

# 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.

#### Distributed by:

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