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Package Insert Ethanol Preserved Transplant Tissue

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. RMLEB is EBAA accredited, FDA registered and licensed by the states of Maryland, California and Florida.

Preservation / Storage Media: Absolute Ethanol

RMLEB preserves ocular tissue in ethanol. Avoid temperature extremes; refrigeration is not required for storage of tissue in absolute ethanol. Avoid sources of heat or ignition, contents are flammable.

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 the tissue.

Culturing:

Aseptic technique and sterile supplies are used in tissue recovery and processing. Tissue, however, is not to be considered sterile. No microbiologic cultures of the storage medium or tissue are performed by RMLEB. Culturing performed at the time of tissue use is at the discretion of the transplanting surgeon.

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. 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.

Suggested Procedure For Rehydration of ethanol preserved ocular tissue

Supplies Needed:

- 200-500ml. sterile saline
- aqueous antibiotic of surgeon's choice (Gentamicin, Neosporin or broad-spectrum antibiotic)
- sterile jar or specimen cup
- sterile forceps

Procedure: Three separate saline washes of tissue.

1. Place 1/3 total saline and 1/3 total antibiotic into a sterile cup.
2. Remove tissue from jar, taking the least amount of preservative (alcohol) with it as possible by letting the preservative drip off. Soak tissue in saline for approximately 10 minutes, stirring occasionally.
3. Repeat wash two more times using fresh saline and antibiotic for each wash, total soaking time taking approximately 30 minutes. Tissue is now ready to be cut to shape for surgery.

Notes: Be sure to maintain aseptic technique. Tissue should return to opaque white and soft, pliable state (Dehydrated sclera is translucent and somewhat hard and inflexible). Three separate rinses are necessary for the removal of preservative in order to avoid a tissue inflammatory response. Studies¹ indicate that 30 minutes of wash removes greater than 99% of preservative. Each preserved tissue is for single patient use only.

¹ Am J Ophthalmology 1999 Oct; 128(4): 522-4