

Remplir™

DESCRIPTION

Remplir™ is a sterile, implantable, biocompatible, resorbable, collagen membrane intended for use in the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue. 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 in which there has been no substantial loss of nerve tissue.

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 coaptation of nerve ends if required.
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.

Note: The maximum amount of Remplir™ that can be implanted in a single surgical procedure is 200cm². This is equivalent to: 66 x (15x20mm) or 33 x (20x30mm) or 16 x (30x40mm) or 10 x (40x50mm)

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

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