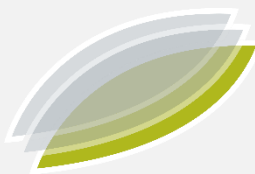




# Healthcare Conference 2023

**Bell Potter**  
**November 2023**





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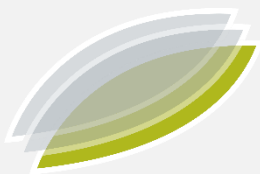
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# Orthocell at a glance

**Commercial-stage medical device company at revenue inflection point and funded to US approval of breakthrough nerve repair device**



## **Best in class products**

Regenerating bone and returning function to paralysed limbs



## **Manufacturing scale up and global partnering deal complete**

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



## **Revenue inflection point**

First year total revenue \$5.2m<sup>1</sup>, up 188% from the previous year with unit volumes for both Striate+™ and Remplir™ ahead of expectations



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

Large, under penetrated markets with concentrated competition



## **Royalty buyout from UWA**

Orthocell now retains all revenue benefits, increasing cashflow to the Company

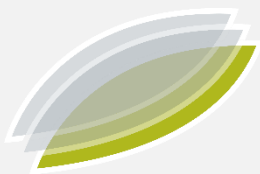


## **Near-term key value driver**

AU\$22.3m cash at bank. Funded to US approval and FY25 launch of breakthrough nerve repair product

1. Unaudited

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



# Corporate snapshot

**Current analyst risk-adjusted valuations per share of \$0.90 and \$1.28**

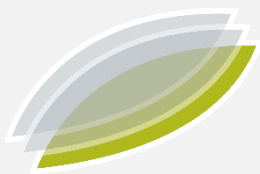
## ASX: OCC TRADING INFORMATION

Share Price	0.38
12 month low/high	\$0.300/\$0.580
Shares outstanding	199,017,317
Market Capitalisation	76M
Cash (31 July)	22.3M
Debt (31 July)	Nil
Enterprise Value	\$54M

## SUBSTANTIAL SHAREHOLDERS

Shareholder	%
Founders & Management	~15%
Institutions	~4%

**With AU\$22.3m 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 Stewart James Washer**

**Non-Executive Director**

- 25+ years of CEO and ASX Board experience in medical technology and biotech companies
- Former CEO of Calzada Ltd (ASX:PNV) and the founding CEO of Phylogica Ltd (ASX:PYC)
- Extensive commercialisation, capital markets and corporate advisory experience



**Mr Matthew Callahan**

**Non-Executive Director**

- Serial founder and ex-investment director of two venture capital firms in life sciences
- Developed four products through FDA approval and launch
- Extensive intellectual property, corporate and US commercialisation experience



**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

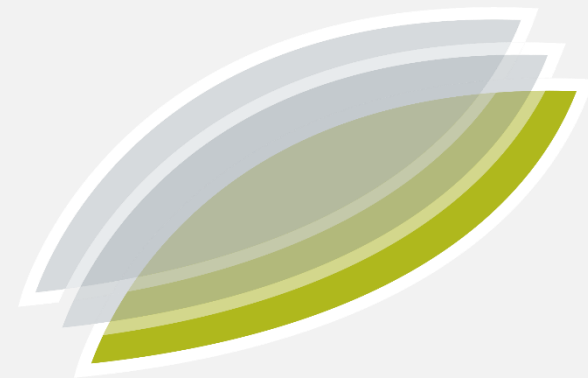


**Dr Rravi I. Thadhani**

**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



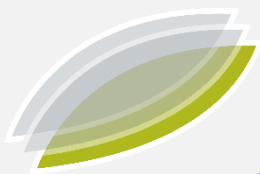


# SMRT™ Manufacturing

DEVELOPING AND MANUFACTURING  
BIOLOGICAL MEDICAL DEVICES







# Medical device manufacturers: market-ready innovation

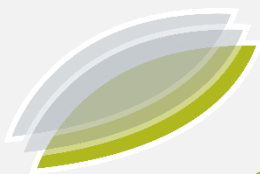
Orthocell develops and manufactures innovative medical devices that facilitate the highest quality surgical repair of bone, nerve and tendon

## 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







# Revenue generating products

Orthocell manufactures medical devices approved for use in bone and nerve repair with an advanced pipeline in tendon and ligament replacement

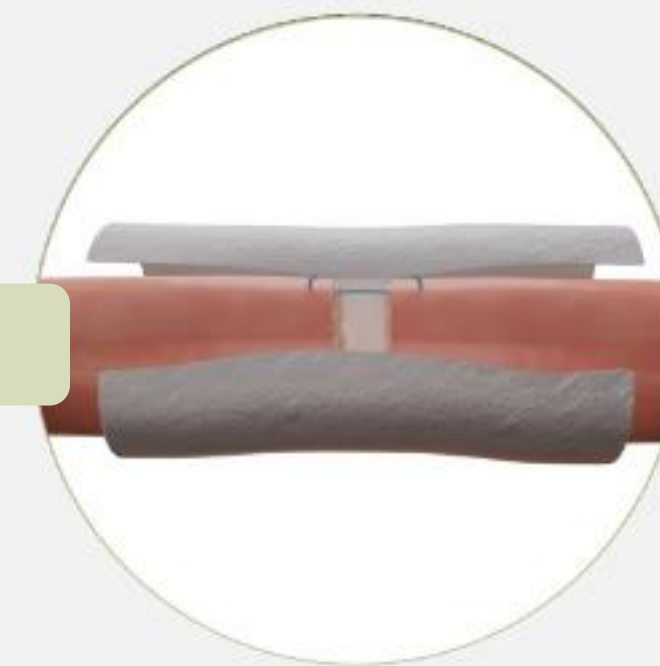
**BONE / STRIATE+™**



- Barrier membrane used in guided bone repair
- Protects the bone defect from ingrowth of gingival tissue
- Global distribution and manufacturing deal completed with BioHorizons in June 2022
- Revenue generating in US, EU/UK and AU
- Expanding into global markets including Canada, Brazil and Japan in the next 12 – 24 months

**>US\$700m  
TAM**

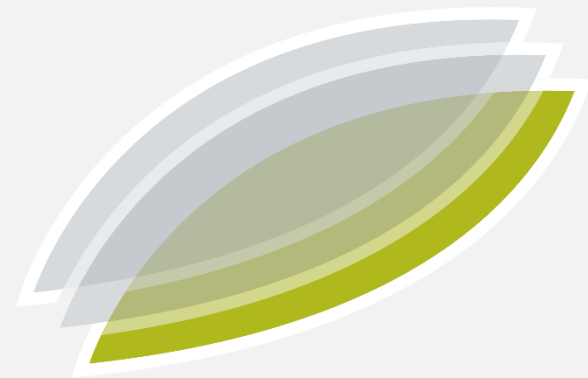
**NERVE / REMPLIR™**



- Unique epineurial substitute for use in peripheral nerve repair
- Creates ideal microenvironment to aid nerve healing
- Exclusive distribution agreement completed with Device Technologies in September 2022
- Reimbursed and revenue generating in AU and NZ
- On track to complete US regulatory study, gain approval and launch product in FY25

**>US\$2.3bn  
TAM**

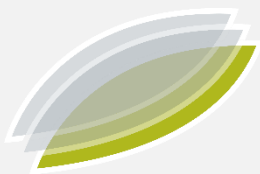




**Stellate**  <sup>TM</sup>

**GROWING BETTER BONE IN  
DENTAL APPLICATIONS**

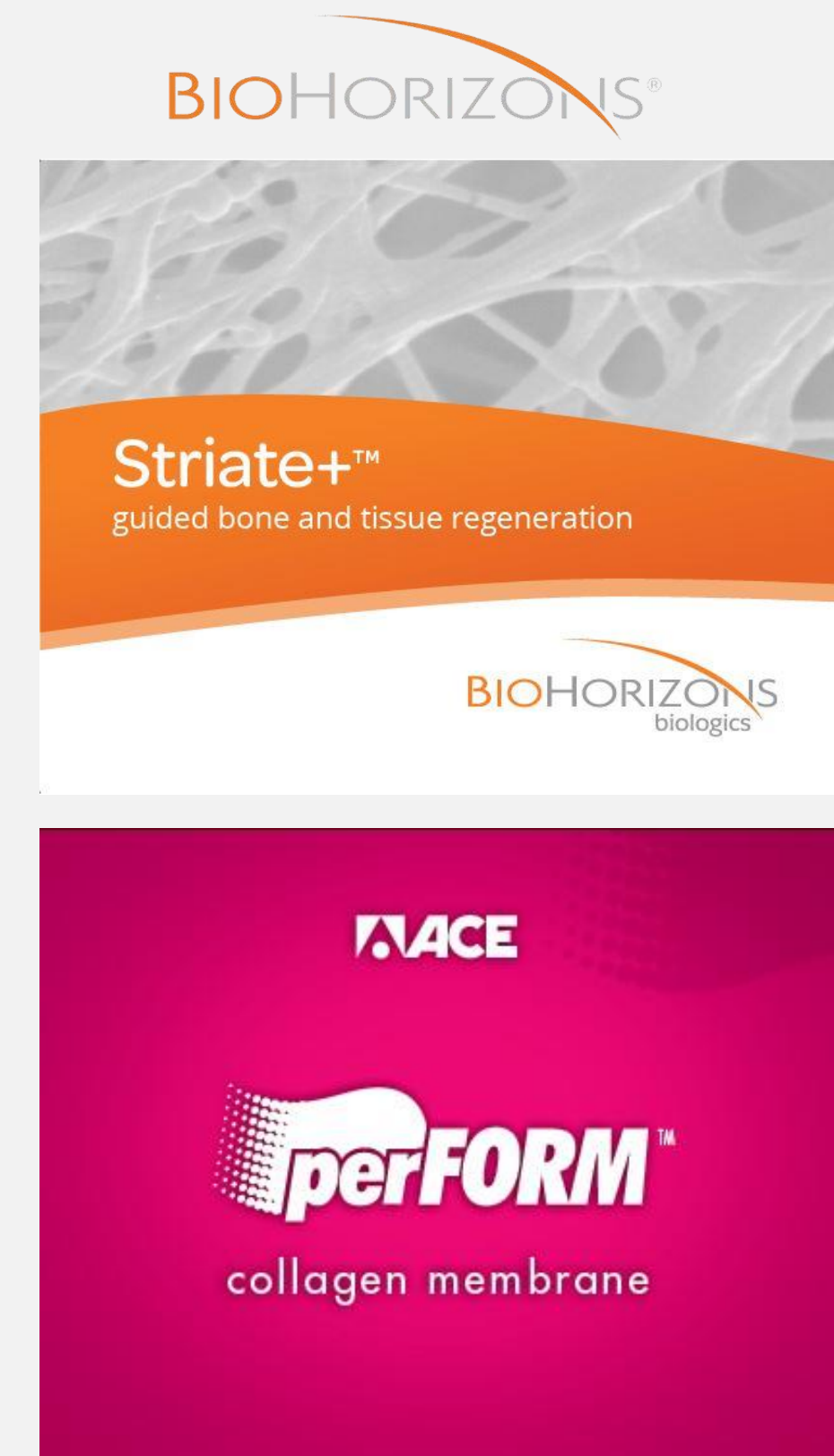




# Striate+™ global license and manufacturing agreement

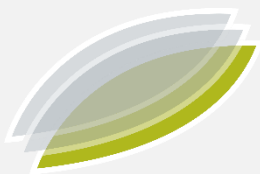
**Innovation backed by world-class KOLs and an exclusive licensing deal with fifth largest global provider of dental products, BioHorizons**

- ✓ **Unrestricted and non-diluting capital** - In consideration of the license granted, Orthocell received in cash **AU \$21.5 million**, net of fees
- ✓ **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>



1. ACE Southern is a subsidiary of Henry Schein and will market and distribute perFORM™ on the same terms and conditions as BioHorizons is marketing and distributing Striate+™



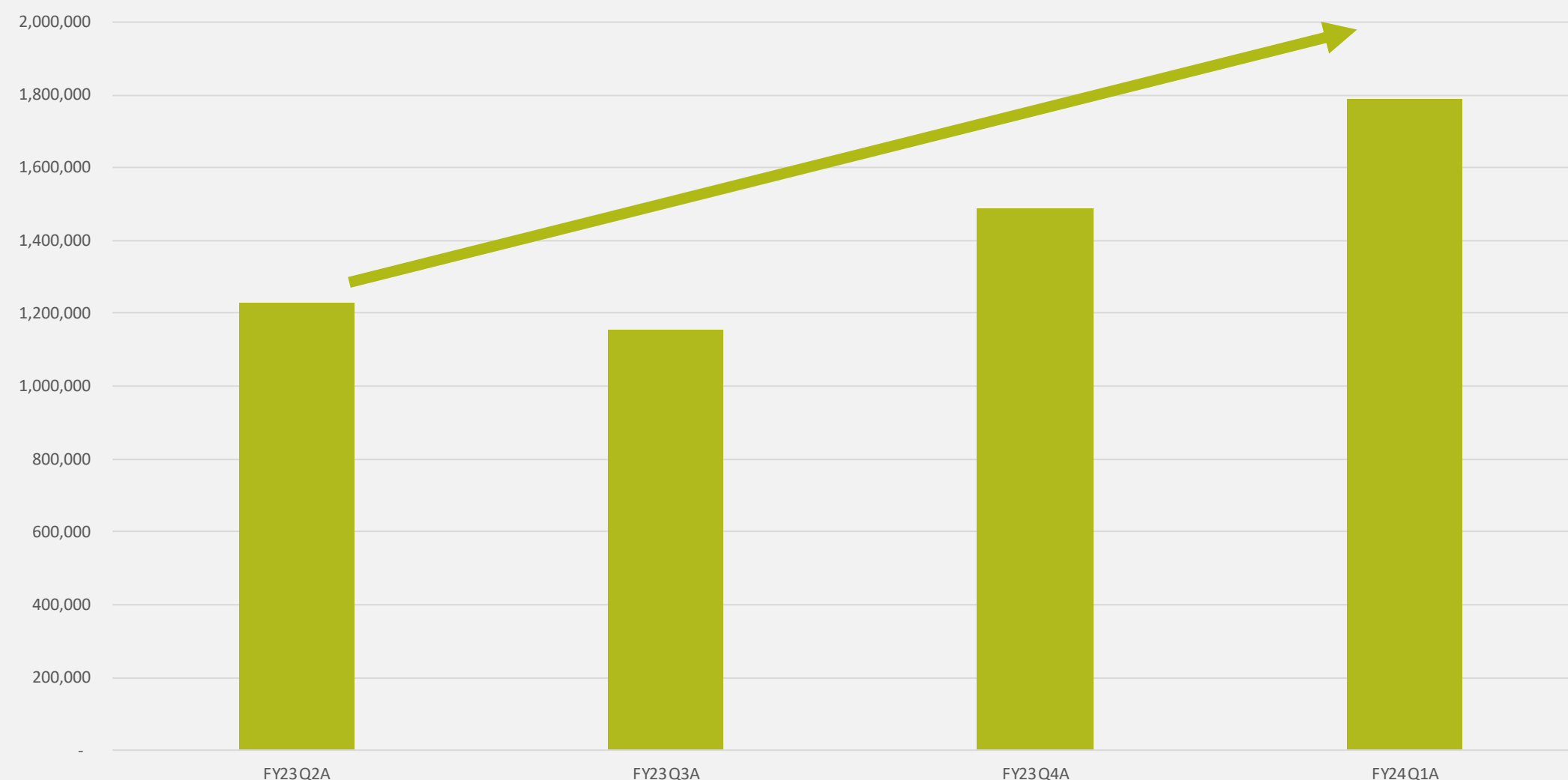


# Successful Striate+™ launch, revenue growing

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

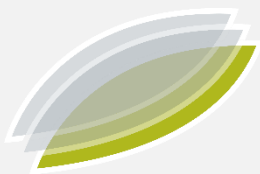
## Product Revenue

First 12 months' Striate+™ dental barrier membrane



- **First 12 months of product sales to HioHorizons significantly exceeded guidance**, 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
- **17% average quarterly growth rate** (compounded for the previous three quarters) since US product launch in Q2 FY23
- **50% increase in Striate+™ sales in Q1 FY24** since the previous quarter Q4 FY2

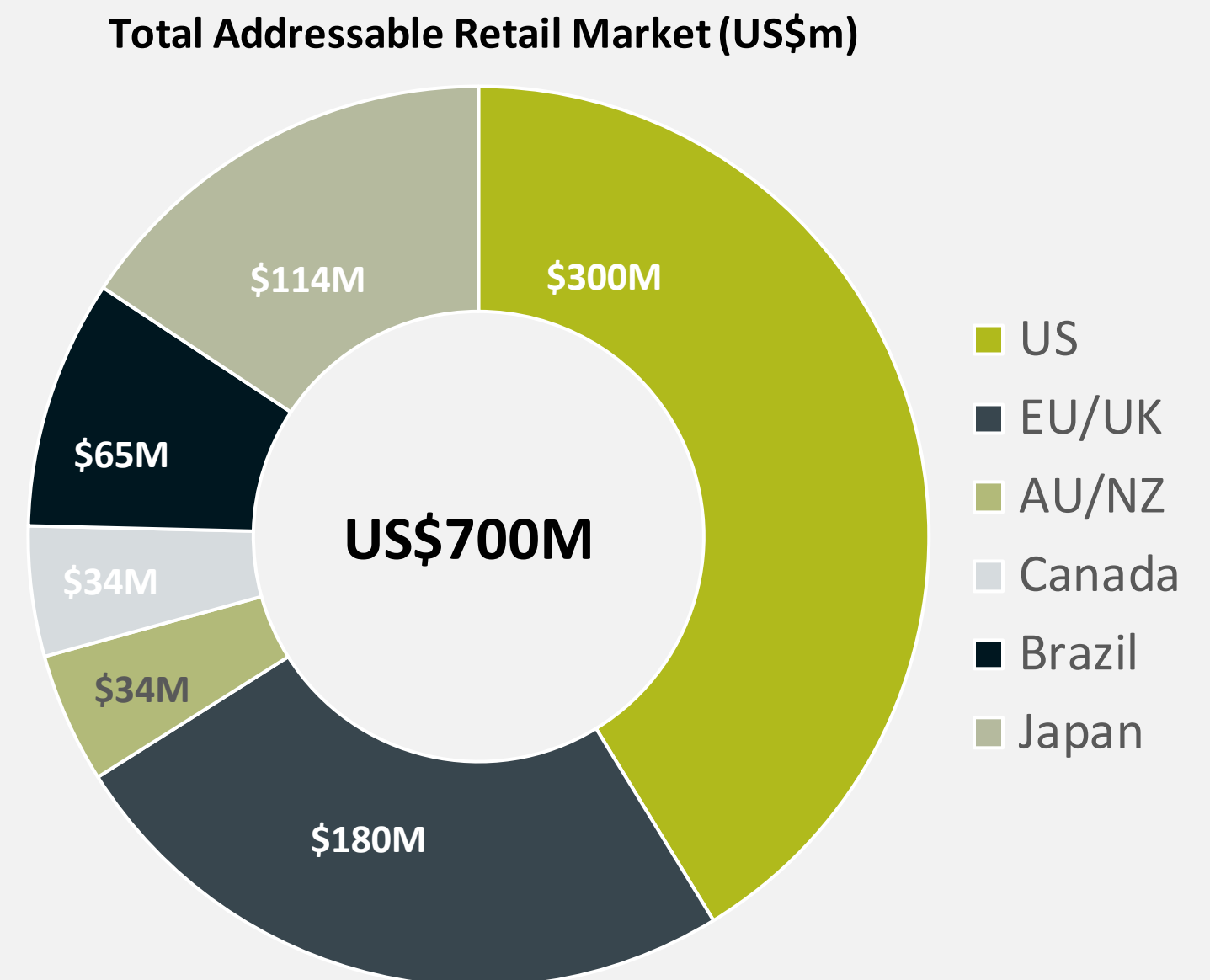
1. Orthocell supplies BioHorizons with Striate+™ products, and BioHorizons exclusively market and distribute Striate+™ globally.



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

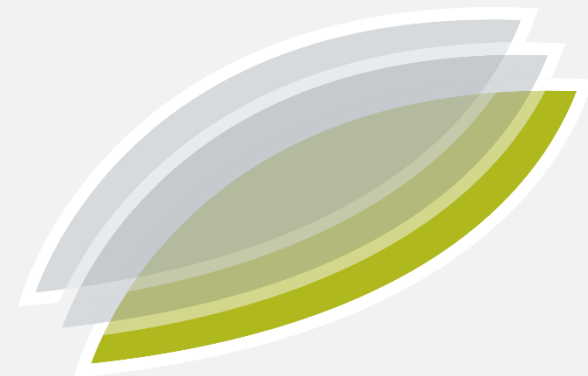
Significant opportunity to secure 20% share of the global dental barrier membrane market generating ~AU \$50 million in recurring wholesale revenue to Orthocell

- **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 (FY25), Brazil and Japan (FY26) over the next 12 – 24 months



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



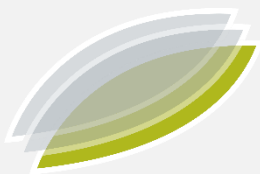


# Remplir<sup>TM</sup>

REVOLUTIONISING NERVE REPAIR



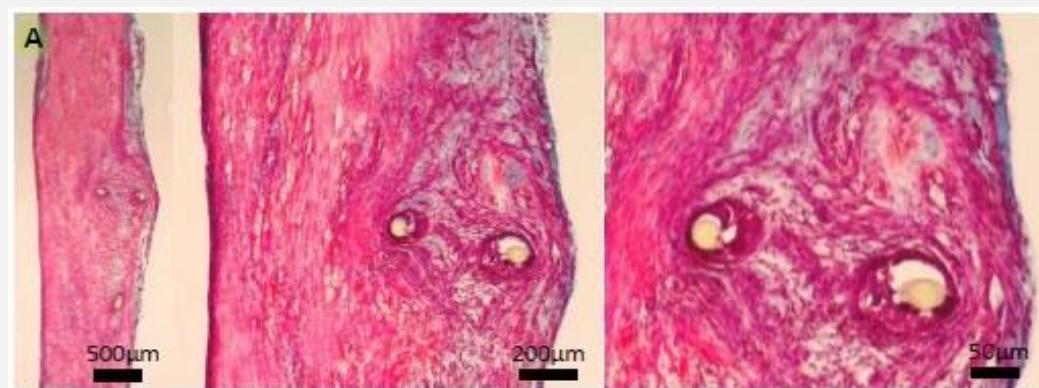
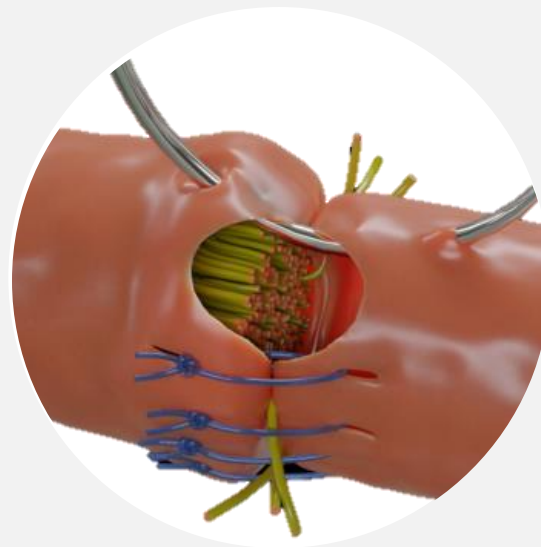




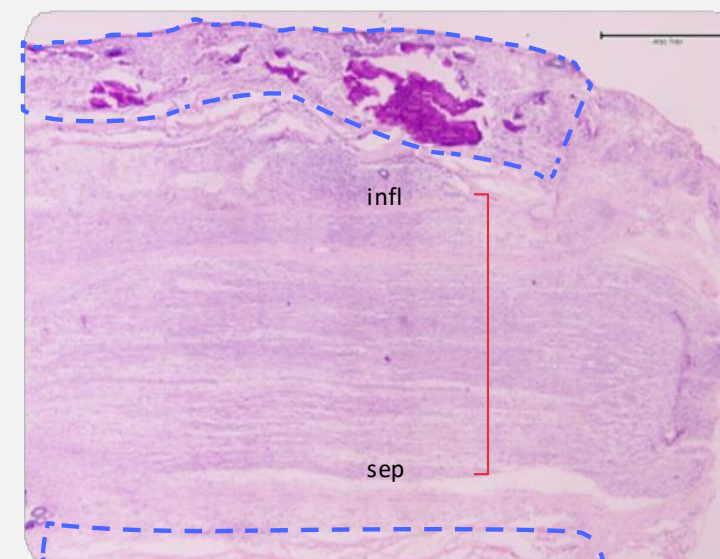
# Nerve repair breakthrough

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

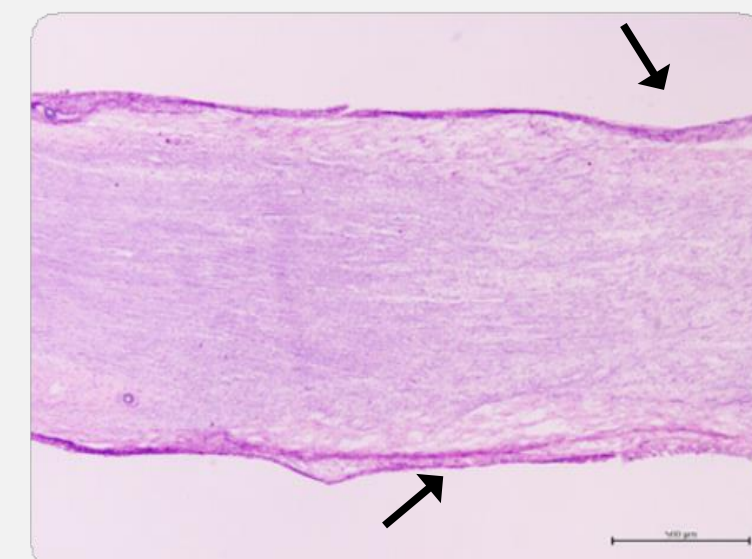
**1860s**  
**Suturing**



**2000s**  
**Conduits**



**2020s**  
**Next generation**



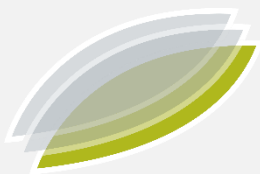
**Success  
Rates**

**50-70%**

**55%**

**85%**



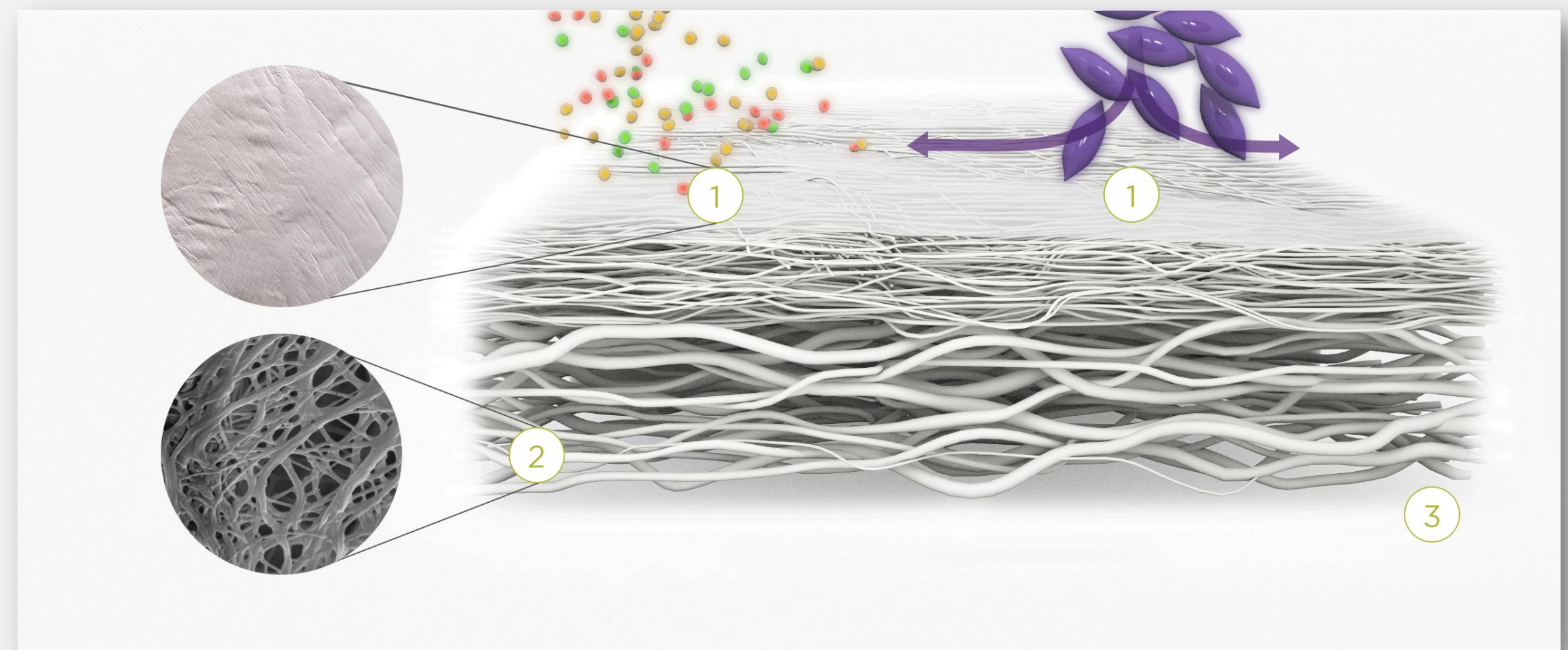


# Remplir™: revolutionising nerve repair

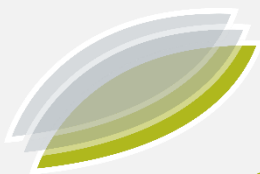
**A breakthrough product guiding predictable outcomes in peripheral nerve repair and return of muscle function**

## 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



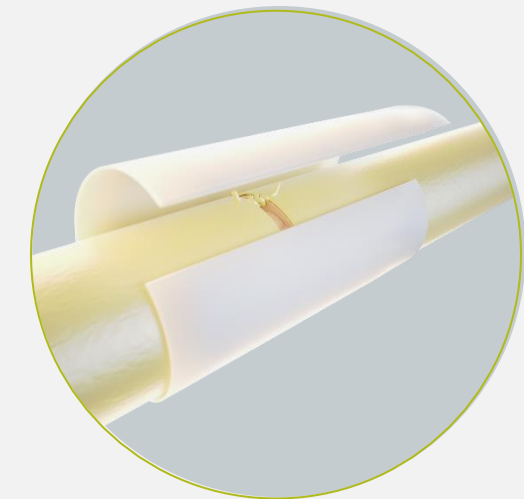
# Remplir™: approved and reimbursed in Australia

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



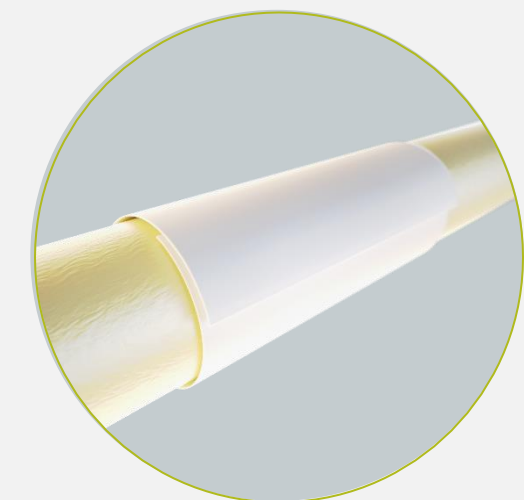
## CONNECT

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



## PROTECT

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

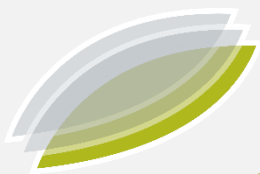


## CAP

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

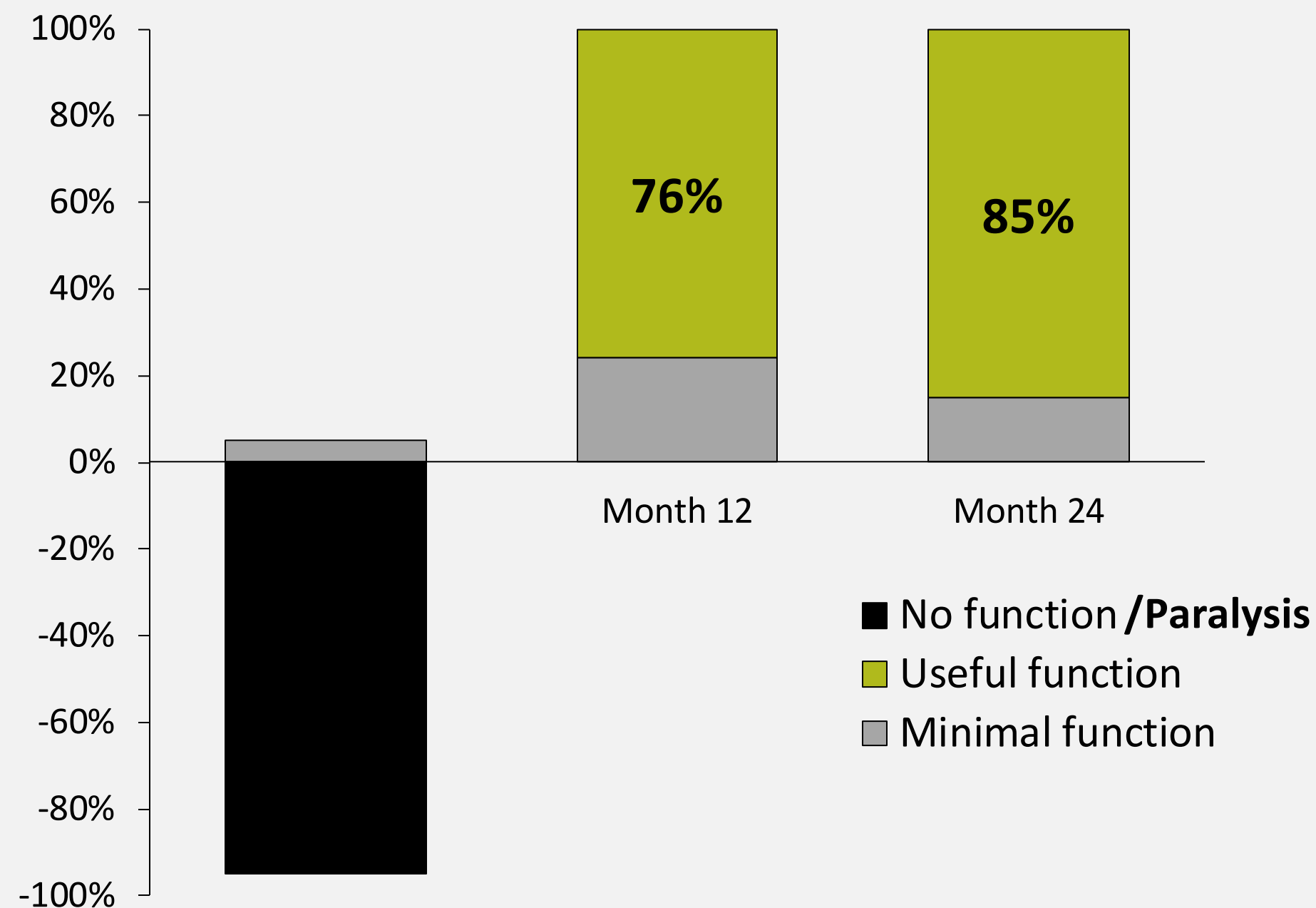






# Remplir™: compelling long term clinical results

**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

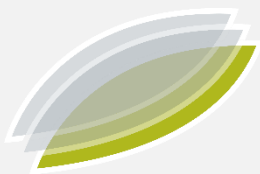
voluntary movement restored, limited strength and range of movement

## 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



# Australian Remplir™ case study opens up global nerve repair opportunity



This treatment has made a world of difference to me.  
The increased strength and mobility in my arm and  
hand has really boosted my independence.  
I am contributing more around the home and can help  
my wife and kids – it feels good.  
- Adrian Walsh, Remplir™ patient

## Injury

- Mountain bike accident
- C5 quadriplegia

## Impact

- No arm strength and no movement in fingers and thumbs
- Life in a wheelchair was difficult

## Surgery

- Nerve transfer using Remplir™

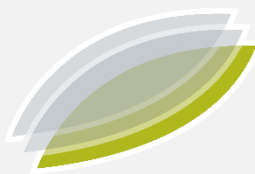
## Outcome

- Better fine motor control and can do things with two hands
- Playing wheelchair rugby and driving his car



Remplir™ patient: Adrian Walsh



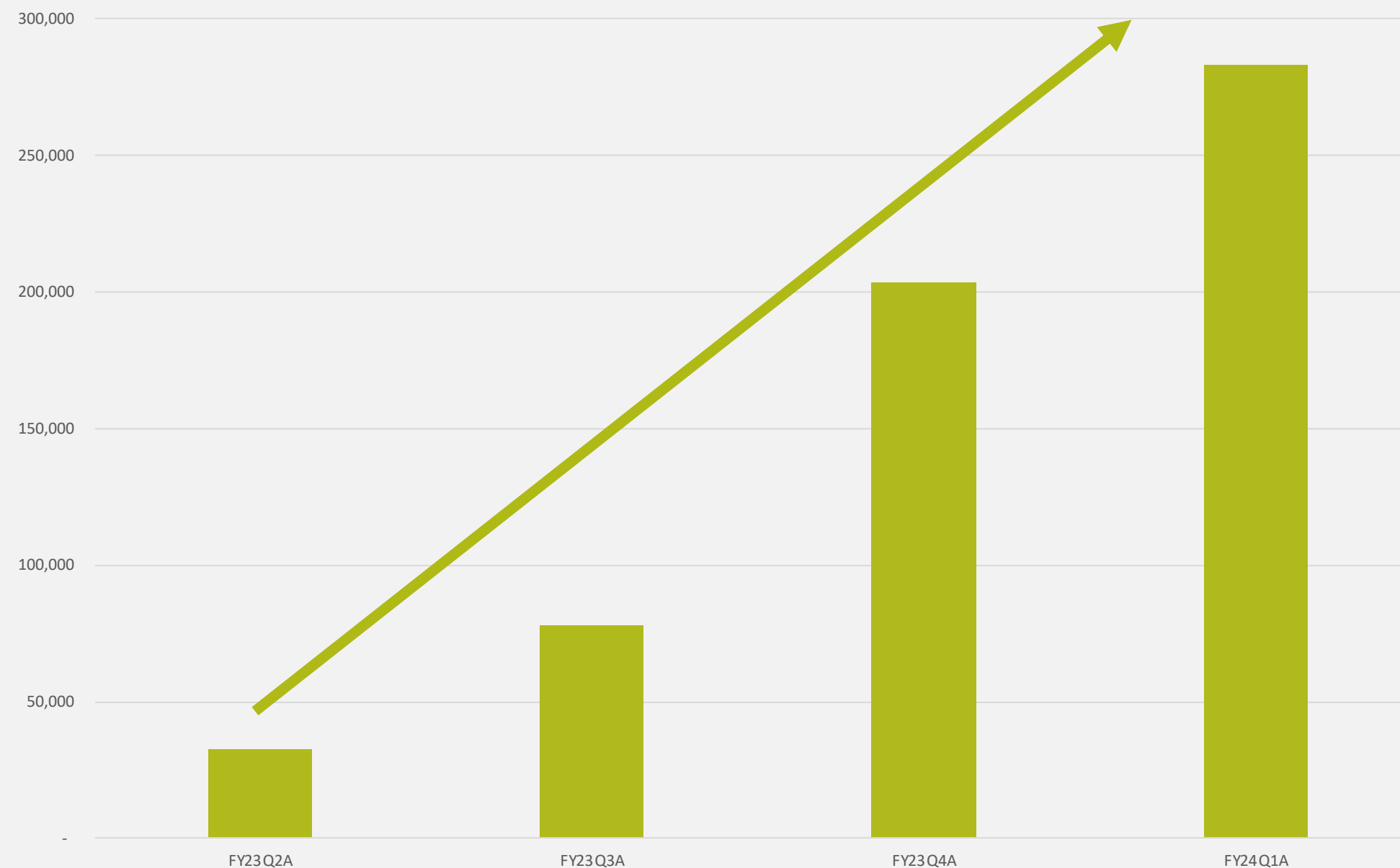


# Successful market launch with revenue building momentum

AUS commercial launch<sup>1</sup> of Remplir™ with Device Technologies in November 2022, with sales unit volumes exceeding expectations

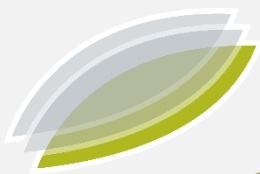


Remplir™ product revenue



- **First 12 months of product sales to Device Technology significantly exceeded guidance** – over 90 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
- **105% average quarterly growth rate** (compounded for the previous three quarters) since AUS product launch in Q2 FY23
- **39% increase in Remplir™ sales in Q1 FY24 since the previous quarter Q4 FY23.**

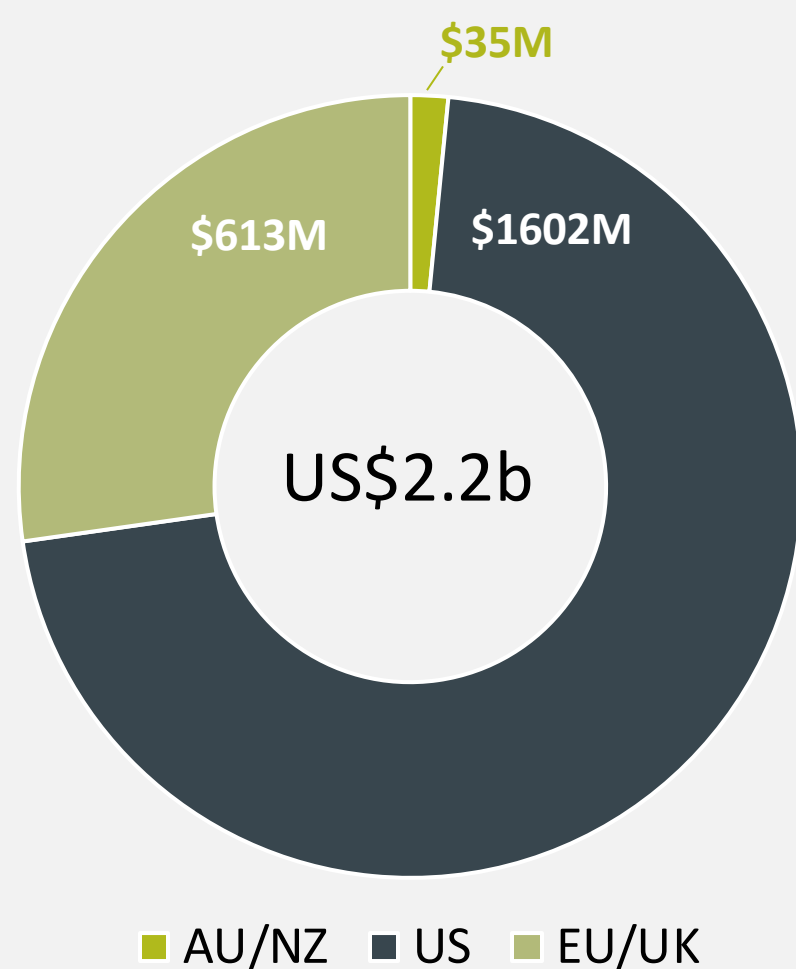
1. Orthocell supplies Device Technologies (DVT) with Remplir™ products, and DVT exclusively market and distribute Remplir™ globally.



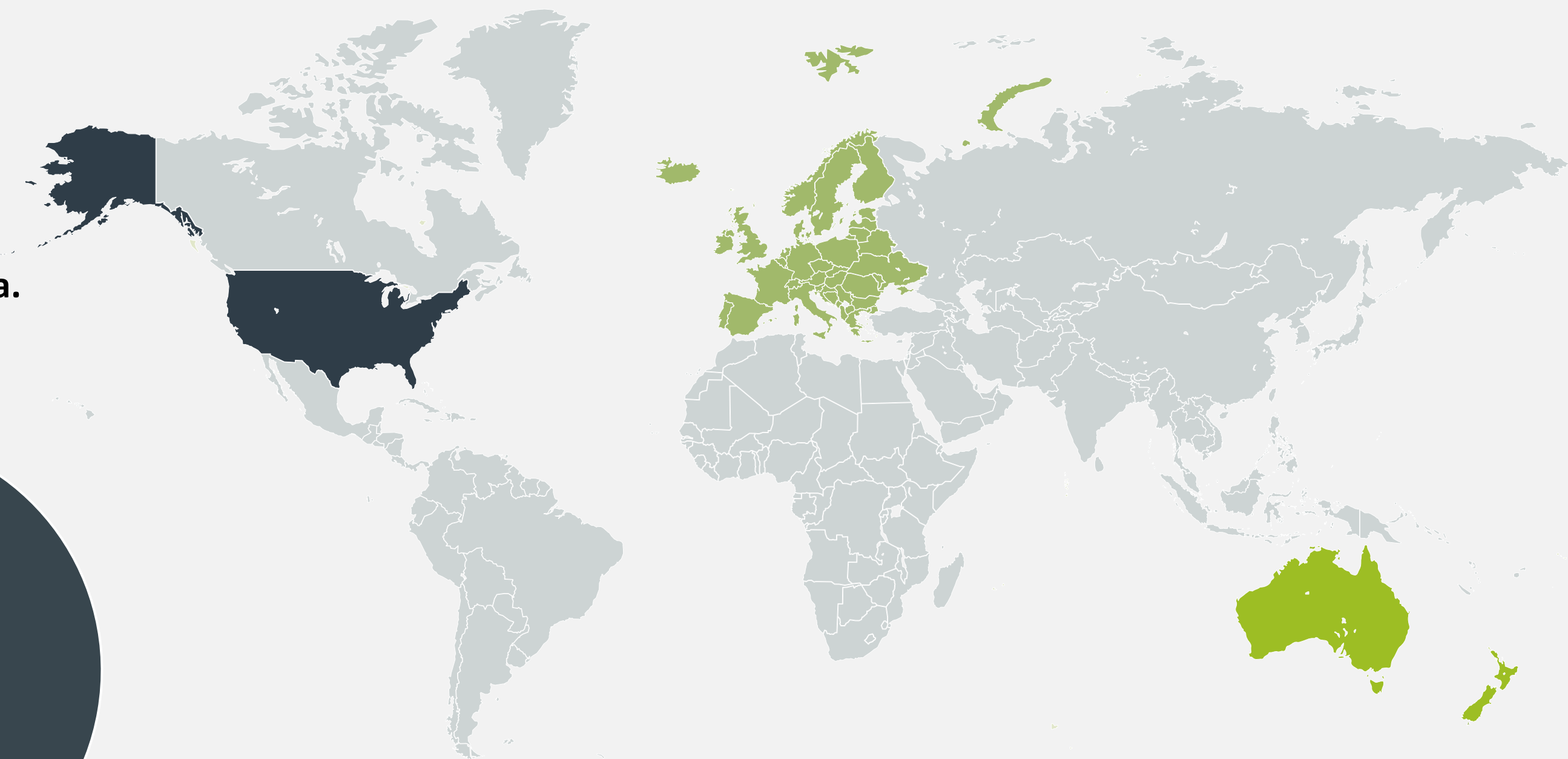
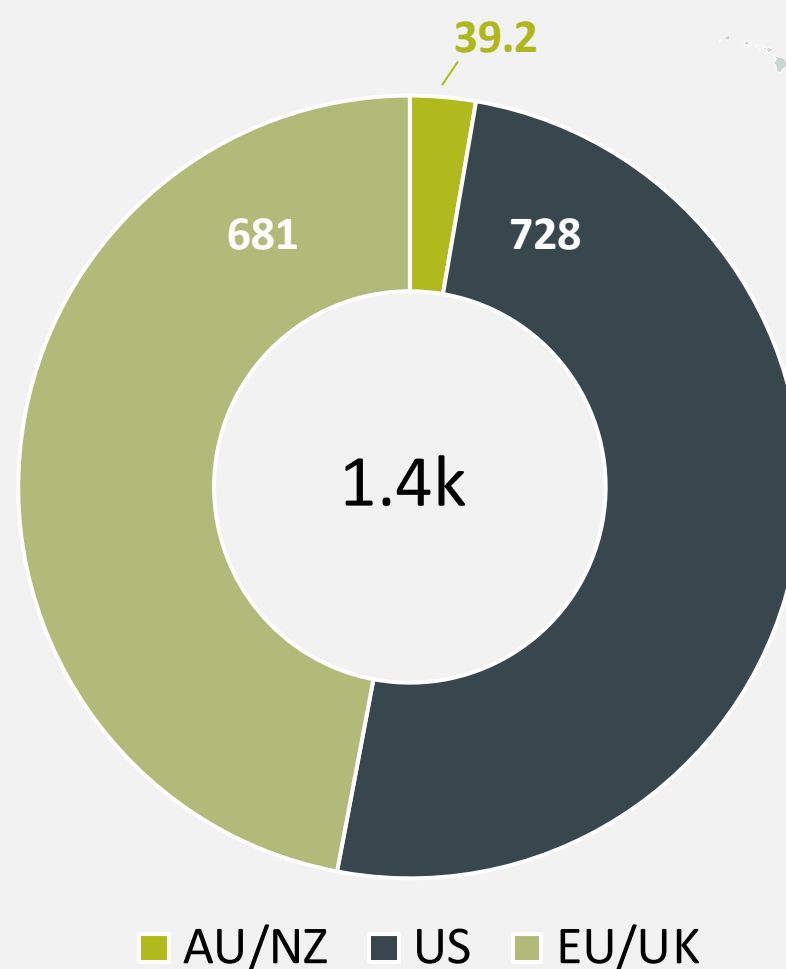
# Large addressable market in nerve reconstruction

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)

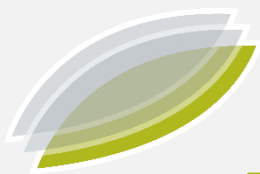


Est. procedures p.a. at peak ('000)



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



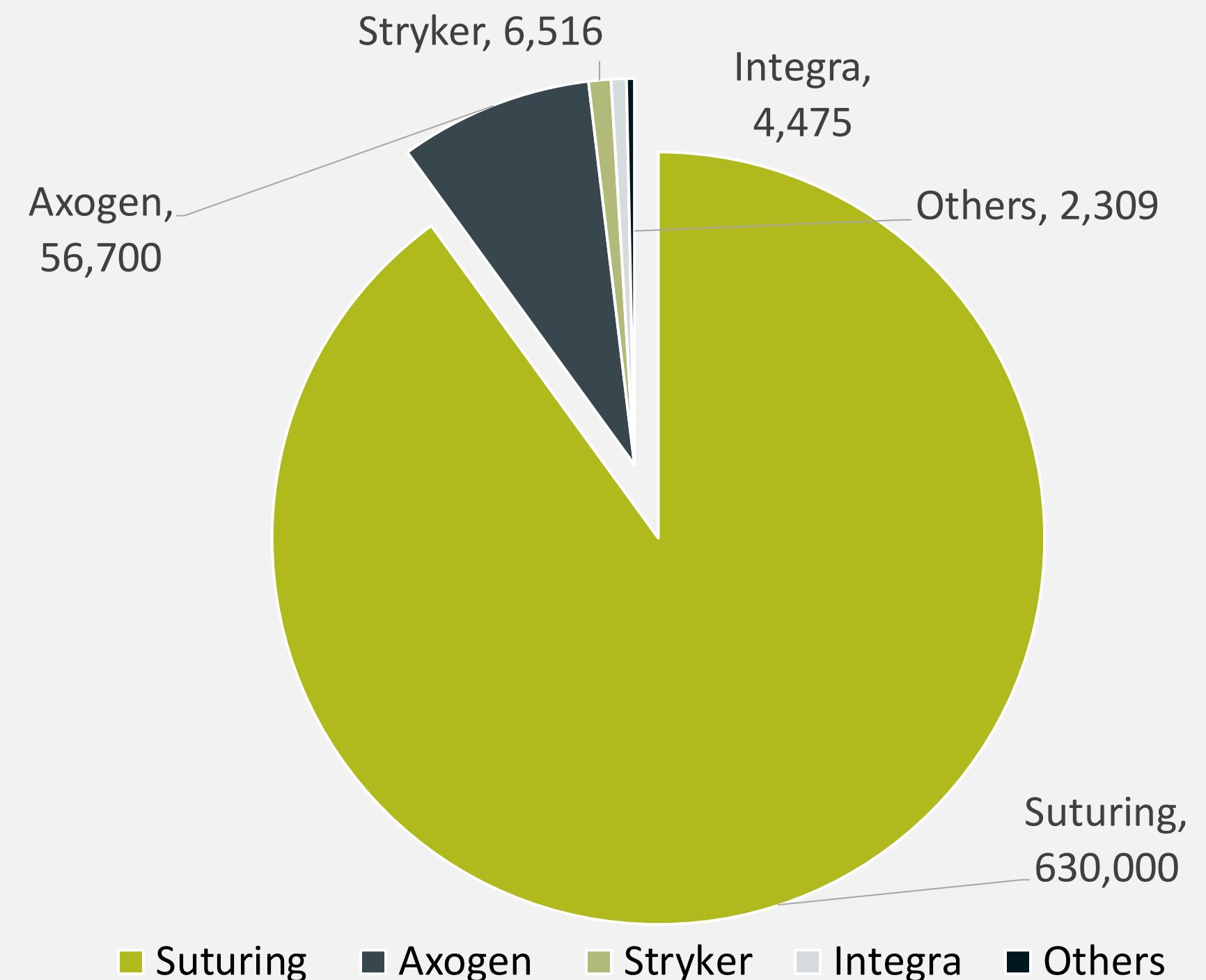


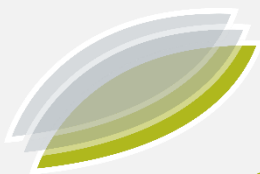
# The US is our 1<sup>st</sup> Target Market

**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) of procedures are 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

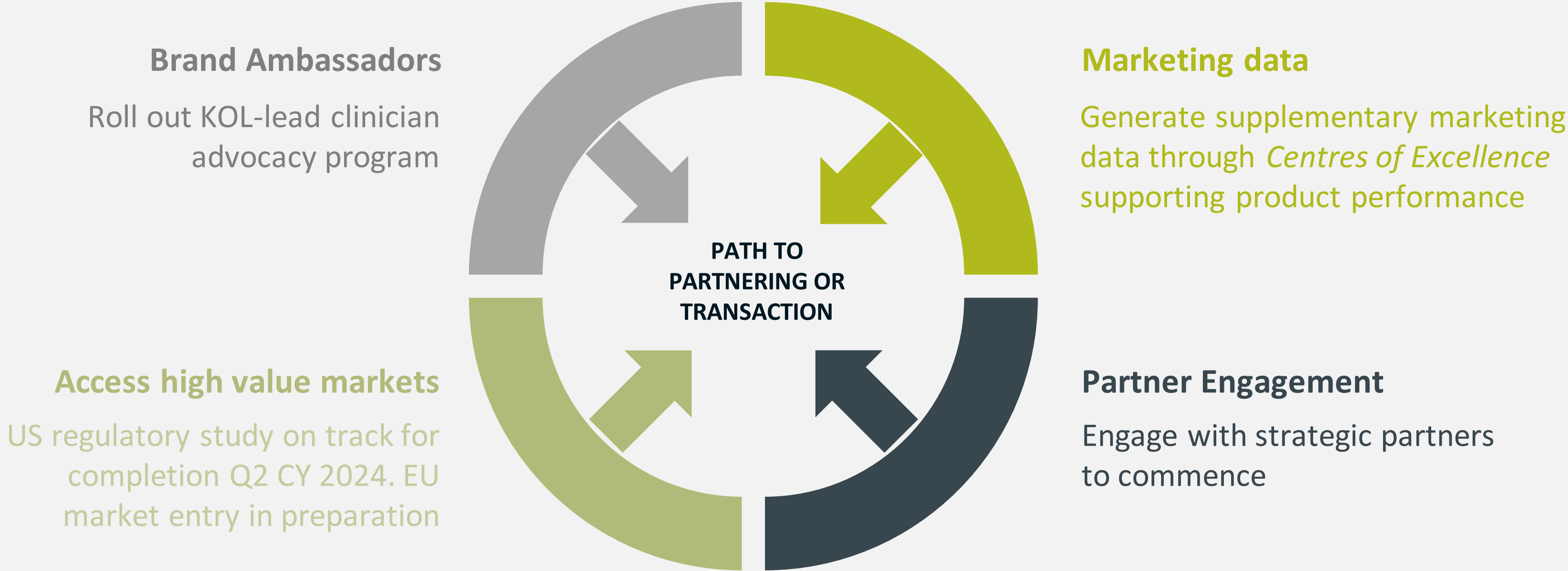
**Annual US nerve reconstructions**



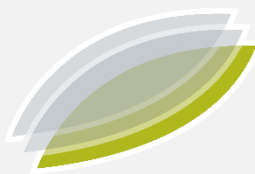


# Remplir™: path to US market

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







# Remplir™ upcoming catalysts<sup>1</sup>

## US and EU/UK regulatory approval program

US registration study results

2Q CY24

US product registration

1Q CY25

EU/UK product registration

4Q CY25

## Generate further marketing data

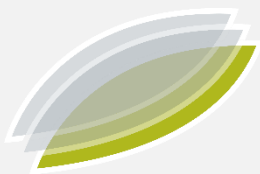
US centre of excellence – commencement of Washington University study

4Q CY23

AU centre of excellence – PMCF study results

1Q CY24

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

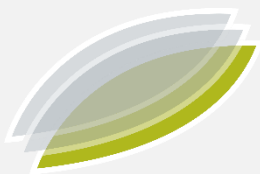


# Pipeline

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	Pre-clinical and clinical study in development	>200,000 procedures per year
<b>Tendon Cell Therapy</b>			
Rotator cuff	RCT shows significantly more effective than steroid injection	US partnering strategy in development	>1,000,000 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** in bone regeneration and returning function to paralysed limbs
- ✓ **Strengthened board** with the appointments of highly experienced executives John Van Der Wielen and Professor Fiona Wood
- ✓ **\$22.3M cash at bank, no royalty liabilities and funded to US approval** of breakthrough nerve repair device
- ✓ **Near term value drivers** including interim nerve data in Q1 CY24



**Co-Founder and Managing Director, Paul Anderson**

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**orthocell.com**

