4. Remove the allograft from the opened container. The allograft is ready to use and requires no further preparation.
5. The allograft must be transplanted immediately upon removal from the container.

Tissue Tracking:

The Consignee is responsible for tracking the tissue and completing the Tissue Usage Card to include:

- Recipient's Name,
- Unique Identification Number,
- Recipient's Age or Date of Birth,
- Diagnosis,
- Date of Surgery,
- Location of Surgery,
- Type of Surgery,
- Name of the Transplanting Surgeon, and
- ISBT 128 Tissue Identifier

The completed Tissue Usage Card must be returned to LEITR.

Reporting Adverse Reactions:

The physician is responsible for reporting all Adverse Reactions that may be potentially attributable to the allograft by completing the Adverse Reaction Form included with every allograft, completing the Adverse Reaction Form in the One World Sight Alliance (OWSA) website, or by calling LEITR Quality and Regulatory department at (813) 289-1200.

LEITR is accredited by the Eye Bank Association of America (EBAA) and is registered as a Tissue Establishment with the Food and Drug Administration (FDA).

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FOR TRANSPLANT & RESEARCH

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To order call: 813.289.1200

QA-F-030 Rev. A

OptiGraft™ Sterile Ophthalmic Allografts

Sterile Cornea in Albumin

Description:

OptiGraft Sterile Cornea is intended for transplant where viable endothelium is not required.

OptiGraft Sterile Cornea is recovered from deceased human donors who have granted authorization for recovery. The tissue is processed and packaged using aseptic techniques, terminally sterilized using irradiation and is provided sterile for use in ocular surgery.

Donor Selection and Screening:

Lions Eye Institute for Transplant and Research's (LEITR's) commitment to tissue safety begins with Donor Eligibility. All potential donors are screened for medical suitability, which includes a physical assessment, interview with a knowledgeable historian for the donor, and a review of all available medical records. All allografts from the eligible donors have been evaluated by LEITR to meet FDA Regulations, the Medical Standards of the Eye Bank Association of America (EBAA) and LEITR's internal quality control procedures.

Potential donors with clinical evidence and/or physical evidence of infectious/communicable disease or other contraindicated condition at the time of death are deemed ineligible for donation. Examples include, but are not limited to:

- HIV/AIDS, including risk factors such as injectable drugs for non-medical use, or high-risk behaviors
- Viral Hepatitis
- Sepsis/Systemic infections
- West Nile Virus
- Human transmissible spongiform encephalopathy (TSE), including variant Creutzfeldt-Jacob Disease (vCJD)
- Dementia, any degenerative or demyelinating disease of the central nervous system or neurological disease of unknown etiology
- Communicable disease risk associated with xenotransplantation

Infectious disease tests were performed by a CLIA certified and FDA registered laboratory. FDA approved tests were used for infectious disease testing as

required by the FDA and EBAA, some of which are approved for pre-mortem blood and FDA approved tests for cadaveric blood were used where available to test for:

- HIV Type I/II antibody (HIV I/II)
- HIV I Nucleic Acid Test (NAT)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody (HBcAb)
- HBV and HCV Nucleic Acid Test (NAT)
- Syphilis (Treponema pallidum) or another acceptable serological test

Additional, non-required tests may be performed and when that occurs those results are also provided. Test results are documented on the Tissue Detail Form (TDF) included with every allograft. Lions Eye Institute for Transplant and Research does not perform pre-surgical cultures on the ocular tissues. Donor Tissue Donor Eligibility determination is made by LEITR staff in strict compliance with the U.S. Food and Drug Administration (FDA) regulations and the Eye Bank Association of America (EBAA) Standards.

Storage and Handling:

- OptiGraft Sterile Cornea in Albumin is supplied ready to use, no rehydration necessary.
- It is the responsibility of the transplant facility and/or clinician to maintain the allograft intended for transplantation at the appropriate recommended storage conditions prior to transplant.
- The cornea is stored between 2°C and 30°C. DO NOT FREEZE.
- The packaging system for this allograft has been established for the safe delivery of the allograft to the physician.

Potential Complications:

- The allograft may not elicit the intended response for the Recipient.
- The host site may become infected.
- The allograft may cause an inflammatory response.

Precautions:

The allograft is considered sterile as long as the packaging is not opened or damaged. The package must be inspected upon receipt and prior to use to ensure package integrity. LEITR should be notified immediately if there is any evidence of tampering observed upon receipt. DO NOT USE THE ALLOGRAFT UNDER THE FOLLOWING CONDITIONS:

- The container in which the tissue is stored is damaged or the label has been removed or defaced.
- The indicated Expiration Date has passed.
- The recommended Storage Conditions have not been maintained.

Warnings:

- Unused allograft, whole or partial, may not be repackaged or re-sterilized.
- While every effort has been made to ensure the quality of the allograft, LEITR makes no claims concerning the biologic or biomechanical properties of the allograft.
- 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 suitability of the tissue for transplantation rests with the transplanting surgeon.
- As with any allograft, despite strict screening, testing and quality procedures, there is the potential for the transmission of infectious agents to the recipients.

Sterility Controls:

The OptiGraft Sterile Cornea is provided sterile following established methods for ongoing process monitoring and recognized validation standards for irradiation sterilization.

Directions for Use:

The allograft is intended for single patient use only by a licensed physician; under no circumstances may the tissue be used for more than a single patient. It is important to utilize aseptic techniques when unpacking the allograft. The allograft must be transplanted immediately upon opening the package. DO NOT STERILIZE/RE-STERILIZE.

Prepare the Allograft for Use:

Follow the allograft preparation steps described below prior to surgery.
Do not use the allograft if there is evidence that the pouch is damaged or sterility has been compromised.

1. Examine the pouch for package integrity. Do not use the allograft if there is any evidence that the pouch is damaged or sterility has been compromised.
2. Aseptically present the container onto the sterile field.
3. Remove the lid from the container.