

## Investor Presentation

**Perth, Australia; 02 February 2023:** Regenerative medicine company Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) is pleased to release an investor presentation to be delivered at the **Euroz Hartleys Healthcare Forum**, 02 February 2023 in Perth. The presentation provides an overview of the Company’s recent landmark global exclusive license and manufacturing agreement with BioHorizons for our Striate+™ dental membrane, together with the latest developments for our advanced pipeline of regenerative medicine products.

**Release authorised by Paul Anderson**  
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Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of bone and soft tissue injuries. Orthocell’s portfolio of products include CelGro™, a collagen medical device which facilitates tissue reconstruction and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications, is cleared for use in US FDA (510k), Australia (ARTG) and Europe (CE Mark) and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently received approval and reimbursement in Australia and is distributed exclusively by Device Technologies in the Australian market SmrtGraft™, for tendon repair, is available in Australia under Special Access Scheme or participation in a clinical trial. The Company’s other major products are autologous cell therapies which aim to regenerate damaged tendon and cartilage tissue. Orthocell is accelerating the development of its tendon cell therapy in the US with technology transfer, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

For more information on Orthocell, please visit [www.orthocell.com](http://www.orthocell.com) or follow us on Twitter **@OrthocellLtd** and LinkedIn [www.linkedin.com/company/orthocell-ltd](http://www.linkedin.com/company/orthocell-ltd)

### Forward Looking Statement

Any statements in this press release about future expectations, plans and prospects for the Company, the Company’s strategy, future operations, and other statements containing the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company’s ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company’s ability to obtain marketing approvals for its product candidates. In addition, the forward-looking statements included in this press release represent the Company’s views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof.





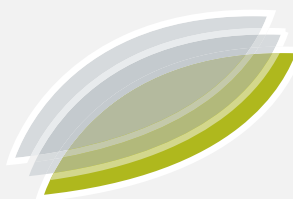
ortho·cell

# Investor Presentation

EUROZ HARTLEYS HEALTHCARE FORUM

February 2023





# Disclaimer

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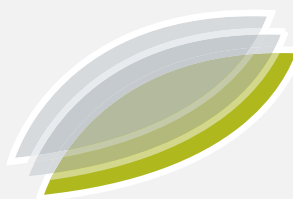
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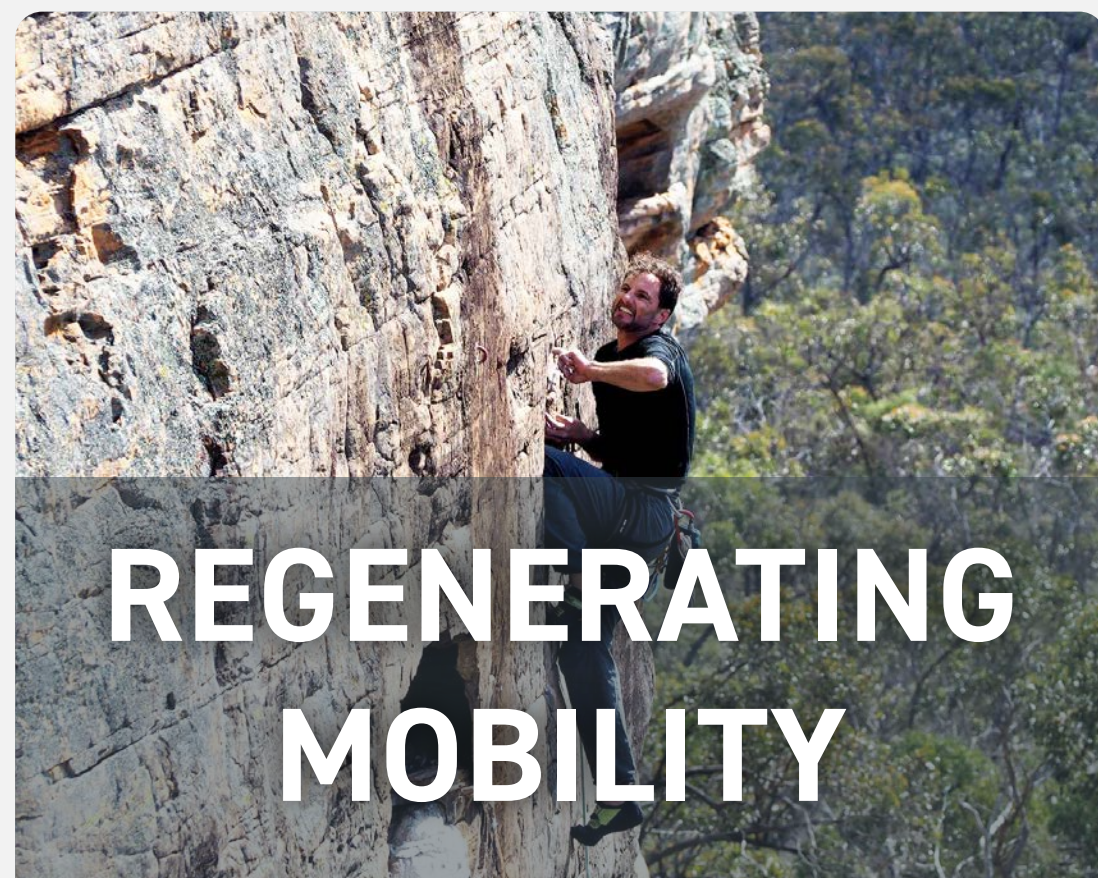
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It is acknowledged that the Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this presentation except as required by law or by any appropriate regulatory authority.



# Key investment highlights



## REGENERATING MOBILITY

### DELIVERING NOVEL BIOLOGICAL PRODUCTS

- ✓ returning function to paralysed limbs
- ✓ returning patients to work, sport and recreation pain free



## COMMERCIAL PARTNERS

### GLOBAL LICENCE EXECUTED AND AUSTRALIAN DISTRIBUTOR IN PLACE

- ✓ strengthening balance sheet
- ✓ validating platform and supports pipeline progression



## MANUFACTURING & PATENTS

### MANUFACTURING FACILITY SCALE UP COMPLETE

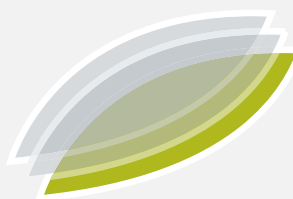
- ✓ first orders dispatched for AUS, US and EU markets
- ✓ comprehensive global patent portfolio



## NEAR-TERM MILESTONES

### 1H CY2023 COMMERCIAL MILESTONES

- ▶ US/AUS/EU market launch
- ▶ MDR CE Mark planned
- ▶ US pre-clinical comparator study (510K)
- ▶ OrthoATI vs Surgery RCT pivotal data release



# Corporate snapshot

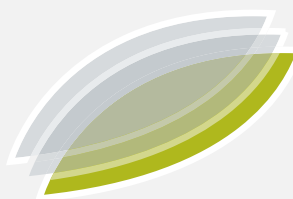
## ASX: OCC TRADING INFORMATION

<b>Share Price</b>	<b>0.39</b>
12 month low/high	\$0.300/\$0.580
Shares outstanding	197,127,913
<b>Market Capitalisation</b>	<b>80M</b>
Cash (31 December)	26.81M
Debt (31 December)	Nil
<b>Enterprise Value</b>	<b>\$54M</b>

## SUBSTANTIAL SHAREHOLDERS

<b>Shareholder</b>	<b>%</b>
Founders & Management	15.10%
Institutions	4.5%

**With AU\$26.81m 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.**



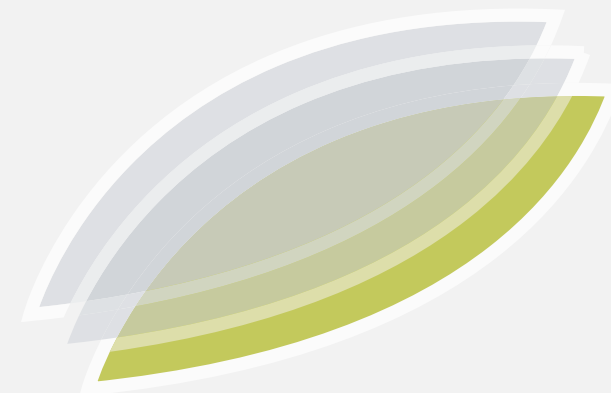
# US strategic focus

Advanced product portfolio with near term milestones and emerging pipeline

Product	Application	Clinical Development Phase	US Regulatory Phase			Status (CY)
			Design Trial	Implement Trial	Approved	
<b>CelGro™</b> Medical Device	Striate+ <sup>1</sup>					<b>Engaged BioHorizons</b> - exclusive license and manufacturing partner. Market launch 4Q 2022.
	Remplir <sup>2</sup>					<b>AUS</b> - Engaged Device Technologies as exclusive marketing and distribution partner. Reimbursement 4Q 2022. ..... <b>US</b> - commence pre-clinical comparator study 1Q 2023.
	SmrtRope (Ligament replacement)					<b>Pilot study complete</b> - pre-clinical and clinical study in development.
<b>OrthoATI™</b> Cell Therapy	Rotator Cuff					<b>US pilot study complete</b> - commercialisation strategy in development.
	Lateral epicondyle					<b>AUS Patient treatment complete</b> - OrthoATI vs surgery. Results planned 2Q 2023.

<sup>1</sup> Approved in the US, AUS & EU

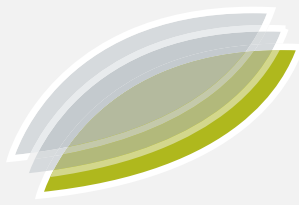
<sup>2</sup> Approved in AUS



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

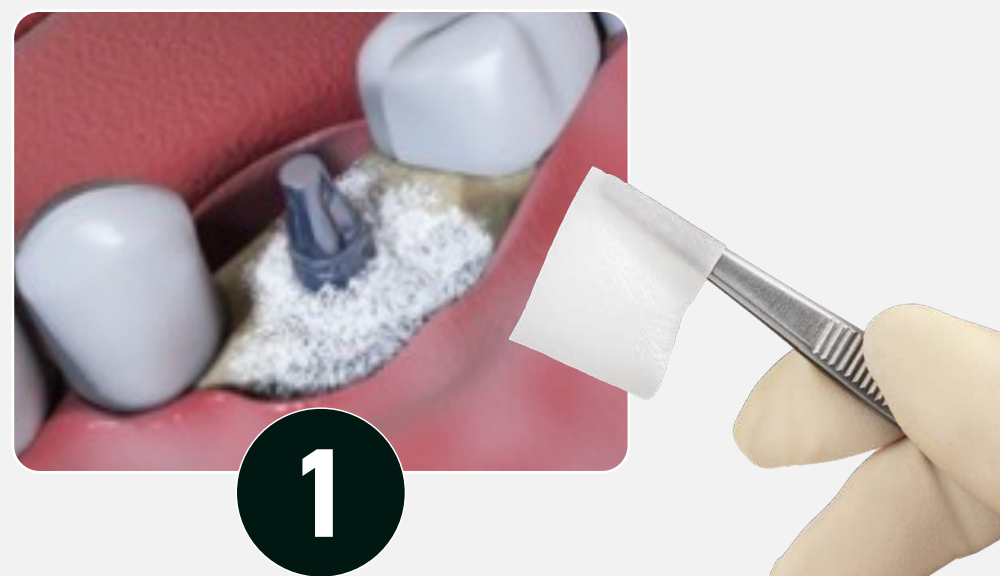
**MORE THAN A  
BARRIER MEMBRANE**



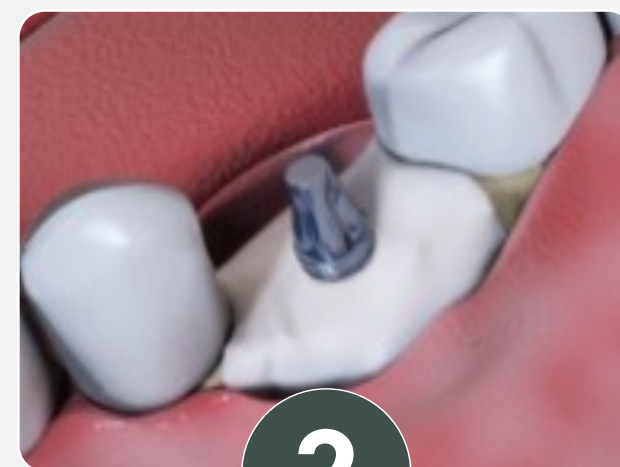


# Striate+™ premium dental membrane

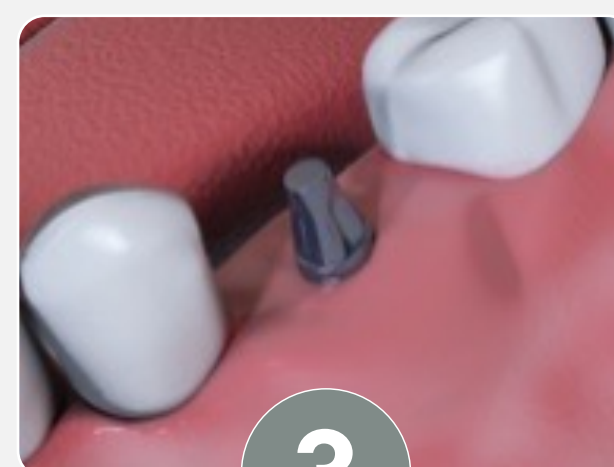
- Striate+ is a sterile, resorbable collagen membrane for use in dental bone and tissue regeneration procedures.
- Striate+ is designed to protect the bone defect from ingrowth of gingival tissue, to provide a favourable environment for osteogenesis and to assure reliable formation of high-quality bone.



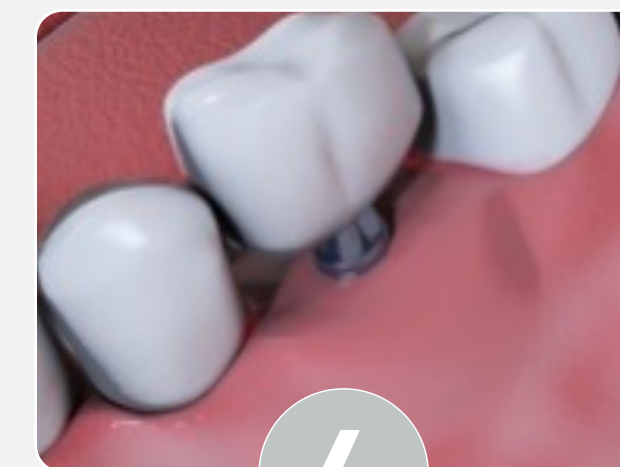
**1**  
Preparation of repair site. Defect site is filled with bone graft



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

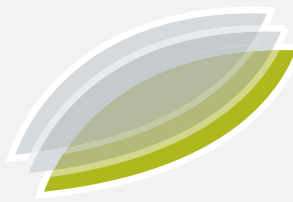


**3**  
Wound closure



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





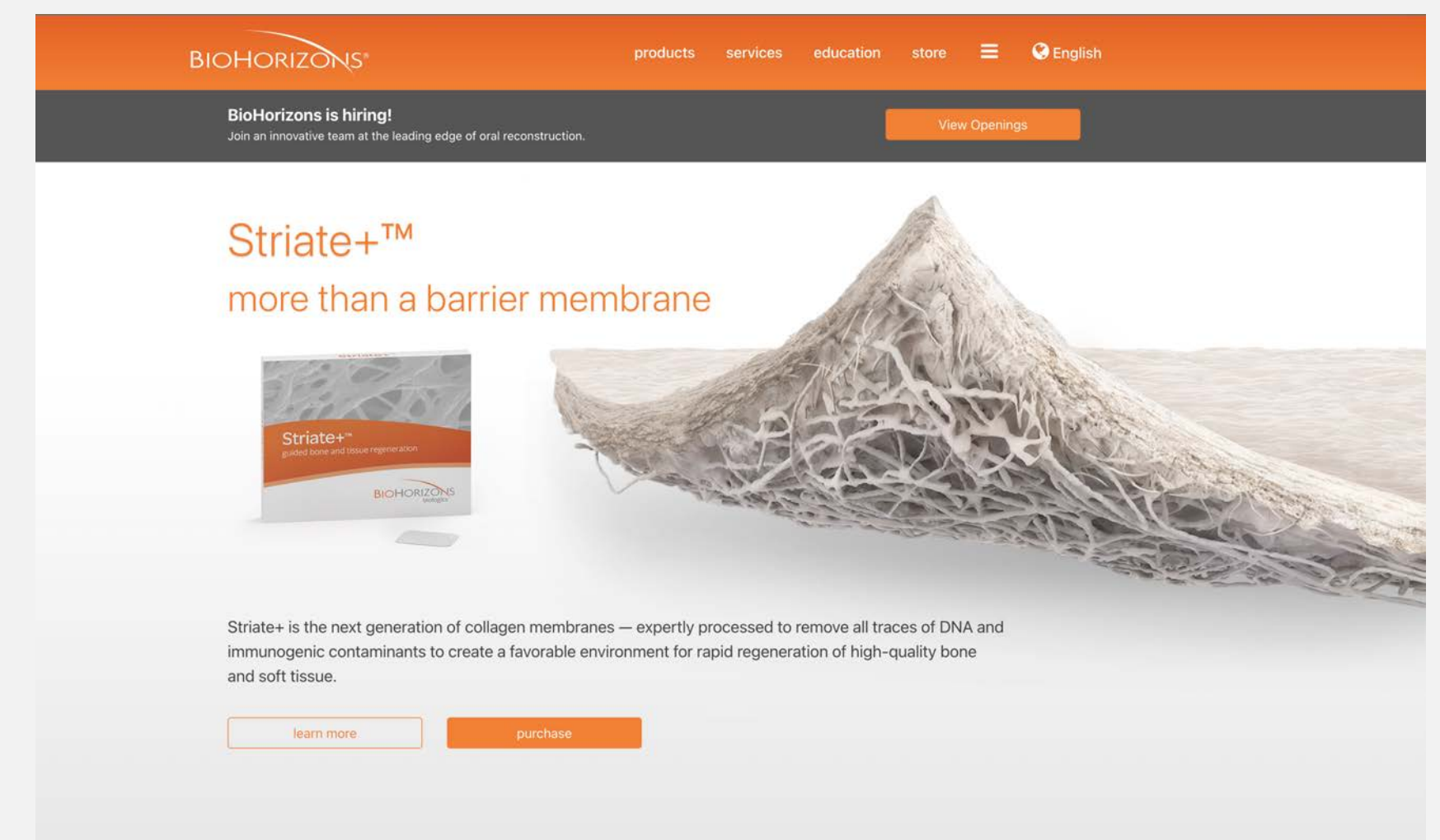
# Striate+™ global exclusive license and manufacturing agreement with BioHorizons

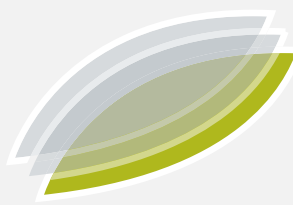


We are very pleased to partner with Orthocell to offer our valued customers a dental membrane with excellent handling properties and regenerative potential. Striate+™ will be a highly complementary addition to our global biomaterials product portfolio for dental tissue regeneration.

- President and CEO of BioHorizons, Steve Boggan

- In consideration of the license granted, Orthocell has received in cash **AU \$21,461,686 million**, net of fees.
- BioHorizons is part of Henry Schein, Inc (NASDAQ: HSIC) and a leading global provider of dental implants and tissue regenerative products for dentists.
- Orthocell will supply BioHorizons with Striate+™ products, and BioHorizons will exclusively market and distribute Striate+ globally.





# Positioned for growth



## Unrestricted and non diluting capital

- Non diluting payment is free of encumbrances - cash can be used without restrictions.

## Strong capital position

- \$26.81m cash at bank<sup>1</sup>
- Well positioned to advance the commercialisation of the US nerve and tendon repair programs.

## Validation of the portfolio

- Proves the platform potential and positions company to commercialise US nerve repair product – BioHorizons deal is restricted to the dental field only and does not prohibit a nerve or tendon deal.

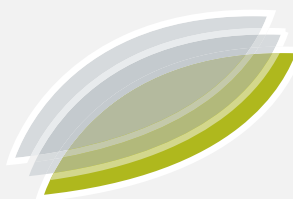
## Established local manufacturer

- This supports the scaling of production to meet both BioHorizons supply requirements and the Company's nerve production requirements.

## Global market launch

- Actively preparing for US market launch with recurring revenue growth driving towards sustainability.

1. Cash at bank as at 31 December



# Striate+™: path to partnering



Executed a strategy to engage a global partner to manage the distribution and marketing of Striate+



## Clinical data and regulatory approval

Successful regenerative medicine-driven product development strategy produced a market leading product approved in US, EU and AUS.



## Clinician advocacy and awareness

Established a world-class KOL network to validate the product and support ongoing discussion with potential distribution partners.



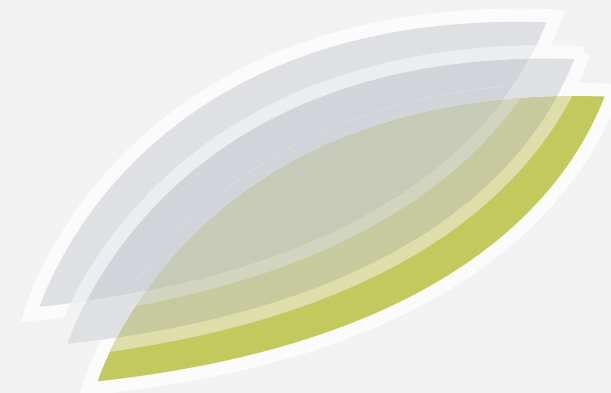
## Manufacturing and logistics

Scaling up to >100,000 units per annum. High-quality US and EU warehouse and logistics solution established.



## Extensive partner engagement

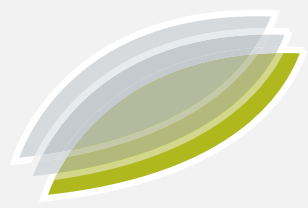
Engaged early with multi-national dental companies for US marketing and distribution rights.



**Remplir**<sup>TM</sup>

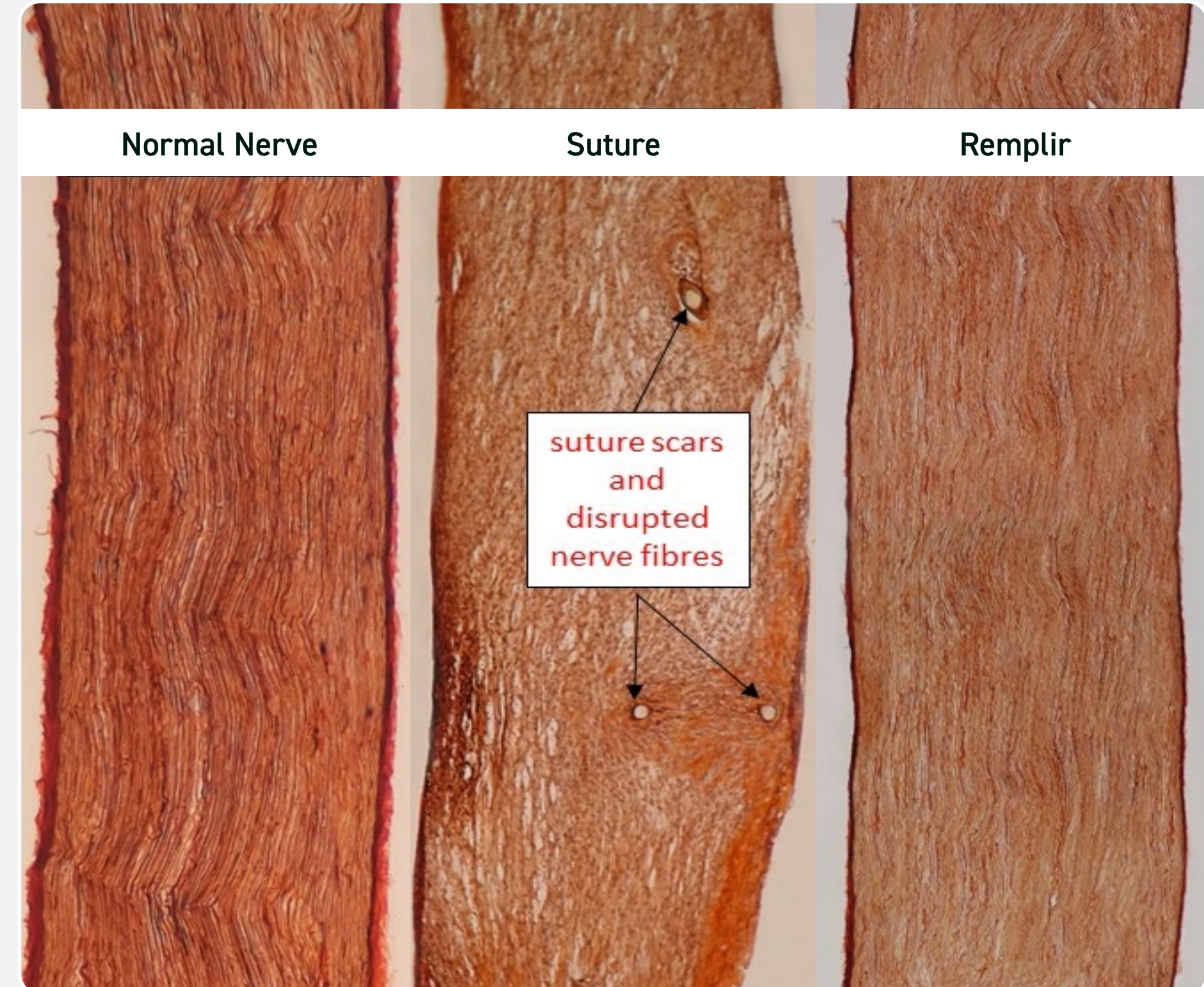
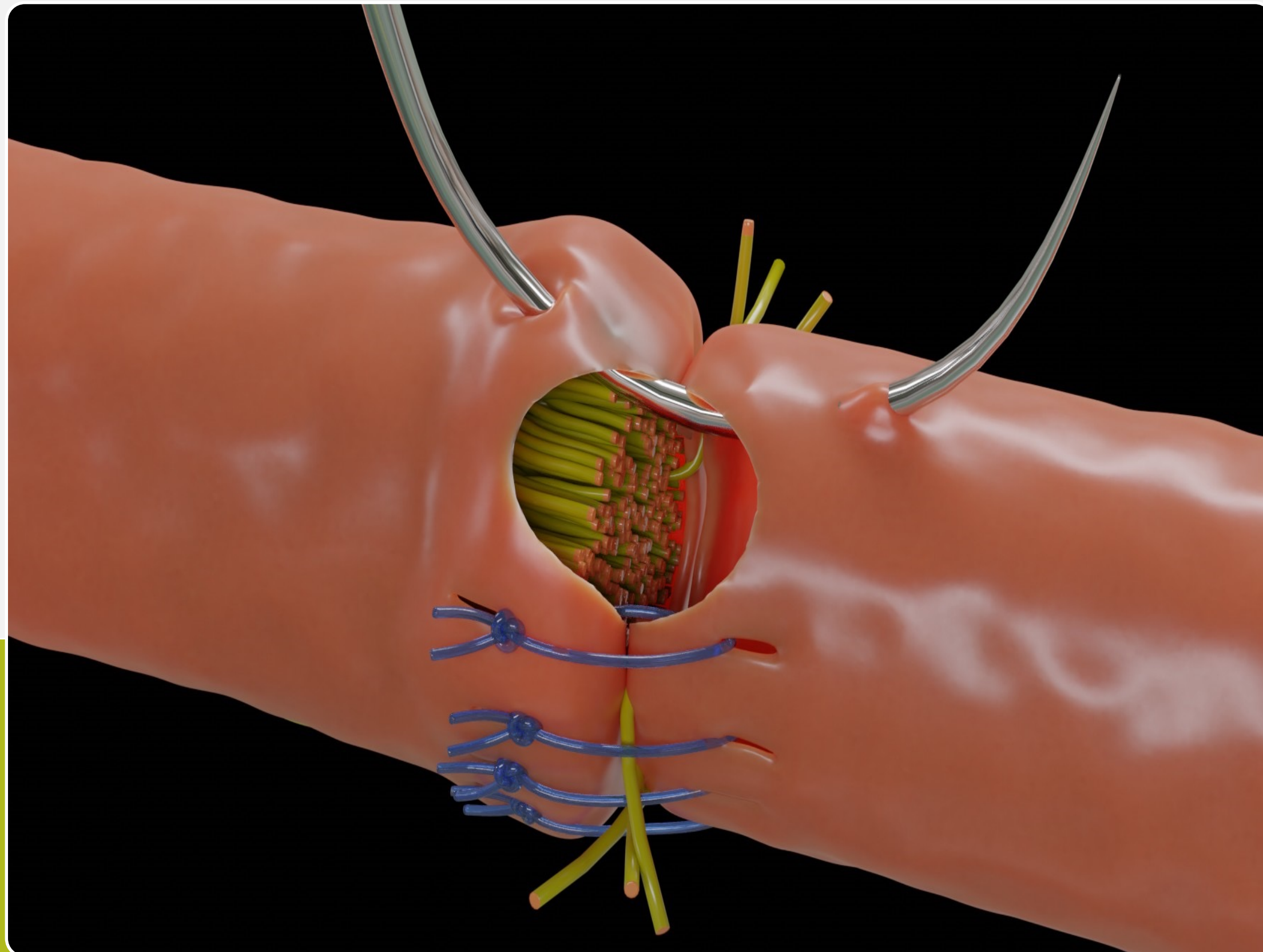
REVOLUTIONISING  
NERVE REPAIR

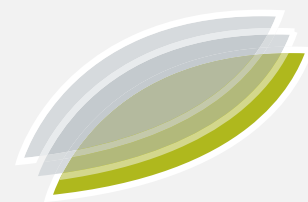




# Traditional repair outcomes are suboptimal

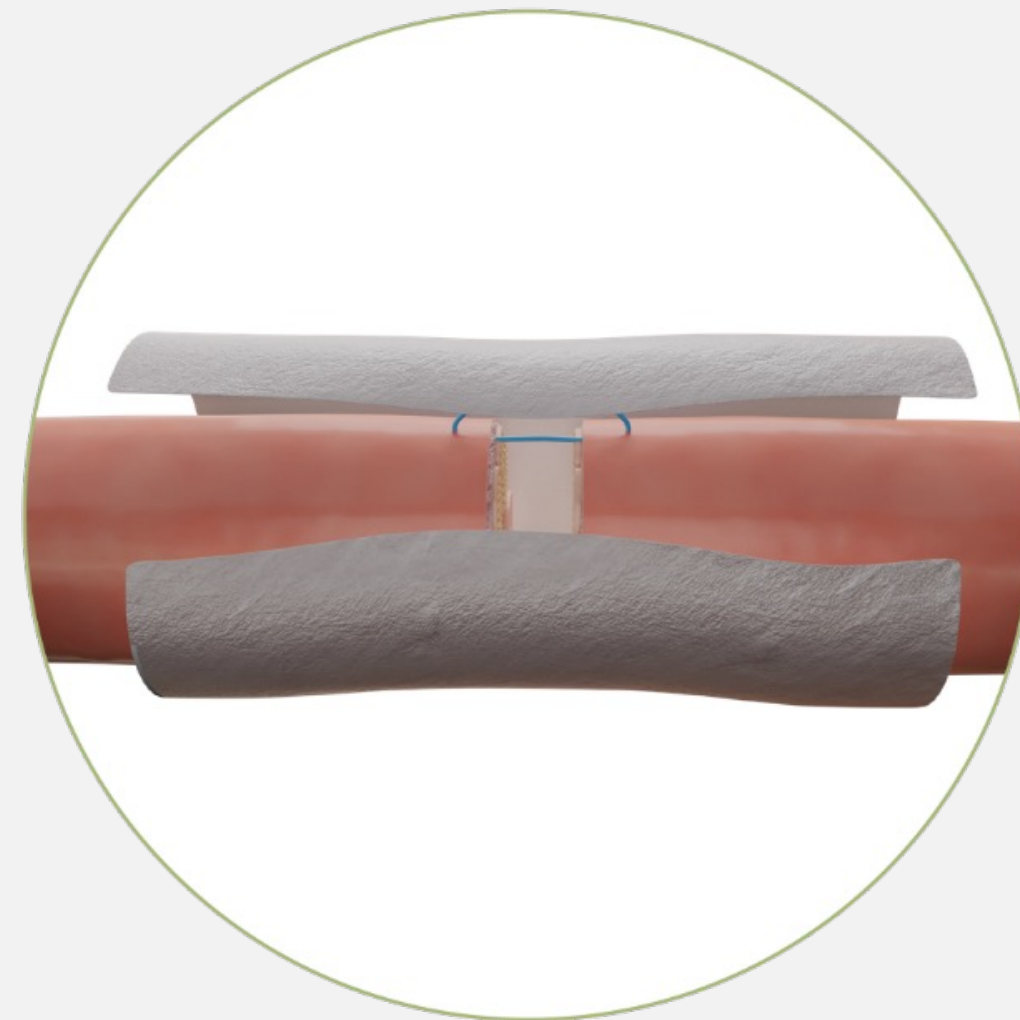
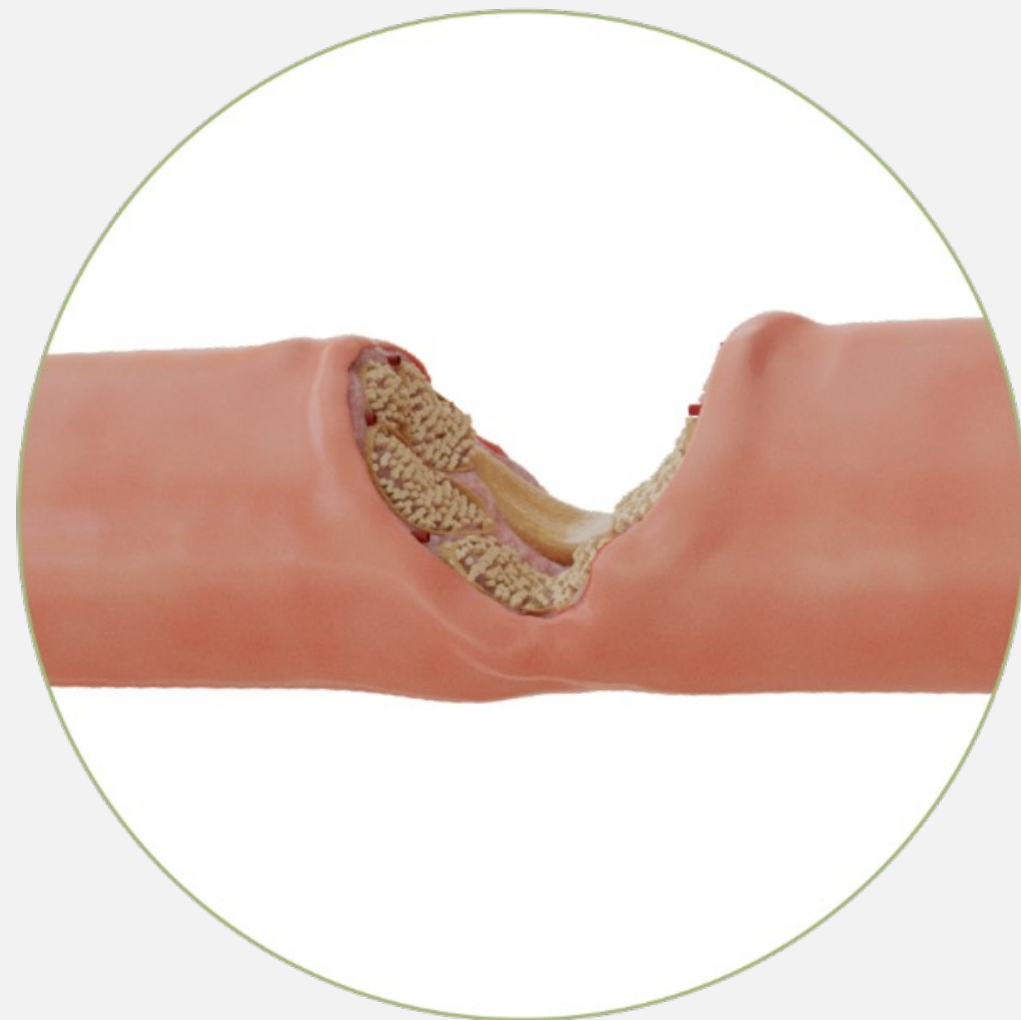
Direct suture = tension, buckling and can be ineffective and unpredictable in restoring function.





# Remplir™ – approved in Australia (TGA)

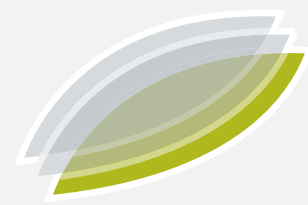
Collagen nerve wrap intended for use in peripheral nerve repair



GUIDING PREDICTABLE  
OUTCOMES IN  
PERIPHERAL  
NERVE REPAIR

- Exceptional handling characteristics
- Healing microenvironment
- Mimics epineurium (nerve outer layer)

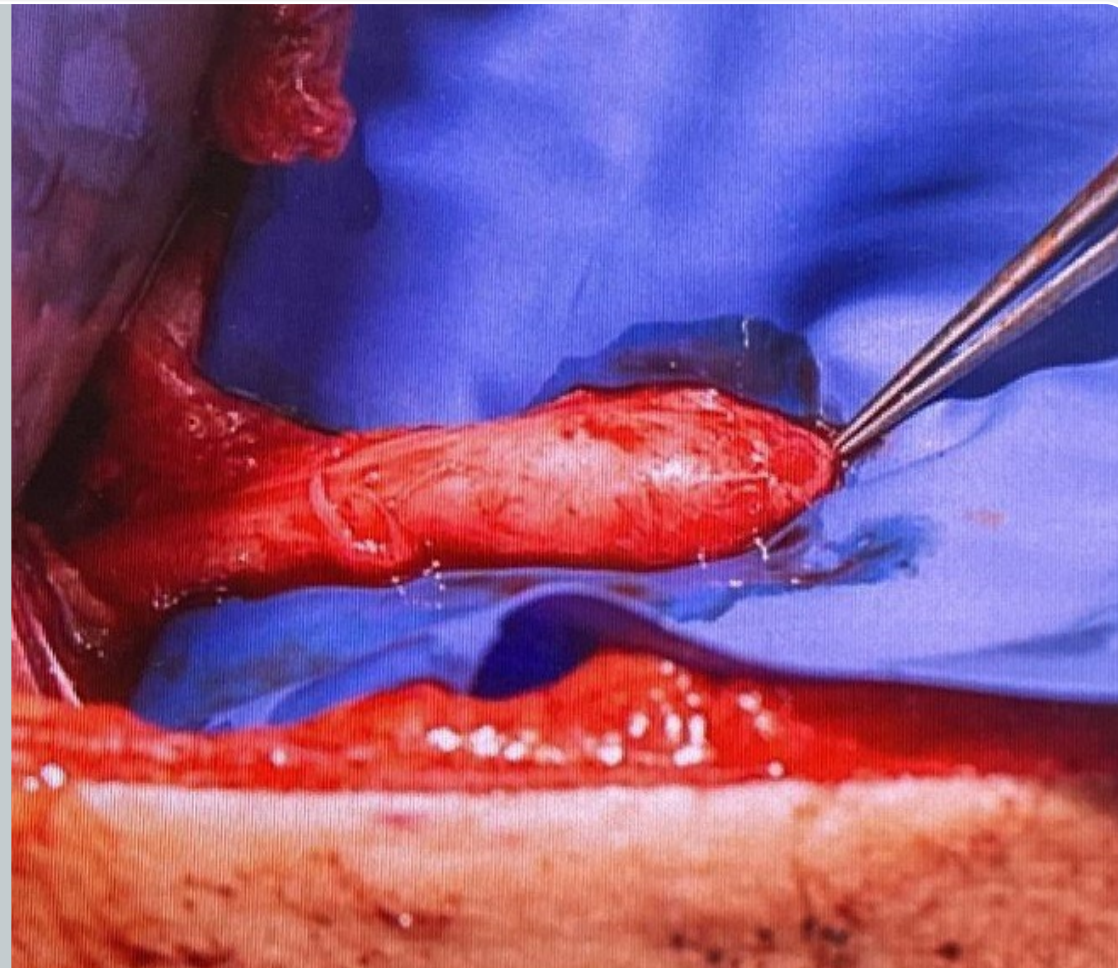




# Surgical technique – Remplir™ assisted coaptation

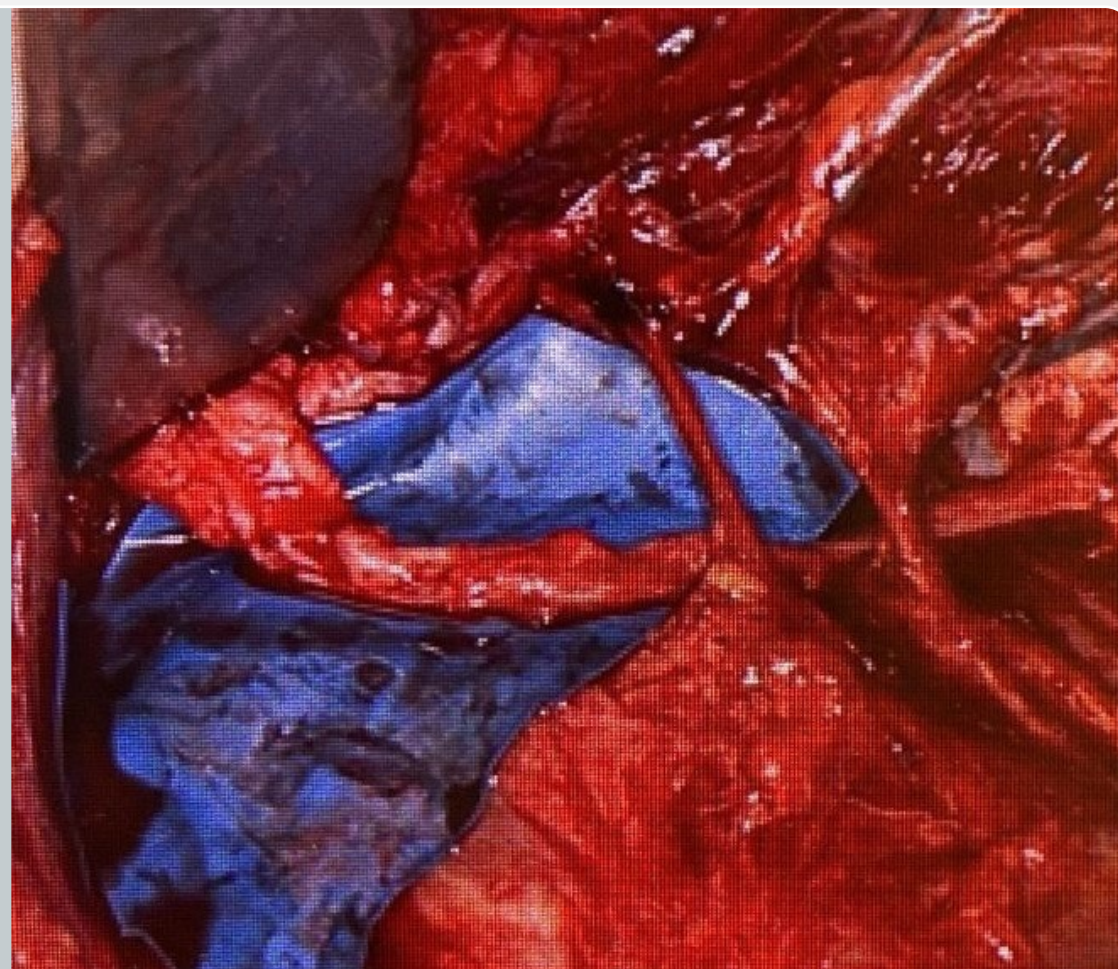
1

Isolating donor nerve



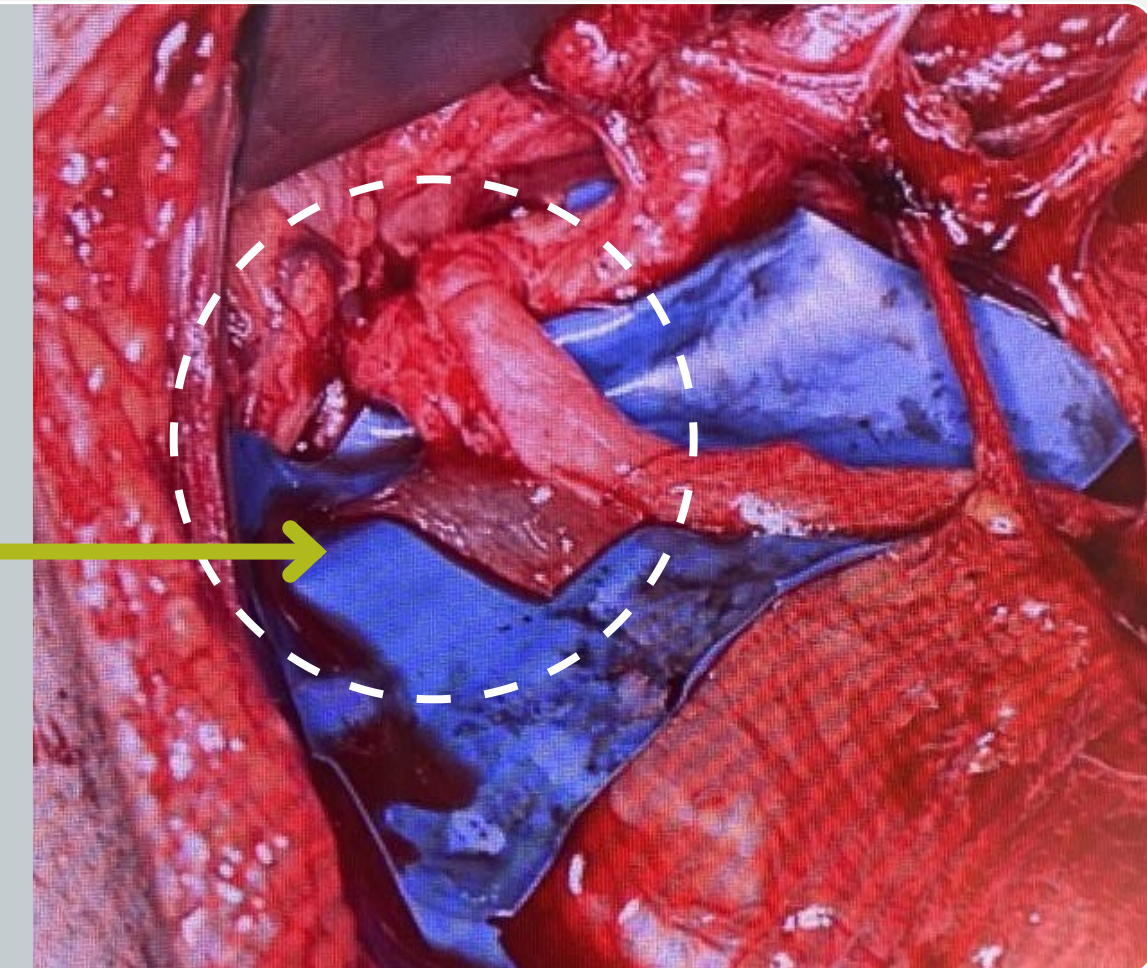
2

Co-adapting donor and recipient nerve



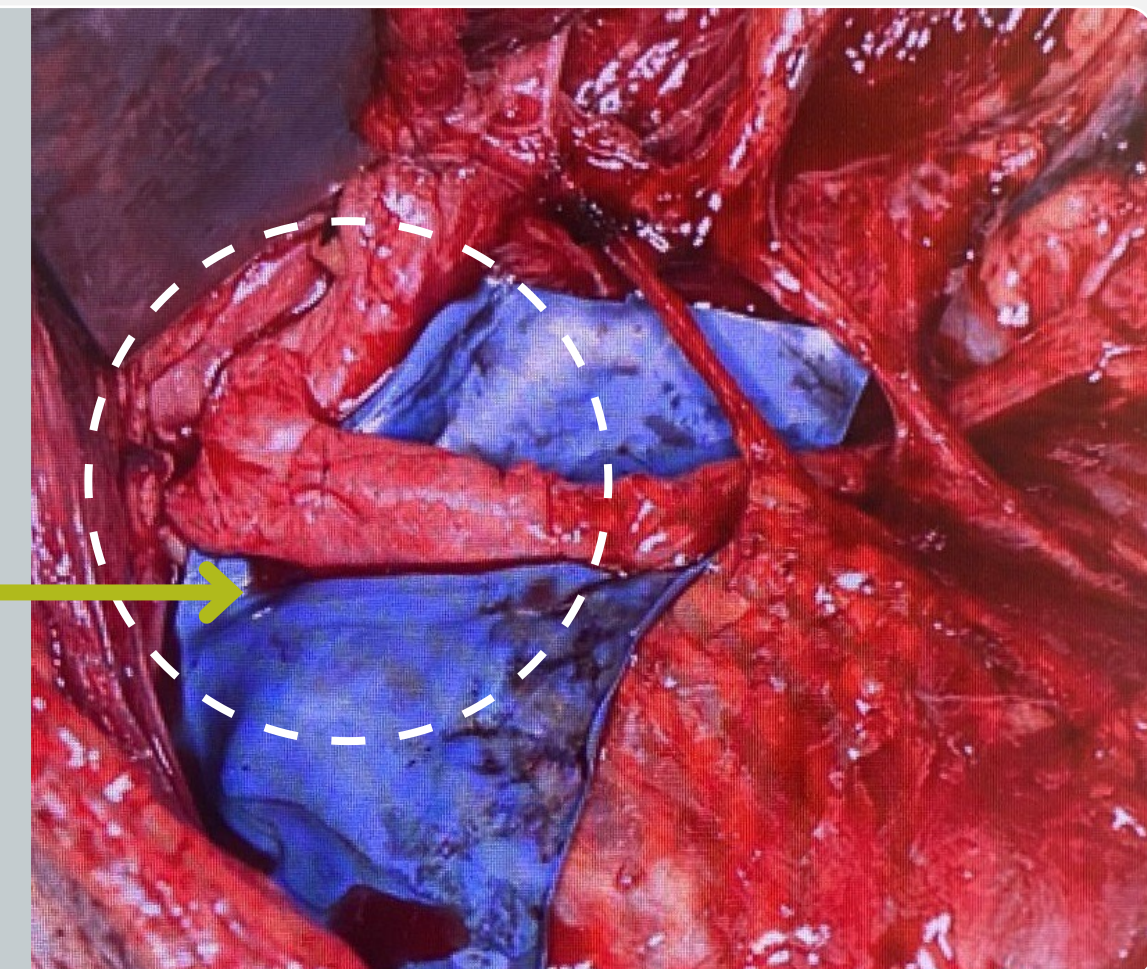
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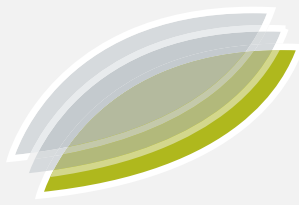
Wrapping Remplir around nerve ends to create a customised conduit



4

Remplir guides and supports nerve repair





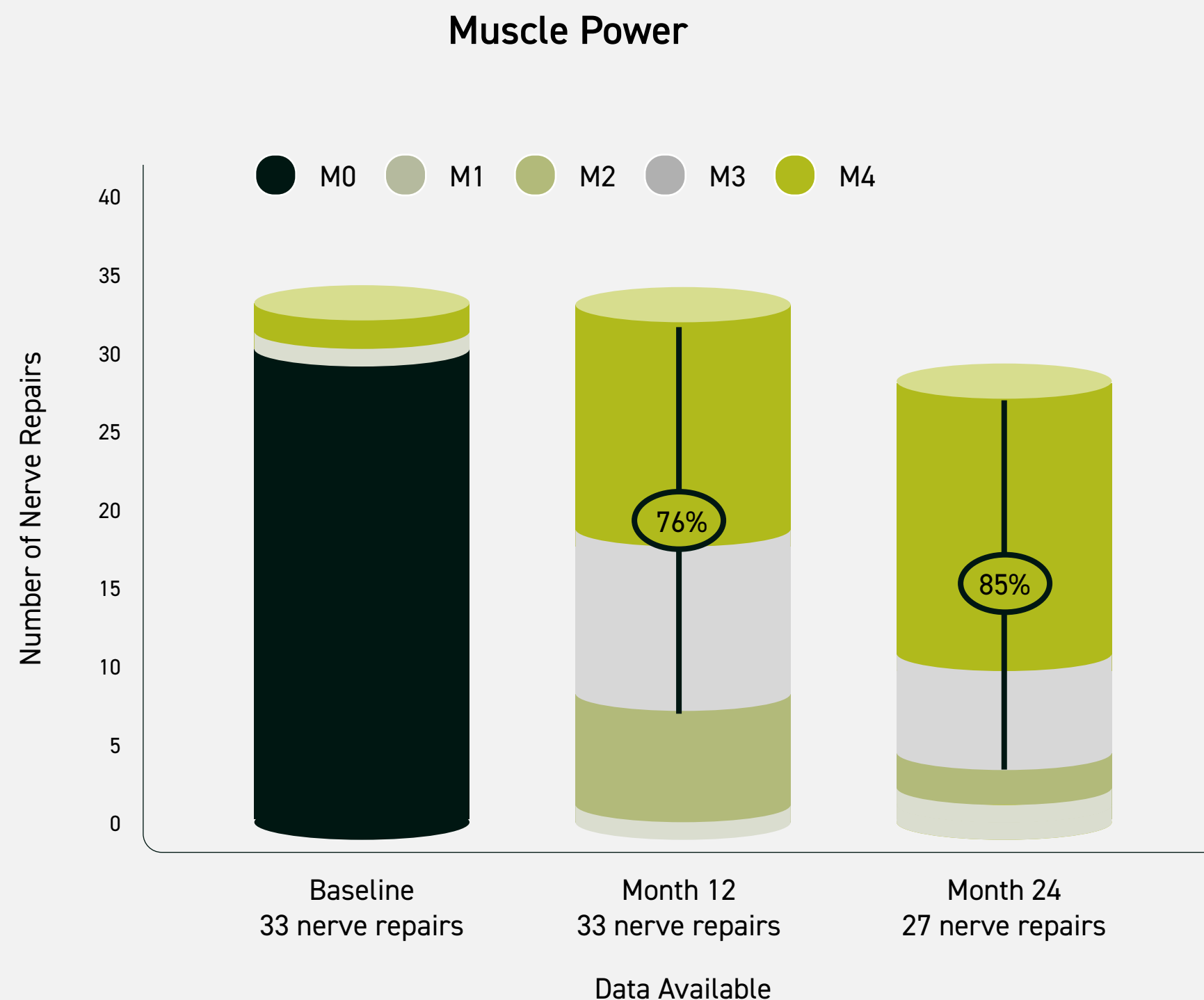
# Remplir™: compelling long term clinical results

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



**M3 and M4**  
voluntary movement with improved strength and range of motion

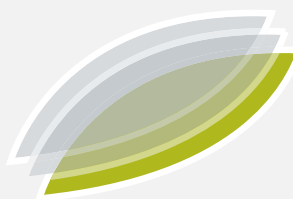
**M2**  
voluntary movement restored, limited strength and range of movement

**M0 and M1**  
no voluntary movement

## FINAL RESULTS

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





# Remplir™ case study

## Injury

- . Left hand injured skateboarding
- . Severely damaged motor nerve resulting in permanently closed fist

## Impact

- . Lost full function of hand, significantly affecting activities of daily living
- . Unable to work as a rock climber instructor

## Surgery

- . Nerve transfer using Remplir™

## Outcome

- . Complete tasks unassisted and pain free
- . Returned to rock climbing instructing and competition

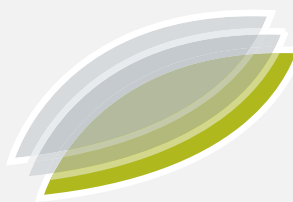


The treatment I received to repair my nerve damage has been completely life-altering...I have now made a full recovery and am now able to compete tasks unassisted and pain-free giving me back my freedom and independence.

- Damien Hall, Remplir patient



Remplir patient: Damien Hall



# Remplir™: Australian exclusive marketing and distribution partner

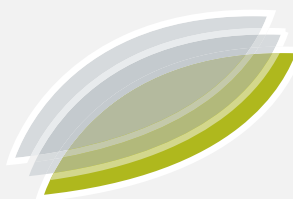
## AUS

- Device technologies has established relationships with leading plastic reconstructive and orthopaedic surgeons and an experienced sales team throughout Australia
- Orthocell will supply Device Technologies with Remplir™ products, and Device Technologies will exclusively market and distribute Remplir in Australia
- Significant Australian addressable market, with 11,780 surgical repairs of peripheral nerves completed in public and private hospitals in the 2019/20 financial year
- Reimbursement and first orders completed 4Q 2022

I am extremely excited to partner with Orthocell to bring their Australian made range of peripheral nerve repair membranes to plastic and orthopaedic surgeons around Australia. At Device Technologies we believe in investing in innovative technologies as part of a holistic portfolio that provides value to our customers and benefits their patients.

- CEO of Device Technologies,  
Mick Trevaskis








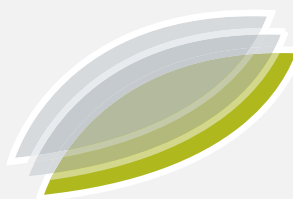
# Valuation upside

Valuation comparison to other medical device and life science companies.

**Significant upside potential for OCC.**



Market Capitalisation	\$80m	\$320m	\$1.7B
Company			
Device	Medical device and autologous injectable therapy	Autologous cell harvesting device	Synthetic scaffold device
Indication	Bone, tendon and nerve	Acute thermal burn wounds	Dermal wound repair
Stage	US Approved 2021	US Approved 2018	US Approved 2015



# Upcoming catalysts<sup>1</sup>

## Striate+™ premium periodontal membrane

MDR CE Mark certification

Academy of Osseointegration Annual Meeting

EU & AU product launch

1Q 2023

1H 2023

## Remplir™ premium nerve wrap

Australian Hand Surgery Society Annual Meeting

US pre-clinical comparator study (510k)

US KOL engagement

1Q 2023

## OrthoATI™

OrthoATI vs Surgery (RCT) last patient 12mth follow-up (elbow)

2Q 2023

1. Timelines are an estimate only and may be subject to change due to matters not under the Company's control.



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