

Patient Information Leaflet

Geistlich Bio-Gide® / Geistlich Bio-Gide® Perio / Geistlich Bio-Gide® Compressed / Geistlich Bio-Gide® Forte / Geistlich Bio-Gide® Shape

Name of the material/device and available sizes:

Geistlich Bio-Gide®

13 mm x 25 mm

25 mm x 25 mm

30 mm x 40 mm

Geistlich Bio-Gide® Perio (provided with sterile stencil templates)

16 mm x 22 mm

Geistlich Bio-Gide® Compressed

13 mm x 25 mm

20 mm x 30 mm

Geistlich Bio-Gide® Forte

13 mm x 25 mm

25 mm x 25 mm

20 mm x 30 mm

30 mm x 40 mm

Geistlich Bio-Gide® Shape

14 mm x 24 mm



The product illustration is exemplary for the product line.

Note: For simplicity, all variants of the product line Geistlich Bio-Gide® are collectively referred to as “Geistlich Bio-Gide®” throughout this document.

Intent and indications for using this material/device

Geistlich Bio-Gide® is intended to be used in surgical treatment of bone and soft tissue defects in the mouth, jaw, and face. It can be used in dental defects, as well as defects and deformities of the face and jaw.

Patient-specific operating instructions

Geistlich Bio-Gide® is a single-use implantable membrane. It resorbs naturally within several months. There are no patient-specific instructions or procedures. After surgery, please attend all follow-up appointments as instructed by your surgeon. This helps reduce the risk of complications and supports the best possible outcome.

Before treatment, you are advised to tell your surgeon if you:

- have any allergies, especially to collagen or porcine (pig) products
- have a wound that is currently infected
- have an ongoing infection in your mouth or at the planned surgery site (for example, periodontitis)
- have diabetes or other metabolic conditions (for example, thyroid disease or osteomalacia)
- are on long term corticosteroid treatment
- have problems with your immune system
- have had radiotherapy
- smoke heavily
- take medicines or have health conditions that can slow healing
- are pregnant or lactating (producing breast milk)

Please contact your surgeon immediately if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. Please call an ambulance or attend the nearest hospital Emergency Department in the event of a life-threatening event.

How does Geistlich Bio-Gide® work?

Geistlich Bio-Gide® is derived from veterinary-certified porcine (pig) tissue. It is made of collagen, a naturally occurring protein. It is carefully purified and well tolerated by the human body. No chemicals were added, no special treatments (e.g. cross-linking) done, and no components left over that can be dangerous for the patient.

The material has two different sides: a) a rough surface which is placed against the bone, and b) a smooth surface facing the soft tissue (gums). Bone takes longer to heal than soft tissue. Geistlich Bio-Gide® acts as a barrier giving new bone time to form. By this separation more and better bone can be formed. Geistlich Bio-Gide® also supports blood flow into the newly forming bone, an important factor in the natural healing process. After wetting, the membrane attaches well to the bone. However, the surgeon may choose to use pins or sutures to hold the material in place.

Geistlich Bio-Gide® resorbs naturally within several months. The resorption time can depend on different factors such as exposure of the membrane, presence of infection, blood supply, and general health conditions (comorbidities). The material is provided sterile.

Potential side effects that can occur

Geistlich Bio-Gide® is designed and manufactured in a way that ensures patient safety and avoids compromising the clinical condition of the patient. Potential risks and complications that could occur are addressed in this patient information leaflet.

Very rarely, allergic reactions to Geistlich Bio-Gide® may happen. There are also other possible side effects after surgery, such as swelling at the surgical site, soft tissue shedding (sloughing), bleeding, local tissue inflammation / tissue death, infection, bone loss, pain, or wound reopening.

Potential interaction(s) of Geistlich Bio-Gide® with other equipment and recommended precautions.

Geistlich Bio-Gide® is a non-metallic material. It cannot be heated or act as a magnet during magnetic resonance (MRI) examination. Geistlich Bio-Gide® has not been specifically studied in the MR environment. In some circumstances, metal hardware may have been employed to secure Geistlich Bio-Gide® in position. Please consult with the radiologist/radiographer if this is the case or if you are unsure if metal hardware has been used. In such circumstances, the radiologist/radiographer may need to seek further information from your surgeon and/or consider other scanning methods; the risk of MR scanning in such situations could result in patient injury.

Notice regarding any serious incident that occurs in relation to this material/device

Report any serious incident (e.g. serious deterioration of a patient's health) that occurs in relation to these devices to the manufacturer (Geistlich Pharma AG) and to the Therapeutic Goods Administration (TGA).

The Therapeutics Goods Administration (TGA) website

<https://www.tga.gov.au/>

The legal manufacturer's address and website

Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland
www.geistlich-pharma.com

The distributor's address and website (Australian sponsor)

Geistlich Pharma Australia Pty Ltd.
The Zenith – Tower A, Level 21
821 Pacific Highway
Chatswood NSW 2067
Australia
info@geistlich.com.au
www.geistlich.com.au

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