

ASX Announcement

12 January 2026

ReNerve achieves broader approval in Hong Kong for NervAlign® Nerve Cuff

- **Complete access for ReNerve in the Hong Kong market**
- **The new listing approval included an independent review of the safety and effectiveness outcomes following clinical usage of the NervAlign® Nerve Cuff**
- **Positive assessment of the Clinical evaluation Report validates ReNerve pursuing approval 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 listing approval in Hong Kong. This facilitates extending previous access to the product to public hospitals as well as the private hospital systems in the Hong Kong region, including facilitating Greater Bay Area hospital access.

The review and approval process included assessment of the clinical evaluation report containing data from the clinical studies conducted with the NervAlign® Nerve Cuff, which illustrates its effectiveness in assisting nerve repairs and patient recovery. In addition to providing broader approval, it also provides independent validation of the patient clinical and post-surgery recovery outcomes when used in peripheral nerve repair.

ReNerve is currently marketing its NervAlign® Nerve Cuff in the US, Bahrain, New Zealand, Hong Kong and Thailand whilst pursuing approvals in more than 10 further countries. This positive review provides ReNerve with further validation of the effectiveness of Nerve Cuff to support initiating the approval processes in additional countries including Europe.

"This is important for ReNerve as it broadens the marketing ability for our team in Asia in the Hong Kong region and importantly it means that an independent Government medical device regulatory authority has assessed the clinical evidence behind the NervAlign® Nerve Cuff and accepts the clinical and patient benefits our nerve cuff provides, further validating the quality and utility of the ReNerve Nerve Cuff." **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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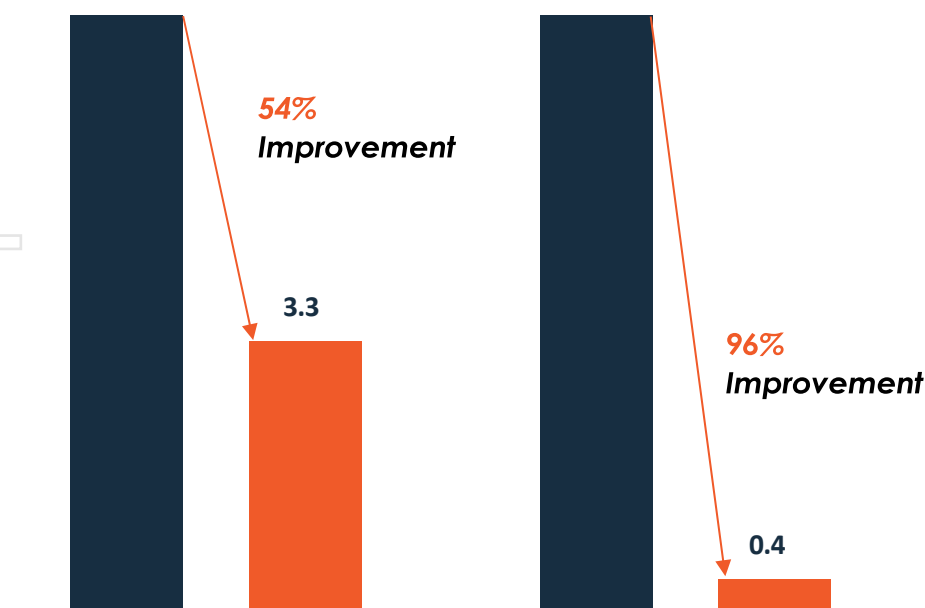
About ReNerve Limited (ASX:RNV)

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 2031.¹

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.

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