ReNerve

ASX:RNV

Transforming Nerve Repair Through Science

ReNerve Annual General Meeting presentation | November 2025

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ReNerve Ltd ABN 23 614 848 216

Executive Summary

Development of Novel Nerve Repair & Regeneration Products

ReNerve is developing a comprehensive portfolio of products for the nerve repair and regeneration markets and related surgical procedures, with clearly defined commercial position and demand.

Expanding Product Portfolio

3 product ranges in the US market with more coming

Strong Sales & Distribution Presence

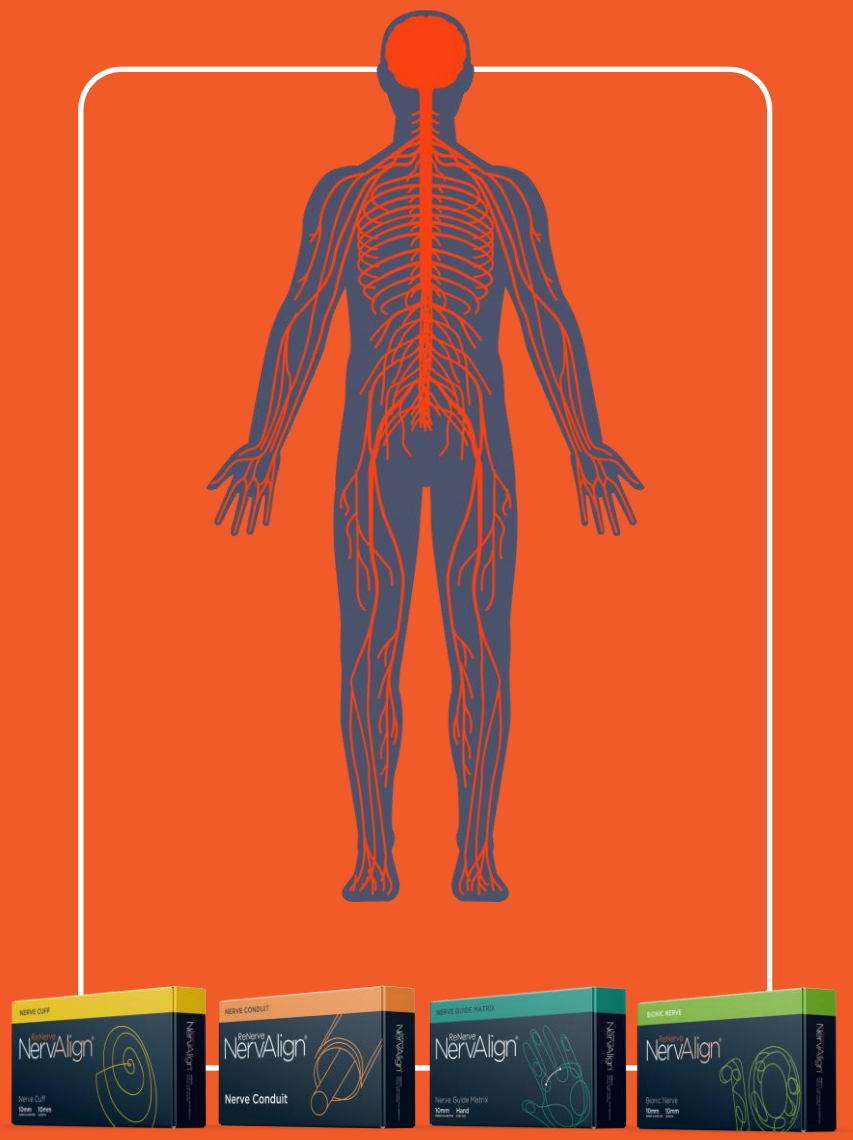
ReNerve has established logistics, warehouse and invoicing infrastructure with a strong focus on building a sales distribution network for all products in the US.

Global Expansion & Commercialisation

Successful ongoing expansion within the first year of ASX listing into Ex-US markets in Asia, India, The Middle East, and The Americas.

Clinical & Professional Validation

Improved patient outcomes for post-surgical measures of pain and surgery satisfaction, as well as proven ease of use for surgeons.



Activities for the past 12 months

Expanding our commercialisation presence

Completed an ASX IPO

Multiple regional partners

- Middle East, Mexico, India, Hong Kong

Partnership with Berkeley Biologics

- Brings Empliq brand of products
- Adds 4 product lines to the ReNerve sales portfolio
- Helps accelerate company sales
- Complementary to existing product portfolio

Added direct salespeople in the US

- 21 US distribution partners
- Ongoing hospital approvals and surgeon engagement

Positive NervAlign Nerve Cuff clinical study

- Expanded into a more comprehensive study

Company revenue rose 53% year on year

Company Portfolio

	Product	R&D	Product Development	Commercial Development	On Market
NervAlign®	Nerve Cuff	✓	✓	✓	✓
	Nerve Tube	✓	✓		
	Nerve Protector	✓	✓		
	Nerve Guide Matrix	✓	✓		
	Nerve Cap	✓			
Empliq™	Dermal Tissue	✓	✓	✓	✓
	AmnioLite	✓	✓	✓	✓
	AmnioDuo	✓	✓	✓	✓
	Placental	✓	✓	✓	✓

ReNerve LTD

Target Market

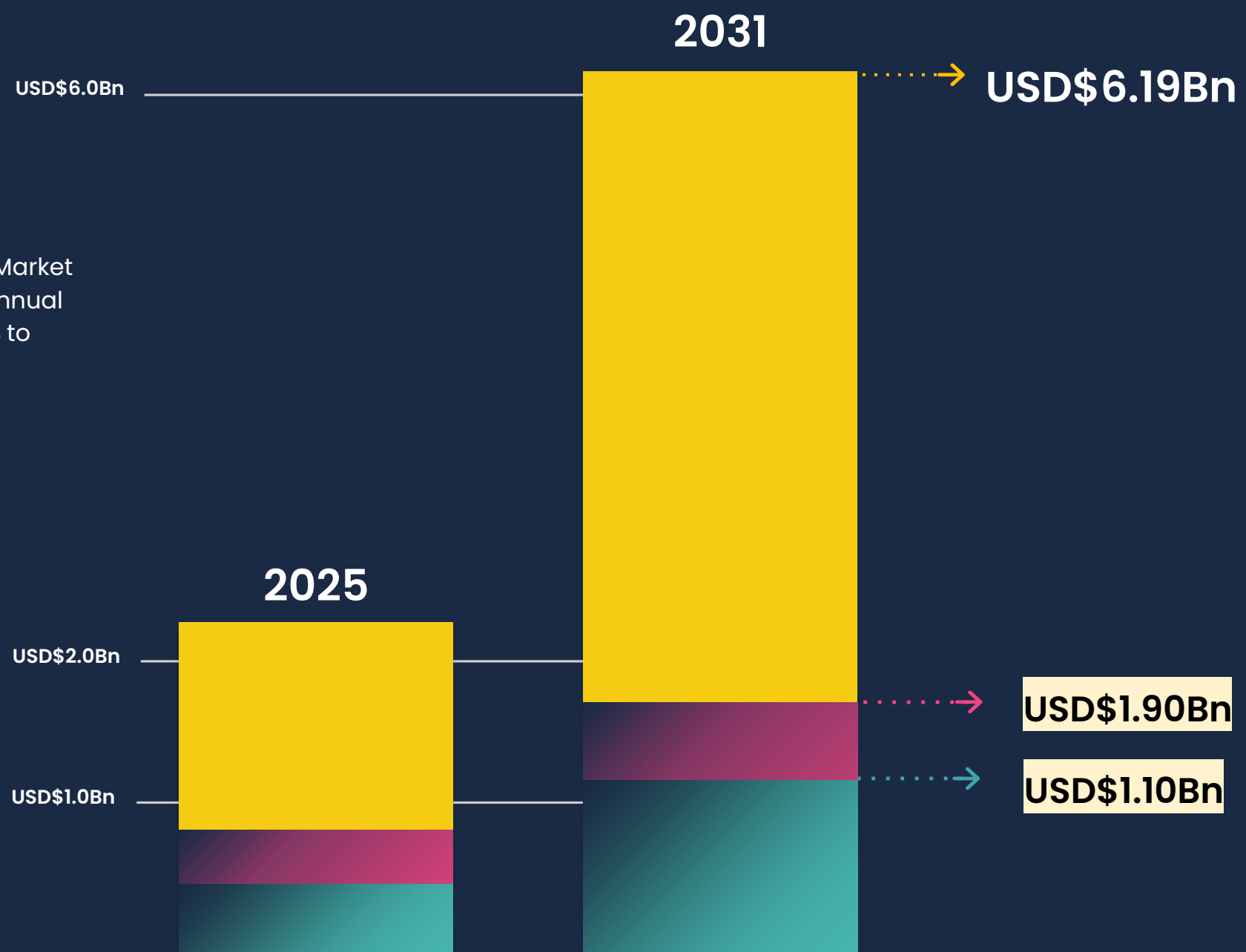
The Global Nerve Repair Biomaterials Market is projected to grow at a compound annual growth rate (CAGR) of 17.8% from 2024 to 2031 to USD$6.19Bn.

Our Target Markets

Global Nerve Repair Biomaterial Market

Dermal and Amniotic Tissue
Surgical Applications (Trauma, plastic surgery)

Dermal and Amniotic Tissue
Orthopaedics

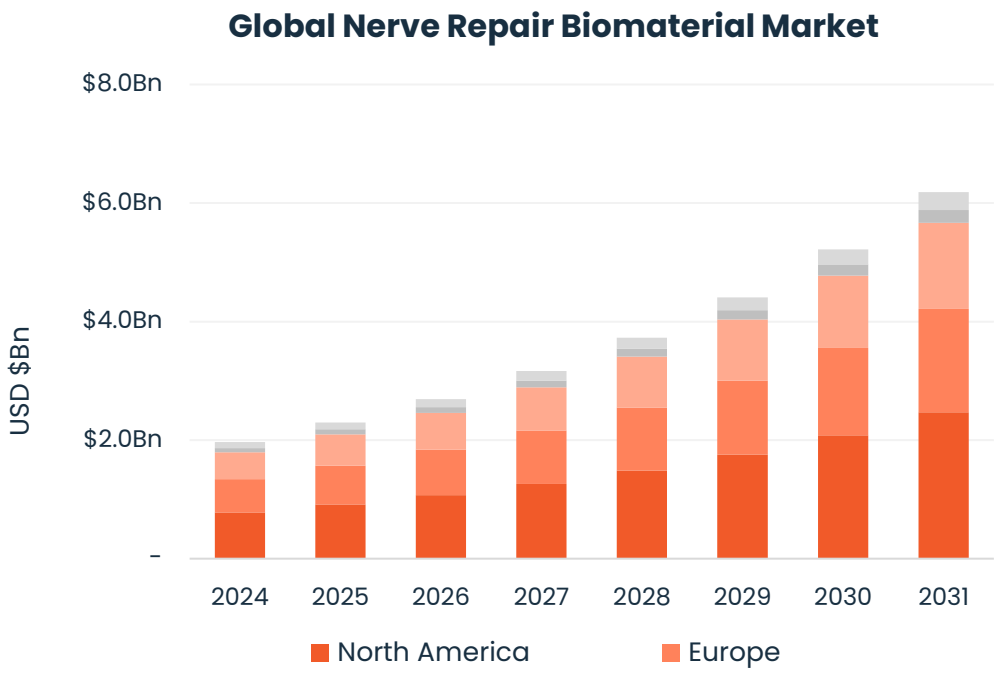


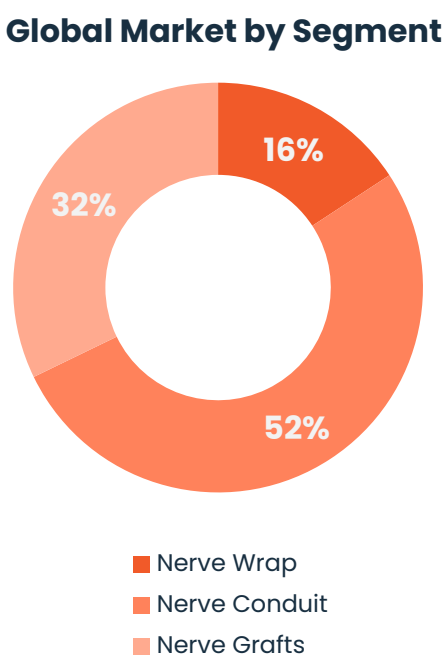
MarketWide Research – Dermal and Amniotic tissue market report 2025-2032, Published 2025.

ReNerve's Nerve Opportunity

	ReNerve **Nerve Cuff**	ReNerve **Nerve Conduit**	ReNerve **Nerve Guide Matrix**	ReNerve **Bionic Nerve**
Product	• Used on damaged or transected nerves with no gaps or gap closure	• Improved Nerve Cuff developed from scCO2 tissue, offering better product profile	• An 'off-the-shelf', ready to use nerve graft replacement with internal guidance infrastructure	• An 'off-the-shelf', continuous nerve replacement, in a ready to use nerve structure
Procedure Use	• End to end suturing covered with a wrap/cuff • Protective cuff for grafts	• Protecting injured nerve repairs	• Replaces damaged nerve section instead of using donor or harvested tissue	• The Bionic Nerve is a nerve guide matrix with ionic polymers designed to replace injured and damaged nerves for lengths from 1cm to 20cm
Application	• Trauma • Breast reconstruction • Orthopaedics • Oral & maxillofacial surgery	• Trauma • Breast reconstruction • Orthopaedics • Foot and ankle	• Trauma • Breast reconstruction • Orthopaedics • Hand & wrist	• Trauma • Craniotomy • Spinal cord injury • Spinal cord surgery
Benefit	• Bio-absorbed removing need for additional surgery • Pliable and conforms	• Improved product profile to Nerve Cuff • Stronger patient reimbursement	• Can be cut to ideal length • Off-the-shelf, reducing logistics issues • Simple to use and cost effective	• Enable production of nerves of bespoke dimension
FDA Status	**Approved**	**Targeting market release 1H '26**	**Targeting CY27 filing**	**Targeting CY28 filing**
TAM (USD)	$314m (2024) $975m (2030)	$1015m (2024) $3219m (2030)	$635m (2024) $1991m (2030)	>$400m (2023)

Global Nerve Repair Biomaterial Market





USD$1.69Bn

The Global Nerve Repair Biomaterials Market was valued at USD$1.69Bn in 2023 and is projected to grow at a compound annual growth rate (CAGR) of 17.8% from 2024 to 2031 to USD$6.19Bn.*

~900k

Nerve surgeries occur in the United States (US) per annum, with no more than 24% of nerve surgeries restoring to 'as good as it was'.

Nerve Compression

Approximately 1-in-4 nerve repair cases receive surgery repair, with 30% failure/revision rates.

* Global Nerve Repair Biomaterials Market Research Report (2020 – 2031)

Distribution Network

US Market Expanded Distribution Channels

Robust portfolio

- Expanded to 21 distributors across the US
- Full logistics, warehousing and invoicing in place
- Distributors can sell the entire ReNerve product range
- Will add additional to the network as products come to market

Focus surgical areas Subspecialties

- Hand (upper extremity)
- Breast
- Lower Extremity (M.D. & DPM)
- Plastics Reconstruction
- Head & Neck
- Spine

Ex-US Sales & Marketing

Sales Highlights

- Final stages of approval process in India
- Seeking multiple approval applications across Asia
- Will use the US data and "Align" study for European approval submission
- Looking to support the US sales growth

ReNerve Distribution

India	Asia	MIDDLE EAST
Significant potential due to population and open market. Have partnered with NetCentrix for approval and sales and marketing	On market in Hong Kong and Thailand, moving to strategic partners across the region	Entered into exclusive partnership with Union Mediscience B.S.C in the Middle East.

Strategy

Leveraging US approval and patient data for entry into global markets

- Targeting meaningful markets such as India and Asia
- Leveraging off FDA clearance and US patient data for Europe
- More approvals due in the next 12 months

* Global Nerve Repair Biomaterials Market Research Report (2020 – 2031)

ReNerve

NervAlign®

Nerve Cuff

Key Features

1 Product

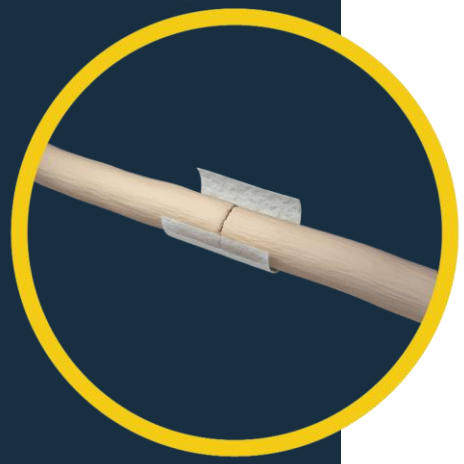
- Protects nerves during recovery post peripheral nerve repair
- Great handling characteristics and absorbed within 6 months

2 Patient Benefit

- Bio-absorbed within 6-months.
- Produced using a non-toxic method.
- Terminally sterilised with no residual chemicals.
- Covered under procedural reimbursement rather than individual product reimbursement.
- Promotes revascularisation and remodelling
- Semi-translucent

3 Surgeon Benefit

- Requires no change to surgical technique or procedures.
- Available in various sizes with ability to be trimmed to required shape.
- Is pliable and conforms, semi-translucent and easy to use



ReNerve's "Align" Clinical Study

Patient Results

- Definitive clinical study on using NervAlign Nerve Cuff for nerve repair
- 120 patients per cohort
- Comparing standard of care vs treatment with NervAlign Nerve Cuff

Clinical Use

- Hundreds of patients implanted to date
- Received positive feedback from surgeons stating it handles well, is pliable and conforms and has resulted in strong patient outcomes.
- Positive surgeon feedback when used with attachment methods including sutures, glue, micro clips and 'nothing'.

The “Align” Study

Undertaking a definitive study in nerve repair following surgical neurolysis to show the benefit of protecting the nerve post nerve repair surgery.

Study Design: Two patient cohorts

- Control Group: Standard neurectomy repair
- Test Group: Neurectomy repair with NervAlign™ Nerve Cuff
- Based on the study which showed clear benefit for using the NervAlign™ Nerve Cuff

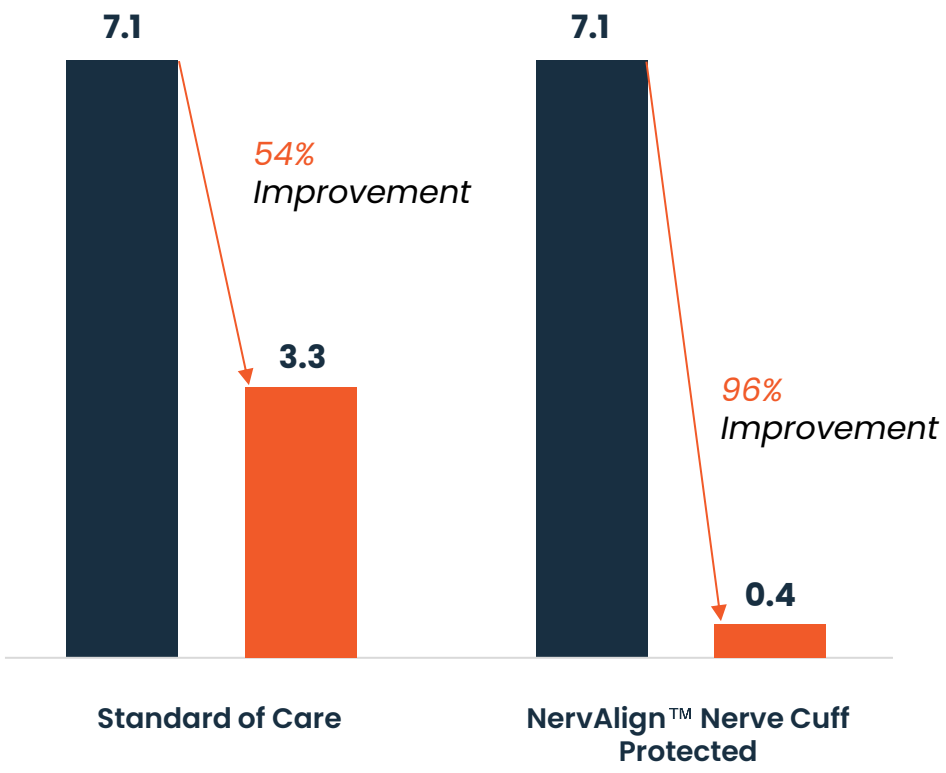
Key Outcomes:

- Testing for significance in Pain Reduction:
  - Secondary outcomes in patient recovery
  - Product performance in surgery
- Patient follow up around 6 to 9 months

Data presentation

- Aiming to complete recruitment by mid 2026
- Data accumulated along the way
- First 50 patients recruited to date
- Data likely to be published and presented in late 2026/early 2027

Comparison of Patient Pre & Post Surgery Pain Score



The comparison of pain scores between the two cohorts of patients

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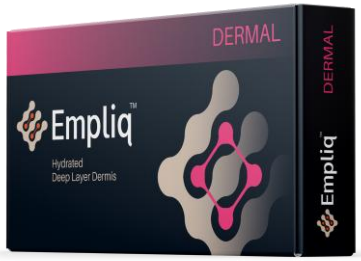
Empliq™

Product Range

Empliq Product Portfolio

Empliq™



	Empliq AmnioLite	Empliq AmnioDuo	Empliq Placental	Empliq Dermal
Description	Single-layer amniotic membrane allograft	Double-layer amniotic membrane allograft	Placental allograft including amniotic membrane and chorion	Deep-layer dermal matrix
Clinical Value	Natural barrier to protect wounds from external environment	Thicker barrier for complex wounds Improved handling characteristics	Natural barrier to protect wounds from external environment Additional structural support	Natural scaffold for protection, reinforcement and capillary formation No basement membrane - rapid tissue ingrowth and healing
Potential Applications	DFUs, VLUs, surgical wounds, vulnerable tissue	DFUs, VLUs, pressure injury, surgical wounds		Breast reconstruction, Tendon augmentation, abdominal wall repair, hernia repair

DFU = Diabetic foot ulcer; VLU = Venous leg ulcer

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Product Development Pipeline

Product Development Pipeline

Nerve conduit range

→ Nerve Conduit and protector ranges

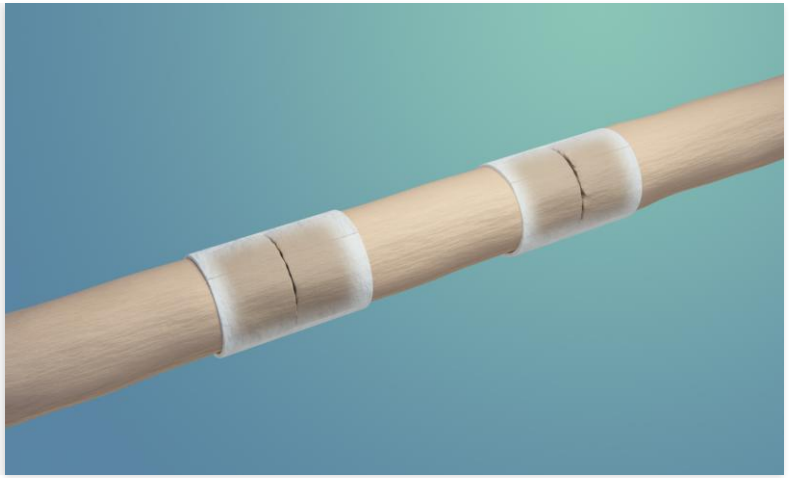
- Includes the Nerve cap
- Entering commercial validation batches
- 3 types of conduits to come to market

Nerve guide matrix

→ In the commercial development phase

→ FDA approval pathway confirmed

→ Next step GMP, commercial



Value drivers for the next 12 months

Driving sales and new products into market

2026 about major commercial progress

Empliq products ranges now in the US market

- 4th product coming to market
- Complements the nerve cuff
- Faster sales growth through multiple products
- Ongoing hospital approvals and surgeon engagement

Continue to expand into Ex-US markets

- Establishing partners Ex-USA
- Pending approval in several countries in 2026
- Will leverage all clinical data and cases to expand globally
- Follow the same path for new products

Working with distributors for additional approvals

- Building our network of US distributors
- 2026 is about gaining more customer approvals

Ongoing Clinical Study

- Strong, positive data in 2025
- Ability to definitive clinical study
- The “Align” study underway and actively recruiting
- Initial data due in 2026

Company Milestones

2025

- Partnership Signed for Mexico Market
- R&D Tax Incentive Refund Received
- Thailand Approval & First Hong Kong Sale
- Positive Nerve Cuff Clinical Study Results Presented
- Partnership for Indian Market Announced
- Empliq launched in the US
- Empliq initial sales

Next 6 months

- NervAlign® Nerve Conduit into Market
- Growing the Empliq brand
- Initial Clinical Cases for the Nerve Conduit
- Starting GMP manufacturing (Stage 3) runs of the Nerve Guide Matrix
- NervAlign® Nerve Cuff approval in India
- NervAlign® Nerve Cuff approval in Taiwan
- NervAlign® Nerve Cuff Approvals in New Countries & Territories

Near Term

- Nerve Guide Matrix GMP production
- ReNerve 'Align' Study data
- First clinical cases using the nerve guide matrix
- Expansion of the Nerve Repair product portfolio
- Continued sales growth
- NervAlign® Nerve Cuff filing for European approval

Investment Highlights

In Market Products

Nerve Cuff transitioned from R&D to commercial sales with 3 product lines in market and nerve coduits coming.

Immediate Market Need

Products promote nerve injury recovery and wound repair leading to faster patient recovery and better outcomes.

Growing Market

Nerve repair biomaterials and related markets are forecast to grow by >17% pa, estimated to be worth >**US$6.19Bn by 2031.**
USD$1Bn+ market for human tissue product ranges

Diverse Product Portfolio

Building a complete product range in market with 3 in market and more coming in 2026. Additional products currently under development.

Growing Distribution

Continuing to build sales representation with a targeted-direct sales approach. Expanding globally.

Board & Management

Highly accomplished executive team with a proven track record in the development & commercialisation of medical opportunities.

ReNerve

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Contact

ReNerve Limited

+61 (03) 9482 3940

info@renerve.com.au

Level 10/99 Queen St, Melbourne, Victoria 3000 Australia