

StarGraft | Granules

Synthetic Mineral Bone Graft

INSTRUCTIONS FOR USE

StarGraft Granules is a sterile, biocompatible synthetic calcium phosphate mineral for use in periodontal, oral and maxillofacial surgery.

Description:

StarGraft Granules is a synthetic calcium phosphate mineral matrix. The synthetic calcium phosphate mineral has a carbonate apatite structure, which is physically and chemically comparable to the mineralized matrix of human bone. It is available in granular form, sterile, non-pyrogenic, and for single use only.

Indications and Usage:

StarGraft Granules 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).

Instructions for Use:

- After exposure of the bony defect with a mucoperiosteal flap, all granulation tissue must be carefully removed.
- Mix *StarGraft Granules* with autogenous bone, osseous coagulum, patient's blood or sterile normal saline. If large maxillofacial defects are present, *StarGraft Granules* should be mixed with autogenous bone in a ratio of approximately 1:1.
- In order to assure the formation of new bone, *StarGraft Granules* should only be placed in direct contact with well vascularized bone. Cortical bone should be mechanically perforated.
- Loosely pack *StarGraft Granules* into osseous defect using a sterile instrument. Use of excessive force will result in compression of the particles and loss of trabecular architecture.
- 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.
- If primary wound closure cannot be achieved completely, further immobilization of the flap (e.g., by incision through the periosteum) should be performed and/or a bioabsorbable membrane should be placed over the bone graft site.

Contraindications:

Contraindications customary to the use of bone grafts should be observed. *StarGraft Granules* should not be used in patients with:

- Acute or chronic infection (osteomyelitis) at the surgical site
- Metabolic diseases (diabetes, hyperparathyroidism, osteomalacia)
- Severe renal dysfunction, severe liver disease
- High dose corticosteroid therapy
- Vascular impairment at the implant site
- Osteoporosis

Precautions:

In order to facilitate the formation of new bone *StarGraft Granules* should only be implanted in direct contact with a well vascularized bony tissue. Drilling may be recommended to facilitate bleeding from cortical bone. In larger defects a mixture of autogenous bone or bone marrow may improve the formation of new bone.

Implantology

Generally, in augmented areas, the placement of titanium fixtures should take place once the bone has sufficient strength and integrity for dental implant placement, which is typically greater than 6 months after implantation of a bone graft material. For sinus floor elevation, typically 9-12 months should be allowed after implantation of bone graft material before placement of the titanium fixtures. X-rays should be taken to confirm the bone integrity prior to dental implant placement.

Periodontology

The filling of periodontal defects with *StarGraft Granules* requires (along with plaque control) the successful local treatment of the periodontal lesion (e.g. root planning, debridement of granular tissue) prior to implantation.

StarGraft Granules cannot be re-sterilized or re-used. Open, unused *StarGraft Granules* must be discarded. *In vivo* stability may be adversely affected if re-sterilized. Cross-contamination and infection may occur if re-used.

Do not use if the product sterilization barrier or its packaging is compromised.

Adverse Reactions:

No adverse reactions have been reported in relationship to *StarGraft Granules*.

Special Storage Conditions:

None

How Supplied:

One (1) unit per package:

Catalogue Number	Weight	Volume
SGG050	0.25g	0.5cc
SGG100	0.5g	1.0cc
SGG200	1.0g	2.0cc
SGG350	2.0g	3.5cc

Caution: (Rx only)

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or dentist.

Labeling Symbols:

Symbols may be used on some international package labeling for easy identification.



See instructions for use



Expiration Date



Do not reuse after opening



Lot number



Method of sterilization – gamma



Catalog Number

Rx Only



USA law restricts this device to sale by or on the order of physician

Manufacturer



Do not use if the product sterilization barrier or its packaging is compromised.

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