BIOTECK®

3 SYNT®

TECHNICAL SHEET

3 SYNT® **Disposable sterile device**	CE 0434

Description

3 SYNT® — Bioteck 3 SYNT® is a synthetic bone substitute designed to fill bone defects during dental surgery. It is made from pure and resorbable ß tricalcium phosphate.

Composition and technical features

ß tricalcium phosphate (ß-TCP): $Ca_3(PO4)_2$. Tricalcium phosphate (TCP) is a bioactive calcium phosphate salt that is more soluble than hydroxyapatite in a biological medium and very similar to the mineral phase of human bone. It is completely resorbable and will gradually be replaced by new bone. The TCP used in the manufacture of Bioteck 3 SYNT® complies with the ASTM 1088-04 standard.

Granule size:	500-1000 µm or 1000-2000 µm
Porosity:	60 to 80% interconnected pores.
Pores size:	200-500 µm

Indications

Bioteck 3 SYNT® is intended for filling and/or reconstructing multiwall bone defects, in oral surgery, in periodontology and in implantology. Indications are:

- Periodontology
- Filling of two-wall or multi-wall bone pockets as well as bifurcations and trifurcations of the teeth.
  If larger cavities are to be filled, covering with membranes is recommended.
- Augmentation of the athrophied alveolar ridge.
  Covering with membranes is unrenounceable for protecting and fixing larger boundary surfaces.
- Implantology
- Sinus lift.
- Filling of alveolar defects after extraction.
- Cysts and defects after apicoectomy.
- Resection for impacted teeth.
- After corrective osteotomies.

Expected results

There are four successive phases after implanting Bioteck 3 SYNT®:

- FIRST PHASE: invasion of Bioteck 3 SYNT® by slack conjunctive tissue after resorption of the post-surgery hematoma.
- SECOND PHASE: osteoblast differentiation from the fibroblast-like cells of the conjunctive tissue.
- THIRD PHASE: osteoid matrix synthesis on the surface of the ceramic.
- FOURTH PHASE: modeling of newly formed bone tissue or creeping substitution.

After Bioteck 3 SYNT® has been used, a waiting time of at least 4 to 6 months should be kept before endosseus implants are applied. In case of a sinus lift waiting time is 9 to 12 months.

Instructions for use

1.While holding the Bioteck 3 SYNT® cup firmly in one hand, slowly peel back the lid at an acute angle to the top edge of the cup to avoid loss of powder.
2. Using the patient's own blood, sterile saline or sterile water, apply 8-12 drops per cc to the Bioteck 3 SYNT® granules in the mixing cup. Do not over wet. Excess solution may be blotted with a corner of a sterile sponge.
3. The flat end of a sterile spatula can be used to mix the Bioteck 3 SYNT® with the solution. The spoon end is useful for delivering the moistened material to the surgical site.
4. Gently fill each defect, in small increments, to the highest level of bony defect. Regeneration will occur best when blood and blood vessels can infiltrate the graft material.
5. After placement of the TCP granules, the flaps are carefully adapted and completely closed. Membrane may also be used to achieve closure.

Warnings and precautions

- Bioteck 3 SYNT® can be introduced directly in the cleaned, freshly bleeding cavity.
- In case of larger defects, it is recommended to mixed it with fresh autologous blood or with autologous bone of a comparable particle size.
- The shape and the size of the implant are chosen by the surgeon depending on size and morphology of the bone defect to fill.
- The filling must be complete with slight impaction (do not under fill).
- The wound closure should be complete and airtight (closure without tension).
- The association with any drug is under the responsibility of the surgeon.
- TCP granules should be used under strict aseptic conditions.
- This medicinal product must be handled and/or implanted by qualified persons who have read the instructions for use.
- Contraindications are the same as for bone grafts in general: acute or chronic infection of the surgical site, metabolic disease (hyperphosphatemia or hypercalcemia) and/or sites where ceramic granules may pass into joint cavities or meningeal spaces.

Side effects

Up to the present day, no adverse reactions have been reported.
The product has not been tested on pregnant women. The device is latex-free.

Sterilisation and storage

Bioteck 3 SYNT® is delivered in a sterile, packaging. It is sterilized by gamma irradiation (minimal dose: 25 kGy). Do not re-sterilize. Single-use. Carefully check that the outer packaging is not damaged, otherwise sterility is compromised. The expiry date is 5 years after the date of sterilization. In case of implant removal, it cannot be reutilized because of the significant risk of transmission of pathogenic agents. Store at room temperature.

Package

One or more sterile, double PETG blister packs. Patient labels. Informative leaflet.

Patient labels

Copies are provided inside the packaging.

Breakage of casing and disposal of packaging

Sterility is only guaranteed if the outer packaging is intact..
The product must be disposed of in accordance with facility-specific measures.

Manufacturer

Bioteck S.p.A., Via E. Fermi 49 - 36057 Arcugnano (Vicenza), Italy.

Risk Class

The risk class of this device, according to current EEC regulations is III (three).

Codes

SY-M05N	Beta-TCP granules, size 500-1000 µm, 1 blister/0.5 cc
SY-M05	Beta-TCP granules, size 500-1000 µm, 3 blisters/0.5 cc
SY-M10N	Beta-TCP granules, size 500-1000 µm, 1 blister/1.0 cc
SY-M10	Beta-TCP granules, size 500-1000 µm, 3 blisters/1.0 cc
SY-M20N	Beta-TCP granules, size 500-1000 µm, 1 blister/2.0 cc
SY-M20	Beta-TCP granules, size 500-1000 µm, 3 blisters/2.0 cc
SY-G05N	Beta-TCP granules, size 1000-2000 µm , 1 blister/0.5 cc
SY-G05	Beta-TCP granules, size 1000-2000 µm , 3 blisters/0.5 cc
SY-G10N	Beta-TCP granules, size 1000-2000 µm , 1 blister/1.0 cc
SY-G10	Beta-TCP granules, size 1000-2000 µm , 3 blisters/1.0 cc
SY-G20N	Beta-TCP granules, size 1000-2000 µm , 1 blister/2.0 cc
SY-G20	Beta-TCP granules, size 1000-2000 µm , 3 blisters/2.0 cc