VisionGraft®

**VisionGraft® Sterile Cornea Package Insert**

## Description

VisionGraft® Sterile Cornea is intended for transplant where living endothelium is not required. VisionGraft® Sterile Cornea is recovered from consented human cadaveric donors, processed and packaged using aseptic techniques, and provided terminally sterilized for use in ocular surgery.

## 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-I/II, 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 presurgical microbiologic cultures on corneas.

## Storage and Handling

- VisionGraft® Sterile Corneas are supplied ready to use, no rehydration necessary.
- VisionGraft® Sterile Corneas are stored in human albumin media.
- 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.
- VisionGraft® should be stored between 2°C and 30°C. DO NOT FREEZE.
- The packaging system used for this allograft allows for the safe delivery of tissue to the physician.

## Potential Complications

The allograft may not provide the intended outcome 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. 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.
- The 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

VisionGraft® Sterile Cornea is provided sterile using gamma irradiation.

## 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. Use the allograft upon opening. DO NOT STERILIZE/RE-STERILIZE.

## Prepare Allograft for Use

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

1. Examine pouch for package integrity. Do not use if there is evidence that the pouch is damaged or sterility has been compromised.
2. Important: Allograft is extremely clear. The presence of the allograft has been verified multiple times during the manufacturing and labeling process. Visualize the allograft by gently swirling the pouch with adequate light behind the pouch. DO NOT OPEN the pouch or the vial until the graft has been visualized.
3. Remove the flip top with the metal safety-sealing band from the bottle and stopper.
4. Gently swirl the solution in the vial to reduce the likelihood of the cornea becoming adhered to the inside walls of the vial.
5. Remove the stopper of the bottle. Pour the contents of the bottle into a sterile preparation basin on the sterile field. The allograft is ready to use and requires no further preparation.

## 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 or 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). VisionGraft® is a registered trademark of CorneaGen.

VisionGraft® allografts are prepared by:

CorneaGen
6000 Shoreline Ct., Suite 202
South San Francisco, CA 94080

CorneaGen™