# Orthocell Announces First Surgical Use of its Breakthrough Nerve Repair Product Remplir™ in the US

- **Orthocell has recorded the first use of its Remplir™ nerve repair device in the US overnight following recent US FDA clearance for Remplir in April 2025**
- **Crucial step in the rollout of Remplir in the significant US$1.6 Billion[1] US market, building surgical experience and knowledge of the product that will be key in driving product sales.**
- **Surgical case sourced directly from Orthocell's established and growing US distributor network, which now includes 14 specialist nerve distributors with mature, direct-to-surgeon, hospital and other customer relationships across 25 US states.**
- **Orthocell's in-house Marketing, Medical Affairs and Sales executives are working closely with the distributor network and making significant headway on the Remplir rollout.**
- **US rollout plan on track to deliver sales growth to be reported in 1H FY26 supported by cash reserves of circa AU$30 million.**

**Perth, Australia; 27 June 2025:** Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce the achievement of a critical milestone in the commercialisation of Remplir™ in the US$1.6 Billion US market with the successful completion of the first US surgery using the Company's flagship nerve repair product.

The procedure, performed overnight at a hospital in Ohio, used Remplir™ in a surgical procedure to repair a foot nerve injury, observed by Orthocell's dedicated Medical Education team. The surgery was conducted using product manufactured at Orthocell's facility in Perth, Western Australia.

The first use of Remplir in the US follows the product's US FDA 510(k) clearance in April 2025 and the subsequent appointment of 14 specialist distributors to drive adoption across key regions. The first surgery resulted directly from a distributor's relationship with a nerve repair surgeon in Ohio.

Remplir is a collagen wrap used in nerve repair surgery to improve regeneration of damaged nerves and patient outcomes. It is supported by robust clinical evidence, including recent studies confirming its superiority over standard suture techniques in nerve regeneration, earlier return to function, and higher quality nerve tissue restoration.

**Orthocell CEO and MD, Paul Anderson, said**: "This first US surgery is a significant milestone for Orthocell and for the roll out of Remplir™ in the US. It signals the start of our commercial journey in the world's largest healthcare and nerve repair markets, and reflects our commitment to delivering innovative, clinically proven solutions to surgeons and their patients.

A critical first step in the US starts with getting Remplir into surgeons' hands for them to gain familiarity with its key features and benefits in clinical practice. These early cases play an important broader strategic role in building experience and knowledge amongst the surgical community.

We are confident our efforts in the US are on track to drive material growth in sales of Remplir during the second half of calendar 2025."

[1] USA nerve repair market size was estimated using referenced papers from both US and OUS databases and studies.

Orthocell is targeting a large global addressable nerve repair market estimated to be worth in excess of US$3.5 billion[2] with an estimated ~2.0M peripheral nerve repairs performed across Australia/New Zealand, Singapore, USA, EU/UK, Canada, Brazil, Japan, Hong Kong and Thailand.

The Company has a strong balance sheet with approximately ~AU$30 million cash at bank and no debt and is very well funded to continue to broaden its commercial footprint and grow revenues in existing and new markets.

**Release authorised by:**
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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, with first sales expected to follow shortly. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies Group. 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

[2] Company estimate of addressable market size for Remplir (AUS, NZ, SGP, USA, EU/UK, CAN, BRZ, JAP & THA). Sources include iData Research Inc and other publicly available market research reports and published literature.

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 is 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.