

# ReNerve

TRANSFORMING NERVE REPAIR  
THROUGH SCIENCE

Company business update  
Annual General Meeting  
October 2022



## 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.

*"We have not seen any real advancement in nerve repair and replacements in 20 years – ReNerve has a real opportunity to make a difference and be a market leader"*

Dr Fox – Stanford Medical

# KEY HIGHLIGHTS

## Company Overview

- Founded by neurosurgeon and experienced Medtech researchers
- Developing a portfolio of products for nerve injury repairs
- Products promote nerve injury recovery & nerve regrowth leading to faster patient recovery and better outcomes
- Company moving from R&D to commercial sales post FDA market clearance and initial market entry.

## Target Market

- Estimated to be > USD\$1.2Bn by 2025
- Growing by >10% pa
- Ability to expand market with cleaner, safer, better products
- US ~900,000+ trauma cases pa
- Used when nerves are damaged (trauma, tissue resections - breast, prostate)

## Company's products

- NervAlign® Nerve Cuff – On market in USA & NZ
- NervAlign® Nerve Graft successful nerve replacement data - progressing to clinical studies
- Dura mater replacements for craniotomies and spinal cord surgery
- NervAlign® Bionic replacement nerve

# PROBLEM

**\$1.25B\***

Market for nerve repair  
and regeneration  
annually

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**~900K**

nerve surgeries in  
in the US per  
annum

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No  
more  
than **24%#**

nerve surgeries  
restore to 'as good  
good as it was'

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## VALUE PROPOSITION

# ReNerve

- ▶ Cleaner
- ▶ Safer
- ▶ Better

Improved quality of  
outcome & function

Reduced inflammation  
and scarring

Targeting full  
recovery

restoring back  
to native 'natural'  
state

# PORTFOLIO & TIMELINES

Product (Brand name)	Procedure use	Application	CY'21	CY'22	CY'23	CY'24	CY'25	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+ (2020) \$224.2M (2025)	Multiple	Launching in the USA & NZ Opening additional markets
<b>NervAlign® nerve graft</b>	Replaces 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 (2020) USD\$792.7M (2025) CAGR 14%	Multiple	CY'25
<b>Dura mater replacement</b>	Developing two tissue-based products for the replacement of damaged or removed dura mater	<ul style="list-style-type: none"> <li>Trauma</li> <li>Craniotomy</li> <li>Spinal cord injury</li> <li>Spinal cord surgery</li> </ul>						> USD\$400M	Multiple	CY'24

R&D   
 Clinical trials   
 Commercial sales

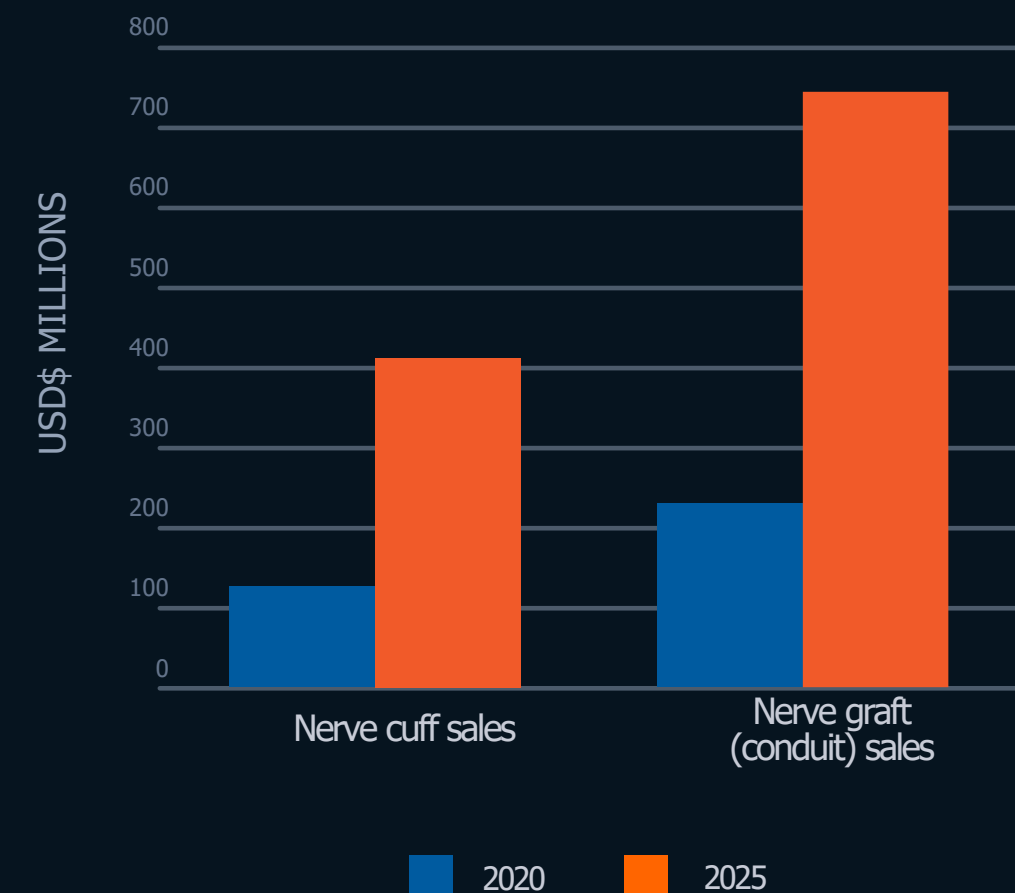
\* Taken from Markets and Markets nerve repair and regeneration regeneration report -Global forecast to 2025 -July 2020

# PERIPHERAL NERVE INJURY REPAIR MARKET

Opportunity to expand markets with better products and patient outcomes - offering genuinely safer, cleaner alternatives than harvested tissue, that deliver superior outcomes through better nerve regeneration.

- Estimated current global biomaterials sales market is USD\$537.6M\*
- Growing at CAGR of 14.0%
- Growing to USD\$1.25Bn by 2025\*
- Single largest market is the US - followed by Europe

Nerve cuff and graft/conduit markets for 2020 to 2025



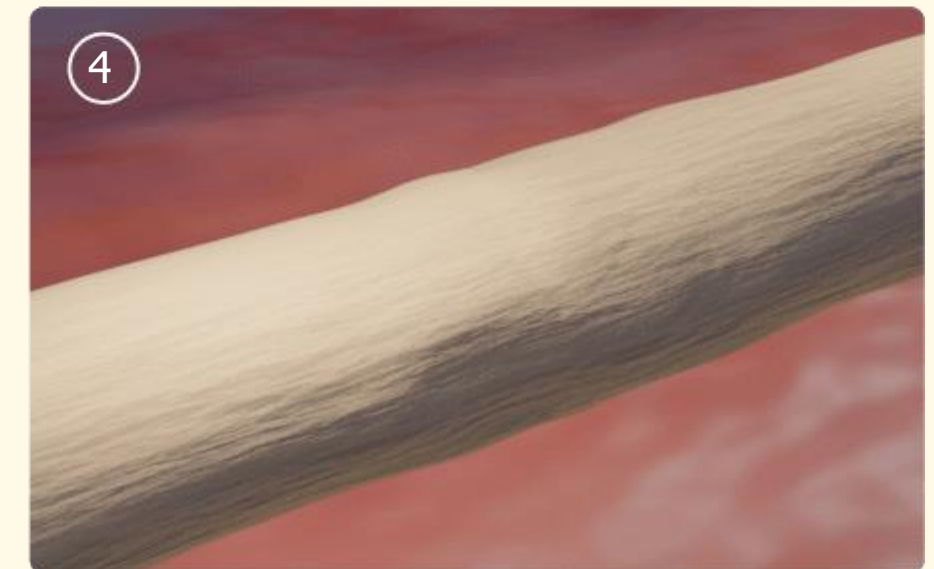
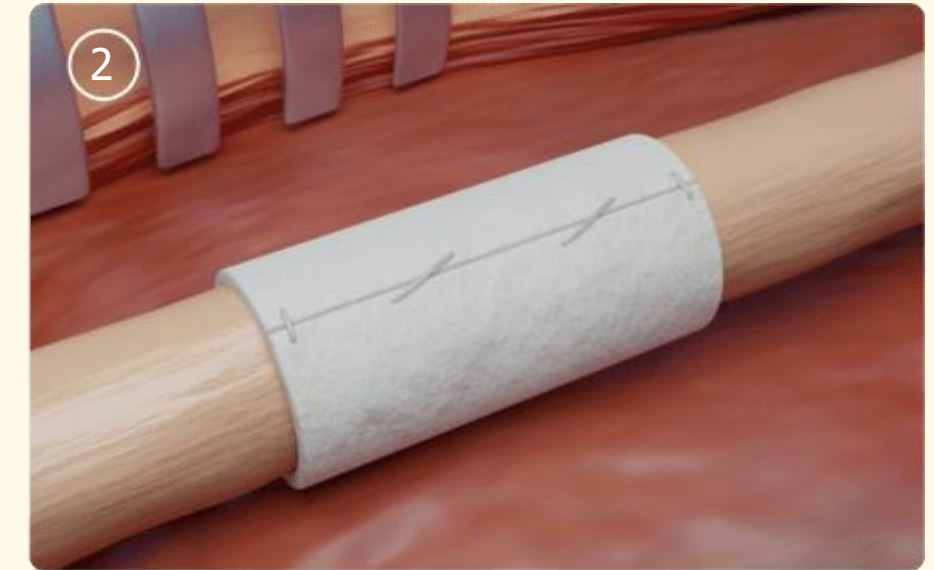




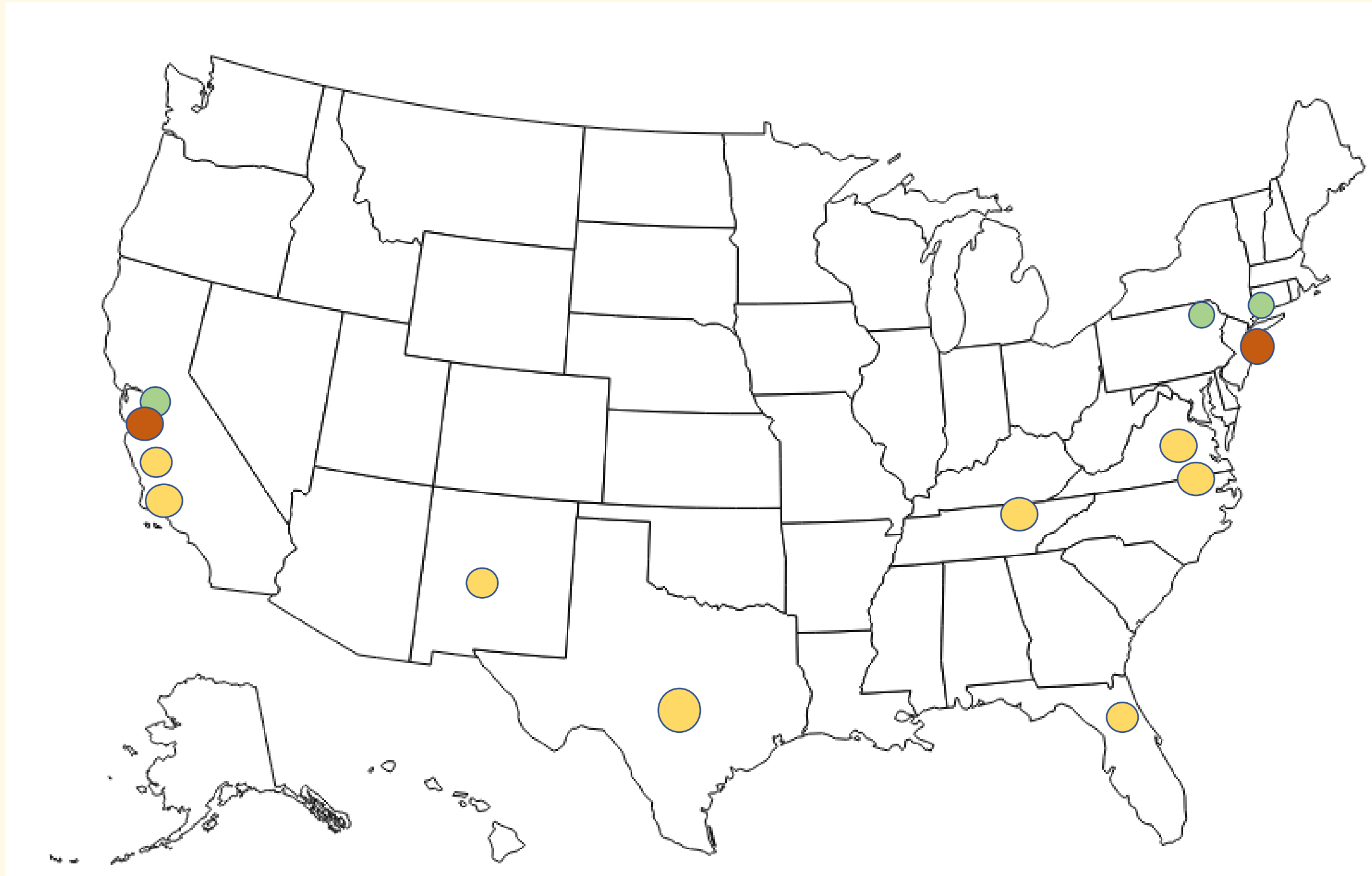
# NERVALIGN® NERVE CUFF

The data shows:

- Bio-absorbed over 6 months
- 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



# NERVALIGN® NERVE CUFF



## US commercial launch

- Now have several distributors in place in the US
- Sales team of 14 people
- Focus on new accounts and orders
- Looking for greater US coverage

- Initial sale ●
- Pending order ●
- New product approval process ●

# NervAlign® Nerve Cuff eCOO® Technology

Using carbon dioxide under pressure to create a gas and liquid state. Ideal for cleaning and sterilizing tissue - eCOO® Technology permeates like a gas and cleans like a liquid.

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



The NervAlign® Nerve Cuff implanted  
in a carpal tunnel revision patient.

## eCOO® Technology

- Retains structural and mechanical properties
- Environmentally friendly
- Process ensures effective viral and pathogen inactivation
- Minimal residues and hazardous materials

## eCOO® Clean

- 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)

## NERVALIGN® NERVE CUFF

### Next 12 months

- Continue to expand US sales and open new accounts
- Expand US distributors for National coverage
- Working on other countries for approval including Sth Africa, Taiwan, Indonesia, Thailand, India and others
- Building a database of cases as well as clinical study
- Will aim for a European clinical study in conjunction with a surgical research group
- Establish a US Scientific Advisory Board for surgical case input
  - Complements the Australian SAB



ReNerve ASSH stand Boston Sept/Oct 2022

# NervAlign® Nerve Graft



# NERVALIGN® NERVE GRAFT

ReNerve's NervAlign® Nerve Graft product is an 'off-the-shelf', ready to use nerve graft with internal guidance infrastructure.

Currently in relevant large animal studies using a cross-over model (sheep) and looking to progress into clinical studies in damaged nerves of the hand, upper and lower limbs

***Market insight indicates strong market demand and interest***

Aim to file under the 510(k) and de novo 510(k) routes in the US

- Use clinical data for EU filing as well

Offering an alternative to autologous and donor nerves as well as being superior to on market nerve connectors

- Genuine alternative to transplant of the sural nerve
- Aiming for varying diameters and lengths to better match patient nerves

Results to date show:

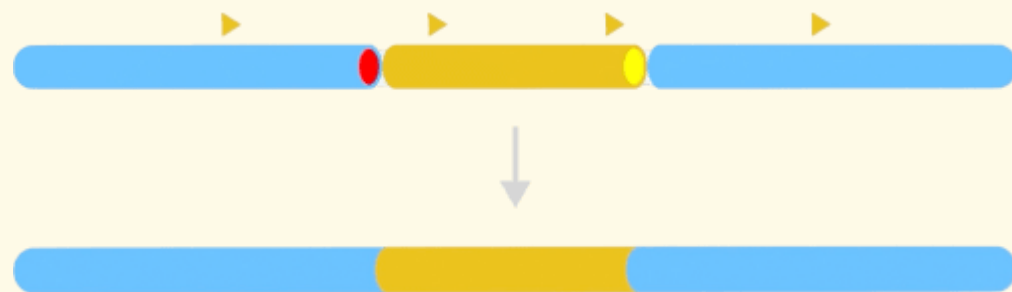
- ReNerve's Nerve Graft shows established, structured nerve growth equivalent to autologous nerve grafts
- Histology shows replacement nerve scaffolds are clean and free of DNA and support functioning axon formation
- Re-establishment of clinically detectable sensory and motor function shortly after surgery

# NERVALIGN® NERVE GRAFT

## NervAlign® nerve graft vs Autologous Implantation study

### Results showed:

- Ready to implant and no special training required
- Rapid recovery post surgery
- Histology showed nerve regrowth through grafts equivalent to autologous (native) tissue
- Full nerve formation through entire length of nerve graft - including new axon and fascicular formation and functional nerves
- Recovery of normal gait within 3 months



## Nerve graft implant results after three completed 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 like structures over the four-month implantation period
- Return of function to distal parts of limb

Rapid recovery of animals post surgery

- Walking with splint within hours post surgery
- ~3 months to complete recovery
- Re-establishment of sensory and motor function shortly after surgery

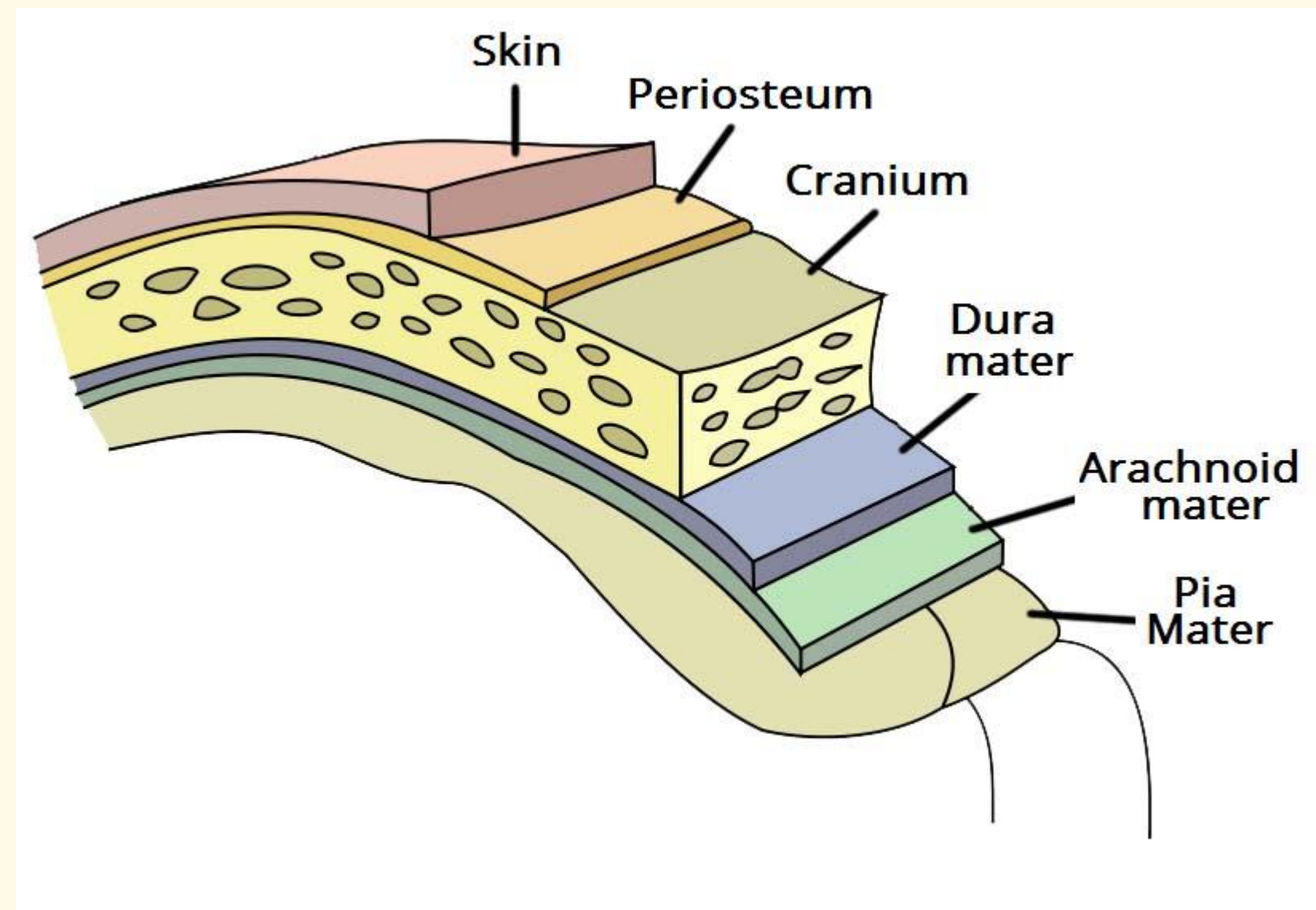
No short or long-term post-surgery complications

Next implantation studies planned for early 2023



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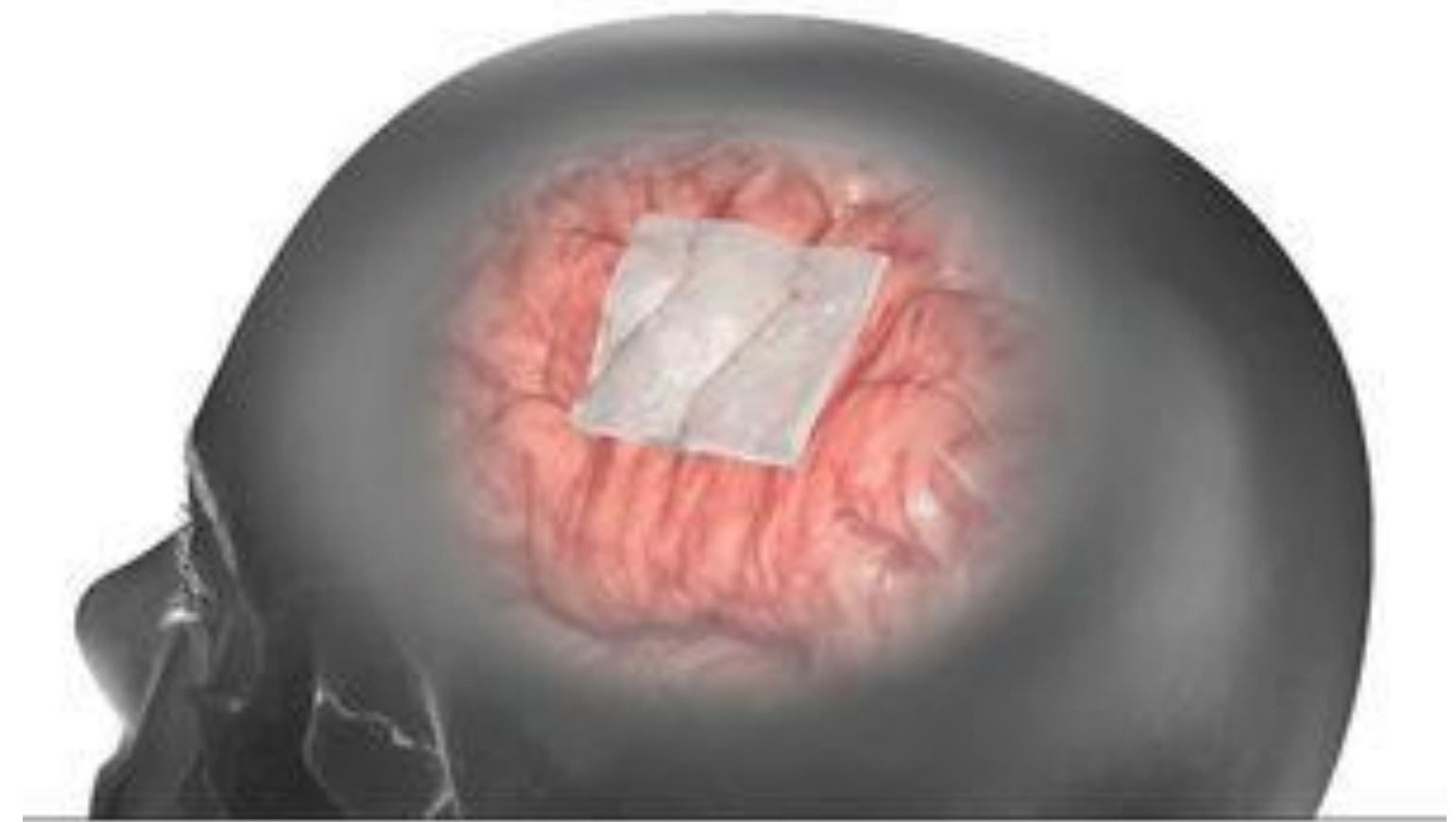
## Dura mater replacement



# Dura mater replacement

## Developing two products for the replacement of dura mater

- **Product one**
  - Short term, remodelling dura replacement
  - For small craniotomies and back/spinal surgery
  - Based on the nerve cuff eCOO Technology
  - Designed to be sutured in place and allow for remodelling repair
  - Very clean and avoids chemical meningitis seen with other products
- **Product two**
  - Long term dura replacement
  - Multi-functional product
  - Sealed, anti-adhesion product for all craniotomies and spinal surgery
  - Antibacterial to prevent surgical site infections



- Aiming for 1<sup>st</sup> FDA submission within 15 months
- Look to expand into novel multi-functional dura product

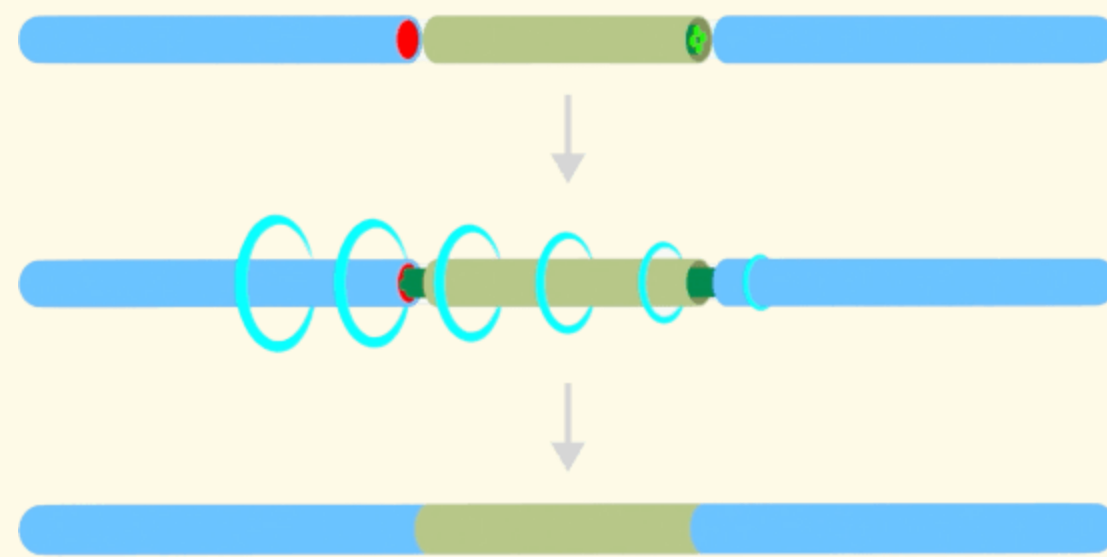
R&D project

# NervAlign<sup>®</sup> Bionic Nerve



# NERVALIGN® BIONIC NERVE

ReNerve's NervAlign® Bionic Nerve is intended to be an off-the-shelf, continuous nerve replacement, in lengths from 1cm to 20+ cm long, in a ready to use nerve structure, to replace damaged nerves.



- 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 - eg. reinnervation post mastectomy
- Current practice to use donor or autologous (patient's own graft) nerves if possible but limited in length
- Generally, nerves regrow at around 1mm per day in a stable environment, but outcomes are poor over 2 to 5 cm. Outcomes become progressively worse as regrowth distances increase
- Regrowth areas need to be protected from scarring and infiltration of other cells that will inhibit nerve regrowth and reconnection
- Enable production of nerves of bespoke dimensions and incorporation of neurostimulation through the 'bionic' nerve

## COMPANY BOARD & MANAGEMENT MANAGEMENT



**Stephen Cooper**  
Chairman

Senior director at 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 a PhD in Muscle Physiology and worked in healthcare and biotechnology for private equity, investment banking and venture capital.



**Adj. Assoc. Prof. David Rhodes**  
Executive Director & CSO

More than 20 years of experience in healthcare and biotechnology. Has held a number of senior roles, including CSO with the ASX listed medical devices company Admedus. He has 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. Dr Rhodes has successfully led technology development programs across diverse fields and has attracted significant levels of funding. He publishes in high impact peer reviewed journals and is an inventor on numerous patents. David is an Adjunct Associate Professor in the Faculty of Engineering at Monash University. David has a PhD in Biochemistry.

## FINANCIAL INFORMATION

<b>Item</b>	<b>2021/22</b> AUD	<b>2020/21</b> AUD
<i>Closing cash balance</i>	<b>\$1,710,186</b>	<b>\$2,169,676</b>
<i>Revenue</i>	<b>\$578,171</b>	<b>\$490,581</b>
<i>R&amp;D tax rebate</i>	<b>\$350,486</b>	<b>\$272,448</b>
<i>Net Profit/Loss</i>	<b>-\$1,757,480</b>	<b>-\$875,027</b>
<i>Total current assets</i>	<b>\$2,655,866</b>	<b>\$2,535,957</b>

## SUMMARY

- Developing products that target US\$1+bn peripheral nerve repair and replacement market
- Aiming for 3 products on market in 4 years
- NervAlign® Nerve Cuff US device listing and establishment registration May '22
- NervAlign® Nerve Cuff achieved first commercial sales
- Establishing US distributor network, logistics & warehousing
- First US sales generated
- Strong product margins on wholesale product sales
- Clear market position and advantages
- Technology has potential beyond peripheral nerves
- Management with extensive experience and a successful track record in tissue product development, approvals, global marketing and sales

## Future milestones

- Continued expansion in the US market with the NervAlign® Nerve Cuff
- Additional country distributor partnerships for the NervAlign® Nerve Cuff
- Growth of NervAlign® Nerve Cuff sales
- NervAlign® Nerve Graft entering formal studies ahead of clinical trials
- NervAlign® Nerve Cuff clinical study
- NervAlign® Nerve Graft development and manufacturing partnership
- Dura mater animal testing for FDA submission
- Dura mater first FDA submission



# ReNerve

TRANSFORMING NERVE REPAIR



[renerve.com.au](http://renerve.com.au)

# NERVE REPAIR & REPLACEMENT MARKET

Main market is the ~900,000+ trauma cases per annum in the US

Surgical transections also result in nerve damage\*:

- ~60% for limb amputation
- 20% -40% mastectomy
- 20%-40% thoracotomy
- ~20% post hernia repair

## Nerve compression

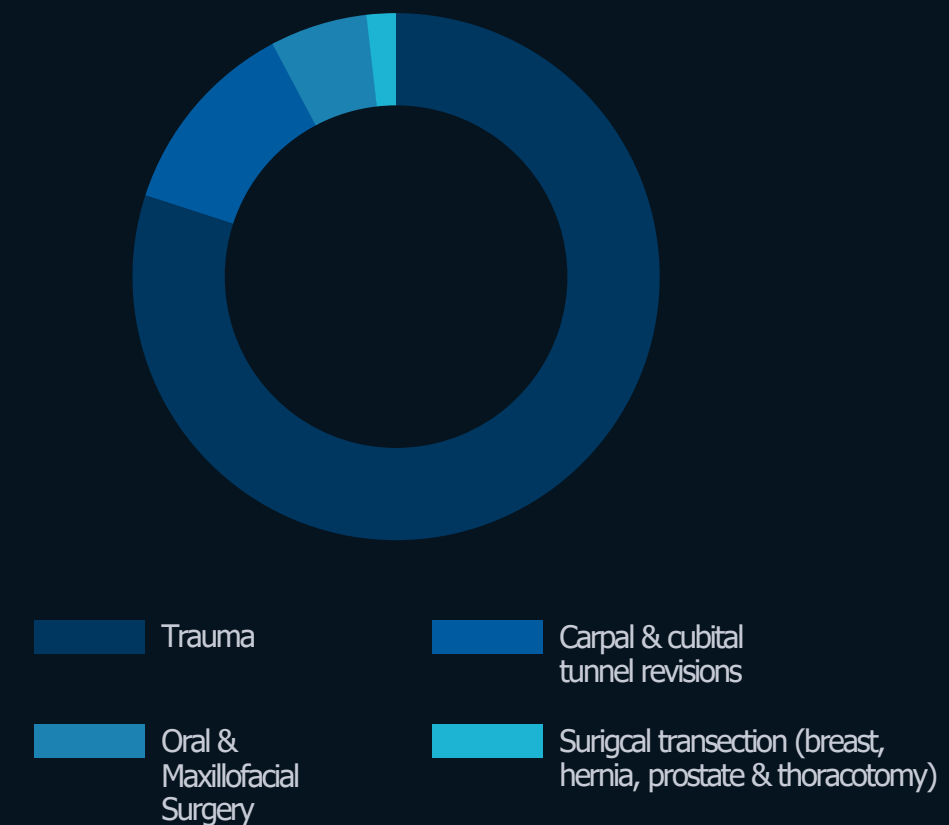
Median nerve (carpal tunnel)

- 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

US nerve related surgical procedure numbers



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

# NERVALIGN® NERVE CUFF

## On the market



## Clear market advantages

- Bio-absorbed through natural processes within 6 months
- Cleaner, safer, better
- Antigen and toxin free material, protecting against inflammation and scarring
- Creates binding nerve to nerve protective junction useful in conjunction with small gap repairs and nerve transfers
- Manufactured using proprietary technology in supercritical CO<sub>2</sub> for cleaner, better-quality tissue

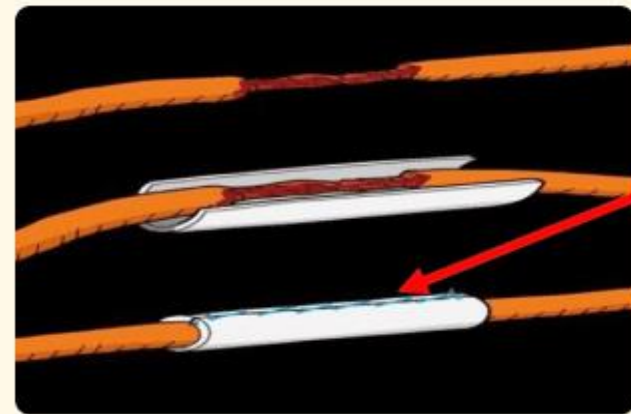
# NERVALIGN® NERVE CUFF

## NervAlign® Nerve Cuff with eCOO® Technology

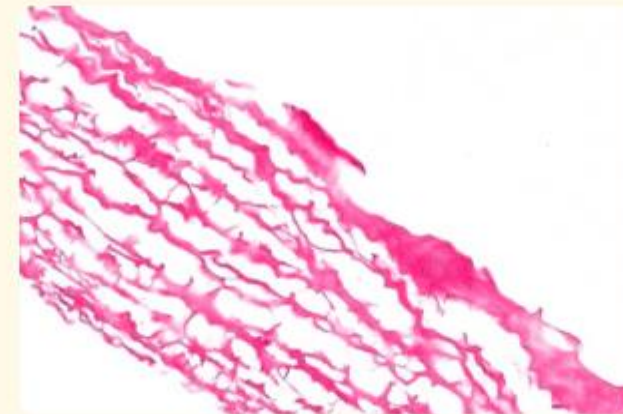
- On market in the US and NZ for repairs of damaged or crushed nerves with no gaps and in tensionless end to end repair
- Distributors in US (two), NZ and Taiwan. Working on other countries
- Can be used with grafts and replacement nerves
- Product designed to limit intra-nerve scar formation and enables nerves to recover and re-grow

## NervAlign® is superior to existing products

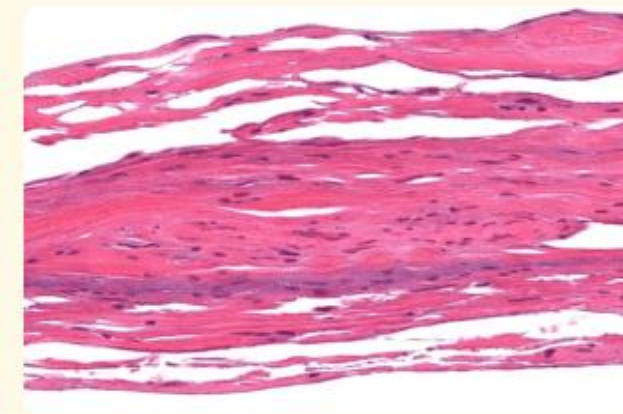
- ✓ Non-toxic
- ✓ Antigen free
- ✓ Cost effective



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 competitor tissue (dark blue stain shows residual tissue contamination)