

## Remplir™ gains Australian reimbursement

- **Remplir™ granted inclusion on the Australian Prostheses List**
- **The Prostheses List defines the minimum value of benefit private insurers pay for Remplir™ used in approved peripheral nerve repair and reconstruction procedures**
- **Significant Australian addressable market, with 11,780<sup>1</sup> surgical repairs of peripheral nerves completed in public and private hospitals in the 2019/20 financial year**
- **Device Technologies appointed as exclusive distributor of Remplir in Australia, with first orders shipped in September 2022**
- **Orthocell is well-positioned to gain traction in Australia and to expand into the US, the largest global healthcare market.**

**Perth, Australia; 01 November 2022:** Regenerative medicine company Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) is pleased to announce it has received notification from the Australian Government Department of Health that Remplir has been included on the Australian Prostheses List (PL). Inclusion on the PL enables surgeons to receive reimbursement from private insurers for the use of Remplir™ in peripheral nerve repair procedures, reducing costs to the patient.

**Orthocell Managing Director Paul Anderson, said:** “Inclusion of Remplir on the Prostheses List is the culmination of translational research and a regulatory program to bring this product to the Australian market. I am delighted that patients now have access to a premium nerve repair device that has been designed, manufactured and now reimbursed in Australia.”

The Australian addressable market for nerve repair and reconstruction is significant, with 11,780<sup>1</sup> surgical repairs of peripheral nerves completed in public and private hospitals in the 2019/20 financial year. The Company believes Remplir will become the market-leading nerve repair device, with uptake driven by the surgeon’s preference for high quality, easy to use devices that reduce the need for damaging sutures and facilitates better patient outcomes (Figure 1). The Company is well-positioned to achieve further international approvals for Remplir in nerve repair.

Inclusion on the Prostheses List follows Australian market approvals for Remplir™ medical device in March 2022, and the appointment of Device Technologies (“DVT”) as the exclusive distributor of Remplir™ across Australia and New Zealand in September 2022. DVT will market and distribute Remplir, undertaking targeted promotion activities, initiating sales, and expanding the network of referring plastic and orthopaedic surgeons. Orthocell have been actively working with the internal sales and marketing team at DVT preparing for Australian market entry, leading in-person product training sessions and participating in marketing workshops. DVT are focused on the establishment of key accounts with leading plastic, reconstructive and orthopaedic specialists.

### The Remplir Advantage

Remplir™ is manufactured by Orthocell at its quality-controlled facility in WA, using the Company’s proprietary SMRT™ manufacturing technology, developed in conjunction with Professor Minghao Zheng and the University of Western Australia.

<sup>1</sup> The Australian Institute of Health and Welfare, <https://www.aihw.gov.au/reports-data/myhospitals>

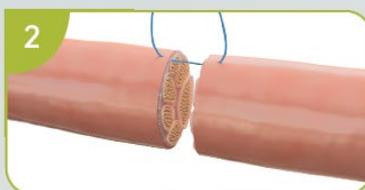


Clinical studies have shown nerve repair with Remplir™ consistently restores arm and hand function. Final results of patients in Orthocell's nerve repair clinical study showed **85% (23 of 27) of nerve repairs with Remplir™, at 24 months post treatment, resulted in functional recovery of muscles controlled by the repaired nerve.** This is of significant interest to patients and clinicians due to potential improvement in efficiency and efficacy of nerve repair procedures.

## NERVE WRAP FOR PERIPHERAL NERVE REPAIR



**1**  
**PERIPHERAL NERVE INJURY**  
Damaged peripheral nerve after traumatic injury to limb



**2**  
**PREPARATION OF REPAIR SITE**  
Damaged section of nerve is removed, and the ends are brought together without tension



**3**  
**MICROSURGICAL REPAIR**  
Remplir is wrapped around the nerve, reducing suture requirements and facilitating optimal coaptation



**4**  
**MICROSURGICAL REPAIR**  
Remplir easily conforms to the repair site while mimicking the nerves natural epineurium



**5**  
**GUIDES AND SUPPORTS NERVE REPAIR**  
Remplir creates a protected healing micro-environment allowing new axons to reconnect



**6**  
**HEALED NERVE**  
Healed nerve restores function to affected limb

**Figure 1: Remplir Nerve wrap Procedure**

Release authorised by Paul Anderson  
Managing Director  
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## About Orthocell Limited

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 CelGro™, a collagen medical device which facilitates tissue reconstruction and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications and is cleared for use in US FDA (510k), Australia (ARTG) and Europe (CE Mark). Remplir™, for peripheral nerve reconstruction, recently received approval in Australia (ARTG). 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, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

For more information on Orthocell, please visit [www.orthocell.com](http://www.orthocell.com) or follow us on Twitter [@OrthocellLtd](https://twitter.com/OrthocellLtd) and LinkedIn [www.linkedin.com/company/orthocell-ltd](http://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.

