

You have received this information leaflet because your surgeon has recommended that Remplir™ should be used as part of your nerve repair surgery. Remplir™ is a nerve wrap used to help your nerve injury to heal.

WHAT IS A NERVE WRAP FOR?

Nerve repair surgery aims to re-connect a nerve that has been cut or badly crushed so that a new nerve grows in its place. A nerve wrap provides protection to the injured nerve while it heals. It does this by preventing other tissues growing where the new nerve should grow.

WHAT IS REMPLIR™?

Remplir™ is a type of nerve wrap. Remplir™ forms a protective layer over the repair site while the new nerve grows.

Remplir™ is made of collagen. Collagen is a common substance in humans found mainly in skin, bones, muscles and tendons. Remplir™ is made of collagen from pigs, but has been treated so that it is safe to use in people.

Remplir™ is wrapped around your damaged nerves during nerve repair surgery. Around 3 to 6 months later, the nerve wrap will have completely dissolved. You have been provided with a Patient Implant Card to keep, which includes the Lot Number of the nerve wrap you received, so you can get more information about the nerve wrap used in your surgery if you need to. Your treating surgeon also keeps a record of the Lot Number of your nerve wrap.

WHAT SHOULD I EXPECT FOLLOWING MY TREATMENT?

Your surgeon will give you instructions on what to do after your nerve repair surgery. It is important to keep the repair site clean to avoid infection and to keep the area undisturbed while it heals. Your surgeon will advise you what you need to do after your surgery and any rehabilitation you may need.

ARE THERE ANY RISKS TO USING REMPLIR™?

Like any surgery, there are risks associated with nerve repair surgery. The main risks are infection, pain, the feeling that there is something under the skin, and numbness or sensitivity at the repair site. Your surgeon will provide you with more information about the risks associated with nerve repair surgery.

There are few risks related to using Remplir™ in nerve repair surgery. Remplir™ should not be used in anyone with an allergy to collagen, or an allergy to pigs. These allergies are rare, but if you are worried, ask your surgeon for more information. Remplir™ can be removed if necessary.

WHEN TO GET HELP

If you experience any symptom that you are concerned about, contact your surgeon immediately. They will tell you how best to manage your symptoms and if any other action needs to be taken.

A serious reaction to Remplir™ should be reported to:

The Manufacturer

Orthocell Ltd

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

The Distributor

Device Technologies Australia Pty Ltd

1 Garigal Road
Belrose NSW 2085 Australia
device.com.au

The Australian Government Regulator

Therapeutic Goods Administration (TGA)

PO Box 100
Woden ACT 2606 Australia

Go to www.tga.gov.au and follow the instructions on how to complete the online adverse event form, or phone the TGA on **1800 809 361**.