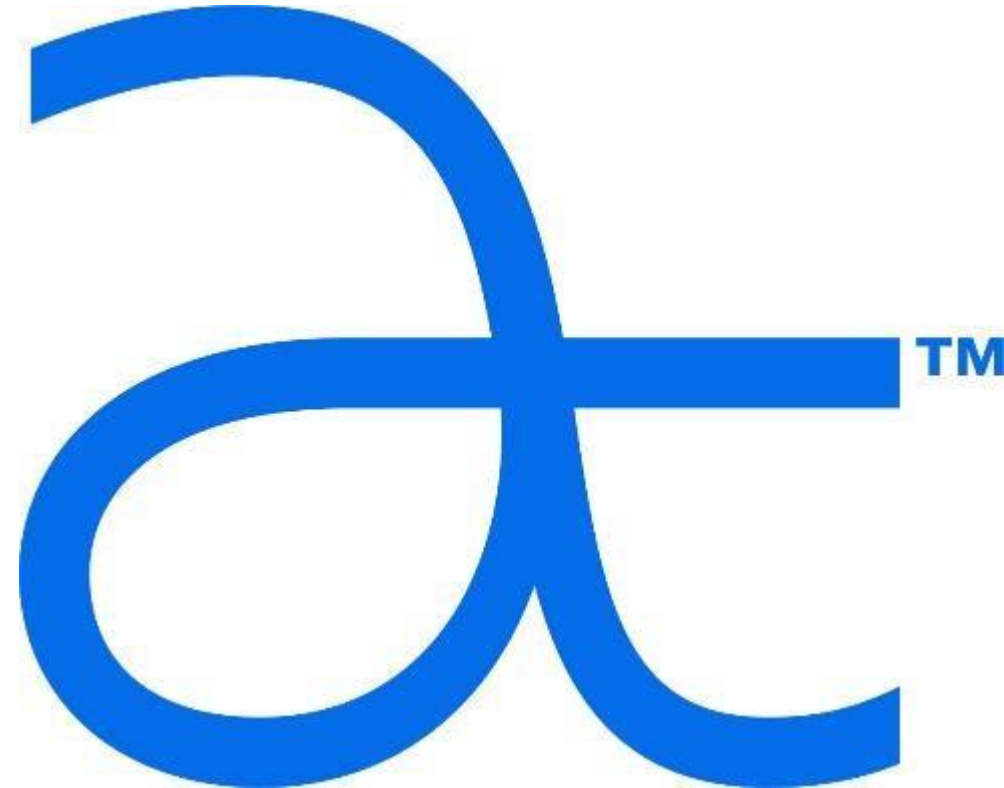


# Corporate presentation

November 7, 2024

nasdaq: axgn

**axogen**<sup>®</sup>



# Safe harbor statement

This presentation contains “forward-looking” statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or predictions of future conditions, events, or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “projects,” “forecasts,” “continue,” “may,” “should,” “will,” “goals,” and variations of such words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements include (1) the TAM for the targeted nerve markets, (2) 2024 financial guidance, including revenue range and gross margins, (3) growth drivers for the business, (4) expectations regarding the commercial performance of Avive+ Soft Tissue Matrix™, (5) the expectation that the Axogen Processing Center will support our BLA filing, (6) our expectations regarding our potential for BLA approval in September 2025, (7) the expectation that a new (non-biosimilar) competitive processed nerve allograft would need to complete clinical testing and obtain BLA approval prior to clinical release, and that it would likely take 8 years to achieve this, (8) the expectation that Avance® would be designated as the reference product for any biosimilar nerve allograft product and the expectation that approval of such a biosimilar would not occur for at least 12 years from approval of our BLA, and (9) the expectation that RECON<sup>SM</sup> study topline results will support our BLA filing.

Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, statements related to potential disruptions caused by leadership transitions, global supply chain issues, record inflation, hospital staffing issues, product development, product potential, expected clinical enrollment timing and outcomes, regulatory process and approvals, financial performance, sales growth, surgeon and product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events, global business disruption caused by Russia's invasion of Ukraine and related sanctions, recent geopolitical conflicts in the Middle East, potential disruptions due to management transitions, as well as those risk factors described under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K for the most recently ended fiscal year. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements.

# The Axogen platform for nerve repair

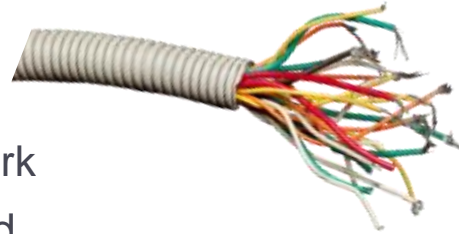


- Exclusively focused on peripheral nerve repair with a differentiated platform
- 15+ years of demonstrated clinical outcome consistency
- 275 peer-reviewed clinical publications
- Over 100,000 Avance<sup>®</sup> nerve grafts implanted
- Significant barriers to competitive entry
- Patient activation and surgeon education capabilities

# The function of nerves and injury types

## Nerves are like wires

- Transfer signals across a network
- If cut, data cannot be transferred
- If crushed, short circuits and data corruption may occur



## The peripheral nervous system is a vast network from every organ to and from the brain

- Sensory
- Motor
- Mixed



## Nerves can be injured in three ways:

### 1. Transection

Traumatic nerve injuries e.g., motor vehicle accidents, power tool accidents, battlefield injuries, gunshot wounds, surgical injuries, neuroma-in-continuity

### 2. Compression

Carpal, cubital, tarsal tunnel revisions, blunt trauma, previous surgeries

### 3. Stump Neuroma

Amputations, mastectomies, previous surgeries

# Comprehensive platform for addressing nerve injuries

 **avance<sup>®</sup>**  
nerve graft



Biologically active, processed human nerve allograft developed for bridging nerve discontinuities up to 70 mm

 **axoguard**  
nerve connector<sup>®</sup> 



Semi-translucent coaptation aid for nerve transections up to 5 mm

 **axoguard HA<sup>+</sup>**  
nerve protector 



Extracellular matrix base layer with a hyaluronate-alginate gel coating to facilitate enhanced nerve gliding, aid in minimizing soft tissue attachments and remodeling of the base layer to provide long-term protection

 **axoguard**  
nerve protector<sup>®</sup> 



Extracellular matrix that remodels to protect injured nerves and reinforce nerve reconstructions

 **avive<sup>+</sup>**  
soft tissue matrix



Multi-layer amniotic soft tissue barrier for protection during the critical stage of healing

 **axoguard**  
nerve cap<sup>®</sup> 



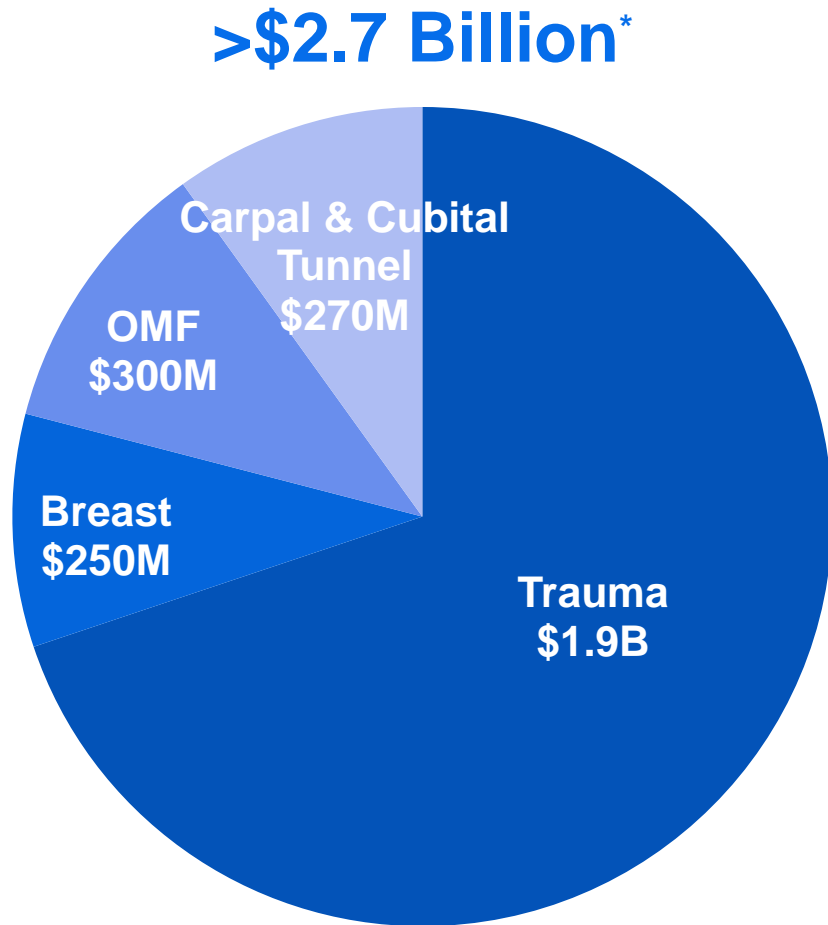
Separates nerve end from surrounding environment to protect from mechanical stimulation and reduce painful neuroma formation

Connection

Protection

Termination

# Targeted nerve markets (U.S.)



## U.S. potential procedural estimates >900,000\*\*

- Trauma<sup>1-4</sup>: > 700,000
- Carpal and Cubital Tunnel Revisions<sup>5-8</sup>: 130,000
- Oral Maxillofacial (OMF)<sup>9-17</sup>: 56,000
- Breast Neurotization Procedures<sup>18</sup>: 15,000\*\*\*

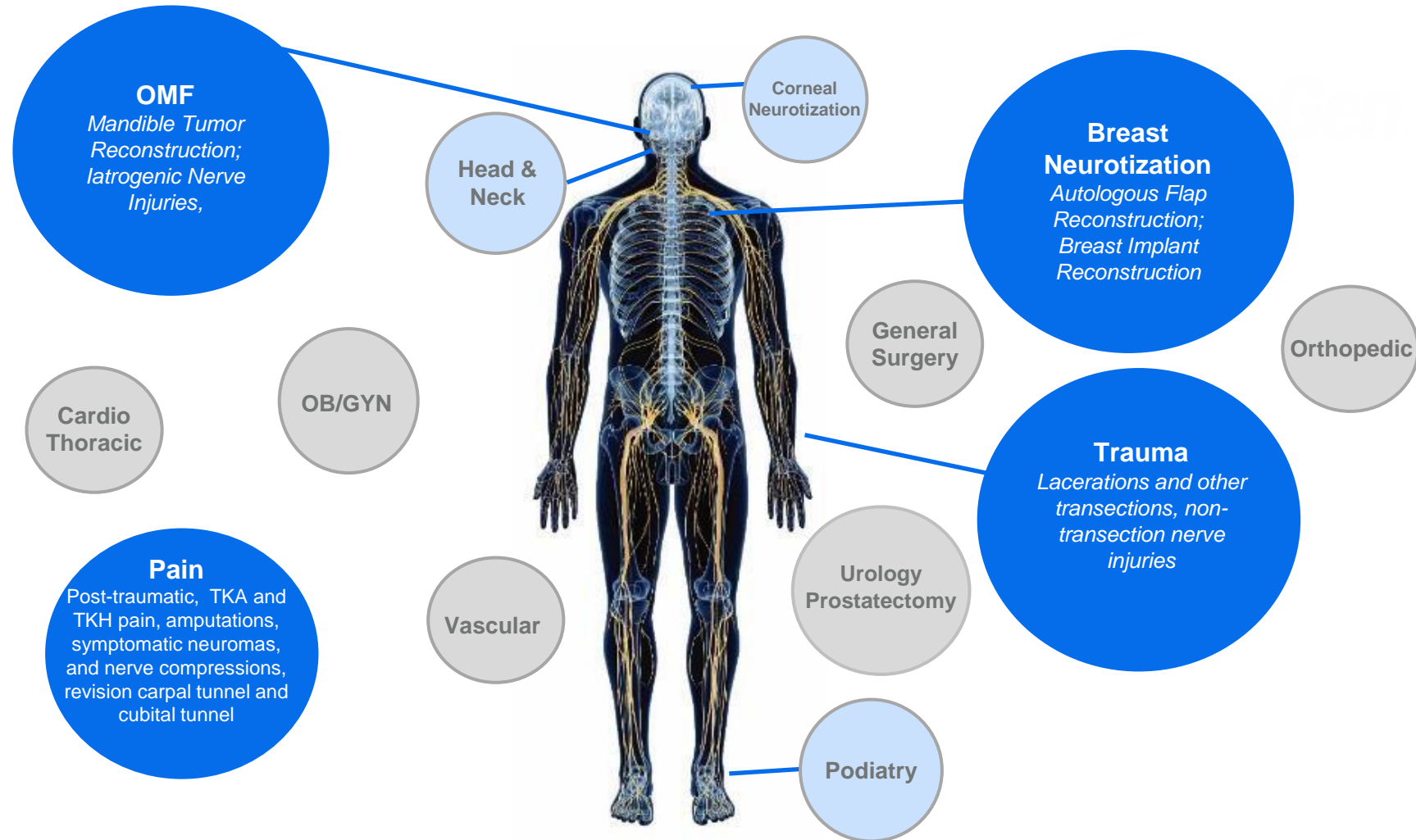
*\*\$2.7B estimate does not include pain market or implant breast reconstruction neurotization*

*\*\*Referenced papers were used to derive specific assumptions in the procedure potential estimates. Papers used include both U.S. and OUS databases and studies. See Appendix for data sources.*

*\*\*\* Does not include implant-based procedures*

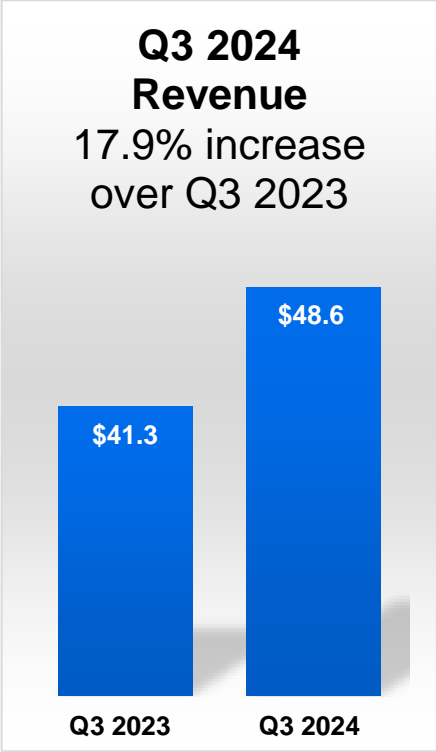
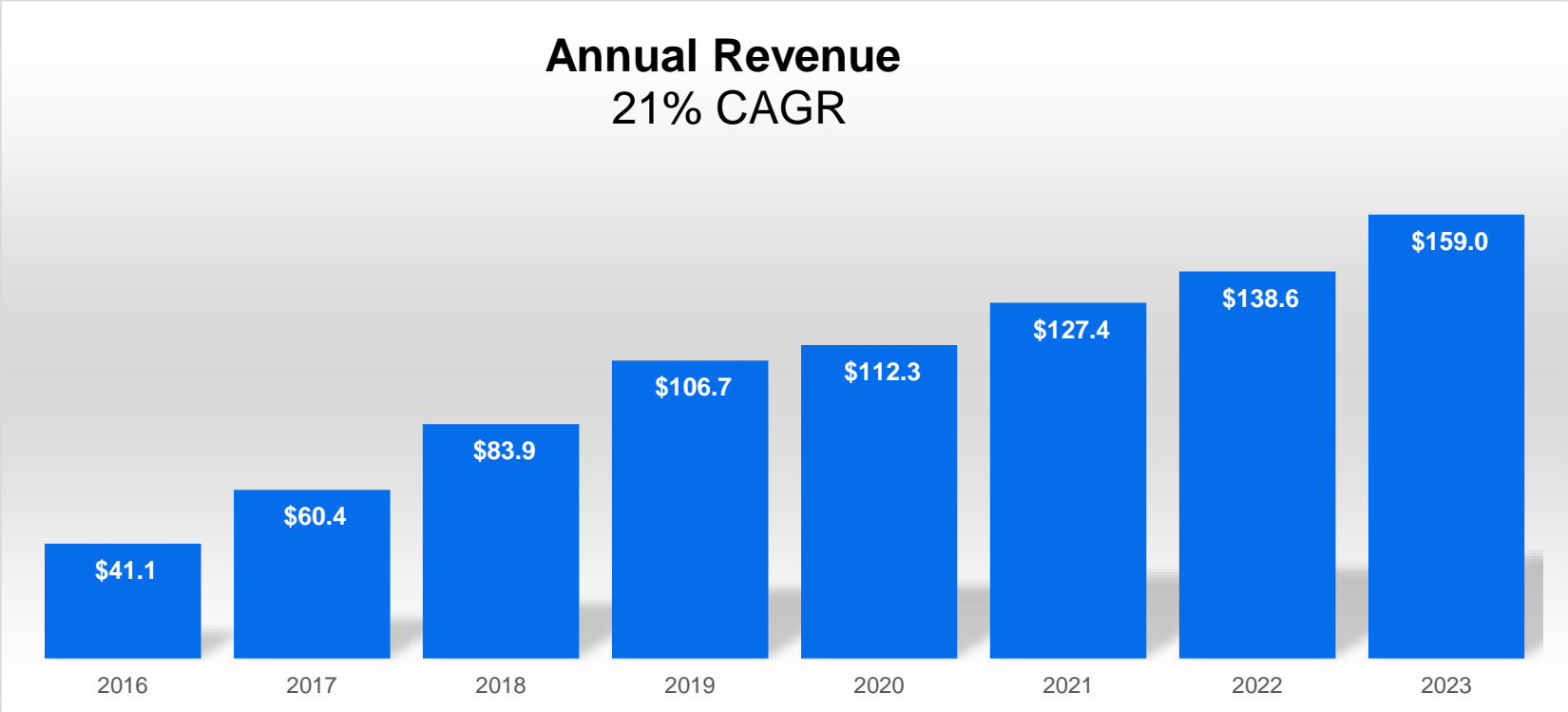
# Opportunities in nerve repair

Core business anchored in Trauma and Upper Extremity, and expanded to Breast, OMF and Pain. Further Market Expansion Opportunities in Head & Neck, Corneal Neurotization and Podiatry.



# Delivering strong revenue growth and gross margins

U.S. \$ in millions



## Management expects:

- Full-year 2024 revenue to be in the range of **\$182 million to \$186 million**.
- Additionally, we anticipate gross margin for the full year to be at the high end of the range of **74%-76%**.
- We expect to be net cashflow positive cumulatively in the period from April 1st through year end.

**74.9% gross margin for the quarter ended September 30, 2024**



# Growth drivers

## Clinical Data

- Clinical data published supports increased adoption particularly with middle adopters
  - RECON<sup>SM</sup> 19
  - Meta Analysis of clinical outcomes and Medicare Economic Data<sup>20</sup>
  - Premier Economic Data<sup>21</sup>
  - Cost–effectiveness analysis of Avance<sup>22</sup>

## Innovation

- New product launches in nerve protection: Axoguard HA+ Nerve Protector<sup>TM</sup> launched in Q2 2023, Avive+ Soft Tissue Matrix<sup>TM</sup> launched in Q2 2024
- Resensation<sup>®</sup> for breast neurotization expansion into implant-based reconstructions

**Sales Rep Productivity** driving penetration in high-potential accounts

**Patient Activation Programs** for breast neurotization, surgical treatment of pain, and OMF

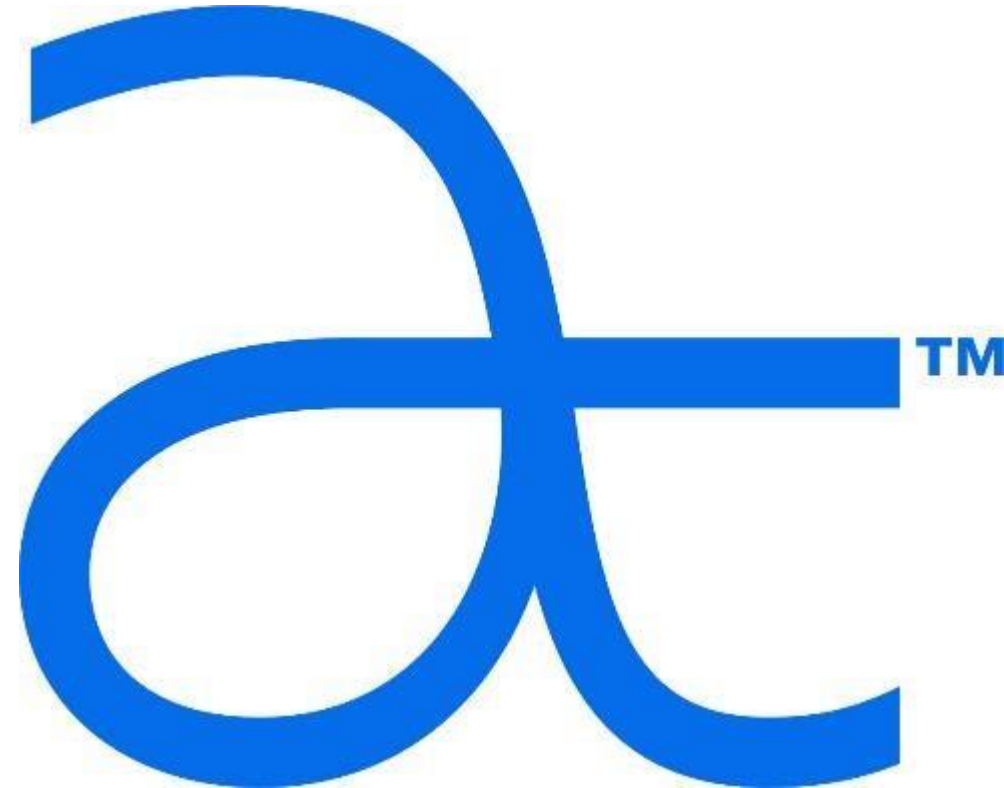
**Surgeon Education** across nerve repair applications

# Axogen Processing Center (APC)

- Fully transferred all Avance processing to APC in December 2023
- Supports BLA requirements for Avance Nerve Graft®
- Provides 3x previous capacity, designed for long-term growth and expansion



# Product Portfolio

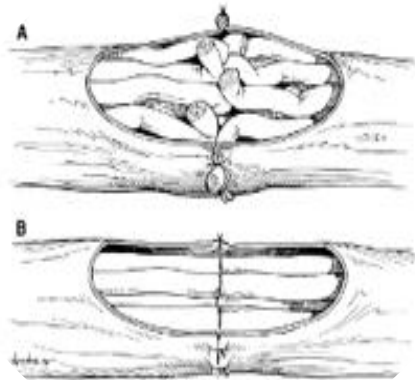


# Traditional Transection repair options are suboptimal

## SUTURE

### Direct suture repair of no-gap injuries

- Common repair method
- May result in tension to the repair leading to ischemia
- Concentrates sutures at the coaptation site



## AUTOGRAFT

### Traditional method despite several disadvantages

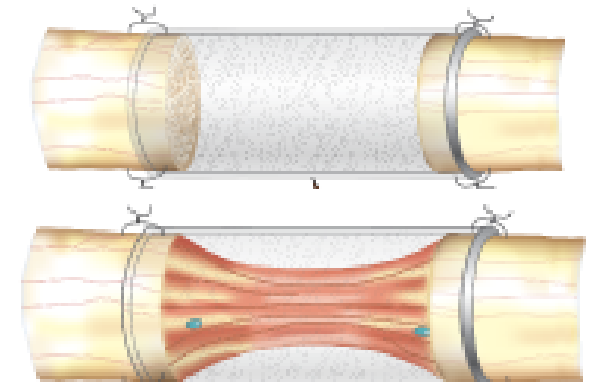
- Secondary surgery
- Loss of function and sensation at harvest site<sup>23</sup>
- High complication rates including wound healing (7%) and chronic pain (23%)<sup>23</sup>
- Limited availability of graft length and diameter



## SYNTHETIC CONDUITS

### Convenient off the shelf option; limited efficacy & use

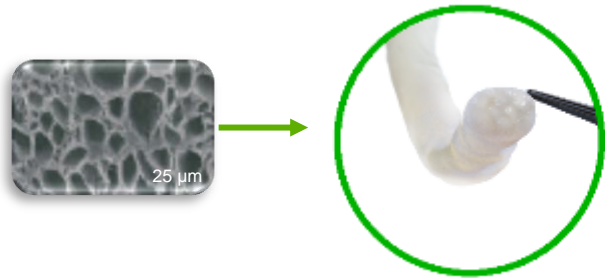
- Provides only gross direction for regrowth
- Limited to small gaps
- 34%-57% failure rate >5mm gaps<sup>24, 25</sup>
- Semi-rigid and opaque material limits use and visualization
- Repair reliant on fibrin clot formation





# Axogen solutions for **Transection** repair

 **avance**<sup>®</sup>  
nerve graft



## **Processed human nerve allograft for bridging nerve gaps**

Clinically studied off-the-shelf alternative

- A biologically active nerve therapy with more than ten years of comprehensive clinical evidence
- 82-84% meaningful recovery in sensory, mixed and motor nerve gaps in multi-center study<sup>26</sup>
- Eliminates need for an additional surgical site and risks of donor nerve harvest<sup>23</sup>
- Reduces OR time<sup>21</sup>

Structural support for regenerating axons

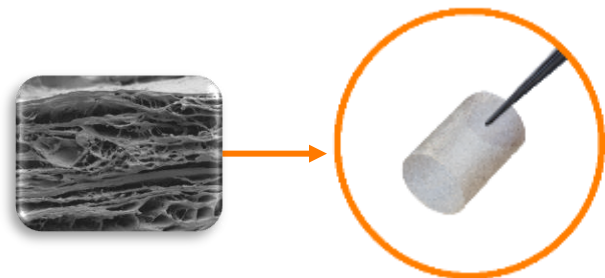
- Cleansed and decellularized extracellular matrix (ECM)
- Offers the benefits of human peripheral nerve micro-architecture and handling

Revascularizes and remodels into patient's own tissue similar to autologous nerve<sup>27</sup>

16 size options in a variety of lengths (up to 70mm) and diameters (up to 5mm)

These highlights do not include all the information needed to use **Avance<sup>®</sup> Nerve Graft** safely and effectively. See full instructions for use (IFU) for **Avance<sup>®</sup> Nerve Graft**

 **axoguard**  
nerve connector<sup>®</sup>



## **Minimally processed porcine ECM for connector-assisted coaptation**

Alternative to direct suture repair

- Reduces the risk of forced fascicular mismatch<sup>28,29</sup>

Alleviates tension at critical zone of regeneration

- Disperses tension across repair site<sup>30</sup>
- Moves suture inflammation away from coaptation face<sup>31</sup>

Remodels into vascularized patient tissue<sup>32-37</sup>

14 size options in lengths of 10mm and 15mm, and diameters up to 7mm

These highlights do not include all the information needed to use **Axoguard Nerve Connector<sup>®</sup>** safely and effectively. See full instructions for use (IFU) for **Axoguard Nerve Connector<sup>®</sup>**

# Traditional **Compression** repair options are suboptimal

## VEIN WRAPPING

### Autologous vein

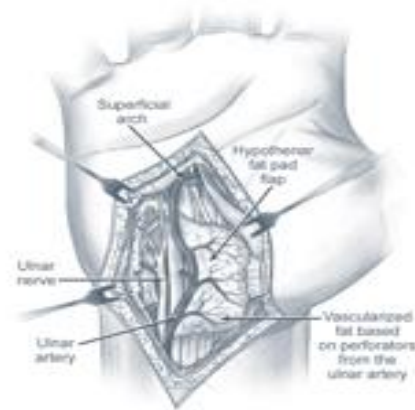
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



## HYPOTHENAR FAT PAD

### Autologous vascularized flap

- Barrier to attachment to surrounding tissue
- Only wraps part of the nerve circumference
- Increases procedure time



## COLLAGEN WRAPS

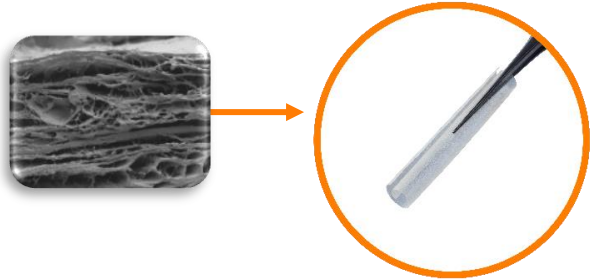
### Off-the-shelf

- Semi-rigid material limits use
- Degrades over time and does not provide a lasting barrier to soft tissue attachment



# Axogen solutions for **Compression** repair

## **axoguard** nerve protector<sup>®</sup>



### Minimally processed porcine extracellular matrix for wrapping and protecting injured peripheral nerve

#### Protects repair site from surrounding tissue

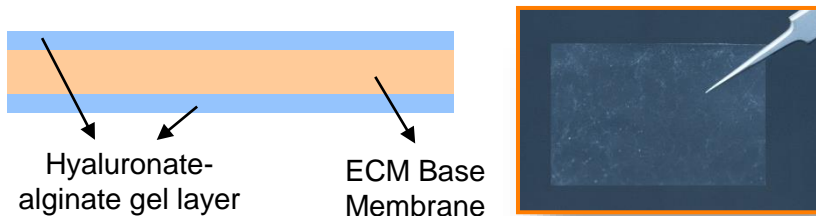
- Processing results in an implant that works with the body's natural healing process<sup>38</sup>
- Minimizes soft tissue attachments<sup>35</sup>

#### Allows nerve gliding

- Minimizes risk of entrapment<sup>35</sup>
- Creates a barrier between repair and surrounding tissue bed<sup>35</sup>
- ECM revascularizes and remodels into patient's own tissue<sup>32-37</sup>

These highlights do not include all the information needed to use **Axoguard Nerve Protector<sup>®</sup>** safely and effectively. See full instructions for use (IFU) for **Axoguard Nerve Protector<sup>®</sup>**

## **axoguard HA+** nerve protector<sup>™</sup>



### Minimally processed porcine extracellular matrix with hyaluronate-alginate gel layer

#### Lubrication layer:

- Protects nerve in the early critical phase of healing
- Enhances nerve gliding for nerve protection applications where nerve mobility is critical and aids in minimizing soft tissue attachments<sup>32</sup>

#### Handling characteristics:

- Flat sheet design that easily conforms to tissue
- Coverage of more anatomical locations

***Launched August 2023***

These highlights do not include all the information needed to use **Axoguard HA+ Nerve Protector<sup>™</sup>** safely and effectively. See full instructions for use (IFU) for **Axoguard HA+ Nerve Protector<sup>™</sup>**

# Avive+ Soft Tissue Matrix™



Avive+ Soft Tissue Matrix is a unique, multi-layer amniotic membrane allograft ideal for providing temporary protection for acute injuries.

## **Resorbable**

Avive+ Soft Tissue Matrix is a temporary resorbable soft tissue barrier for the prevention of soft tissue attachment in an acute wound bed. Made from human birth tissue that will resorb after the critical stage of healing.

## **Ease of use**

The unique multi-layer design of amnion and chorion provides structural integrity that makes Avive+ easy to handle and, with the epithelial layer facing out on both sides, it can be applied in either direction intra-operatively.

## **Inherent properties of amnion**

Avive+ leverages the properties of amnion offering a homologous tissue option that has a low immune response and serves as a barrier to separate and reestablish tissue planes.

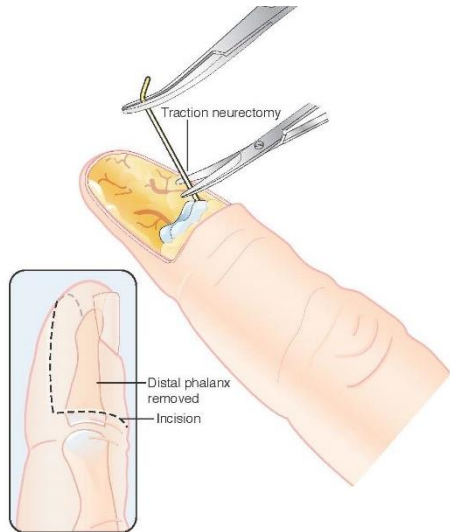


# Traditional Stump Neuroma options are suboptimal

## TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

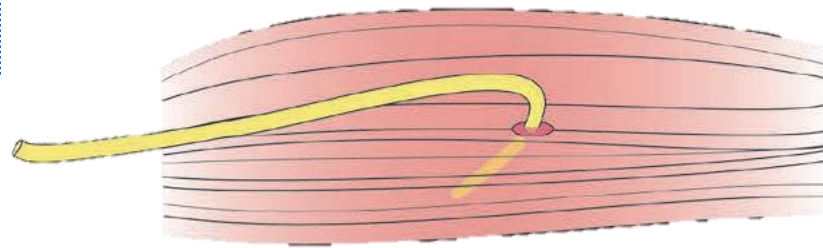
- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Causes traction injury
- High risk of recurrence<sup>39</sup>



## BURYING IN MUSCLE/BONE

Traditional method of neurectomy and neuromyodesis

- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Pain due to muscular contraction or localized pressure
- Larger surgical dissection
- Only 33-40% of patients were satisfied with treatment after burial into bone or muscle<sup>40</sup>



## INJECTIONS

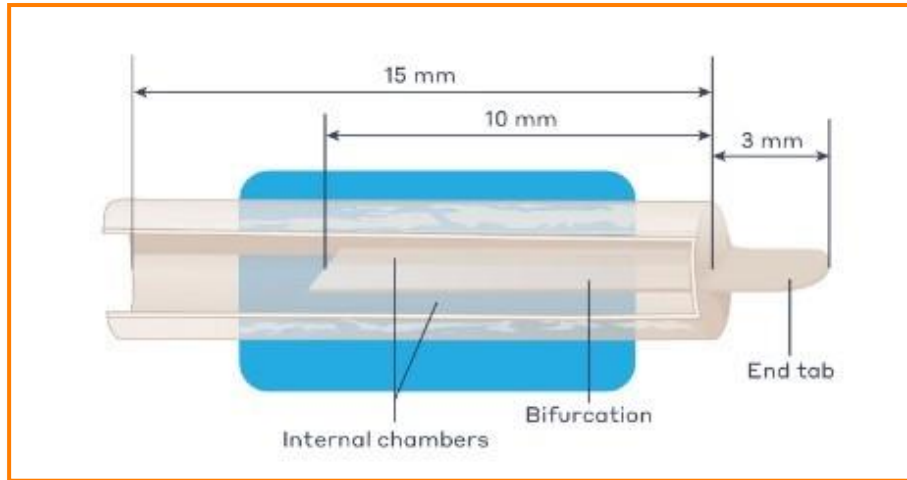
Pharmacologic intervention, typically alcohol or steroids

- Chemical injections are only successful 40% of the time<sup>41,42</sup>
- Temporary solution that has a reduced benefit over time
- May cause considerable side effects



# Axogen solution for Stump Neuroma

 axoguard  
nerve cap®



Large Diameter Nerve Cap launched in February 2024. 3 larger sizes for larger diameter nerves. Expands addressable procedures in upper and lower extremity.

Proprietary small intestine submucosa (SIS) matrix designed to separate the nerve end from the surrounding environment to protect it from mechanical stimulation and reduce painful neuroma formation\*.

Protects and isolates

- Reduces the development of symptomatic or painful neuroma formation
- Provides a barrier from neurotrophic factors and mechanical stimulation

SIS Material allows for vascularization and gradual remodeling (as shown in animal studies)<sup>32-37</sup>

- Material gradually incorporates into patient's own tissue, creating a physical barrier to surrounding soft tissue<sup>43</sup>

Intra-operative versatility

- Ideal for anatomic areas with limited or no musculature
- Alternative to historical techniques such as burying in muscle or bone
- Available in a variety of diameters

# Avance Patents and Regulatory Landscape

## Avance nerve graft

Avance nerve graft is processed and distributed in accordance with US FDA requirements for Human Cellular and Tissue-based Products (HCT/P)

## Axogen's nerve graft-related IP

### Issued U.S. Patents (additional patents pending)

9,572,911  
9,690,975  
9,996,729  
10,311,281  
10,783,349  
11,156,595  
11,513,039  
11,523,606  
11,737,451  
11,847,844  
11,885,792  
11,932,837  
11,959,903

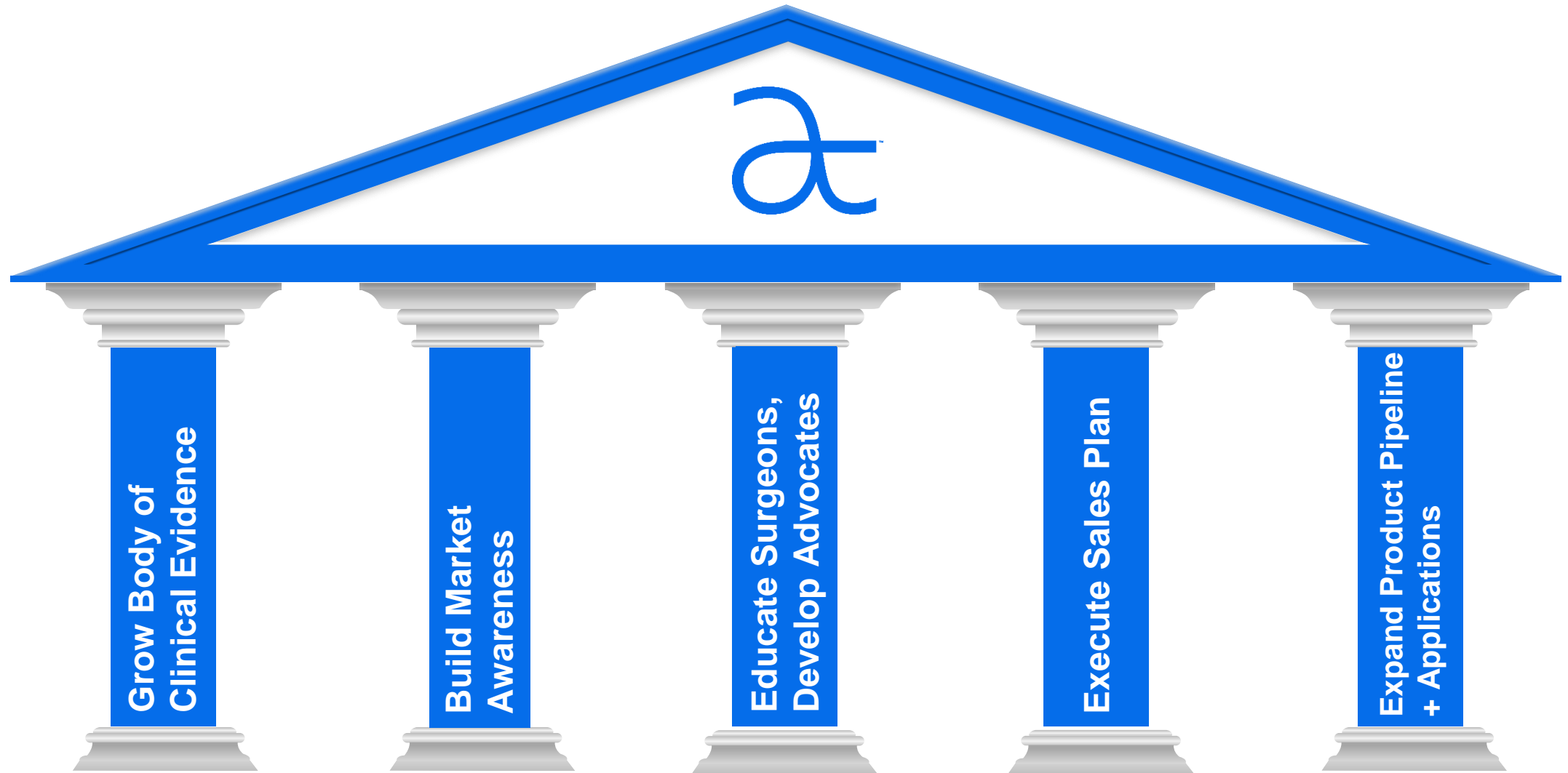
### New (non-biosimilar) competitive BLA product estimated 8 years

Axogen has Enforcement Discretion from FDA allowing continued sales under controls applicable to HCT/Ps with agreed transition plan to regulation as a Biological Product under a Biologic License Application (BLA) if approved. A new (non-biosimilar) competitive processed nerve allograft, we believe, would need to complete clinical testing and obtain BLA approval prior to clinical release, and it would likely require at least 8 years to achieve this.

### Protection from biosimilars using Avance as the reference application –at least 12 years from Avance BLA approval

Avance expected to be the reference product for the category of processed nerve allograft

# Market development strategy



# Strong commitment to developing clinical evidence



## RANGER® Registry Study: Enrollment Complete

- Multi-center clinical study in PNR with >2,700 enrolled to date
- Overall meaningful recovery rates of 82-84%; comparable to autograft

## MATCH® Registry Study: Enrollment Complete

- Avance compared to matched cohort of autograft and synthetic conduits

## Sensation-NOW® Registry Study: Enrollment Ongoing

- Multi-center clinical study in breast neurotization

## REPOSE® : Top line Data Read Out Complete

- Prospective, randomized, controlled study of Axoguard Nerve Cap® vs neurectomy

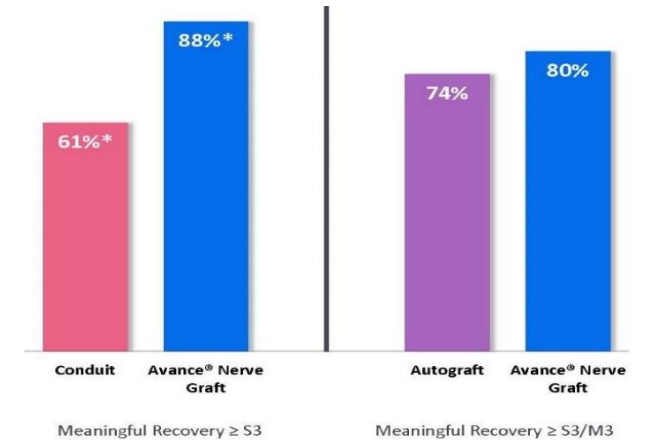
## REPOSE-XL<sup>SM</sup>: Pilot Study Enrollment Ongoing

- Pilot study evaluating the feasibility of large-diameter Axoguard Nerve Cap® for protecting and preserving terminated nerve ends after trauma or amputation

## COVERED<sup>SM</sup>: Enrollment Ongoing

- Prospective, multi-center clinical case series evaluating Axoguard HA+ Nerve Protector™ in first revision cubital tunnel decompression

Outcomes from RANGER Registry 44,45

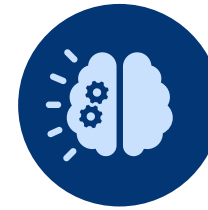




# RECON<sup>SM</sup> : A Multicenter, Prospective, Randomized, Subject & Evaluator Blinded Comparative Study of Nerve Cuffs & Avance Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities



Safety & efficacy non-inferiority comparison of Avance vs conduit



Evaluated upper extremity digital nerve repair for nerve gaps 5-25mm



220 subjects from up to 25 U.S. centers stratified into gap lengths with two-thirds in the 5-14mm group and one-third in the 15-25mm group

# RECON Study Topline Results

## Primary Endpoint Achieved

- This phase three pivotal study met its primary endpoint for the return of sensory function as measured by static two-point discrimination, and the safety profile was consistent with previously published data
- The data will support the company's Biologics License Application (BLA) with a potential for approval in September 2025.

## Statistical superiority demonstrated at increasing gap lengths

- ✓ Avance demonstrated statistical superiority for return of sensory function (measured by static two-point discrimination) as compared to conduits in gaps greater than 12 mm (p-value 0.021).<sup>19</sup>
- ✓ Avance demonstrated statistical superiority for time to recovery of static two-point discrimination as compared to conduits, returning normal sensation\* up to 3 months earlier in gaps greater than 10 mm (p-value 0.037).<sup>32</sup>

## The safety profile was consistent with previously published data

- ✓ Conduit repairs were observed to have an increased likelihood of persistent and unresolved nerve pain with an incidence of 9 (8%) conduit subjects as compared to 2 (2%) Avance subjects.<sup>32</sup>

\*Normal Sensation is defined by the Medical Research Council Classification (MRCC) score as S4 or return of static two-point discrimination outcomes of  $\leq 6$ mm.

# REPOSE Study Top Line Results

## Primary Endpoint Achieved

**REPOSE met primary endpoint of non-inferiority between the Month 12 pain visual analog scale scores for neurectomy with Axoguard Nerve Cap vs. standard-of-care neurectomy alone (p-value <0.05).**

## Statistical superiority demonstrated in Reduction of Total Pain

- ✓ Axoguard Nerve Cap demonstrated statistical superiority vs. standard-of-care neurectomy in the Reduction of Total Pain reported by participants over the full 12-month course of follow-up (p-value <0.05)

REPOSE is a post-market, randomized, comparative clinical study of standard-of-care neurectomy followed by reconstruction of the nerve end with Axoguard Nerve Cap, evaluating recovery outcomes for the treatment of symptomatic neuroma.

### Study Details:

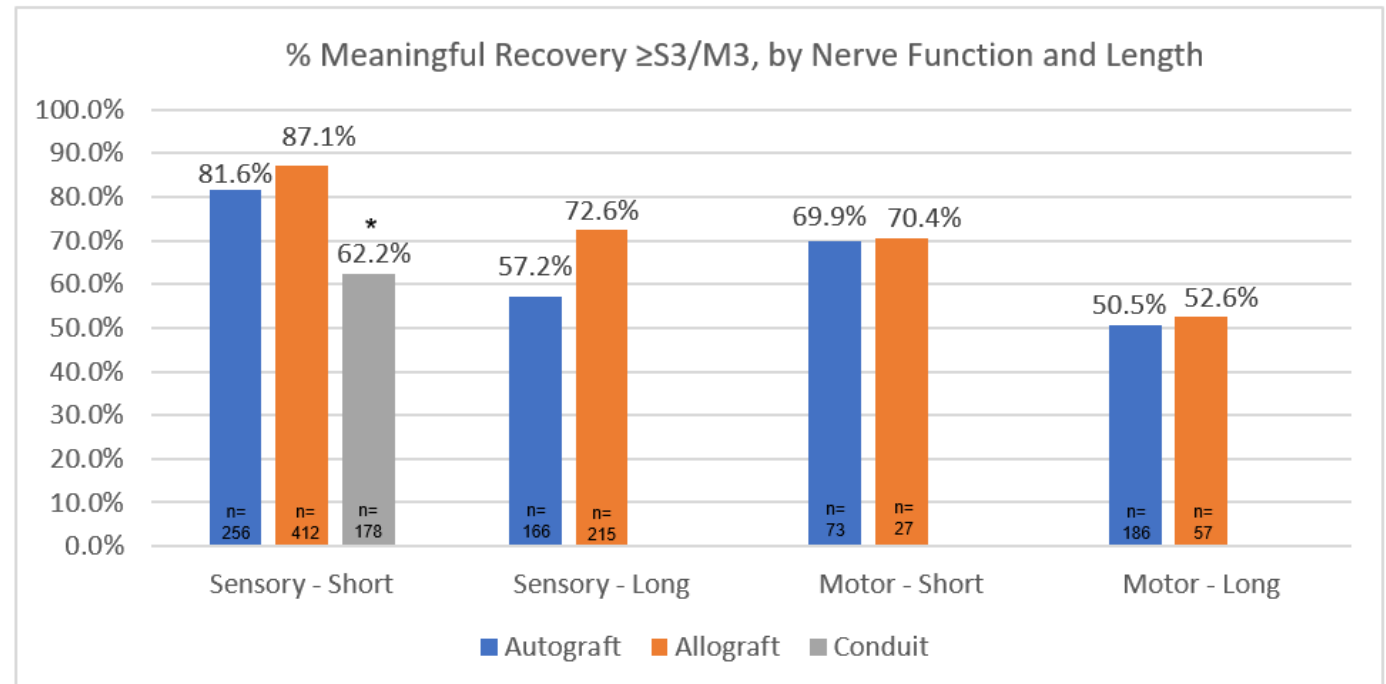
- Multicenter, prospective, randomized, subject blinded trial
- 86 randomized participants
- 12-month follow-up
- Pain, medication, Quality of Life questionnaires, recurrence of neuroma endpoints



# Independent Publication of Nerve Meta-Analysis Provides the Strongest Clinical and Economic Evidence To-Date of the Performance of Avance® Nerve Graft Across All Gap Lengths and Nerve Types

## “Lans et al., A systematic review and meta-analysis of nerve gap repair: Comparative effectiveness of allografts, autografts, and conduits” – *Journal of Plastic and Reconstructive Surgery*<sup>20</sup>

- Analyzed 35 peer-reviewed studies with 711 allograft, 670 autograft, and 178 conduit repairs, over four decades.
- There were no statistical differences between allograft and autograft outcomes over all gap lengths for both sensory and motor nerve repairs.
- Allograft and autograft repairs delivered significantly better rates of meaningful sensory recovery in short gaps as compared to conduit repairs; 87.1% and 81.6% vs. 62.2%, respectively,  $p < 0.05$ .
- The cost analysis found that allograft does not represent an increased economic burden compared to autograft.



\*statistically significant difference

# Procedure Costs of Peripheral Nerve Graft Reconstruction

Raizman et al.  
PRS Global Open<sup>21</sup>



- Retrospective study of U.S. all-payer data on facility procedure costs from 2018 to 2020. Included over 1,300 nerve repairs.

## Conclusions:

- No significant differences in procedure costs for autograft and allograft repair in either inpatient or outpatient setting.
- OR time was *significantly shorter* for allograft repairs, in both outpatient and inpatient settings.

## Procedure Costs of Nerve Repair

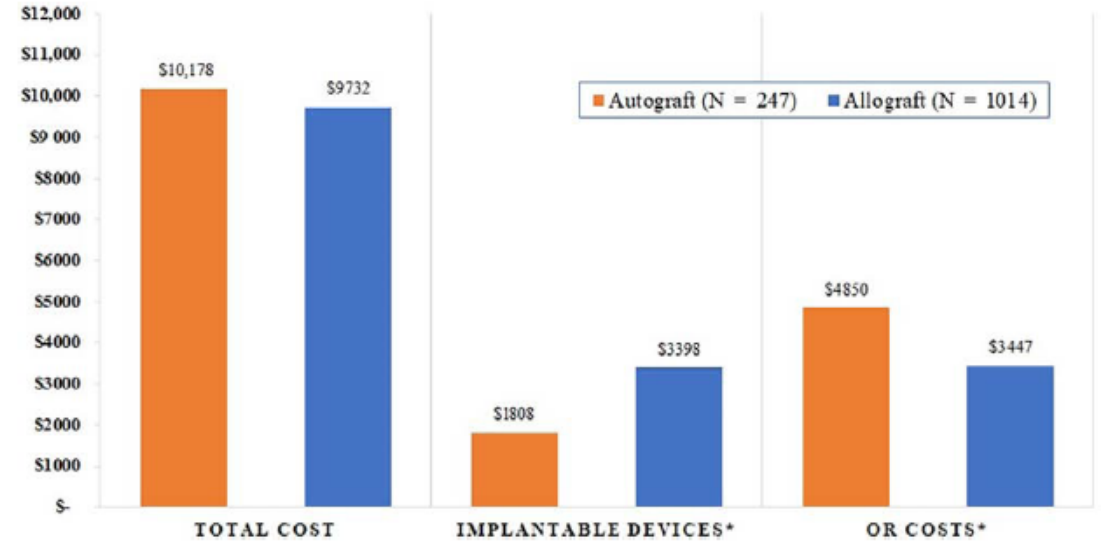


Fig. 2. Outpatient descriptive costs of nerve graft repair type (n = 1261).

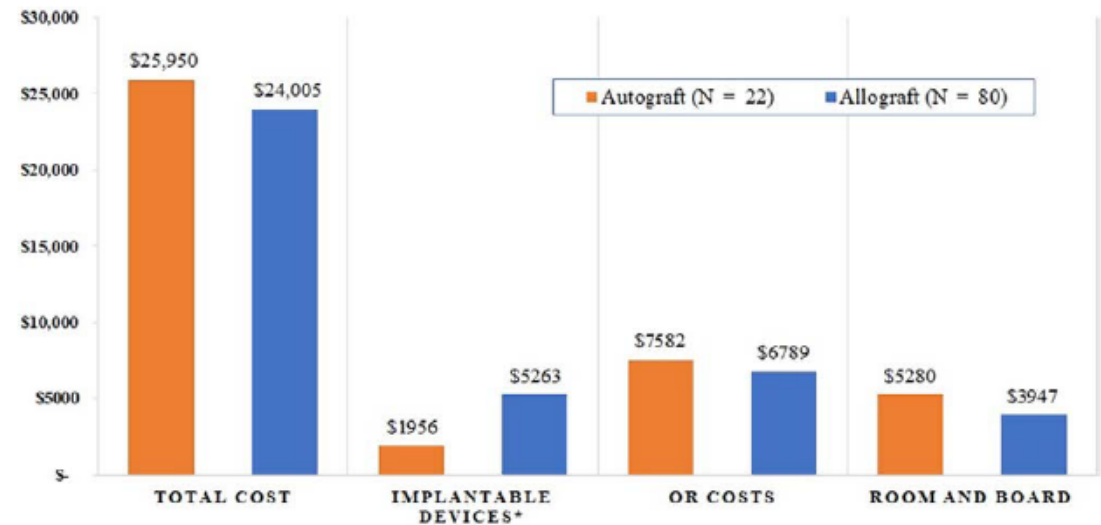


Fig. 3. Inpatient descriptive costs of nerve repair graft type (n = 102).

# Focus on building awareness among clinicians and patients

## Build Market Awareness

- Increasing omnichannel engagement with clinicians and patients
- Continuing clinical conference participation both virtually and in-person as appropriate
- Ongoing patient ambassador program
- Garnering positive media attention
- Growing social media presence



.....<sup>®</sup>  
resensation

rethink pain<sup>®</sup>



Knowledge is power: continued education and advocacy efforts with patients, clinicians and key legislators elevates the problems associated with numbness.



## Creating A NEW WAY TO DEFINE BREAST CANCER

THE DESIGNATION OF HER2-LOW STATUS IS RAPIDLY RESHAPING HOW RESEARCHERS AND CARE PROVIDERS THINK ABOUT BREAST CANCER.

## Coping With Sensation Loss After Mastectomy

Chest numbness can be truly daunting, but patients don't have to suffer in silence — and it may not be something they have to live with.

By CARLA MARIE MANLY, PH.D.

**JUST AS** A loss of hearing or sight can fundamentally shape a patient's identity, so too can a loss of sensation, especially in an area of the body as essential to

### SPEAK UP, INVESTIGATE OPTIONS

A patient who underwent a mastectomy may be hesitant to talk about chest numbness. Perhaps she feels she should just be grateful others will think it's just a loss of chest sensation without a loss of chest sensation in the intimate area

psychologist, my first intention was to talk with my physician about interventions are available whenever I don't have to wait for the potential for my care team. I potentially restore my nerves are severed is removed. If the connection between the chest and their abdomen. Mastectomy years ago I had neurotization (breast reconstruction) connect nerves cut a nerve graft at the time or during some revision over time, which can



4 things to consider when finding the right plastic surgeon  
Page 16

Helping a woman reclaim her body in time  
HELP WOMEN RECLAIM AFTER MASTECTOMY Page 6



Features  
Regaining Feeling and Restoring Intimacy by Jessica de Paz



### SIDE-EFFECTS MANAGEMENT BREAST CANCER

## Dealing with Chest Numbness After Mastectomy

By Kristen Casey, PsyD

October 2022 Vol 8 No 5

Chest numbness is a side effect often ignored or not discussed in breast cancer, but losing physical sensation in nearly 10% of the body can have a profound impact on a woman's physical and emotional life.



# Emphasis on education

Educate Surgeons,  
Develop Advocates

- In-person and virtual national education programs
- Customized multimodal learning programs to specific surgeon groups for advanced learning
- Ongoing interactive webinar series covering the principles of nerve repair
- Emphasis on training hand and micro-surgery fellows



masterminds  
of nerve



# Focused sales execution, increasing market penetration



## Execute Sales Plan

### **Sales execution focused on driving results**

- Continue driving penetration in High-Potential Accounts

### **Broad sales reach**

- U.S. direct sales team
- Supplemented by independent agencies



**Committed to our patients, the communities we serve, and our pursuit of advancing the science of nerve repair in ethical and sustainable ways**

**People Sustainability Business**

**Diversity, Equity, and Inclusion** - Being the Company where exceptional people want to work

**Cybersecurity** – Data Privacy, Training, and Policies

**Compliance** – Quality Management System, Regulatory, and Good Manufacturing Practices

**Governance** – Framework for Ethics Codes and Accountability

**Environment** – Responsible, Sustainable Operations

# Executive team



**Michael Dale**  
Chief Executive Officer & Board  
Director  
Abbot Laboratories  
Effective: 8.9.2024



**Marc Began**  
Executive Vice President, General Counsel  
Abiomed, Boehringer Ingelheim, Novo Nordisk



**Nir Naor**  
Chief Financial Officer  
Arbor Pharmaceuticals, Mölnlycke  
Healthcare, UCB



**Erick DeVinney**  
Chief Innovation Officer  
Angiotech, PRA Intl



**Jens Schroeder Kemp**  
Chief Marketing Officer  
Ambu, Pera International



**Ivica Ducic, M.D., Ph.D.**  
Chief Medical Officer  
Washington Nerve Institute



**Todd Puckett**  
VP, Operations  
NuVasive, Zimmer



**Stacy Arnold**  
VP, Product Development and Clinical  
Research  
Artivion (CryoLife)



**Al Jacks**  
VP, Quality Assurance  
VERO Biotech, Alimera Sciences

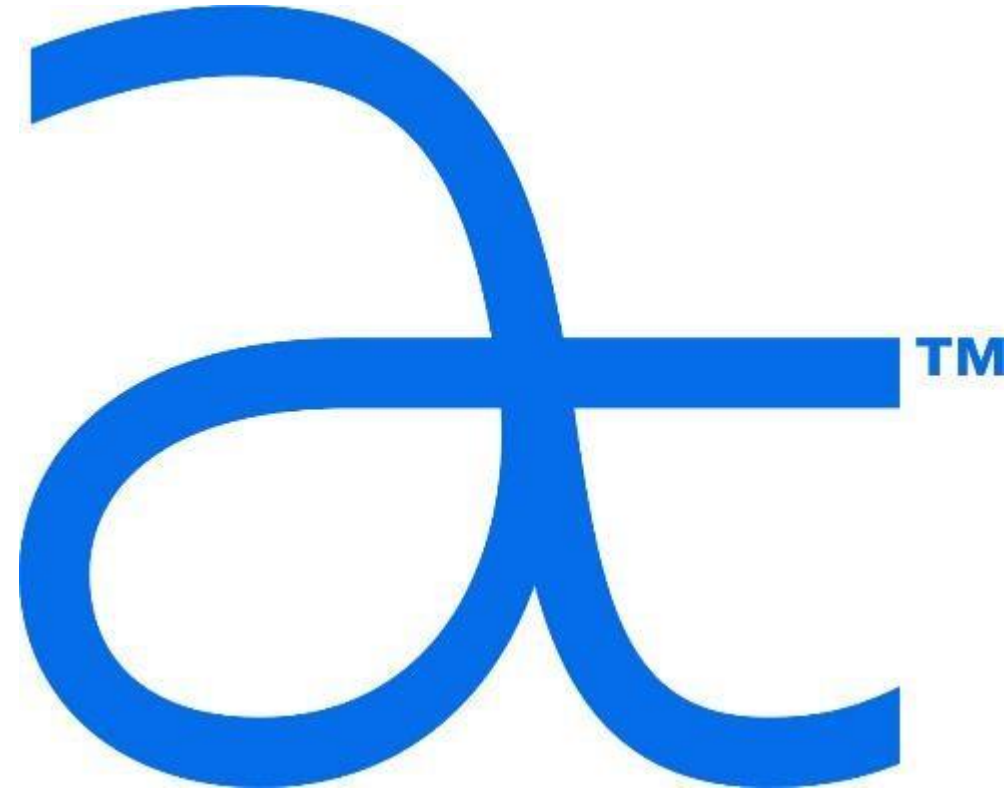


**Doris Quackenbush**  
VP, Sales  
Convatec



# Appendix

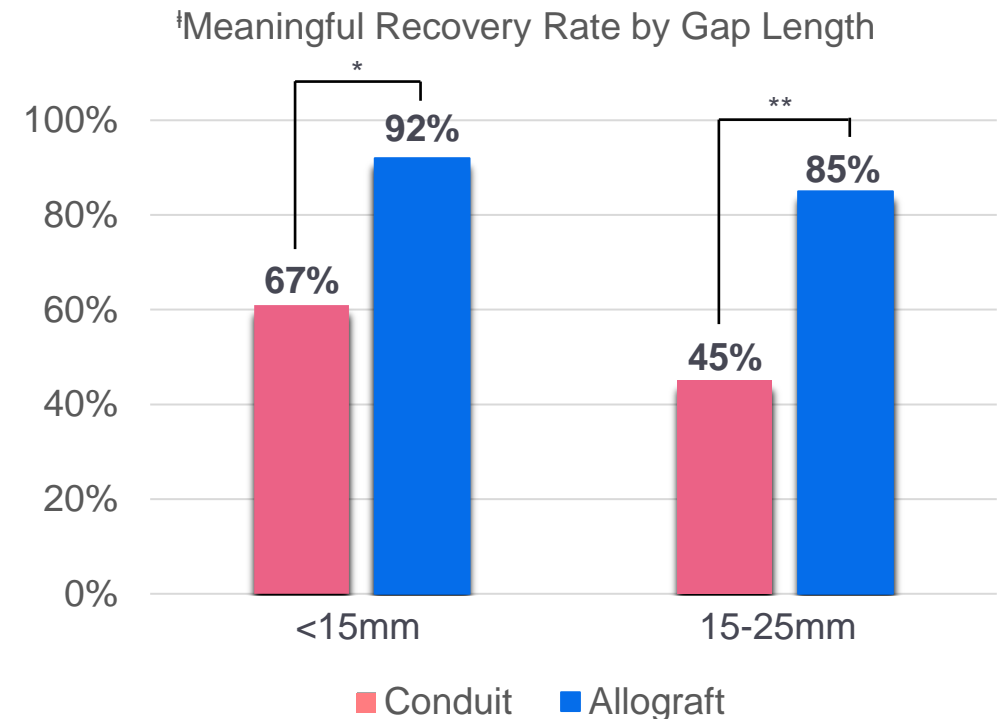
- Key clinical data
- CMS outpatient and ASC reimbursement rates
- Total addressable market
- Cash, debt, and capital structure
- Axogen product portfolio and indications for use



# Avance nerve graft repairs found to be significantly better than conduit repairs

“Liversedge et al., A Multicenter Matched Cohort Study of Processed Nerve Allograft and Conduit in Digital Nerve Reconstruction” – *Journal of Hand Surgery, September 2020*<sup>44</sup>

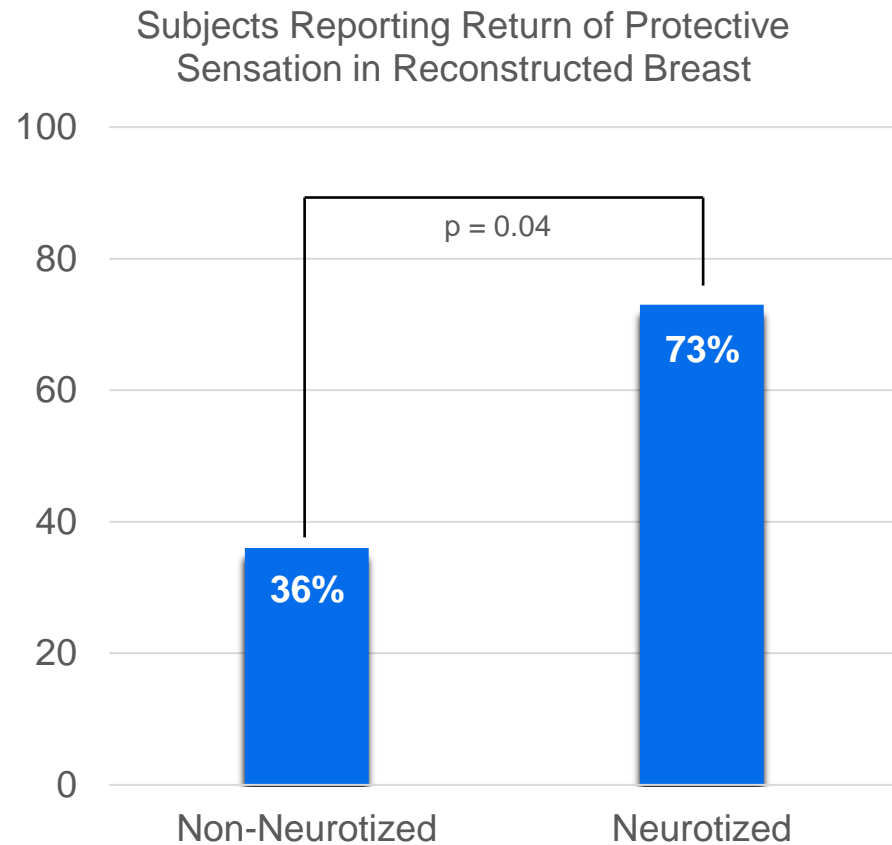
- Peer-reviewed publication from the MATCH cohort of the RANGER Registry
- Includes outcomes from 110 subjects with 162 nerve injuries; 113 were repaired with Avance nerve graft and 49 were repaired with manufactured conduit
- Findings show overall meaningful recovery rate was 88% for Avance nerve graft and 61% for conduit (p=0.001) for gaps up to 25mm
- Average static two-point discrimination improved to 9.7mm for Avance nerve graft as compared to 12.2mm for conduit (p=0.018)
  - Note: lower measurement is reflective of improved discrimination and a better outcome
- As gap length increased, Avance nerve graft outcome rates remained consistent while conduit rates declined significantly



†Meaningful Recovery =  $\geq$ S3 on the MRCC Scale  
\*p=0.008, \*\*p=0.001

# First publication on breast neurotization outcomes with Avance Nerve Graft demonstrated greater return of protective sensation

“Momeni et al., Flap Neurotization in Breast Reconstruction with Nerve Allografts: 1-year Clinical Outcomes” – *Plastic and Reconstructive Microsurgery Global Open, January 2021*<sup>46</sup>



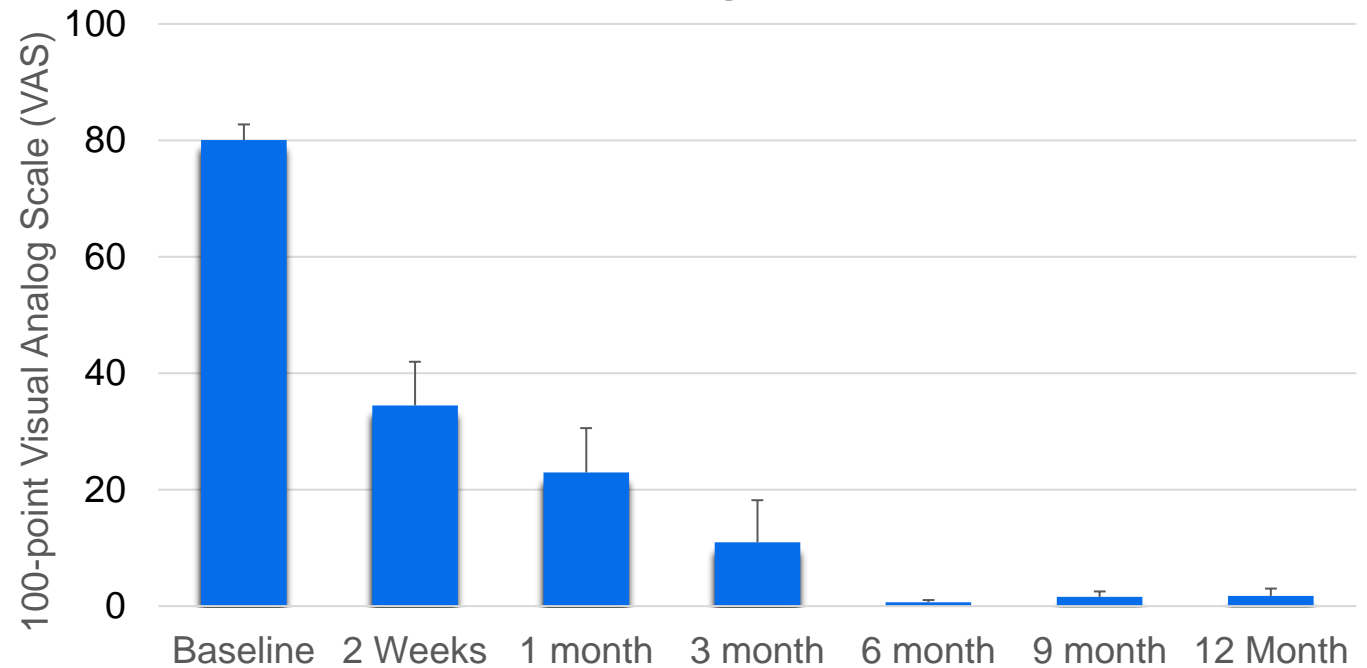
- Early outcomes from a single center study, as part of the Sensation-NOW<sup>®</sup> registry
- 36 breast reconstructions that included:
  - 22 breast reconstructions with Resensation<sup>®</sup>
  - 14 standard non-neurotized breast reconstructions
- Return of Protective Sensation (p=0.04)
  - 73% of the Resensation group
  - 36% of the non-neurotized group
- Neurotization with Avance Nerve Graft resulted in greater return of sensation and return of sensation in more of the breast as compared to standard reconstruction without nerve repair.

# Axogen sponsored REPOSE<sup>SM</sup> pilot study analysis demonstrates clinically significant improvement for subjects with chronic neuropathic pain when using Axoguard Nerve Cap<sup>®</sup> following neurectomy<sup>47</sup>

15-subject, single arm pilot phase evaluating reduction in pain from baseline following surgical excision of the neuroma and placement of the Axoguard Nerve Cap

- Significant & clinically meaningful reduction in pain
- Significant and clinically meaningful improvements in Fatigue, Physical Function, Sleep Disturbance, Pain Interference, Pain Intensity, and Pain Behavior as measured by the validated PROMIS<sup>®</sup> measures
- Positive indicators for reduction in pain medication burden, including opioids
- No recurrence of neuroma

Clinically meaningful reduction in pain sustained through 12 months



Minimal Clinically Important Difference (MCID): 17mm

$\Delta$  3 months:  $-69 \pm 23$ ;  $p < 0.0001$

$\Delta$  12 months:  $-80 \pm 13$ ;  $p < 0.0001$

# 2024-25 YOY CMS *Proposed* outpatient reimbursement rates - hospital and ASC

Although CMS rates<sup>1</sup> only apply to Medicare cases, which represents a small percentage of traumatic injuries, private payors are often influenced by the analysis and decisions made by CMS

CPT Code	Descriptor	C-APC	Hospital Outpatient (HOPD)			Ambulatory Surgery Center (ASC)		
			2024	Proposed 2025	% Change	2024	Proposed 2025	% Change
64912	Nerve allograft repair <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,579	<b>\$4,644</b>	<b>1.41%</b>
64910	Conduit or vein allograft repair <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,288	<b>\$4,495</b>	<b>4.82%</b>
64885	Autograft repair (head and neck ≤4cm) <sup>6</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,496	<b>\$3,136</b>	<b>-30.25%</b>
64886	Autograft repair (head and neck >4cm) <sup>3</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,013	<b>\$3,984</b>	<b>32.23%</b>
64890	Autograft repair (hand and foot ≤4cm) <sup>6</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,583	<b>\$3,136</b>	<b>-31.58%</b>
64891	Autograft repair (hand and foot >4cm) <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,794	<b>\$3,984</b>	<b>5.01%</b>
64892	Autograft repair (arm and leg ≤4cm) <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,616	<b>\$4,875</b>	<b>5.62%</b>
64893	Autograft repair (arm and leg >4cm) <sup>6</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,677	<b>\$3,136</b>	<b>-32.95%</b>
64897	Autograft repair (arm and leg ≤4cm multiple strands) <sup>6</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$4,083	<b>\$3,136</b>	<b>-23.20%</b>
64895-96,98	Autograft repair (all other nerve type) <sup>5</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,013	<b>\$3,136</b>	<b>4.08%</b>
64834-36, 40, 56, 57, 62-64	Direct Repair (other hand / foot, arm/leg, repair / transpose, facial, low back,) <sup>5</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,013	<b>\$3,136</b>	<b>4.08%</b>
64865	Direct Repair of facial nerve <sup>2</sup>	5432	\$6,354	<b>\$6,437</b>	<b>1.30%</b>	\$3,796	<b>\$3,984</b>	<b>4.95%</b>
64831, 61	Direct Repair (digital, brachial plexus/arm) <sup>4</sup>	5431	\$1,842	<b>\$1,946</b>	<b>5.66%</b>	\$898	<b>\$921</b>	<b>2.52%</b>
64858	Direct Repair (sciatic) <sup>4</sup>	5431	\$1,842	<b>\$1,946</b>	<b>5.66%</b>	\$1,497	<b>\$921</b>	<b>-38.50%</b>

1. National average payment rates. Commercial payments are traditionally 1.5-2x higher than Medicare.
2. Nerve allograft repair CPT 64912, conduit repair CPT 64910, autograft repairs hand/foot >4cm CPT 64891, arm/leg≤4cm CPT 64892, direct repair of facial nerve CPT 64865 remain in C-APC 5432 all continue to meet ASC device intensive criteria
3. Autograft repair head/neck >4cm CPT 64886 meets ASC device intensive criteria in 2025
4. Direct repair digital CPT codes 64831, brachial plexus/arm 64861, and sciatic 64858 remain in C-APC 5431 and do not meet ASC device intensive criteria and in 2025 direct repair sciatic 64858 lost device intensive status.
5. Autograft repair all other nerve type CPT 64895-96,98 and Direct repair other hand/foot CPT 64834-36, leg CPT 64840, repair/transpose CPT 64856, arm/leg CPT 64857, low back CPT 64862-64 remain in C-APC 5432 and do not meet ASC device intensive criteria
6. Autograft repair head/neck >4cm CPT 64885, head/neck >4cm CPT 64890, arm and leg >4cm, and arm and leg ≤4cm multiple strands CPT 64897 remains in C-APC 5432 and no longer meets ASC device intensive criteria in 2025.

# 2024-25 YoY Center for Medicare and Medicaid Services (CMS): *Proposed* Physician Fee Schedule (PFS)

CPT Codes to f	Descriptor	Physician Fee Schedule (PFS)		
		2024	2025 Proposed	% Change
64912	Nerve allograft repair	\$897	<b>\$880</b>	<b>-1.95%</b>
64910	Conduit or vein allograft repair	\$765	<b>\$752</b>	<b>-1.65%</b>
64885 to 64898*	Autograft repair	\$1,053 to \$1,427	<b>\$1,032 to \$1,400</b>	<b>-1.9% to -2.00%</b>
64831 to 64865*	Direct Repair	\$701 to \$1,548	<b>\$691 to \$1,514</b>	<b>-1.49% to -2.17%</b>

\*excludes add-on procedure codes

# 2019-25 CMS *Proposed* outpatient reimbursement rates - hospital and ASC

Although CMS rates<sup>1</sup> only apply to Medicare cases, which represents a small percentage of traumatic injuries, private payors are often influenced by the analysis and decisions made by CMS

CPT Code	Descriptor	C-APC	Hospital Outpatient (HOPD)				Ambulatory Surgery Center (ASC)			
			2019	2024	2025 Proposed	6Y % Change	2019	2024	2025 Proposed	6Y % Change
64912	Nerve allograft repair <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,579	<b>\$4,644</b>	<b>141.88%</b>
64910	Conduit or vein allograft repair <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$2,613	\$4,288	<b>\$4,495</b>	<b>72.02%</b>
64885	Autograft repair (head and neck ≤4cm) <sup>6</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,496	<b>\$3,136</b>	<b>63.33%</b>
64886	Autograft repair (head and neck >4cm) <sup>3</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$3,127	\$3,013	<b>\$3,984</b>	<b>27.41%</b>
64890	Autograft repair (hand and foot ≤4cm) <sup>6</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$3,075	\$4,583	<b>\$3,136</b>	<b>1.98%</b>
64891	Autograft repair (hand and foot >4cm) <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$3,794	<b>\$3,984</b>	<b>107.50%</b>
64892	Autograft repair (arm and leg ≤4cm) <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,616	<b>\$4,875</b>	<b>153.91%</b>
64893	Autograft repair (arm and leg >4cm) <sup>6</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,677	<b>\$3,136</b>	<b>63.33%</b>
64897	Autograft repair (arm and leg ≤4cm multiple strands) <sup>6</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$4,083	<b>\$3,136</b>	<b>63.33%</b>
64895-96,98	Autograft repair (all other nerve type) <sup>5</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$3,013	<b>\$3,136</b>	<b>63.33%</b>
64834-36, 40, 56, 57, 62-64	Direct Repair (other hand / foot, arm/leg, repair / transpose, facial, low back,) <sup>5</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$3,013	<b>\$3,136</b>	<b>63.33%</b>
64865	Direct Repair of facial nerve <sup>2</sup>	5432	\$4,566	\$6,354	<b>\$6,437</b>	<b>40.98%</b>	\$1,920	\$3,796	<b>\$3,984</b>	<b>107.50%</b>
64831, 61	Direct Repair (digital, brachial plexus/arm) <sup>4</sup>	5431	\$4,566	\$1,842	<b>\$1,946</b>	<b>-57.38%</b>	\$1,920	\$898	<b>\$921</b>	<b>-52.03%</b>
64858	Direct Repair (sciatic) <sup>4</sup>	5431	\$4,566	\$1,842	<b>\$1,946</b>	<b>-57.38%</b>	\$1,920	\$1,497	<b>\$921</b>	<b>-52.03%</b>

- National average payment rates. Commercial payments are traditionally 1.5-2x higher than Medicare.
- Nerve allograft repair CPT 64912, conduit repair CPT 64910, autograft repairs hand/foot >4cm CPT 64891, arm/leg≤4cm CPT 64892, direct repair of facial nerve CPT 64865 remain in C-APC 5432 all continue to meet ASC device intensive criteria
- Autograft repair head/neck >4cm CPT 64886 meets ASC device intensive criteria in 2025
- Direct repair digital CPT codes 64831, brachial plexus/arm 64861, and sciatic 64858 remain in C-APC 5431 and do not meet ASC device intensive criteria and in 2025 direct repair sciatic 64858 lost device intensive status.
- Autograft repair all other nerve type CPT 64895-96,98 and Direct repair other hand/foot CPT 64834-36, leg CPT 64840, repair/transpose CPT 64856, arm/leg CPT 64857, low back CPT 64862-64 remain in C-APC 5432 and do not meet ASC device intensive criteria
- Autograft repair head/neck >4cm CPT 64885, head/neck >4cm CPT 64890, arm and leg >4cm, and arm and leg ≤4cm multiple strands CPT 64897 remains in C-APC 5432 and no longer meets ASC device intensive criteria in 2025.

# 2019-25 Center for Medicare and Medicaid Services (CMS): *Proposed* Physician Fee Schedule (PFS)

CPT Codes <sup>3</sup>	Descriptor	Physician Fee Schedule (PFS)			
		2019	2024	2025 Proposed	6Y % Change
64912	Nerve allograft repair	\$804	\$897	<b>\$880</b>	<b>9.40%</b>
64910	Conduit or vein allograft repair	\$825	\$765	<b>\$752</b>	<b>-8.80%</b>
64885 to 64898*	Autograft repair	\$1,096 to \$1,495	\$1,053 to \$1,427	<b>\$1,032 to \$1,400</b>	<b>-5.84% to -6.36%</b>
64831 to 64861*	Direct Repair	\$713 to \$1,604	\$701 to \$1,548	<b>\$691 to \$1,514</b>	<b>-3.15% to -5.58%</b>

\*excludes add-on procedure codes



# Estimated Trauma total addressable market

Patient Population <sup>(a)</sup>	Source	Adjustments and Rationale
<p><b>136,943,000</b> Annual emergency department visits in the U.S.</p>	<p>2015 National Hospital Ambulatory Medical Care Survey (Table 1)<sup>1</sup></p>	
<div style="border: 1px solid black; padding: 10px; text-align: center;"> <p><b>30,238,000</b> Annual emergency department visits <u>due to injury</u> in the U.S.</p> <p>✖</p> <p><b>4.76%</b> Percentage of emergency department visits <u>with nerve injury</u></p> <p>=</p> </div>	<p>2015 National Hospital Ambulatory Medical Care Survey (Table 18)<sup>1</sup></p> <p><i>Noble, et al: J Trauma, Volume 45(1) July 1998.116-122</i><sup>2</sup></p>	<ul style="list-style-type: none"> <li>Adjusted from 38,959,000 to exclude 8,721,000 injuries that are unlikely to include a nerve injury (i.e., mental disorders, skin conditions, etc.)</li> <li>2.8% rate cited in <i>Noble, et al</i> study excluded 113 patients coded with nerve injuries outside of the study scope, but that are in the Axogen scope of nerve repair (brachial plexus and digital nerve injuries). Including these injuries increases the rate to 4.76%.</li> </ul>
<div style="border: 1px solid black; padding: 10px; text-align: center;"> <p><b>1,440,000</b> Annual emergency department visits with nerve injury in the U.S.</p> <p>✖</p> <p><b>46.2%</b> Percentage of ED nerve injuries estimated to be treated surgically</p> <p>=</p> <p><b>~665,000</b></p> <p><b>Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions</b></p> </div>	<p><i>Noble, et al: J Trauma, Volume 45(1) July 1998.116-122</i><sup>2</sup></p>	<ul style="list-style-type: none"> <li>Calculated rate based on various rates in <i>Noble et al</i> study for upper and lower extremity and an estimate for other trauma nerves.</li> </ul>

a) Patient population figures rounded to the nearest thousandth.

# Trauma total addressable market (continued)

Patient Population <sup>(a)</sup>	Source	Adjustments and Rationale
<div style="text-align: center;"> <p><b>~665,000</b></p> <p>Annual emergency department visits with nerve injury that can be treated surgically in the U.S., <u>excluding revisions</u></p> <p><b>×</b></p> <p><b>7.4%</b></p> <p>Revision cases</p> <hr style="width: 20%; margin: 10px auto;"/> <p><b>=</b></p> <p><b>714,000</b></p> <p>Annual emergency department visits with nerve injury that can be treated surgically in the U.S., <u>including revisions</u></p> <p><b>↓</b></p> <p><b>~700,000</b></p> <p><b>Company estimate of trauma total addressable market</b></p> </div>	<p>See calculation on previous slide</p> <p><i>Portincasa et al: Microsurgery 27:455-462, 2007<sup>4</sup></i></p>	<ul style="list-style-type: none"> <li><i>Portincasa et al</i> suggests that a revision procedure was necessary in 7.4% of the patients within 6 months of the initial surgery.</li> </ul>

a) Patient population figures rounded to the nearest thousandth.

# Estimated \$2.7B value of market opportunity in existing applications

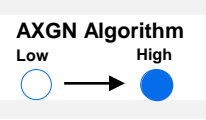
	Projected Incidence <sup>(a)</sup>	×	Weighted Average Procedure Value	=	Estimated Total Addressable Market
Trauma	700,000 100%		\$2,715		\$1,900M 100%
Transection injuries >5mm (b)	203,000 29%		\$5,515		\$1,120M 59%
Transection injuries <5mm	198,000 29%		\$1,200		\$238M 12%
Non-Transected Injuries (c)	293,000 42%		\$1,825		\$535M 28%
Carpal and Cubital Tunnel Protection	130,000		\$2,100		\$270M
Oral and Maxillo-Facial (OMF)	56,000		\$5,400		\$300M
Breast Reconstruction Neurotization	24,500 flaps (15,000 patients)		\$10,200		\$250M
<b>Totals</b>	<b>&gt;900,000 (potential)</b>				<b>&gt;\$2.7B</b>

a) Estimated Annual incidence of PNI surgery are figures rounded to the nearest thousandth except for Breast Reconstruction Neurotization (rounded to nearest hundredth).

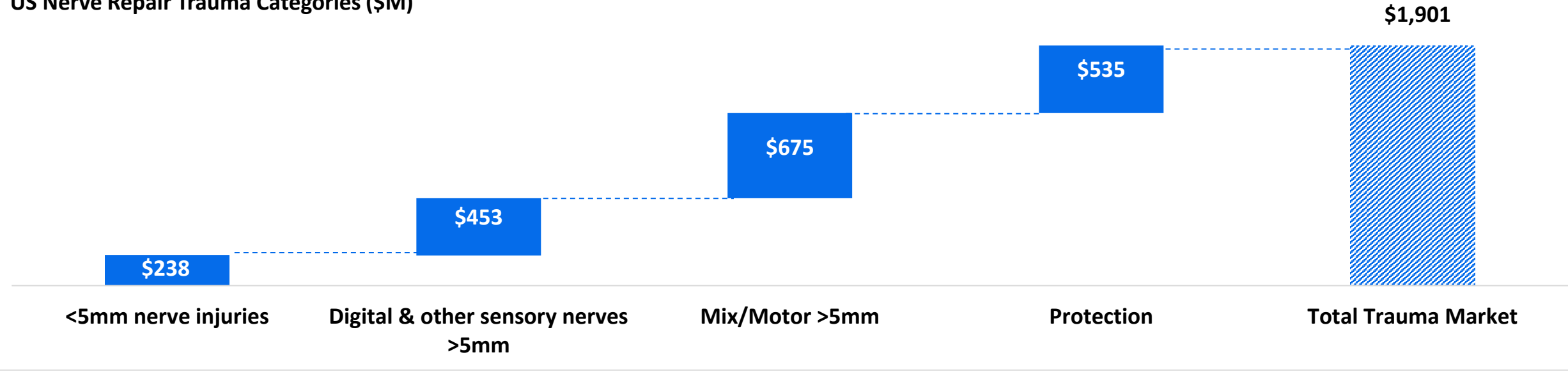
b) Transection injuries > 5mm assumes a factor of 1.22 nerve repairs per procedures, and utilization of the Axogen portfolio of products, based upon data observed in the RANGER® registry.

c) Protection includes non-transected compression and crush injuries including protection from surrounding soft tissue attachments.

# We continue to see a significant growth opportunity in the trauma market as we leverage new clinical & health economic data and product launches, by category



US Nerve Repair Trauma Categories (\$M)



Category	Trends and Growth Levers
<ul style="list-style-type: none"> <li>Short gap transected nerve injuries</li> </ul>	<ul style="list-style-type: none"> <li>Routine trauma moving to ASCs and lower cost sites of care</li> <li>Education and awareness of proper nerve repair technique</li> <li>Improve procedure awareness and scheduling across all care settings</li> <li>Private payer adoption of improved CMS reimbursement guidelines</li> </ul>
<ul style="list-style-type: none"> <li>Digital Sensory 5-25mm</li> <li>Digital Sensory &gt;25mm</li> </ul>	<ul style="list-style-type: none"> <li>Routine trauma moving to ASCs and lower cost settings</li> <li>Education and awareness of proper nerve repair technique</li> <li>New Clinical data from Recon/Meta-analysis</li> <li>All Payor Procedural Cost analysis</li> <li>Societal support for standard of care</li> <li>Improved private payer reimbursement</li> <li>Activating middle adopters</li> </ul>
<ul style="list-style-type: none"> <li>Mixed/Motor 5-25mm</li> <li>Mixed/Motor &gt;25mm</li> </ul>	<ul style="list-style-type: none"> <li>Motor clinical outcome data from Meta-analysis</li> <li>Societal support for standard of care</li> <li>Prof ed on appropriate surgical technique &amp; algorithm</li> <li>Improved private payer reimbursement</li> <li>Activating middle adopters</li> </ul>
<ul style="list-style-type: none"> <li>Protection from non transected nerve injuries</li> </ul>	<ul style="list-style-type: none"> <li>New product launches of Axoguard HA+™ and Avive+ Soft Tissue Matrix to address acute and chronic applications</li> <li>Increased awareness of Non-Transected Nerve Injuries</li> <li>Clinical evidence generation</li> <li>Professional education on appropriate surgical technique &amp; algorithm</li> <li>Reimbursement coding and coverage</li> </ul>

Axogen has, until now, focused primarily in digital and short gap but new evidence and product launches will open full peripheral nerve injury trauma market

# Balance sheet and capital structure

Balance Sheet Highlights	September 30, 2024
Cash	\$30.5 million*
Total Long-term Debt	\$47.3 million**

Capital Structure (shares)	September 30, 2024
Common Stock	44,002,323
Common Stock Options, RSUs, PSUs	9,436,475
Common Stock and Common Stock Equivalents	53,438,798

\* Includes Cash, Cash Equivalents, Restricted Cash, and Investments

\*\* Total long-term debt includes debt proceeds under the terms of the agreement with Oberland Capital does not include unamortized debt discount and deferred financing fees.

# Axogen comprehensive portfolio of products

## Avance<sup>®</sup> Nerve Graft

- **Regulatory Classification:** Avance Nerve Graft is processed and distributed in accordance with US Food and Drug (FDA) requirements for Human Cellular and Tissue-based Products (HCT/P) under 21 CFR Part 1271 regulations, US State regulations, and applicable international regulations. Axogen Corporation is accredited by the American Association of Tissue Banks (AATB). Additionally, international regulations are followed as appropriate.
- **Indication for Use:** Avance Nerve Graft is processed nerve allograft (human) intended for the surgical repair of peripheral nerve discontinuities to support regeneration across the defect.
- **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.

## Axoguard Nerve Connector<sup>®</sup>

- **Regulatory Classifications:** Class II Medical Devices - 510(k) cleared, Class III Medical Devices, CE Marked (EU), Class 4 (CA)
- **Indications for Use (US):** The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity. The Axoguard Nerve Connector is supplied sterile and is intended for single use.
- This product is intended for use by trained medical professionals.
- **Indications for Use (EU and UK):** The Axoguard Nerve Connector is indicated for the repair of peripheral nerve discontinuities with gaps up to 5 mm. The Axoguard Nerve Connector is supplied sterile and is intended for single use.
- This product is intended for use by trained medical professionals.
- **Contraindications:** This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material. This device is not intended for use in vascular applications.

## Axoguard Nerve Protector<sup>®</sup>

- **Regulatory Classifications:** Class II Medical Devices - 510(k) cleared, Class III Medical Device, CE Marked (EU), Class 4 (CA)
- **Indication for Use:** Axoguard Nerve Protector is indicated for the repair of peripheral nerve injuries in which there is no gap. The Axoguard Nerve Connector is supplied sterile and is intended for single use.
- This product is intended for use by trained medical professionals.
- **Contraindications:** This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material. This device is not intended for use in vascular applications.



# Axogen comprehensive portfolio of products (Cont'd)

## Axoguard Nerve Cap®

- **Regulatory Classification:** Class II Medical Device – 510(k) cleared
  - **Indications for Use:** Axoguard Nerve Cap is indicated to protect a peripheral nerve end and to separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma.
  - This product is intended for use by trained medical professionals.
  - **Contraindications:** Axoguard Nerve Cap is derived from a porcine source and should not be used for patients with known sensitivity to porcine derived materials. Axoguard Nerve Cap is contraindicated for use in any patient for 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. Axoguard Nerve Cap should not be implanted directly under the skin. This device is not intended for use in vascular applications.
- **Axoguard HA+ Nerve Protector™**
    - **Regulatory Classifications:** Class II Medical Devices - 510(k) cleared (K223640)
    - **Indication for Use:** Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap.
    - This product is intended for use by trained medical professionals.
    - **Contraindications:** Axoguard HA+ Nerve Protector base membrane is derived from a porcine source and the lubricant coating is composed of sodium hyaluronate and sodium alginate. The Axoguard HA+ Nerve Protector should not be used for patients with known sensitivity to porcine, alginate, or hyaluronate materials. This device is not intended for use in vascular applications.
  - **Axoguard HA+ Nerve Protector™**
    - **Regulatory Classifications:** Class II Medical Devices - 510(k) cleared ( K231708)
    - **Indication for Use:** Axoguard HA+ Nerve Protector is indicated for the management of peripheral nerve injuries where there is no gap, or following closure of the gap.
    - This product is intended for use by trained medical professionals.
    - **Contraindications:** Axoguard HA+ Nerve Protector base membrane is derived from a porcine source and the lubricant coating is composed of sodium hyaluronate and sodium alginate. The Axoguard HA+ Nerve Protector should not be used for patients with known sensitivity to porcine, alginate, or hyaluronate materials. This device is not intended for use in vascular applications.

# Axogen comprehensive portfolio of products (Cont'd)

## Avive+ Soft Tissue Matrix™

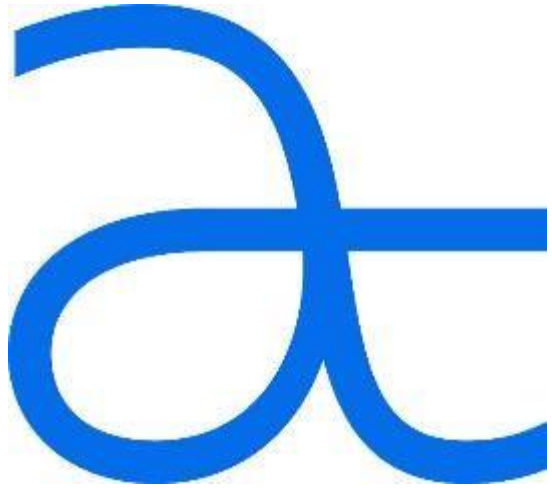
- **Regulatory Classification:** Avive+ Soft Tissue Matrix is processed and distributed in accordance with US Food and Drug (FDA) requirements for Human Cellular and Tissue-based Products (HCT/P) under 21 CFR Part 1271 regulations, and US State regulations. Axogen Corporation is accredited by the American Association of Tissue Banks (AATB).
- **Intended Use:** Avive+ Soft Tissue Matrix is processed amniotic membrane intended for use as a soft tissue barrier.
- This product is intended for use by trained medical professionals.
- **Contraindications:** Avive+ Soft Tissue Matrix 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.

# Footnotes

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# Footnotes

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