Geistlich

Patient Information Leaflet

Geistlich Fibro-Gide®

Name of the material/device and available sizes:

Geistlich Fibro-Gide®
15 × 20 × 3 mm
20 × 40 × 3 mm
15 × 20 × 6 mm
20 × 40 × 6 mm

The product illustration is exemplary for the product line.

Intent and indications for using this material/device
Geistlich Fibro-Gide® is intended to be used as an implantable device for regeneration and augmentation of soft tissue in oral surgery and the surgery relating to the jaws and face (maxillofacial surgery). Geistlich Fibro-Gide® is used in treatment of receding gums or lack of soft tissue volume. The defects to be treated may result from injuries caused by external forces, diseases, medical treatments and therapies, or from history of personal lifestyle habits.

Patient-specific operating instructions
Geistlich Fibro-Gide® is a single-use implantable matrix. 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 known sensitivity to porcine material or animal protein (collagen).
- have a wound that is currently infected.
- have a chronic infection at the surgical site (e.g., around implants, around gums).
- are pregnant or lactating (producing breast milk).
- have clinical conditions decreasing tissue healing, especially:
  - diseases that disturb normal body (metabolism) like heart disease, stroke and type 2 diabetes (uncontrolled metabolic diseases).
  - prolonged corticosteroid therapy.
  - weak immune system (immune impairment).
- are taking medications or undergoing therapies that may impair tissue healing, especially radiation therapy.
- smoke heavily.
- are not an adult.

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.

Geistlich

How does Geistlich Fibro-Gide® work?
Geistlich Fibro-Gide® is derived from veterinary-certified porcine (pig) tissue. It is made of collagen, a naturally occurring protein, and elastin. It is carefully purified to minimise the risk of immunological reactions and well tolerated by the human body. 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.

The material is of a spongy consistency and readily absorbs fluids. Geistlich Fibro-Gide® exhibits mechanical properties that enable soft-tissue augmentation and provides sufficient space for the ingrowth of desired cells and blood vessels that support the generation of new soft tissue. Due to the good biological properties (good biocompatibility and low antigenicity) Geistlich Fibro-Gide® integrates well into the surrounding soft tissue.

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

Potential side effects that can occur
Geistlich Fibro-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.

Possible side effects: allergic reaction, displacement or loss of device, swelling at the surgical site, soft tissue shedding / necrosis, wound reopening, bruising, bleeding, local tissue inflammation / local breakdown of tissue, infection, tissue loss, pain, and discomfort.

Potential interaction(s) of Geistlich Fibro-Gide® with other equipment and recommended precautions
Geistlich Fibro-Gide® is a non-metallic material. It cannot be heated or act as a magnet 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 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.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

Date of information: 2026-07