

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

What is Guided Bone Regeneration (GBR)?

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) is used help heal your bone or gums.

What is Striate+™?

Striate+™ is a type of patch used in GBR. Striate+™ forms a protective layer over the treatment site while the new bone forms.

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

The Striate+™ patch is implanted into your gum during your procedure and will have dissolved completely by about 6 months after your GBR treatment. You have been given a Patient Implant Card to keep which includes the Lot Number if you would like more information about your implant. Please keep the Patient Implant Card somewhere safe so that you can check it if needed. You will need to keep the Patient Implant card for 1 year after your treatment. Your treating dentist also keeps a record of the Lot Number of your implant. An explanation of the symbols used on the Patient Implant Card are provided below.

What should I expect following my treatment?

Your dentist will give you instructions on what to do after your GBR 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 Striate+™?

There are very few risks related to using the Striate+™ patch. Striate+™ 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 Striate+™ patch can be removed if necessary.

Are there any risks to having GBR treatment?

Like any surgery, GBR 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. Occasionally, the wound may open slightly and expose the Striate+ patch. If this happens you should contact your dentist for instructions on what to do.

Some medical conditions might affect healing after GBR, 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.

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.

Striate+™ is MRI (Magnetic Resonance Imaging) safe as it is composed of materials that are electrically non-conductive, non-metallic and non-magnetic.

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 Striate+™ should be reported to the distributor:

BioHorizons

2300 Riverchase Center
Birmingham AL 35244 USA
www.biohorizons.com

Other contacts:

Manufacturer:

Orthocell Ltd

Building 191 Murdoch University
South Street, Murdoch WA 6150
Australia
Email: info@orthocell.com.au

European Authorised Rep.:

MDSS GmbH

Schiffgraben 41,
30175 Hannover, DE
Email: info@mdssar.com
Phone: +49 511 6262 8630

Swiss Authorised Rep.:

MDSS CH GmbH

Laurenzenvorstadt 61,
5000 Aarau, CH
Email: info@mdssch.com
Phone: +41 79 853 3664

European Importer:

MedEnvoy Global BV

Prinses Margrietplantsoen 33 – Suite 123
2595 AM, The Hague, NL
Phone: +31 70 326 2148

Swiss Importer:

MedEnvoy

Gottharstrasse 28
6302, Zug, CH
Phone: +41 41 562 01 42

Symbols used on the Patient Implant Card



Manufacturer



Device Name



Batch code



Unique device identifier



Date of implantation



Healthcare centre or doctor



Patient Name



Manufacturer's website address