



Instrutions for Use



Customer Care:  
Direct Dial: 888 AxoGen1 (888.296.4361)  
International: 1.386.462.8800  
CustomerCare@AxoGenInc.com

#### DESCRIPTION

Avive® Soft Tissue Membrane is a human umbilical cord membrane allograft that is prepared from a donor determined to be eligible based on results of screening and testing. The umbilical cord tissue is minimally processed and provided sterile.

Avive® Soft Tissue Membrane is supplied sterile in a variety of lengths and widths to allow the surgeon to choose the appropriate size to address the injured tissue. Approximate lengths and widths are listed on the package label. It is for single patient use only.

#### REGULATORY CLASSIFICATION

Avive® Soft Tissue Membrane 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. US State regulations and the standards of the American Association of Tissue Banks (AATB). Additionally, international regulations are followed as appropriate.

Avive® Soft Tissue Membrane is to be dispensed only by or on the order of a licensed health professional.

#### INDICATIONS FOR USE

Avive® Soft Tissue Membrane is processed umbilical cord intended for homologous use as a soft tissue covering.

#### CONTRAINDICATIONS

Avive® Soft Tissue Membrane is contraindicated for use in any patient in whom soft tissue implants are contraindicated. This includes any pathology that would limit the wound repairs 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 risk of transmission of communicable diseases. As with any processed human donor tissue, Avive® Soft Tissue Membrane cannot be guaranteed to be free of all pathogens and may transmit infectious agents.

Do not reuse or re-sterilize Avive® Soft Tissue Membrane.

#### DONOR RECOVERY AND SCREENING

After consent for donation is obtained, collection of the umbilical cord tissue is performed in an aseptic manner by FDA registered and state licensed (where required) US tissue donors. Donor eligibility is carefully evaluated as required by the US FDA and US State regulations. Additionally, donor eligibility is determined in accordance with AATB standards and appropriate international regulations. Tissue donors are evaluated using a variety 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)  
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)  
West Nile Virus (WNV) Nucleic Acid Test (NAT)

Additional testing may be performed, as required by local authorities in international markets. If required, each donor is tested and shown to be **negative** or **nonreactive** for the following:

Human T-Cell Lymphotropic Virus (HTLV) Type 1 Antibody  
Human T-Cell Lymphotropic Virus (HTLV) Type II Antibody

All testing is performed by a laboratory registered with 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 Medicine and Medical Services (CMS). The testing is conducted using test kits approved by the US FDA.

The Medical Director of AxoGen (US state licensed) has determined that the tissue is suitable for transplantation in humans. Records of all testing and medical releases are maintained by AxoGen.

#### PROCESSING

Avive® Soft Tissue Membrane is processed in controlled environments using Good Tissue Practices (GTP) methods designed to prevent contamination and cross contamination of the tissue. Processing involves the use of proprietary solutions and the processed tissue may contain traces of Polyhexamethylene Biguanide. The cleansing process preserves the inherent structure and properties of the tissue. After completion of processing, Avive® Soft Tissue Membrane is sized, packaged and sterilized by irradiation in accordance with ISO 11137 guidelines.

Avive® Soft Tissue Membrane has been tested in accordance with ISO 10993 standards. The test results demonstrated that the processed allograft is biocompatible.

#### HOW SUPPLIED

Avive® Soft Tissue Membrane is packaged and inserted into two pouches. Each chevron pouch is vacuum and heat-sealed to provide a sterile barrier and each pouch has a chevron seal. The chevron pouches provide a moisture barrier. Approximate lengths and widths are listed on the package label. Avive® Soft Tissue Membrane is dried, then irradiated and supplied sterile. Contents of the outer foil package are sterile unless the package is open or damaged. Use caution when opening since Avive® Soft Tissue Membrane is a small thin membrane and is extremely light weight.

#### TRANSPORT AND STORAGE

Avive® Soft Tissue Membrane must be stored at room temperature (15-30°C (59-86°F)). The allograft was processed and packaged aseptically, terminally sterilized, and must be handled in an aseptic manner to prevent contamination. **See product label for expiration date. The expiration date is in the form Year-Month and expiration is the last day of the labeled month.**

It is the responsibility of the Healthcare Institution and end-use clinician to maintain Avive® Soft Tissue Membrane in appropriate storage conditions prior to transplantation and recipient records must be maintained for the purpose of tracing tissue post-transplantation.

**WARNING: DO NOT USE IF THE CHEVRON POUCH INTEGRITY HAS BEEN COMPROMISED. NOTIFY AXOGEN® CUSTOMER CARE IF THE CHEVRON POUCH INTEGRITY HAS BEEN COMPROMISED UNDER RECEIPT.**

#### PREPARATION INSTRUCTIONS FOR AVIVE® SOFT TISSUE MEMBRANE

1. Remove the pouch containing the graft from the box packaging.
2. Utilizing standard aseptic technique, peel open the outer foil chevron pouch and pass the inner pouch to the sterile field. Once the outer foil chevron pouch seal has been broken, the graft must be transplanted (if appropriate) or otherwise discarded.
3. When ready, open the inner pouch (peel from chevron end) to place the graft.
4. Remove Avive® Soft Tissue Membrane from the pouch using sterile smooth forceps.
5. If necessary, trim the Avive® Soft Tissue Membrane to the appropriate dimensions.
6. The Avive® Soft Tissue Membrane 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 to rehydrate. Hydrate Avive® Soft Tissue Membrane until the desired handling characteristics are achieved.
7. If desired, Avive® Soft Tissue Membrane may be sutured or secured in place.
8. If you wish to orient Avive® Soft Tissue Membrane epithelial side up, place the handling tab in upper left corner.

#### TISSUE UTILIZATION REPORT (TUR)

Each Avive® Soft Tissue Membrane package contains a Tissue Utilization Report (TUR) and small peel-off product labels. In accordance with US FDA, US Joint Commission and international requirements, a **TUR should be completed for each Avive® Soft Tissue Membrane used in the procedure and returned to AxoGen or other representative as described on the TUR.**

Record the distinct HCT/P identification code in hospital or facility records and in the patient's file. Collect all information on the card, affix ONE (1) peel-off label of each Avive® Soft Tissue Membrane used, seal and return to AxoGen or other representative 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 Report is **NOT** intended to be a substitute for a facility's internal tissue transplantation tracking system.

#### POTENTIAL COMPLICATIONS

Inherent risks of any surgical procedure include, infection, blood loss, and anesthesia associated complications.

Additional complications that may be associated with these types of procedures may potentially occur after implantation:

- Mild incisional redness
- Tenderness of surgical area;
- Mild edema of surgical area;
- Controllable pain at surgical area;
- Decreased sensation; and,
- Numbness

These complications may be expected and are not required to be recorded unless they increase in severity. Avive® Soft Tissue Membrane is processed human tissue. As with all donated human tissue products the risk for transmission of communicable diseases does exist. Robust donor screening and selection criteria, controlled as required by the US FDA and in accordance with AATB, state, and federal guidelines and regulations, processing controls, and terminal sterilization with electron beam irradiation greatly reduce but cannot totally eliminate this risk. 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.

**SINGLE EUROPEAN CODE (SEC) FOR TISSUES**  
If applicable, SEC Code is found on or attached to the outer carton.

#### DISPOSAL

Dispose of Avive® Soft Tissue Membrane in accordance with local, state and federal or country regulations for disposal of human tissue.

#### REFERENCES

1. ISO 11137:2006 Sterilization of health care products — Radiation guidelines
2. ISO 10993:2003 Biological evaluation of medical devices

#### COMPLAINTS AND RETURNS

Adverse outcomes potentially attributable to the tissue must be reported promptly to AxoGen. Other complaints should be reported to AxoGen in a timely manner. If for any reason tissue must be returned, a return authorization is required from AxoGen.

Contact Customer Care prior to shipping. 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 errors, accidents or potential complications, contact:

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AxoGen® Customer Care  
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Customers outside of the US:  
Contact the AxoGen authorized distributor servicing your facility, email AxoGen Customer Care or contact AxoGen directly in the US at 1.386.462.8800

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Avive® Soft Tissue Membrane is DONATED HUMAN TISSUE processed in The United States by:

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Mode d'emploi



Service à la clientèle  
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#### DESCRIPTION

Avive® Soft Tissue Membrane consiste en un greffon membranaire de cordon ombilical humain provenant d'un donneur admissiblement valide selon les résultats du dépistage et des tests. Le tissu de cordon ombilical après avoir subi un traitement minimal est fourni à l'état stérile.

#### DISPOSAL

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#### REFERENCES

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