

Remplir™

US Commercialisation Update

*First surgical use achieved
Roll out on target*

July 2025



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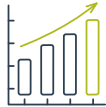
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Remplir™ US Roll Out Update



First US Remplir Surgical Use Achieved

First use into US\$1.6 billion total addressable market¹ achieved within 3 months of achieving US FDA 510(k) clearance. Low volumes initially to build surgical familiarity.



US Remplir Commercialisation on Target

Key workstreams required for US roll out all progressing on track with a view to sales ramp up over 1H FY26.



14 Nerve Repair Specialist Distributors in Place

Initial focus on east coast market for coverage from distributor network. Relationships with surgeons and hospitals over 25 states



Internal Sales , Marketing & Med Ed Team Closely Engaged with Distributors

Individual business plans underway with each distributor targeting specific surgeons/hospitals. Sales force training program in progress.



Logistics Provider in Place, first 2,000 units shipped to US from Australia

Ready to fill sales orders with inventory 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 validated.



Broader Remplir Market Development Activities Continuing

US KOL Dr/Captain Ian Valerio visit to Australia for educational and promotional tour. Humanitarian donation to volunteer trauma surgeons performing procedures on Ukrainian war victims.

1. USA nerve repair market size was estimated using referenced papers from both US and OUS databases and studies.

Remplir™ US Path to High Volume Sales

First surgical use completed, 1H FY26 ramp up expected



Market Access

- ✓ FDA Clearance
- ✓ State Licenses
- 🔄 Hospital Procurement Approvals (3-6 months)
- 🔄 Onboarding ASCS



Product Launch

- ✓ Customer Segmentation
- ✓ Pricing
- ✓ Medical Education Program
- ✓ Compliance System
- ✓ Key Account planning
- 🔄 KOL's & early user adoption
- 🔄 Product awareness & promotion
- 🔄 Clinical data to support adoption



Operations

- ✓ US Team
- ✓ Regional distributors (14 in pause)
- ✓ Warehousing & Logistics
- ✓ Sales forecasting & manufacture
- ✓ Invoice to pay
- ✓ Performance metrics & reporting

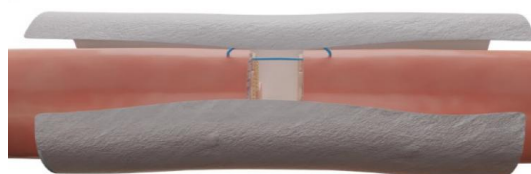
Remplir™

Redefining Nerve Repair



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



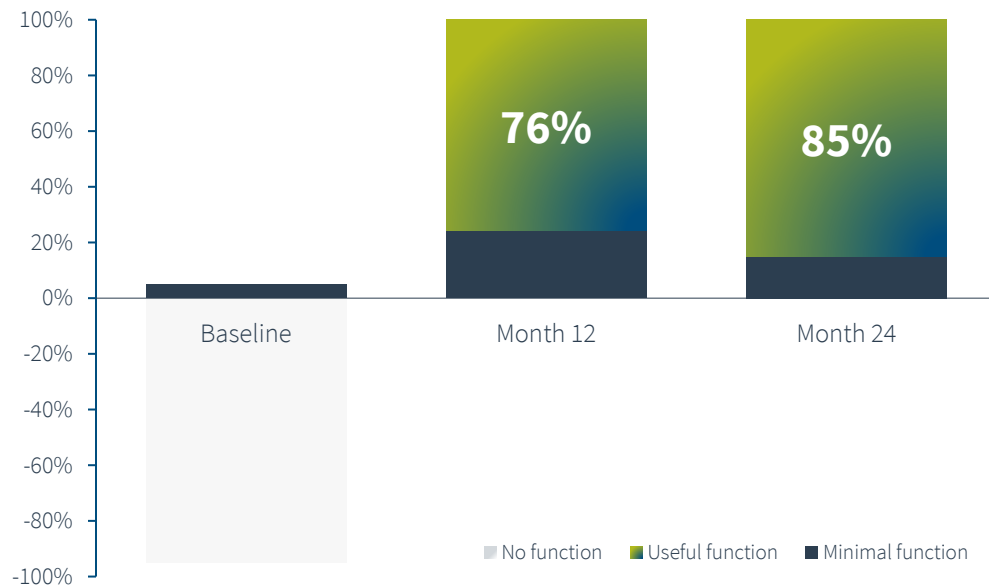
Returns nerve to pre-injured state

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



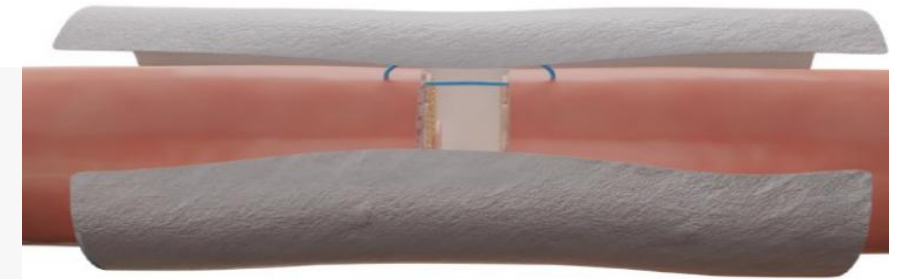
We are now seeing a consistent return of arm and hand function following nerve transfer surgery with Remplir. Remplir is increasing the success rate and efficiency of nerve transfer surgery.

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

Remplir™ Superiority over Standard Nerve Repair Technique

Interim results from new study evaluating the impact of sutures on nerve regeneration and functional recovery in surgical repair of severed peripheral nerves

- Suturing Study commissioned by Orthocell to support US sales roll out.
- Compelling results to form cornerstone of medical education efforts in the US
- Key outcomes in the use of Remplir as compared to current standard suture only nerve repair technique:
 - Earlier return of function
 - Restoration of nerve structure
 - Higher quality nerve regeneration
 - No inflammatory response
- Interim results presented at key medical conference with final results to be prepared for publication.



**Repair using 1 suture
augmented with Remplir**

Study involved repair of surgically severed nerves evaluated in 48 rats across 4 treatment groups: (i) repair using 1 suture, (ii) repair using 3 sutures, (iii) repair using 6 sutures, and (iv) repair using 1 suture augmented with Remplir. Nerve function and regeneration were evaluated up to 12 weeks post-treatment with earlier restoration of nerve function and regeneration of high-quality nerve tissue observed in the Remplir group compared to suture-only repair.

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



> 200 surgeons

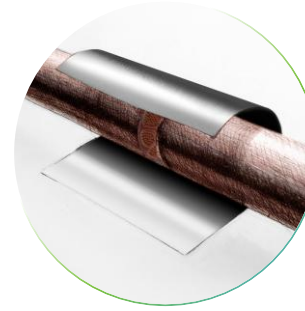
now using the device in existing markets



> 165 hospitals

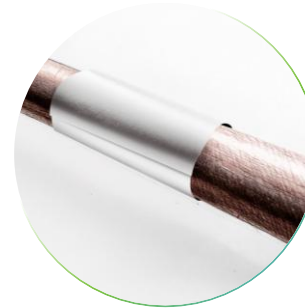
now supply the device to plastic reconstructive and orthopedic surgeons

Repair with Remplir™



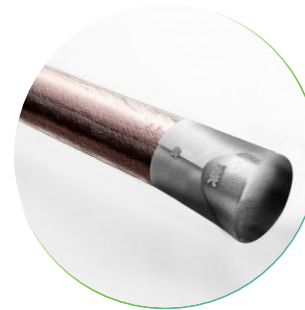
CONNECT

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



PROTECT

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



CAP

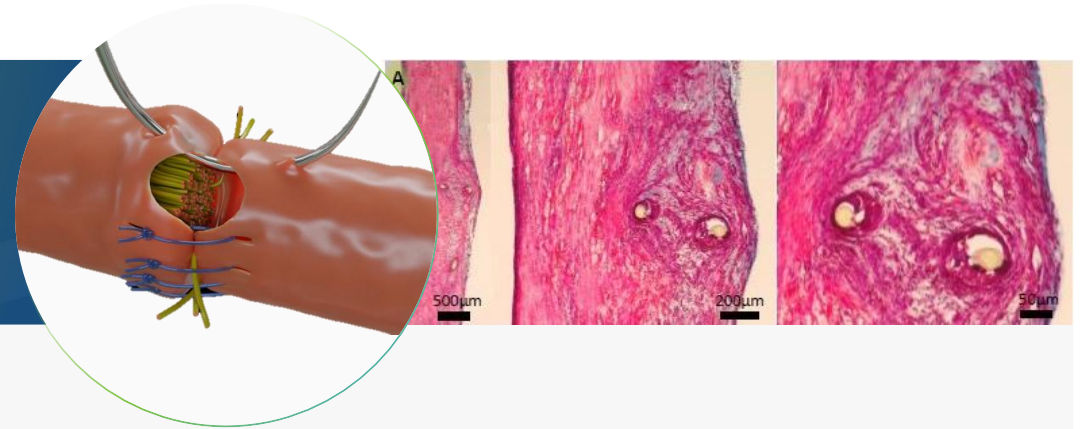
Amputation: amputations, stump neuroma, mastectomies, schwannoma

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

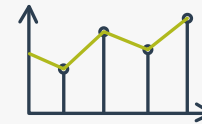


Over 700,000¹ peripheral nerve repair procedures in the US per year, 90% undertaken using suture only method.



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

Orthocell has commenced commercial distribution into an estimated US\$1.6 billion total addressable nerve repair market¹ in the US alone



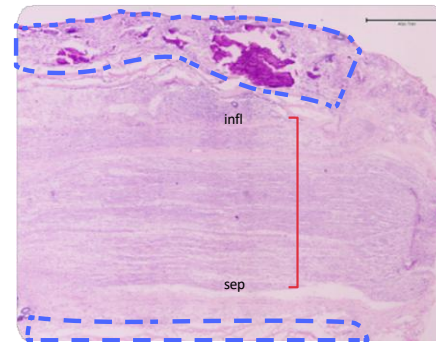
Remplir is not seeking to replace a current dominant market incumbent.
Devices are only used in ~10% of procedures.

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

First surgical use completed, 1H FY26 ramp up expected



Manufacturing

Existing GMP facility in place
in Western Australia



Logistics / Shipping

US based central
warehousing, order
fulfillment, customer service

1,000 units of inventory
in place, additional 1,000
shipped from Australia



US Market Roll Out

Internal Sales and Med
Ed team combined with
external Distributor Network



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**



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Logistics / Shipping

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



Logistics /
Shipping

- Stable product for shipping, **no temperature control required**
- **First inventory of 1,000 units in place**, additional 1,000 units shipped from Australia
- Stock 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 – order fulfillment process has been validated





US Market
Roll Out

Remplir™ US Market Roll Out

First 14 distributors appointed

- Hybrid sales approach of in-house sales and medical education team combined with **engagement of external distributors**
- Immediate focus post FDA clearance **was signing a portfolio** of nerve repair specialist distributors.
- **14 specialist distributors** now appointed covering 25 states with an initial focus on the east coast
- With a critical mass of distributors now in place, internal Orthocell team working closely **with them on:**
 - Tailored business plan **development by distributor**
 - Identification of specific target **surgeons/hospitals**
 - Sales force **training**
- East Coast Sales Director appointment imminent to complement existing **heads of Sales, Medical Affairs and Marketing.**



Regional Focus
USA (Only)



14
Distributors




100+
Sales Representatives



Remplir™ Further Medical Education Initiatives

Orthocell's Third Annual Nerve Repair and Reconstruction Symposium, Melbourne May 2025

- **US KOL Dr Ian Valerio was the keynote** and figurehead of the symposium conducted in Melbourne
 - **Division of Plastic and Reconstructive Surgery:** Harvard Medical School, Massachusetts General Hospital
 - **US Navy Captain**
- Attended by a faculty of world-class **leading nerve repair specialists**
- **Medical education focus:** comprehensive understanding of advanced techniques
- Dr Valerio **conducted the following interview** while in Australia:
- [Long Shortz with Orthocell: Capt. Valerio on OCC's nerve repair device Remplir - Stockhead](#) 



Left to Right: Dr Natasha Van Zyl, Dr Tanya Burgess, Dr Alex O'Beirne, Dr Ian Valerio, Dr Sharon Chu, Dr Vaikunthan Rajaratnam

Front: Prof Ming Hao Zheng



Remplir™ Further Medical Education Initiatives

Orthocell provides Remplir shipment to Ukrainian war victims

- Shipment of Remplir nerve repair technology to volunteer trauma surgeons **performing critical procedures in Ukraine.**
- The **donated product will assist surgeons** in addressing peripheral nerve injuries and managing nerve-related complications in amputation cases.
- **Result of collaborative efforts across multiple organisations** and individuals, most notably Western Australian government officials, whose engagement was instrumental in facilitating this mission and Ukrainian Ambassador to Australia, Vasyl Myroshnychenko.



Upcoming Catalysts¹



Remplir™ Redefining nerve repair

US FDA market clearance and Pre-Launch	Achieved
Appoint initial US distributors	Achieved
HKG product registration	Achieved
US first surgical use	Achieved
US first sales	3Q CY25
Appoint further US sales team members	3Q CY25
Appoint first distributors in new markets including CAN, HKG and THA	3Q/4Q CY25
EU+UK & Brazil submissions lodged	4Q CY25

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

Remplir™

Investment Highlights



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



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



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



Best in class products for Bone, Nerve and Tendon repair approved in eight jurisdictions. Compelling supportive clinical data.



~\$28.5M cash at bank, strengthened share register, share market momentum, well-funded for US roll out



Authorised for release by
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