

AlloFlo™ Uveo and AlloSpan™ Canal Sterile Pre-Loaded Sclera Package Insert

Description

AlloFlo Uveo™ and AlloSpan™ Canal Sterile Pre-Loaded Scleral allograft tissue is recovered from consented human cadaveric donors, processed and packaged using aseptic techniques, and provided terminally sterilized for use in ocular surgery. AlloFlo Uveo and AlloSpan Canal Sterile Pre-Loaded Sclera have been processed according to EBAA best practices and using advanced micro-trephination techniques.

The AlloFlo Uveo scleral allograft tissue is pre-loaded in a carrier compatible with the Iantrek CP-300 AlloSert Uveo Microinterventional Cycloidalysis and Allograft Delivery Platform. Product code CP-260 includes 1 carrier with allograft. Product code CP-262 includes 2 carriers with allograft.

The AlloSpan Canal scleral allograft tissue is pre-loaded in a carrier compatible with the Iantrek AlloSert Canal handpieces, CFL-100 or CFL-102. Product code CFL-160 includes 1 carrier with allograft. Product code CFL-162 includes 2 carriers with allograft.

Donor Selection and Screening

The enclosed ocular tissue has been evaluated by CorneaGen using the Medical Standards of the Eye Bank Association of America and FDA requirements as defined in 21 CFR 1271.

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. The ocular tissue you received may have been recovered and/or processed by a partner which is not accredited by the EBAA; these organizations and their staff have been audited, trained, and approved by CorneaGen to recover and/or process eye tissue following CorneaGen standards. 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.

This tissue was non-reactive when tested by the Eye Bank for **HIV-III, Hepatitis B, Hepatitis C and Syphilis**. Infectious disease testing was performed at a CLIA certified and FDA registered laboratory. If the donor was also an extra-ocular tissue donor, then additional test results not required for ocular tissue may be reported when available. The U.S. Food and Drug Administration (FDA) and EBAA have approved the kits used for this testing, some of which are approved for pre-mortem blood. FDA approved tests for cadaveric blood were used where available. Test results are documented on the enclosed LTT Parent Tissue Information Form sent with the tissue. CorneaGen does not perform pre-surgical microbiologic cultures on sclera tissues.

Storage and Handling

- The packaging system used for the allografts allows for the safe delivery of tissue to the physician.
- It is the responsibility of the transplant facility or clinician to maintain the allograft intended for transplantation in the appropriate recommended storage conditions prior to transplant.
- The allografts should be stored between 2°C and 30°C. DO NOT FREEZE.
- Rehydration of the scleral tissue may be necessary.

Potential Complications

The allografts may not provide the intended outcome for the recipient. The host site may become infected. The allografts may cause an inflammatory response.

Precautions

The allografts are considered sterile as long as the packaging is not opened or damaged. Inspect the integrity of the packaging seals upon receipt and before use. Immediately report to CorneaGen any evidence of possible tampering. 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.

- Recommended storage conditions have not been maintained.

WARNING

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

Sterility Control

This allograft is provided sterile using electron beam (E-Beam) irradiation. DO NOT STERILIZE/RE-STERILIZE.

Directions for Use

This allograft is intended for single patient use by a licensed physician. It is important to utilize aseptic techniques when unpacking the allograft. This allograft should be used with a sterile surgical delivery system. Use allograft upon opening.

This allograft is intended for use to scaffold, bracket, stent, bridge, or provide scleral reinforcement and other structural support in ocular surgery.

AlloFlo Uveo allograft precut dimensions: length 5 mm, width 0.5 mm, thickness 0.4-0.6 mm.
AlloSpan Canal allograft precut dimensions: diameter 0.2 mm, thickness 0.4-0.6 mm.

Prepare Allograft for Use

Follow the allograft preparation steps described below prior to surgery. The outer peel pouch is not considered sterile. The inner pouch and allograft are sterile.

1. Examine pouch for package integrity. Do not use allograft if there is evidence that the pouch is damaged, or sterility has been compromised.
2. Aseptically present the inner pouch onto a sterile field.

Tissue Tracking

The physician is responsible for the tracking of tissue post-use including:

- The tissue recipient's name and unique identification number,
- Age and/or date of birth, diagnosis, date of surgery, location of surgery, type of surgery,
- The name of the transplanting surgeon when the tissue is transplanted, and
- The ISBT 128 tissue identifier.

Complete the Usage Report included with each allograft and return as indicated.

Reporting Adverse Reactions

The physician is responsible for reporting all Adverse Reactions that may be potentially attributable to the allograft. Call 800-858-2020.

CorneaGen is accredited by the Eye Bank Association of America (EBAA).

AlloFlo Uveo and AlloSpan Canal Sterile Pre-Loaded Sclera are prepared by:

CorneaGen

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