Bioresorbable bone replacement from microporous and macroporous β-tricalcium phosphate.

BetaBASE®

BetaBASE consists of pure-phase β-TCP and since it is a synthetic material it is widely noncritical for the patient.

BetaBASE has an interconnected pore system with micropores and macropores that reproduce the well-known osteoconductive effect very well.

Osteoblasts and blood vessels are able to proliferate rapidly in the open pore system and grow swiftly in the BetaBASE. This also enables internal resorption of the materials.

The high overall porosity of BetaBASE (> 60 %) means that the body has to break down a far smaller quantity of bone replacement material, based on the volume of the defect. This accelerates the resorption process and also creates new opportunities to fill large bone defects. Clinical studies have demonstrated that the material is completely resorbable after ca. 6 to 24 months.

The polyhedric granular structure of BetaBASE makes it safe and easy to apply to the defect, in particular when mixed with the patient's blood.

BetaBASE conforms to ASTM F 1088-04, the internationally recognised standard for materials.

INDICATIONS

Addition of the material to autogenic or allogenic spongiosa to reconstruct bone defects e.g. in cases of spondylodesis, vertebral body replacement and in joint replacement surgery.

Filling defects in correction osteotomies.

Filling the sites from which autogenic bones have been removed.

Filling bone cysts.

Use in arthrodesis.

Filling defects after the removal of benign bone tumours.

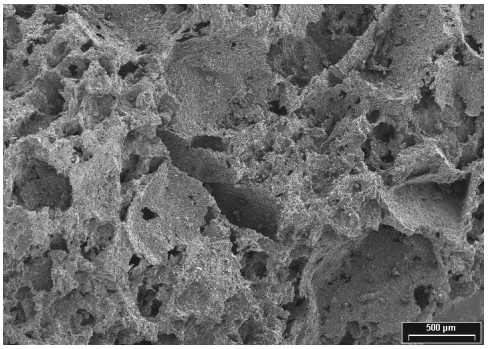

Figure 1: Macropores up to 500 µm are visible.

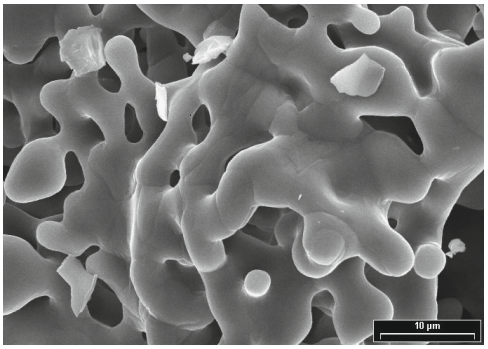

Figure 2: Micropores in detail, approx. 5 µm, sinter necks are visible.

APPLICATION

It is advisable to apply BetaBASE in a moist state. The patient's own blood or blood plasma should be used. If neither option is available in sufficient quantities, a sterile isotonic saline solution may be used.

Where defects are larger than approx. 2 cm^3 it is advisable to mix BetaBASE with spongiosa.

BENEFITS

Interconnected porosity
As a result of the open, consistent struc tures of the granulate, the bone obtains the possibility of ingrowth via complete osteone structures. Moreover, the granu late has extraordinary tamponing properties due to its capillaries.

Osteoconductivity
BetaBASE stimulates the direct ingrowth of the bone into its through-pores before the resorption procedure begins. Hence BetaBASE acts as a guide rail for the formation of new bone.

Complete resorption
The resorption rate of BetaBASE is adapted to the formation of new bone. Simultaneously to the degradation of the β-TCP, the formation of the natural bone in the augmentation area is variable, depending on the regeneration dynamics.

Biocompatible
The high biocompatibility of β-tricalcium phosphate (TCP) has been extensive established in numerous clincal trials. Neither unfavourable tissue reac tions nor immunological defensive reactions could be established.

BetaBASE exhibits very satisfying integration into the natural bone without connective tissue encapsulation or pathological tissue changes. No osteoclast activity has been demonstrated.

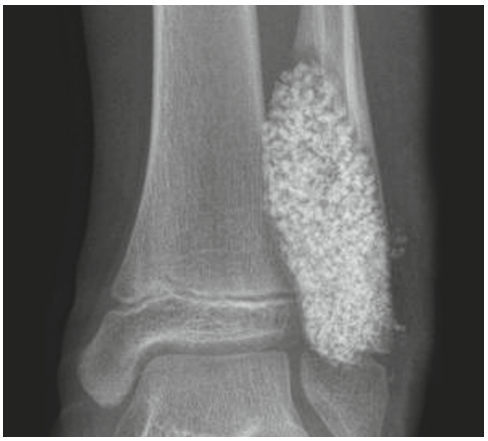

Figure 3: Cyst filled with 30 ml.

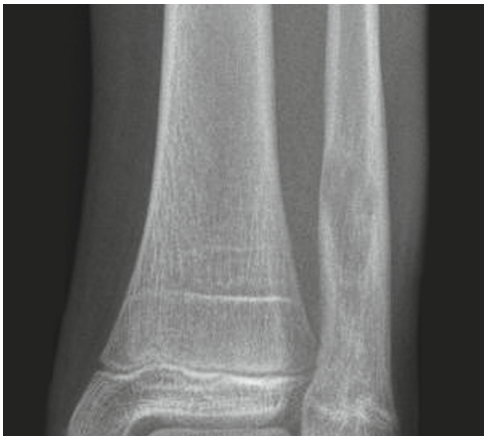

Figure 4: The material is virtually invisible 16 months later.

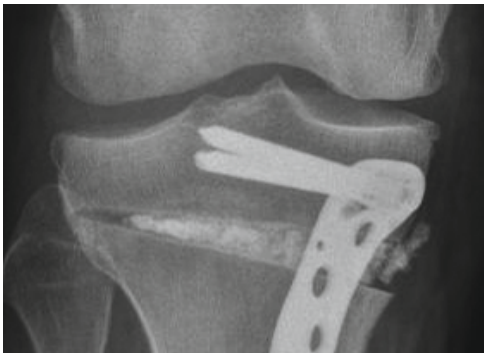

Figure 5: Mesh graft after correction osteotomy.

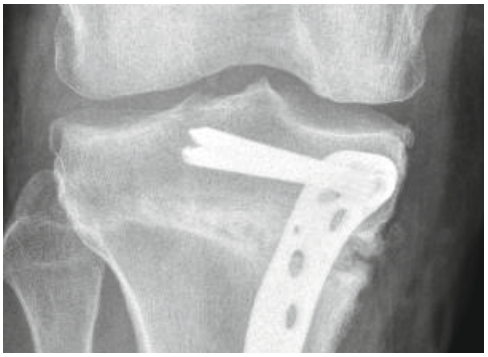

Figure 6: Good resorption after 10 months.

DECOMPOSITION BEHAVIOUR

The decomposition of BetaBASE leads exclusively to products which are constituents of the tissue fluid (calcium ions, phosphate ions) and their physiological variance is not exceeded in the course of the bioresorption. New bone formation and resorption of the granulate run parallel pro portional, i. e., while new bone forms in the defect, the bone substitute material is simultaneously degraded. According to the size of the granulate, the resorption process is normally completed after approximately 6 to 24 months, depending on the regeneration dynamics of the patient. The complete resorption is checked radiographically for the purpose of implantation.

DURABILITY

BetaBASE is available in 2 ml, 5 ml and 10 ml vials. BetaBASE is sterile and free of pyrogens and, as long as the packaging remains intact, has a shelf life of 5 years at room temperature.

Information for ordering:

BetaBASE	2 ml	0.5 – 1.0 mm	KE 03.02010.010
BetaBASE	2 ml	1.0 – 2.0 mm	KE 03.02020.020
BetaBASE	5 ml	1.4 – 3.2 mm	KE 03.05032.001
BetaBASE	5 ml	3.2 – 5.0 mm	KE 03.05050.002
BetaBASE	5 ml	5.0 – 8.0 mm	KE 03.05080.003
BetaBASE	10 ml	1.4 – 3.2 mm	KE 03.10032.100
BetaBASE	10 ml	3.2 – 5.0 mm	KE 03.10050.101
BetaBASE	10 ml	5.0 – 8.0 mm	KE 03.10080.102

We are indebted to Dr. med. Uwe Maus for his assistance.

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Ordering: www.biovision.de/en/order

BIOVISION specialises in the development and manufacturing of biomaterials. In particular in the processing of resorbable polymer products by means of injection moulding and the production of resorbable ceramic products. These technologies are used inter alia in our products for dental surgery/implantology and for orthopedics. The following products are also included in our portfolio:

Orthopedics:

BetaBASE bioresorbable bone replacement

BioBASE bioresorbable bone replacement

PolyPIN bioresorbable bone pin

Wound Care:

EpiGARD synthetic skin replacement

Dental Surgery:

BetaBASE MP bioresorbable bone replacement

BioBASE AP bioresorbable bone replacement

LeadFIX bioresorbable membrane pin

PRODUCTION

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