PROVENDA®
AMNIOTIC MEMBRANE

Human Amniotic
Membrane Allograft

Information / Instructions for Use

AMENDIA.
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**Provena® Description**

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

Provena 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.

Provena 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.

**Tissue Uses**

Provena is intended for homologous use in the treatment of acute and chronic wounds to reduce scar tissue formation, modulate inflammation, provide a barrier, and enhance healing.

**Contraindications**

Provena 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**

- Provena allografts remain 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.
- These allografts are intended for single-patient use only. Discard all unused material.
- The 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. These allografts have 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.
- These products have not been tested in combination with other products.
- DO NOT RE-STERILIZE.

**Preparation, Reconstitution and Use**

Prior to implantation, carefully follow the Provena allograft preparation steps below using aseptic technique:

**Removing Provena from Packaging**

- The outer peel pouch is NOT sterile. The inner pouch that contains Provena 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.
- In the sterile field, SLOWLY peel a corner of the inner peel pouch and grasp Provena with fingers or non-toothed, sterile forceps.
- Use Provena promptly after opening the inner, sterile pouch.

**PLEASE TAKE GREAT CARE WHEN REMOVING THE PRODUCT FROM THE INTERNAL POUCH. THE ALLOGRAFT IS THIN AND EXTREMELY LIGHTWEIGHT.**
Provenda Application

- In its dry state and prior to hydration, the allograft may be cut with sharp scissors to the appropriate and approximate size required.
- The allograft should then be placed on the site, using the orientation of the embossment lettering as a guide. Proper orientation of the allograft can be noted when the embossment nomenclature reads correctly from left to right. The orientation of the allograft at the site will vary based on use.
- The allograft can then be hydrated while on the site with sterile saline solution. During and following hydration, the embossment on the allograft will begin to fade.
- Suture material (absorbable, non-absorbable) and/or tissue adhesives can be used to fixate Provenda allografts to the site of application or to itself, if desired.

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 reported immediately to MiMedx®.

Acceptable Storage

Provenda 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. Provenda 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). All tissues are recovered under full informed consent of the donors (mothers of the newborn children). The donors have consented to the transfer of the allografts to third parties. A thorough medical and social history of the donor is also obtained.

The listed communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

The donor is screened for:

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1&amp;2 Plus O Antibody</td>
<td>Hepatitis B Surface Antigen</td>
</tr>
<tr>
<td>HIV Type 1 (Nucleic Acid Test (NAT))</td>
<td>Hepatitis C Antibody</td>
</tr>
<tr>
<td>HTLV-1&amp;2 Antibody</td>
<td>Hepatitis C Virus (Nucleic Acid Test (NAT))</td>
</tr>
<tr>
<td>Syphilis (Serologic Test)</td>
<td>Hepatitis B Virus (Nucleic Acid Test (NAT))</td>
</tr>
<tr>
<td>Hepatitis B Core Antibody</td>
<td>West Nile Virus (Nucleic Acid Test (NAT))*</td>
</tr>
</tbody>
</table>

*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, 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 the 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. These allografts have been determined to be suitable for transplantation.

Allograft Processing/Preservation/Sterilization

Provena 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 e-beam irradiation. Provena 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 the processor (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.

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

Processed with:

Processing and donor suitability performed by MiMedx Tissue Services, LLC

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

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LB-187 Rev. 1