BIO-OSS®

Natural Bone Grafting Material

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A sterile, biocompatible natural porous bone mineral for use in periodontal and maxillofacial surgery.

DESCRIPTION:

Bio-Oss® is a natural, non-antigenic, porous bone mineral matrix. It is produced by removal of all organic components from bovine bone. Due to its natural structure Bio-Oss® is physically and chemically comparable to the mineralized matrix of human bone. It is available in cancellous (spongiosa) and cortical granules and blocks. Bio-Oss® is sterilized by γ-irradiation.

PROPERTIES/ACTIONS:

Bio-Oss®: The anorganic bone matrix of Bio-Oss® has macro- and microscopic structures similar to human bone. The formation and ingrowth of new bone at the implantation site of Bio-Oss® is favored, due to its trabecular architecture, interconnecting macro and micro pores and its natural consistency. The use of Bio-Oss® may be considered when autogenous bone is not indicated, or insufficient in quantity to fulfill the needs of the proposed surgical procedure.

INDICATIONS AND USAGE:

Bio-Oss® is recommended for:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Elevation of the maxillary sinus floor.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Bio-Oss® blocks are recommended for:

- Filling of large oral and maxillofacial osseous cavities.

INSTRUCTIONS FOR USE:

- After exposure of the bony defect with mucoperiosteal flap, all granulation tissue must be carefully removed.
- Mix Bio-Oss® with autogenous bone, osseous coagulum, patients blood or sterile normal saline. If large maxillofacial defects are present, Bio-Oss® should be mixed with autogenous bone in a ratio of approximately 1:1. The further addition of microfibrillar collagen (e.g. Avitene®) allows for increased cohesiveness and moldability.
- In order to assure the formation of new bone, Bio-Oss® should only be placed in direct contact with well vascularized bone. Cortical bone should be mechanically perforated.
- Loosely pack Bio-Oss® granules into osseous defect using a sterile instrument. Use of excessive force will result in crushing of particles and loss of trabecular architecture.
- Bio-Oss® Cancellous Block may be carved to the desired size using a scalpel after moistening with sterile normal saline. The shaped block is then placed loosely into the bone cavity in direct contact with well vascularized and bleeding bone.
  Cortical bone should be mechanically perforated.
- Bio-Oss® Cortical Block may be carved to the desired size using a scalpel or bur after moistening with sterile normal saline. The shaped block is then placed loosely into the bone cavity in direct contact with well vascularized and bleeding bone.
  Cortical bone should be mechanically perforated.
- Overfilling of the defects should be avoided.
- The mucoperiosteal flaps should be sutured to achieve primary closure, if possible. A surgical dressing may be placed over the wound for one to two weeks.
- Sites grafted with Bio-Oss® should be allowed to heal approximately 6 months prior to implant placement.

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CONTRAINDICATIONS:

Contraindications customary to the use of bone grafts should be observed.

Bio-Oss® should not be used in patients with:

- Osteomyelitis at the surgical site
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Severe renal dysfunction, severe liver disease
- High dose therapy with corticosteroids
- Vascular impairment at the implant site

PRECAUTIONS:

In order to facilitate the formation of new bone Bio-Oss® should only be implanted in direct contact with a well vascularized bony tissue (selective osteoplasty of adjacent cortical bone may be necessary).

In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.

The implantation of titanium fixtures should not take place until about 6 months after the use of Bio-Oss® in any implant site.

ADVERSE REACTIONS:

No adverse reactions have been reported.

STABILITY:

The contents of the bottle or blister are designed for single use only. Resterilization with dry heat is not recommended. Do not use after expiration date.

STORAGE:

Store at controlled room temperature 15°-25°C (59°-77°F) and in a dry place.

HOW SUPPLIED:

Re-Order No.	Product	Weight	Particle Size	Packaged
03-0202	Bio-Oss® cancellous granules	0.25g	0.25 - 1.0mm	Individually
03-0502	Bio-Oss® cancellous granules	0.5 g	0.25 - 1.0mm	Individually
03-2002	Bio-Oss® cancellous granules	2.0 g	0.25 - 1.0mm	Individually
03-5002	Bio-Oss® cancellous granules	5.0 g	0.25 - 1.0mm	Individually
03-0510	Bio-Oss® cancellous granules	0.5 g	1.0 - 2.0mm	Individually
03-2010	Bio-Oss® cancellous granules	2.0 g	1.0 - 2.0mm	Individually
03-5010	Bio-Oss® cancellous granules	5.0 g	1.0 - 2.0mm	Individually
01-0505	Bio-Oss® cortical granules	0.5g	0.5 - 1.0mm	Individually
01-2005	Bio-Oss® cortical granules	2.0g	0.5 - 1.0mm	Individually

Re-Order No.	Product	Block size (approx.)	Packaged
03-1012	Bio Oss® cancellous block	1x1x2cm	Individually

Distributed by:
OSTEOHEALTH COMPANY
Division of Luitpold Pharmaceuticals, Inc.
Shirley, New York 11967-4799
(800) 874-2334

Manufacturer:
GEISTLICH PHARMA AG
CH-6110 Wolhusen
Switzerland

Made in Switzerland from bovine bone

CAUTION: Federal law restricts this device to sale by or on the order of a dentist or physician.

package insert: www.osteohealth.com

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