

ASX Announcement

15 January 2026

Approval secured in Malaysia for NervAlign® Nerve Cuff

- Provides ReNerve with access to Malaysian market, an important part of its Asia-Pacific strategy
- Result of the positive assessment of the clinical evaluation report validates ReNerve pursuing approvals in more countries

ReNerve Limited (ASX, "ReNerve" or "the Company"), a leading Australian medical device innovator focused on solutions for peripheral nerve injury (PNI), is pleased to announce that its NervAlign® Nerve Cuff has received market registration (approval) in Malaysia.

The milestone marks another country approval for ReNerve in the Asia-Pacific region, to go with those received for Hong Kong and Thailand. Malaysia has a population of 35 million people and forms an important part of the broader Asia-Pacific strategy for the Company, with many hospitals operating in Malaysia having a presence in multiple other countries. The nerve repair market across Asia-Pacific is estimated to be worth around USD\$100 million in 2026¹.

"Our approval in Malaysia is part of our regional strategy and is another major piece of validation, showing the strong clinical data package and clear benefit patients receive when the ReNerve Nerve Cuff is used in peripheral nerve repairs. We look forward to growing our presence in Malaysia and beyond that within the Asia-Pacific region." said **Dr Julian Chick, CEO of ReNerve**.

The NervAlign® Nerve Cuff represents a significant advancement in peripheral nerve repair technology, offering clinicians a precise and effective solution for supporting nerve regeneration and recovery following traumatic injuries, surgical procedures, and other conditions affecting peripheral nerves.

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This announcement has been approved for release by the Company's Board of Directors.

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¹Global Nerve Repair Biomaterials Market Research Report (2020 – 2031)



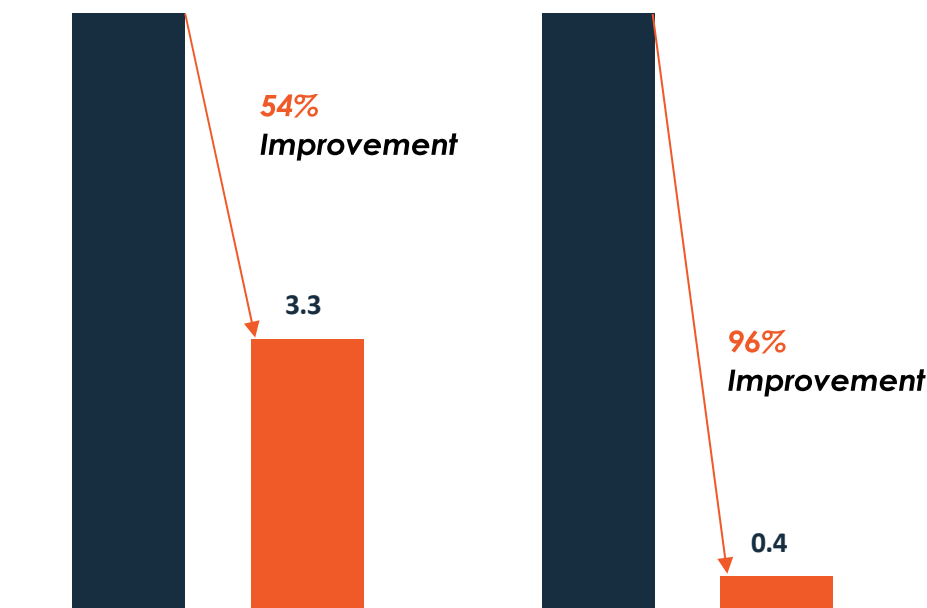
About ReNerve Limited (ASX:RNV)

ReNerve Limited (ASX:RNV) is transforming nerve repair and improving lives through breakthrough medical technology. Founded by a neurosurgeon and medtech researchers, ReNerve is a rapidly growing medical device company that has revolutionised peripheral nerve surgery with its innovative, ready-to-use solutions for peripheral nerve injuries (PNI). Our scientifically backed products are delivering measurably better outcomes for patients worldwide.

Proven Clinical Success

ReNerve's first flagship product, the FDA-cleared **NervAlign® Nerve Cuff**, is already making a dramatic difference in surgical outcomes across the United States. A recently announced clinical study has demonstrated remarkable results, showing that patients treated with the NervAlign® Nerve Cuff experienced post-surgical pain scores dropping from 7.1 to just 0.4, compared to from 7.1 to 3.3 without the device being used – a statistically significant improvement that's changing lives.

Comparison of Patient Pre & Post Surgery Pain Score



Standard of Care vs NervAlign™ Nerve Cuff Protected Nerve Repairs

The comparison of pain scores between the two cohorts of patients

Comprehensive Product Portfolio

ReNerve is advancing a complete suite of nerve repair solutions:

- **NervAlign® Nerve Cuff** – Our bioabsorbable protective wrap, naturally absorbed within six months of surgery.
- **Deep Dermal tissue product** -- A unique deep dermal product used in the repair of reconstructive and cosmetic surgical cases.
- **Amniotic tissue product ranges** -- Three amniotic tissue product ranges used to aid the healing of wounds.
- **NervAlign® Nerve Conduit Range** – Next-generation nerve conduit leveraging advantages of eCOO technology in a material designed to facilitate nerve growth over short gaps between nerve ends.
- **NervAlign® Nerve Guide Matrix** – a customised and ready-to-use alternative to existing nerve grafts, for treatment of longer nerve gaps and more severe nerve injuries. It will eliminate the need for patients to undergo additional sural nerve harvesting.
- **NervAlign® Bionic Nerve** – Next-generation combination technology for the most challenging nerve repairs.

Market Leadership and Growth

With demonstrated market traction since the Company's 2022 product launch, ReNerve achieved 53% revenue growth in FY25, reaching \$271k in sales. Our high-margin, scalable products are positioning us as the go-to solution for surgeons seeking superior patient outcomes in the rapidly expanding global nerve repair market, valued at US\$1.6 billion in 2024 and is projected to reach \$6.2 billion by 2031.²

Vision and Values

We're not just developing medical devices – we're engineering hope. By creating the ideal healing environment for nerve repair and regeneration, ReNerve bridges critical gaps in healthcare while empowering the human body's natural healing process. Our cleaner, safer, and more effective solutions represent the future of peripheral nerve surgery.

² Global Nerve Repair Biomaterials Market Research Report (2020 – 2031)