

► Patient Information Leaflet

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

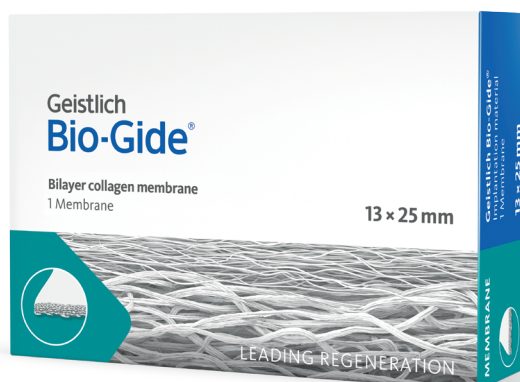
Name of the material/device and available sizes:

Geistlich Bio-Gide®:
13 x 25 mm / 25 x 25 mm / 30 x 40 mm

Geistlich Bio-Gide® Perio:
16 x 22 mm

Geistlich Bio-Gide® Shape:
14 x 24 mm (pre-shaped)

Geistlich Bio-Gide® Compressed:
13 x 25 mm / 20 x 30 mm



The product illustration is exemplary for the product family

Intent and indications for using this material/device

Geistlich Bio-Gide® is a resorbable material that is surgically placed into the body to assist with bone and soft tissue healing. This material, which is porcine (pig) derived, is commonly used in the treatment of tissue deficiencies in the jaws and facial region. The material acts as a temporary barrier, thereby ensuring early separation of the healing bone from the overlying soft tissues. This temporary separation promotes improved bone quantity and quality during healing. Provided active infection is not present at the surgical site, this material can be safely used in most patients. However, there is no data available on use of this material during pregnancy and lactation. Until such time that additional data becomes available, it is recommended that Geistlich Bio-Gide® be avoided in pregnant and lactating women.

Patient-specific operating instructions

As Geistlich Bio-Gide® is an implantable material that resorbs and disappears naturally over time (several months), there are no patient-specific operating instructions or maintenance procedures required for this material. It is important that all post-operative instructions and precautions advised by the surgeon are followed and that any post-operative follow-up appointments are attended. This will help reduce the risk of any post-operative complications and maximise the likelihood of a successful clinical outcome. Please contact your surgeon immediately for advice if any signs of post-operative infection (i.e., increase in redness, excessive swelling, worsening pain, fever, malaise, etc.) or allergic reaction (i.e., wheezing, chest tightness, shortness of breath and a cough, and swollen lips/tongue/eyes/face) become evident. Please call an ambulance or attend the nearest hospital Emergency Department in the event of a life-threatening emergency.

How does Geistlich Bio-Gide® work?

Geistlich Bio-Gide® is a natural collagen material derived from veterinary-certified porcine (pig) tissue. It is carefully purified such that it becomes biocompatible with human tissues. No chemical additives or further cross-linking have been employed, and no residual components are present that can pose a threat to the patient.

The material has two distinct surfaces (i.e., bilayer); a) a rough surface which is placed against the healing bone, and b) a smooth surface which is placed facing the soft tissues (gums).

Since bone takes longer to heal relative to the overlying soft tissues, Geistlich Bio-Gide® acts as a temporary barrier to prevent the soft tissues from invading the space reserved for healing bone. This temporary separation promotes improved bone quantity and quality during healing. This material also encourages better blood flow to the newly forming bone, an important factor in the natural healing process. Studies indicate that better bone quality can be achieved when a barrier membrane is used. The material becomes self-adherent to the underlying bone when it becomes wet. In certain circumstances, the surgeon may choose to use small pins or sutures to hold the material in the desired position. Geistlich Bio-Gide® resorbs naturally over several months with no specific precautions or other measures required after the surgical procedure. The resorption rate and lifetime of the material can be affected by a number of factors including exposure of the membrane, presence of infection, nature of the blood supply to the surgical site, and patient comorbidities. The material is sterilised using gamma sterilisation.

Potential side effects that can occur

Geistlich Bio-Gide® has been proven to be a safe and reliable material. It is derived from natural collagen. Any history of collagen or atypical allergies should be discussed with your surgeon prior to using this material. As with any surgical procedure, possible side effects that may occur includes swelling at the surgical site, flap sloughing, bleeding, local inflammation/tissue death, and infection. These side effects could lead to reduced tissue healing. Other surgery related disturbances that may appear include bone loss and pain.

Geistlich Bio-Gide® is designed and manufactured in a way that ensures patient safety and avoids compromising the clinical condition of the patient. Although every effort is taken to

minimise risks associated with the clinical use of this material, any potential risks and complications that could occur are addressed in this patient information leaflet.

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

Geistlich Bio-Gide® is a non-metallic material. It does not demonstrate magnetic behaviour or generate heat during magnetic resonance (MR) 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 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 these devices

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 Therapeutics Goods Administration (TGA).

The Therapeutics Goods Administration (TGA) address and website

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia
<https://www.tga.gov.au/>

The manufacturer address and website

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

The distributor address and website (Australian sponsor)

Geistlich Pharma Australia Pty Ltd.
The Zenith – Tower A,
Level 21, Suite 21.02
821 Pacific Highway
Chatswood NSW 2067
Australia
Phone +61-(1)-800 776 326
info@geistlich.com.au
www.geistlich.com.au

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