AMBIOdisk™

Human Amniotic Membrane Allograft

Nominal Thickness: 100 Microns

Product Insert & Instructions for Use

Katena Products Inc.

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CS103.006

AmbioDisk™ Specifications

AmbioDisk™ is a processed, dehydrated, sterilized human amnion/chorion membrane allograft.

Human amniotic membrane is a collagenous membrane derived from the placenta, the area in which the human fetus grows and develops within the mother's uterus. Human amniotic membrane is composed of multiple layers.

AmbioDisk™ is a minimally manipulated, dehydrated, non-viable cellular amniotic membrane allograft that contains multiple extracellular matrix proteins, growth factors, cytokines and other specialty proteins present in amniotic tissue to provide a barrier membrane that enhances healing.

AmbioDisk™ allografts are human tissue products and appearance may vary between donors. Variations in color (tan to light brown), opacity, and thickness are normal due to the nature of human tissue.

Conventional Uses

AmbioDisk™ is intended for homologous use in ocular repairs to reduce scar tissue formation, modulate inflammation, provide a barrier, and enhance healing.

Contraindications

AmbioDisk™ should not be used on: (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.

Precautions/Warnings

- AmbioDisk™ remains suitable for transplantation in an unopened, undamaged package under proper storage conditions.
- Please inspect the integrity of the package upon receipt. If package and contents appear defective or damaged in any way, immediately contact the distributor.
- AmbioDisk™ is intended for single-patient use only, discard all unused material.
- This procedure should be performed by an authorized medical professional.
- Strict donor screening and laboratory testing, along with dedicated processing and 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. This allograft has the potential to transmit infectious disease to the recipient.
- The reaction of the body to any biological implant is not completely understood.
- Caution should be used when treating patients with a known sensitivity to aminoglycoside antibiotics.
- Discard all damaged, mishandled or potentially contaminated tissue.
- This product has not been tested in combination with other products.
- DO NOT RE-STERILIZE.

Instructions

Prior to application, carefully follow the AmbioDisk™ allograft preparation steps below using aseptic technique:

- AmbioDisk™ is packaged in a double peel-pouch packaging configuration. The outer peel pouch is NOT sterile. The inner pouch, which contains the allograft, is sterile (unless the pouches are damaged or compromised).
- Carefully open the peelable corner of the outer pouch and present the inner pouch onto the sterile field. Ensure the inner pouch does not come in contact with any portions of non-sterile surface of the outer pouch.
- 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, left-to-right nomenclature orientation of the “IOP” lettering embossed on the center of the graft.

- In the sterile field, SLOWLY peel a corner of the inner peel pouch and grasp the AmbioDisk™ with fingers or non-toothed, sterile forceps.
- Use AmbioDisk™ promptly after opening the inner, sterile pouch.

PLEASE TAKE GREAT CARE WHEN REMOVING THE GRAFT FROM THE INTERNAL POUCH. THE ALLOGRAFT IS THIN AND EXTREMELY 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 size required (if necessary).
- Immediately following application, the “IOP” embossment will begin to fade.
- Suture material (absorbable, non-absorbable) and/or tissue adhesives may be used to fixate the AmbioDisk™ to the site of application.
- Alternatively, a contact lens may be used to self-retain the AmbioDisk™ to the ocular surface.

Adverse Effects & Reporting

- As with any procedure, the possibility of infection exists.
- Proprietary processing and validated sterilization methods are employed to eliminate potential deleterious components 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 Katena Products Inc.

Acceptable Storage

AmbioDisk™ allografts should be stored in a clean, dry environment at ambient conditions. The allografts have a 5 year shelf life. Check the label for the expiration date.

Recovery & Quality Control

All tissue recovered meets stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease. AmbioDisk™ allografts are procured and processed in the United States according to standards and/or regulations established by the American Association of Tissue Banks (AATB) and the United States Food & Drug Administration (FDA). Tissues are recovered under full informed consent of the donor (mothers of the newborn children). The donors have consented to transfer of the tissue to third parties. A thorough medical and social history of the donor is also obtained. The donor is tested by a CLIA licensed facility for:

HIV-1&2 Plus 0 Antibody	Hepatitis B Surface Antigen
HIV Type 1 (Nucleic Acid Test (NAT))	Hepatitis C Antibody
HTLV-1&2 Antibody	Hepatitis C Virus (Nucleic Acid Test (NAT))
Syphilis (Serologic Test)	Hepatitis B Virus (Nucleic Acid Test (NAT))
Hepatitis B Core Antibody	West Nile Virus (Nucleic Acid Test (NAT))*

**WNV NAT screening conducted on donors based on exposure risk per FDA Guidance for Industry.*

All tests produced negative results and were reviewed prior to the release of the tissue. Only tissue from donors with acceptable test results, according to the standards of MiMedx Tissue Services, LLC, as well as the standards and/or regulations of all state and federal regulatory bodies, are released.

Recovery & Quality Control (cont.)

The infectious disease test results, 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 that may pertain to donor suitability, and tissue procurement test results, have been evaluated by the MiMedx Medical Director 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.

Donated Human Tissue. This AmbioDisk™ has been determined to be suitable for transplantation.

Allograft Processing/Preservation/Sterilization

AmbioDisk™ allografts are processed based upon strict, quality-controlled protocols that have demonstrated bioburden control. An additional assurance of safety is achieved by terminally sterilizing each allograft. Based upon validations, each graft has been effectively sterilized using gamma irradiation. AmbioDisk™ allografts are processed with aminoglycoside antibiotics.

Recipient Tracking

The FDA requires that recipient records be maintained for the purpose of tracking the allograft following transplantation. The authorized medical professional must complete the enclosed Tissue Utilization Record, attach a peel-off, allograft-tracking label provided, and mail to Mimedx Tissue Services, LLC (postage-paid). Please use the remaining peel-off, allograft-tracking labels for patient and hospital records.

Caution: This product must be administered by an authorized medical professional.

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**.**

Processed with:

PURION®

Processed by MiMedx Tissue Services, LLC

Patents and patents pending see: www.mimedx.com/patents

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MiMedx's dehydrated Human Amnion/Chorion Membrane (dHACM) allografts are now described in an official U.S. Pharmacopeia – National Formulary monograph with the publication of USP 40-NF 35.