Geistlich

Patient Information Leaflet

Geistlich Bio-Oss®/ Geistlich Bio-Oss Pen®

Name of material/device and available sizes:

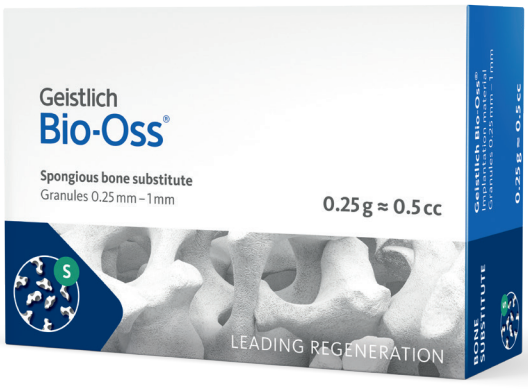
Geistlich Bio-Oss® granule sizes:

0.25 mm – 1 mm; vials of 0.25g, 0.5g, 1.0 g, and 2.0 g
1 mm – 2 mm; vials of 0.5g, 1.0g, and 2.0g

Geistlich Bio-Oss® block:
1 cm x 1 cm x 2 cm

Geistlich Bio-Oss Pen® granule sizes:

0.25 mm – 1 mm: content 0.25g ≈ 0.5 cc, and 0.5g ≈ 1.0cc
1 mm – 2 mm: content 0.5g ≈ 1.5 cc



The product illustration is exemplary for the product family

Intent and indications for using this material/device

Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® is a material that is surgically placed to fill bone defects and augment bone. This material, which is bovine (cow) derived, is commonly used in the treatment of bone defects and deficiencies in the 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 such time that additional data becomes available, it is recommended that use of Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® be avoided in pregnant and lactating women, and in children (before achieving skeletal maturity).

Patient-specific operating instructions

As Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® is an implantable material that slowly resorbs naturally 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® / Geistlich Bio-Oss Pen® work?

Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® is a natural material derived from veterinary-certified bovine (cow) bone tissue. The highly purified osteoconductive mineral structure is produced from natural bone in a multi-stage purification process, adhering to the strictest safety regulations. Because of its natural origin, Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® is chemically as well as structurally comparable to mineralised human bone. No chemical additives have been employed, and no residual components are present that can pose a threat to the patient.

The material has a macro- and microporous structure similar to human spongious bone. 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 Bio-Oss® / Geistlich Bio-Oss Pen® 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. The overlying soft tissues should cover the material (i.e., primary wound closure) and the flap secured with sutures. Over time, Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® becomes part of the natural bone remodelling process (physiological remodelling). The material 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 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 using gamma sterilisation.

Potential side effects that can occur

Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® has been proven to be a safe and reliable material. Incompatibility reactions with Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® cannot be totally excluded. Any history of 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, bone loss, infection, or pain. These side effects could lead to reduced tissue healing. 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® / Geistlich Bio-Oss Pen® 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® / Geistlich Bio-Oss Pen® with other equipment and recommended precautions

Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® is a non-metallic material. It does not demonstrate magnetic behaviour or generate heat during magnetic resonance (MR) examination. Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® has not been specifically studied in the MR environment. In some circumstances, metal hardware may have been employed to secure Geistlich Bio-Oss® / Geistlich Bio-Oss Pen® 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) 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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