



Instructions for Use



Customer Service
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DESCRIPTION

Avance[®] is allograft tissue for bridging nerve discontinuities. Avance[®] is a decellularized and cleansed extracellular matrix from donated human peripheral nerve. The cleaning process preserves the inherent and relevant structural characteristics of the tissue.

Avance[®] simply connects the proximal and distal ends of a transected nerve. Regenerating axons can grow through the allograft scaffold, into the patient's distal nerve tissue toward the target muscle or skin.

Similar to nerve autografts, Avance[®] provides the surgeon with desired handling and structural characteristics: pliability of soft tissue, an intact epineurium to suture the graft in place, and intact endoneurial tubes for the axons to grow through.

It is supplied sterile in a variety of lengths and diameters. It is for single patient use only. Approximate graft lengths and diameters are listed on the package label.

REGULATORY CLASSIFICATION

Avance[®] is a human tissue for transplantation. It is processed and distributed in accordance with FDA requirements for Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271), State regulations and the guidelines of the American Association of Tissue Banks (AATB).

This graft is to be dispensed only by or on the order of a licensed physician.

APPLICATIONS FOR USE

Avance[®] is allograft tissue for bridging peripheral nerve discontinuities.

CONTRAINDICATIONS

Avance[®] 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 gamma irradiation have been utilized to minimize the risks of transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, Avance[®] cannot be guaranteed to be free of all pathogens.

- Do NOT reuse or re-sterilize.
- Do NOT refreeze product if thawed.

DONOR RECOVERY AND SCREENING

After consent for donation is obtained, surgical recovery of the peripheral nervous tissue is performed in an aseptic manner by appropriately licensed tissue banks. Donor eligibility is carefully evaluated as required by the US FDA and in accordance with AATB, and State guidelines. Tissue donors are evaluated for high risk behaviors and relevant communicable diseases. Screening includes a review of the donor medical and social history, a physical assessment of the donor, a review of an autopsy (if performed), serology testing, tissue recovery microbiology, and cause of death.

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

- Human Immunodeficiency Virus Type 1 Antibody
- Human Immunodeficiency Virus Type 2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody (total)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- Human T-Cell Lymphotropic Virus Type I Antibody
- Human T-Cell Lymphotropic Virus Type II Antibody
- HIV1/HCV Nucleic Acid Test (NAT)

This testing is performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988. The testing is conducted using test kits approved

by the FDA for testing cadaveric specimens where available.

The Medical Director of AxoGen, Inc. has determined that the donor of the tissue contained in this product is suitable for transplantation. The record of this testing and medical release is maintained by AxoGen, Inc.

PROCESSING

Avance[®] is processed in controlled environments using methods designed to prevent contamination and cross contamination of the product. Processing involves the use of proprietary physiological buffers, enzyme and surfactants and the allograft tissue may contain traces of these processing agents. The cleaning process preserves the inherent and relevant structural characteristics of the allograft tissue. The final product is sized, packaged and sterilized using gamma irradiation in accordance with ISO 11137 guidelines.

Avance[®] has been tested in accordance with ISO 10993 standards. The test results demonstrated the graft is biocompatible.

Note: The allograft tissue will naturally vary in color from white, off-white, pink, pale pink, and yellow to pale yellow. Occasional dark spots or localized discoloration is a normal occurrence.

HOW SUPPLIED

Avance[®] is placed into a plastic tray and then inserted into a double pouch. Each pouch is heat-sealed to provide a sterile barrier and each pouch has a chevron peelable seal. The outer pouch is foil to provide a moisture barrier. Approximate graft lengths and diameters are listed on the package label. The product is irradiated and supplied frozen. Contents of the foil package are sterile unless the package is opened or damaged.

TRANSPORT AND STORAGE

Grafts are shipped frozen on dry ice via overnight carrier. Upon arrival, grafts should be removed from the shipping container and placed in a freezer at or below -40°C (-40°F). Expiration date is 3 years from date of packaging when stored at temperatures at or

below -40°C (-40°F). *See product label for expiration date.*

Alternate storage conditions

Grafts may be stored for 6 months or less from -20 to -39°C (-4 to -39°F).

It is the responsibility of the health care institution to track expiry date.

WARNING

If the outer foil pouch and/or inner Tyvek[®] pouch is compromised (show evidence of being torn or opened in any manner). Do NOT Use!

INSTRUCTIONS FOR USE

1. Follow standard operating procedures for exposure and mobilization of the injured nerve.
2. At the time of use, remove the double pouch Avance[®] product, product insert, record labels and Tissue Utilization Report (TUR) from the package.
3. Compare the distinct lot number on the outer pouch with the lot number on the package. If the numbers do not match, Do NOT Use the graft and notify AxoGen immediately.
4. Using standard aseptic technique, peel open the outer foil chevron pouch and pass the inner Tyvek[®] pouch to the sterile field for further handling.
5. Open the inner Tyvek[®] chevron pouch and remove the product tray.
6. Open the tray and fill the pre-molded thawing reservoir with room temperature sterile saline or sterile Lactated Ringer's Solution.

The graft will thaw in approximately 5-10 minutes.

- Do NOT heat the graft.
- Do NOT add heated saline to the graft.

Allow graft to thaw completely before use. A thawed graft is soft and pliable throughout. The graft must be either implanted or discarded within 12 hours. NEVER IMPLANT A PARTIALLY OR FULLY FROZEN GRAFT.

7. Avance[®] should be transplanted using the same tensionless surgical technique used when implanting a nerve autograft. Either end of the graft can be coapted to the proximal stump of the host nerve.
8. Destroy any thawed tissue not used in the surgical procedure in accordance with local, state, and federal regulations for human tissue.
9. Complete and mail the postage pre-paid Tissue Utilization Report (TUR) back to AxoGen, Inc.

TISSUE UTILIZATION REPORT (TUR)

Each graft package has a Tissue Utilization Report (TUR).

In accordance with FDA and JCAHO requirements, a TUR should be completed for each nerve graft.

Record the distinct HCT/P identification code in hospital or facility records and in the patient's file. Complete all information on the card, affix ONE (1) peel-off label of each graft used, seal and return to AxoGen, Inc.

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

Hypersensitivity, allergic reactions, or other immune responses have not been seen in preclinical studies. Because Avance[®] is composed of proteins such as collagen and laminin; the potential may exist for such reactions. All adverse outcomes potentially attributed to the Avance[®] must be promptly reported to AxoGen, Inc.

Possible complications can occur with any nerve repair surgical procedure including pain, infection, decreased or increased nerve sensitivity, impaired motor or sensory function, and complications associated with use of anesthesia.

Disease screening methods are limited; therefore, certain diseases may not be detected.

The following complications of tissue transplantation may occur:

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

DISPOSAL

Allograft disposal shall be in accordance with local, state and federal regulations for human tissue.

INQUIRIES

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

AxoGen Customer Service at 888.AxoGen1 (888.296.4361) or email customerservice@axogeninc.com

Processed under U.S patents 6,972,168 and 7,402,319. Other patents pending.
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Avance[®] is processed for and distributed by:



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