FDA Clearance For Groundbreaking Australian Nerve Regeneration Product

MEDIA RELEASE
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Perth-based regenerative medicine company, Orthocell Ltd, has received 510(k) clearance from the US Food and Drug Administration (FDA) to commence commercial distribution of Remplir™ in the United States (US) – a nerve repair device invented, developed and manufactured in Australia.

Remplir is redefining the global standard of care for nerve repair procedures, by unlocking the power of the human body to heal. Remplir is made from pure collagen (acellular, type 1) and in clinical practice, creates a bioactive healing chamber to support new tissue formation and integration. By comparison, suturing nerves can place delicate tissue under tension, causing scarring, fibrosis and neuroma formation.

Clearance for Remplir in the US – the largest healthcare market in the world – is a major achievement for Australia's innovation sector. Remplir is also cleared for use and sale in Australia, New Zealand, and Singapore, with other jurisdictions imminent.

The true human impact of this device is now measured and celebrated. Pioneering orthopaedic surgeon and lead Investigator in the Remplir clinical trial program, Dr Alex O'Beirne, has utilised Remplir in transformative cases of recovery in quadriplegic patients.

"Treating patients who have experienced a catastrophic spinal cord injury and quadriplegia is a high stakes pursuit in medicine – for the patient, restoring mobility and sensation can completely transform their quality of life. In this cohort of patients, we use Remplir to support nerve transfer surgery – a delicate procedure that involves transferring healthy nerves to the site of injury and creating a healthy healing environment to allow them to grow back together. The results so far have been outstanding," he said.

The media is invited to view two short films capturing the treatment and recovery journey of quadriplegic patients who have been treated with Remplir. Click here to meet Jasmine and Liam.

Remplir is highly regarded in the surgical community for its widespread clinical utility and ease of use. It can be used in nerve repair procedures to connect (trauma, e.g. motor vehicle accident), protect (compression, e.g. blunt trauma injury) and cap (amputation, e.g. mastectomies).

Orthocell Chief Executive Officer and Managing Director, Paul Anderson, said feedback from surgeons around the world has been extremely positive.

“Remplir is empowering surgeons to repair and rewire crucial nerve pathways in the body – and the results speak for themselves, with our key clinical study showing 85% (23 of 27) of nerve repairs resulted in functional recovery of muscles controlled by the repaired nerve,” he said.

“It is heartening to see this technology being embraced by surgeons in Australia and abroad. FDA clearance provides a regulatory blueprint that will significantly extend the reach and impact of Remplir with patients all over the world.”

Orthocell retains control of the entire intellectual property (IP) position for Remplir, together with SMRT™ manufacturing at its Perth-based facility, providing a robust production runway for the US launch. A logistics partner and key hires have also been appointed in the US, poised to leverage Orthocell’s deeply established market engagement strategy in partnership with reputable centres of excellence and key opinion-leading surgeons.

For more information visit orthocell.com

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MEDIA RESOURCES

Click here to access a digital media kit, inclusive of medical images and illustrations, images of the Orthocell manufacturing HQ and key personnel from Orthocell.