Globally Significant Opportunity Emerges as Remplir™ is used in Nerve-Sparing Prostate Cancer Surgery

Potential to reduce the risk of erectile dysfunction and urinary incontinence

- **Australian urologists are using Remplir during prostate cancer surgery in a promising new application aimed at reducing post-surgical complications due to peripheral nerve injury — a development with potential for globally significant impact.**
- **Currently up to 80% of men experience erectile dysfunction, and up to 35% suffer from urinary incontinence, after radical prostatectomy due to damage of the peripheral nerves in the neurovascular bundle (NVB) surrounding the prostate.**
- **Despite procedures aimed at preserving nerve function (i.e. nerve-sparing), and with the enhanced surgical precision offered by robotic assisted radical prostatectomies (RARP), there remains a significant risk of post-surgical erectile dysfunction and/or urinary incontinence.**
- **Similar to peripheral nerve repair procedures that restore function to the arms and legs, Remplir can be used to protect the NVB from damage and promote restoration of normal nerve function. Remplir has been used in approximately 40 nerve-sparing RARP by urologists across Australia.**
- **Orthocell is currently collaborating with urologists to collect and analyse retrospective outcome data from these nerve-sparing procedures using Remplir, with data to be released once available. The Company also intends to invest in further research to build evidence and assist medical education initiatives related to this innovative use of Remplir for peripheral nerve repair.**
- **The Company believes the use of Remplir in nerve-sparing RARP represents a significant opportunity to expand Remplir's Total Addressable Market.**
- **Remplir rollout in the US$1.6 Billion US market[1] 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.**

Perth, Australia; 16 September 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce its flagship nerve repair device, Remplir, has been introduced to Urologists in Australia for use in nerve-sparing Robotic-Assisted Radical Prostatectomies (RARP). Remplir has been used in approximately 40 surgical cases to assist in improving recovery of erectile function and urinary continence post-surgery.

Orthocell is collating clinical data on initial patients who underwent radical prostatectomies with Remplir in Australia and will release the clinical data once available. The Company will also invest in further clinical studies to build evidence and assist medical education initiatives to drive further adoption of Remplir in this market.

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

Orthocell CEO and MD, Paul Anderson, said: "The use of Remplir in nerve-sparing robotic-assisted radical prostatectomy highlights the product's versatility and superior performance in the protection and reconstruction of damaged peripheral nerves.

Surgeons across multiple specialties—including orthopaedics, plastic and reconstructive surgery, and now urology—are increasingly adopting Remplir to simplify procedures, minimise scarring, and improve functional recovery.

This represents a significant step forward in Remplir's organic expansion into broader peripheral nerve repair applications and has the potential to substantially increase the device's global total addressable market."

Prostate cancer and radical prostatectomies

Prostate cancer remains the most diagnosed cancer among men in Australia. More than 26,000 new cases of prostate cancer were diagnosed in 2024 alone.[2] If the tumour has not spread beyond the prostate, first-line treatment is radical prostatectomy, the complete removal of the prostate gland, including some of the surrounding tissue, to ensure all cancer cells are removed.

Radical prostatectomy is associated with high rates of urinary incontinence (UI) and erectile dysfunction (ED) after treatment, which has a significant impact on quality of life. Rates of post-operative ED vary, depending on both patient risk factors and surgical technique, can be as high as 80% 12 months post-surgery.[3] Similarly, rates of UI 3 months post-surgery are reported in up to 35% patients.[4]

The introduction of robotic-assisted RP (RARP) offers increased precision and preservation of prostate anatomy not possible by other means. However, while the use of RARP has resulted in lower rates of ED and UI, both are still significant risks associated with the procedure.

Use of Remplir in robotic assisted radical prostatectomies

ED and UI are caused by damage to the neurovascular bundle (NVB), a network of peripheral nerves and blood vessels surrounding the prostate, during surgery. Preserving the NVB is the key to maintaining sexual function and continence post-surgery, but damage to the NVB is difficult to avoid.

In low-risk patients, such as those with low grade cancer, "nerve-sparing" procedures, to preserve integrity of the NVB, have been shown to reduce the number of patients who experience post-surgical ED and UI. It is estimated that up to 75% of patients undergoing radical prostatectomy could be eligible for nerve-sparing procedures.[5]

Remplir, a nerve wrap used in peripheral nerve repair procedures, is being adopted by Australian Urologists in nerve sparing RARP to protect the NVB. Use of Remplir helps to heal any damage to the NVB that occurs during surgery, which will potentially reduce the rates of ED and UI.

In Australia, over 12,000 RARP procedures are performed annually using the da Vinci Surgical System (DVSS). Orthocell's distribution partner, Device Technologies, is the exclusive distributor of the DVSS across Australia, New Zealand, and Southeast Asia. This strategic alignment is facilitating the introduction of Remplir to Urologists performing RARP procedures, further supporting the product's expansion into new surgical specialties.

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[2] https://www.canceraustralia.gov.au/cancer-types/prostate-cancer/prostate-cancer-australia-statistics
[3] Kesch C, Heidegger I, Kasivisvanathan V, et al Front Surg. 2021 May 28;8:684088.
[4] Geraghty K, Keane K, Davis N. Ir J Med Sci. 2024 Jun;193(3):1603-1612.
[5] Moris, Lisa et al (2022) European Urology Focus, Volume 8, Issue 3, 690 - 70

With circa $27 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 market[6] 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. The Company is also accelerating the launch of Remplir in Canada and remains on schedule to submit its EU/UK application in Q4 CY25.

Release authorised by:
Paul Anderson
Orthocell Ltd CEO and MD

For more information, please contact:

General enquiries

Paul Anderson
Orthocell Limited
CEO and MD
P: +61 8 9360 2888
E: paul.anderson@orthocell.com

Media enquiries

Haley Chartres
H^CK Director

P: +61 423 139 163
E: haley@hck.digital

Investor enquiries

Shaun Duffy
VECTOR Advisors

P: +61 404 094 384
E: sduffy@vectoradvisors.au

About Orthocell Limited

ACN 118 897 135
Registered Office – Building 191 Murdoch University, 90 South Street, Murdoch WA 6150 Australia

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,"

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

"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 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.