ROCKY MOUNTAIN LIONS EYE BANK
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Transplant Cornea Package Insert

Attention Transplanting Surgeon

Rocky Mountain Lions Eye Bank:

Transplantable tissue delivered by RMLEB is procured and processed in compliance with EBAA Medical Standards and government regulations. 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. RMLEB is EBAA accredited, FDA registered and licensed by the states of California, Florida and Maryland. Special pre-surgical cornea preparation or pre-sectioning may be performed by an establishment for RMLEB following EBAA Medical Standards. Establishments performing such processing for RMLEB are registered with the FDA but may not be EBAA accredited.

Preservation / Storage Media:

The specific corneal preservation media brand/type is listed in the enclosed tissue information documents. Corneas are shipped with wet ice under cool conditions. Package should contain remaining coolant upon receipt. If there is no remaining coolant or if contents are not cool notify the eye bank. Tissue is packaged in a way that can maintain cool condition for a limited period. Upon receipt it is recommended to place tissue in storage or replenish ice within package as needed. Recommended storage temperature for corneas in media is between 2-8°C - DO NOT FREEZE. It is recommended, when possible, to remove the cornea from refrigeration approximately 1 hour prior to surgery. The tissue container should be examined for evidence of tampering and leakage. The tissue container has had a tamper evident seal applied. If container integrity appears to be compromised call the eye bank before using tissue. The storage media should be examined for color change prior to tissue use. A color change may indicate a shift in pH. Normal media color should be an orange color. If media color is bright red or yellow, the tissue should not be used and the eye bank should be notified.

Culturing:

Aseptic technique and sterile supplies are used in tissue recovery and processing. Tissue is not, however, to be considered sterile. No microbiologic cultures of the storage medium or cornea/sclera are performed by RMLEB. Culturing performed at the time of tissue use is at the discretion of the transplanting Surgeon. Perioperative subconjunctival antibiotic injections of both an aminoglycoside and a cephalosporin are used by many surgeons to maximize gram-positive and gram-negative coverage.

Recipient and Tissue Tracking:

Tissue is intended for single patient application. As the consignee of the tissue you are responsible for the tracking of; 1.The tissue recipient's name and unique identifier, 2. Age and/or date of birth, diagnosis, date of surgery, location of surgery, type of surgery, 3. The name of the transplanting surgeon and 4. The ISBT 128 tissue identifier. The eye bank must be notified in writing of recipient information for the purpose of tracking the tissue from the donor to the recipient. Tissue related adverse reactions, to include post-operative infections, are to be reported to the eye bank as soon as possible.

Donor Eligibility - Tissue Suitability:

A summary of records reviewed to determine eligibility for transplant is listed on the enclosed donor and tissue information documents. Records reviewed may include donor medical chart, family medical/behavioral history interview, physical body assessment, gross autopsy findings, or other relevant and available records specified. The donor is believed to be free of potentially transmissible disease. The donor social history appears to be free of medical and behavioral high risk based upon the hearsay statements of an individual identified as knowledgeable. A physical examination of the donor body found no evidence of high-risk behavior, HIV, infectious hepatitis or other relevant communicable diseases. All EBAA and or FDA required infectious disease testing is negative as performed by a CLIA accredited and FDA registered laboratory. A list of the tests performed is enclosed on the donor and tissue information documents. Infectious disease tests used are FDA approved, some of which are approved for pre-mortem blood. When approved and made available for use by FDA, tests for cadaveric blood are used. If the donor was also an extra-ocular tissue donor, then additional test results not required for ocular tissue may be reported when available.

Any suggested tissue use indications from the eye bank are based on general tissue observations, and commonly requested surgeon preference. This tissue is delivered with no warranty as to the merchantability or fitness for a particular purpose, and 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.