

Remplir™

Description

Remplir™ is a sterile, resorbable collagen membrane intended for use in peripheral nerve repair.

Remplir™ is a highly purified collagen membrane of porcine origin produced using quality-controlled manufacturing processes. Raw materials are sourced exclusively from within Australia and collected at certified facilities under strict quality controls. The collagen is purified to remove materials that may elicit antigenic reactions. Remplir™ is manufactured without crosslinking.

Properties

Remplir™ is designed to protect the injured nerve following repair and provide a favourable environment for nerve regeneration to occur. Remplir™ permits passage of fluids but acts as a barrier to cellular ingrowth.

Remplir™ is soft and pliable with a smooth outer surface and rough inner surface, providing excellent handling characteristics. Remplir™ is wettable and may be sutured in place, if required.

Animal studies have shown that Remplir™ is still visible 5-13 weeks after implantation but is fully resorbed through normal physiological processes within 26 weeks.

Indications for use

Remplir™ is indicated for the repair of peripheral nerve injuries.

Directions for use

These directions are intended as a general guide and are not intended to supersede professional clinical judgement.

1. Follow standard procedures for nerve exposure and mobilisation. Perform neurolysis and/or coaptation of nerve ends if required.
2. Trim Remplir™ to required size.
3. Hydrate if required with sterile saline or other physiological solution.
4. Wrap Remplir™ around the site of nerve injury/repair without constricting or compressing the nerve.

5. If necessary, fix Remplir™ in place with atraumatic sutures.
6. Follow standard post-operative procedures and care. Application of Remplir™ does not modify post-operative treatment.

Limitations of use

Contraindications

The use of Remplir™ in patients with known sensitivity to porcine-derived materials or collagen is contraindicated.

Adverse reactions

Possible complications of peripheral nerve surgery include pain, infection, swelling, inflammation, foreign body sensation and changes in nerve sensitivity (paraesthesia or hyperaesthesia) at the implant site.

Adverse reactions to porcine-derived collagen nerve wraps such as Remplir™ are extremely rare. Patients should be monitored closely in the initial post-operative period to identify and address any adverse reactions that may occur.

Precautions

Safety and efficacy for use in patients <18 years cannot be assured.

Peripheral nerve repair with Remplir™ should only be undertaken by suitably qualified surgeons.

Storage and handling

Store Remplir™ in its original packaging at room temperature (15-25°C) in a dry place.




















How supplied

Remplir™ is supplied in a double PETG/Tyvek blister pack contained in a labelled cardboard box.

Remplir™

Size	Code
15x20mm	ON-152
20x30mm	ON-203
30x40mm	ON-304
40x50mm	ON-405

Symbols used in labelling

-  Use-by date
-  Batch code
-  Catalogue number
-  Distributor
-  Sterilized using irradiation
-  Do not resterilize
-  Do not use if package is damaged
-  Double sterile barrier system
-  Keep away from sunlight
-  Keep dry
-  Temperature limit (15-25°C)
-  Do not re-use
-  Consult instructions for use
-  Unique Device Identifier
-  Manufacturer
-  Date of manufacture
-  Contains biological material of animal origin
-  Medical device
-  Device size



Manufacturer

Orthocell Ltd, Building 191,
Murdoch University
South Street
Murdoch WA 6150
Australia



Distributor

Device Technologies
Australia Pty Ltd
1 Garigal Road
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device.com.au

If you have any concerns or questions about this product please contact Orthocell:

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