Remplir™ Sales Training - USA

Module 3

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This training includes general information on nerve repair that may not apply to Remplir.

Please refer to Remplir's IFU.

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Learning Objectives

- Gain in-depth knowledge of Orthocell's collagen-based nerve repair solution, **Remplir**.
- Understand Remplir's unique features (biocompatibility, resorbability, ease of use).
- Learn how to position Orthocell's solutions in terms of value (better outcomes, surgeon/patient benefits).

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Paradigm shift in design and application

Remplir is engineered with Orthocell's proprietary SMRT™ manufacturing technology to:

- Create optimal healing environment
- Be easy to handle and suture-sparing
- Protect from scarring, adhesion and inflammation
- Resorb and integrate into host tissue

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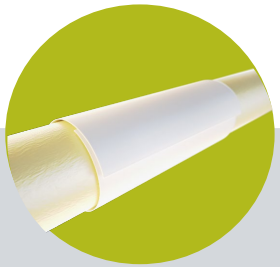
One wrap, multiple applications

Remplir's flat sheet design enables the broadest application in nerve repair procedures such as connecting, protecting and capping

Connect

Enables tensionless repair of transected nerve injuries, supporting direct repairs with or without grafts, as well as nerve functioning muscle transfers.[1,2]



Protect

Helps manage non-transected nerve injuries by reducing the risk of adhesion formation and supporting smooth nerve gliding in conditions such as carpel and cubital tunnel syndrome.[1]

Cap

Prevents neuroma regrowth after resections of a terminal neuroma, or formation of new neuromas post amputation,[1]

1. Data on file
2. O'Beirne, A., *et al*. (2024). "Reconstruction of Upper Extremity Peripheral Nerve Injuries Using an Epineurial-Like Collagen Device—A Prospective Clinical Study." Journal of Reconstructive Microsurgery Open 09(01): e78-e88.

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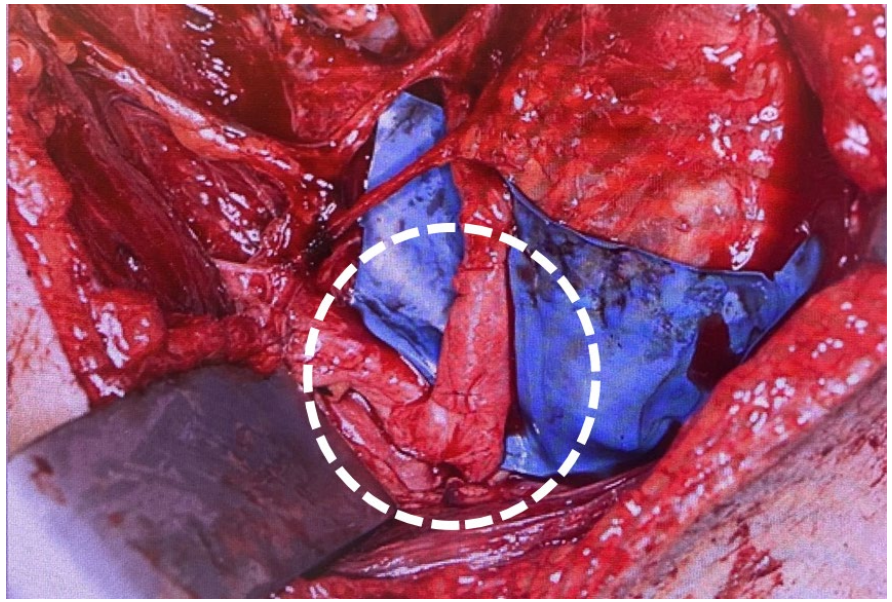
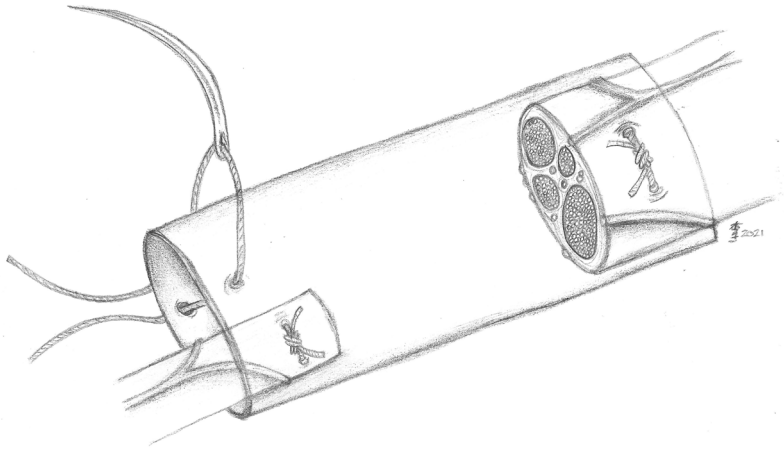
Additional advantages of Remplir

Seals closely around coaptation site even where there is significant size mismatch. Elastic properties prevent nerve compression during healing



Other products are too rigid: a good seal cannot be achieved when there is size mismatch (increasing the risk of neuroma formation and poor treatment outcomes), and can also cause nerve compression during healing



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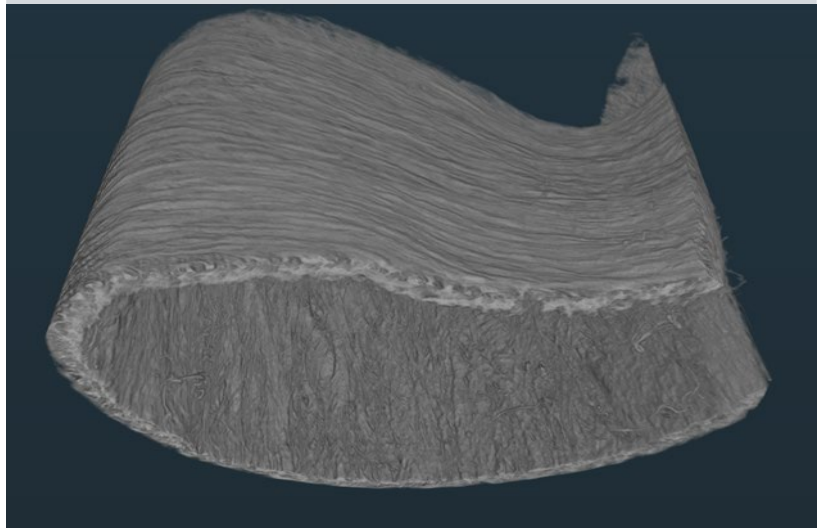
Introducing Remplir

An absolute collagen membrane

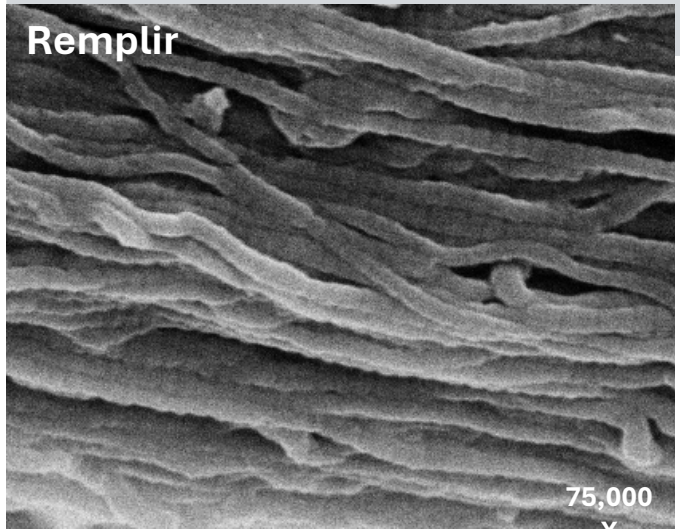
Similar structure to native epineurium:

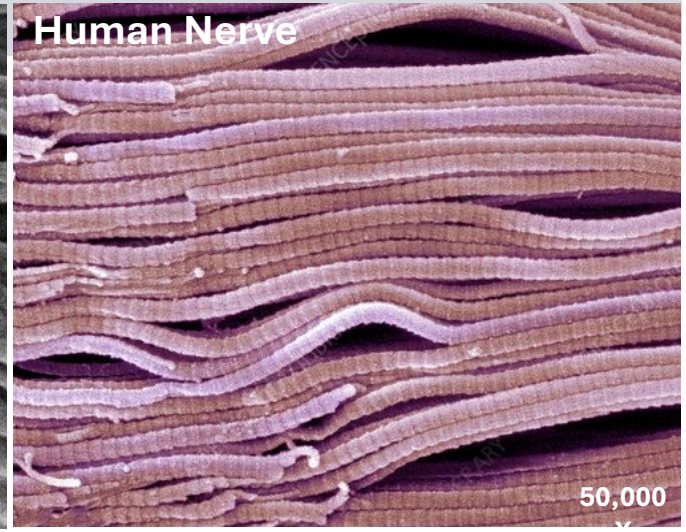
- Type I collagen with rough and smooth sides



Individual collagen fibers with characteristic D-banding pattern showing similarity to human collagen:

- Native collagen structure preserved after SMRT™ manufacturing process





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Highly organized structure

Clinical application:
Place rough side towards nerve for adhesion, with smooth outer surface allowing surrounding structures to glide

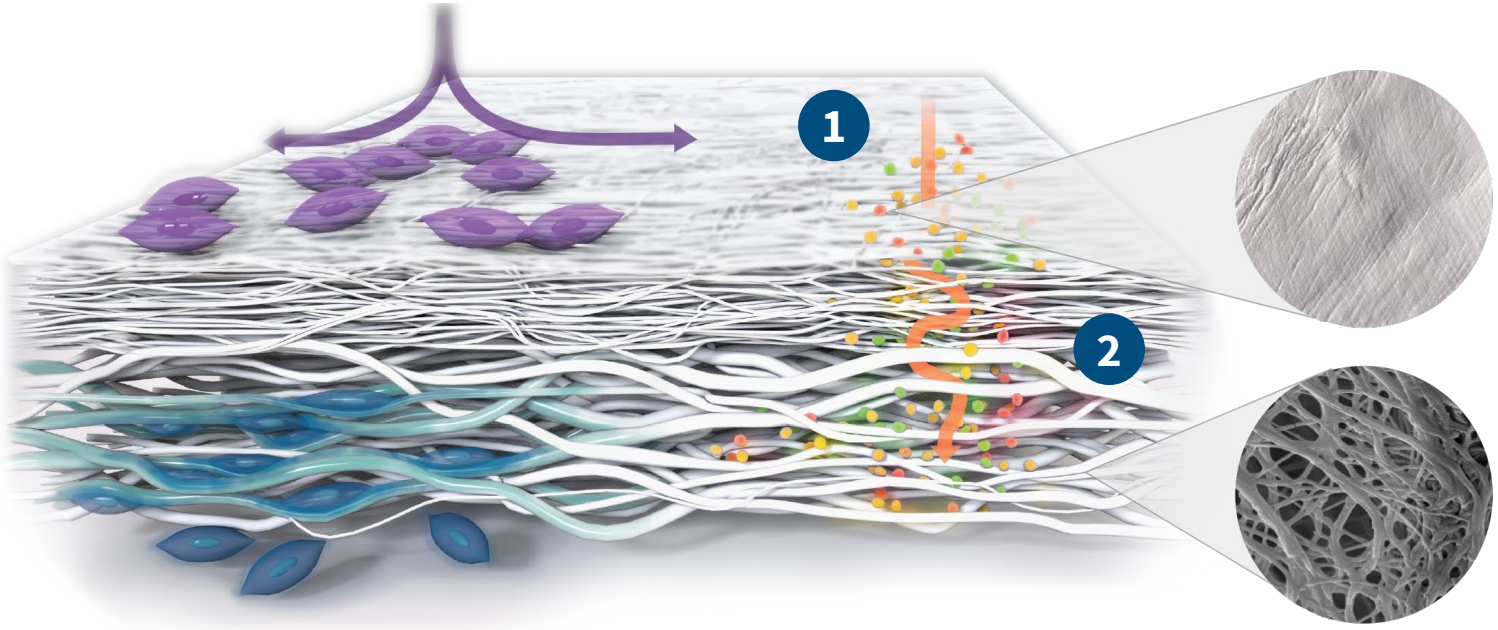
Note:
Rough side faces up in packaging

1 Smooth outer surface

- Densely packed collagen bundle
- Cell occlusive surface minimizes the risk of adhesions and facilities nerve gliding[1]
- Permits passage of fluids and nutrients while retaining neurotrophic factors[1]

2 Rough inner surface

- Loosely distributed collagen bundles
- Creates favourable microenvironment for nerve healing[1,2]



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Importance of SMRT™ manufacturing

Removes porcine DNA and cellular components, resulting in a highly purified, compatible Type I collagen membrane which mimics nerve epineurium

- ✓ **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

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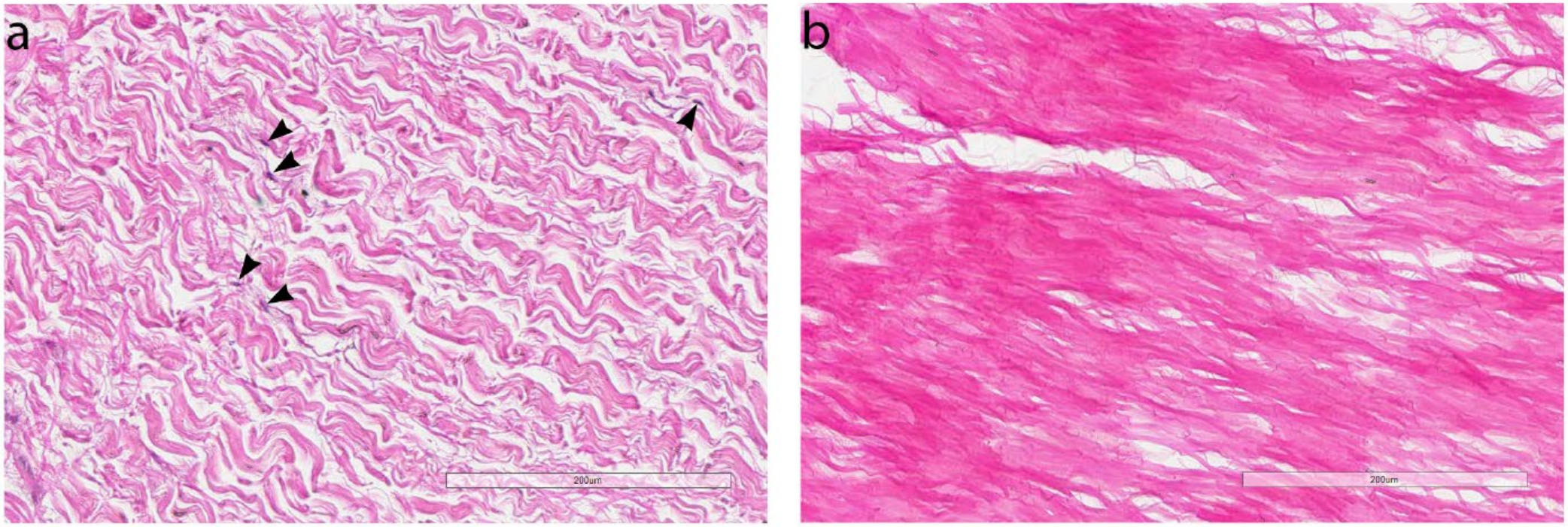
Principles of Nerve Repair

No DNA detected via picoGreen assay and real-time PCR

Remplir raw material with abundance of cells

SMRT manufacturing process

Remplir, acellular



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Remplir: Created with exceptional handling in mind

Elastic and naturally pliable

Enables easy, tension-free nerve coaptation

Type 1 collagen with a thin flat profile designed to mimic epineurium

Allows for free gliding of the repaired nerve

High mechanical strength

Visibility of repaired nerve

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Remplir: A Non-Permanent Barrier

Breakdown process:
Collagen breaks down into amino acids, supporting natural tissue replacement

Host response:
Integration of Remplir collagen fibers into epineurium without inflammatory response

Factors influencing degradation:
No cross-linking in manufacturing process resulting in preservation of natural collagen architecture

Remplir's advantage:
Designed for predictable resorption and seamless tissue integration

Material fate:
Fully integrates into the epineurium in 4-6 months

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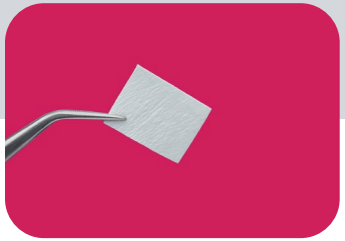
Product range



15x20mm

20x30mm

30x40mm

40x50mm

Nerve diameter			
Up to 3mm	Up to 5mm	Up to 10mm	Used for longitudinal wrapping
Note: Smooth side away from nerve			
Order codes			
ON-152	ON-203	ON-304	ON-405

IFU and storage requirements

Indication For Use:

- Remplir is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

Storage Requirements:

- Store Remplir in its original packaging at room temperature (15-25°C / 59-77°F) in a dry place.
- Remplir is supplied in a double PETG/Tyvek blister pack contained in a labelled cardboard box
  - Remplir product is always “Rough Side Up” in the package

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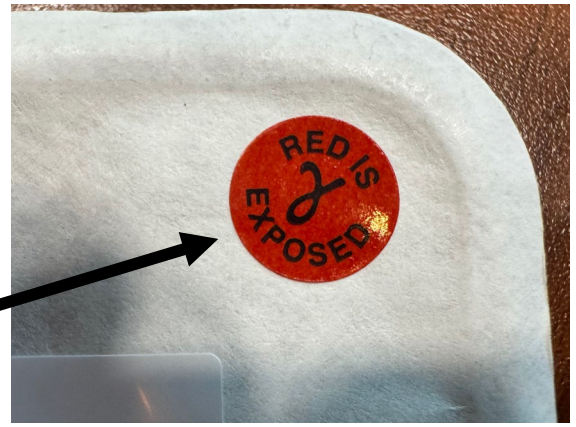
Packaging



Note: The red sticker indicates that the product has undergone **sterilization**.

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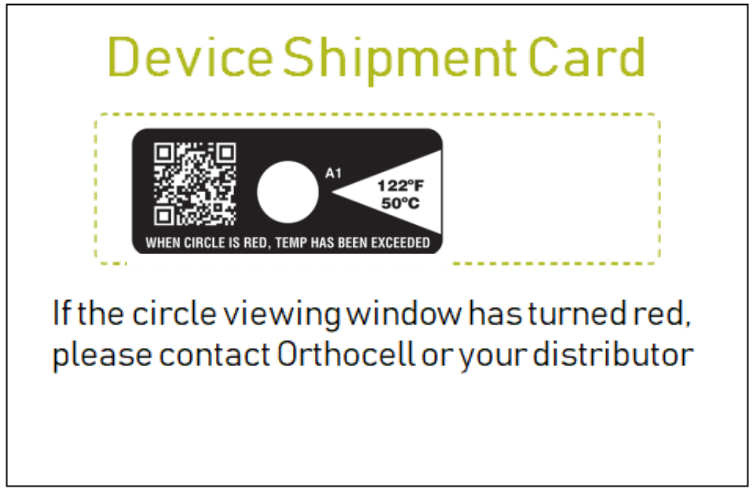
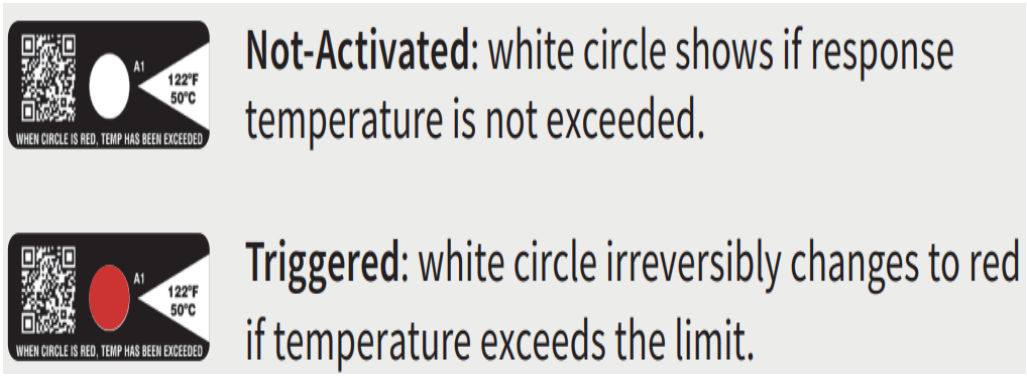
Device shipping temperature label

- The temperature label will indicate if the device has been exposed to temperature out of range
- Please contact customer care immediately if “Triggered”





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Summary

Description

- Soft, flexible, resorbable collagen wrap placed around an injured nerve
- Compression-free protection to the nerve, generating an ideal microenvironment to aid nerve healing
- SMRT™ manufacturing process maintains the natural collagen structure for optimal tissue integration, leaving no DNA or other porcine cellular components in the tissue
- Semi-permeable: allows nutrient exchange and reduces the risk of formation of adhesions and scar tissue

Mechanism of Action – "Mimics Epineurium"

- Creates a protected neurotrophic environment
- Reduces risk of adhesions and scar tissue
- Provides a scaffold for regeneration of healthy nerve tissue

Product Benefits & Differentiators

- Biocompatible and ***fully resorbable***—no chronic inflammation
- ***Ideal biomaterial*** for regeneration of healthy nerve tissue
- Versatility: can be used for wrapping, protecting, and capping nerve ends

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Summary

A versatile, single solution device

- Connect, Protect, and Cap

Demonstrated clinical efficacy

- Compelling 85% success rates from Remplir™ nerve repair study published in peer-reviewed clinical journal
- Consistent and predictable outcomes in peripheral nerve repair surgeries

Exceptional handling characteristics

- Thin, strong and flexible flat sheet

Native collagen architecture

- Similar to normal human epineurium, making it an ideal biomaterial

Biocompatible and non-immunogenic

- SMRT manufacturing process produces a pure collagen medical device with no impurities that may cause an immune reaction

Healing microenvironment

- Promotes nerve gliding through the surrounding soft tissues and reduces the risk of adhesions

Fore more information, head to the website: remplir.orthocell.com

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Testimonials

Dr. Alex O’Beirne, Perth, Australia

Leading Australian orthopaedic nerve specialist and clinical trial lead

“Remplir facilitates tensionless repair and can prevent regenerating nerves being compressed or trapped by scar tissue. 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.”

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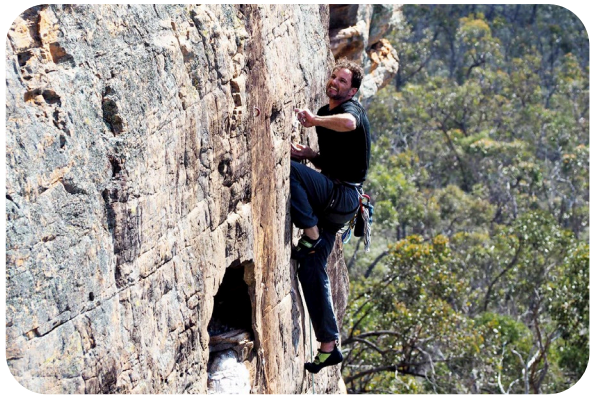
Testimonials



Damien Hall, Remplir patient

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

Adrian Walsh, Remplir patient

“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.”

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