Geistlich

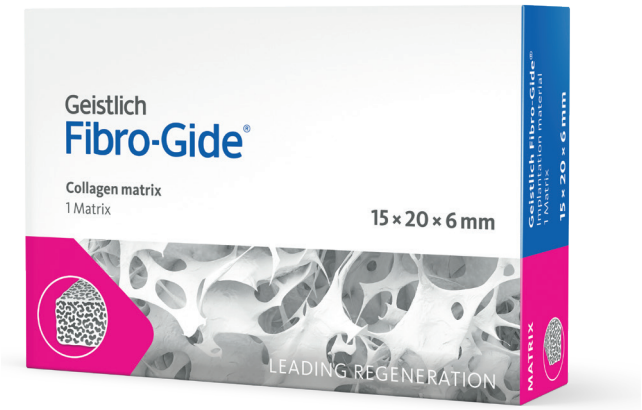
Patient Information Leaflet

Geistlich Fibro-Gide®

Name of material/device and available sizes:

Geistlich Fibro-Gide®:

15 x 20 x 3 mm
20 x 40 x 3 mm
15 x 20 x 6 mm
20 x 40 x 6 mm



The product illustration is exemplary for the product family

Intent and indications for using this material/device

Geistlich Fibro-Gide® is a resorbable, porous, and volume-stable material that is surgically implanted into to the body to support the formation of soft tissue (i.e., regeneration and augmentation). This material is porcine (pig) derived and is used in the treatment of soft tissue volume deficiencies in the oral and maxillofacial areas. The material acts as a volume-stable temporary collagen matrix that stabilises the blood clot and supports ingrowth of blood vessels and surrounding soft tissue cells. The material gradually resorbs over several months and is replaced by the patient's own soft tissues. 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 or in children. Until such time that additional data becomes available, it is recommended that Geistlich Fibro-Gide® be avoided in pregnant and lactating women, and children.

Patient-specific operating instructions

As Geistlich Fibro-Gide® is an implantable material that degrades 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 Fibro-Gide® work?

Geistlich Fibro-Gide® is a natural material (Collagen Types I and III and Elastin) derived from veterinary-certified porcine (pig) tissue using standardised and controlled manufacturing processes. It is carefully purified to minimise the risk of immunological reactions.Geistlich Fibro-Gide® is weakly cross-linked to improve the volume stability of the material. No residual components are present that can pose a threat to the patient.

Geistlich Fibro-Gide® provides sufficient space for the ingrowth of desired cells and blood vessels that support the generation of new soft tissues. The dimensions of the material can be easily adapted to the desired size and shape prior to placement. Once inserted into the surgical site, Geistlich Fibro-Gide® must be completely covered by the overlying soft tissue in order to support wound healing by primary intention. Any tension on the soft tissue around/over Geistlich Fibro-Gide® should be avoided to prevent opening of the wound. Geistlich Fibro-Gide® resorbs naturally over several months with no specific precautions or other measures required after the surgical procedure. The degradation rate and lifetime of the material can be affected by a number of factors including the patient's metabolism, compliance with the post-operative instructions, or side effects (e.g., local inflammation). The material is sterilised by gamma sterilisation.

Potential side effects that can occur

Geistlich Fibro-Gide® has been proven to be a safe and reliable material. It is derived from natural collagen (Collagen Types I and III and Elastin) that is carefully purified to minimise risk of immunological reactions. Nevertheless, any history of collagen or atypical allergies should be discussed with your surgeon prior to using this material (i.e., mammalian meat allergy). As with any surgical procedure, possible side effects that may occur includes swelling at the surgical site, soft tissue flap sloughing, dehiscence, hematoma, bleeding, local inflammation/death of local tissue, and infection. These side effects could lead to reduced tissue healing. Other surgery related disturbances that may appear include tissue loss and pain. In case of exposure of the material, the standard practice is to keep the exposed material clean by rinsing with a bactericidal solution. In some rare instances, removal of the material may be necessary.Geistlich Fibro-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 Fibro-Gide® with other equipment and recommended precautions

Geistlich Fibro-Gide® is a non-metallic material. It does not demonstrate magnetic behaviour or generate heat during magnetic resonance (MR) examination. Geistlich Fibro-Gide® has not been specifically studied in the MR environment. In some circumstances, metal hardware may have been employed to secure Geistlich Fibro-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 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
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https://www.geistlich.com.au

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