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SURGICAL MATERIAL FOR RESTORATION OF HARD TISSUES DEFECTS

GDT SYNTHETIC GRAFT PASTE INSTRUCTIONS FOR USE

PURPOSE:

GDT Synthetic Graft paste is used as osteoplastic material, for optimization of bone regeneration in dental surgery, clinic in general and maxillofacial surgery, as well as in traumatology and orthopedics.

It consists of granules β -tricalcium phosphate (β -TCP) coated with a thin shell of biodegradable copolymer named polylactideglycolide and the cosolvent. After mixing the granules with the solvent, granules stick together, forming a plastic material with a high micro-and intergranular porosity, which can be introduced into the bone defect directly from the syringe. By contact with blood or oral fluids, the material takes the form of

a bone defect, which provides stability to the defect and facilitates the procedure of suturing the wound. Biomaterial is completely resorbed within 9-15 months. Resorption takes place in parallel to the regeneration of bone tissue.

INDICATIONS:

Parodontics: filling a two-or multi-bone pockets and bi-and tri-furcations of the teeth, augmentation of the atrophied sinus.

Implantology: sinus lifting or sub-antral augmentation, filling of alveolar defects for supporting of sinus base after the tooth extraction, filling the extraction defects in order to create the basis for the implant.

Cyst defects: Defects after extirpation of the bone cyst, defects after resection of the root apex and defects after removal of impacted teeth surgically, as well as other multi-grid bone defects of the alveolar processes and facial bones.

DIRECTIONS FOR USE:

The contents of sterile syringes should be mixed immediately before injection into the bone defect under the conditions of full sterility.

- Extract syringes from the sterile packaging.
- Remove the cap from the syringe with the co-solvent.
- Remove from the syringe with granules a long plunger and pour into a cosolvent.
- Insert into the syringe with granules a long plunger and wet granules with co-solvent, moving both short and long plungers 2-3 times till the granules are wet.
- Remove the short plunger and squeeze out the excess of cosolvent with a long plunger. Put the resulting mass into prepared bone defect directly from the syringe.
- To speed up the hardening of the material it is recommended to irrigate copiously the defect area with sterile saline.

Defect (hole) filled with the material is sutured. Before filling periodontal defects previously purified the hard tissues from the dental plaque and removed from the pockets the necrotic tissues and debris after the polishing of the root.

STERILITY:

Radiation sterilization by radiation 18±3.0 kGy.

STORAGE:

GDT Synthetic Graft paste is intended for single use only; once opened it must be used or discarded. This product cannot be resterilized.

Do not use after the expiry date mentioned on the outer package.

Store in a dry and dark place in tightly closed containers at temperature (+5°C...+25°C). Avoid contact with moisture!

Don't freeze!

PACKAGING:

Syringe Bone Graft	0.5cc
Syringe Solvent	0.25cc

Ref: GD-SP100



Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material.

The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.