StarGraft | Putty

Synthetic Mineral-Collagen
Composite Bone Graft

INSTRUCTIONS FOR USE

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

Description:
StarGraft Putty is a synthetic calcium phosphate mineral matrix with type I collagen derived from bovine Achilles tendon. *StarGraft Putty* is provided as a sterile, dry material that is hydrated at the point of use and can be molded to fit the bone defect. The synthetic calcium phosphate mineral has a carbonate apatite structure, which is physically and chemically comparable to the mineralized matrix of human bone.

StarGraft Putty is available in block form, sterile, non-pyrogenic, and for single use only.

Properties/Actions:
The mineral component of *StarGraft Putty* has macro- and microscopic structures similar to human bone. The formation and ingrowth of new bone at the implantation site of *StarGraft Putty* is favored, due to its trabecular architecture, interconnecting macro and micro pores and its natural consistency.

The collagen facilitates handling of the mineral particles and acts to hold the *StarGraft Putty* at the desired place. The consistency of this material readily allows it to take the shape of the defect.

The use of *StarGraft Putty* 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
StarGraft Putty 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 Putty* with autogenous bone, osseous coagulum, patient's blood or sterile normal saline. If large maxillofacial defects are present, *StarGraft Putty* should be mixed with autogenous bone in a ratio of approximately 1:1.
- In order to assure the formation of new bone, *StarGraft Putty* should only be placed in direct contact with well vascularized bone. Cortical bone should be mechanically perforated
- Loosely pack *StarGraft Putty* 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 Putty* 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
- Allergy to collagen

Warning:
StarGraft Putty in the block form is not intended for load bearing applications. The block shape of the mineral and collagen composite is intended for ease of handling.

Precautions:
In order to facilitate the formation of new bone *StarGraft Putty* 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 Putty* 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 Putty cannot be re-sterilized or re-used. Open, unused *StarGraft Putty* 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 Putty.* Due to the additional collagen component allergic reactions cannot be totally excluded.

Storage:
The product should be stored at room temperature (15°C to 30°C). Avoid excessive heat and humidity.

How Supplied:
One (1) unit per package:

Catalogue Number	Size
SGP050	9 mm x 8 mm (0.5 cc)
SGP100	11 mm x 10.5 mm (1.0 cc)
SGP200	11 mm x 21 mm (2.0 cc)

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	Lot number
STERILE R	Method of sterilization – gamma
	Temperature Limitation
REF	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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