

ASX Announcement

Excellent clinical outcomes demonstrated by Remplir™ in nerve sparing prostate cancer surgery

Company to gather further clinical evidence in preparation of U.S. launch, with no further FDA approvals needed

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- **Remplir™ adoption in Australian prostatectomy procedures is gathering momentum**, with more than 300 procedures now completed and multiple surgeons routinely using the product, including several who have performed more than 20 procedures.
 - **Building on this positive clinical experience**, the Company is presenting the initial five-patient case series as a pilot to inform the development of a larger real-world body of evidence to support a U.S. launch.
 - **Initial Remplir prostatectomy case series shows excellent early functional recovery** in clinically complex patients with advanced prostate cancer.
 - **All patients underwent extensive removal of tumour tissue with nerve preservation only feasible on one side**, presenting significant challenges for post-operative return of urinary continence and erectile function.
 - **80% of patients demonstrated encouraging urinary continence outcomes**, including three who were pad-free by six months which is sooner than expected in cases like these.
 - **75% of patients with erectile function prior to surgery demonstrated a return of erectile function**, including one patient reporting erections with oral medication, and two reporting partial function with second-line treatment at 12 months.
 - **Remplir was successfully placed in all five patients** undergoing robotic prostatectomy, with no technical difficulties or significant additional operative time.
 - **No Remplir-related complications were reported** during surgery or over approximately 12 months of follow-up, providing encouraging early safety and usability data.
 - **Remplir's use in nerve-sparing robotic prostatectomy represents a significant potential expansion of its TAM, with approximately 12,000 procedures performed annually in Australia and 115,000 in the US alone.** Multiple devices may be used per procedure. No additional regulatory approvals are required across the seven jurisdictions where Remplir is currently approved.
 - **The Company remains well funded, with A\$44.1 million in available funds¹** as at 30 June 2026 and no debt, supporting continued commercial expansion.

¹ AU\$44.1M as of 30 June 2026, this includes \$5.0 million in cash and cash equivalents and \$39.1 million in term deposits with maturities ranging from 3 to 12 months.

Perth, Australia; 13 October 2026: Regenerative medicine company Orthocell Limited (ASX: OCC, “Orthocell” or the “Company”) is pleased to announce excellent early functional recovery data from an initial Remplir™ prostatectomy case series in clinically complex patients with advanced prostate cancer.

The successful case series will inform the planned prospective clinical trial, which will investigate Remplir’s potential to support a more consistent and earlier return of erectile function and urinary continence following radical robotic prostatectomy. This clinical development builds on Remplir’s established role in protecting and supporting peripheral nerve healing and its growing use in prostate surgeries.

Urological Surgeon Dr Peter Chong said: “I am encouraged by these early results, particularly given that these patients underwent limited nerve-sparing surgery. In this setting, recovery of urinary and sexual function can be challenging, so seeing these functional outcomes at this early stage is promising. The technique does not add significant operating time, and I look forward to building on these results as we treat more patients and continue to strengthen the clinical evidence.”

Clinical context - What would a surgeon expect from this group?

Recovery following robotic prostatectomy is influenced by patient characteristics, disease severity and the extent of nerve preservation possible during surgery. These five patient case series provides preliminary evidence in a clinically complex group. Patients were aged 57–69 years and most had other health conditions that can make recovery more challenging, including diabetes, high blood pressure and obesity. Some also experienced urinary symptoms or erectile dysfunction before surgery.

All five patients had prostate cancer that had grown beyond the outer edge of the prostate. Two had high-grade tumours, while the other three had intermediate-grade tumours. All patients had cancers that were severe enough that extensive removal of prostate tissue was required, including the nerves on the affected side. Only partial preservation of nerve tissue on the unaffected side was possible. This made recovery of urinary continence and erectile function even more challenging.

Clinical findings - What have we seen so far?

The surgical robot was able to successfully place Remplir over the prostate nerve regions in all five patients, with no technical difficulties or significant additional operative time reported. No Remplir-related complications were reported during surgery or post-treatment follow-up (approximately 12 months).

Recovery of urinary continence was observed in the majority of patients, with two patients achieving pad-free continence by three to four months and a third achieving pad-free continence by six months. The two patients who did not achieve full continence had pre-existing urinary symptoms prior to surgery.

Of the four patients with erectile function prior to surgery, one reported erectile function with oral medication alone at 12 months, while two reported partial erectile function with second-line treatment. One patient had not regained erectile function at the time of assessment.

All five patients had undetectable PSA levels at the time of reporting, including one patient who had a small amount of tumour tissue that could not be surgically removed.

Orthocell Managing Director Paul Anderson said: “This pilot did what a first series should. It showed Remplir can be placed reliably in a difficult and variable nerve-sparing setting, and it provided early safety, usability and functional data. The next step is a larger, adequately powered, prospective trial to support use of Remplir in improving recovery of erectile function and continence after nerve-sparing robotic prostatectomy.”

Globally significant opportunity emerging

Remplir is already approved in seven jurisdictions globally, including Australia, New Zealand, the United States, Canada, Singapore, Hong Kong and Thailand. These existing approvals provide Orthocell with an opportunity to expand Remplir into a significant new surgical application without the need for additional regulatory clearance for use during prostatectomy procedures in these markets.

Nerve-sparing techniques are used during radical prostatectomy to preserve the neurovascular bundles (NVBs) responsible for erectile function and urinary continence. Published research estimates that up to 75% of patients undergoing radical prostatectomy may be eligible for nerve-sparing procedures². Remplir is designed to protect peripheral nerves and support nerve healing following surgical handling or injury, with the potential to support post-operative functional recovery.

Adoption by Australian urologists is growing, with Remplir now used in more than 300 prostatectomy procedures. More than 12,000 robotic-assisted radical prostatectomy (RARP) procedures are performed annually in Australia, representing a significant opportunity for further adoption.

The opportunity is also significant in the United States, where approximately 115,000 prostatectomies are performed annually, the majority using robotic techniques. Orthocell estimates that adoption of Remplir in nerve-sparing RARP could expand its estimated US total addressable market (TAM) from US\$1.6 billion to approximately US\$2.0 billion³.

The initial case series outcomes support further investigation of Remplir in nerve-sparing robotic prostatectomy. The Company is progressing the development of a larger prospective clinical study to generate more evidence on post-operative erectile function and urinary continence outcomes. The resulting clinical evidence is intended to support medical education and inform broader adoption and commercialisation across existing approved international markets, with an initial focus on the United States.

Release authorised by:

Paul Anderson

Orthocell Ltd CEO and MD

² Moris, Lisa et al (2022) European Urology Focus, Volume 8, Issue 3, 690 - 70

³ 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 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.