Geistlich

Patient Information Leaflet

Geistlich Mucograft®/ Geistlich Mucograft® Seal

Name of the material/device and available sizes:

Geistlich Mucograft®:

15 x 20 mm;
20 x 30 mm;
30 x 40 mm

Geistlich Mucograft® Seal:

8 mm diameter
12 mm diameter

The product illustration is exemplary for the product family

Intent and indications for using this material/device

Geistlich Mucograft® / Geistlich Mucograft® Seal is a resorbable material that is surgically implanted into the oral cavity to support soft tissue regeneration and augmentation, or onto the head and face area for the management of skin wounds. This material, which is porcine (pig) derived, is used in the treatment of soft tissue deficiencies in the oral cavity or for the treatment of skin defects and deficiencies in the head and face area. The material acts as a temporary collagen matrix that stabilises the blood clot and supports ingrowth of 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. Until such time that additional data becomes available, it is recommended that Geistlich Mucograft® / Geistlich Mucograft® Seal be avoided in pregnant and lactating women.

Patient-specific operating instructions

As Geistlich Mucograft® / Geistlich Mucograft® Seal 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. Before and after treatment with Geistlich Mucograft® / Geistlich Mucograft® Seal, disinfectants containing chlorhexidine or containing iodine in combination with povidone can be used. Mouth or skin disinfectants containing tea tree oil should be avoided.

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 Mucograft® / Geistlich Mucograft® Seal work?

Geistlich Mucograft® / Geistlich Mucograft® Seal is a natural collagen material obtained 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 smooth (dense) surface which is placed facing the soft tissues (oral cavity), and b) a rough (porous) surface which is placed against the open wound bed. Geistlich Mucograft® / Geistlich Mucograft® Seal acts as a collagen matrix that stabilises the blood clot and supports the ingrowth of new blood vessels and surrounding soft tissue cells. Depending on the surgical indication, the material may be allowed to heal in either an open or closed fashion. Geistlich Mucograft® / Geistlich Mucograft® Seal degrades and disappears naturally over time (several months); no specific precautions or other measures are required after the surgical procedure. The degradation rate and lifetime of the material can be affected by several factors including the patient's metabolism, compliance with the post-operative instructions, or side effects (e.g. inflammation). The material is sterilised by gamma sterilisation.

Potential side effects that can occur

Geistlich Mucograft® / Geistlich Mucograft® Seal has been proven to be a safe and reliable material. It is derived from natural collagen (collagen types I/III) 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 shedding (dental applications only), wound reopening, localized bleeding outside of vessels (haematoma), bleeding, tissue inflammation, local tissue necrosis, pain, and infection. Moreover, reactions towards applied antibiotics cannot be excluded.

These side effects could lead to reduced or abnormal tissue healing, an unplanned surgery, or loss of the material.

Geistlich Mucograft® / Geistlich Mucograft® Seal 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 Mucograft® / Geistlich Mucograft® Seal with other equipment and recommended precautions

Geistlich Mucograft® / Geistlich Mucograft® Seal is a non-metallic material. It does not demonstrate magnetic behaviour or generate heat during magnetic resonance (MR) examination. Geistlich Mucograft® / Geistlich Mucograft® Seal has not been specifically studied in the MR environment. In some circumstances, metal hardware may have been employed to secure Geistlich Mucograft® / Geistlich Mucograft® Seal 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,
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Date of information: 2024-07