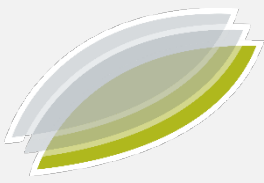




ortho·cell  
**Company Presentation**  
July 2024





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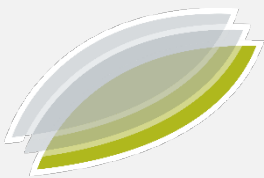
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# Orthocell at a glance

**Well funded Australian medical device company with growing international revenue and US approval of breakthrough nerve repair device pending**



**Best in class products revenue generating in international markets**

Bone / Striate+: US, EU/UK and AUS  
Nerve / Remplir: AUS and NZ



**Manufacturing scale up and global Striate+ partnering deal complete**

Validates the business model, reduces execution risk and opens doors in US



**Revenue inflection point**

FY24 revenue of \$6.72 million, up 30.40% from the previous year (FY23) of \$5.15 million. Striate+™ and Remplir™ ahead of expectations



**>US\$3bn p.a. TAM<sup>2</sup>**

Large, under-served and under-penetrated markets



**Well funded with no royalty liabilities**

AU\$20.60m cash at bank and the Company retains all revenue benefits, increasing cashflow to the Company

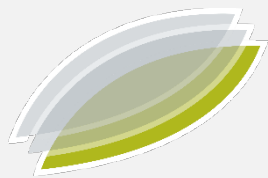


**Near-term key value driver**

Remplir breakthrough nerve repair product is funded to US approval and FY25 market launch

1. Unaudited

2. TAM for CelGro medical devices Striate+™ and Remplir™



# Corporate snapshot

Current analyst risk-adjusted valuations per share of \$1.00 and \$1.28/sh

## ASX: OCC TRADING INFORMATION

<b>Share Price</b>	<b>\$0.40</b>
12 month low/high	\$0.300/\$0.580
Shares outstanding	209,326,818
<b>Market Capitalisation</b>	<b>~\$85M</b>
Cash (30 Jun)	\$20.60M
Debt (30 Jun)	Nil
<b>Enterprise Value</b>	<b>~\$65M</b>

## SUBSTANTIAL SHAREHOLDERS

Shareholder	%
Founders & Management	~13%
Institutions & HNW's (Mr Chris Ellison, Mr Rod Jones, Mr Michael Malone, the McCusker Family & Merchant Biotech)	~8%

With AU\$20.60m cash at bank, OCC is well positioned to gain commercial traction with partners, funded to achieve US approval of Remplir™, and advance commercialisation of pipeline products.



# High-profile 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 Ravi 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**  
**Independent Non-Executive Director**

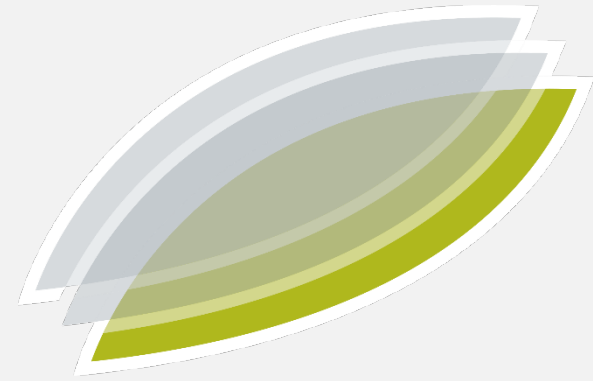
- 30+ years experience as a plastic and reconstructive surgeon
- Inventor of RECELL “spray on skin” treatment, now supplied by Avita Medical Inc, a AU\$450M dual-listed company with operations in 30+ countries including the US
- Unrivalled track record in development and commercialisation of innovative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



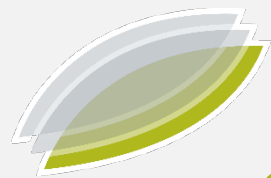


# SMRT™ Manufacturing

DEVELOPING AND MANUFACTURING  
BIOLOGICAL MEDICAL DEVICES







# SMRT™ manufacturing

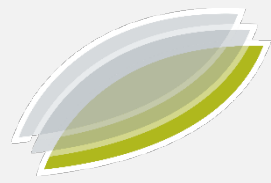
Orthocell develops and manufactures innovative collagen medical devices that facilitate the highest quality surgical repair of bone, nerve and tendon

## SMRT™ manufacturing process:

- ✓ **Pure collagen:** decellularization process removes all cellular and genetic material
- ✓ **Mimic human collagen:** natural collagen structure is preserved creating the ideal environment for cellular attachment and proliferation
- ✓ **No immunogenic reaction:** devices integrate and degrade commensurate with the tissue healing process







# Collagen medical device platform

Our **collagen medical device platform** is comprised of a range of acellular, type 1 collagen used to treat bone, nerve, tendon and cartilage.

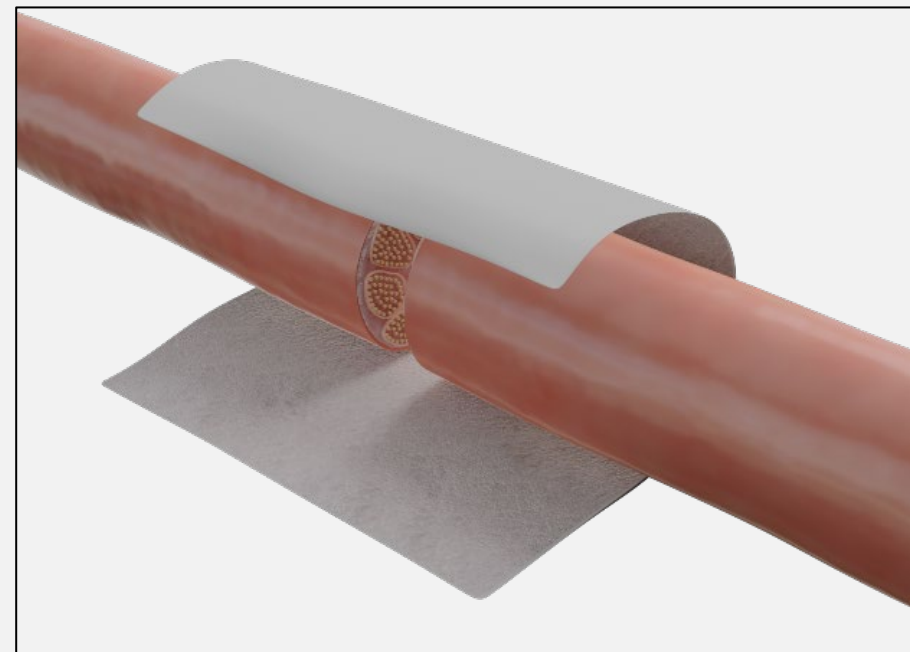
## **Striate+™ resorbable collagen membrane**

- Guided bone and tissue repair



## **Remplir™ nerve wrap**

- Repair of peripheral nerve injuries

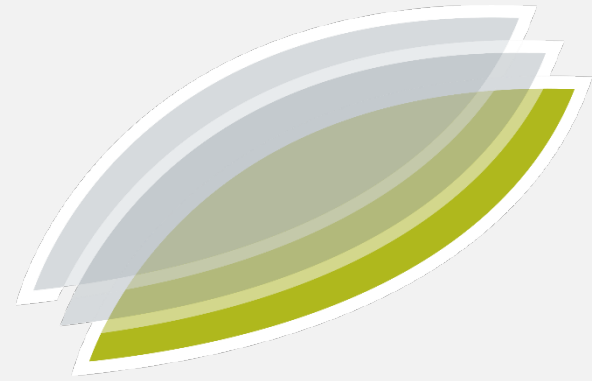


## **SmrtGraft™ scaffold**

- Tendon repair



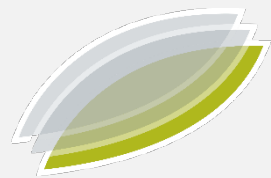




**Striate**  <sup>TM</sup>

**GROWING BETTER BONE IN  
DENTAL APPLICATIONS**

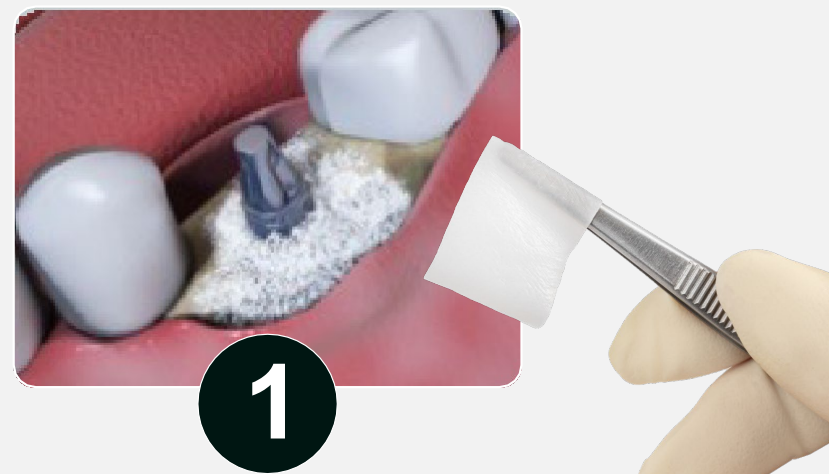




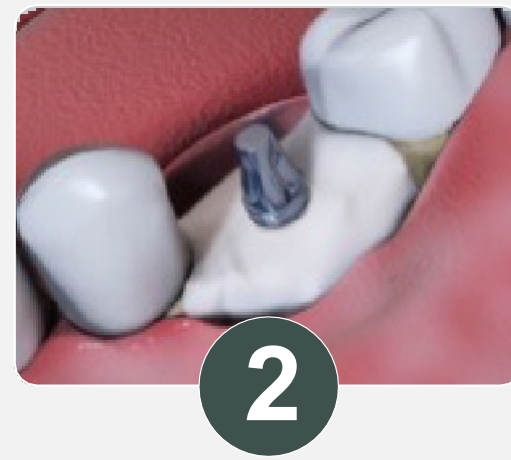
# Striate+™ premium dental membrane

**Next generation dental membrane for high quality bone repair.**

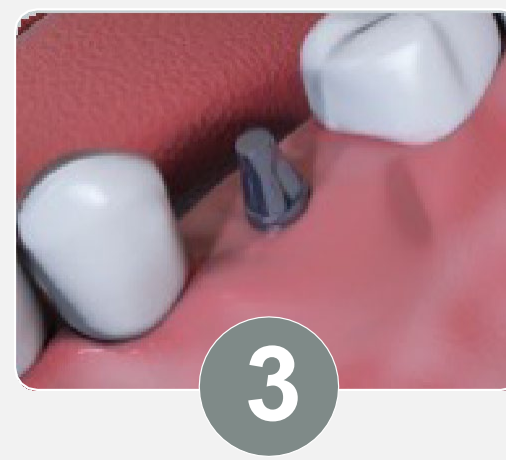
- Striate+ is a sterile, resorbable collagen membrane for use in dental bone and tissue regeneration procedures.
- Striate+ is designed to protect the bone defect from ingrowth of gingival tissue, to provide a favourable environment for osteogenesis and to assure reliable formation of high-quality bone.



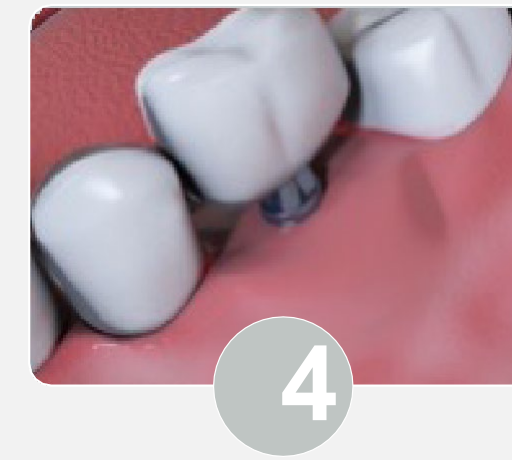
**1**  
Preparation of repair site. Defect site is filled with bone graft



**2**  
Striate+ placed over defect and implant abutment installed



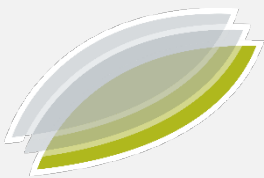
**3**  
Wound closure



**4**  
Crown placement 3-6 months later



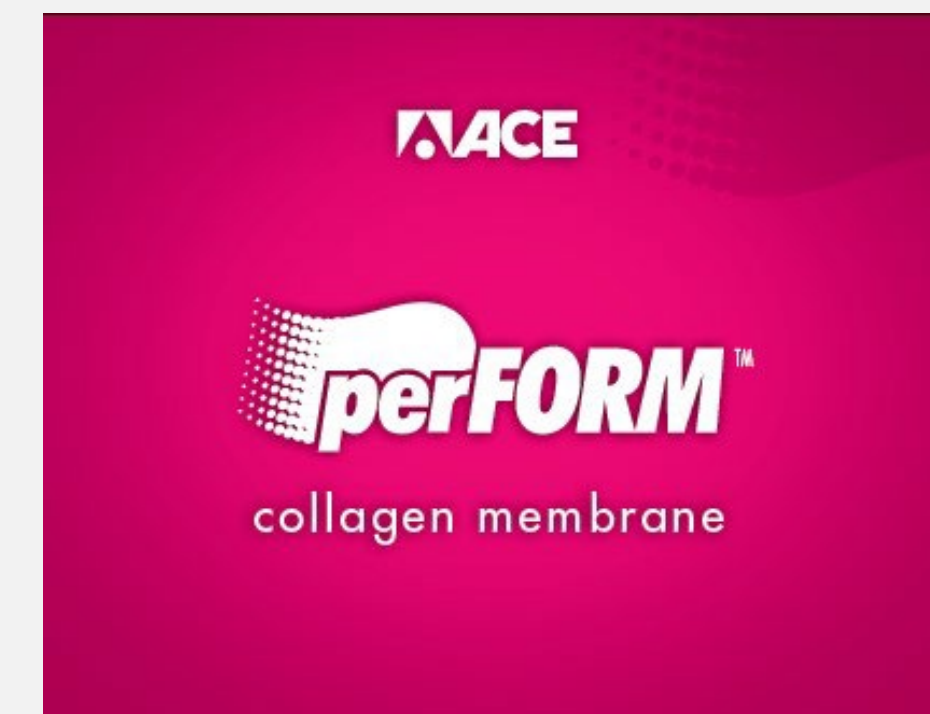
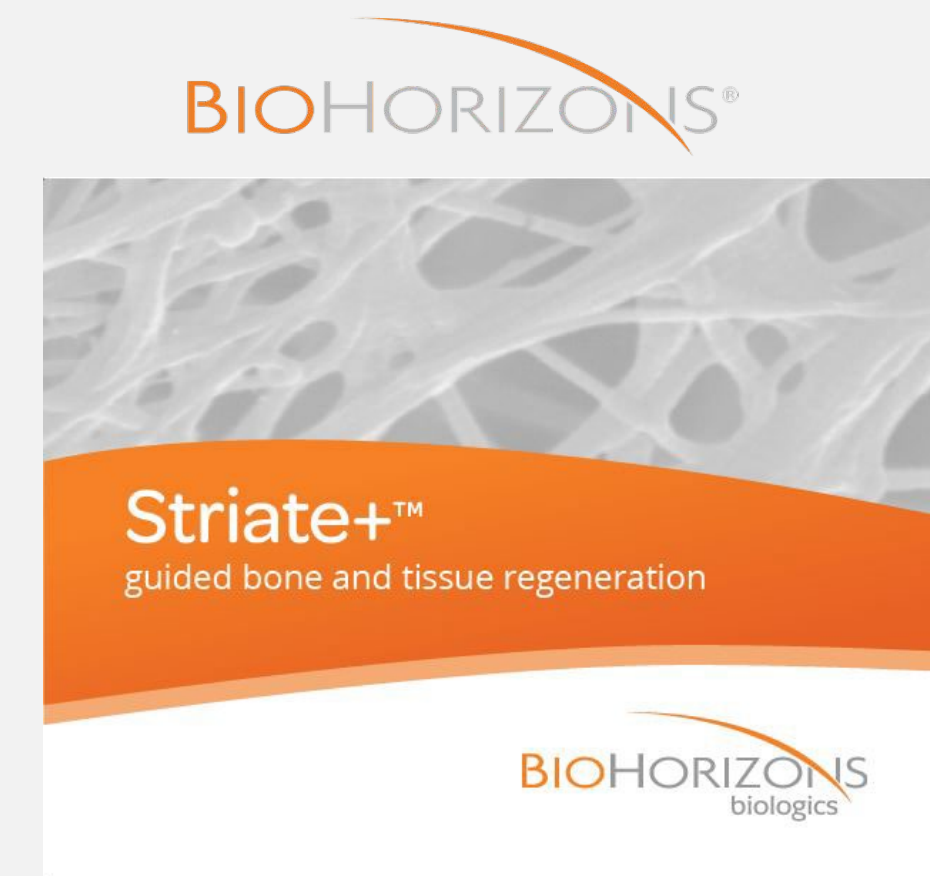


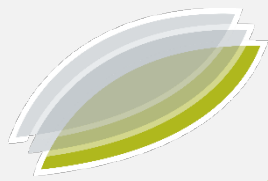


# Striate+™ global license and manufacturing agreement

**Innovation backed by world-class KOLs and an exclusive licensing deal with fifth largest global provider of dental products, BioHorizons**

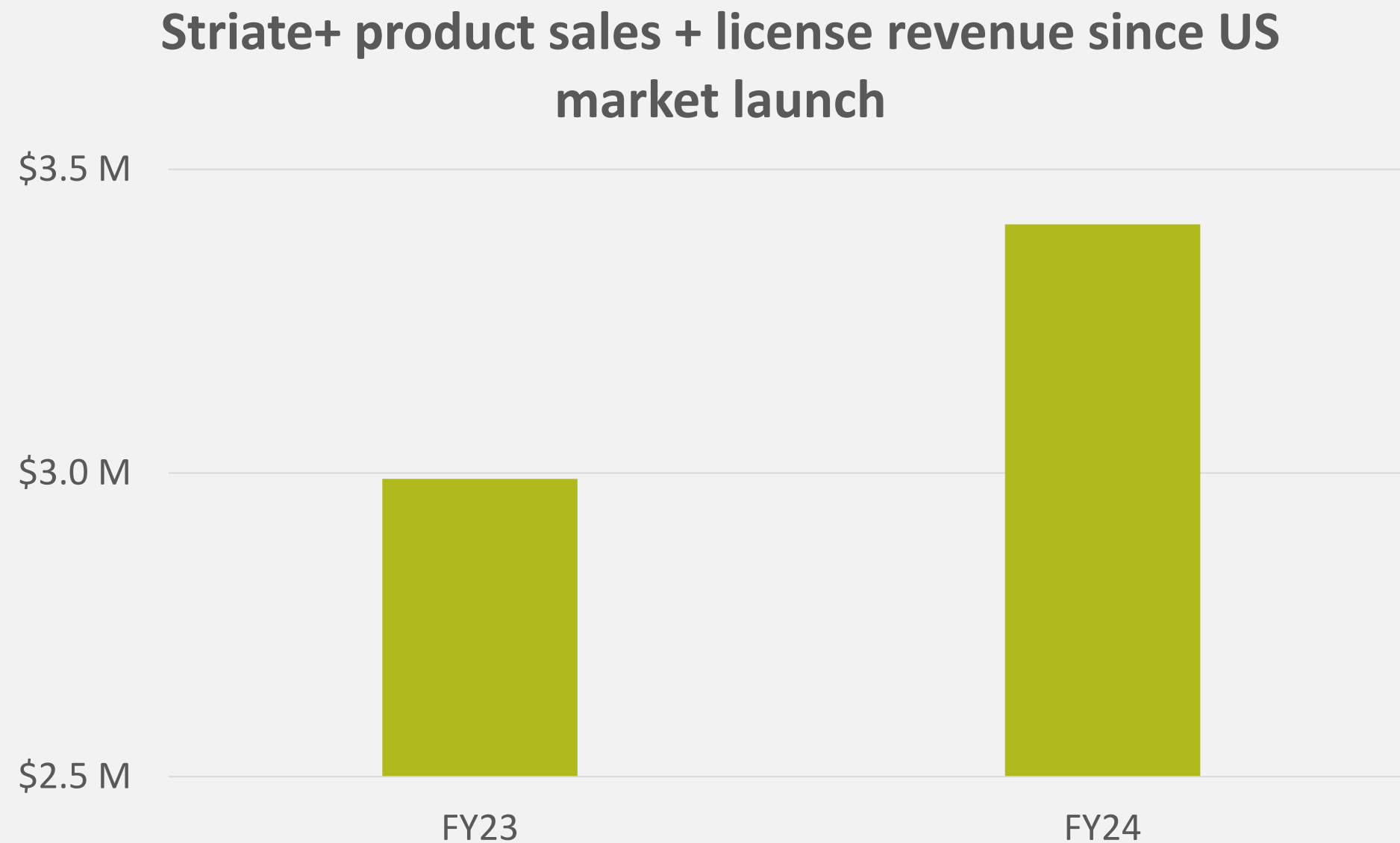
- ✓ **AU \$21.5 million in upfront cash received** net of fees in consideration of the global license granted
- ✓ **Major validation of Striate+™ and the CelGro™ Platform** – opens the doors to the largest healthcare markets, reduces execution risk and provides a clear sight to revenue growth
- ✓ **Establishes the manufacturing business** - enables the scale up of manufacturing alongside the expected rapid growth in purchase orders from BioHorizons
- ✓ **Access to global distribution network** – BioHorizons is a global operator and a subsidiary of Henry Schein Inc. (NASDAQ: HSIC. US \$11bn market capitalisation) enabling access to an international network of distribution partners. For e.g. First private label called perFORM™ launched by ACE Southern, September 18, 2023<sup>1</sup>





# Successful Striate+™ launch, revenue growing

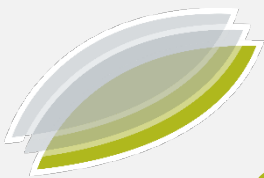
**US commercial launch<sup>1</sup> of Striate+™ dental barrier membrane in November 2022, sales unit volumes now exceeding expectations**



- **14% growth in Striate+™ revenue** from \$2.99M in FY23 to \$3.41M in FY24
- **Forecast product sales to BioHorizons now exceeded expectations**, driven by a high performing distributor and the surgeons' preference for a high-quality dental membrane that is easier to use and facilitates better, more efficient bone growth

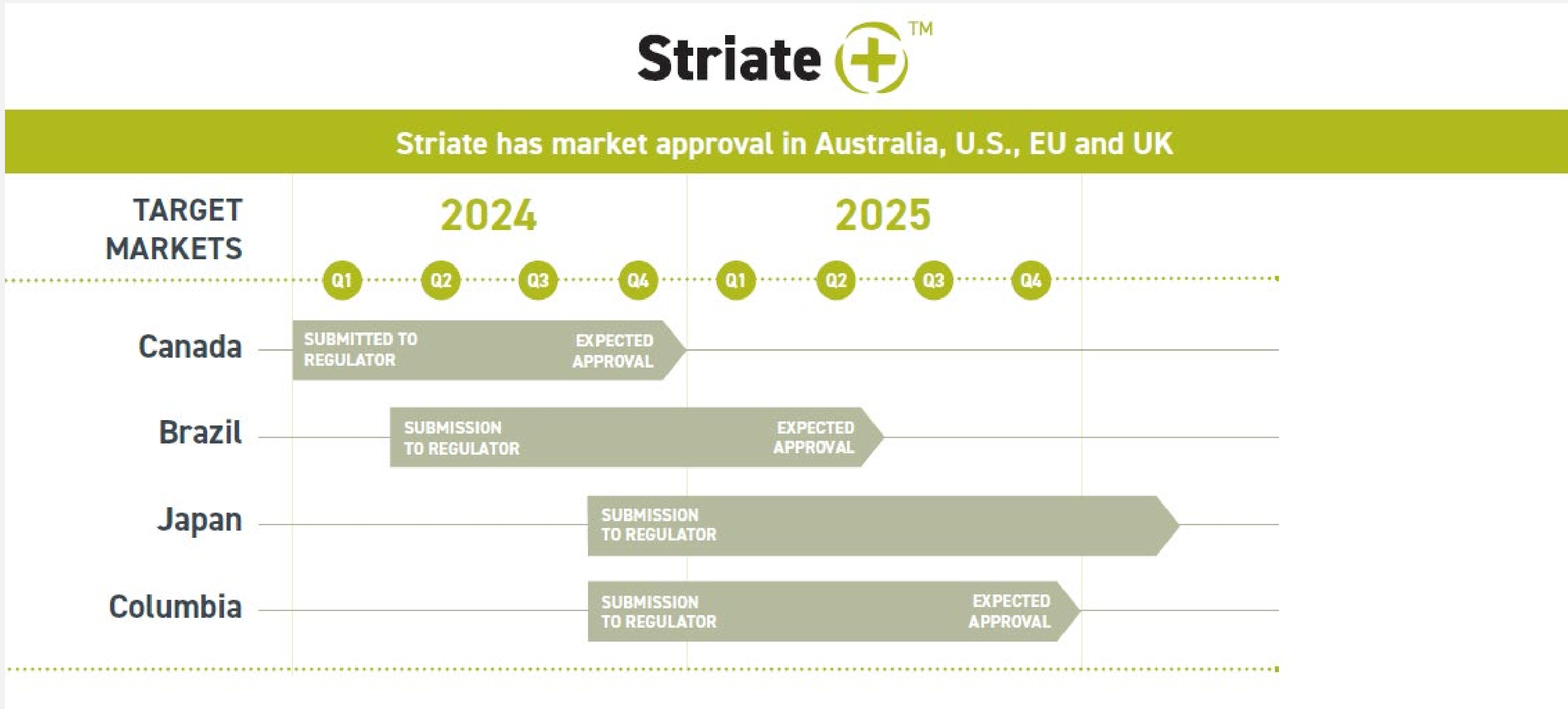
1. Orthocell supplies BioHorizons with Striate+™ products, and BioHorizons exclusively market and distribute Striate+™ globally.

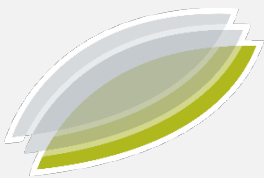




# Striate+ Market Expansion

Regulatory approval for Striate+ in Canada and Brazil anticipated within 6-12 months with a further two applications planned in Columbia and Singapore in 2H CY24.



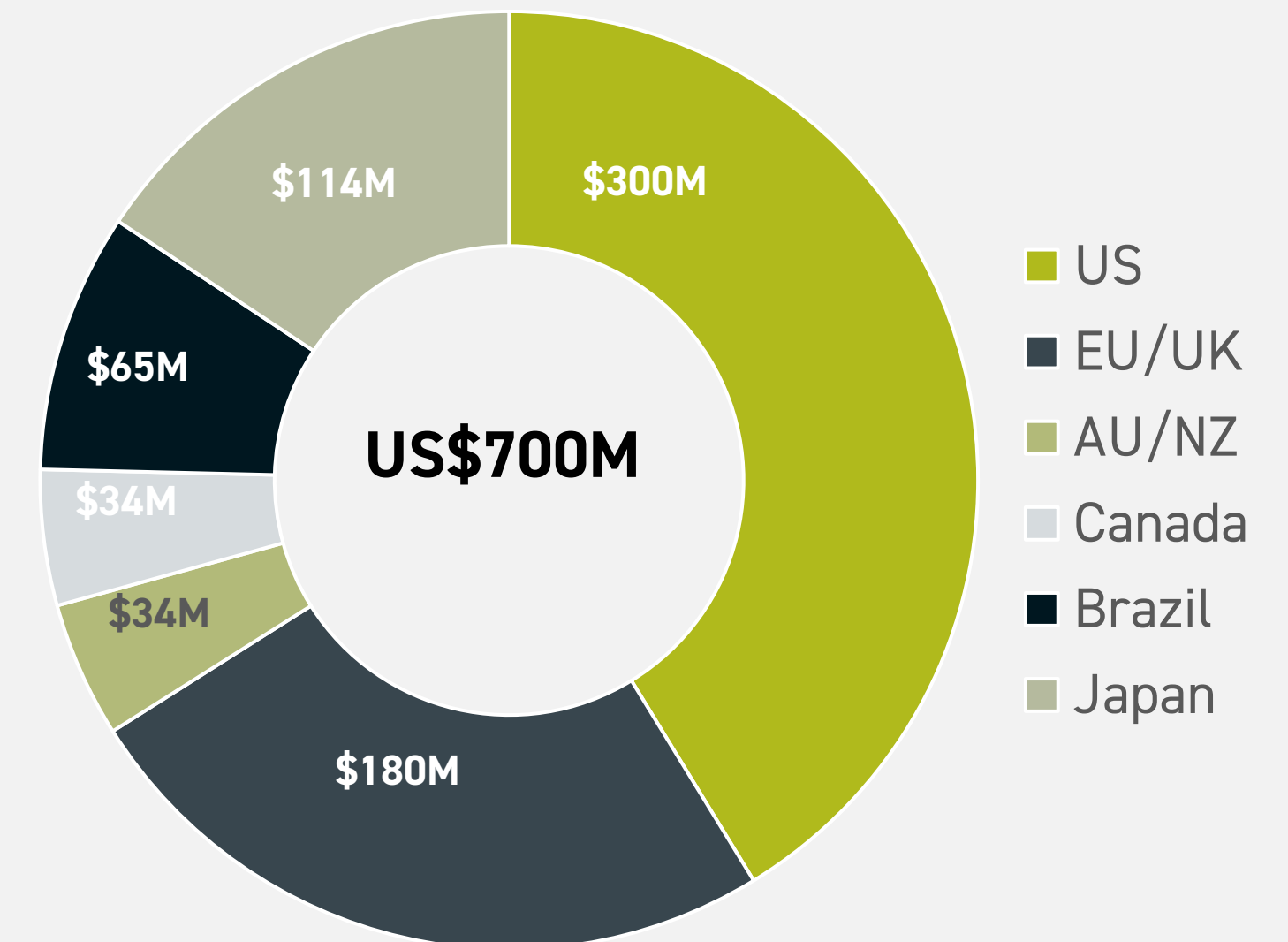


# Striate+™ revenue growing in US, EU/UK & AUS – and beyond

Significant opportunity to secure 20% share of the \$700M global dental barrier membrane market which would generate ~AU \$50 million in recurring wholesale revenue to Orthocell

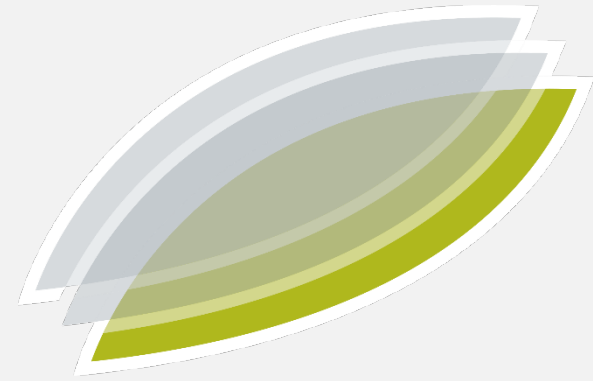
- **Well positioned to gain significant US market share** - BioHorizons and ACE Southern collectively control ~20% of the US market
- **Successful EU/UK market launch completed in 3Q CY2023** and on track to exceed initial unit guidance
- **Expanding into other international markets** – Orthocell is working with BioHorizons to register product for approval in Canada (Q4 CY24), Brazil (Q2 CY25) and Columbia (Q4 CY25)

Total Addressable Retail Market (US\$m)



20% Market Share = AU \$50 million in wholesale revenue to OCC



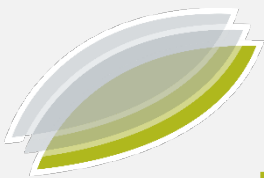


# Remplir™

REDEFINING NERVE REPAIR



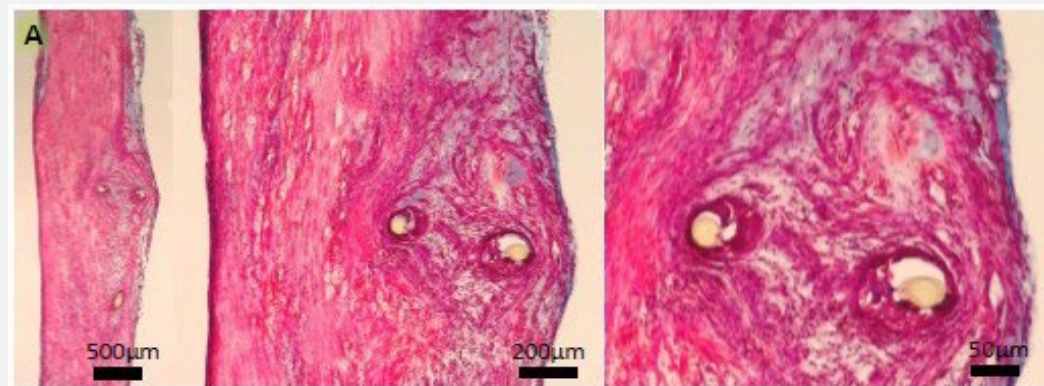
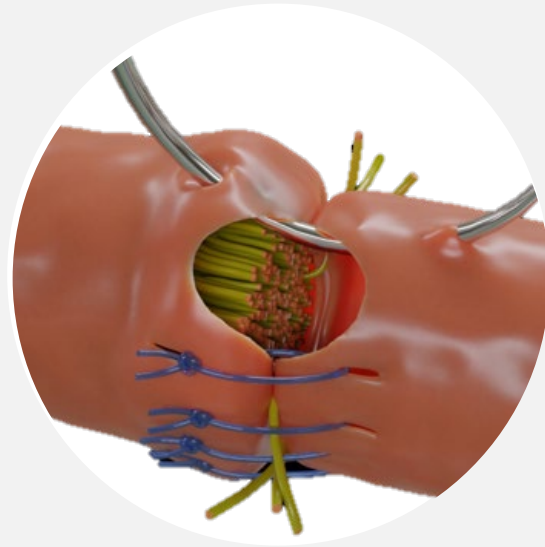




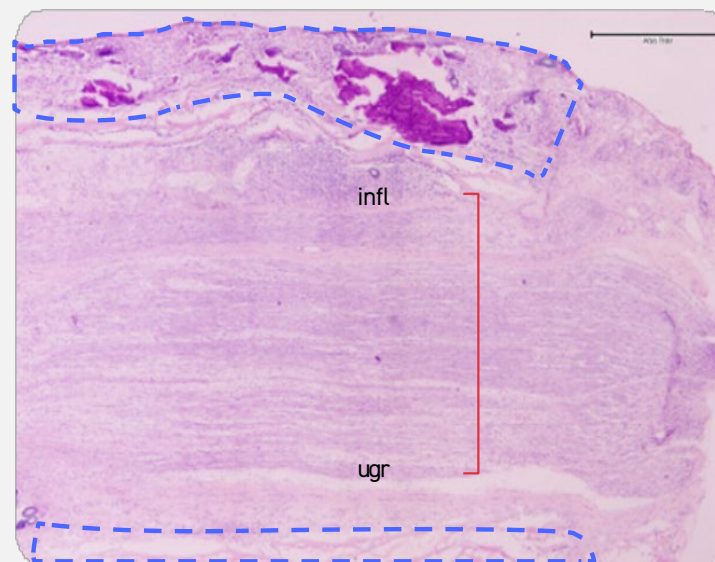
# Nerve repair breakthrough

Current repair methods can place delicate nerve tissue under tension, causing scarring, fibrosis and neuroma formation.

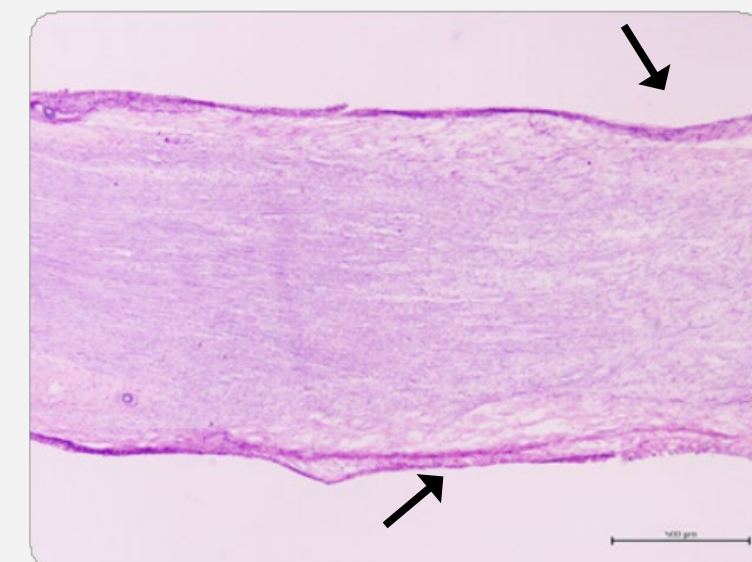
1860s  
Suturing



2000s  
Conduits



2020s  
Next generation



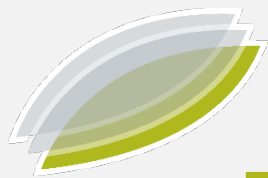
Success  
Rates

50-70%

55%

85%



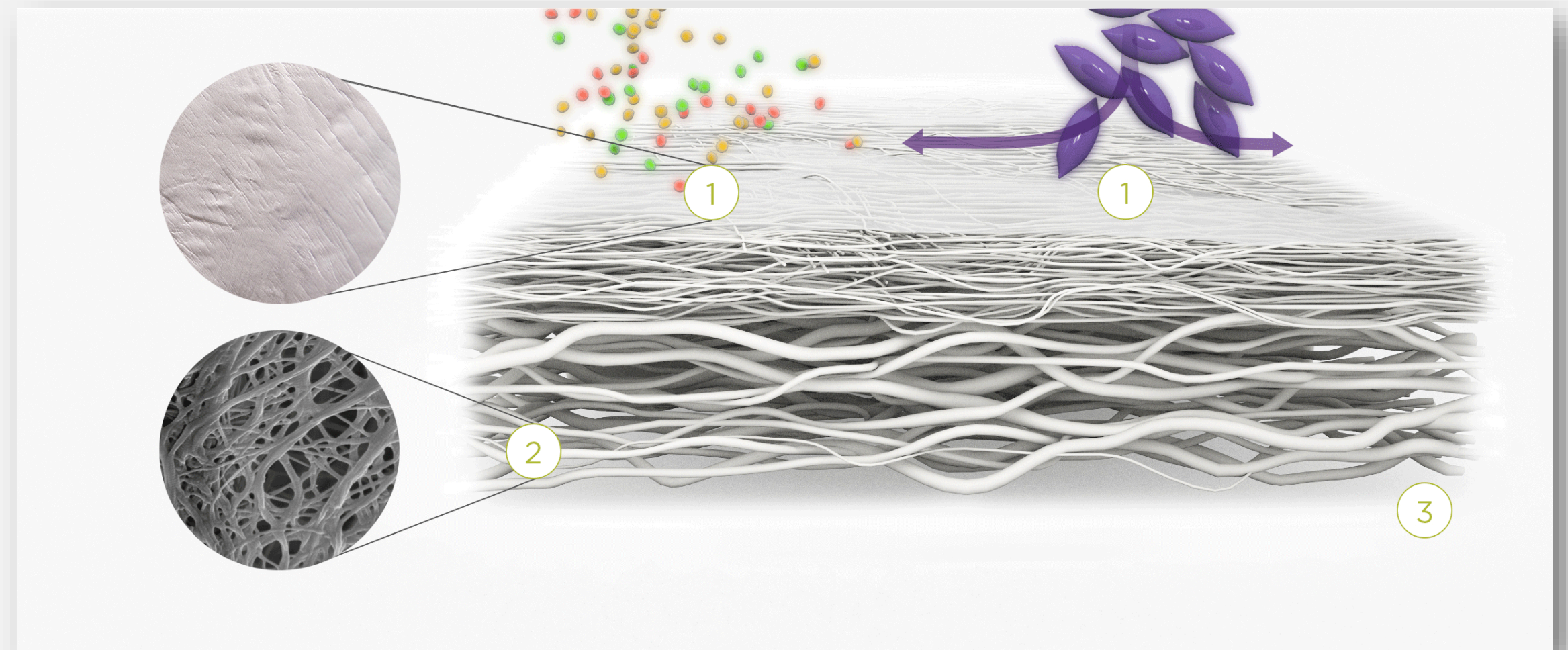


# Remplir™: redefining nerve repair

**A breakthrough product guiding predictable outcomes in peripheral nerve repair and return of muscle function**

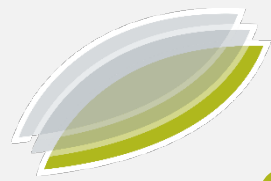
## Key Characteristics

- ✓ Reducing sutures
- ✓ Only product today that mimics the epineurium (nerve outer layer) creating the ideal environment for repair
- ✓ Returns the nerve to its pre-injured state without causing an immunogenic response (no foreign body reaction)



- ① Barrier function prevents infiltration of cells not involved in tissue repair but enables the passage of bioactive molecules and proteins
- ② Porous network of collagen fibres promotes cellular attachment and proliferation
- ③ Bioactive chamber supports new tissue formation and integration



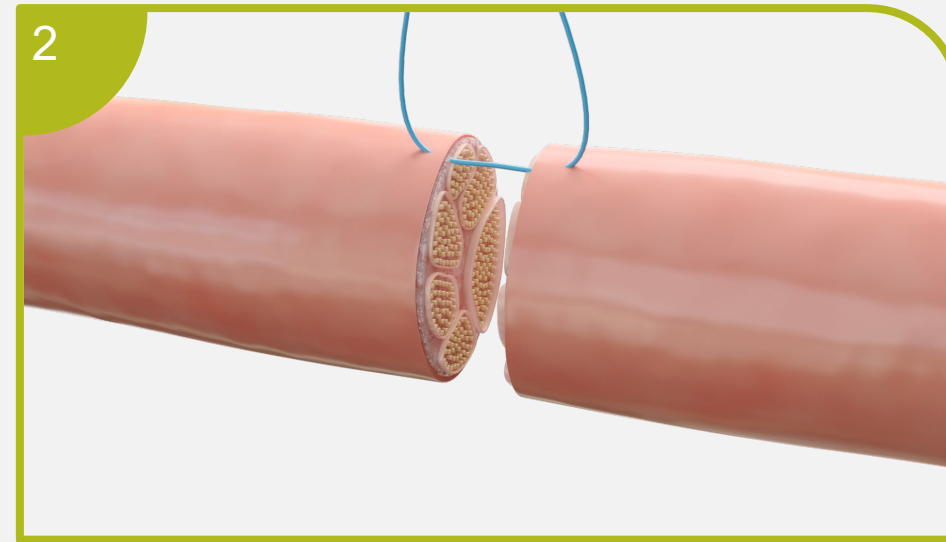


# Surgical technique

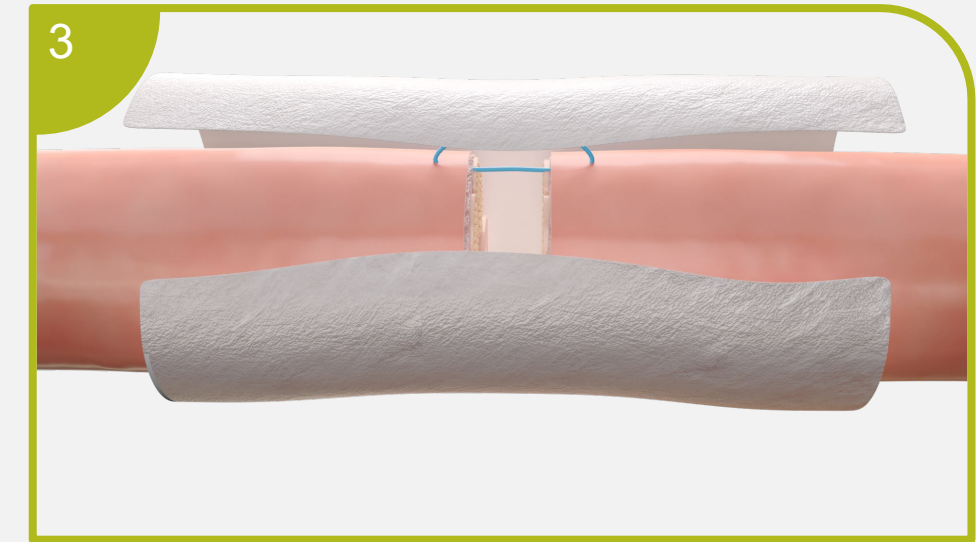
## Example of traumatic nerve injury repair



1 Damaged peripheral nerve after traumatic injury to limb



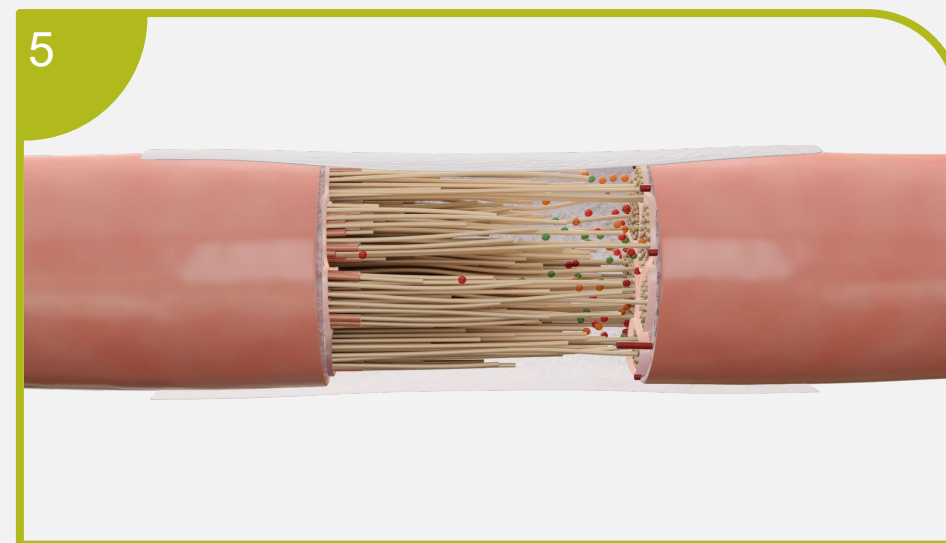
2 Damaged section of nerve is removed, and ends brought together without tension



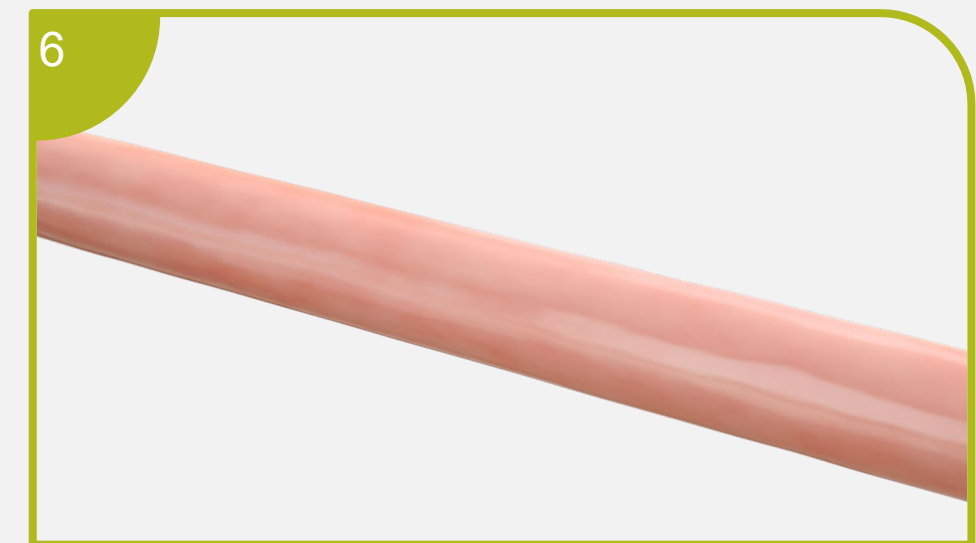
3 Remplir is wrapped around nerve, reducing suture requirements and facilitating optimal coaptation



4 Remplir easily conforms to the repair site while mimicking the nerve's natural epineurium

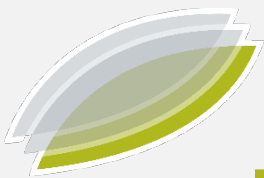


5 Remplir creates a protected healing environment allowing new axons to reconnect



6 Healed nerve restores function to affected limb





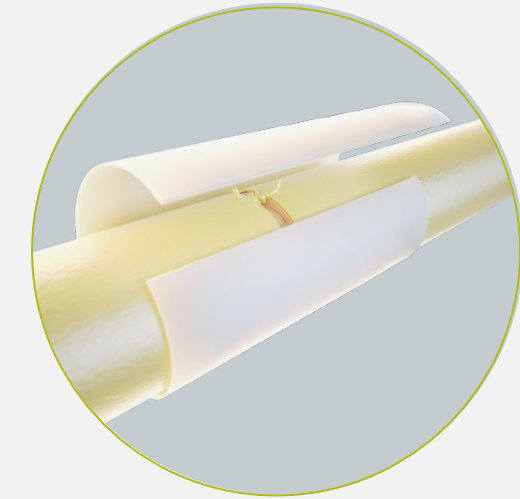
# Remplir™: approved and reimbursed in Australia

Remplir™ is the only device that can be used for either connecting severed nerves, protecting damaged nerves or capping amputated nerves



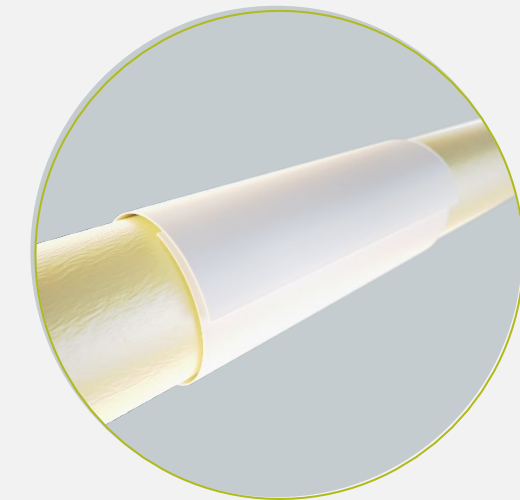
## CONNECT

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



## PROTECT

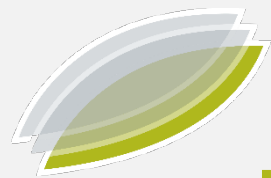
**Compression:** blunt trauma, revisions surgeries (e.g. carpal/cubital tunnel)



## CAP

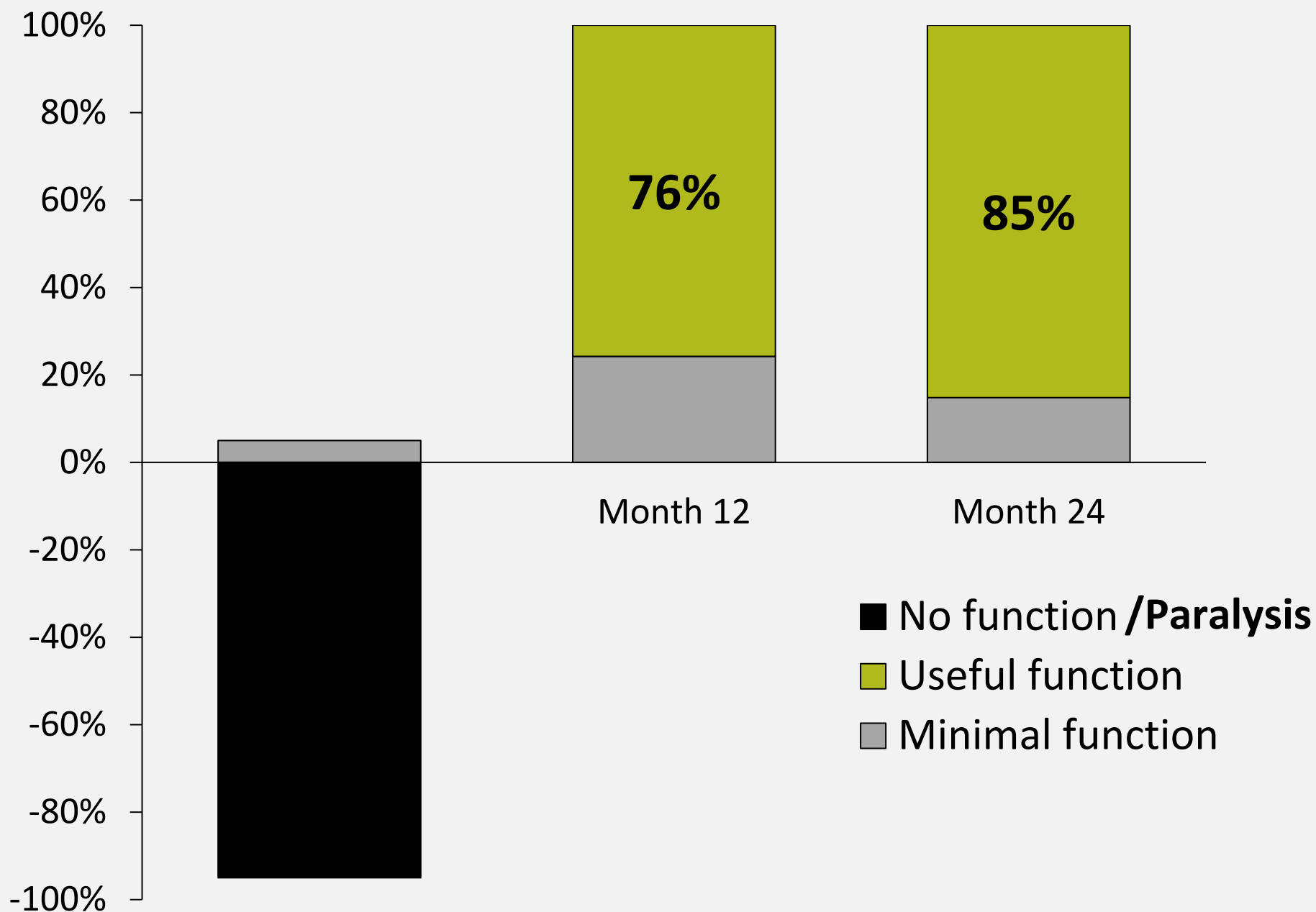
**Amputation:** amputations, stump neuroma, mastectomies, schwannoma





# Remplir™: compelling long term clinical results

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



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

**Useful Function**  
voluntary movement with improved strength and range of motion

**Minimal Function**  
voluntary movement restored, limited strength and range of movement

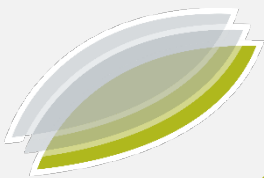
**No Function**  
no voluntary movement

## FINAL RESULTS

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

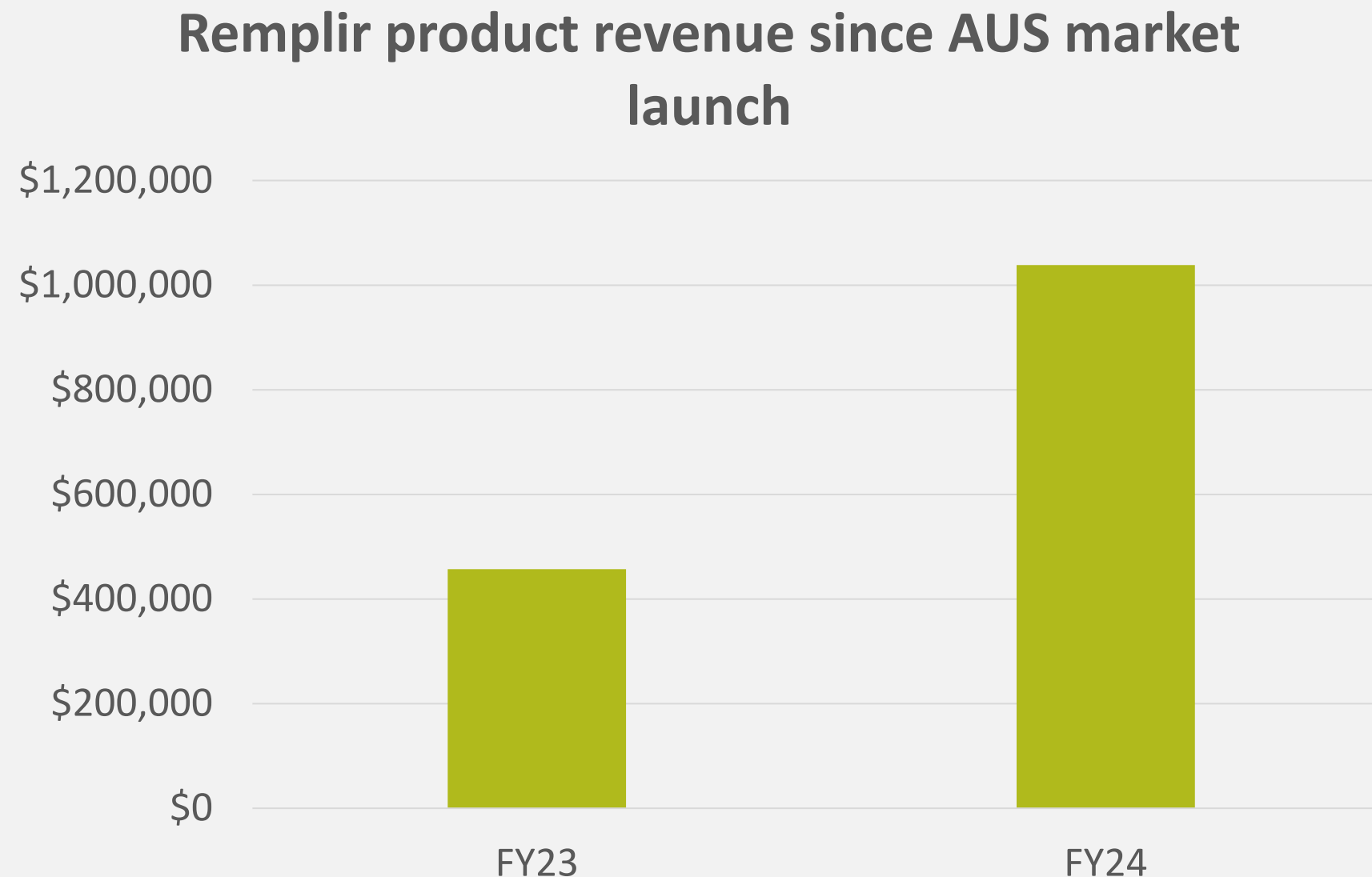


**Meet Adrian Walsh, a 43-year-old father  
of three who was diagnosed with  
quadriplegia after he broke his neck  
in a mountain bike accident  
in June 2017.**



# Successful market launch with revenue building momentum

**AUS commercial launch<sup>1</sup> of Remplir™ with Device Technologies reimbursed in the private healthcare system in November 2022, with sales unit volumes exceeding expectations**

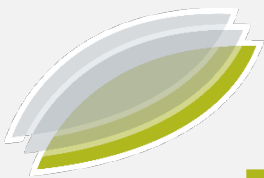


- **127% growth in Remplir™** revenue from \$457K in FY23 to \$1.04M in FY24
- **Product sales to Device Technology significantly exceeded guidance** – over 120 orthopaedic and plastic reconstructive surgeons
- **Adoption drivers** - enables less suturing, creation of the optimal healing microenvironment and facilitation of free gliding within the repair site during the critical healing period



1. Orthocell supplies Device Technologies (DVT) with Remplir™ products, and DVT exclusively market and distribute Remplir™ in Australia.



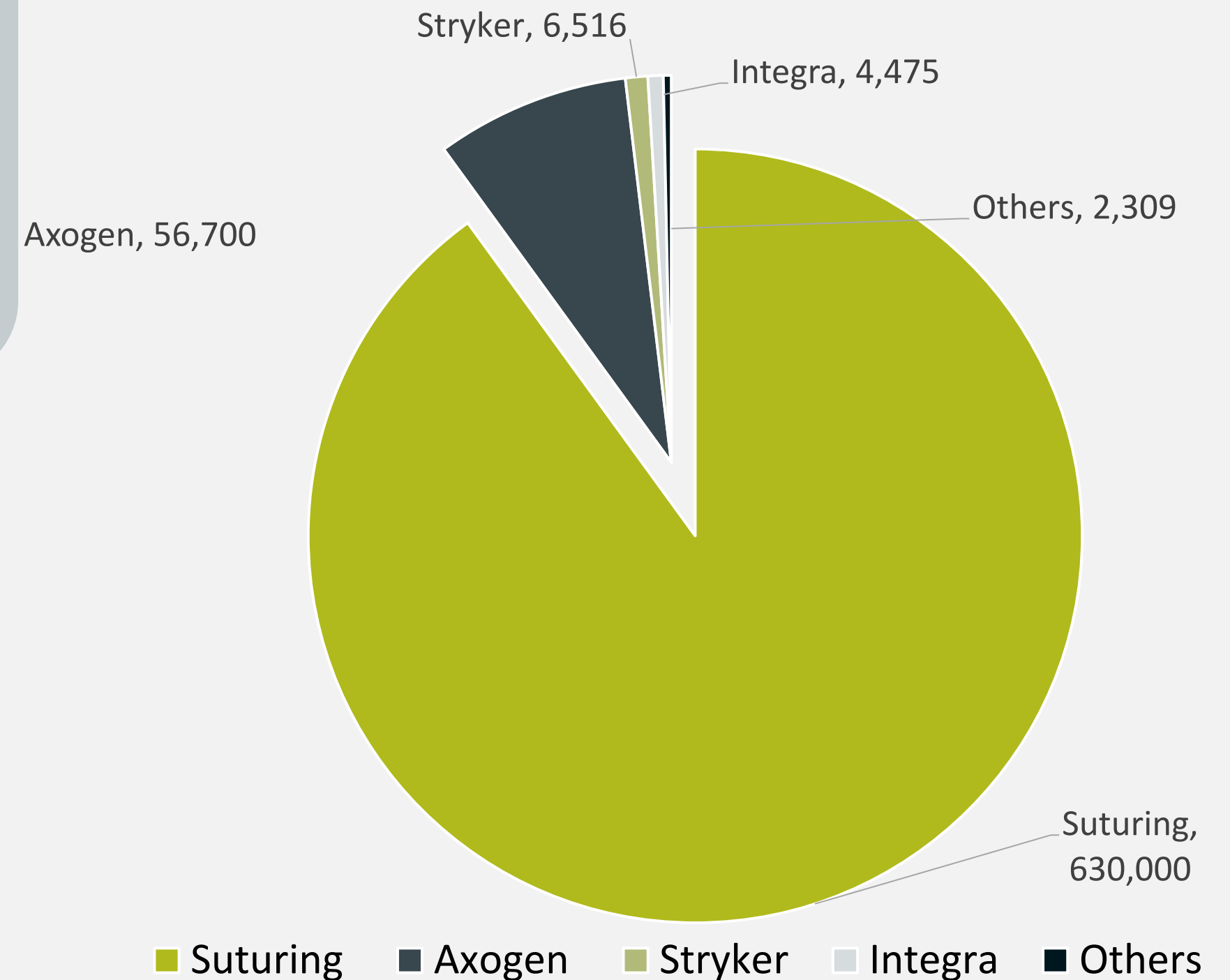


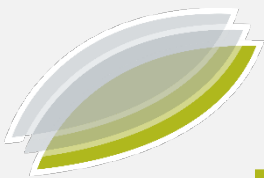
# The US is our primary target market

**Significant opportunity to dominate the US nerve repair market, by providing surgeons with confidence to perform surgical reconstructions efficiently, with consistent and predictable return of muscle function.**

- Over 700,000 peripheral nerve repair procedures in the US per year, 90% (630,000) undertaken using suture only method
- Current devices are not widely adopted due to suboptimal outcomes – Axogen, Integra and Stryker collectively sell ~70k units per year (10% of procedures)
- **Remplir 510K Study market authorisation study on track for completion in 3Q CY24 and US approval in 1Q CY25**

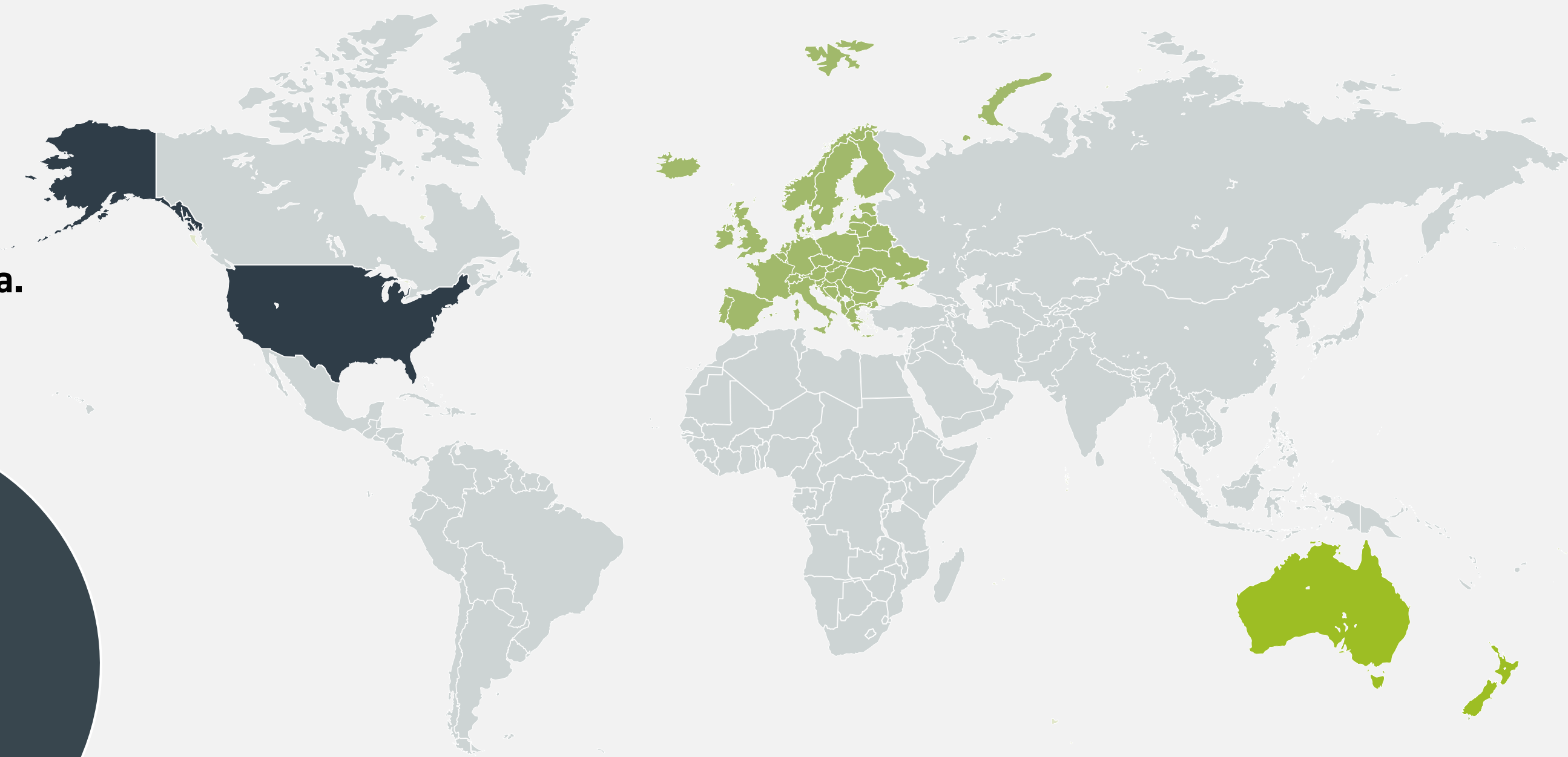
**Annual US nerve reconstructions**



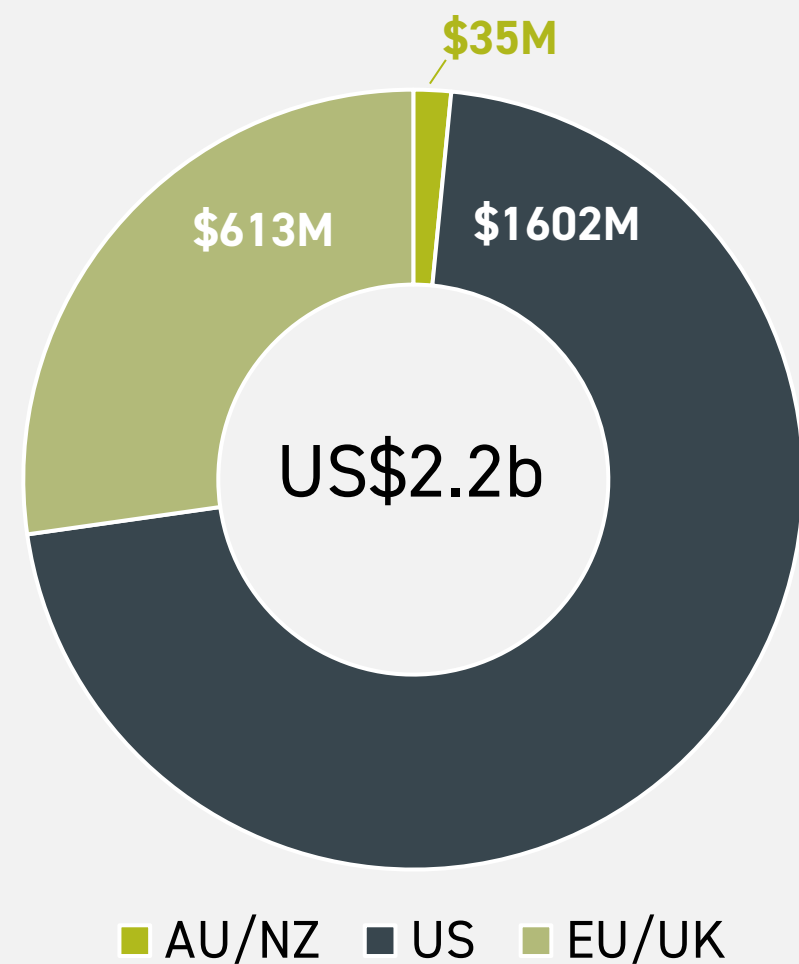


# Large addressable market in nerve reconstruction

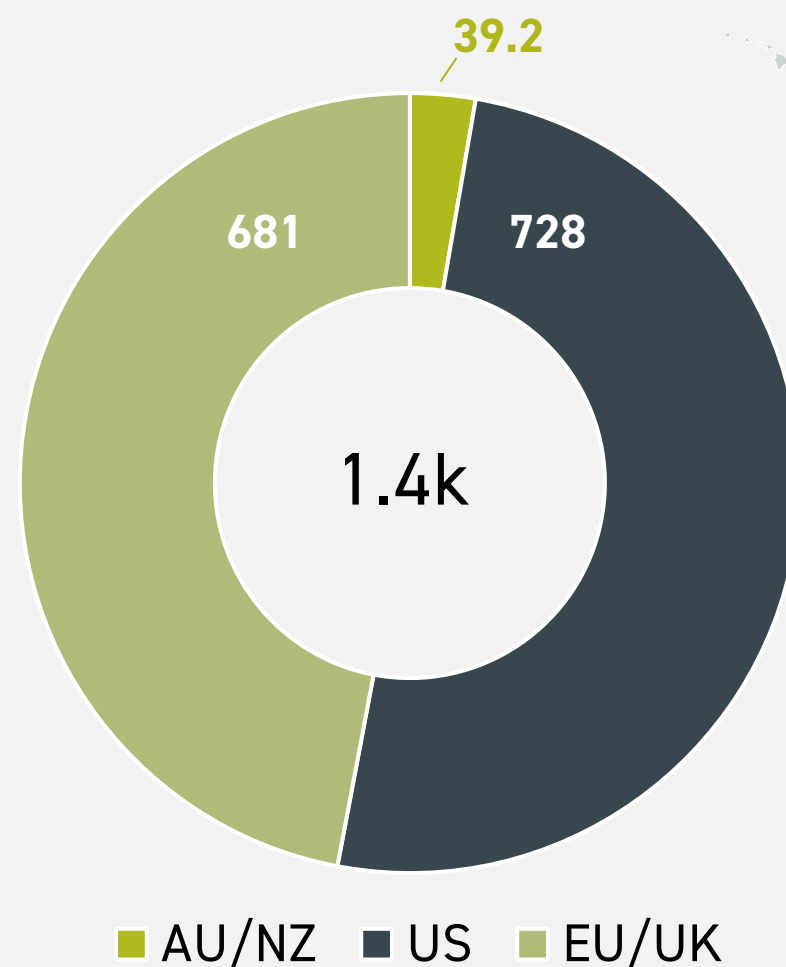
Remplir™ is a breakthrough product on track to be the global market leader in peripheral nerve repair – a retail market estimated to exceed US\$2.2 billion<sup>1</sup> per annum



Total Addressable Retail Market (US\$m)

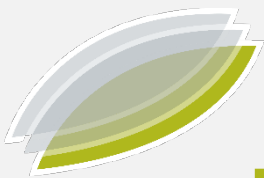


Est. procedures p.a. at peak ('000)



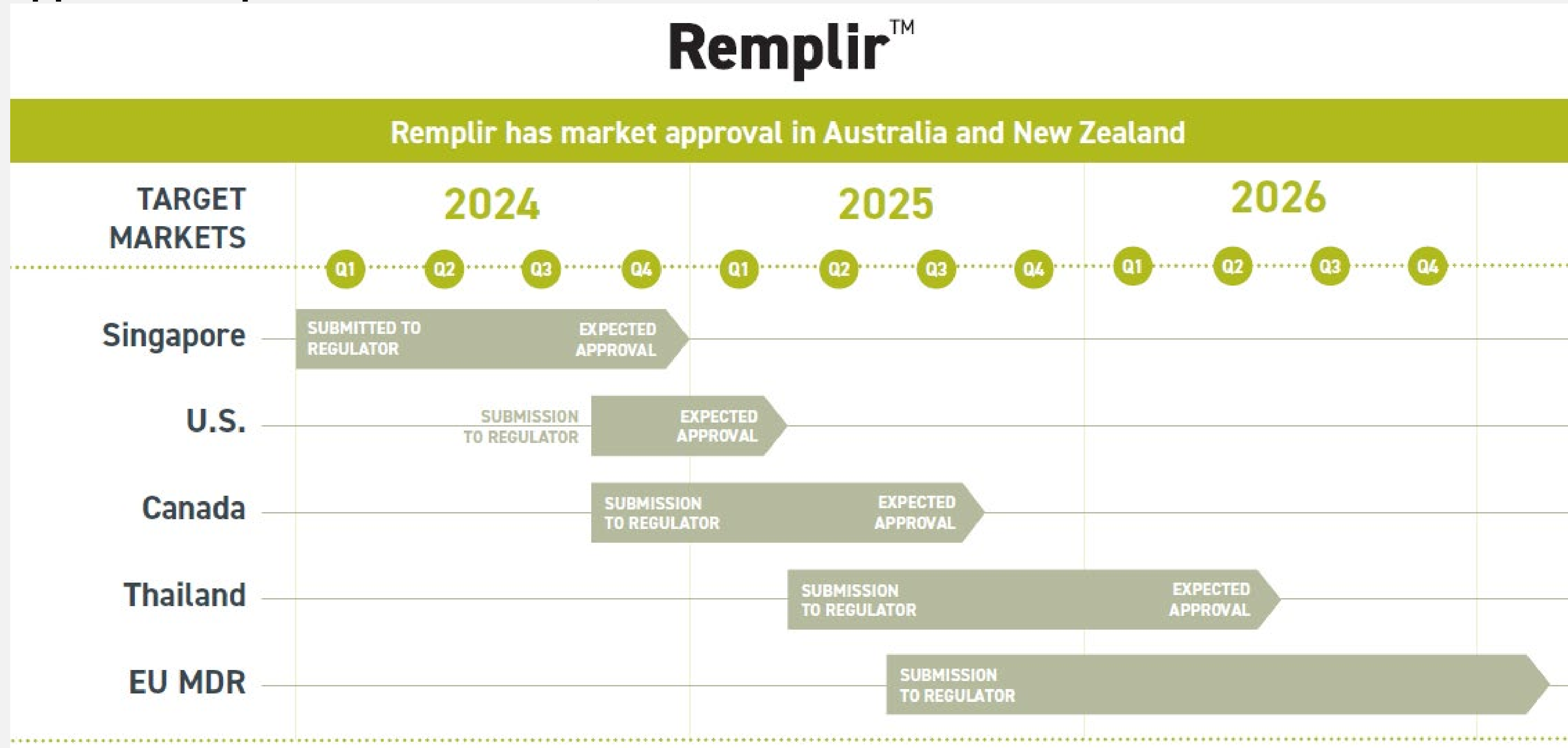
20% Market Share would generate AU \$255 million in wholesale revenue to OCC

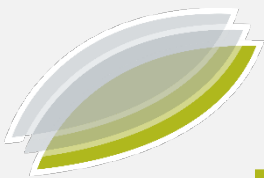




# Remplir Market Expansion

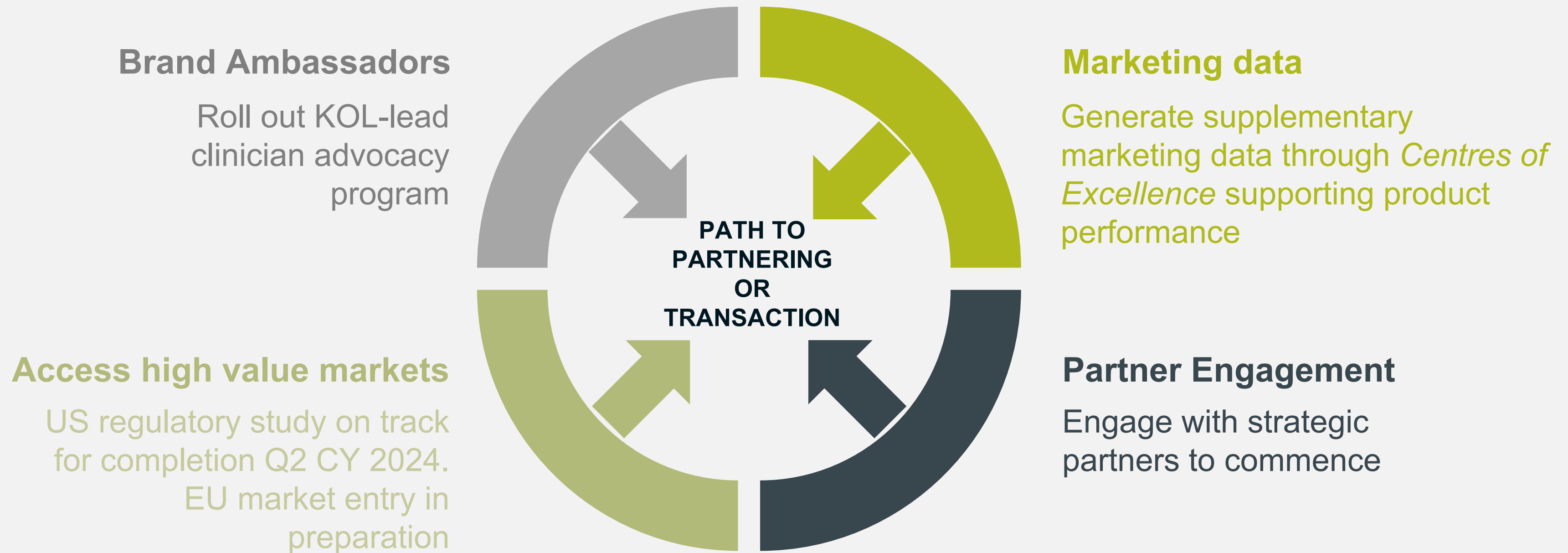
Regulatory approval for Remplir in Singapore anticipated in 2H CY24 with a further three applications planned in Thailand, Eu and Canada in the next 6-12 months.



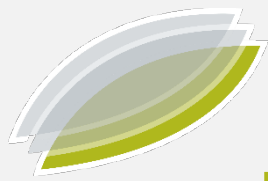


# Remplir™: path to US market

Orthocell is underpinned by an intelligent business model for innovating, developing and successfully launching medical device products







# Upcoming catalysts<sup>1</sup>

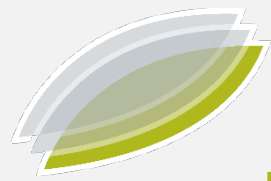
## Remplir international regulatory approval program

US registration study results .....	3Q CY24
US market authorisation .....	1Q CY25
Singapore product registration .....	4Q CY24
Canada product registration .....	3Q CY25

## Striate international regulatory approval program

Canada product registration .....	4Q CY24
Brazil product registration .....	2Q CY25
Columbia product registration .....	4Q CY25

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

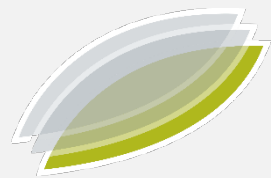


# Pipeline

Advanced product portfolio with near term milestones and emerging pipeline

Product	Status	Next Steps	Multi-Billion US Markets
<b>Medical Devices</b>			
Ligament replacement	Successful pilot study completed	<b>Pre-clinical and clinical study in development</b>	<b>&gt;200,000</b> procedures per year
<b>Tendon Cell Therapy</b>			
Rotator cuff	RCT shows significantly more effective than steroid injection	<b>US partnering strategy in development</b>	<b>&gt;1,000,000</b> procedures per year
Lateral epicondyle	RCT shows as effective, and potentially better than surgery		





# Key Investment Highlights

- ✓ **Commercial-stage** medical device company at **revenue inflection** point
- ✓ **Best in class products** for Bone, Nerve and Tendon repair
- ✓ **Strengthened board** with the appointments of highly experienced executives John Van Der Wielen, Professor Fiona Wood and Kim Beazley
- ✓ **\$20.1M cash at bank, strengthened register, no royalty liabilities and funded to US approval** of breakthrough nerve repair device
- ✓ **Near term value drivers** including Remplir 510k study results Q3 CY24 and market clearance 1Q CY25



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