PROVENDA® INJECTABLE
MICRONIZED AMNIOTIC MEMBRANE

Dehydrated Human Amnion/Chorion Membrane Allograft Injectable Suspension

Information / Instructions for Use

AMENDIA.
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LB-191 Rev. D
**Provenda® Injectable 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.

Provenda Injectable 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 enhance healing.

Provenda Injectable is a human tissue product and appearance may vary between donors. Variation in color (tan to light brown) and opacity are normal due to the nature of human tissue.

**Tissue Uses**

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

**Contraindications**

Provenda Injectable should not be injected into (1) the spinal canal; (2) vital organs, including the heart; and/or (3) other areas of the circulatory system or the central nervous system. Provenda Injectable should not be used (1) on areas with active or latent infection; (2) on a patient with a disorder that would create an unacceptable risk of post-operative complications; (3) in intravenous, intra-arterial, or intrathecal applications.

**Precautions/Warnings**

- Provenda Injectable 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.
- This allograft is 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. 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.
- Within 72 hours, the patient may experience a moderate increase in tenderness and pressure in the treated area.
- This product has not been tested in combination with other products.
- **DO NOT RE-STERILIZE.**
- **DO NOT MIX WITH ANYTHING OTHER THAN STERILE 0.9% SALINE SOLUTION.**

**Preparation, Reconstitution and Use**

Prior to implantation, carefully follow the Provenda Injectable preparation steps below using aseptic technique:

**Removing Provenda Injectable from Packaging**

- The outer peel pouch is NOT sterile. The inner pouch containing the Provenda Injectable vial is sterile (unless the pouches are damaged or compromised).
- Using aseptic technique, SLOWLY peel a corner of the inner peel pouch and remove the vial.

**Injection Preparation Technique**

**Recommended Materials**

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile 0.9% Saline Solution</td>
<td>One (1) x 5 mL Syringe</td>
</tr>
<tr>
<td>One (1) x 18-25Gauge Needle</td>
<td>Alcohol Swab</td>
</tr>
</tbody>
</table>

*LB-191 Rev. 0*
• Flip open the aluminum top of the vial. Wipe injection port with 70% isopropyl alcohol prep pad.
• Draw up the recommended volume of 0.9% sterile saline needed for rehydration from the table below into a 5 mL syringe using an 18-25 gauge needle.
• The volume used is left to the discretion of the authorized medical professional.

<table>
<thead>
<tr>
<th>Amount of Material</th>
<th>Minimum Recommended Volume of Saline</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 mg</td>
<td>1.0 mL</td>
</tr>
<tr>
<td>40 mg</td>
<td>1.0 mL</td>
</tr>
<tr>
<td>100 mg</td>
<td>2.5 mL</td>
</tr>
<tr>
<td>160 mg</td>
<td>4.0 mL</td>
</tr>
</tbody>
</table>

• Transfer a portion, 2 mL or less, of the recommended volume of 0.9% sterile saline into the vial of Provenda Injectable.
• Using a back and forth transfer with the plunger, mix the particulate to create a full suspension in the syringe. Because the reconstituted material is viscous, use proper pre-injection techniques to reduce possible air introduction.
• If time elapses between rehydration and administration and product separates, re-suspend by shaking.
• Use within 12 hours of reconstitution.
• Dispose of any material remaining after procedure is complete in accordance with biohazardous protocols. This product is for single patient use only.

If utilization as a paste is desired, product may be transferred into a sterile cup; apply single drops of saline while mixing until desired consistency is achieved.

Dry Application
• Remove the foil and stopper from the vial
• Apply a thin layer of the product onto the area to be treated

Adverse Effects & Reporting
• As with any injection, the possibility of infection exists. To minimize the risk of infection limit the exposure of the needle to pathogens.
• 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 Injectable should be stored in a clean, dry environment at ambient conditions. Provenda Injectable has 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 Injectable tissues 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).
Recovery & Quality Control (Cont.)

The donor is screened for:

<table>
<thead>
<tr>
<th>Test</th>
<th>Antigen</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 &amp; 2 Plus 0 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 recovered beginning February 1, 2017.

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.

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. This allograft has been determined to be suitable for transplantation.

Allograft Processing/Preservation/Sterilization

Provena Injectable 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. The 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 distributor (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:

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Processing and donor suitability performed by MiMedx Tissue Services, LLC
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