

ASX Announcement



Orthocell Achieves US Market Adoption Milestone of 100 Unit Sales of Remplir™

US rollout continues to accelerate as more surgeons and hospital networks use Remplir for surgical repair of peripheral nerves

- Orthocell has reached 100 units sales in the US of its flagship nerve repair product, Remplir™, marking a key early adoption milestone in the US\$1.6 billion¹ US nerve repair market.
- The successful surgical uptake reflects growing momentum in the US rollout, driven by a combination of Orthocell's concerted medical education and awareness campaign and a specialist distributor network across 25 states covering 40% of the US population.
- The first US sales and surgeries follow the submission of 61 applications to hospital Value Analysis Committees (VAC) in progress, of which 17 have been approved, ahead of schedule. VAC approvals are critical to facilitate access and sales within hospital networks.
- Strong surgeon engagement with >250 engaged from medical education programs and 14 Medical Advisory Board members under contract.
- The growing US surgical uptake will support anticipated growth in adoption in the US during 2026 and inform first surgeries in Canada, targeted to commence in early 2026.
- The Company remains focused on driving rapid market adoption of Remplir™ supported by a strong balance sheet (circa A\$50 million in cash and no debt) and ongoing investment in clinical evidence and medical education initiatives.

Perth, Australia; 18 December 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has achieved 100 Remplir™ unit sales in the United States, a key milestone in the commercial rollout of its flagship nerve repair product. The milestone has been reached within the US\$1.6 billion¹ total addressable US nerve repair market and underscores the growing clinical use of Remplir in complex peripheral nerve procedures.

Orthocell's 100 US unit sales have been driven by a combination of Orthocell's concerted medical education and awareness campaign and a specialist distributor network across 25 states covering 40% of the US population. Distributors are leveraging established relationships with surgeons and hospitals, supported by Orthocell's internal Sales, Marketing and Medical Education teams, to build surgeon familiarity and drive procedural uptake. To date Orthocell has engaged >250 surgeons from

¹ US nerve repair market sizes estimated using referenced papers from both US and OUS databases and studies

medical education programs leading to the early case volumes that are expected to grow through FY26 as hospital approvals and state licences continue to progress. A further 14 Medical Advisory Board members are also under contract.

Orthocell CEO and MD, Paul Anderson said “Reaching 100 US unit sales is an important validation of our commercial strategy and of Remplir’s potential to reshape nerve repair practice. The early case experience, growing surgeon engagement and increasing hospital VAC approvals give us confidence that we are building the right foundations for sustained growth in the US.

“The early surgical adoption is ahead of our expectations and closely following the trends we saw with the early take-up of Remplir in Australia. Given the materially larger market size in the US, we see significant upside if we continue on this trajectory.”

The milestone follows 61 active submissions to US hospital Value Analysis Committees (VACs), with 17 approvals secured ahead of schedule and additional approvals anticipated in FY26. VACs serve as hospital gatekeepers and are a critical step in the US rollout to facilitate market access and sales within hospital networks.

The VAC approvals, together with active accounts and validated logistics via a US-based warehousing and fulfilment partner, provide a scalable platform to support increasing case volumes. The first 4,000 units of Remplir have been shipped from Australia and warehoused in the US, ensuring product availability to meet growing demand.

The expanding US surgical experience will also be leveraged to support international growth, including first Remplir surgeries in Canada planned for early 2026 in partnership with specialist distributors covering the full Canadian population with established networks in nerve, spine and orthopaedic implants.

Orthocell ultimately targets a Total Addressable Market (TAM) in selected jurisdictions of more than US\$3.5 billion². The Company remains focused on driving rapid market adoption of Remplir supported by a strong balance sheet (circa A\$50 million in cash and no debt) and ongoing investment in clinical evidence and medical education initiatives.

Release authorised by:

Paul Anderson

Orthocell Ltd CEO and MD

² Nerve repair market size estimated using referenced papers from both US and OUS databases and studies

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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 14 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 Thailand and Canada. 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.