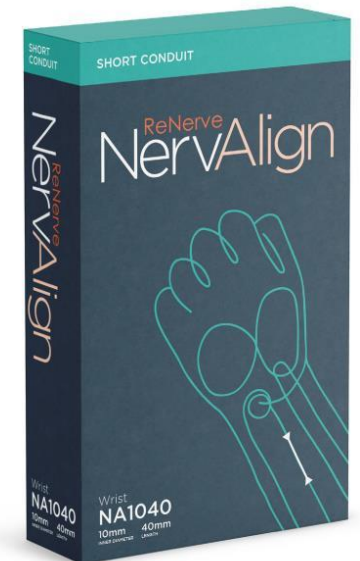
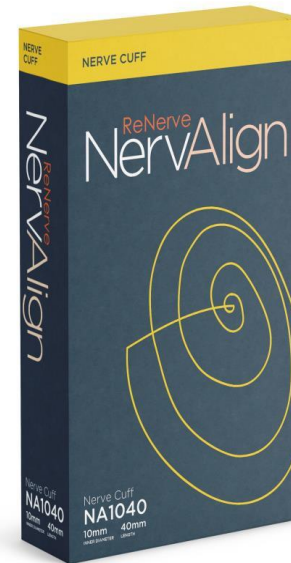


# ReNerve

Transforming nerve repair

## Company presentation

May 2021





## Disclaimer

***This presentation includes forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks and important factors that may cause the actual results, performance or achievements of ReNerve to be materially different from the statements in this presentation.***

***Actual results could differ materially depending on factors such as the availability of resources, the results of pre-clinical proof-of-concept studies, the timing and effects of regulatory actions, the strength of competition and the effectiveness of patent protection. Additional information regarding risks and uncertainties can be obtained from the Company.***

# Key Highlights

## Company Overview

- Founded by neurosurgeon and experienced Medtech researchers
- Developing a portfolio of products for nerve injury repairs
- Focused on peripheral nerve repair and replacement
- Products protect against nerve injury & promote nerve regrowth leading to better and faster patient recovery and outcomes
- Company moving from R&D to commercialisation

## Target Market

- Estimated to be > USD\$1.2Bn by 2025
- Growing by >10% pa
- Ability to expand market with cleaner, safer, better products
- US 700,000+ trauma cases pa
- Used when nerves are damaged (trauma, tissue resections - breast, prostate)

## Company's products

- NervAlign® Nerve Cuff – FDA marketing approval application filed
  - Targeting end 21/early '22 approval
- NervAlign® nerve graft – successful nerve replacement data
  - Progressing to clinical studies
- 'Bionic' replacement nerve
- OR harvested tissue treatment kit – In prototype development

# ReNerve Portfolio & Timelines

Product (Brand name)	Procedure use	Application	CY'20	CY'21	CY'22	CY'23	CY'24	Total target market (USD\$)*	Sales channels	Launch
<b>NervAlign® nerve cuff</b>	End to end suturing covered with a wrap/cuff Protective cuff for grafts	<ul style="list-style-type: none"> <li>Trauma</li> <li>Breast reconstruction</li> <li>Orthopaedics</li> <li>Oral &amp; maxillofacial surgery</li> </ul>						\$125M+ ('20) \$224.2M (2025) CAGR 13.5%	MLM Medical (US)	CY'21/'22
<b>OR “Wallerian” tissue kit</b>	Treatment of harvested tissue while in the OR	<ul style="list-style-type: none"> <li>Nerves</li> <li>Tendons</li> <li>Vascular tissue</li> <li>Cardiovascular tissue</li> </ul>						> 700,000 procedures annually	Various (non-US) US MLM Medical	CY'23
<b>NervAlign® nerve graft</b>	Replace damaged nerve section instead of donor or harvested tissue	<ul style="list-style-type: none"> <li>Trauma</li> <li>Breast reconstruction</li> <li>Orthopaedics</li> </ul>						USD\$412M ('20) USD\$792.7M (2025) CAGR 14%	MLM Medical (US)	CY'24
<b>NervAlign® 'bionic' replacement nerve</b>	Nerve graft for longer, difficult to repair damaged nerve	<ul style="list-style-type: none"> <li>Trauma</li> <li>Breast reconstruction</li> <li>Orthopaedics</li> <li>Spinal cord injury</li> </ul>						> USD\$790M	MLM Medical (US)	CY'26



R&D



Clinical trials



Commercial sales

\* Taken from Markets and Markets nerve repair and regeneration report – Global forecast to 2025 – July 2020

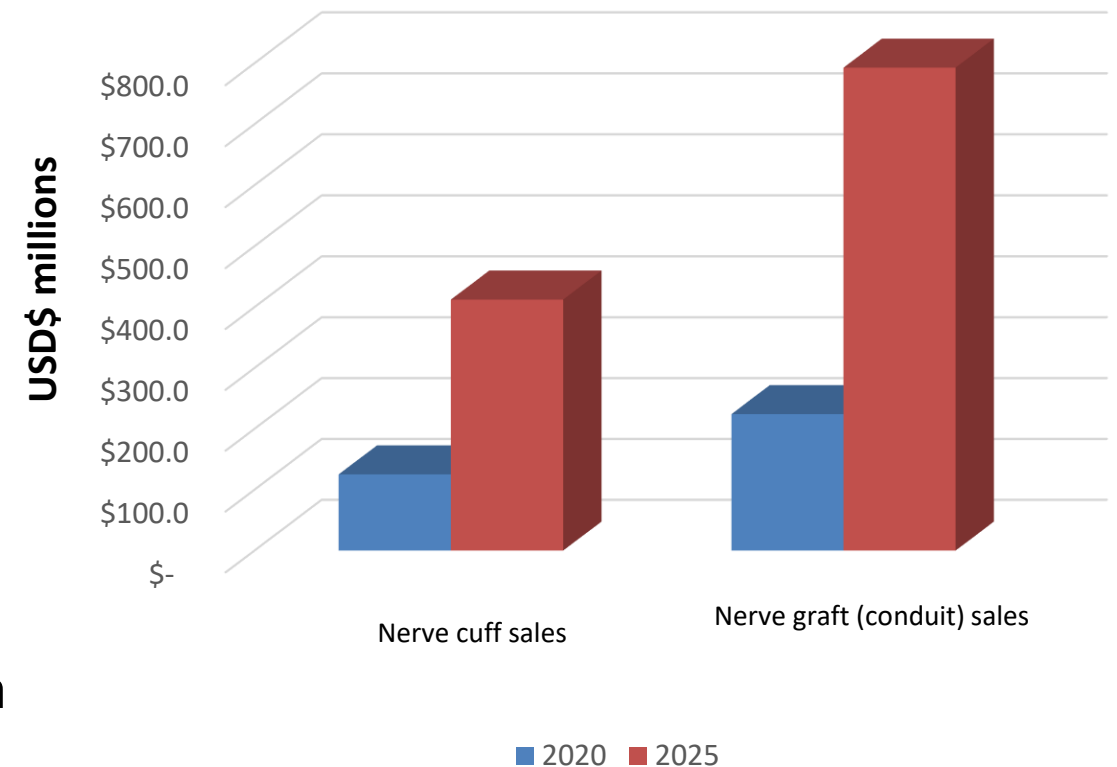
# Nerve injury repair market



# Peripheral Nerve Injury repair market

- **Estimated current global biomaterials sales market is USD\$537.6M\***
  - **Market estimates range from \$537M\* to \$2.4+Bn#**
- **Growing at 13.6%\***
- **Forecast to be over USD\$1.2Bn by 2025\***
- **Single largest market is the US**
  - **Followed by Europe**
- **Opportunity to expand markets with better products & outcomes**
  - **Offering genuine, safer, cleaner alternatives to harvest tissue with better outcomes through better nerve regeneration**

Nerve cuff and graft/conduit markets for 2020 to 2025



• \* Markets and Markets report July 2020

• # Leerink Axogen market report

# Nerve repair & replacement market

## ReNerve products for rapid and more consistent, improved patient outcomes post surgery

Main market is the 700,000+ trauma cases per annum in the US

- Surgical transections result in nerve damage:
  - ~ 60% for limb amputation
  - 20% - 40% mastectomy
  - 20%-40% thoracotomy
  - ~ 20% post hernia repair

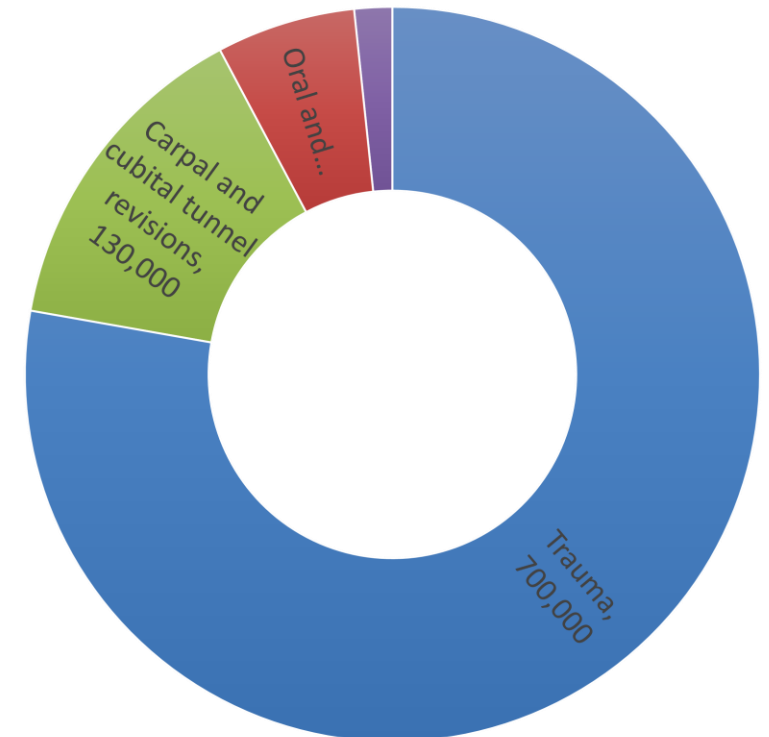
Nerve compression

- Ulnar nerve ( e.g. cubital tunnel syndrome)
  - 25% to 60% of surgeries have negative outcomes, only a few have full recovery
- Median nerve (carpal tunnel)
  - 1 in 4 cases get surgery repair & 30% failure/revision rates\*
- Repair or replacement of nerves currently gives variable patient outcomes
  - Meaningful repairs (M3, not full function) in 30% to 70% of cases
  - 43% efficacy across digital, radial, medial, ulnar and facial nerve repairs+

\* Kokkalis et al, 2015; Georgiou et al 2015; + Wangenstein & Kallianen (2010); # Brooks et al 2012

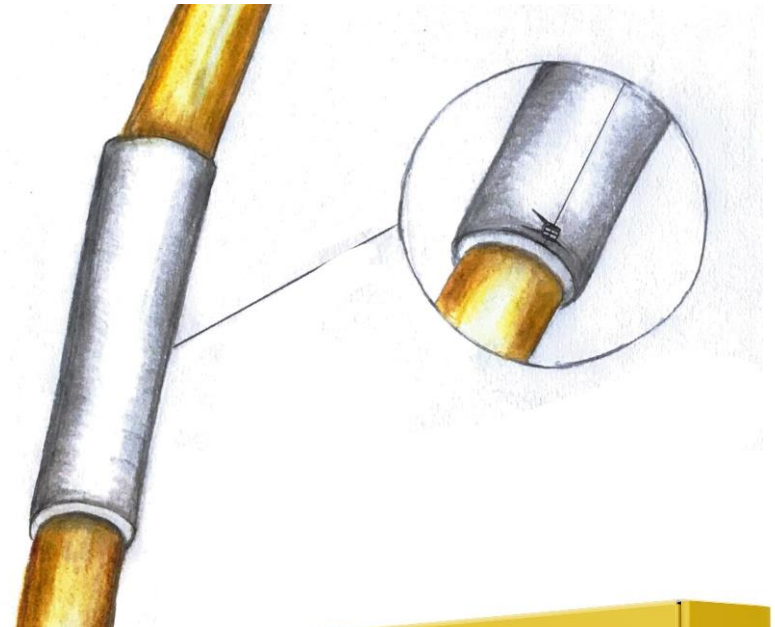
## US nerve related surgical procedure numbers

- Trauma
- Oral and Maxillofacial Surgery
- Carpal and cubital tunnel revisions
- Surgical transection (breast, hernia, prostate & thoracotomy)



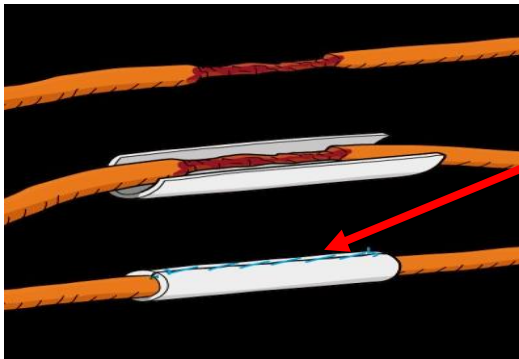
# Nerve Repair

## NervAlign® Nerve Cuff

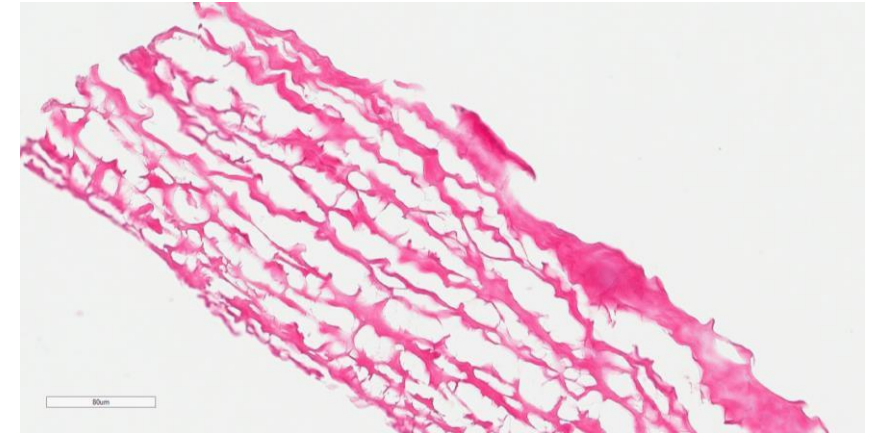


# NervAlign® Nerve Cuff

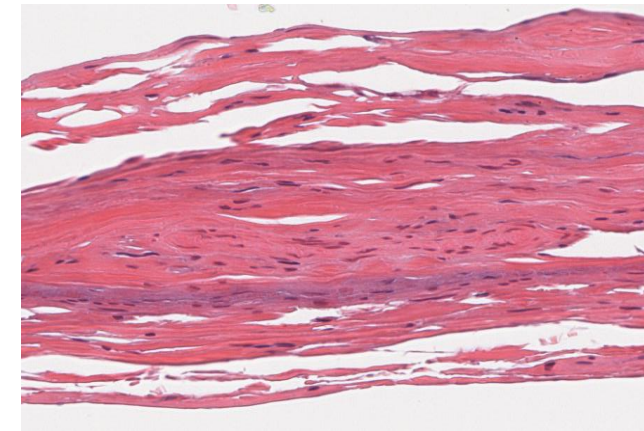
- **NervAlign® Nerve Cuff with -eCOO® Technology**
- Used for damaged or crushed nerves with no gaps and in tensionless end to end repair
  - Can be used with grafts and replacement nerves
  - Potential use in tendon repair as a tendon wrap
  - Product prevents scar formation and enables nerves to recover and re-grow
- **NervAlign® is superior to existing products**
  - Non-toxic, antigen free, cost effective



ReNerve cuff  
sutured in  
place to  
protect nerve  
damage,  
repairs or  
replacements



**NervAlign® Cuff - Supercritical CO<sub>2</sub> collagen patch – clean and native structure**



**Typical currently used tissue  
(manufactured by Cook Medical, porcine SIS)  
(dark blue stain shows residual DNA nuclear  
contamination)**

# NervAlign® Nerve Cuff

eCOO® Technology

eCOO® Technology  
CLEANER GRAFTS, SAFER OUTCOMES

eCOO® Technology

- Using carbon dioxide under certain pressure
- Creates a gas and liquid state
- Ideal for cleaning and sterilizing tissue
- Permeates like a gas and cleans like a liquid

- ✓ Retains structural and mechanical properties
- ✓ Environmentally friendly
- ✓ Viral inactivation via scCO<sub>2</sub> and rising steps
- ✓ Minimal residues and hazardous materials

eCOO® Technology products have been in thousands of surgical procedures across Europe

eCOO® Clean  
ADVANTAGES

- ✓ Maintains natural crosslinking of extracellular matrix (ECM)
- ✓ Promotes cell attachment
- ✓ Low immunogenic risk
- ✓ Deep microstructural penetration



## Benefits over conventional tissue treatments

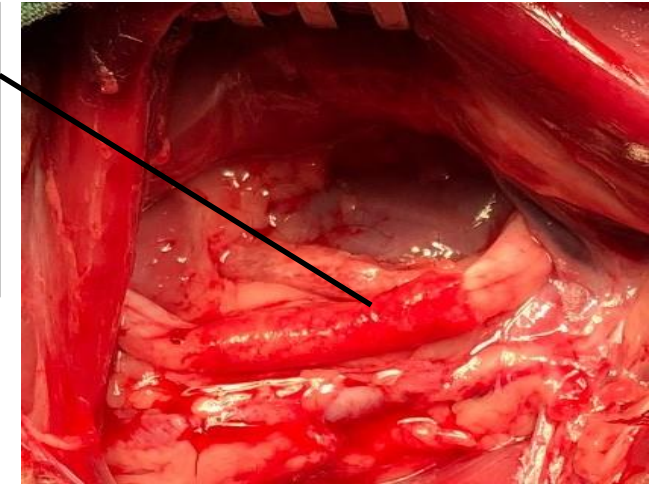
- No glutaraldehyde, Triton X-100, sodium dodecyl sulphate (SDS), acetone and enzymes
  - No ethylene oxide (EtO)

# ReNerve NervAlign® Nerve Cuff: The data

- The data shows:
  - Non-toxic solvent production method
  - Terminally sterilised with no residual chemicals
  - NervAlign nerve cuff is pliable and conformable
  - User-friendly, no change of surgical method
  - Promotes cell attachment with vascular tissue formation on surrounding fascia tissue post implant
  - Shown to reduce scarring & inflammation
  - Bio-absorbed over 6 months

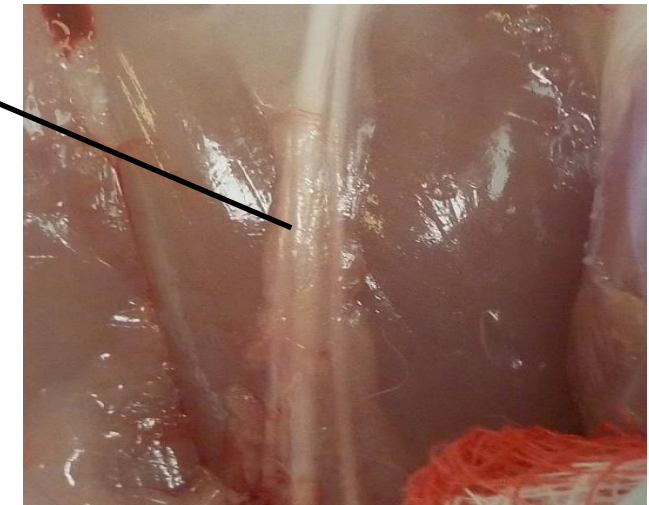
NervAlign initial implant

NervAlign® Nerve Cuff wrapped around a nerve to provide protection against scarring and inflammation



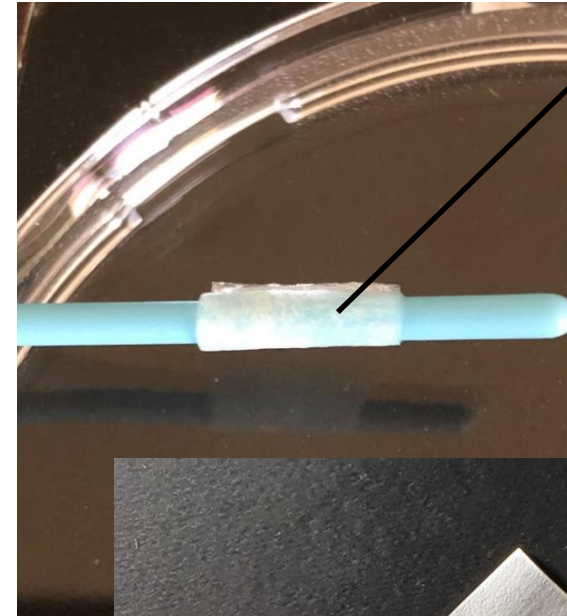
NervAlign 6 months post implant

NervAlign® Nerve Cuff wrapped 6 months post repair. NervAlign absorbed and nerve functioning normally – back to native state

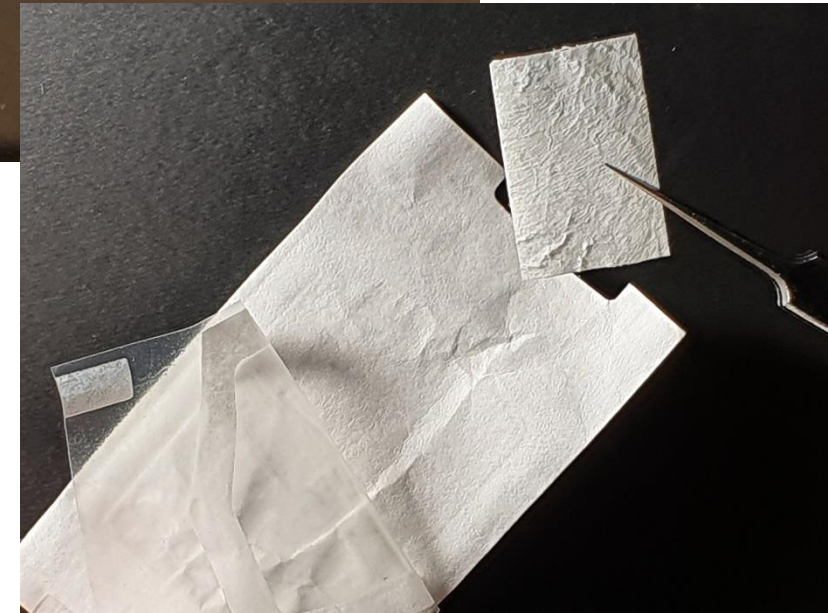


# ReNerve NervAlign™ Nerve Cuff: Next Steps

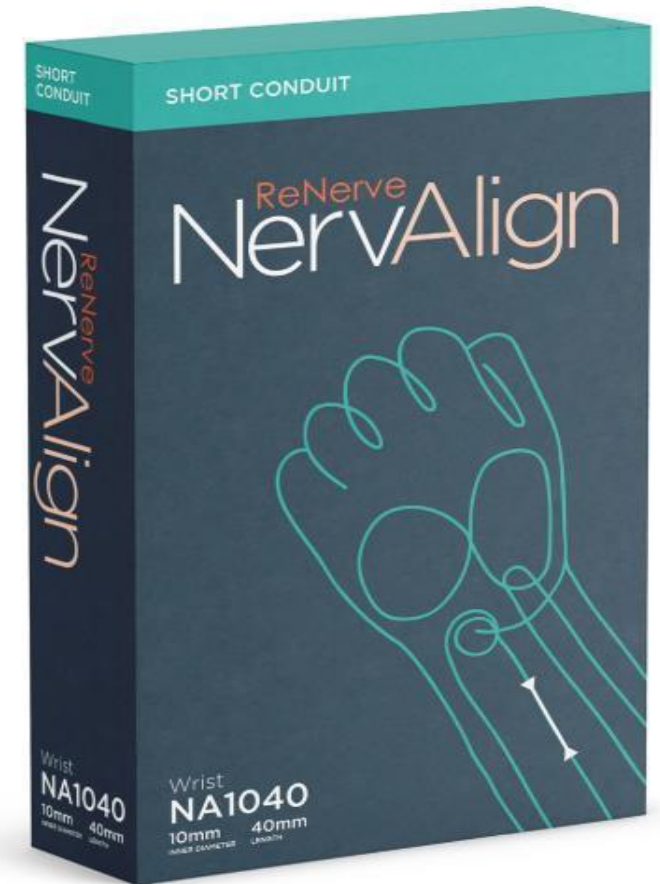
- All R&D development has been completed
  - In substantive review at FDA for marketing clearance
- Manufacturing scaled to commercial levels & ready for commercial sale
  - Commercial inventory in stock
  - ReNerve ISO13485 certified
- Clear market advantages
  - Cleaner, safer, better
  - Antigen and toxin free material, protecting against inflammation and scarring
  - Creates binding nerve to nerve protective junction useful in small gap repairs and nerve transfers
  - Manufactured using proprietary technology in supercritical CO<sub>2</sub> for cleaner, better quality tissue
- Looking at applications in spinal cord repair with cell therapies



NervAlign® Nerve Cuff is pliable, conformable and translucent and holds its shape once in place

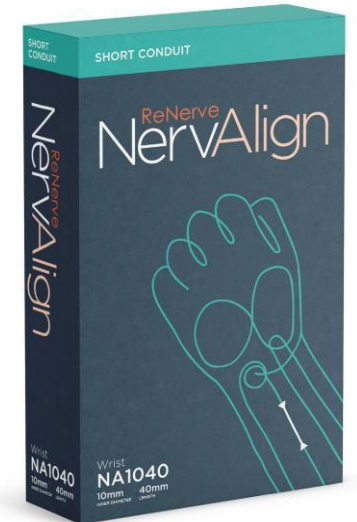


# NervAlign® Nerve Graft

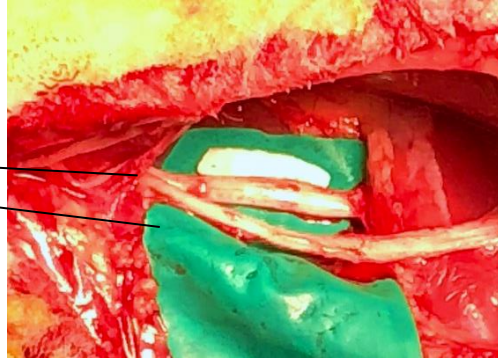
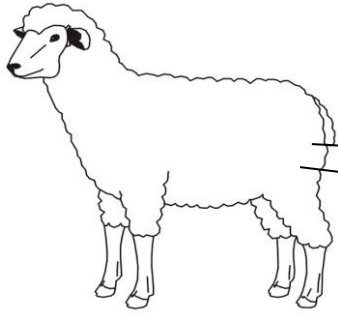


# Nerve Graft

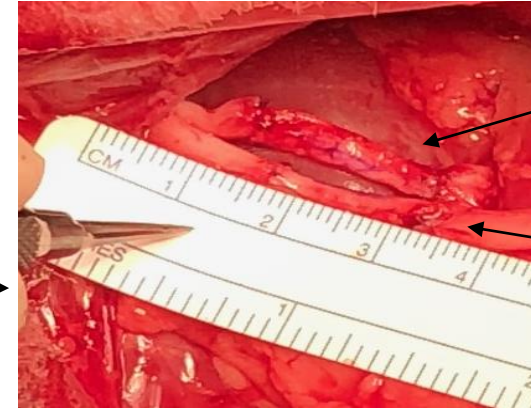
- ReNerve's NervAlign® Nerve Graft product is an '**off-the-shelf**', ready to use nerve connector with internal guidance infrastructure
- Currently in relevant large animal studies (sheep model) using a cross-over model
- Looking to progress into clinical studies in damaged nerves of the hand, upper and lower limbs
- Aim to file under the de Novo 510(k) route in the US
  - Use clinical data for EU filing as well
- Offering an alternative to autologous and donor nerves and better than on market connectors
  - Genuine alternative to transplant of the sural nerve
- Results to date show:
  - ReNerve's Nerve Graft shows established, structured nerve growth equivalent to autologous nerve grafts
  - Histology shows replacement nerves are clean and free of DNA with functioning axon formation
  - Re-establishment of sensory and motor function shortly after surgery



# NervAlign™ nerve graft vs Autologous Implantation study



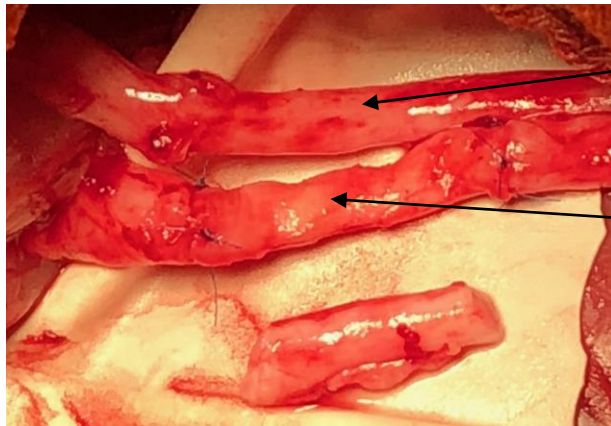
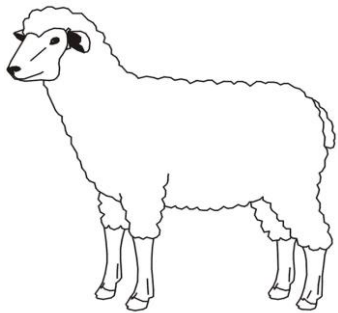
**Sheep 1**  
(Replacement  
Nerve batch 1)



2cm conduit  
(in tibial)

Autologous

**Sheep 2**  
(Replacement nerve batch 2 prep)



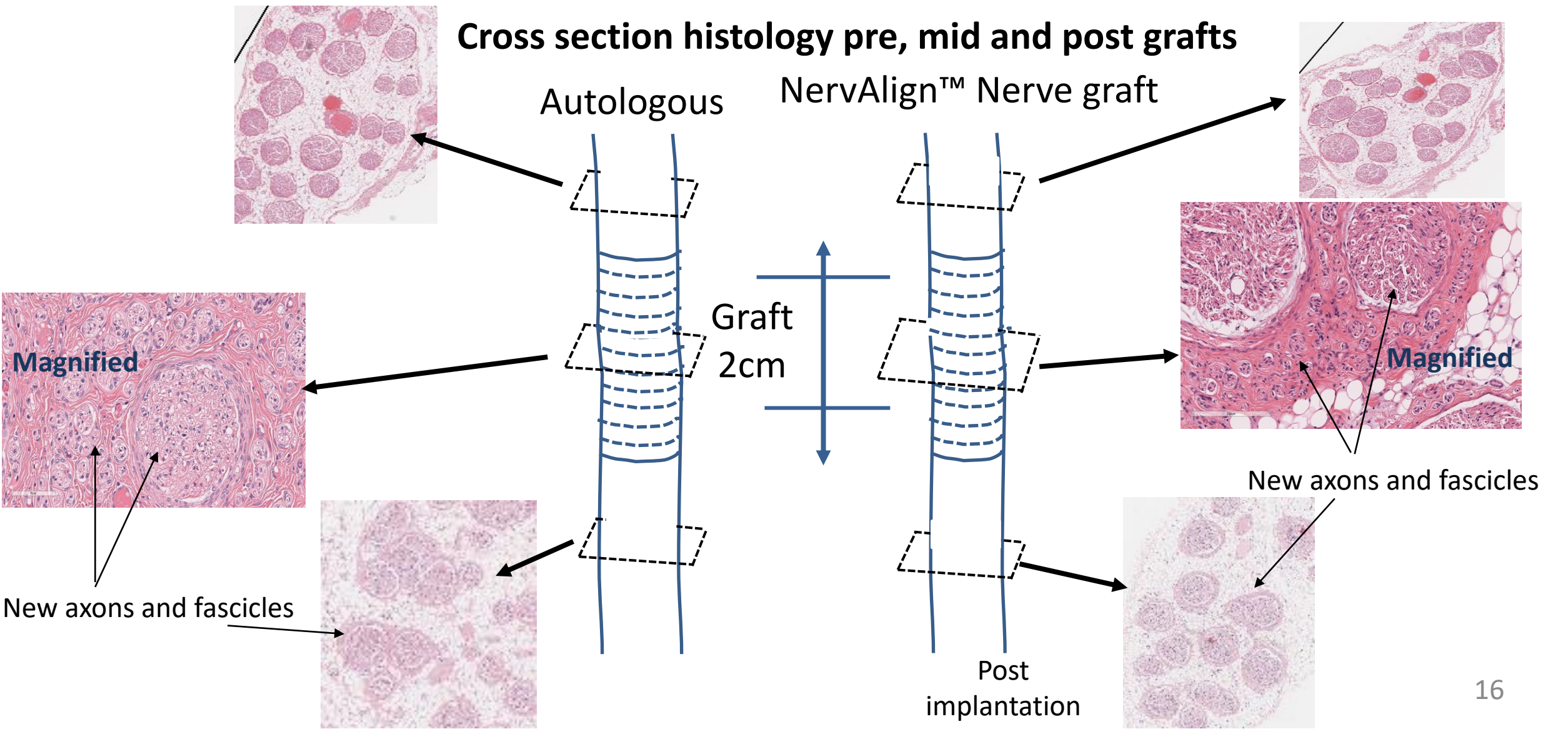
Nerve graft  
(in tibial)

Autologous

## Results showed:

- Rapid recovery post surgery
- Histology showed nerve regrowth through conduits as good as autologous (native) tissue
- Full nerve formation through entire length of nerve graft
  - Including new axon and fascicular formation and functional nerves
- Recovery of walking within 3 months

# NervAlign™ Nerve graft implants vs Autologous post implantation

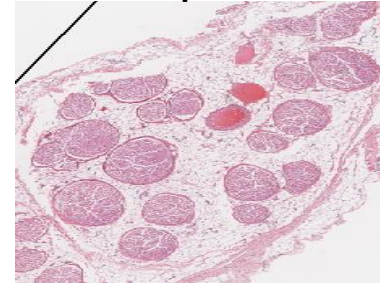


# Nerve graft implant results

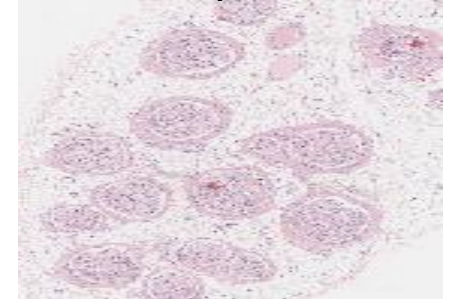
- Completed 3 rounds of animal study implants
- Restored 'native state' nerve function
- Formation of new, functioning axon structures through full length of implant (2cm)
  - Also formation of fascicular structures over the 4 month implantation period
  - Full function for entire nerve length
- Rapid recovery of animals post surgery
  - Walking with splint within hours post surgery
  - ~3 months to complete recovery
- No short or long term post-surgery complications
- Post-graft area back to fully functioning nerve

## Pre & post implant cross section histology

Pre-nerve replacement  
implant

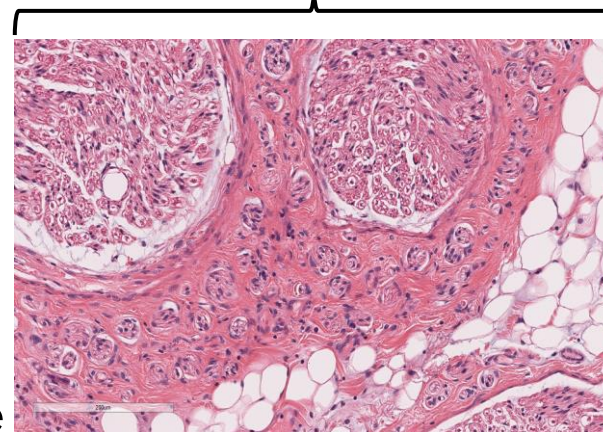


Post-nerve replacement  
implant



## Histology of ReNerve's nerve graft 4 months post implantation

- Functioning nerve
- Full length axon formation



## Silver staining of new axons

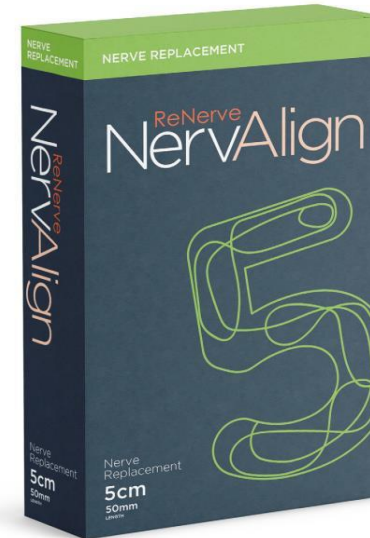


# NervAlign 'Bionic' Nerve Replacement

## ➤ NervAlign® 'bionic' nerve replacement

From 1cm to 20+ cm long

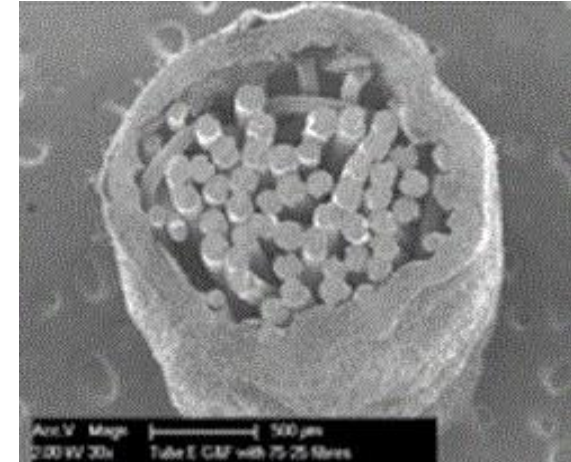
- Regrowing nerves need support to grow across long gaps
- The most challenging repair: currently few (if any) effective solutions for surgeons with long nerve repairs
  - E.g. reinnervation post mastectomy
- Current practice to use donor or autologous (patient's own graft) nerves if possible but limited to length
- Generally nerves regrow at around 1mm per day in a stable environment but outcomes poor over 2 to 5 cm but the longer the regrowth the poorer the outcome
- Regrowth areas need to be protected from scarring and infiltration of other cells that will inhibit nerve regrowth and reconnection
- ReNerve's project is aiming for a continuous off-the-shelf, ready to use nerve structure to replace damaged nerves from small to very long lengths



Initial ReNerve nerve replacement prototypes using a combination of biological collagen and polymer technology

# Development Plan: 'Bionic' Nerve Replacements

- Building polymers with CSIRO to enhance cell migration & nerve repair.
- Utilises ReNerve know how and technologies, improve material compliance, includes ReNerve's proprietary nerve materials
- Incorporates additional selective schwann cell and axon preferred guiding materials. Materials are less conducive to fibroblast growth
- Include ionic polymers to enhance conductivity and regrowth
- Sterilisation with novel sCO<sub>2</sub> instrumentation (not detrimental to polymer structure)
- Exploring use of regenerative growth factors to accelerate repair



**Synthetic  
nerve  
prototype  
from CSIRO**



**Initial ReNerve nerve replacement  
prototypes using a combination of  
biological collagen and polymer  
technology**

# Autologous OR tissue Processing Kit

- Uses ReNerve's proprietary tissue treatment technology
- Disposable tissue treatment product
- Allowing for in-OR tissue processing of autologous tissue
- Have developed two methods:
  - 20 minute kit for in theatre use by surgeon and supporting team
  - Longer lasting tissue for donor tissue providers like tissue banks
- Targeting the segment of the surgery market using autologous tissue
- **Can be used on all nerves post harvest and pre-implantation**
- **Potential use in nerves, tendon, cardiac and vascular tissue**
- Currently exploring its use in donor tissue products
- **Complimentary to product pipeline**
- **Short time to market**



# Company Board & Management

## **Mr Stephen Cooper - Chairman**

Managing director of Grant Samuel, a leading Australian investment bank. Over twenty years of experience in finance, investment banking, mergers and acquisitions, capital raisings. Strong emphasis on corporate governance. Stephen was chairman of Avexa, an ASX-listed biotechnology company.

## **Dr Michael Panaccio – Non-Executive Director**

Director of numerous technology businesses in Australia and the USA including SIRTEx Medical Ltd (ASX listed), ImpediMed Ltd (ASX listed), Engana Pty Ltd (now part of Finisar Corporation), Protagonist Therapeutics Inc (Nasdaq listed) and Energy Response Pty Ltd (sold to EnerNoc Inc). Founder of Starfish Ventures, a \$0.5 billion technology fund.

## **Dr Julian Chick – Executive Director**

Experienced healthcare professional with over 20 years of experience running early and late stage R&D projects, launching medical devices into the global markets, sales and marketing. As the COO at the ASX listed Admedus, Dr Chick oversaw the R&D development, regulatory approvals and launch of several tissue products in North America, Europe and Asia. During his time, the company grew from \$12M to > \$100M. He has PhD in Muscle Physiology and worked in healthcare and biotechnology for private equity and venture capital.

## **Dr David Rhodes – Executive Director & CSO**

More than 20 years of experience in healthcare and biotechnology. Held senior roles, including CSO with the ASX listed medical devices company Admedus where he developed technologies from early stage through to market approval. He was the Head of Drug Discovery and Senior Vice President Biology at ASX listed Avexa Ltd and Amrad. Dr Rhodes has successfully led multiple technology development programs attracting significant levels of funding. He publishes in high impact peer reviewed journals and is an inventor on numerous patents. David is a visiting scientist at CSIRO, an Adjunct Associate Professor in the Faculty of Engineering at Monash University and a member of the Australian Regenerative Medicine Institute Leadership Advisory Board. David has a PhD in Biochemistry.

# Financial and corporate information

- **Cash balance AUD \$2.8M (31<sup>st</sup> Mar '21)**
  - **>2 years capital assuming Zero sales**
  - **Last capital raising = \$2M**
  - **Market cap \$12M**
  - **Supported by AusIndustry Commercial Ready grant**
- **Cash burn for 19/20 year = <\$1M**
- **FTE = Direct 2.6, supporting 8**
- **Forecast for cash burn around \$1.4M in 20/21**
- **R&D tax rebate = \$274K received Oct '20**
  - **Similar expected in Oct '21**

# Company milestones

- ✓ 4<sup>th</sup> Qtr '19 Completed nerve graft studies in animals
- ✓ 4<sup>th</sup> Qtr '19 Completed animal safety study for nerve wrap FDA 510(k) filing
- ✓ 2nd Qtr '20 Completed nerve cuff FDA submission package
- ✓ 3rd Qtr '20 FDA marketing approval submission
- ✓ Formal FDA review underway
- 1H '21 Partnership in spinal cord repair
- **4Qtr '21/1<sup>st</sup> qtr '22 FDA marketing approval**
- **1H '22 Forecast for initial company revenue**
- '22 Initial clinical studies for NervAlign™ nerve graft
- '22 Complete initial testing of 'bionic nerve' prototypes in nerve replacement models

# Summary

- Developing products that target US\$1+bn peripheral nerve repair and replacement market
- NervAlign® Nerve Cuff and tissue treatment ready for marketing
- FDA NervAlign® Nerve Cuff approval anticipated in late '21/early '22
- Establishing US distributor network & US surgeon outreach
- Strong product margins ~ 80% on wholesale product sales
- Clear market position and advantages
- Technology has potential beyond peripheral nerves
- Strong pipeline of products backed by positive data from large animal models
- Management with extensive experience and a successful track record in tissue product development, approvals, global marketing and sales
- Ongoing receipt of non-dilutive grant funding



Thank you.

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Dr Julian Chick  
[jchick@renerve.com.au](mailto:jchick@renerve.com.au)  
+61 417 137 291

ReNerve

# IP & Trademarks

***ReNerve technology and products are covered by a series of patents and trademarks with the company continuing to pursue new patents and trademarks where possible.***

## **Current patents**

- **ReNerve has a license to the following patents**
  - **U.S. patents 7,108,832, 8,974,730, 7,771,652, 8,034,288 (relating to the Nerve Cuff)**

## **Current trademarks**

- **ReNerve™ (number 1879717)**
  - **NervAlign Cuff™**
  - **NervAlign conduit™**
  - **NervAlign Replacement Nerve™**
- 
- **All Trademarks are filed in Australia, EU and the US and under the Madrid system. Trademarks are filed under Classes 5 & 10**

# NervAlign™ Nerve Cuff - Product Specifications

- **Semipermeable** – allows small-sized nutrients and neurotrophic factors to pass, yet provides a barrier to scar forming cells
- **Highly biocompatible** – Type 1 collagen is non-inflammatory and well accepted by body
- **Completely absorbable** - collagen matrix eventually degrades after nerve has repaired. Degraded and resorbed by normal metabolic processes
- **Easy to use** – wraps and cuffs are either in flat or tubular shapes for simple application to damaged nerves. Provided in a variety of dimensions to suit majority of peripheral nerves
- **Non-toxic manufacturing process** – important with changing requirements for devices in theatre
- **Antigen free nerve wrap**



ReNerve NervAlign manufactured product

<u>Lengths</u>	<u>Wrap size</u>	<u>Nerve Diameters</u>
1.5, 2, 3 and 4cm	2.5mm	to 2mm
1.5, 2, 3 and 4cm	5mm	to 4mm
1.5, 2, 3 and 4cm	7.5mm	to 6mm
1.5, 2, 3 and 4cm	15mm	to 12mm

# NervAlign Nerve Cuff Commercial Strategy

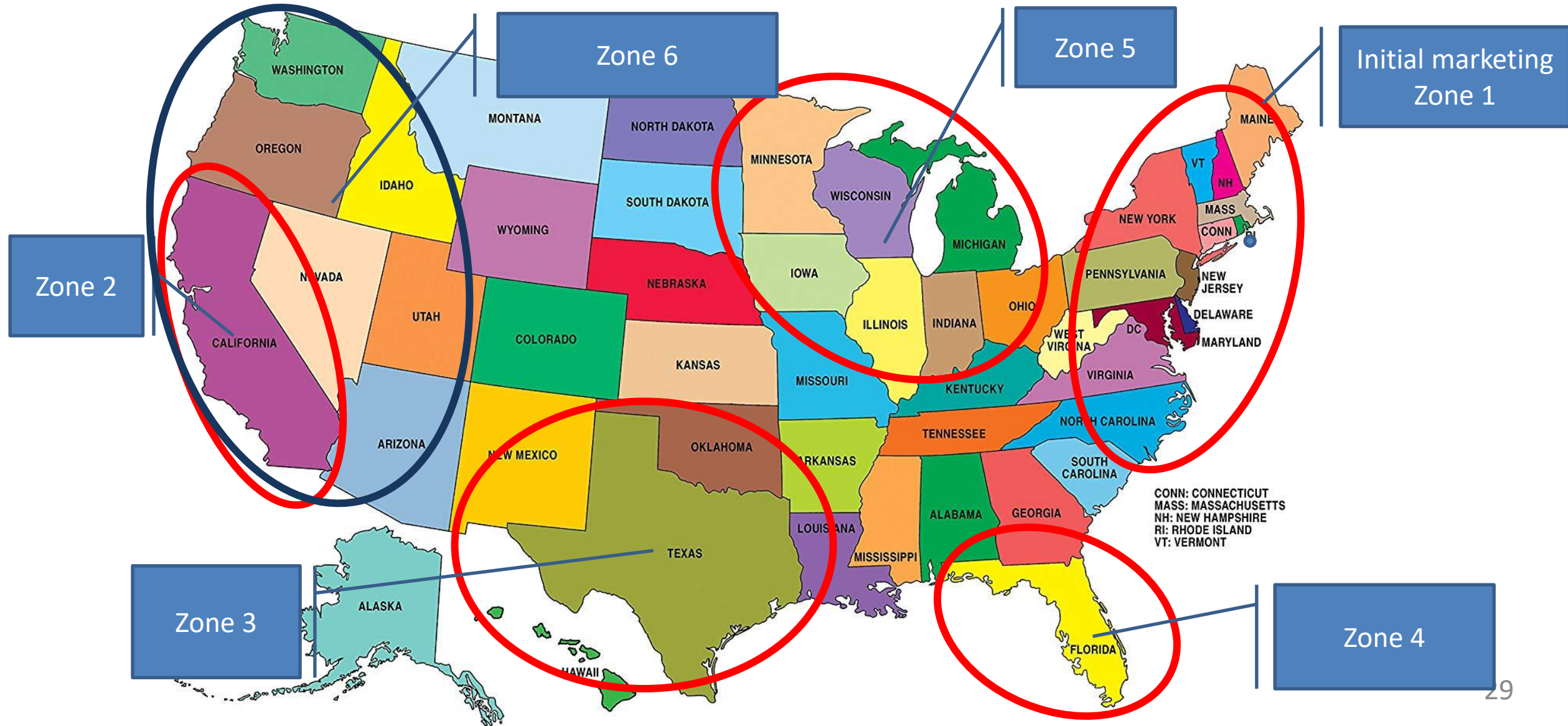
- Targeting approval in early 2021
- Undertaking pre-marketing surgeon engagement
- Working with surgical specialist US distributor
  - Team & network of experienced medtech sales reps
- Working on a wholesale selling to ASP listing price
  - COGS (landed) at 7% of lowest list price
  - 85% margins on wholesale price to distributors
  - Good margins to work with wholesalers and distributors
  - Reimbursed through procedure DRG coding
- Initially targeting roll out in six US 'zones'
  - NY/NJ & New England
  - California
  - Texas & NM
  - Florida
  - Mid-west (MN, WI, IL & IA)
  - California backup and surrounding states

## Indicative product pricing

Average Cost Based On (Up to) Manufacturers/ ASP Listings (US\$)			
Three-Tier Gap length levels	Wrap	Hollow Tubes or Connector	Processed Nerve Allograft
No/short gap	\$1400-\$1800	\$1336	N/A
Small Gap	\$1400-\$2800	\$1400-\$1800	\$3660
Large Gap	\$1800-\$3200	NA	\$7320

Adapted from Brattain, 2015.

# Initial US marketing zones with US distributor MLM Medical



# Listed soft tissue comparable

Company	Market Cap	Cash (30 <sup>th</sup> June 2020)	Enterprise value	Gross revenue	Total target market
<b>Polynova (ASX:PNV)</b>	AUD\$2Bn	\$11M	\$1.9Bn+	\$19M	> USD\$2Bn
<b>Aroa Biosurgery (ASX:ARX)</b>	AUD\$390M	\$30M	\$360M+	\$20M	>\$1.5Bn
<b>AxoGen (NASDAQ:AXGN)</b>	USD\$590M	AUD\$75M	AUD\$515M	AUD\$92M	>\$1.6Bn
<b>Orthocell (ASX:OCC)</b>	AUD\$70M	~ AUD\$20M	EV ~ \$50M	<AUD\$1M	>\$1Bn
<b>Osteopore (ASX:OSX)</b>	AUD\$45M	AUD\$7M	EV ~ \$35M	~AUD\$1.2M	>\$1Bn
<b>ReNerve</b>	AUD\$9.5M	\$1M	\$8.5M	<AUD\$0.5M	>\$1Bn

# Competitor product comparison



Company	Cuff/Wrap	Hollow Conduit	Nerve grafts (up to 5cm)	Replacement nerve
<b>Integra</b> (mcap USD\$3.96Bn)	Bovine tendon collagen Harsh sodium hydroxide treatment Sterilised with ethylene oxide	No product	No product	No product
<b>Stryker</b> (mcap USD\$71Bn)	Bovine type I collagen Kink resistant walls Crosslinked Gamma irradiated (Collagen Matrix Product)	No product	No product	No product
<b>AxoGen</b> (mcap USD\$440M)	Porcine SIS Low purity 18mth shelf life EtO sterilised (Cook Biotech product)	Empty tube Collapse on bending Poor axon re-alignment EtO sterilised (Cook Biotech product)	Delayed processing due to harvest from cadaver Detergent cleaning method Possible rejection Stored frozen Gamma-irradiated Other infectious agents?	No product
<b>ReNerve</b>	Porcine collagen High purity/complete decellularisation ECM maintained Non-toxic solvent production method 3 year+ shelf life No Ethylene oxide	<b>Graft containing axon guides - biocompatible</b> <b>Ready, consistent supply - processed immediately</b> <b>Proprietary antigen removal technology</b> <b>Superior nerve structures maintained. Convenient transport and storage – ready to use</b>		<b>ReNerve replacement nerve</b> <b>Based on the nerve conduit</b> <b>Also includes ionic polymers to provide conductance and improved recovery &amp; prevents distant necrosis</b>