

ASX Announcement



First Remplir™ Surgical Case Completed in Hong Kong

Successful Launch at Hong Kong Orthopaedic Association 45th Annual Congress

Remplir now selling in Australia, New Zealand, Singapore, the US and Hong Kong, with Canada and Thailand to follow

- Remplir™ has been used in the first surgical case in Hong Kong and was successfully launched at the Hong Kong Orthopaedic Association (HKOA) 45th Annual Congress.
- These important milestones closely follow the recent appointment of highly-credentialed local distributor MontsMed and marks a significant step forward in Orthocell's Asian commercialisation strategy.
- In partnership with MontsMed, Orthocell is well-positioned to drive market penetration through leading hospitals and specialist surgeons in Hong Kong.
- Hong Kong represents a significant growth opportunity, serving as a strategic entry point into the Guangdong–Hong Kong–Macao Greater Bay Area (GBA)—a region encompassing nine major cities and a population of approximately 100 million people.
- The recently appointed Commercial Director will oversee Remplir commercialisation and distributor management in Australia and Asia.
- Orthocell continues to execute its global commercialisation strategy according to plan, with initial surgeries completed in Singapore, the USA, and now Hong Kong in the past 12 months, and sales in Canada and Thailand expected in the near term.
- With over A\$50 million in cash and no debt, Orthocell remains strongly funded to continue expanding its global footprint and delivering on its commercialisation objectives.

Perth, Australia: 3 November 2025: Orthocell Limited (ASX: OCC) is pleased to announce the successful completion of the first Remplir™ surgical case in Hong Kong and the launch of their flagship nerve repair medical device at the Hong Kong Orthopaedic Association (HKOA) 45th Annual Congress.

These achievements mark important milestones in Orthocell's Asia-Pacific commercialisation program and closely follow the appointment of MontsMed as the exclusive in-country distributor for Remplir in Hong Kong.

Major milestone in Asian commercialisation strategy

This first surgical case using Remplir in Hong Kong represents the start of clinical use and commercial sales in the region. With regulatory approval secured and a strong local distribution partner in place, Orthocell is now positioned to drive market penetration through leading hospitals and specialist surgeons.

Hong Kong has strategic importance in the overall commercialisation program, serving as a gateway to the Guangdong–Hong Kong–Macao Greater Bay Area (GBA)—a region encompassing nine major cities and a population of approximately 100 million people. Under the Regulatory Innovation and Development of Pharmaceutical and Medical Device work plan, Hong Kong–registered medical devices such as Remplir may be imported by designated GBA healthcare institutions to meet urgent clinical needs.

Remplir launched at HKOA 45th Annual Congress

Orthocell, in partnership with MontsMed, officially launched Remplir at the HKOA 45th Annual Congress held over 1st and 2nd November 2025. The Congress provided an excellent opportunity to introduce Remplir to key opinion leaders and specialists in orthopaedic and reconstructive surgery, and to highlight Remplir’s clinical advantages in nerve repair and the growing body of evidence supporting improved patient outcomes.

Orthocell CEO and MD, Paul Anderson said “The completion of our first Remplir surgical case and successful launch at the Hong Kong Orthopaedic Association Annual Congress represent important progress in our deliberate and considered approach to commercialising Remplir across Asia.

Hong Kong’s advanced healthcare system and its role as a gateway to the Greater Bay Area present a compelling opportunity for expansion. We are pleased to be working with MontsMed to build awareness and drive adoption among leading surgeons.”

Momentum building across global markets

Orthocell’s global commercialisation program continues the strong forward momentum achieved since product launch in Australia in 2022. Initial surgeries using Remplir were completed in Singapore, USA, and now Hong Kong in the past 12 months. Sales in Canada (a US\$75 million market) and Thailand are expected to commence in the near term, supported by local distributor partnerships.

The Company’s Asian distributor network and regional commercial strategy will be overseen by Commercial Director Mr Hamish Thrum, who brings extensive experience across the ANZ and APAC medical device sectors.

With over A\$50 million in cash and no debt, Orthocell remains strongly funded and well-positioned to drive rapid product adoption and deliver a step change in revenue in FY26.

Remplir rollout in the US\$1.6 billion¹ US market also continues to build momentum, with in-country representatives working closely with distributors to gain hospital approvals, onboard surgeons, and establish active accounts. Initial US surgical case numbers continue to build.

Release authorised by:

Paul Anderson

Orthocell Ltd CEO and MD

¹ 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.