

Granular product based on tricalcium phosphate

Description

PG β -TCP is a synthetic product with grain size in the range 500-1000 μ m, rough and corners shaped, suitable for filling bone defects in dental and maxillofacial surgery.

Composition

PG β -TCP product is composed of beta tricalcium phosphate (β -Ca₃(PO₄)₂) in pure phase. Tricalcium phosphate is a biocompatible bioresorbable phosphocalcic compound very similar with human bone. Completely resorbable and is gradually replaced by new bone. The product is radiopaque to X-rays, which allows visualisation during surgery and postoperative.

Indications

PG β -TCP can be used in following cases:

- filling defects cyst type, ascension alveolar crest, alveolar crest restoration post extraction.

Properties/ Effects

First interaction: PG β -TCP penetration in conjunctive tissue

Second interaction: osteoblast differentiation in fibroblasts

Third interaction: osteoid formation on the ceramic surface

Fourth phase: modelling of new bone

Contraindications

The product is contraindicated in acute or chronic infection in surgical area, or in metabolic diseases (hypercalcemia or hyperphosphatemia).

Operating instructions

Before using of PG β -TCP product, to remove all granulation tissue in the expose area.

- Keep firmly in hand the containers with granular product; with a scalpel aluminium cap is removed by cutting around the bottle, to release granules..

- PG β -TCP granules are placed in a cup, mixed with patient blood or physiological serum.

- PG β -TCP product can be mixed with solution using a sterilized flat spatula. To insert the product in the affected area is used a spatula shaped spoon; powerful compacting or

destroying grain structure (ex. Crushing) should be avoided.

- Regeneration take place better when blood infiltrate into the substitution material.

- After placing the PG β -TCP granules is advisable to close the area using an organic membrane.

- Using PG β -TCP removes any problems eventualele probleme that occur from irregular cavities.

- The product can be used only by, or under supervision of professional staff, with expertise in the required techniques and the use of biomaterials;

Prezentation

- 500-1000 μ m granules/bottle of 0,5g and 1g

Packaging/sterilization

PG β -TCP product is delivered in sterile form, packed in 2ml bottle, containing ceramic granules (500 ÷ 1000 μ m) of 0,5 \pm 0,1g respectively, 1 \pm 0,1g

Sterilized by gamma sterilization (25KGy).

No resterilization.

It is single use only.

The expiration date is five years after sterilization.

Storage

Not require any special storage conditions. Store at room temperature.

bookmark:

⚠ - See the instructions for use

⊗ - Do not re-use (single use only)

☒ - Sterilization by irradiation

Manufacturer

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Date: 12.11.2012