

Remplir™

DESCRIPTION

Remplir™ is a sterile, implantable, biocompatible, resorbable, collagen membrane intended for use in the management of peripheral nerve injuries. Remplir™ is a single-ply sheet of porcine-derived, non-crosslinked collagen.

Remplir is supplied as a single device in a double PETG/Tyvek blister pack in a labelled cardboard box. Remplir is available in 4 size variants for the convenience of clinicians (15mm x 20mm, 20mm x 30mm, 30mm x 40mm, 40mm x 50mm). All size variants are identical in composition and function.

INDICATIONS FOR USE

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

PROPERTIES

Remplir™ is designed to protect the injured nerve following repair and provide a favorable environment for nerve regeneration to occur.

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.

Remplir™ can be cut to the desired size and wrapped around the injured nerve in either its wet or dry form.

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 mobilization. Perform neurolysis and/or tensionless coaptation of nerve ends if required. If present, the gap between nerve ends should not exceed 20mm.
2. Trim Remplir™ to desired size, if required.
3. Hydrate if desired with sterile saline or other physiological solution. Device is full hydrated when uniformly translucent.
4. Wrap Remplir™ around the site of the nerve repair, with the rough surface of the device facing the nerve.
5. Fix Remplir™ in place with sutures, if required. Do not compress the nerve.
6. Follow standard post-operative procedures and care. Application of Remplir™ does not modify post-operative treatment.

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 (paresthesia or hyperesthesia) 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

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

Remplir™ should be used with caution in infected regions.

Do not use if the product package is damaged or opened.

STORAGE AND HANDLING

Store Remplir™ in its original packaging at room temperature (15-25°C /59-77°F) in a dry place.

HOW SUPPLIED

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





















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

MANUFACTURER



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

SYMBOLS USED IN LABELLING

 Use-by date	 Batch code	 Catalogue number	 Date of manufacture	 Sterile using irradiation	 Double sterile barrier system
 Do not re-sterilize	 Do not re-use	 Do not use if package is damaged and consult Instructions for use	 Contains biological material of animal origin	 Keep dry	 Keep away from sunlight
 Temperature limit	 Consult instructions for use	 Medical Device	 Unique Device Identifier	 MR Safe	 Prescription only
 Device size	 Manufacturer				