Patient Information Leaflet

SigmaGraft

Device Identification

InterOss® is a natural anorganic hydroxyapatite bone grafting mineral of bovine origin. This bone substitute provides a mineralized osteoconductive structure and has the physical properties necessary to promote cellular migration, adhesion and maturation which results in promoting new bone formation. Following placement in bony voids or gaps, InterOss® acts as a scaffold for the ingrowth of adjacent viable bone. InterOss® gradually resorbs and is replaced with bone during the healing process.

Granules Form in vial for InterOss®

MODEL NO.	PRODUCT DESCRIPTION
IOSG015	InterOss Anorganic Cancellous Granules (250-1000 µm) - 0.15 g / 0.32 cc
IOSG025	InterOss Anorganic Cancellous Granules (250-1000 µm) - 0.25 g / 0.54 cc
IOSG050	InterOss Anorganic Cancellous Granules (250-1000 µm) - 0.5 g / 1.08 cc
IOSG100	InterOss Anorganic Cancellous Granules (250-1000 µm) - 1.0g / 2.16cc
IOSG200	InterOss Anorganic Cancellous Granules (250-1000 µm) - 2.0 g / 4.32 cc
IOLG050	InterOss Anorganic Cancellous Granules (1000-2000 µm) - 0.5 g / 2.0 cc
IOLG100	InterOss Anorganic Cancellous Granules (1000-2000 µm) - 1.0 g / 4.0 cc
IOLG200	InterOss Anorganic Cancellous Granules (1000-2000 µm) - 2.0 g / 8.0 cc

Granules Form in syringe for InterOss®

MODEL NO.	PRODUCT DESCRIPTION
IOSGS025	InterOss Anorganic Cancellous Granules (250-1000 µm) - 0.2 5cc syringe
IOSGS050	InterOss Anorganic Cancellous Granules (250-1000 µm) - 0.5 cc syringe
IOSGS100	InterOss Anorganic Cancellous Granules (250-1000 µm) - 1.0 cc syringe
IOLGS050	InterOss Anorganic Cancellous Granules (1000-2000 µm) - 0.5 cc syringe
IOLGS100	InterOss Anorganic Cancellous Granules (1000-2000 µm) - 1.0 cc syringe
IOLGS150	InterOss Anorganic Cancellous Granules (1000-2000 µm) - 1.5 cc syringe

Intended Purpose

InterOss® is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region adding volume and density to areas where bone loss has occurred. After InterOss® is placed in the lost bone, the surrounding bone creates new bone cells around the grafted material building new bone. New bone growth will eventually replace the material.

Operating Instructions

There is no patient-specific operating instruction for this device. Follow post-operative instructions and precautions advised by the surgeon.

Intended Performance

InterOss® has similar physical and chemical characteristics as human bone, and it is biocompatible. Thus, following placement in bony voids or gaps, InterOss® acts as a scaffold for the ingrowth of adjacent viable bone, and it gradually resorbs and is replaced with bone during the healing process.

Patient Target Group

Healthy patients who require such treatment (i.e. to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region) and for whom the dentist sees the benefit of it.

Undesirable Side Effects

Possible adverse effects include but not limited to allergy to bone graft, hematoma, adverse tissue reaction, infection, swelling at the surgical site, flap sloughing, bleeding, local inflammation, and bone loss. Contact your surgeon immediately for advise if there are any signs of adverse effects.

Precautions

Effects on pediatric patients, patients with pre-existing disease conditions (metabolic bone disorder, cardiovascular disease, radiation) is not known, and safety and effectiveness during pregnancy has not been established.

Patient Care Following Treatment

It is important that post-operative instructions and precautions advised by the surgeons are followed. After the treatment, apply surgical dressing on the surgical area for 1 to 2 weeks and do not apply pressure to the surgical site during the bone healing process. Please contact your surgeon immediately for advice if any signs of side effects or any allergic response become evident.

Potential Interaction(s) of InterOss® with Other Equipment and Recommended Precautions

InterOss® is a non-metallic material and it does not have magnetic behavior or generate heat during magnetic resonance (MR) examination. InterOss® has not been specifically studied in the MR environment.

Notice of Serious Incident

Report any serious incident that occurs in relation to the device to the manufacturer and to the Therapeutic Good Administration.

Manufacturer

SigmaGraft, Inc.
575 Sally Place
Fullerton, CA 92831, USA
https://www.sigmagraft.com/

The Therapeutics Goods Administration (TGA)
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