**Sterile**

Sterilized by Irradiation

**DONATED HUMAN TISSUE**

RESTRICTED TO USE BY OR ON THE ORDER OF A LICENSED HEALTHCARE PROFESSIONAL (physician, dentist, podiatrist, optometrist, nurse practitioner or physician assistant).

**80-172 Rev. 04**

Provenda® Flo and Provenda® Li are amniotic fluid products that are derived from donated human birth tissue and fluid. Birth tissue is obtained with consent from healthy mothers during cesarean section delivery. Provenda® Flo and Provenda® Li are processed using aseptic techniques. The allograft is aseptically packaged in a sterile inner tear pouch within a Chevron peel pouch configuration and frozen. The allograft has been sterilized using a low dose of electron beam radiation and secured in an outer container.

**INTENDED USE**

Provenda® Flo and Provenda® Li are intended to provide cushioning within joint capsules when a physician concludes that such function is medically indicated.

**CONTRAINDICATIONS**

Provenda® Flo and Provenda® Li have no known contraindications.

**DONOR ELIGIBILITY**

Provenda is recovered from a qualified donor and processed using aseptic techniques in accordance with federal, state, and/or international regulations and to the standards of the American Association of Tissue Banks. The donor is screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the donor screening and testing are reviewed by the Medical Director (or licensed physician designee) of Vivex Biomedical, Inc. and the donor is deemed suitable for transplantation.

Communicable disease testing is performed by an FDA-registered laboratory certified to perform such 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. Results from the following infectious disease tests are found to be nonreactive or negative:

- **HIV-1/2 Antibodies (HIV-1/2-Ab)**
- **Nucleic Acid Test for HBV DNA (HIV-1 NAT)**
- **HBV Surface Antigen (HBsAg)**
- **HBV Core Antibody (IgG & IgM) (HBcAb)**
- **Nucleic Acid Test for HBV DNA (if performed) (HBV NAT)**
- **HCV Antibody (HCV Ab)**
- **Nucleic Acid Test for HCV RNA (HCV NAT)**
- **HTLV-I/II (Antibody HTLV-I/II-Ab)**
- **Rapid Plasma Reagin (RPR) Test**
- **T. Pallidum IgG**
- **WNV Virus (WNV)**
- **Nucleic Acid Test for WNV RNA (WNV NAT)**

* A donor with a reactive result for the HTLV-I/II Antibody test is suitable for use only when the result from a confirmatory assay is nonreactive.

**A donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as the RPR test, or with a reactive result from the non-treponemal screening assay, is suitable for use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

Screening tests for exposure to other viruses or parasites such as those listed below may have been completed. A negative/nonreactive result is not required for these tests, however, all results are evaluated on a case-by-case basis by the Medical Director (or licensed physician designee).

- **Cytomegalovirus**
- **CMV Ab (IgG & IgM)**
- **Epstein Barr Virus**
- **EBV Ab (IgG & IgM)**
- **Toxoplasma gondii**
- **Toxoplasma Ab (IgG & IgM)**
- **Trypanosoma cruzi**
- **T. cruzi Ab (IgG & IgM)**

**WARNINGS**

The donor of Provenda is screened and tested for relevant communicable diseases and disease agents in compliance with the FDA regulations relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). Provenda is processed using aseptic techniques and microbiologically tested. The allograft is terminally sterilized by electron beam radiation technology in accordance with ANSI/AAMI/ISO 11137. Although all efforts are made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination.

**DO NOT RE-FREEZE** the allograft by any method.

**FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY.**

**DO NOT RE-STERILIZE** the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide or other chemical sterilants may render the allograft unfit for use.

**80-172 Rev. 04**
PRECAUTIONS
Provena is processed and packaged using aseptic techniques and sterilized. The allograft must be handled in an aseptic manner to prevent contamination.

ADVERSE EVENTS
Allogeneic cells or tissues can induce an immunologic response in the recipient. The possibility that a patient may develop alloantibodies should be considered for any patient who might be a future recipient of allograft tissue or cells.

Possible adverse events may include: immunologic response, transmission of disease of unknown etiology and transmission of infectious agents including but not limited to: HIV, hepatitis, syphilis, or microbial contaminants.

STORAGE
Provena Flo and Provena Li must be transferred to a monitored freezer which maintains the temperature at -20°C or colder for short term storage (less than 6 months) or at -40°C or colder for long term storage (until expiration date on graft). It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with the earlier expiration date is preferentially used and expiration is avoided.

ALLOGRAFT PREPARATION
THE CHEVRON PEEL POUCH IS NOT STERILE AND SHOULD NOT BE PLACED ON AN OPERATIVE FIELD.

ONCE THE TEAR POUCH SEAL HAS BEEN OPENED, the allograft must be used, or otherwise discarded.

ONCE THAWED, the allograft must be used within 2 hours, or otherwise discarded.

DO NOT USE THE ALLOGRAFT if the pouch integrity has been compromised.

THE INNER TEAR POUCH IS STERILE AND MAY BE PRESENTED TO THE OPERATIVE FIELD.

It is not necessary to dilute the allograft prior to implantation.

Step 1. Remove outer container from either the freezer or the dry ice shipping carton. Open and remove the pouch from the outer container.

Step 2. Outside of the operative field, from the chevron end, peel open the pouch and remove the sterile inner tear pouch that contains the cryovial containing the allograft.

Step 3. Open the sterile inner tear pouch and remove the cryovial containing the Provena Flo or Provena Li using standard aseptic technique.

Step 4. Thaw the cryovial in hand prior to taking the cap off. Allow allograft to thaw completely prior to implantation.

Step 5. Draw the allograft out of the cryovial with a sterile 30g or larger needle into a syringe.

Step 6. Apply the allograft using a 30g or larger needle into and around the targeted area.

RECIPIENT INFORMATION
Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide Vivex Biomedical, Inc. with information pertaining to the traceability of the allograft used. For this purpose, the postage paid Tissue Utilization Report (TUR) card is provided with the allograft. Once the allograft is used, peel off the small product labels provided on the product packaging and affix on the TUR card and applicable patient records. Complete the TUR card and mail to Vivex Biomedical, Inc., scan and e-mail to turs@vivex.com, or fax to (888) 630-4321.

ADVERSE OUTCOME AND COMPLAINT REPORTING
Adverse outcomes potentially attributable to the Provena should be promptly reported to Vivex Biomedical, Inc. at (888) 684-7783. Any other complaints must be promptly reported to Spinal Elements at (760) 607-0121.

RETURNED GOODS POLICY
Due to the delicate biological nature of a processed allograft, it cannot be returned for credit. If for any reason the allograft must be returned, a return authorization is required from Spinal Elements prior to shipping. It is the responsibility of the healthcare institution returning the allograft to adequately package and label it for return shipment.

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