AmbioDisk™

Product Insert/Instructions for Use

AmbioDisk Specifications
AmbioDisk is a processed, dehydrated, sterilized human amniotic membrane tissue graft.

Human amniotic membrane is a unique collagenous membrane derived from the innermost submucosa of the placenta, the area in which the human fetus grows and develops within the mother's uterus. Human amniotic membrane is composed of: (1) a single epithelium layer; (2) a thick basement membrane; and (3) an avascular stromal matrix.

AmbioDisk allografts are processed and sterilized based upon strict, quality-controlled methods. Each allograft is thoroughly cleaned using a process that leaves no deleterious residue. An additional assurance of safety is achieved by terminally sterilizing each allograft. Based upon validations, AmbioDisk is effectively sterilized without causing adverse effects to the biomechanical properties of the tissue. AmbioDisk allografts are processed with Streptomycin Sulfate and Gentamicin Sulfate.

Conventional Uses
AmbioDisk is intended for the overlay use on the ocular surface to treat the following:

- Non-Healing Epithelial Defects
- Neurotrophic Ulcerations
- Corneal Erosions
- Acute Chemical/Thermal Burns
- Post-infectious Keratitis (herpetic, vernal, bacterial)

Contraindications
AmbioDisk should not be implanted into: (1) areas with active or latent infection; and/or (2) into a patient with a disorder that would create an unacceptable risk of post-operative complications.

Recovery & Quality Control AmbioDisk allografts are procured and processed according to standards established by the American Association of Tissue Banks (AATB) and the U.S. FDA. Tissues are recovered under full informed consent of the donor (represented by the mother of the newborn child). The donor has consented to transfer of the tissue to third parties. A thorough medical and social history of the donor is also obtained, including detailed family history. The donor is screened for:

Hepatitis C-NAT	HIV Type 1-NAT	Hepatitis B Core Antibody
CMV Total Antibody	HTLV-1 & 2 Antibody	Hepatitis B Surface Antigen
HIV-1 & 2 Antibody	Syphilis Serological Screen	Hepatitis C Antibody

All tests results are reviewed prior to the release of the tissue. Only tissue from donors that have a normal CBC, test negative for serology and bacteriology and test negative or non-reactive for infectious diseases and contamination are released.

The infectious disease test results, together with the consent documents, donor medical history and behavior risk assessment according to current public health services guidelines, physical assessment, available relevant medical records, as well as information from other sources or records which may pertain to donor suitability, along with tissue procurement test results, have been evaluated and are sufficient to indicate that the donor suitability criteria current at this time of tissue recovery have been met.

The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the suitability of this allograft are on file and available upon request.

This AmbioDisk has been determined suitable for transplantation.

Recommended Storage
AmbioDisk must be stored in a clean, dry environment at controlled room temperature of 0º C to 38º C (32º to 100º F).

Instructions

● AmbioDisk is packaged in a double peel-pouch packaging configuration. The outer peel pouch is NOT considered sterile. The inner pouch, which contains the allograft, is considered sterile.

● Carefully open the corner of the outer pouch and present the inner pouch to the sterile field.

● AmbioDisk is packaged with the stromal matrix side down to or in contact with the metallic side of the pouch. The basement membrane side is packaged FACE UP or away from the metallic side of the pouch. Visual identification of the BASEMENT MEMBRANE can be noted by the correct, right-to-left nomenclature orientation of the "IOP" lettering embossed on the center of the graft.

● SLOWLY peel a corner of the inner peel pouch and allow the surgeon to grasp the AmbioDisk with fingers or non-toothed, sterile forceps. PLEASE TAKE GREAT CARE WHEN REMOVING THE GRAFT FROM THE INTERNAL POUCH. THE ALLOGRAFT IS THIN AND LIGHTWEIGHT.

● Place the dry AmbioDisk on the corneal surface and smooth the graft with forceps. For optimal adherence, maintain a dry ocular surface during placement. Prior to placement, the AmbioDisk may be trimmed in its dry state with sharp scissors to the appropriate and approximate sized required (if necessary).

● Immediately following application, the "IOP" embossment will begin to fade.

● Surgically, absorbable, non-absorbable suture material and/or tissue adhesives may be used to fixate the AmbioDisk to the surgical site.

● Alternatively, a contact lens may be used to self-retain the AmbioDisk to the ocular surface.

Precautions/Warnings

• AmbioDisk remains suitable for transplantation in an unopened, undamaged package. If package and contents appear defective or damaged in any way, immediately contact the distributor.

• AmbioDisk is intended for single-patient use only, performed by physician. Discard all unused material.

• Strict donor screening and dedicated processing/sterilization methods are employed to reduce the risk of any disease transmission. However, as with all biological implants, an absolute guarantee of tissue-safety is not possible.

• Discard all damaged, mishandled or potentially contaminated tissue. DO NOT RE-STERILIZE.

Adverse Effects & Reporting

• As with any surgical procedure, the possibility of infection exists.

• Dedicated processing and sterilization methods are employed to eliminate deleterious properties of the allograft. However, as with all biological implants, the possibility of rejection exists.

• Any adverse reactions, including the suspected transmission of disease attributable to this allograft, should be immediately reported to IOP Ophthalmics.

Recipient Tracking

US FDA requires that recipient records be maintained for the purpose of tracing the allograft following surgical transplantation. The surgeon or operating staff member must complete the enclosed Allograft Utilization Record, attach a peel-off, allograft-tracking label provided, and mail to the distributor (postage-paid). Please use the remaining peel-off, allograft-tracking labels for patient and hospital records.

Caution: Federal law (U.S.A.) restricts this unit to sale by or on the order of a physician.

IOP Ophthalmics and its affiliates supply this allograft without any express or implied warranties. All statements or descriptions are informational only and not made or given as a warranty of the allograft in any way. IOP Ophthalmics and its affiliates make no guarantee whatsoever concerning the biological or biomechanical properties of the allograft. The user shall be solely responsible for determining the adequacy and appropriateness of the allograft for any and all uses to which the user shall apply the allograft.

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U.S. Patent Nos. 5,932,205 and 6,143,315