Geistlich

Patient Information Leaflet

Geistlich Bio-Oss® Flow

Name of the material/device and available sizes:

Volume	Content
0.2 cm³	1 x Geistlich Bio-Oss® Flow in mixing syringe with cap 1 x applicator tip 1 x 1 ml syringe
0.5 cm³	1 x Geistlich Bio-Oss® Flow in mixing syringe with cap 1 x applicator tip 1 x spare cannula 1 x 1 ml syringe

The product illustration is exemplary for the product line.

Intent and indications for using this material/device
Geistlich Bio-Oss® Flow is a material that is surgically implanted to treat hard tissue defects. This material, which contains both bovine (cow) and porcine (pig) derived elements, is commonly used in the treatment of bone defects and deficiencies in the oral cavity, jaws, and facial region. The material acts as an osteoconductive scaffold, thereby stimulating and supporting the formation of the patient's own bone. 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, and in children (before achieving skeletal maturity). Until further data is available, it is recommended that use of Geistlich Bio-Oss® Flow be avoided in pregnant and lactating women, and in children (before achieving skeletal maturity).

Patient-specific operating instructions
As Geistlich Bio-Oss® Flow is an implantable material that slowly resorbable over time (many years), 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-Oss® Flow work?
Geistlich Bio-Oss® Flow is a natural material derived from veterinary-certified bovine (cow) bone and porcine (pig) collagen tissues. The mineral components of this material are Geistlich Bio-Oss® granules; highly purified osteoconductive structures produced in a multi-stage purifica-

tion process, adhering to the strictest safety regulations. Because of its natural origin, Geistlich Bio-Oss® component is chemically as well as structurally comparable to mineralised human bone. Collagen fibres are incorporated to help facilitate the adaptation of the Geistlich Bio-Oss® granules to the defect site. No chemical additives have been employed, and no residual components are present that can pose a threat to the patient.
Due to the large interconnecting pore volume and the natural composition, the formation and ingrowth of new bone at the implantation site is encouraged. It is recommended that, where possible, Geistlich Geistlich Bio-Oss® Flow is covered with a temporary barrier membrane (i.e., Geistlich Bio-Gide®) in order to stabilise the material and to support the formation of improved bone quality and quantity. Over time, Geistlich Bio-Oss® Flow becomes part of the natural bone remodelling process (physiological remodelling). Geistlich Bio-Oss® Flow resorbs naturally over many years as part of this physiological remodelling process; no specific precautions or other measures are required after the surgical procedure. The resorption rate and lifetime of Geistlich Bio-Oss® Flow 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 collagen fibre component of Geistlich Bio-Oss® Flow resorbs within several weeks. Geistlich Bio-Oss® Flow is sterilised by irradiation.

Potential side effects that can occur

Geistlich Bio-Oss® Flow has been proven to be a safe and reliable material. Incompatibility reactions with Geistlich Bio-Oss® Flow cannot be totally excluded. 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, flap sloughing, bleeding, local inflammation, local tissue necrosis, bone loss, implant loss, infection, transient discomfort, or pain, which may lead to additional treatment. Increased pain and swelling after surgery for longer periods than expected may be indicative of failure. In such circumstances, immediately contact your surgeon for advice.
Geistlich Bio-Oss® Flow 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-Oss® Flow with other equipment and recommended precautions

Geistlich Bio-Oss® Flow is a non-metallic material. It cannot be heated or act as a magnet during magnetic resonance (MRI) examination. Geistlich Bio-Oss® Flow has not been specifically studied in the MR environment. In some circumstances, metal hardware may have been employed to secure Geistlich Bio-Oss® Flow 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

Date of information: 2026-01