Orthocell Presenting at Canaccord Genuity South-West Connect ASX Showcase

Perth, Australia, 28 October 2021: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce its participation in the Canaccord Genuity South-West Connect ASX Showcase, being held on 27 and 28 October 2021 at Abbey Beach Resort, Busselton.

Orthocell MD, Paul Anderson, will be presenting an updated investor presentation at the conference at **10.15am on Thursday 28th October**, to share the latest news and developments for the Company's Ortho-ATI™ and CelGro™ platform technologies. A copy of the presentation being made is attached to this announcement.

Orthocell Managing Director, Paul Anderson, said: *"We look forward to showcasing the promising and maturing investment opportunities within Orthocell's regenerative medicine product portfolio. Attendance is free, so I encourage you to either register for or live stream the event for details of the latest developments and the significant upcoming catalysts."*

Interested investors are invited to attend or live stream the event for free:

- Investors in Western Australia are invited to attend event in-person and may register here: https://www.southwestconnect.com.au
- The event is also being livestreamed live via Zoom. Connection details here: https://www.southwestconnect.com.au/livestreamswconnect
- Latest investor presentation is available on the Company's website here.

Release authorised by Orthocell Ltd Managing Director, Paul Anderson.

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advancing tissue repair & regeneration

About Orthocell Limited

Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of soft tissue injuries. Orthocell's portfolio of products include CelGro®, a collagen medical device which facilitates tissue repair and healing in a variety of dental, nerve and orthopaedic, reconstructive applications. Orthocell recently received FDA 510(k) approval for Striate+, the first application of the CelGro® platform for dental GBR applications. Striate+ is also approved in Australia (ARTG) and Europe (CE Mark) for the same. The Company's other major products are the cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), which aim to regenerate damaged tendon and cartilage tissue respectively. Orthocell is moving forward with Ortho-ATI® clinical studies designed to assist in the US (FDA) approval process and has completed its pre-IND meetings with the FDA.

For more information on Orthocell, please visit www.orthocell.com.au or follow us on Twitter **@Orthocellltd** and LinkedIn 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 is 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.

Investor Presentation

Canaccord Genuity South-West Connect ASX Showcase

October 2021

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Disclaimer

This presentation prepared by Orthocell Ltd ("Company") does not constitute, or form part of, an offer to sell, or the solicitation of an offer to subscribe for or buy any securities, nor the solicitation of any vote or approval in any jurisdiction, nor shall there be any sale, issue or transfer of the securities referred to in this presentation in any jurisdiction in contravention of applicable law. Persons needing advice should consult their stockbroker, bank manager, solicitor, accountant or other independent financial advisor.

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This document contains certain forward-looking statements which involve known and unknown risks, delays and uncertainties not under the Company's control which may cause actual results, performance or achievements of the Company to be materially different from the results, performance or expectations implied by these forwardlooking statements. The Company makes no representation or warranty, express or implied, as to or endorsement of the accuracy or completeness of any information, statements or representations contained in this presentation with respect to the Company.

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

Orthocell is a regenerative medicine company delivering breakthrough products for the treatment of serious musculoskeletal disorders.

Advanced product portfolio with significant clinical evidence	GMP-certified and TGA-licensed manufacturing capabilities	Global patent portfolio	Credentialed and highly aligned leadership	Near-term milestones
Leading de-risked portfolio of regenerative medicine products that have shown in clinical studies and real world evidence to return patients to work, activities of daily living and elite sport pain-free.	Orthocell's Good Manufacturing Practice certified and Therapeutic Goods Administration licensed manufacturing facility underpin the Company's competitive advantage and can be readily scaled to meet market demand.	Regenerative medicine manufacturing technologies, products and treatment processes patent protected in all major jurisdictions including US, EU, China, Japan and AUS.	Credentialed and highly aligned leadership Orthocell is led by an experienced Board and management team with a successful track record of developing and commercialising novel healthcare and technology products.	Multiple near-term catalysts including commercialisation of Striate+ into the US and advancing the development and approvals of breakthrough products in nerve and tendon regeneration.

$ Well-funded with $14.6m cash as at September 30, 2021

About Orthocell Ltd

Orthocell is a regenerative medicine company delivering breakthrough products that restore mobility and function.

CelGro®

Collagen medical device

- **Designed to augment surgical repair of soft tissue**
- **Represents a breakthrough** in soft tissue reconstruction
- **Multiple applications** in nerve, tendon, and bone repair
- **Demonstrated superior clinical performance** when compared to the current market leading product
- **Initial US, EU and AUS approval achieved**

Ortho-ATI™

Cell therapy for tendon regeneration

- **First injectable clinical stage cellular therapy** for treatment of chronic tendon injuries
- **Multiple tendon sites** including shoulder, elbow, hip, hamstring and Achilles
- **Addressing a significant unmet clinical need** for a safe, effective and non-surgical solution
- **Ortho-ATI v Corticosteroid (RCT) study results on track for Q4 CY2021**

Significant market opportunity

At the forefront of a large and growing market opportunity in regenerative medicine in the musculoskeletal space.

CelGro® – – – – – – – – – **Ortho-ATI®** – – – – – – – **Total addressable market**

>US$10bn

>US$7.7bn

>US$17 billion p.a.

Driven by rising rate of musculoskeletal disorders and demand for efficient and cost-effective treatments.

1. Addressable markets include US, Japanese, European and Australian markets, Ortho-ATI™ addressable market includes the following indications: tennis elbow, rotator cuff, gluteal, patellar, hamstring and Achilles. CelGro® addressable market includes the following indications: dental, rotator cuff and nerve

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US Strategic Focus

Advanced product portfolio with near term milestones and emerging pipeline

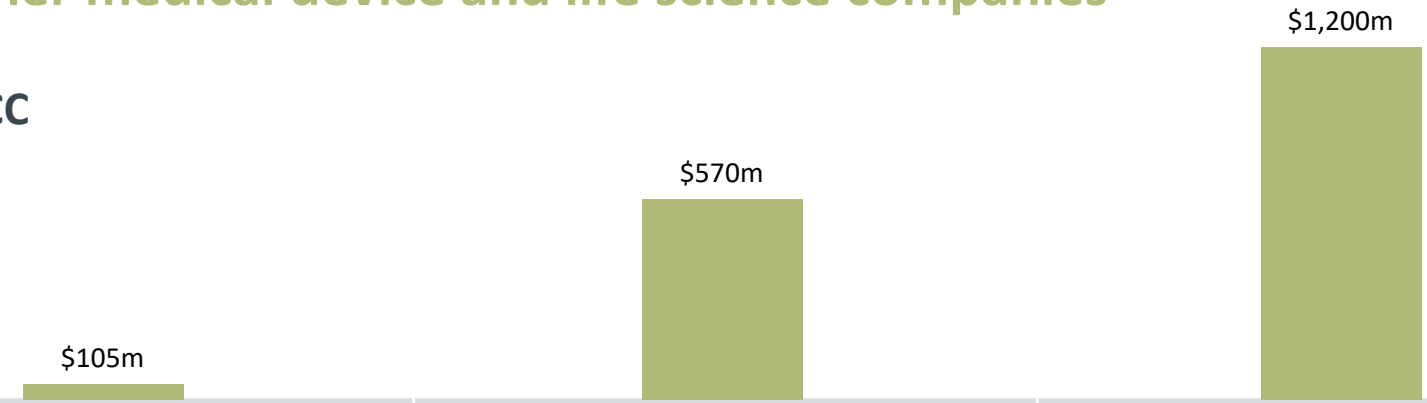
Product	Application	Clinical Development Phase	US Regulatory Phase			Upcoming Catalysts
			Design Trial	Implement Trial	Approved	
CelGro® Medical Device	Striate+[1]					**US market entry** - engage marketing and distribution partner
	Remplir[2]					**US commercialisation strategy** - finalise US regulatory/reimbursement study
	SMRT Rope (Ligament replacement)					**Commence pre-clinical study** - ACL repair
Ortho-ATI™ Cell Therapy	Rotator cuff					**Release RCT results** - Ortho-ATI v corticosteroids
	Lateral epicondyle					**Finish recruitment** - Ortho-ATI v surgery

1. Approved in the US, AUS and EU
2. Application submitted for AUS approval

Valuation upside

Valuation comparison to other medical device and life science companies

Significant upside potential for OCC



Market Capitalisation	**$105m**	**$570m**	**$1,200m**
Company	ortho·cell	avita medical	PolyNovo®
Device	Autologous Injection and medical device	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

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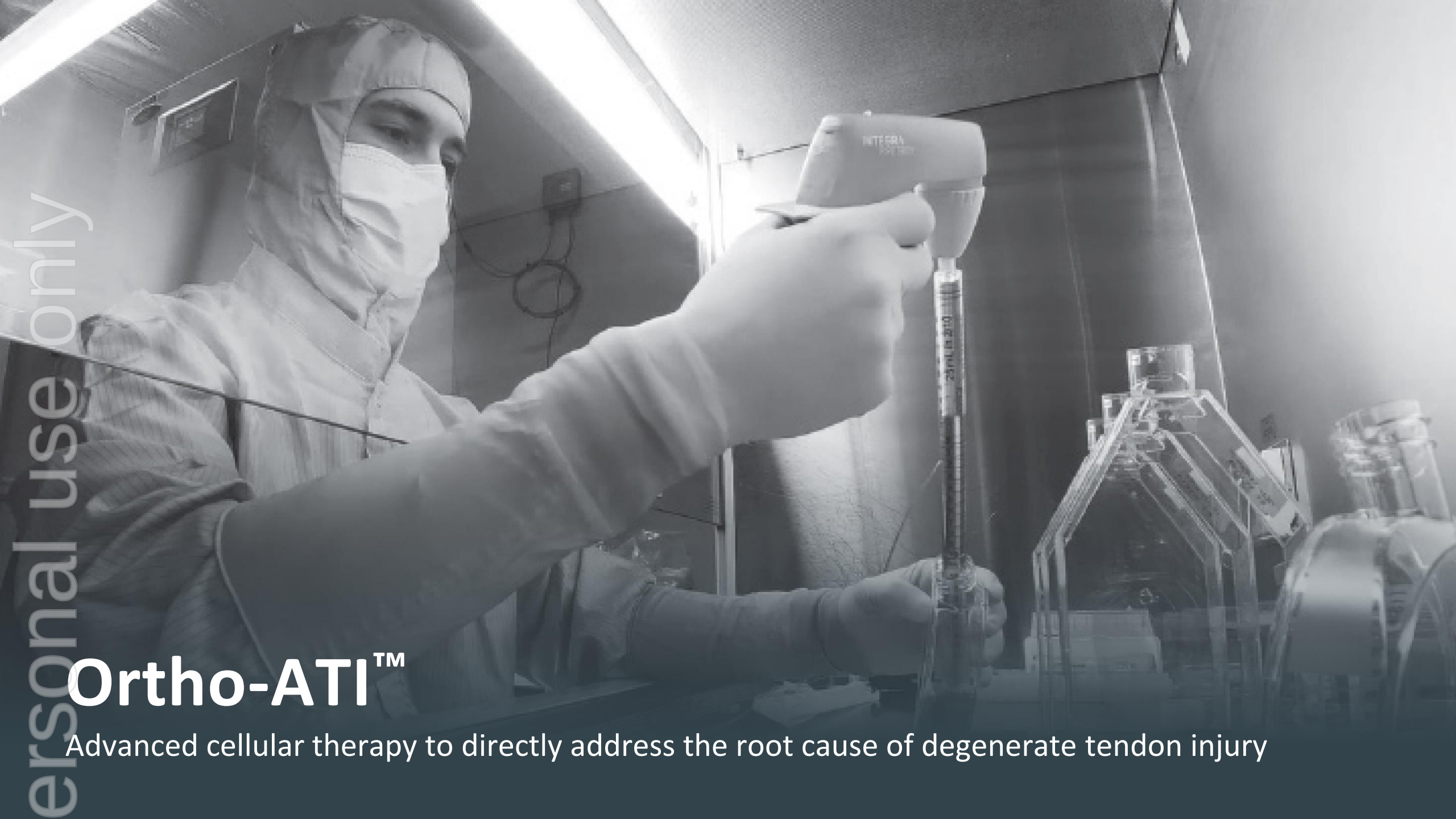


Ortho-ATI™

Advanced cellular therapy to directly address the root cause of degenerate tendon injury

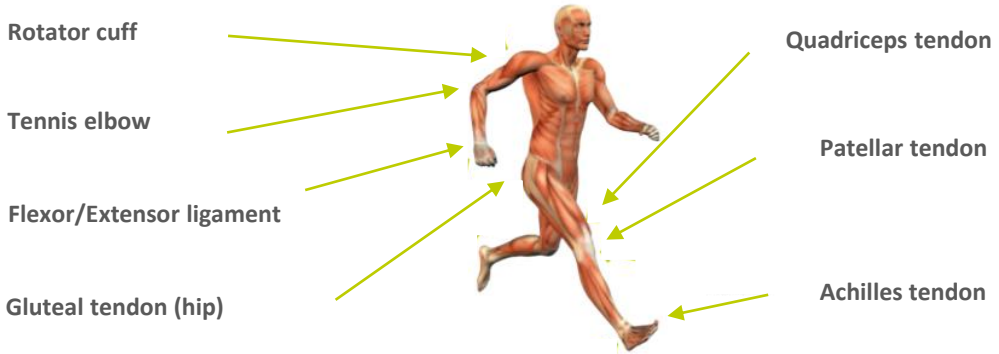
Chronic tendon injury: significant unmet clinical need

Chronic tendon injury is a common and painful disorder affecting millions of people every year with no effective, non-surgical treatments currently available

Significant unmet clinical need

- **Millions of people suffer** from chronic tendon injury every year
- **Traditional repair outcomes suboptimal**
  i.e. PRP, corticosteroids and surgery
- **Chronic tendon injury significantly reduces** the ability of patients to work, exercise, and perform routine daily activities

Multiple tendon injury sites



There are no 'non-surgical' treatments currently available to treat chronic tendon injury

Ortho-ATI™: a global clinical first

Injectable cell therapy that returns patients to the workplace, recreational activities and elite sport pain-free, with minimal down-time.

Ortho-ATI™ is a novel treatment

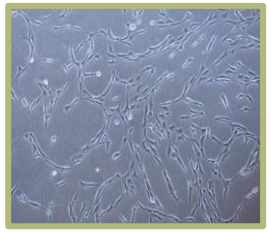
- ✓ **Breakthrough** in regenerative medicine directly addressing the root cause of injury
- ✓ **Replenishes degenerative tissue** with healthy mature tendon cells, accelerating regeneration of tendon tissue
- ✓ Extensive clinical validation - **over 700 patients treated** with Ortho-ATI™ to date
- ✓ **Optimised manufacturing capabilities**: GMP-certified and TGA-licensed facility[1] and PPI[2] release criteria in place

Two stage, minimally invasive procedure

1. Biopsy procedure

Healthy tendon cells removed via minimally invasive procedure

Tenocyte (cell) cultivation



Healthy cells grown at Orthocell's laboratory

2. Tenocyte (cell) implantation

Ultrasound-guided implantation of healthy cells

4-5 week end-to-end process

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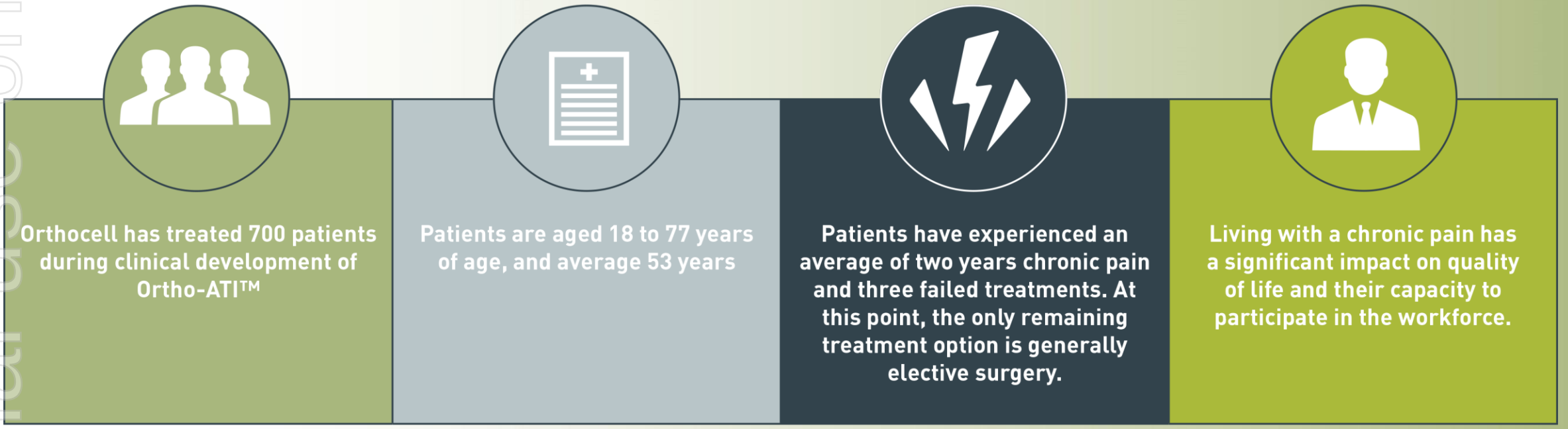
1. GMP: good manufacturing practices; TGA: Therapeutic Goods Administration
2. PPI: purity, potency and identity

Ortho-ATI™ : compelling clinical evidence



References for the above data, as at June 20 2020 : 1. Ortho-ATI workers compensation study; 2. Ortho-ATI clinical studies; 3. Annual Quality Survey.

Ortho-ATI™ : reducing pain

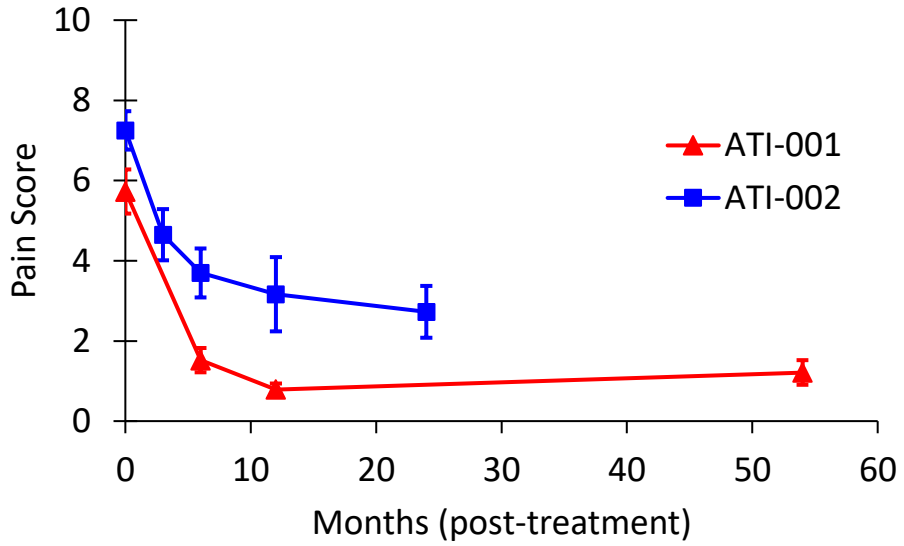
Ortho-ATI™ treatment provides a meaningful and lasting reduction in pain

Clinical studies of Ortho-ATI™

Clinical Study Results

- **Reduction in pain** - Patients in clinical studies of Ortho-ATI™ for lateral epicondylitis (ATI-001) and gluteal tendinopathy (ATI-002) experienced a significant reduction in pain within 6 months of Ortho-ATI™ treatment

- **Sustainable outcome -** The improvements in pain were maintained in all studies, for up to 4.5 years post-treatment in the case of ATI-001, and two years post-treatment in ATI-002



Pre-and post-treatment VAS pain score in clinical studies of Ortho-ATI for lateral epicondylitis (ATI-001), gluteal tendinopathy (ATI-002).

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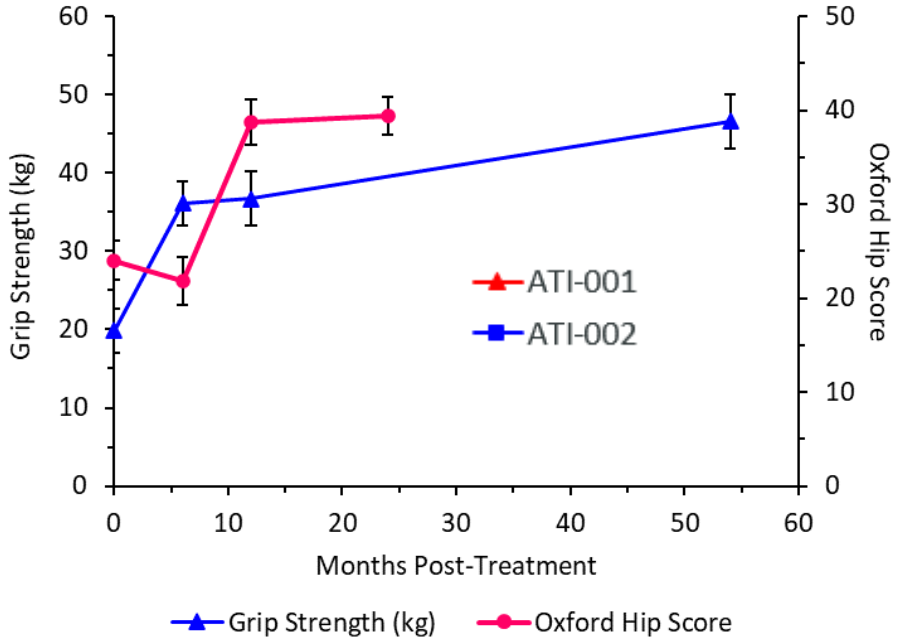
Returning to function

Ortho-ATI™ treatment improves strength and function

Clinical studies of Ortho-ATI™

Clinical study results

- **Long term increases in strength -** Average grip strength for patients in clinical study of Ortho-ATI™ for lateral epicondylitis (ATI-001) was 19.85kg at baseline, improving to 37.38kg at one year and 46.60kg at final follow-up.
- **Sustainable increases in function** – Average Oxford Hip Score for patients in clinical study of Ortho-ATI™ for gluteal tendinopathy (ATI-002) improved from 24.0 points at baseline to 38.8 points at 12 months and 39.4 at 24 months post-treatment.



Pre-and post-treatment disability and function scores in clinical studies of Ortho-ATI for lateral epicondylitis (ATI-001), gluteal tendinopathy (ATI-002).

Ortho-ATI™ : Upcoming US milestones

Orthocell is focused on completing current clinical studies[1] and preparing for US market entry

Randomised shoulder tendon clinical study results

- **First high-quality RCT completed** in the Rotator Cuff indication
- **Results expected in Q4 2021**
- **US$2.8b market opportunity,** approx. 470,000 rotator cuff patients per year in the US alone

US Next Steps

- **Well-positioned to become the first FDA approved injectable cell therapy in orthopaedics** for the treatment of chronic tendon injuries
- **US regulatory strategy** to be pursued to enable rapid approval by FDA

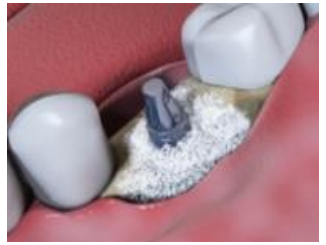
Results expected in Q4 2021

Mark LeCras, Ortho-ATI patient

1. Orthocell is undertaking two RCT's. The first is targeting the rotator cuff indication comparing Ortho-ATI to corticosteroids (30 patients) – results are due in Q4, 2021. The second is targeting the elbow (LE) comparing Ortho-ATI to surgery (50 patients) with recruitment 92% complete.

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 space from ingrowth of gingival tissue, to provide a favourable environment for osteogenesis and to assure reliable formation of high-quality bone.
- **Approved in the US, EU and AUS**



1. Preparation of repair site. Defect site is filled with void-filler

2. Striate+ placed over defect and implant abutment installed

3. Wound closure

4. Crown placement 3-6 months later

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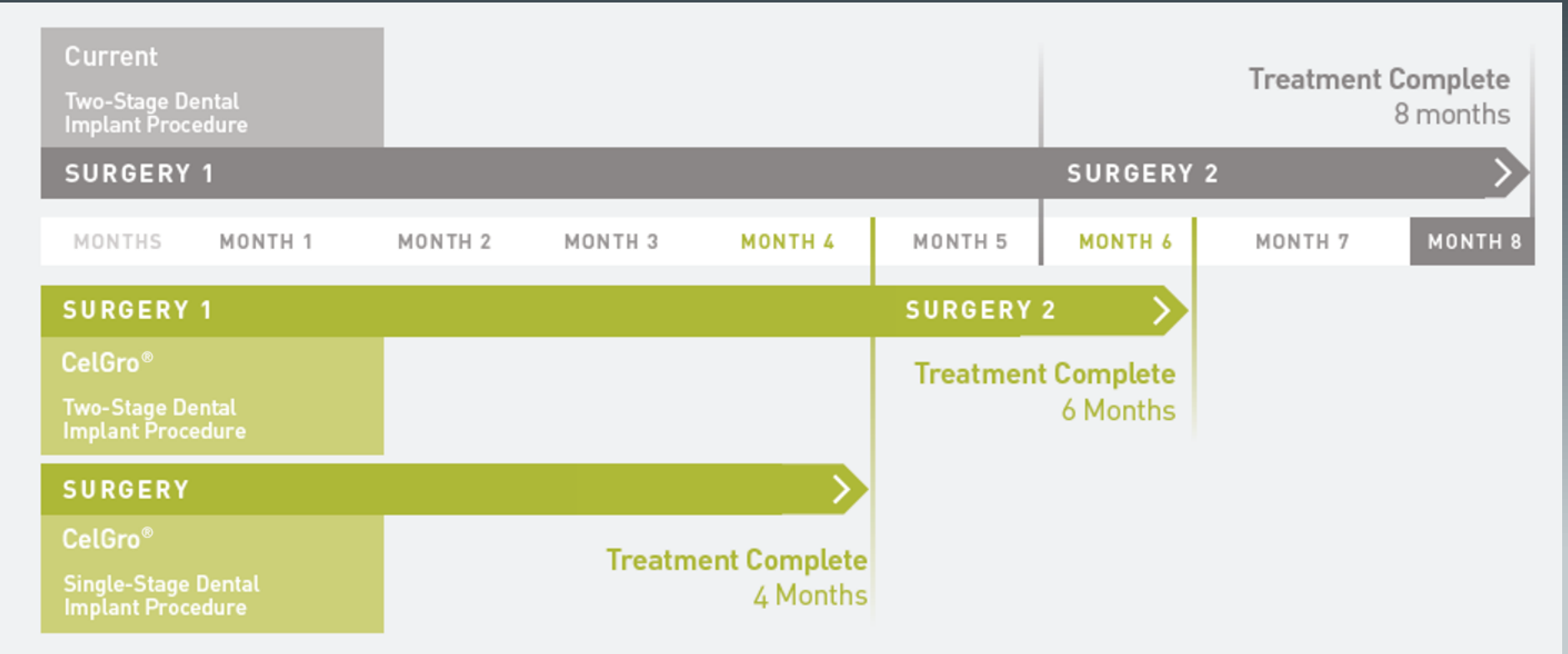
Striate+™: better results sooner

Patients treated using Striate+™ successfully generated enough new bone to stabilise their implants and complete their treatment in approximately 4 months, compared to the 8 months required for standard dental implant treatment[1].



1. 1. CG-002 Study of CelGro membrane in guided bone regeneration around exposed dental implants. ACTRN12615000027516. TGA trial number 2015/0171

Striate+™: world class KOL group

USA / AUS


Justin Bonaventure
Louisiana


Anthony Feck
Kentucky

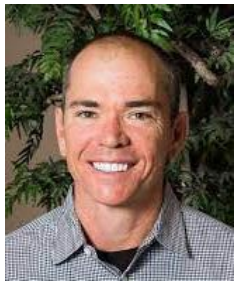

Kathy Frazar
Texas


Maria Lopez Howell
Texas


David Little
Texas


Marc Nevins
Massachusetts


Sammy Noumbissi
Maryland


John Phillips
Oklahoma


Pamela Ray
Texas


Amanda Seay
South Carolina


Lou Shuman
Washington DC


Brent Allan
Australia

UK / EU


Nick Fahey
Reading


Elaine Halley
Scotland


Céline Higton
London


Giuseppe Luongo
Rome


Sinead McEnhill
Northern Ireland


Massimo Simion
Milan

Striate+™: path to partnering

Executing a strategy to engage high quality partners to manage the distribution and marketing of Striate+™ - *10% market share equates to AU$35M revenue per annum*[1]

Path to partnering	Market development activities
Clinician advocacy program	• Product advocacy and education led by Orthocell's KOL's with significant digital following (e.g. interactive webinars and podcasts) • Increase key dental editorial coverage • Support key dental associations (UK – association of dental implantology, ADI) and education academies (UK – Fitz Fahey Academy) • Inclusion in dental education books written by Orthocell's KOL's • Seattle study club program – 270 affiliates globally, 5,700 dental surgeons, specialist GP's and periodontists, 8,000+ EDM database
Build awareness amongst leading clinicians and potential partners	• Digital marketing engagement with clinicians • Increase key dental editorial coverage • Clinical conference participation • Targeted clinician workshops • Direct product representation
Grow body of clinical evidence and product adoption	• Gain reimbursement from private insurers • Data generation e.g. post-market clinical follow ups • Publication in high impact journals

1. Orthocell's estimate based on 350,000 units sold @ competiive transfer prices per product size in target jurisdictions (US, EU and AU).

Remplir™

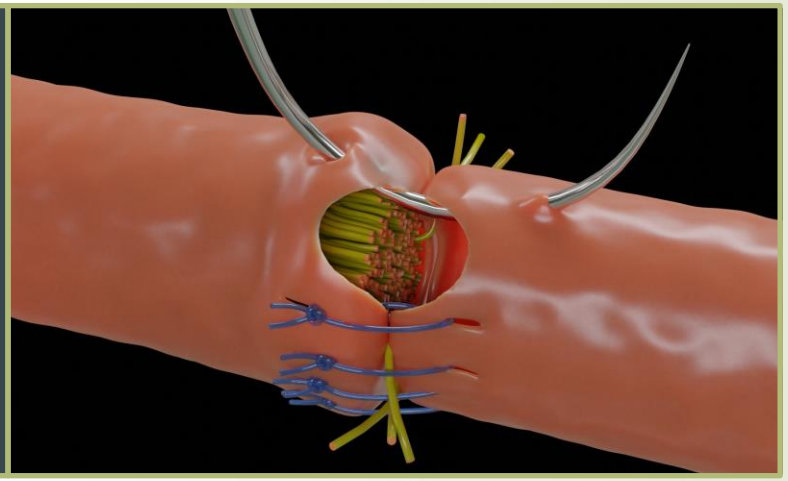
Revolutionising nerve repair

Traditional repair outcomes are suboptimal

Using traditional repair methods for crushed/severed nerves can be ineffective and unpredictable in restoring function to affected limbs.

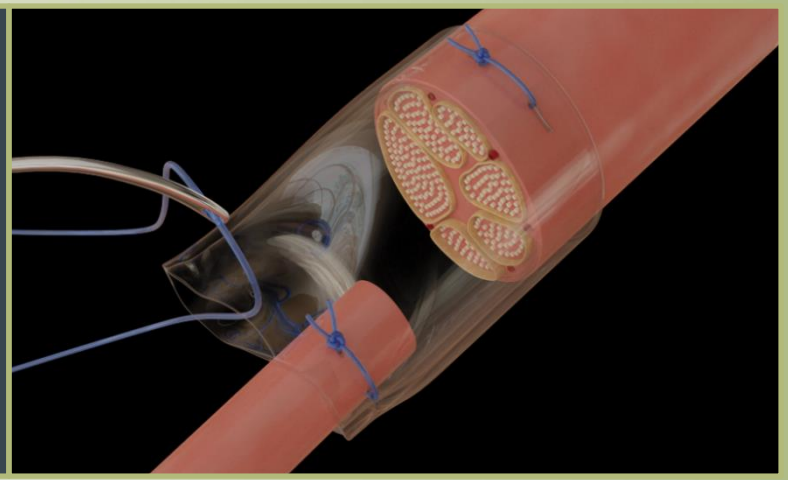
Direct suture

Tension can result in buckling and misdirection of regeneration nerve fibres



Rigid hollow tube

Rigid tubes are limited in use and efficacy and can result in a 34-57% failure rate[1]



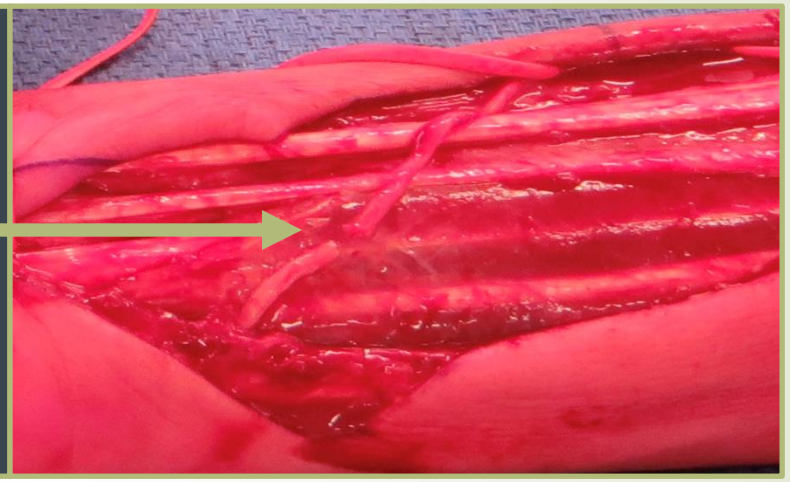
Strong demand for a medical device that enables surgeons to perform complex surgical repairs efficiently with better results

1. Weber, et al. A randomized prospective study of polyglycolic acid conduits for digital nerve reconstruction in humans. PlastReconstrSurg. 2000; 106(5): 1036-1045.

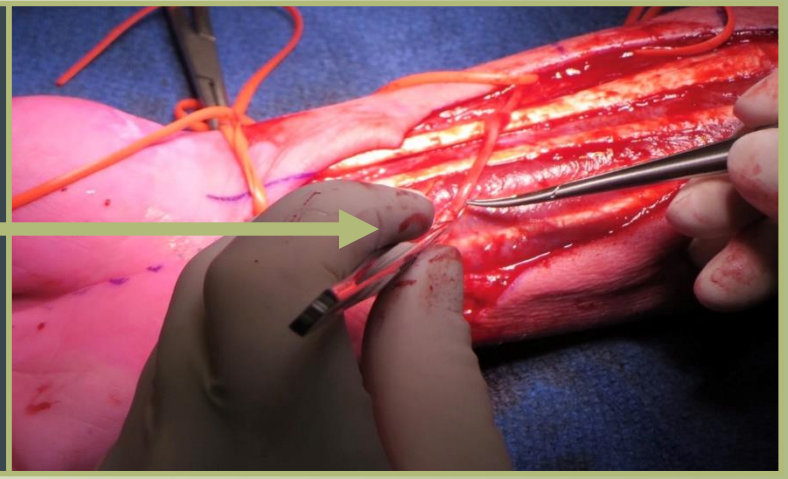
Remplir™: nerve transfer surgery

Remplir is a versatile medical device that can be used to repair, protect and cap nerve injuries to return function to impaired or paralysed muscles.

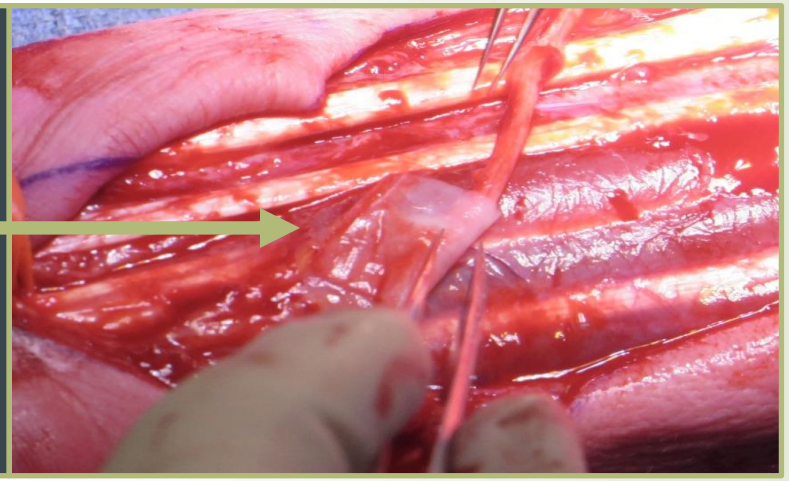
1
Transferring superficial radial to ulnar nerve



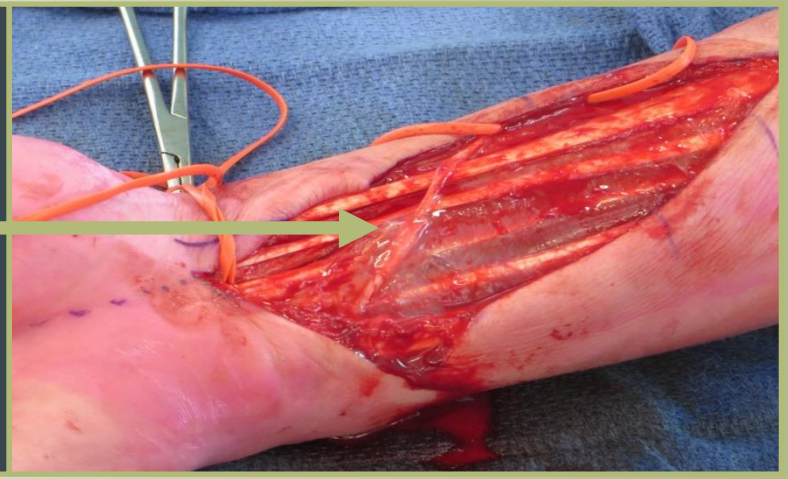
2
Placing a stay suture to oppose nerve ends



3
Wrapping Remplir around nerve ends to create a customised conduit



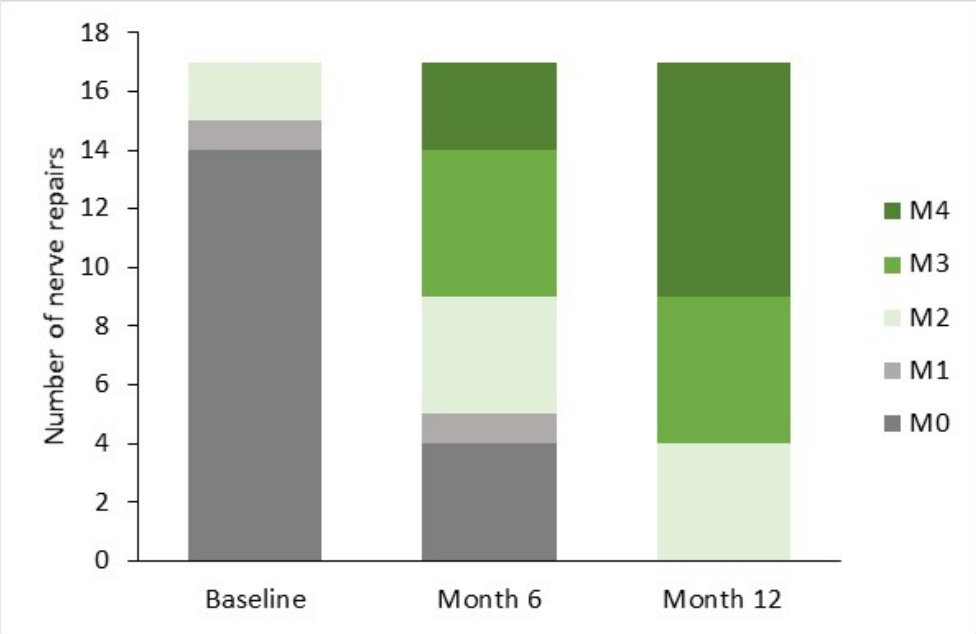
4
Remplir guides and supports nerve repair



Remplir™: compelling long term clinical results

Quadriplegic patients regained voluntary muscle movement within 12 months

Figure 1 – Recovery of Muscle Power in Patients with Quadriplegia



Grade 3 and 4 – voluntary movement with improved strength and range of motion. **Maximum level of recovery expected.**

Grade 2 – voluntary movement restored, limited strength and range of movement.

Grade 0 or 1 – no voluntary movement.

- 75.8% of all nerve repairs (25 of 33) in the clinical study resulted in functional recovery (MRC grade 3 or 4[1])
- Quadriplegic patients regain independence - brushing teeth, drinking from a cup, and transferring into and out of a wheelchair without assistance

Leading Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O'Beirne, said *"We are now seeing a consistent return of arm and hand function following nerve transfer surgery with Remplir. The quadriplegic patient results are particularly promising, with improved results at 12 months post treatment compared to the literature.* ***Remplir is increasing the success rate and efficiency of nerve transfer surgery****."*

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.

Remplir™: nerve repair market opportunity

Remplir's addressable market in peripheral nerve repair is estimated to be worth more than >US$7.5 billion per year.

Orthocell is focused on executing its regulatory program to gain approval in AUS and the US.

Clinical trial patient Adrian Walsh (far left) wheelchair rugby national champion – following treatment with Remplir

1. Addressable markets include US, Japanese, European and Australian markets . Referenced papers were used to derive specific assumptions in the procedure potential estimates. Papers used include both U.S. and OUS databases and studies.

Upcoming catalysts[1]

Ortho-ATI

Ortho-ATI v Corticosteroid (RCT) study results	4Q CY2021
Ortho-ATI v Surgery (RCT) rec't complete (estimate)	1Q CY2022

Striate+ premium periodontal membrane

Expand manufacturing capacity	4Q CY2021
First US KOL order	4Q CY2021
Engage US marketing and distribution partner/s	CY2022

Remplir premium nerve wrap

Australian market authorisation estimate	CY2022
Final 24-month results of all patients in the nerve regeneration study	2Q CY2022

Pipeline

Collagen rope pre-clinical study	CY2022

1. Timelines are an estimate only and may be subject to change due to matters not under the Company's control such as COVID-19 mitigation measures.

CEO and Managing Director, Paul Anderson

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