

# Operative Technique Guide

**Avance**<sup>®</sup>  
Nerve Graft  
**The Natural Connection**



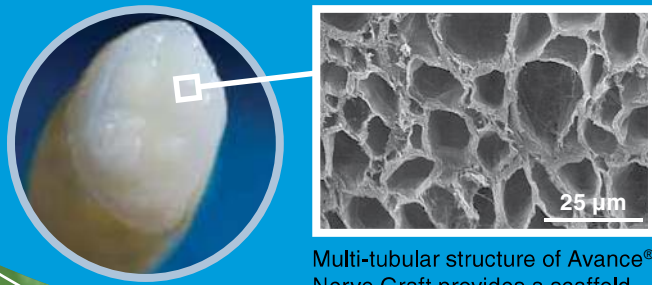
Connecting nerves.  
**Connecting lives.**

 **AxoGen**<sup>®</sup>  
Nerve Regeneration

**Bringing the science of nerve repair to life.**

# Avance® Nerve Graft is peripheral nerve allograft for bridging nerve discontinuities.

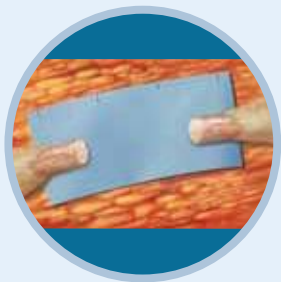
Avance® Nerve Graft is a decellularized and cleansed extracellular matrix from donated human peripheral nerve. The cleaning process preserves the inherent and relevant structural characteristics of the tissue.



Multi-tubular structure of Avance® Nerve Graft provides a scaffold for axons to grow through

## Avance® Nerve Graft provides the following features:

- Decellularized and cleansed extracellular matrix.
- Structurally supports the body's own regeneration process.
- Handling similar to an autograft nerve without the loss of donor nerve function.
- Flexible and pliable.



### 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 will often weep out of the resected nerve ending and may be one indication of adequate debridement.



### Step 2: Select appropriate size Avance® Nerve Graft

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® Nerve Graft.

If the diameter of Avance® Nerve Graft 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® Nerve Graft

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® Nerve Graft preserves the inherent and relevant structural characteristics of human nerve tissue.

The decellularized and cleansed extracellular matrix of Avance® Nerve Graft works with the natural healing process of the body. It has intact endoneurial tubes that provide a pathway for regenerating axons from the proximal to the distal end of the transected nerve.

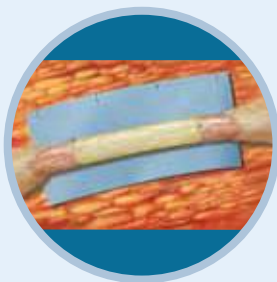
Similar to nerve autografts, Avance® Nerve Graft provides the surgeon with desired handling and structural characteristics: pliability of soft tissue, an intact epineurium to suture the graft in place, and intact endoneurial tubes for the axons to grow through.

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



#### **Step 4: Handle Avance® Nerve Graft**

Avance® Nerve Graft 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® Nerve Graft to nerve stumps**

Avance® Nerve Graft 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 stumps. Gently draw the nerve stump flush with Avance® Nerve Graft 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.

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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.**

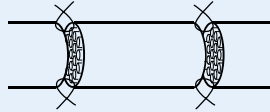
Each graft package has a Tissue Utilization Report (TUR) and a set of product identification labels. In accordance with FDA and JCAHO requirements, a TUR should be completed for each nerve graft.

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.

Length of Nerve Injury

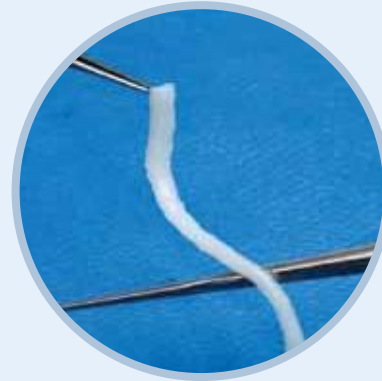
0 mm 5 mm 10 mm 15 mm 20 mm 25 mm 30 mm 35 mm 40 mm 45 mm 50 mm 55 mm 60 mm 65 mm 70 mm



- Bridge gaps up to 70 mm
- Cable grafting (alone or in combination with autograft)
- Bridge a partially severed nerve

Material Features	Avance® Nerve Graft	Collagen or Synthetic
Remodeled into patient's own tissue	✓	
Body revascularizes the tissue during natural healing process	✓	
Easy to suture	✓	○
Flexible, pliable	✓	○
Variety of sizes available	✓	✓
Off-the-shelf option available	✓	✓

○ not representative of all materials



### Avance® Nerve Graft The Natural Connection

Code	Dimensions	Approximate Size
111215	1 – 2 mm x 15 mm	
211215	2 – 3 mm x 15 mm	
311215	3 – 4 mm x 15 mm	
411215	4 – 5 mm x 15 mm	
111230	1 – 2 mm x 30 mm	
211230	2 – 3 mm x 30 mm	
311230	3 – 4 mm x 30 mm	
411230	4 – 5 mm x 30 mm	
111250	1 – 2 mm x 50 mm	
211250	2 – 3 mm x 50 mm	
311250	3 – 4 mm x 50 mm	
411250	4 – 5 mm x 50 mm	
111270	1 – 2 mm x 70 mm	
211270	2 – 3 mm x 70 mm	
311270	3 – 4 mm x 70 mm	
411270	4 – 5 mm x 70 mm	

Actual sizes may vary

**Regulatory classification:** Avance® Nerve Graft 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® Nerve Graft is allograft tissue for bridging peripheral nerve discontinuities.

**Contraindications:** Avance® Nerve Graft 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; 7, 732, 200 and other patents pending.



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