

Operative Technique Guide

Avance[®]
Nerve Graft
The Natural Connection



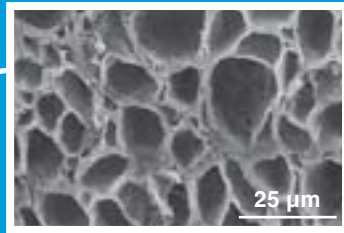
Connecting nerves.
Connecting lives.

 **AxoGen**[®]
Nerve Regeneration

Bringing the science of nerve repair to life.

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.



Multi-tubular structure of Avance® for axons to grow through.

- **Scaffold.** Decellularized and cleansed to preserve the tissue's extracellular matrix.
- **Support.** Structurally supports the body's own regeneration process.
- **Simplicity.** No donor-nerve surgery, therefore no loss of donor nerve function. Handles similar to an autograft: flexible and pliable.
- **Size-matching.** Supplied sterile in lengths of 15 mm to 50 mm and diameters up to 5 mm.



Step 1: Prepare nerve

Expose nerve at the appropriate incision site according to standard operating procedures. Prepare the nerve bed. Examine the local tissues, resecting scar tissue as needed.

The proximal and distal segments of the injured nerves should be debrided to healthy tissue by visual and tactile cues.

NOTE: Axoplasmic fluid often will weep out of the resected nerve ending, and may be one indication of adequate debridement.



Step 2: Select appropriate size Avance®

After measuring the distance between the proximal and distal nerve stumps, as well as the diameters of each nerve stump, select the appropriate size Avance®.

If the diameter of Avance® is smaller than the nerve diameter, cable grafting may be performed.

Individual fascicles may be isolated and used to connect to fascicles of a smaller-diameter nerve.



Step 3: Prepare and thaw Avance®

Using standard aseptic technique, peel open the outer foil chevron pouch and pass the inner Tyvek® pouch to the sterile field for further handling.

Open the inner Tyvek® chevron pouch and remove the product tray. Open the tray and fill the premolded thawing reservoir with room temperature sterile saline or sterile Lactated Ringer's Solution.

The graft will thaw in approximately 5 to 10 minutes. Do NOT heat the graft or add heated saline to the graft.

Allow graft to thaw completely before use. A thawed graft is soft and pliable throughout.

NEVER IMPLANT A PARTIALLY OR FULLY FROZEN GRAFT.

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.

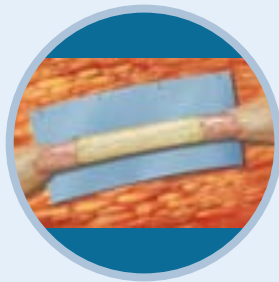
Similar to nerve autografts, Avance® provides the surgeon with desired handling and structural characteristics: pliability of soft tissue, an intact epineurium to suture the graft in place, and intact endoneurial tubes for the axons to grow through.

Avance® is supplied in a variety of lengths and diameters.



Step 4: Handle Avance®

Avance® should be handled like an autograft nerve. The grafts should be held by the epineurium. The graft can be trimmed using a scalpel.



Step 5: Suture Avance® to nerve endings

Avance® can be transplanted using the same micro-surgical technique used when implanting a nerve autograft. Either end of the graft can be coapted to the proximal stump of the host nerve.

Typically, nerve repair is performed with nylon micro-sutures placed in the epineurium. Usually, a simple suture technique is used to coapt the nerve ends. Gently draw the nerve stump flush with Avance® prior to tying the knot, making sure the graft endings are aligned with the nerve stumps.

Destroy any thawed tissue not used in the surgical procedure in accordance with local, state, and federal regulations for human tissue.

Note: Avoid tension on the peripheral nerve to be repaired during the entire procedure.

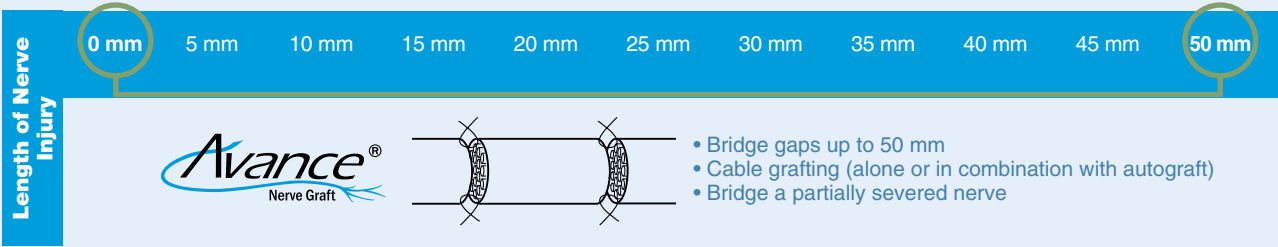


Step 6: Complete and mail the Tissue Utilization Report back to AxoGen, Inc.

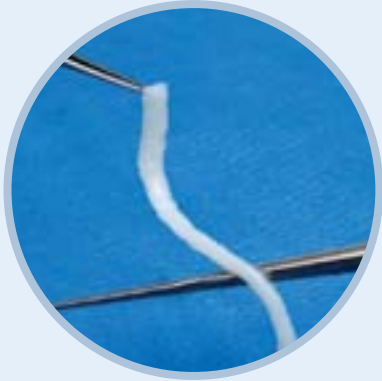
Each graft package has a Tissue Utilization Report (TUR) and a set of product identification labels. In accordance with FDA and JCAHO requirements, a TUR should be completed for each nerve graft.

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) product identification label of each graft used, seal, and return to AxoGen Inc. It is the responsibility of the healthcare 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.



Peripheral Nerve Injury Type	Examples	Avance® Nerve Graft
Avulsion/Stretch Injury	Brachial Plexus Injury Erb's Palsy	●
Partial Transection	Traumatic Injury	●
0 – 5 mm Gap	Neuroma Resection Sharp Laceration	●
6 – 50 mm Gap	Neuroma Resection Traumatic Injury Nerve Reconstruction	●



Avance® Nerve Graft
The Natural Connection

Product Code	Diameter*	Length*
111215	1 – 2 mm ○	15 mm
211215	2 – 3 mm ○	15 mm
311215	3 – 4 mm ○	15 mm
411215	4 – 5 mm ○	15 mm
111230	1 – 2 mm ○	30 mm
211230	2 – 3 mm ○	30 mm
311230	3 – 4 mm ○	30 mm
411230	4 – 5 mm ○	30 mm
111250	1 – 2 mm ○	50 mm
211250	2 – 3 mm ○	50 mm
311250	3 – 4 mm ○	50 mm
411250	4 – 5 mm ○	50 mm

Actual sizes may vary
*Approximate size shown here.

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 (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.

U.S. Patents: 6, 972, 168; 7, 402, 319



13859 Progress Blvd., Suite 100, Alachua, Florida 32615
©2009 AxoGen, Inc. | Avance® and its logo are trademarks of AxoGen, Inc.

To place an order, contact:
AxoGen Customer Service
Phone: 888-AXOGEN1 (888-296-4361)
Fax: 386-462-6801
Email: customerservice@axogeninc.com
www.axogeninc.com