

You have received this information leaflet because your dentist, orthodontist or surgeon has recommended that you have guided bone regeneration (GBR) or guided tissue regeneration (GTR) as part of your dental treatment.

What is Guided Bone Regeneration and Guided Tissue Regeneration (GBR/GTR)?

Teeth are held in place in your jaw by bone and gums. For many different reasons, the bone holding your teeth in place can break down or become weak and need repair. The gums can also be damaged by infection or injury. So that your teeth stay healthy and stable, guided bone regeneration (GBR) and guided tissue regeneration (GTR) is used help heal your bone or gums.

What is CelGro™ Dental?

CelGro™ Dental is a type of patch used in GBR and GTR. CelGro™ Dental forms a protective layer over the treatment site while the new bone forms.

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

The CelGro™ Dental patch is implanted into your gum during your procedure and will have dissolved completely by about 6 months after your GBR or GTR treatment. You have been provided with a Patient Implant Card to keep which includes the Lot Number if you would like more information about your implant. Your treating dentist also keeps a record of the Lot Number of your implant.

What should I expect following my treatment?

Your dentist will give you instructions on what to do after your GBR or GTR treatment. The aim is to keep the treatment area clean and undisturbed while it heals. This may involve using a medicated mouthwash, specific instructions on how and when to brush your teeth, or avoiding certain foods or drinks. It is very important that you follow the instructions provided by your dentist carefully.

Are there any risks to using CelGro™ Dental?

There are very few risks related to using the CelGro™ Dental patch. CelGro™ Dental should not be used in anyone with an allergy to collagen, or an allergy to pigs. These allergies are very rare, but if you are worried ask your dentist for more information. The CelGro™ Dental patch can be removed if necessary.

Are there any risks to having GBR or GTR treatment?

Like any surgery, GBR/GTR has some risks, like infection, pain, bleeding or swelling. These risks are usually not serious and your dentist can give you information about these risks and how to avoid them.

Some medical conditions might affect healing after GBR/GTR, such as:

- diabetes, auto-immune disease;
- use of warfarin/blood thinning medication;
- anti-inflammatory medication;
- previous radiation therapy; or
- heavy smoking

Heavy smoking is known to affect normal healing and your dentist may recommend that you stop smoking or reduce how much you smoke before you have GBR/GTR.

It is important that you tell your doctor about any health condition you have, and all the medicines you are taking, before you have your procedure.

When to get help

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

A serious reaction to CelGro™ Dental should be reported to:

The Manufacturer

Orthocell Ltd

Building 191 Murdoch University
South Street
Murdoch WA 6150
Australia
Email: info@orthocell.com.au
Phone: 08 9360 2888

and

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.