Although multiple measures to prevent adverse patient reactions have been employed, potential adverse reactions that may occur are consistent with any grafting procedure and include, but are not limited to, wound site infection, skin reaction, or transmission of communicable disease.

## DISCLAIMER

User should consult product labeling and instructions for use for important information about AmbioDisk. All decisions regarding patient care must be made with a healthcare provider, considering the unique characteristics of the patient. Such information is not a warranty, expressed or implied, as to the product. Handling and storage of AmbioDisk by the physician or health care professional, as well as factors related to the patient, the patient's diagnosis, treatment, surgical procedures, and other matters beyond Katena's control may directly or indirectly affect this product and the results obtained from its use. KATENA MAKES NO EXPRESS WARRANTIES AS TO AMBIODISK'S USE OR ANY OUTCOMES RELATED TO SUCH USE AND DISCLAIMS ALL IMPLIED WARRANTIES WITH RESPECT TO THIS PRODUCT, INCLUDING BUT NOT LIMITED TO, THE IMPLIED WARRANTY OF MERCHANTABILITY AND ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. The patient and his/her doctor or medical professional shall be solely responsible for determining the adequacy and appropriateness of AmbioDisk for any potential uses as to the patient. The same medical/surgical conditions or complications that apply to any surgical procedure may occur during the following use of AmbioDisk. The doctor or medical professional solely is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions from use of AmbioDisk. As with any allograft bio-implant, the potential for transmission of infectious agents exists.

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# AMBIODISK® ALLOGRAFT INSTRUCTIONS FOR USE

*DEHYDRATED HUMAN PLACENTAL TISSUE ALLOGRAFT – READ BEFORE USE*

## PRODUCT DESCRIPTION

AmbioDisk is a donated allograft placental tissue, aseptically processed and dehydrated to remove moisture while preserving biologic components and the structure of the placental matrix. The processing method is optimized to preserve the structural matrix and key biological components of the placental tissue. Following preservation via a proprietary dehydration method, AmbioDisk allografts are terminally sterilized to a sterility assurance level (SAL) of 10-6 using Electron Beam irradiation, providing additional assurance of safety.

The AmbioDisk allograft is available as a circular, flat graft in both single layer and full thickness. The graft is packaged amnion (epithelial) side up. The allograft is a translucent dehydrated material. Since the AmbioDisk allografts are human tissue products, appearance may vary between donors. Variation in color (tan to light brown), opacity, and thickness are normal due to the nature of human tissue.

AmbioDisk is donated human tissue regulated by the United States Food and Drug Administration (FDA) as a human cell, tissue, or cellular or tissue-based product (HCT/P) under Section 361 of the Public Health Service (PHS) Act. AmbioDisk allografts are aseptically processed according to FDA current Good Tissue Practice requirements.

## INTENDED USE

The Ambio allografts are intended for use as a covering or barrier applied to the ocular surface following repair or reconstruction procedures in the treatment of ocular diseases and/or abnormalities.

## RECOMMENDED STORAGE

The AmbioDisk allograft should be maintained in its original packaging and stored at ambient temperature (0°C to 38°C) until ready for use. Once the package is opened, use immediately or as soon as reasonably possible. When stored properly in their original packaging, AmbioDisk allografts are shelf-stable for up to five (5) years.

It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplantation.

The expiration date is reflected on the product label in the format MM/YYYY; where MM = two-digit month, and YYYY = four-digit year. The expiration of the graft occurs on the last day of the month indicated on the label.

## CONTRAINDICATIONS

Do not use AmbioDisk on any wound with evidence of active or latent infection or gangrene.

Do not use AmbioDisk on compromised patients where the patient's condition may create an unacceptable risk of post-operative infection or complications.

## CAUTIONS AND WARNINGS

This allograft is for ***single patient use only***. Do not use portions of an allograft from one sterile package on multiple patients. Do not re-sterilize.

Ocular surfaces treated with AmbioDisk should be monitored for signs of infection and treated according to standard practice should infection occur post-transplantation.

Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste.

Store at ambient temperature (0° to 38°C) in a dry environment. Keep away from excessive heat. Do not freeze.

Federal law restricts the use of this allograft to physicians and other healthcare professionals.

This allograft must not be used under any of the following conditions:

- If package integrity has been violated, opened, or damaged; mishandling has caused possible damage or contamination; or if the seal is broken or compromised.
- If any of the product labels are severely damaged, unreadable, or missing.
- If the expiration date shown on the product label has passed.

## TISSUE QUALITY AND SAFETY

The primary goal is to maximize patient safety. To fulfill this goal, stringent donor screening and laboratory testing is employed to reduce the risk of transmitting communicable disease. Donor screening includes, but may not be limited to, review of relevant medical records including a current donor risk assessment interview, a physical examination of the donor, laboratory test results, as well as other information pertaining to risk factors for relevant communicable diseases.

All communicable disease testing was performed on this allograft by a laboratory registered with FDA to perform donor testing and certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR Part 493; or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Donor blood samples taken at the time of tissue recovery were tested for the following:

Human Immunodeficiency Virus (HIV) Type 1 and Type 2 antibody

Human T-Lymphotrophic Virus (HTLV) Type I and Type II antibody

Hepatitis C antibody (HCV)

Hepatitis B surface antigen (HBsAg)

Hepatitis B core total antibody (HBcAb)

Rapid Plasma Reagin (RPR) for Syphilis or Serologic Test for Syphilis (STS)

Human Immunodeficiency Virus Type 1 (HIV-1) Nucleic Acid Test

Hepatitis C Virus (HCV) Nucleic Acid Test

Hepatitis B Virus (HBV) Nucleic Acid Test

Cytomegalovirus Antibody (CMV Total Ab)

West Nile Virus Nucleic Acid-Test (during active mosquito season per FDA Guidance)[1]

The tests for these transmissible infectious diseases produced negative results. The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records are on file and available upon request.

Due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human tissue will transmit disease.

The donor has been evaluated and has been determined to be eligible for transplantation based on the donor eligibility criteria current at the time of tissue recovery in accordance with the United States Food and Drug Administration (FDA) regulations, local and state regulations, and established protocols.

Donor eligibility determination made by:
Stimlabs, LLC.
1225 Northmeadow Parkway
Suite 104
Roswell, GA 30076

## INSTRUCTIONS FOR PREPARATION USE

### Preparation of AmbioDisk for Use

AmbioDisk is packaged in a double peel-pouch packaging configuration. The outer peel pouch is NOT sterile. The inner pouch that contains the AmbioDisk graft is sterile (unless the pouches are damaged or compromised).

Open the outer peel pouch using the chevron opening and present the inner peel pouch into the sterile field, taking care to avoid contamination of sterile field with the non-sterile surfaces of the outer package. Peel open the inner peel pouch using the chevron opening and aseptically remove the graft with non-toothed, sterile forceps from the pouch prior to use.

Please take great care when removing the graft from the internal pouch. The allograft is thin and extremely lightweight.

### Placement of AmbioDisk

Place the AmbioDisk on the corneal surface, amnion (epithelial) side facing the cornea and smooth the allograft with non-toothed forceps. The grafts are packaged amnion (epithelial) side facing up. The pouch label will identify “amnion side up”. For optimal adherence, maintain a dry ocular surface during placement.

To discourage allograft displacement following transplantation, a contact lens should be used to self-retain the AmbioDisk to the ocular surface. Alternatively, AmbioDisk may be affixed to the site using aseptic technique with a variety of wound closure mechanisms including absorbable sutures, non-absorbable sutures, and/or tissue adhesive appropriate for the procedure type.

## TISSUE TRACKING

IMPORTANT NOTICE TO END-USER: Recipient records must be maintained for the purpose of tracking tissue post-transplant per the Joint Commission and FDA requirements, and to facilitate the investigation of suspected transmission of communicable disease. The tissue identification number should be noted in the patient medical record. The Tissue Utilization Record card must be completed and returned using the self-addressed, postage paid mailer. Peel off patient labels, which indicate the tissue identification number, and are contained in this package to aid in the tracking process.

## ADVERSE REACTION REPORTING

Adverse outcomes potentially attributed to AmbioDisk must be immediately reported to Katena Products Inc.

1. Food and Drug Administration. *Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). Guidance for Industry.* September, 2016.