US FDA 510(k) Clearance for Orthocell's Flagship **Remplir**™ Product

April 2025

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Remplir™ US FDA 510(k) Clearance

A Company Defining Moment

US FDA 510(k) clearance

Received for its flagship Remplir nerve repair product. Clears the way to commercial distribution into the US which represents a US$1.6 billion total addressable market[1]

Major Revenue Inflection

Provides the catalyst to drive the Company towards breakeven and profitability within a foreseeable timeframe

Scaled Manufacturing Facility

Orthocell owns and controls its manufacturing process and is prepared to supply the US market, with an annual medical device capacity for > 100,000 units and significant inventory in place. Material capital costs associated with production ramp up have already been incurred.

Outsourced Logistics

Ready to fill sales orders from Day 1. Stock to be warehoused at Uniphar's GMP certified 65,000 square feet facility in the US with central coordination of warehousing, order processing, shipping, and customer service

Proven Sales Model

Pathway to market in the US in place and expanding. **Internal Sales, Marketing and Medical Education team combined with Distributor Network ready to roll out**

Strong Balance Sheet

Existing cash reserves of ~$32 million[2] are sufficient to undertake the US roll out

1. USA nerve repair market size was estimated using referenced papers from both US and OUS databases and studies.
2. Cash at bank as at 26th March, 2025

Remplir™
Redefining Nerve Repair

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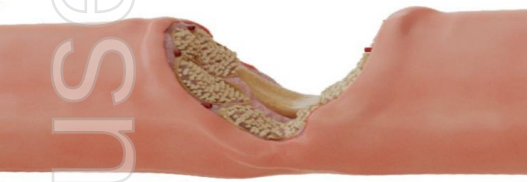
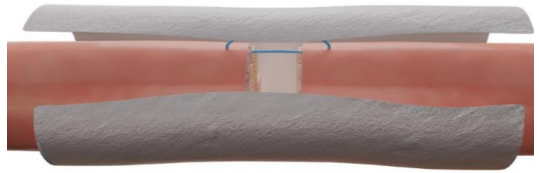
Remplir™ Redefining Nerve Repair

Collagen nerve wrap used in the repair of peripheral nerve injuries. It provides compression-free protection to the nerve, generating an ideal microenvironment to aid nerve healing.



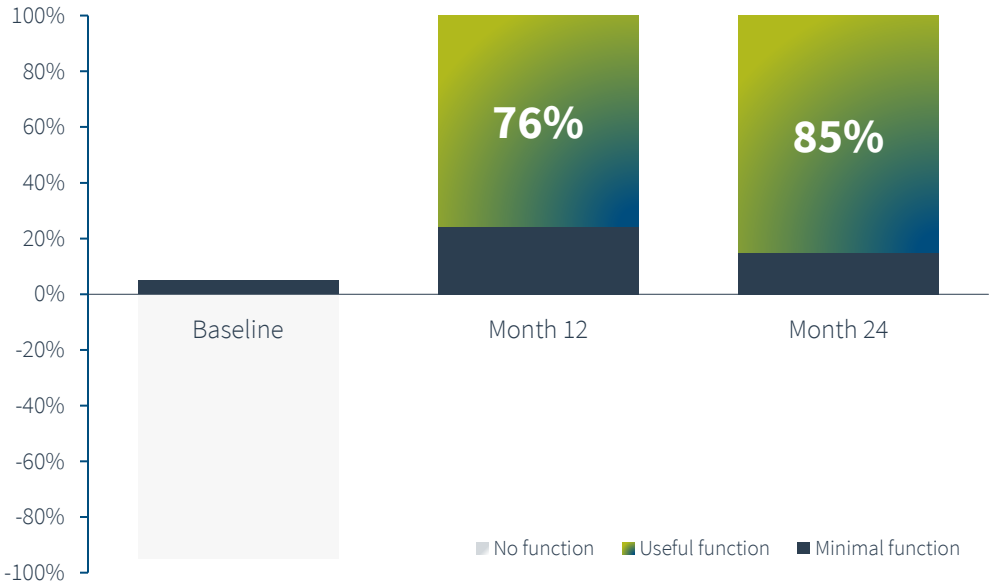


- ✓ Exceptional handling characteristics
- ✓ Mimics epineurium (nerve outer layer)
- ✓ Reduces need for multiple sutures
- ✓ Returns nerve to pre-injured state

Guiding predictable outcomes in peripheral nerve repair

Remplir™ Compelling Clinical Results

Patients regained voluntary muscle movement within 12 months, with increased muscle strength and range of motion at 24 months



Useful Function
Voluntary movement with improved strength and range of motion

Minimal Function
Voluntary movement restored, limited strength and range of movement

No Function
No voluntary movement

Final results
85% (23 of 27)
of nerve repairs resulted in functional recovery of muscles controlled by the repaired nerve

We are now seeing a consistent return of arm and hand function following nerve transfer surgery with Remplir. Remplir is increasing the success rate and efficiency of nerve transfer surgery.

Leading Australian orthopaedic nerve specialist and clinical trial lead, **Dr Alex O'Beirne**

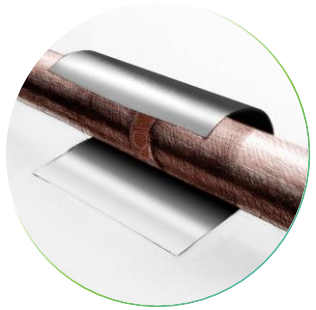
Remplir™ Indications

Remplir is a highly versatile product that delivers a single solution for either connecting severed nerves, protecting damaged nerves or capping amputated nerves

> 180 surgeons
now using the device in existing markets

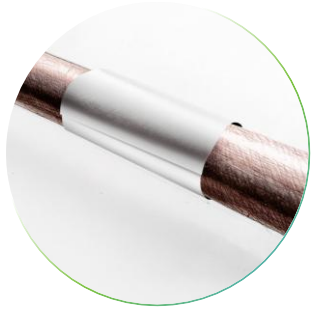
> 150 hospitals
now supply the device to plastic reconstructive and orthopedic surgeons

Repair with Remplir™



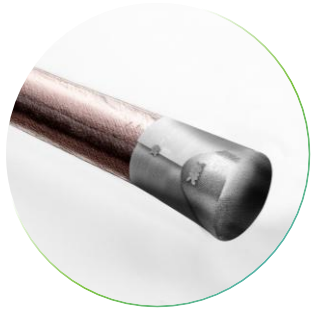
CONNECT

Trauma: motor vehicle, power tool, surgical injuries, sports and military related accidents



PROTECT

Compression: blunt trauma, revisions surgeries (e.g. carpal/cubital tunnel)



CAP

Amputation: amputations, stump neuroma, mastectomies, schwannoma

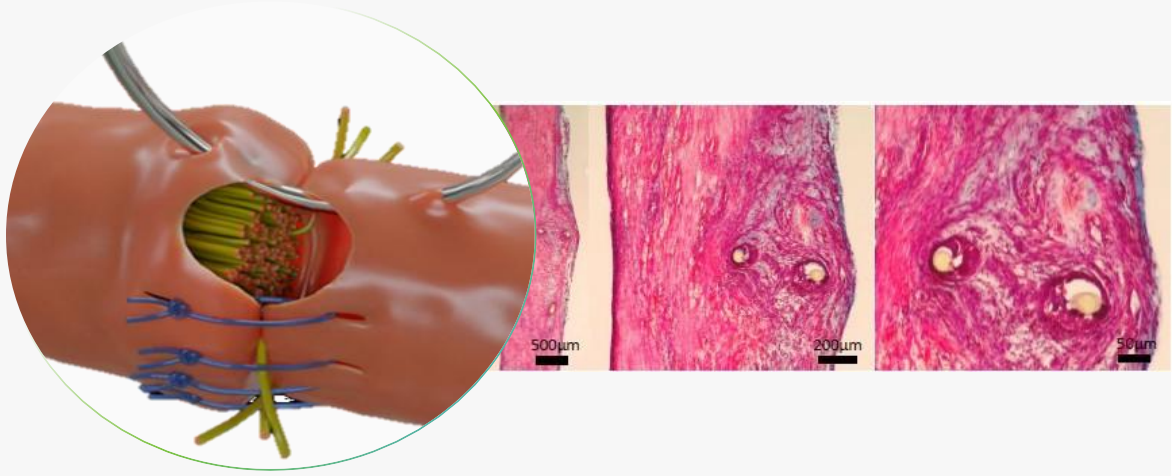
Remplir™ US Peripheral Nerve Repair Trends

Suturing is still the most commonly performed procedure and considered to be the “gold standard” technique for peripheral nerve repair

Over 700,000[1] peripheral nerve repair procedures in the US per year, 90% undertaken using suture only method.

Suturing

- Technically difficult to achieve alignment and tensionless repair
- Induces foreign body reaction leading to chronic inflammation, fibrosis and scarring
- Can lead to suboptimal axonal regeneration and return of function and sensation



Success Rates 50-70%

1. Referenced papers used to estimate peripheral nerve procedures in the US per annum. Papers used included both US and OUS databases and studies

Remplir™ Significant US Market Opportunity

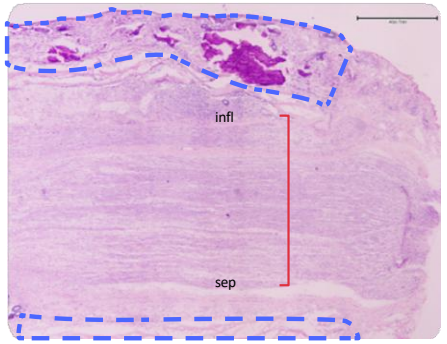
Clearance paves the way for Orthocell to commence commercial distribution into an estimated US$1.6 billion total addressable nerve repair market[1] in the US alone

Remplir is not seeking to replace a current dominant market incumbent. **Devices are only used in ~10% of procedures.**

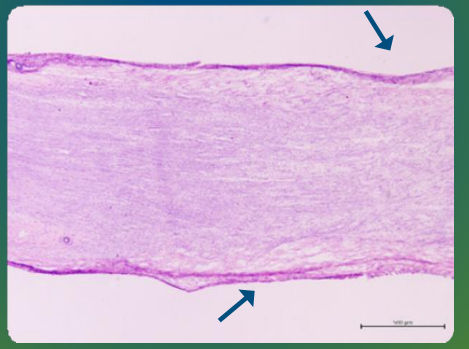
Current devices are not widely adopted

- Materials are too rigid, challenging to deploy and make it difficult to manage size differences between nerve ends, leading to compression injuries or neuroma formation
- Fail to fully integrate into native tissue, leaving residual material that impairs the healing process
- Have not significantly improved the consistency of outcomes

Current devices



Remplir™



1. Referenced papers used to estimate peripheral nerve procedures in the US per annum. Papers used included both US and OUS databases and studies

Remplir™ US Commercialisation Platform

Ready to fill sales orders from day 1

Manufacturing

Existing GMP facility in place in Western Australia

Logistics / Shipping

US based central warehousing, order fulfillment, customer service

US Market Roll Out

Internal Sales and Med Ed team combined with Distributor Network

Manufacturing

Remplir™
Manufacturing / Product Supply

Capacity in place to deliver the volumes through to company profitability

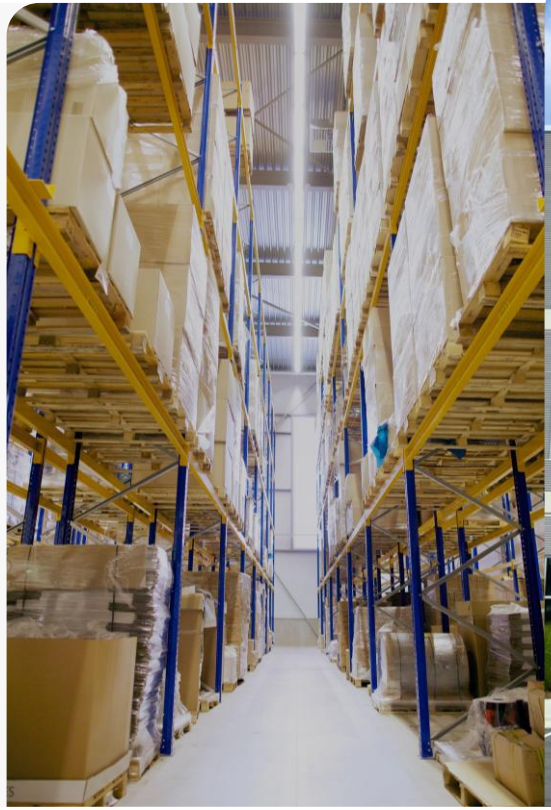
- Annual medical device production capacity of **100,000 units** in place at certified GMP facility in Western Australia
- **No near-term requirement** for increased production capacity
  - Already in production for Australia, New Zealand and Singapore
  - MDSAP, MDR quality standards
- Production ramp up underway in anticipation of US FDA approval with **significant inventory in place** (3-year shelf life)
- Plentiful raw material source, with **back up suppliers**

Logistics / Shipping

Remplir™
Logistics / Shipping

On the ground logistics in the US to deliver into early sales orders

- Stable product for shipping, **no temperature control required**
- Stock to be warehoused at Uniphar's GMP certified **65,000 square feet facility in the US** with central coordination of warehousing, order processing, shipping, and customer service
- The facility is equipped with redundant power supply, environmental monitoring systems, and advanced inventory management, **ensuring compliance with FDA, ISO, and DSCSA regulations.**
- Orders received before 2:00 PM local time will be **shipped the same day** for a next day delivery



US Sales, Marketing and Medical Affairs Executives

Orthocell has appointed experienced US-based executives to drive the market launch and sales of Remplir

John Walker

Vice President – Sales

Mr Walker is a highly experienced sales executive, who has successfully led global product launches and sales strategies, most notably helping to lead the growth of nerve repair device sales at Axogen.

Phillip Edmondson

Vice President – Medical Affairs

Mr Edmondson is an award-winning medical affairs professional, who excels in creating product awareness, building advocacy and implementing successful medical education programs that contribute to sales growth.

Kevin Leach

Head of Marketing

Mr. Leach is a highly regarded senior marketing executive with extensive knowledge and experience in the development and commercialization of technologies for peripheral nerve regeneration and repair in the USA.

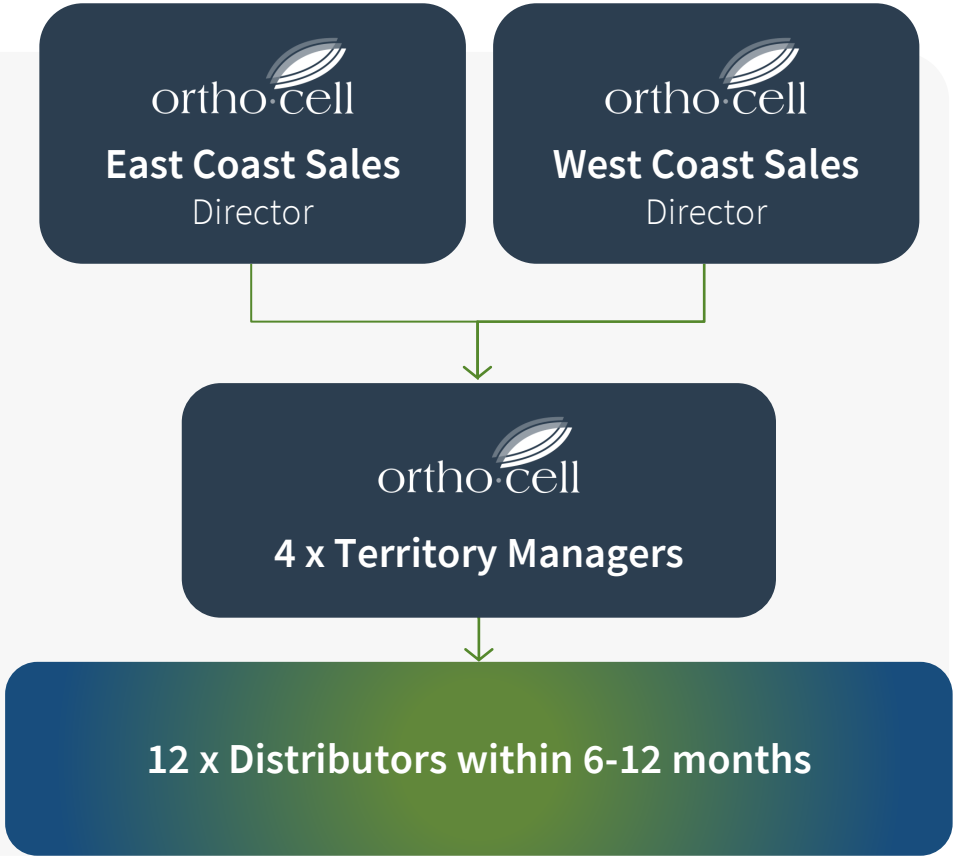
Remplir™ US Market Roll Out

6 months preparation activities already undertaken.
Pre-launch completed in advance of FDA approval

US Market Roll Out

- Hybrid sales approach of in-house sales and medical education team combined with engagement of external distributors
- **Critical pre-launch activities to lay the foundation in anticipation of FDA approval completed:**
  - Strengthening panel of key opinion leaders
  - Influential hospital reference sites to drive early sales orders
  - Sales Distributors screened ready to commit, pending FDA approval
  - Sales training and Medical education programs ready to roll out pending FDA approval
  - Marketing collateral ready to roll out pending FDA approval
  - Reimbursement guidelines

Planned Structure



Remplir™ Pre-launch Completed

Orthocell successfully completed a pre-launch program at the 2025 IFSSH and IFSHT Triennial Congress in the US in advance of FDA approval. Attended by leading peripheral nerve surgeons from the US and other countries.

2025 IFSSH and IFSHT Triennial Congress

International Federation of Societies for Surgery of the Hand

International Federation of Societies for Hand Therapy

Remplir™ Investment Highlights

Commercial-stage medical device company at **revenue inflection** point following US FDA approval for its flagship Remplir product with pre-launch completed

Best in class products for Bone, Nerve and Tendon repair approved in ten jurisdictions

Strengthened board with the appointments of highly experienced executives John Van Der Wielen, Professor Fiona Wood and Kim Beazley

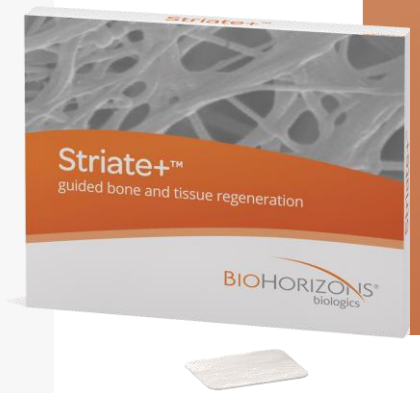
~$32M cash at bank, strengthened share register, share market momentum, well-funded for US roll out

Product margins retained in-house Manufacturing facility and all IP owned by the company

Upcoming Catalysts[1]

Remplir™ Redefining nerve repair

US FDA market clearance and Pre-Launch	Achieved
Appoint US sales team	2Q CY25
Appoint US distributors	2Q CY25
US first sales	2Q CY25
EU+UK & Brazil submissions lodged	3Q / 4Q CY25



Striate+™ Growing better bone

Germany, Austria, Switzerland market launch	Achieved
Singapore product registration	Achieved
Brazil product registration	2Q CY25
Hong Kong submission lodged	2Q CY25

1. Timelines may be subject to change due to circumstances not under the Company's control

Appendices

Corporate Snapshot
Highly Credentialed Board

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Corporate Snapshot

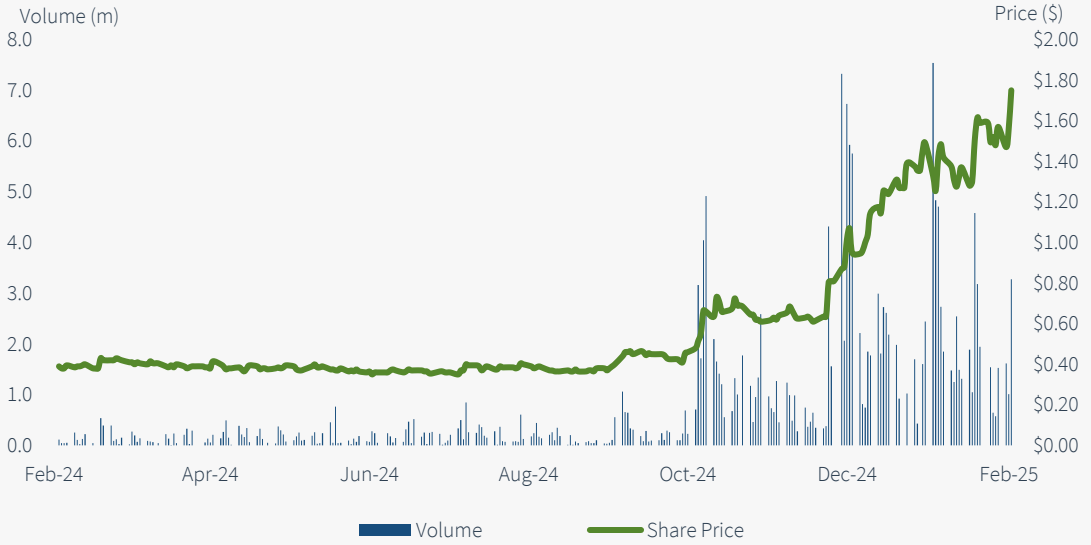
Well funded beyond US market clearance of Remplir, supported by leading life science institutional investors

ASX: OCC Trading Information

Share Price (as @ 03rd March 2025)	**$1.44**
12 month low/high	$0.35/$0.1.79
Shares outstanding	241M
Market Capitalisation	~$347M
Cash (26 Mch)	~$32M
Debt (26 Mch)	Nil

Substantial Shareholders	**%**
Founders & Management	~11%
Institutions & HNW's (Sankofa, Cerutty, Austral Capital, Thesis Asset Mgt, Private Portfolio Mgr's, FundBPO, Wyllie Group)	~14%

12 Month Share Price And Volume



~AU$32m Strong balance sheet, no debt, no royalties

Highly Credentialled Board

Recent appointments of John Van Der Wielen and Professor Fiona Wood AM places Orthocell in a strong position to drive its products into global markets and accelerate revenue growth

Mr John Van der Wielen

Independent Non-Executive Chairman

- 35+ years experience in international financial services including large funds management, insurance and private banking
- Former CEO of HBF with annual revenues over $2B
- Extensive corporate strategy, institutional and strategic investor engagement and M&A transaction experience

Mr Paul Anderson

Founder and Managing Director

- 25+ years in regenerative medicine industry
- Former MD at Verigen, successfully commercialised cartilage repair cell therapy (MACI)
- Extensive experience in product development, navigating regulatory pathways, international market launches, medical education and sales force leadership

Dr Rravi I. Thadhani

Independent Non-Executive Director

- 30 years of specialist experience working in US healthcare sector – highly regarded executive, medical administrator and researcher
- Former professor of medicine at Harvard Medical School and chief academic officer at Mass General Brigham hospital, where he oversaw a $2.3 billion research enterprise
- Extensive US regulatory experience and commercialisation of devices and therapeutics

Professor Fiona Wood AM

Non-Executive Director

- 30+ years experience as a plastic and reconstructive surgeon
- Inventor of RECELL “spray on skin” treatment, now supplied by Avita Medical Inc, a AU$450M dual-listed company with operations in 30+ countries including the US
- Unrivalled track record in development and commercialisation of innovative regenerative medicine products.

Hon Kim Beazley AC

Independent Non-Executive Director

- Unrivalled experience engaging strategic partners in the US-highly regarded politician, executive and strategic adviser
- Former Australian US Ambassador and Governor of Western Australia, Deputy Prime Minister, and Minister for both Defence and Finance
- Extensive experience representing both public and private interests for Australia

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Authorised for release by
Co-Founder and Managing Director, Paul Anderson

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