method.

E1.220 Cornea

Eye banks that process corneas intended for transplant may use one of the following methods. The Medical Director must develop appropriate tissue selection criteria and approve the procedure for each method utilized. All processes must be validated. When changes or process deviations occur, the eye bank shall review and evaluate the process and perform revalidation where appropriate.

E1.221 Processing via Excision of the Corneoscleral Disc from Enucleated Whole Eyes

Processing whole eyes into any combination of tissues, including but not limited to corneoscleral disc and/or sclera, may be performed by manual methods.

E1.222 Lamellar Tissue Processing

Processing of lamellar tissue may be performed using manual or automated methods (e.g., microkeratome).

E1.223 Laser Assisted Processing

Lasers may be used to process lamellar tissue or custom wound architecture (e.g., femtosecond laser).

E1.230 Sclera

There are various methods of processing sclera, including utilizing ethanol (70% or greater ethyl alcohol), sterile glycerol, cryopreservation, radiation sterilization, or some other validated method.

F1.200 Endothelial Cell Density and Pachymetry

Determination of endothelial cell density via specular microscopy (or quantitative light microscopy for organ cultured corneas) shall be a standard method of corneal tissue evaluation (according to Matrix I) for all member eye banks of the EBAA, effective December 2001. Minimal endothelial cell count limits are left to the discretion of the Medical Director. When it is impossible to obtain an endothelial cell count, this requirement may be waived on a case-by-case basis by the Medical Director. Calibration or verification of calibration of endothelial cell counting equipment shall be done according to manufacturer guidelines, when applicable, and on at least an annual basis. Calibration or

verification of calibration procedures shall include specific directions and limits for accuracy.

L1.000 Documentation to Accompany Donor Tissue

L1.100 Tissue Report Form

In special circumstances, like approved research programs, the Medical Advisory Board may waive certain label and tissue report form requirements. Approval for omissions must be obtained in advance from the MAB and surgeons receiving study tissues must consent in advance to any masking of standard required data.

Tissue distributed for transplant use shall be accompanied by a tissue report form and may include additional forms to address all requirements. The tissue report, together with pertinent additional forms shall contain the following:

All Tissues:

1. Name of (Source) eye bank
2. Location of eye bank
3. Telephone number of eye bank
4. ISBT 128 tissue identifier.
5. Type of storage solution
6. All dates shall be written as YYYY-MM-DD HH:MM to harmonize with the ISO 8601 requirements.
7. If Level II processing has occurred, ~~cornea is processed~~, clearly indicate the type of processing performed or the indicated use (e.g., endothelial keratoplasty, posterior lamellar keratoplasty, anterior lamellar keratoplasty, laser assisted keratoplasty, etc.).
8. If the Product Code and Donation Identification Number are not assigned by the same entity, then the label must include the Processing Facility Information Code, which includes the Facility-Defined Product Code (FPC) and Processing Facility Identification Number (FIN(P)).
9. Tissue evaluation reporting requirements according to Matrix II.
10. Name and EBAA Accreditation Status of each establishment that performs any of the following steps in the preparation of tissue: recovery, processing, storage, evaluation, donor eligibility determination and distribution. Steps performed after release of whole cornea for transplant use (e.g., processing, distribution) may be documented on additional forms (e.g., "processing form", "disclosure of eye banking functions form", importing eye bank revised/supplemental Tissue Report Form, or other documents).
11. A summary of records reviewed regarding the eligibility of tissue for transplant.