

ASX Announcement



Orthocell Appoints Second Canadian Distributor for Remplir™

Full national coverage of US\$75m Canadian market now in place

- Orthocell has appointed its second distributor in the US\$75 million¹ Canadian market, further advancing the commercialisation of its flagship nerve repair medical device Remplir™ in Canada.
- The newly appointed Ontario-based distributor has been granted exclusive rights to distribute Remplir across all Canadian provinces outside of Alberta and British Columbia (BC), which are managed by Orthocell's existing distributor.
- The appointment establishes full national distribution coverage across Canada, strengthening Orthocell's position to rapidly drive sales in this important market.
- First Canadian sales are expected this Quarter, following successful launch activities at the prestigious Annual Meeting of the American Society for Surgery of the Hand, held in Vancouver in October.
- The newly appointed Canadian distributor brings extensive experience in nerve, spine and orthopaedic implant sectors, with established networks across both urban and rural markets providing comprehensive coverage and accessibility for healthcare providers.
- Remplir's rollout in Canada will be managed by Orthocell's existing US-based Marketing and Medical Education teams, leveraging the proven medical education programs and scientific data that have underpinned the successful US launch.

Perth, Australia; 5 November 2025: Orthocell Limited (ASX: OCC) is pleased to announce the appointment of its second Canadian distributor for Remplir, the Company's flagship nerve repair medical device. The appointment complements the existing Canadian distributor already in place, ensuring the Company now has full national coverage in the US\$75 million¹ Canadian market.

The new Ontario-based distributor, who brings a wealth of expertise in nerve, spine, and orthopaedic implant distribution, has been granted exclusive distribution rights for Remplir for the provinces of Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island and Newfoundland. With the existing Canadian distributor covering remaining Alberta and British Columbia,

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

Remplir is now available to patients in both rural and urban healthcare facilities across Canada. The distribution team includes 6 product managers driving a team of 30 sales agents.

Orthocell completed initial launch activities for Remplir in Canada at the prestigious Annual Meeting of the American Society for Surgery of the Hand, held in Vancouver in October and expects first sales to be delivered this Quarter. Future launch activities and commercialisation efforts in Canada will be managed by Orthocell's existing US-based Marketing and Medical Education teams, thereby bringing significant efficiencies to the Company's North American rollout.

Orthocell CEO and MD, Paul Anderson said *"We're very pleased to expand our Canadian distributor presence beyond Alberta and BC with this new appointment opening up the entire Canadian market.*

Our focus remains on rolling out Remplir in the jurisdictions where we have regulatory approvals. The most efficient pathway to market is through in-country distributors that hold direct relationships with our end customers – surgeons and hospitals.

Each new distributor appointment is an important step, initiating targeted sales and marketing efforts in their territories and bringing us closer to generating new revenue streams.

We're building significant momentum with our distributor relationships globally, led by our US portfolio covering 25 states alongside recent appointments in Hong Kong and Canada, as well as our longer-term relationship with DVT in Australia and Singapore."

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.

With more than \$50 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 Billion² US market 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 reference 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 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 Thailand, Canada and Hong Kong. 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.