

ASX Announcement



Orthocell Appoints First Distributor for Remplir™ in US\$75m Canadian Market, First Sales Expected in Dec Qtr

- Orthocell pushes forward with the commercialisation of the Company's groundbreaking nerve repair and regeneration device Remplir in the US\$75 million Canadian market¹, with the appointment of its first Canadian distributor.
- Exclusive distributorships have been secured for Alberta and British Columbia (BC), with further appointments anticipated for additional provinces to ensure broad coverage of the material Canadian nerve repair market.
- Official launch activities will commence in early October at the prestigious Annual Meeting of the American Society for Surgery of the Hand (ASSH) in Vancouver, attended by the Orthocell commercial team who will support the rollout.
- The Canadian distributor has a wealth of expertise in nerve, spine and orthopaedic implant distribution, with established networks and a strong reputation in the local healthcare sector to drive product adoption.
- Orthocell's Medical Device Licence for Remplir was granted by Health Canada in April, with first sales targeted for the Dec Qtr and market uptake expected to grow into 2026.
- Canadian Remplir rollout will be overseen by Orthocell's existing in-house US-based Marketing and Medical Education teams.
- Appointment of Canadian Distributor is another important step in the global market expansion of the flagship Remplir product

Perth, Australia; 30 September 2025: Orthocell Limited (ASX: OCC) is pleased to announce the appointment of its first Canadian distributor for Remplir, the Company's groundbreaking nerve repair and regeneration device, ahead of its official in-country launch in early October at the prestigious Annual Meeting of the American Society for Surgery of the Hand (ASSH) in Vancouver.

Exclusive distributorships have been secured for Alberta and British Columbia, with further appointments anticipated for additional provinces to ensure broad Canadian market coverage.

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

Orthocell CEO and MD, Paul Anderson said:

“Securing our first Canadian distributor provides immediate access to key provinces and will build Remplir’s profile as a next-generation nerve repair solution. This is a major step in accelerating Remplir’s international growth and our team is looking forward to supporting Canadian clinicians in delivering improved patient outcomes.

“Our existing US Marketing and Medical Education teams are ideally placed to oversee our Canadian market entry given the significant crossover between jurisdictions with many surgeons operating in both countries.

“We expect to see early surgical cases commence in Canada late this year.”

Orthocell received a Medical Device Licence (MDL) from Health Canada for its flagship nerve repair product Remplir™ in April 2025, well ahead of initial expectations, following lodgement of the regulatory submission in February 2025.

The newly appointed Canadian distributor brings a wealth of expertise in nerve, spine, and orthopaedic implant distribution, with established networks across both urban and rural areas providing comprehensive coverage and accessibility for healthcare providers.

The Distribution team includes five dedicated sales representatives supported by a network of sub-agents, providing direct engagement with surgeons and hospitals throughout Alberta and BC. Approval processes for individual hospitals will be initiated immediately to facilitate swift market entry.

Remplir will be promoted in Canada using the same robust medical education and scientific data that has underpinned the rollout currently underway in the United States. Remplir’s Canadian market rollout will be overseen by Orthocell’s existing in-house US-based Marketing and Medical Education teams who will be in attendance at the upcoming ASSH conference in Vancouver, along with a number of Orthocell executives, for the in-country market launch.

With circa \$27.5 million in cash and no debt, Orthocell is well-positioned to drive rapid product adoption to deliver a step change in revenue in FY26. Remplir rollout in the US\$1.6 Billion US market² continues to build momentum, with in-country representatives making significant progress working with distributors to gain hospital approvals, on-board surgeons and establish active accounts. Initial US surgical cases continue to build.

Release authorised by:

Paul Anderson

Orthocell Ltd CEO and MD

² Nerve repair market sizes 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.