UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

Current Report
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 5, 2024

AXOGEN, INC.

(Exact Name of Registrant as Specified in Charter)

Minnesota	**001-36046**	**41-1301878**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

13631 Progress Boulevard, Suite 400 Alachua, Florida	**32615**
(Address of principal executive offices)	(Zip Code)

(386) 462-6800
(Registrant's telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e- 4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, $0.01 par value	AXGN	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On January 5, 2024, the Company posted an updated corporate presentation to its website at https://ir.axogeninc.com/news-events. The Company may use the investor presentation from time to time in conversation with analysts, investors and others. A copy of the investor update is furnished as Exhibit 99.1.

The information in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section and shall not be deemed incorporated by reference into any filing under the Securities Act or Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits	See the Exhibit index below, which is incorporated herein by reference.

Exhibit No.	Description
99.1	Axogen, Inc. Corporate Presentation, dated January 5, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AXOGEN, INC.

Dated: January 8, 2024

By: Marc Began

Marc Began
Executive Vice President, General Counsel and Chief Compliance Officer

Corporate presentation

January 5, 2024

nasdaq: axgn

axogen®

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) 2023 financial guidance, including revenue range and gross margins, (3) growth drivers for the business, (4) expectation that RECON℠ study topline results will support our BLA filing in the first half of 2024, (5) timing of filing of the BLA and our ability to utilize a rolling submission, (6) timing of transition of the APC facility and APC future capacity, (7) opportunities in the peripheral nerve repair market, (8) 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, and (9) the expected fourth quarter revenue of $42.7 million and full-year 2023 revenue of $158.8 million.

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, APC renovation timing and expense, 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, 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 and Part II, Item 1A., "Risk Factors," for our Quarterly Report on Form 10-Q for the most recently ended fiscal quarter. 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
- 10+ years of demonstrated clinical outcome consistency
- Over 200 peer-reviewed clinical publications
- Over 100,000 Avance® nerve grafts implanted
- Significant barriers to competitive entry
- 116 U.S. sales reps
- Patient activation and surgeon education capabilities

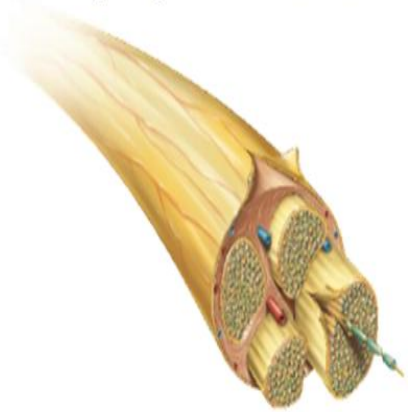
The function of nerves and injury types

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

A comprehensive platform for addressing nerve injuries

one company for all your surgical nerve repair solutions

avance® nerve graft

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

axoguard nerve connector®

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

axoguard nerve protector®

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

axoguard HA+™ 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.

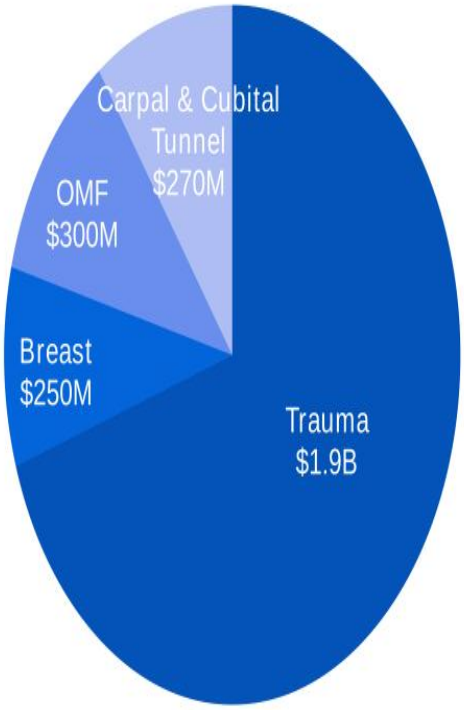
axoguard nerve cap®

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

Connection	Protection	Termination

Targeted nerve markets (U.S.)

>$2.7 Billion*



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

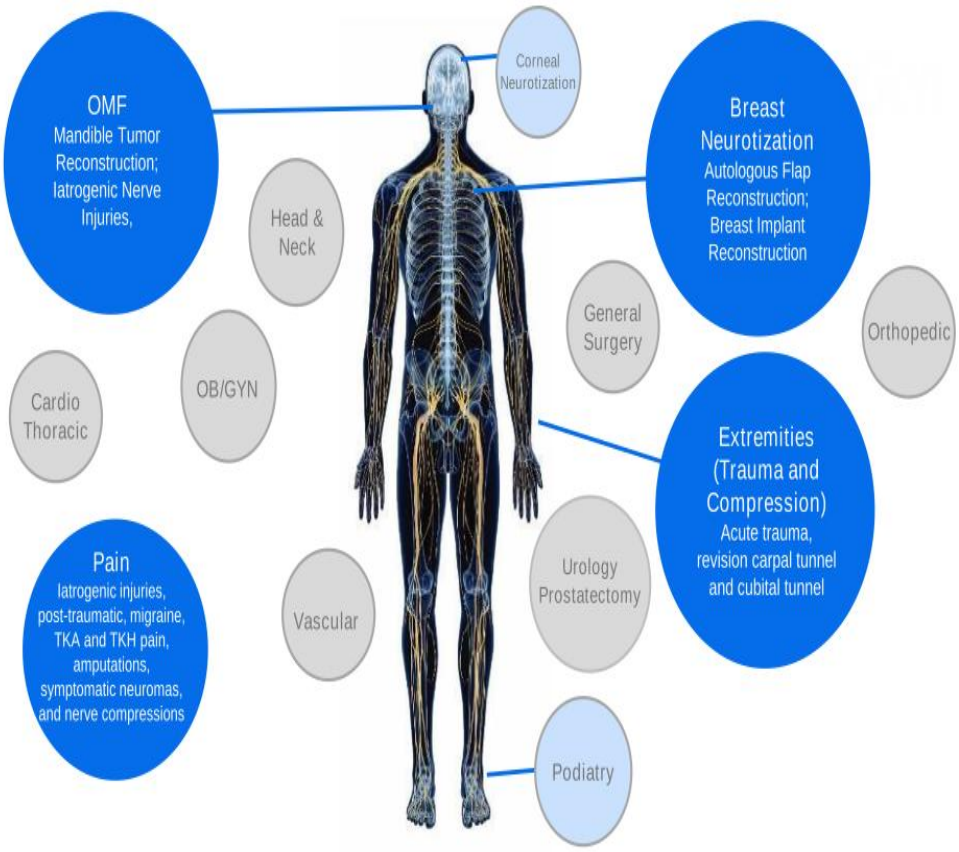
- Trauma: > 700,000
- Carpal Tunnel Revisions & Cubital Tunnel: 130,000
- Oral Maxillofacial (OMF): 56,000
- Breast Neurotization Procedures: 15,000

*$2.7B estimate does not include pain market

**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.

Opportunities in nerve repair

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

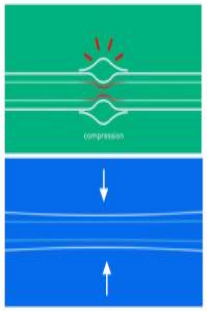


Applications for our products include two primary categories

Emergent Trauma Procedure Examples

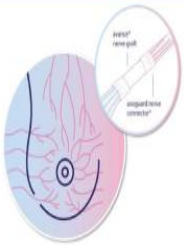
Transected sensory nerves

Transected mixed/motor nerves



Non-transected nerve injury

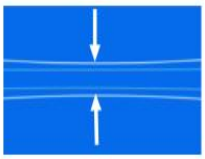
Scheduled Procedure Examples



Breast reconstruction

Mandibular reconstruction

Neuroma repair



Cubital and carpal tunnel revisions

Emergent trauma cases generally result from injuries that initially present in an ER

Emergent Procedures:

- Significant number of nerve injuries typically referred to and completed by a specialist either immediately or within a few days following the injury with limited post op follow-up evaluations
- Emergent and diverse nature of injuries result in variable patient pathways from ER to nerve repair specialist and diverse repair algorithms
- Specialist surgeons typically perform nerve repair as a minor portion of their overall practice
- Opportunity to drive care pathways with surgeon education supported by clinical and economic data
- Opportunity to shift site of care for routine traumatic injuries to more cost-efficient settings (ASC)

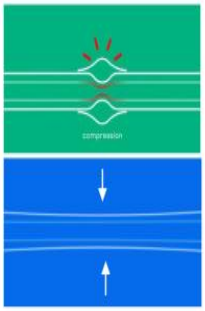
Emergent Trauma Procedure Examples

Transected sensory nerves

Digital nerve injury after sharp lacerations e.g., a knife slipping when cutting an avocado, glass injuries

Transected mixed/motor nerves

More complex trauma injuries e.g., circular saw injury to hand and wrist resulting in ulnar and median nerve damage



Non-transected nerve injury

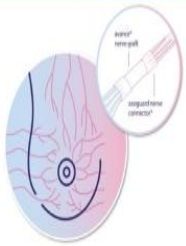
Trauma induced compression and stretch injuries e.g., peroneal nerve compression at the fibular head after knee dislocation, shoulder trauma causing stretching of the brachial plexus

Scheduled procedures involve a patient seeking relief of a condition caused by a nerve defect or surgical procedure

Scheduled Procedures:

- Patients seeking a scheduled procedure weeks or months in advance allows patients to advocate for solutions that may improve quality of life outcomes
- Procedures lend themselves to standardized surgical techniques and more consistent repair algorithms, and extended follow-up evaluations
- Completed in specialist centers on regular intervals, typically in existing core accounts
- Concentrated group of surgeon specialists allow for more focused surgeon training and adoption
- Typically involve a higher value of Axogen products per procedure

Scheduled Procedure Examples



Breast reconstruction

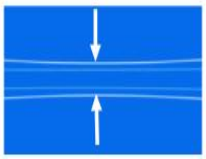
Neurotization of the breast and/or nipple areolar complex may be possible in many delayed or immediate breast reconstruction settings.

Mandibular reconstruction

Reconstruction of the inferior alveolar nerve with ablation of the mandible

Neuroma repair

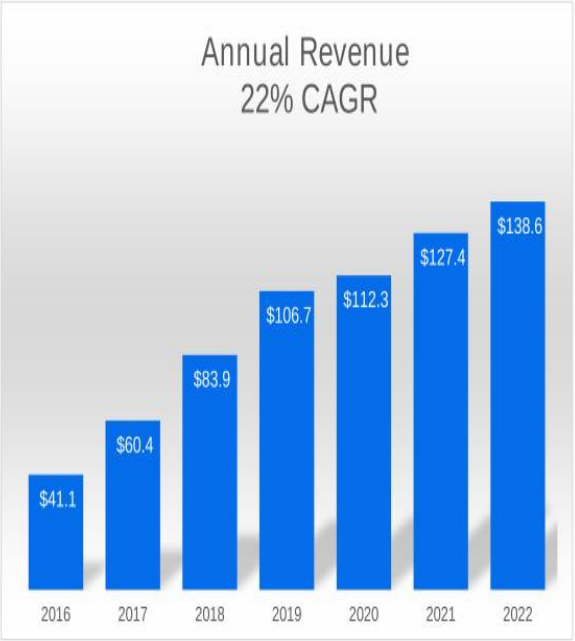
Symptomatic neuroma resection with nerve reconstruction



Cubital and carpal tunnel revisions

Delivering strong revenue growth and gross margins

U.S. $ in millions



80.5% gross margin for the quarter ended September 30, 2023

Revenue by Category

We estimate that:

- Revenues from emergent trauma procedures represented approximately half of total revenues during the third quarter and grew in the mid-single digit range versus the third quarter of 2022
- Revenues from scheduled non-trauma procedures represented approximately half of total revenues during the third quarter and grew approximately 20% from the third quarter of 2022
- We estimate that the mix of emergent and scheduled procedures for fiscal 2022 was approximately 55% and 45%, respectively

We estimate revenue by application using the information received from hospitals and sales representatives and based upon assumptions regarding specific surgeon practice and account information. Accordingly, the accuracy of our estimates is subject to the limited data we receive and accuracy of those assumptions.

2023 Annual Financial Guidance and Revenue Update

The company anticipates:

- Full-year 2023 revenue is expected to be at the high end of the $154 million to $159 million. This represents annual growth of approximately 15%.
- The Company continues to believe that gross margin for the full year 2023 will be approximately 80%.

Preliminary Unaudited Revenue for Fourth Quarter and Full-Year 2023*:

- Fourth quarter revenue is expected to be approximately $42.7 million, which represents an 18% increase over the fourth-quarter of 2022 driven by solid performance across the product portfolio.
- Full-year 2023 revenue is expected to be approximately $158.8 million, which represents a 15% increase over the full-year of 2022.

* Unaudited financials

Growth Drivers

- Recent clinical data published within the past year will support increased adoption particularly with middle adopters
  - RECON℠
  - Meta Analysis of clinical outcomes and Medicare Economic Data
  - Premier Economic Data
- Innovation
  - New product launches in nerve protection: Axoguard HA+ Nerve Protector™ launched in August, strategic roll-out of Avive+ Soft Tissue Matrix™ in Q2 2024
  - Resensation® for breast neurotization expansion into implant-based reconstructions
- Patient activation programs for breast neurotization, surgical treatment of pain, and OMF
- Improving emergent trauma procedure logistics in hospital and ASC sites of care
- Surgeon training across our applications

Axogen Processing Center (APC)

- Began processing tissue in the new facility in August 2023
- Supports BLA requirements for Avance nerve graft
- Provides 3x current capacity, designed for long-term growth and expansion

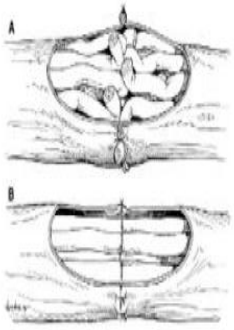
Product Portfolio

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

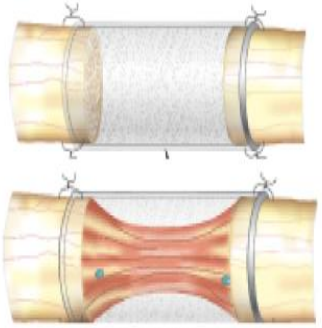
Traditional method despite several disadvantages

- Secondary surgery
- Loss of function and sensation at harvest site
- 27% complication rate including infection, wound healing and chronic pain [19]
- Limited availability of graft length and diameter

SYNTHETIC CONDUITS

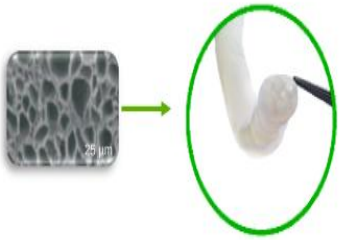
Convenient off the shelf option; limited efficacy & use

- Provides only gross direction for regrowth
- Limited to small gaps
- 34%-57% failure rate >5mm gaps[20, 21]
- Semi-rigid and opaque material limits use and visualization
- Repair reliant on fibrin clot formation



Axogen solutions for TRANSECTION repair

avance® 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[22]
- Eliminates need for an additional surgical site and risks of donor nerve harvest[22]
- May reduce OR time

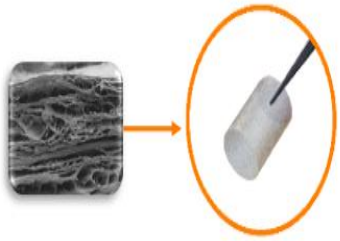
Structural support for regenerating axons

- 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[23]

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

axoguard nerve connector®



Only minimally processed porcine ECM for connector-assisted coaptation

Alternative to direct suture repair

- Reduces the risk of forced fascicular mismatch[24, 25]

Alleviates tension at critical zone of regeneration

- Disperses tension across repair site[26]
- Moves suture inflammation away from coaptation face[27, 28]

Remodels into vascularized patient tissue[28, 29, 30, 31, 32]

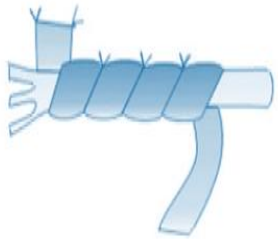
14 size options in lengths of 10mm and 15mm, and diameters up to 7mm

Traditional COMPRESSION repair options are suboptimal

VEIN WRAPPING

Autologous vein

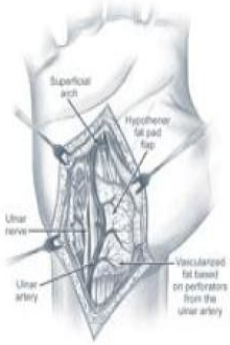
- Barrier to attachment to surrounding tissue
- Requires extra time and skill to perform spiral wrapping technique
- Second surgery site



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 solution for COMPRESSION repair

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

Protects repair site from surrounding tissue

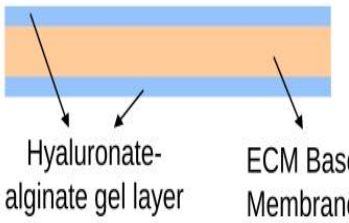
- Processing results in an implant that works with the body's natural healing process[33]
- Minimizes soft tissue attachments[34]

Allows nerve gliding

- Minimizes risk of entrapment[34]
- Creates a barrier between repair and surrounding tissue bed[34]
- ECM revascularizes and remodels into patient's own tissue[29,35]

Axoguard HA+ Nerve Protector™
designed for short and long-term protection

axoguard HA+™
nerve protector



Lubrication layer:
- Protects nerve in the early critical phase of healing
- Enhance nerve gliding for nerve protection applications where nerve mobility is critical and aids in minimizing soft tissue attachments

ECM base membrane:
- Processed porcine submucosa extracellular matrix (ECM) base layer
- Vascularizes and remodels to form a new long-term protective tissue layer

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

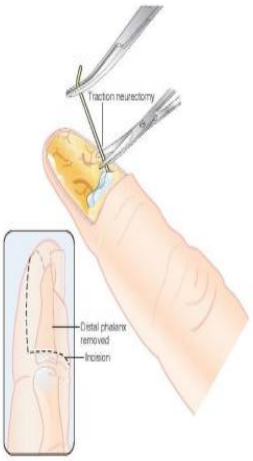
Launched August 2023

Traditional STUMP NEUROMA options are suboptimal

TRACTION NEURECTOMY

Nerve placed in traction and cut to allow for retraction

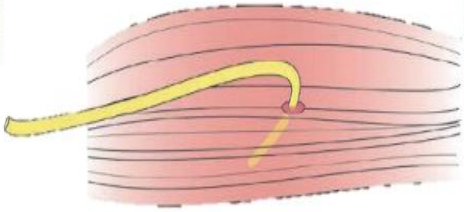
- Simply resecting the nerve results in subsequent neuroma formation and risk of secondary surgery
- Causes traction injury
- High risk of recurrence[36]



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[37, 38, 39]



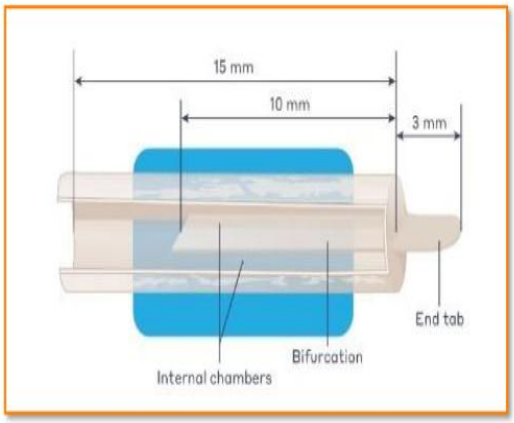
INJECTIONS

Pharmacologic intervention, typically alcohol or steroids[40, 41, 42, 43, 44, 45]

- Chemical injections are only successful 40% of the time[43, 44]
- Temporary solution that has a reduced benefit over time
- May cause considerable side effects

Axogen solution for STUMP NEUROMA

axoguard nerve cap®



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)[46, 47]

- Material gradually incorporates into patient's own tissue, creating a physical barrier to surrounding soft tissue

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)

7,732,200
7,402,319
7,851,447
8,758,794
9,597,429
9,572,911
9,690,975
9,996,729
10,311,281
10,783,349
11,156,595
11,513,039
11,523,606

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

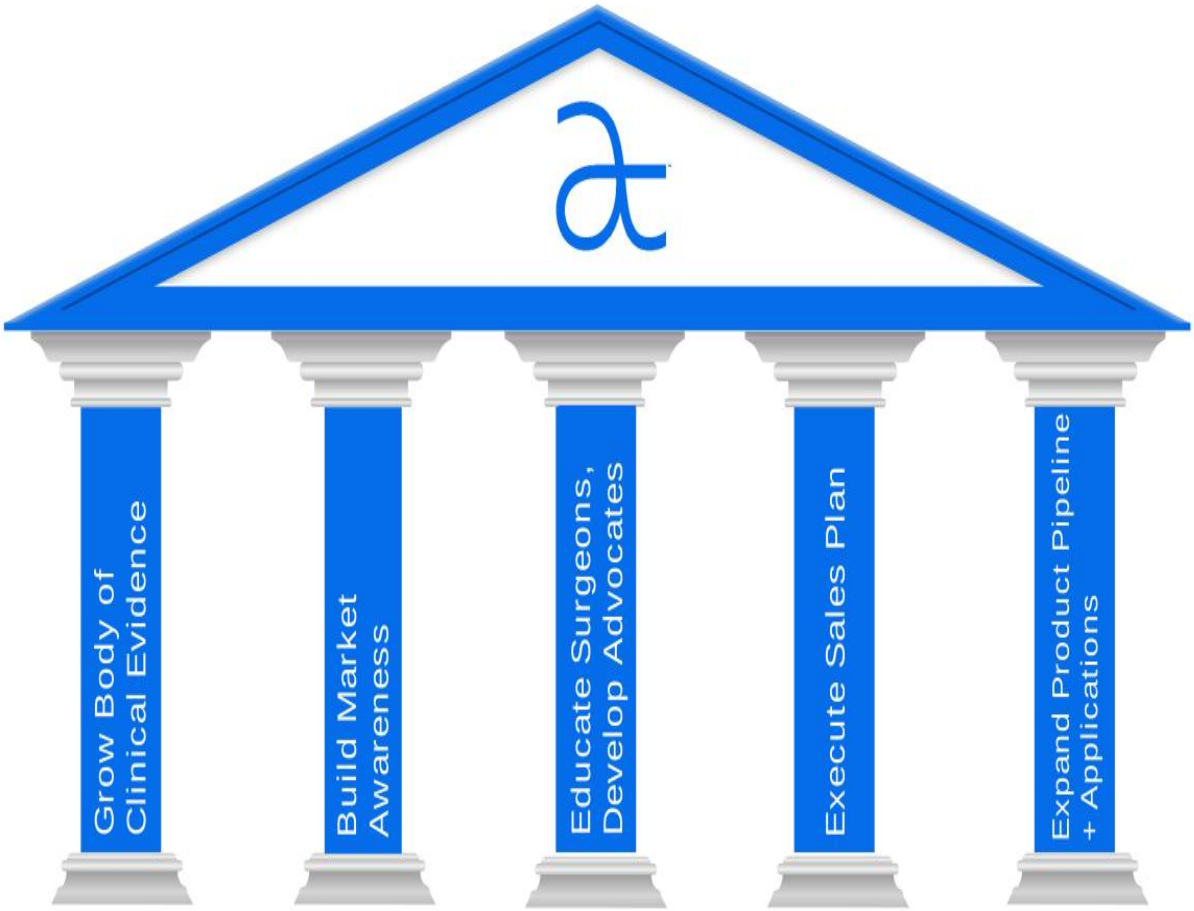
Axogen has Enforcement Discretion from FDA allowing continued sales under controls applicable to HCT/Ps with agreed transition plan to regulation as a Biological Product under a Biologic License Application (BLA) if approved. Axogen expects to file the BLA in the first half of 2024

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 Ongoing
- 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 Ongoing
- Avance compared to matched cohort of autograft and synthetic conduits

Sensation-NOW® Registry Study: Enrollment Ongoing
- Multi-center clinical study in breast neurotization

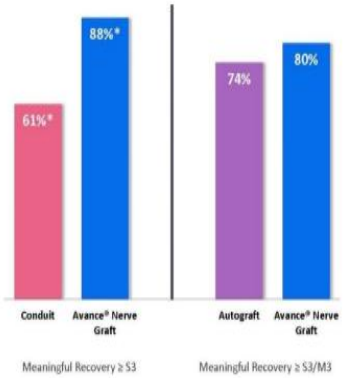
REPOSE® : Enrollment Complete
- Prospective, randomized, controlled study of Axoguard Nerve Cap® vs neurectomy

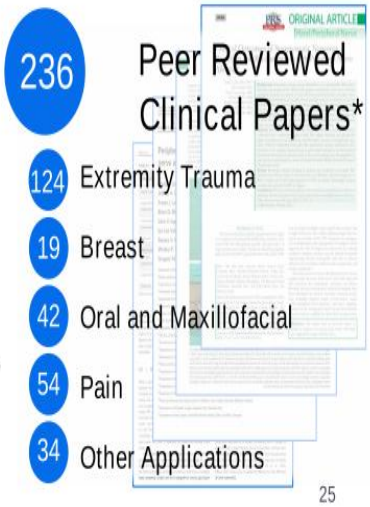
REPOSE-XL℠: Pilot Study Enrollment Ongoing
- Pilot study evaluating the feasibility of large-diameter Axoguard Nerve Cap® for protecting and preserving terminated nerve ends after trauma or amputation

RETHINK PAIN℠ Registry Study: Enrollment Ongoing
- Designed to capture the patient's pain journey, from onset of chronic pain to nerve repair

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

Outcomes from RANGER Registry [48,49]





*Certain publications contain data on multiple applications.

RECON℠: 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[1,2]

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 rolling Biologics License Application (BLA) submission in the first half of 2024

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).
- ✓ 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).

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.

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

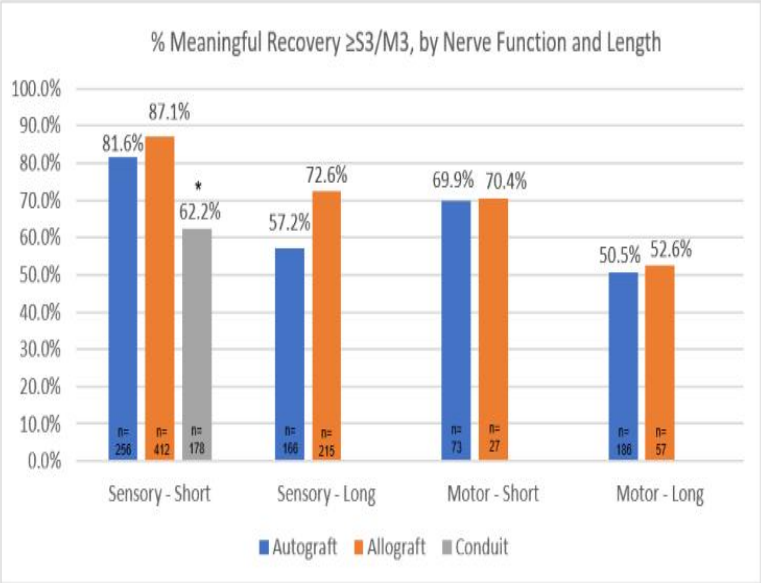
[1]Axogen Data on File;

[2]Isaacs J, Nydick JA, Means KR, Merrell GA, Ilyas A, Levin LS; RECON study group. A Multicenter Prospective Randomized Comparison of Conduits Versus Decellularized Nerve Allograft for Digital Nerve Repairs. J Hand Surg Am. 2023 Aug 2:S0363-5023(23)00297-6. doi: 10.1016/j.jhsa.2023.05.020. Online ahead of print.

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[1]

- 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

[1]Lans J, Eberlin KR, Evans PJ, Mercer D, Greenberg JA, Styron JF. A Systematic Review and Meta-Analysis of Nerve Gap Repair: Comparative Effectiveness of Allografts, Autografts, and Conduits. Plast Reconstr Surg. 2023 May 1;151(5):814e-827e. doi: 10.1097/PRS.0000000000010088. Epub 2022 Dec 26.

Procedure Costs of Peripheral Nerve Graft Reconstruction

Raizman et al.
PRS Global Open[1]

- 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

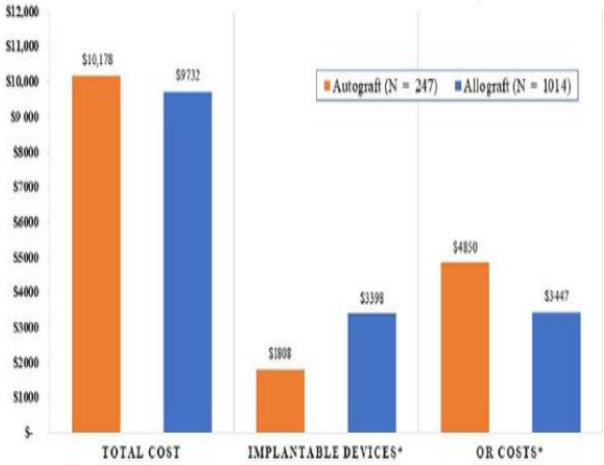


Fig. 2. Outpatient descriptive costs of nerve graft repair type (n = 1261).

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[1]Raizman NM, Endress RD, Styron JF, Emont SL, Cao Z, Park LI, Greenberg JA. Procedure Costs of Peripheral Nerve Graft Reconstruction. Plast Reconstr Surg Glob Open. 2023 Apr 10;11(4):e4908. doi: 10.1097/GOX.0000000000004908. eCollection 2023 Apr.

Focus on building awareness among clinicians and patients

- 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

resensation®

rethink pain®

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

Emphasis on education

- 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

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77th annual meeting of the ASSH

visit Axogen at **booth # 815**

sponsorship level: elite

"Late-Breaking, State-of-the-Art Nerve Reconstruction Data: The How and Why of Implementing this New Data into Your Clinical Practice"

Friday, September 30 • 7:00 - 8:00 am

Axogen Innovation Lab

Taking you beyond the technology

Journey inside the nerve and see how science is improving peripheral nerve repair

masterminds of nerve

Focused sales execution, increasing market penetration

Sales execution focused on driving results

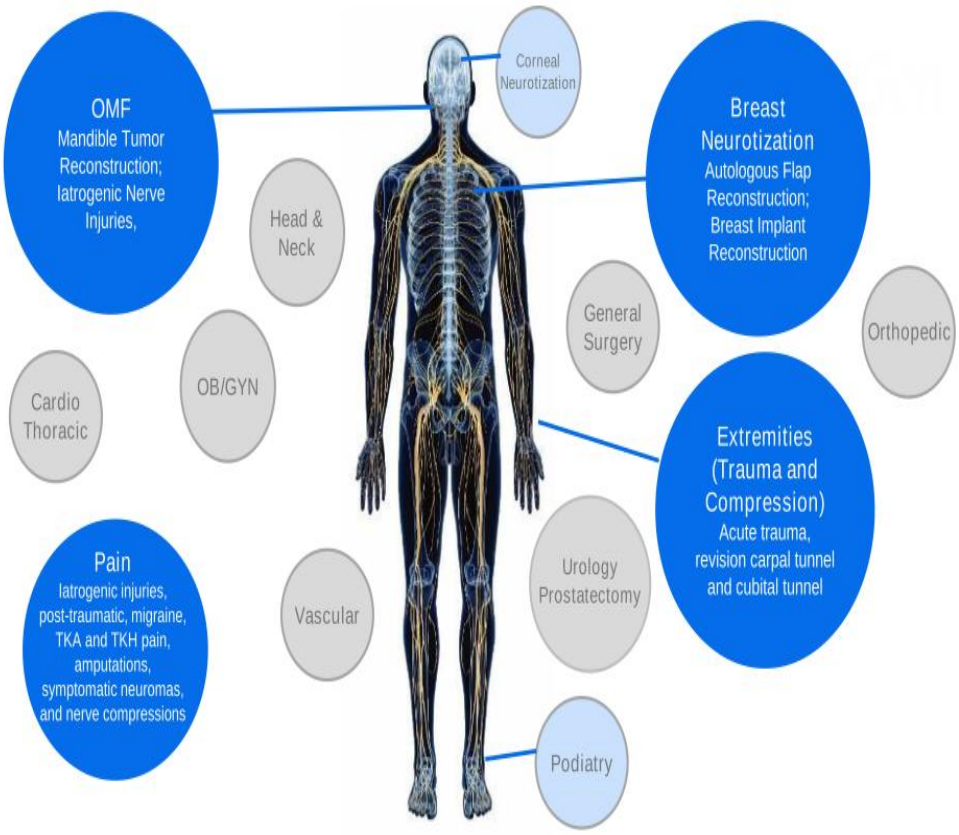
- Continue driving penetration in Core Accounts
- Approximately 5,100 potential U.S. accounts perform nerve repair
- 375 Core Accounts as of December 31, 2023
- Core Accounts now represent approximately 65% of total revenue, up from 60% in prior quarters

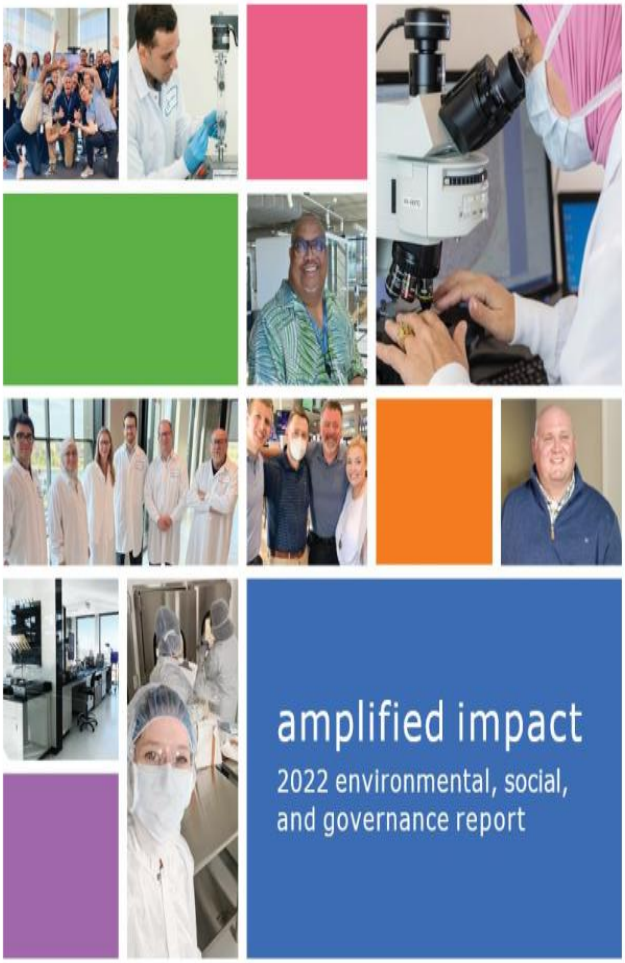
Broad sales reach

- U.S. direct sales team
  - 116 direct sales professionals at the end of Q4 2023
- Supplemented by independent agencies
- Revenue from direct sales channel represented approximately 90% of total revenue

Opportunities in nerve repair

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





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

axogen revolutionizing the science of nerve repair®

FUTURE WE CREATE

Executive team

Karen Zaderej
Chairman, CEO,
and President
J&J (Ethicon)

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

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

Angelo Scopelianos, Ph.D.
Chief Research and
Development Officer
J&J

Erick DeVinney
Chief Innovation Officer
Angiotech, PRA Intl

Jens Schoeder Kemp
Chief Marketing Officer
Ambu, Pera International

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

Angela Nelson
Vice President, Regulatory Affairs MBA, RAC(GS)
PPD part of Thermo Fisher Scientific, Cardinal Health, UMKC School of Medicine

Mike Donovan
VP, Operations
Zimmer

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

Al Jacks
Vice President, Quality Assurance
VERO Biotech, Alimera Sciences

Doris Quackenbush
VP, Sales
Convatec

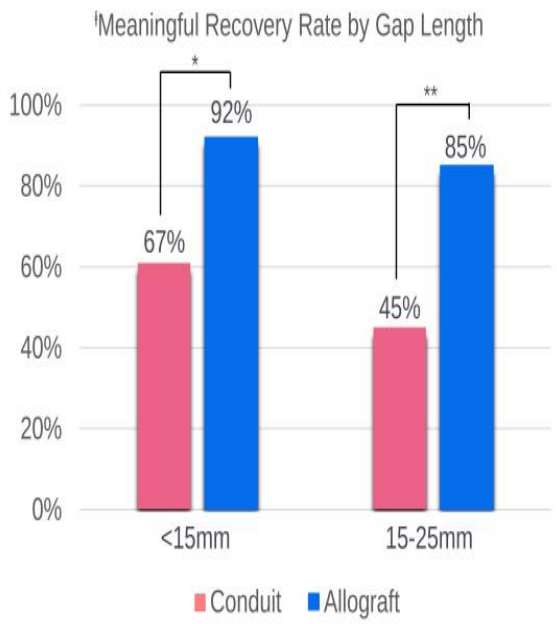
Appendix

- Key Clinical Data
- Historical Core and Active Accounts
- 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

"Leversedge et al., A Multicenter Matched Cohort Study of Processed Nerve Allograft and Conduit in Digital Nerve Reconstruction" – Journal of Hand Surgery, September 2020[48]

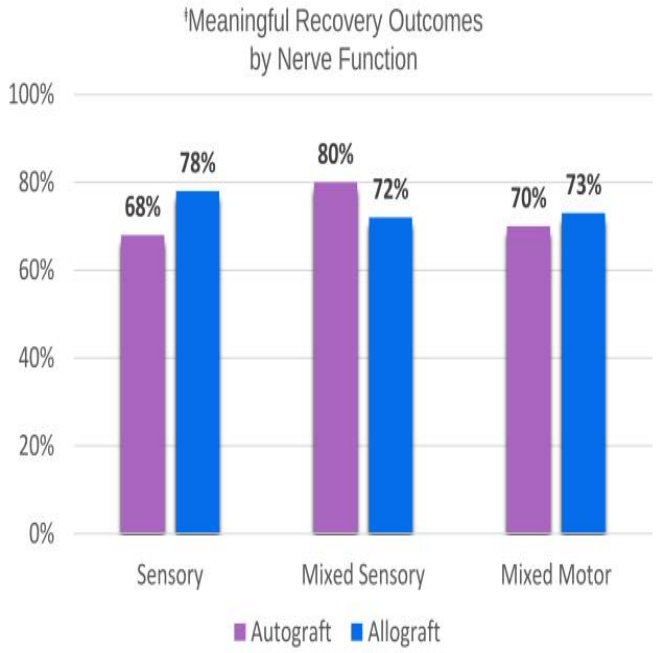
- Peer-reviewed publication from the MATCH cohort of the RANGER Registry
- Includes outcomes from 110 subjects with 162 nerve injuries; 113 were repaired with Avance nerve graft and 49 were repaired with manufactured conduit
- Findings show overall meaningful recovery rate was 88% for Avance nerve graft 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



[1]Meaningful Recovery = ≥S3 on the MRCC Scale
*p=0.008, **p=0.001

Study finds Avance nerve graft (allograft) clinical outcomes recovery rates comparable to nerve autograft

"Safa et al., A Propensity Matched Cohort Study on Outcomes from Processed Nerve Allograft and Nerve Autograft in Upper Extremity Nerve Repairs"[49]



Defined as MRCC Score ≥ S3/M3

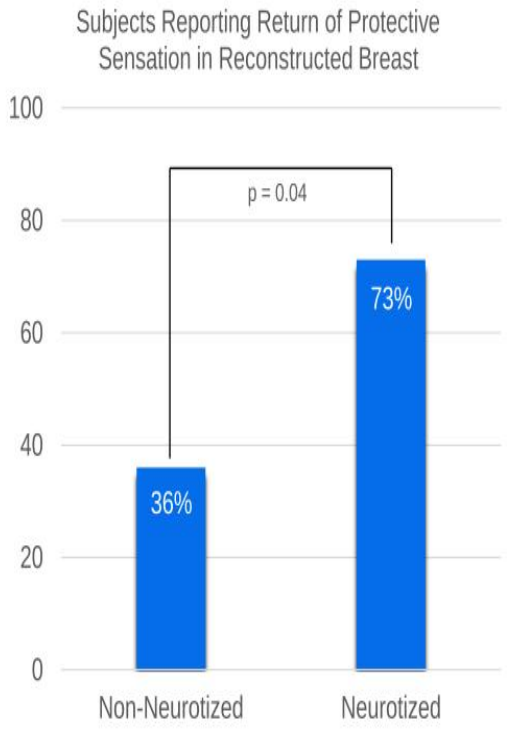
Historical data on Nerve Autograft[50,51,52,53,54,55], Mixed Nerve: 57-80%; Digital Nerve: 60-88%

Presented at American Society for Surgery of the Hand (ASSH), Oct 2020

- Study of 156 nerve repairs found meaningful recovery rates for Avance nerve graft were comparable to autograft for both sensory and motor function

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[59]

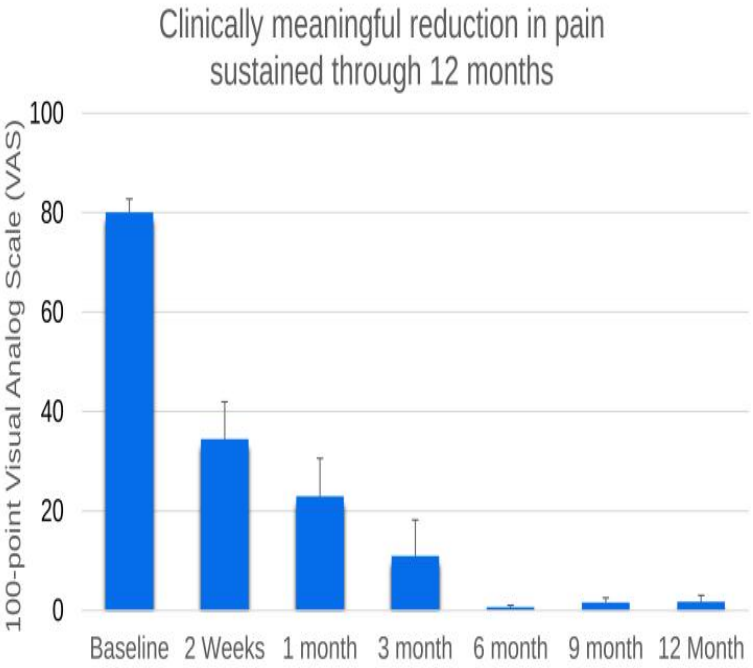


- Early outcomes from a single center study, as part of the Sensation-NOW® registry
- 36 breast reconstructions that included:
  - 22 breast reconstructions with Resensation®
  - 14 standard non-neurotized breast reconstructions
- Return of Protective Sensation (p=0.04)
  - 73% of the Resensation group
  - 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℠ pilot study analysis demonstrates clinically significant improvement for subjects with chronic neuropathic pain when using Axoguard Nerve Cap® following neurectomy[60]

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® measures
- Positive indicators for reduction in pain medication burden, including opioids
- No recurrence of neuroma

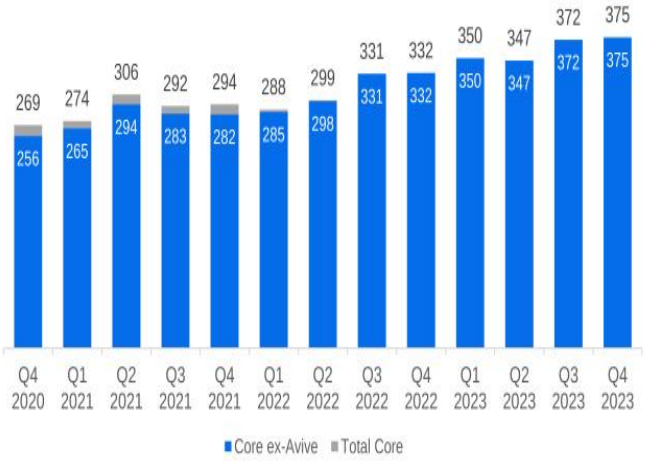


Minimal Clinically Important Difference (MCID): 17mm
Δ 3 months: -69 ± 23; $p < 0.0001$
Δ 12 months: -80 ± 13; $p < 0.0001$

Historical Core and Active Accounts

Core Accounts

≥$100,000 revenue in the last 12 months

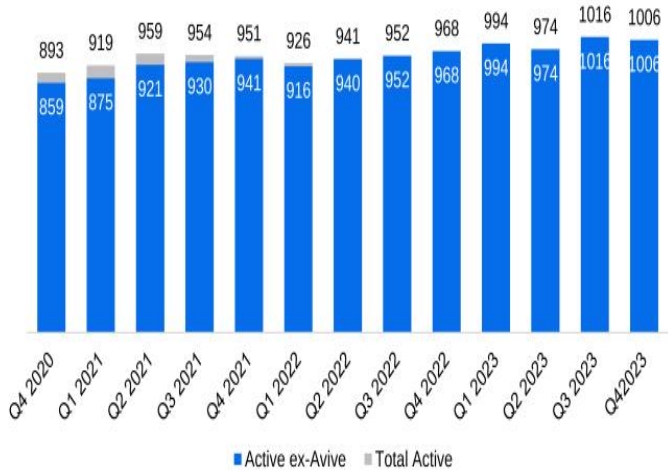


	Q420	Q121	Q221	Q321	Q421	Q122	Q222	Q322	Q422	Q123	Q223	Q323	Q423
Core Acccounts	269	274	306	292	294	288	299	331	332	350	347	372	375
*Adjusted Core Accounts	256	265	294	283	282	285	298	331	332	350	347	372	375

Core Accounts now represent ~65% of revenue, up from approximately 60% in prior quarters

Active Accounts

6 orders in the last 12 months



	Q420	Q121	Q221	Q321	Q421	Q122	Q222	Q322	Q422	Q123	Q223	Q323	Q423
Active Accounts	893	919	959	954	951	926	941	952	968	994	974	1016	1006
*Adjusted Active Acctount	859	875	921	930	941	923	940	952	968	994	974	1016	1006

Active Accounts typically contribute ≈85% of total revenue

Top 10% of Active Accounts typically contribute ≈35% of total revenue

* Axogen voluntarily suspended market availability of Avive® Soft Tissue Membrane on June 1, 2021. Active and Core Account metrics are Adjusted for past Avive revenue.

2024 CMS Final outpatient reimbursement rates - hospital and ASC

Although CMS rates[1] 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	2023	2024	5Y % Change	2019	2023	2024	5Y % Change
64912	Nerve allograft repair[2]	5432	$4,566	$6,179	**$6,354**	39.15%	$1,920	$4,057	**$4,583**	138.69%
64910	Conduit or vein allograft repair[2]	5432	$4,566	$6,179	**$6,354**	39.15%	$2,613	$3,805	**$4,291**	64.21%
64885	Autograft repair (head and neck ≤4cm)[3]	5432	$4,566	$6,179	**$6,354**	39.15%	$1,920	$2,632	**$4,499**	134.33%
64886	Autograft repair (head and neck >4cm)[6]	5432	$4,566	$6,179	**$6,354**	39.15%	$3,127	$4,375	**$3,013**	-3.65%
64890	Autograft repair (hand and foot ≤4cm)[3]	5432	$4,566	$6,179	**$6,354**	39.15%	$3,075	$2,602	**$4,586**	49.14%
64891	Autograft repair (hand and foot >4cm)[2]	5432	$4,566	$6,179	**$6,354**	39.15%	$1,920	$3,383	**$3,796**	97.71%
64892	Autograft repair (arm and leg ≤4cm)[2]	5432	$4,566	$6,179	**$6,354**	39.15%	$1,920	$3,383	**$4,619**	140.59%
64893	Autograft repair (arm and leg >4cm)[2]	5432	$4,566	$6,179	**$6,354**	39.15%	$1,920	$3,383	**$4,681**	143.79%
64897	Autograft repair (arm and leg ≤4cm multiple strands)[3]	5432	$4,566	$6,179	**$6,354**	39.15%	$1,920	$3,660	**$4,085**	112.78%
64895-96,98	Autograft repair (all other nerve type)[5]	5432	$4,566	$6,179	**$6,354**	39.15%	$1,920	$2,632	**$3,013**	56.92%
64834-36, 40, 56, 57, 62-64	Direct Repair (other hand / foot, arm/leg, repair / transpose, facial, low back,)[5]	5432	$4,566	$6,179	**$6,354**	39.15%	$1,920	$2,632	**$3,013**	56.92%
64865	Direct Repair of facial nerve[2]	5432	$4,566	$6,179	**$6,354**	39.15%	$1,920	$3,383	**$3,796**	97.71%
64831, 61	Direct Repair (digital, brachial plexus/arm)[4]	5431	$4,566	$ 1,798	**$1,842**	-59.67%	$1,920	$854	**$898**	-53.24%
64858	Direct Repair (sciatic)[2]	5431	$4,566	$ 1,798	**$1,842**	-59.67%	$1,920	$1,481	**$1,498**	-21.98%

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, arm and leg >4cm CPT 64893, repair arm/leg ≤4cm multiple strands CPT 64897. direct repair of facial nerve CPT 64865 remain in C-APC 5432 and direct repair sciatic CPT 64858 remains in C-APC 5431 and all continue to meet ASC device intensive criteria
3. Autograft repair head/neck ≤4cm CPT 64885, hand and foot ≤4cm 64890 remains in C-APC 5432 and meets ASC device intensive criteria in 2024
4. Direct repair digital and brachial plexus/arm CPT codes 64831 and 64861 remain in C-APC 5431 and do not meet ASC device intensive criteria.
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 64886 remains in C-APC 5432 no longer meets ASC device intensive criteria in 2024

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Note: Hospital inpatient rates for nerve repair align to DRGs 040, 041, 042 and range from $11.1k to $24.6k in the 2024 IPPS Final Rule

2024 Center for Medicare and Medicaid Services (CMS): Final Physician Fee Schedule (PFS)

CPT Codes3	Descriptor	Physician Fee Schedule (PFS)			
		2019	2023	2024	5Y % Change
64912	Nerve allograft repair	$804	$908	**$883**	**9.78%**
64910	Conduit or vein allograft repair	$825	$772	**$752**	**-8.80%**
64885 to 64898*	Autograft repair	$1,096 to $1,495	$1,065 to $1,444	**$1,035 to $1,404**	**-5.54% to -6.12%**
64831 to 64861*	Direct Repair	$713 to $1,604	$708 to $1,560	**$689 to $1,522**	**-3.34% to -5.11%**

*excludes add-on procedure codes

Estimated Trauma total addressable market

Patient Population[a]	Source	Adjustments and Rationale
136,943,000 Annual emergency department visits in the U.S.	2015 National Hospital Ambulatory Medical Care Survey (Table 1)	
30,238,000 Annual emergency department visits due to injury in the U.S.	2015 National Hospital Ambulatory Medical Care Survey (Table 18)	• 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.)
✖		
4.76% Percentage of emergency department visits with nerve injury	*Noble, et al: J Trauma, Volume 45(1) July 1998.116-122*	• 2.8% rate cited in *Noble, et al* 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%.
=		
1,440,000 Annual emergency department visits with nerve injury in the U.S.		
✖		
46.2% Percentage of ED nerve injuries estimated to be treated surgically	*Noble, et al: J Trauma, Volume 45(1) July 1998.116-122*	• Calculated rate based on various rates in *Noble et al* study for upper and lower extremity and an estimate for other trauma nerves.
=		
~665,000 **Annual ED visits with nerve injury estimated to be treated surgically in the U.S., excluding revisions**		

a) Patient population figures rounded to the nearest thousandth.

Trauma total addressable market (continued)

Patient Population[a]	Source	Adjustments and Rationale
~665,000 Annual emergency department visits with nerve injury that can be treated surgically in the U.S., excluding revisions	See calculation on previous slide	
✖ **7.4%** Revision cases	*Portincasa et al: Microsurgery 27:455-462, 2007*	• *Portincasa et al* suggests that a revision procedure was necessary in 7.4% of the patients within 6 months of the initial surgery.
= **714,000** Annual emergency department visits with nerve injury that can be treated surgically in the U.S., including revisions		
↓ **~700,000** **Company estimate of trauma total addressable market**		

a) Patient population figures rounded to the nearest thousandth.

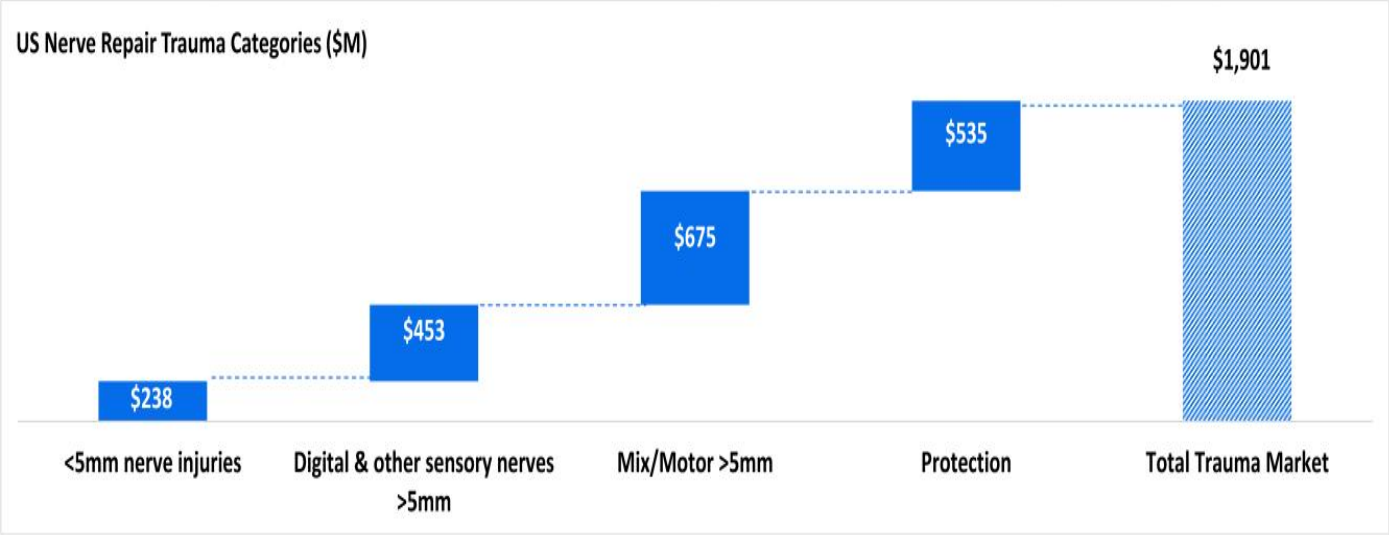
Estimated $2.7B value of market opportunity in existing applications

	Projected Incidence[a]		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%
Protection (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	
Totals	>900,000 (potential)			>$2.7B	

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 & HE data and product launches, by category

AXGN Algorithm
Low → High



Category				
▪ Short gap transected nerve injuries	▪ Digital Sensory 5-25mm ▪ Digital Sensory >25mm	▪ Mixed/Motor 5-25mm ▪ Mixed/Motor >25mm	▪ Protection from non transected nerve injuries	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
Trends and Growth Levers				
▪ Routine trauma moving to ASCs and lower cost sites of care ▪ Education and awareness of proper nerve repair technique ▪ Improve procedure awareness and scheduling across all care settings ▪ Private payer adoption of improved CMS reimbursement guidelines	▪ Routine trauma moving to ASCs and lower cost settings ▪ Education and awareness of proper nerve repair technique ▪ New Clinical data from Recon/Meta-analysis ▪ All Payor Procedural Cost analysis ▪ Societal support for standard of care ▪ Improved private payer reimbursement ▪ Activating middle adopters	▪ Motor clinical outcome data from Meta-analysis ▪ Societal support for standard of care ▪ Prof ed on appropriate surgical technique & algorithm ▪ Improved private payer reimbursement ▪ Activating middle adopters	▪ New product launches of HA+ and Avive replacement to address acute and chronic applications ▪ Increased awareness of Non-Transected Nerve Injuries ▪ Clinical evidence generation ▪ Prof ed on appropriate surgical technique & algorithm ▪ Reimbursement coding and coverage	

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Balance sheet and capital structure

Balance Sheet Highlights	September 30, 2023
Cash, Cash Equivalents, and Investments	$38.6 million
Total Long-term Debt	$50.0 million*

Capital Structure (shares)	September 30, 2023
Common Stock	43,039,399
Common Stock Options, RSUs, PSUs	8,731,054
Common Stock and Common Stock Equivalents	51,770,453

* Total long-term debt includes debt proceeds under the terms of the agreement with Oberland Capital, inclusive of unamortized debt discount and deferred financing fees.

Axogen comprehensive portfolio of products

Avance® Nerve Graft

- Regulatory Classification: Avance Nerve Graft is processed and distributed in accordance with U.S. Food and Drug Administration (FDA) requirements for Human Cellular and Tissue-based Products (HCT/P) under 21 CFR Part 1271 regulations, U.S. State regulations and the guidelines of 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®

- 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®

- 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.

nasdaq: axgn

Footnotes

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