

Compelling 90% Success Rate Achieved in Remplir™ Nerve Repair Real World Study

Data to support continued US sales roll out and EU + UK market launch

- **Latest results from the Remplir™ Real World Evidence (RWE) study demonstrate an overall treatment success rate of 89.7%**, based on performance data from 66 patients (78 nerve procedures).
- Patients were aged 14 to 82 years, with the **majority of procedures performed in the upper limb**, including decompression and reconstruction of severed nerves (nerve transfer and grafting).
- **No post-treatment complications or adverse effects to Remplir were reported**, reinforcing its well-established safety profile and high biocompatibility, and strengthening its position as the **best-performing nerve wrap in Australia**.
- **Cumulative performance data** for motor nerve reconstruction (31 procedures) and nerve decompression procedures (47 procedures) **demonstrated that:**
 - **90.3% of motor nerve repairs resulted in functional muscle recovery;** and
 - **89.4% of nerve decompression procedures resulted in complete relief or significant improvement of symptoms**, including pain, numbness, and burning or tingling sensations.
- **Results are consistent with previously reported outcomes and continue to support the predictable clinical performance** of Remplir across a broad range of nerve repair applications. The growing number of procedures further reinforces these outcomes and is driving increased adoption:
 - **In Australia, more than 300 surgeons across 220+ hospitals** are using Remplir,
 - **In the U.S., more than 49 surgeons across 55+ hospitals** are using Remplir; and
 - **The first surgical case has been completed in a U.S. Department of Defense hospital** following recent approval **across a network of 221 hospitals**.
- The data will play an important role in **driving continued commercial growth across the U.S. and upcoming European markets, with regulatory approval expected in H2 CY26**.

Perth, Australia; 28 April 2026: Regenerative medicine company Orthocell (ASX: OCC, “Orthocell” or the “Company”) is pleased to announce latest results from the ongoing Remplir™ multi-centre post-market clinical follow-up study (“Remplir Real World Evidence study” or “Remplir RWE Study”).



The study demonstrated an overall treatment success rate of 89.7%, based on performance data from 66 patients (78 nerve repair procedures for motor nerve injury or nerve compression). The data will support continued commercial growth across the U.S. and upcoming UK and European markets, with regulatory approval expected in H2 CY26.

The initial results announced in September 2025 included 33 patients. A subsequent data cut, taken six months later, has expanded the cohort to 66 patients, with an additional 33 patients included.

The cumulative results demonstrate the utility of Remplir across a range of peripheral nerve conditions, including restoration of hand function following cervical spinal cord or brachial plexus injury, and relief of symptoms in chronic nerve injuries such as carpal tunnel syndrome. Importantly, results are consistent with earlier findings and previously published clinical trial data in the Journal of Reconstructive Microsurgery Open.

The study was conducted in collaboration with Dr Alex O’Beirne (Western Orthopaedic Clinic), A/Prof Matthew Lawson-Smith (Murdoch Orthopaedic Clinic), Jaslyn Cullen (Innervate Occupational Therapy), and Hand Works Occupational Therapy.

Orthocell Managing Director Paul Anderson said: “These latest results further strengthen Remplir’s position as the best-performing nerve wrap available in Australia, demonstrating strong and consistent clinical outcomes across a broad range of nerve repair procedures, supported by an excellent safety profile. Importantly, this expanding evidence base is also supporting surgeon adoption and commercial expansion in the U.S. and other key markets.”

Cumulative Study Results

The study population includes patients with acute traumatic nerve injuries, (e.g. motor vehicle, work-related and sporting accidents) chronic nerve injuries and conditions (e.g. carpal or cubital tunnel syndrome). These conditions often result in significant impairment, including muscle paralysis, pain, numbness, and burning or tingling sensations, leading patients to seek surgical intervention.

Data from 66 patients, aged 14 to 82 years, were included in the cumulative analysis, with the majority of procedures performed in the upper limb, including decompression and reconstruction of severed nerves (transfer and grafting). **No post-treatment complications or adverse effects to Remplir were reported.**

Performance data (78 nerve repair procedures) demonstrated an **overall treatment success rate of 89.7%** (70 of 78 procedures). A detailed breakdown of outcomes by procedure type is provided in the table below.

Procedure Type	Patients (n)	Nerve Procedures (n)	Treatment Success
Motor nerve reconstruction	19	31	90.3% (28 of 31)
Nerve decompression	47	47	89.4% (42 of 47)
Total	66	78	89.7% (70 of 78)

Performance Outcomes

Performance outcomes assess the effectiveness of motor nerve reconstruction, including restoration of function (e.g. hand function following cervical spinal cord injury) and nerve decompression procedures targeting symptom relief (e.g. carpal tunnel syndrome), over a follow-up period of up to 24 months.

Motor nerve reconstruction

A total of 19 patients, who received 31 motor nerve repairs, were assessed for functional motor recovery using the British Medical Research Council (MRC) grading system, based on the strength of a target muscle controlled by the repaired nerve. The majority of procedures were nerve transfers performed in patients with tetraplegia and severe brachial plexus injuries, with the aim of restoring function to muscles in the arm and hand.

Treatment success was defined as MRC Grade M3 or M4, indicating voluntary movement with improved strength and range of motion, representing the maximum level of functional recovery expected. **Results showed that 90.3% (28 of 31 nerve repairs) achieved functional muscle recovery at an average of 10.8 months following surgery with Remplir.**

In a subgroup of six tetraplegic patients (C4–C7 spinal cord injury), 100% (14 of 14 nerve repairs) resulted in functional recovery of a target muscle, representing clinically meaningful restoration of hand function in patients with previously limited or no use of the affected limb.

Nerve decompression

A total of 47 patients were assessed for nerve decompression procedures, including 18 carpal tunnel revision surgeries and 16 cubital tunnel releases (14 primary cases, and two revision surgeries). Carpal tunnel revision patients had previously undergone decompression surgery but experienced persistent or recurrent symptoms, including pain, weakness, and numbness in the fingers and thumb, often associated with scar tissue formation or impaired nerve gliding.

Treatment success was defined as complete relief, significant improvement, no change, or worsening of symptoms compared to baseline. **Results showed that 89.4% (42 of 47) of nerve decompression procedures resulted in significant improvement or complete relief of symptoms, with no patients requiring additional surgical intervention during follow-up.**

Significance of Study Results and Next Steps

Considering these cumulative study results, published clinical data, and rapid product adoption in existing markets, Orthocell believes Remplir has the potential to significantly expand the global nerve repair market and establish itself as a leading option in nerve repair surgery, supporting restoration of function in paralysed limbs and relief of symptoms. The data will play an important role in driving continued commercial growth across the U.S. and upcoming European markets, with regulatory approval expected in H2 CY26. The cumulative study results will be presented at key medical conferences, and the study continues in the recruitment phase.

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About Orthocell Limited

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Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of bone and soft tissue injuries. Orthocell's portfolio of products include a platform of collagen medical devices which facilitate tissue reconstruction and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications, is cleared for use in the US, Australia, New Zealand, Singapore, UK, Europe, Canada and Brazil and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently gained clearance for use in the US. The Company has appointed a network of specialist US distributors and recorded initial sales. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore where it is distributed by Device Technologies Group. Other Remplir approvals include Canada, Hong Kong and Thailand. SmrtGraft™, for tendon repair, is available in Australia under Special Access Scheme or participation in a clinical trial. The Company's other major products are autologous cell therapies which aim to regenerate damaged tendon and cartilage tissue. Orthocell is accelerating the development of its tendon cell therapy in the US with technology transfer and FDA engagement to confirm the path to the US market and prepare for partnering discussions.

For more information on Orthocell, please visit www.orthocell.com or follow us on Twitter @OrthocellLtd and LinkedIn www.linkedin.com/company/orthocell-ltd

Forward Looking Statement

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.