PREPARATION AND INSTRUCTIONS FOR USE

1. Remove the pouch containing the allograft from the box packaging.
2. Utilizing standard aseptic technique, peel open the outer chevron pouch and pass the inner pouch to the sterile field. Once the outer chevron pouch seal has been broken, the graft must be transplanted (if appropriate) or otherwise discarded.
3. When ready, open the inner chevron pouch (peel from chevron end) to access the graft. Use caution when opening the inner chevron pouch since the allograft is a small thin membrane and is extremely light weight.
4. Remove the allograft from the pouch using sterile smooth forceps.
5. If necessary, trim the allograft to the appropriate dimensions prior to hydration.
6. The allograft may be placed directly on the surgical or wound site or rehydrated prior to placement. If rehydration is desired, room temperature sterile saline or sterile Lactated Ringer's solution (LRS) can be used for rehydration. Hydrate the allograft until the desired handling characteristics are achieved, with a maximum hydration time of 20 minutes.
   a. The allograft should be implanted immediately following hydration.
7. If desired, the allograft may be sutured or secured into place.

TISSUE UTILIZATION RECORD

Each allograft package contains a Tissue Utilization Record (TUR). In accordance with US FDA requirements, a TUR should be completed for each allograft used in the procedure and returned to Axogen as described on the TUR.

Record the distinct HCT/P identification code in hospital or facility records and in the patient's file. Complete required information on the card for each allograft used, and return as described on the TUR.

It is the responsibility of the health care institution to maintain recipient records for the purpose of tracking tissue post-implantation. The Tissue Utilization Record is NOT intended to be a substitute for a facility's internal tissue transplantation tracking system.

DISPOSAL

Dispose of the allograft in accordance with local, state and federal or country regulations for disposal of human tissue.

REFERENCES

1. ISO 11607 Packaging for terminally sterilized medical devices
2. ISO 11137 Sterilization of Healthcare Products - Radiation

COMPLAINTS AND RETURNS

Product complaints must be reported promptly to Axogen, by phone at (888)296-4361 or via email at customercare@axogeninc.com.

If for any reason tissue must be returned, a return authorization (RMA) is required from Axogen. Contact Customer Care prior to shipping allograft returns. It is the responsibility of the health care institution returning the tissue to adequately package and label the tissue for return shipment.

INQUIRIES

For additional information, to place an order, or to report order errors contact:

Axogen® Customer Care

Phone: 888.axogen1 (888.296.4361)

Email: customercare@axogeninc.com

Avive⁺ Soft Tissue Matrix is DONATED HUMAN TISSUE processed in the United States by:

Axogen Corporation
13631 Progress Blvd, Suite 400
Alachua, FL 32615

Customer Care:
Toll Free US: 888.296.4361
Direct Dial Outside the US: 1.386.462.6801
Email: customercare@axogeninc.com
www.axogeninc.com

Avive⁺ Soft Tissue Matrix

axogen, revolutionizing the science of nerve repair‡

Package Insert

Customer Care:
Toll Free US: 888.296.4361
Direct Dial Outside the US:
1.386.462.6801
Email: customercare@axogeninc.com
www.axogeninc.com

LB-1096 R00

DESCRIPTION

Avive+ Soft Tissue Matrix is an amniotic membrane allograft comprised of amnion and chorion layers from the amniotic membrane. The allograft originates from donated human tissue from eligible donors and is minimally processed under an aseptic environment and packaged into sterile dehydrated sheets.

The allograft is supplied in various lengths and widths, as listed on the label, to allow the surgeon to choose the appropriate size to address the injured tissue.

INTENDED USE

Avive+ Soft Tissue Matrix is intended for use as a soft tissue barrier.

The allograft may be used in numerous clinical applications, including covering the peripheral nerve to separate and protect the nerve from the surrounding environment.

℞ Only The allograft is to be dispensed only by or on the order of a licensed health professional.

Each allograft is intended for single-patient use.

CONTRAINDICATIONS

The allograft is contraindicated for use in any patient in whom soft tissue implants are contraindicated. This includes any pathology that would limit the blood supply and compromise healing or evidence of a current infection.

WARNINGS

Careful donor screening, laboratory testing, tissue processing, and irradiation have been utilized to minimize the risks of transmission of relevant communicable diseases. As with any processed human donor tissue, the allograft cannot be guaranteed to be free of all pathogens and may transmit infectious agents.

As disease screening methods are limited, certain diseases may not be detected. The following complications of tissue transplantation may occur:

- Transmission of disease of unknown etiology;
- Transmission of known infectious agents including, but not limited to viruses,bacteria and fungi.

Other complications of allograft transplantation may occur such as immune rejection of HCT/P, allergic reaction, or if left unsecured the allograft may migrate or fold. The allograft has not been studied in immune compromised patients including but not limited to oncologic patients.

PRECAUTIONS

Do not reuse or re-sterilize the allograft. Do not use after expiration date.

Do not use if the allograft or the packaging integrity is compromised. Notify Axogen Customer Care upon receipt if the allograft or the packaging integrity is compromised (e.g. allograft, pouch chevron seal, labeling, missing labeling information, etc.).

POTENTIAL COMPLICATIONS

The same medical/surgical conditions or complications that apply to any medical/surgical procedure may occur during or following placement. The healthcare professional is responsible for informing the patient of the potential risks associated with surgical procedures.

Adverse Reactions

An adverse reaction is defined by the FDA as any noxious or unintended response to any 361 HCT/Ps for which there is a reasonable possibility that the HCT/P caused the reaction. This includes, but is not limited to, the transmission of communicable diseases or infectious agents such as viruses, bacteria or fungi, or allergic reaction. To report SUSPECTED ADVERSE REACTIONS, contact Axogen at (888)296-4361 or via email at customercare@axogeninc.com, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

REGULATORY CLASSIFICATION

The allograft is processed and distributed in accordance with US FDA requirements for Human Cellular and Tissue-based Products (HCT/P) under 21 CFR Part 1271 regulations, and US State regulations.

Axogen Corporation is accredited by the American Association of Tissue Banks (AATB).

DONOR RECOVERY AND SCREENING

The allograft is prepared from a donor determined to be eligible based on the results of screening and testing. After consent for donation is obtained, acquisition of the placental tissue is performed in an aseptic manner by FDA-registered and state licensed (where required) US tissue banks after live birth. Donor eligibility is carefully evaluated as required by the US FDA and US State regulations. Additionally, donor eligibility meets AATB standards for Tissue Banking. Tissue donors are evaluated for medical-social risk behaviors and relevant communicable diseases. Evaluation includes a review of the birth mother medical and social history, a physical examination of the birth mother and infant performed by appropriate healthcare personnel at the time of acquisition, serological testing, and tissue acquisition microbiology cultures.

Each donor is tested and shown to be negative or nonreactive for the following:

- Human Immunodeficiency Virus (HIV) Type 1 Antibody
- Human Immunodeficiency Virus (HIV) Type 2 Antibody
- Hepatitis C Virus (HCV) Antibody
- Hepatitis B Virus (HBV) Surface Antigen
- Hepatitis B Virus (HBV) Core Antibody (total)
- West Nile Virus (WNV) Nucleic Acid Test (NAT)
- Human T-Cell Lymphotropic Virus (HTLV) Type I Antibody
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- Human Immunodeficiency Virus (HIV) Nucleic Acid Test (NAT)
- Hepatitis C Virus (HCV) Nucleic Acid Test (NAT)
- Hepatitis B Virus (HBV) Nucleic Acid Test (NAT)
- Human T-Cell Lymphotropic Virus (HTLV)Type II Antibody

All testing is performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens under the US Clinical Laboratory Improvement Amendments (CLIA) of 1988 and 42 CFR Part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). The testing is conducted using test kits approved by the US FDA.

The Medical Director of Axogen has determined that the tissue is suitable for transplantation in humans. Records of all testing and medical releases are maintained by Axogen (13161 Progress Blvd., Suite 400, Alachua, FL 32615).

PROCESSING

The allograft is processed in controlled environments using current Good Tissue Practices (cGTP) designed to prevent contamination and cross-contamination of the tissue. Processing involves the use of proprietary solutions. The processing preserves the inherent structure and properties of the tissue. After completion of processing, the allograft is sized, packaged and sterilized by irradiation in accordance with applicable sections of ISO 11137[1] and ISO 11607[2] guidelines.

HOW SUPPLIED

The allograft is packaged and inserted into two chevron poly-foil pouches. The outer chevron pouch is considered the sterile and moisture barrier and the inner chevron pouch is to assist in passing the allograft into the surgical sterile field. Lengths and widths are listed on the package label. The allograft is dried, then irradiated and supplied sterile. Contents of the outer foil package are sterile unless the package is open or damaged.

TRANSPORT AND STORAGE

The allograft should only be stored in a clean, dry location at a temperature between 15° to 30°C (59° to 86°F). The allograft was processed and packaged aseptically, terminally sterilized, and must be handled in an aseptic manner to prevent contamination.

The expiration date is in the form Year-Month (YYYY-MM) and expiration is the last day of the labeled month. See allograft label for expiration date.

It is the responsibility of the Healthcare Institution and end-use clinician to maintain the allograft in appropriate storage conditions prior to transplantation. Recipient records must be maintained for the purpose of tracing tissue post- transplantation.