

# Bioresorbable bone replacement from microporous and macroporous $\alpha$ -tricalcium phosphate.



BioBASE is an inorganic, bioresorbable bone replacement from pure-phase  $\alpha$ -tricalcium phosphate. BioBASE is a bone replacement for temporarily filling pathological, traumatic and postoperative bone defects. BioBASE has a system of micropores ( $< 5 \mu\text{m}$ ) and macropores (max. 1 mm) with a porosity of approx. 65 %. This creates a far larger material surface, which enhances the reaction kinetics in the resorption processes.

BioBASE is broken down to the same extent as it forms new bones. Duration of resorption ca 9 to 24 months.

Blood vessels and osteoblasts grow in the macropores and guarantee rapid proliferation of the new bone substance.

Tissue fluid penetrates the pore system, thereby enabling a complete hydrolytic breakdown of the material.

BioBASE acts as a conductor for the proliferating bones by producing an osteoconductive effect.

The constant and precise composition with a calcium-phosphorus atomic ratio of 1.5 is very similar to the calcium-phosphorus atomic ratio of the mineral phase of the human bone of 1.6 and guarantees the high degree of biocompatibility of BioBASE.

## 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 cases of arthrodesis.

Filling defects after the removal of benign bone tumours.

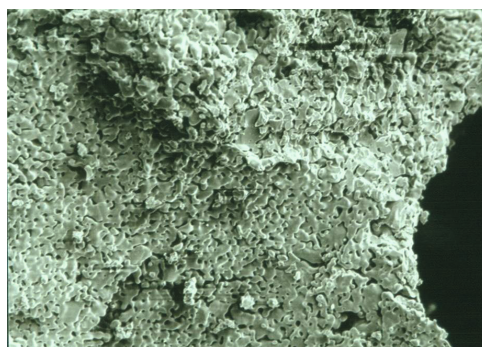


Figure 1: The microporosity is visible in this enlargement.

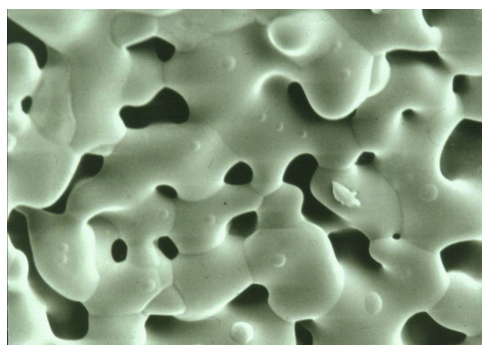


Figure 2: Microporosity in detail, pores up to approx.  $5 \mu\text{m}$ ; sinter necks are discernible.

## APPLICATION

It is advisable to apply BioBASE 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.

A mixture of BioBASE and spongiosa in a ratio of 1:1 is recommended to fill larger defects ( $> 2 \text{ cm}^3$ ).

## DEGRADABILITY

The results of hard tissue implantations of BioBASE exhibit a tissue-free accumulation of bone at BioBASE. A compound osteogenesis with extensive direct bone growth is formed between the implant and the newly formed bone at the implant site. Parallel to this process, the bioresorption of the material begins. The degradation of BioBASE is accomplished as a result of the physicochemical solubility and due to direct cellular attack.

The substance defects forming at the implant site will be replaced successively by the own vital bone of the patient. The resorption time is dependent on the size of the defect to be treated

and on the intensity of the metabolic processes at the implantation site and takes between 9 months and 2 years. An implant can be placed in the bone filled with BioBASE after approximately 6 months.

BioBASE is a transient bone replacement granulate, and when used, resorption and new bone formation take place parallel. In contrast to this, granulates that are produced on the basis of hydroxylapatite (synthetically produced or manufactured on the basis of bovine bone) are sparsely or non resorbable and consequently remain as extraneous substances in the body.

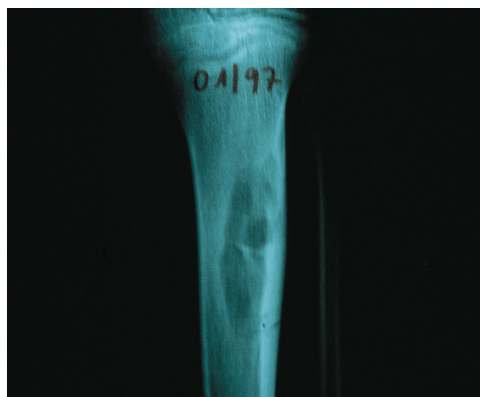


Figure 3: Dysplasia, proximal tibia.

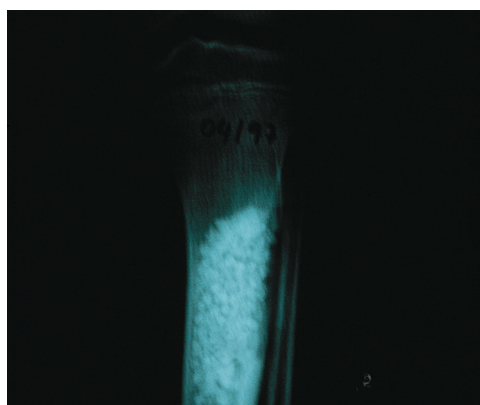


Figure 4: Debridement of the fibrosis, filling the defect with BioBASE.



Figure 5: After 8 months: visible osseous reorganisation of the granules.

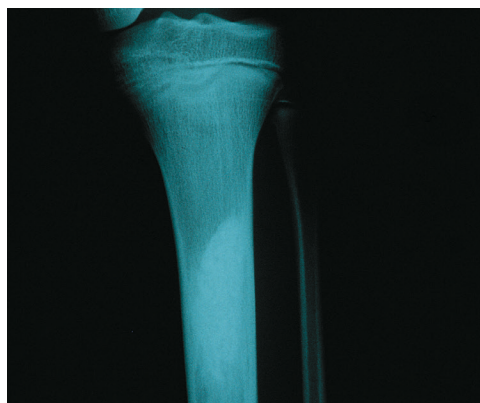


Figure 6: After 13 months: bony growth and start of resorption.

## SAFETY

BioBASE exhibits an very good tissue compatibility with the organism of the recipient.

In comparison to bioglasses, BioBASE contains only chemical ingredients which are contained in human tissue or in the tissue fluid. These ingredients are either used by the body for the building up of tissue or excreted, meaning that no extraneous matter remains in the body. In contact with aqueous media (e. g. tissue fluid), BioBASE has a pH value within the physiological pH range of 7.4.

The  $\alpha$ -form has been specifically selected for BioBASE (sintered at high temperature), as this is degraded ionically/ hydrolytically due to the compact sinter grain. Due to the crystalline structure of  $\alpha$ -TCP, connected at the contact points by so-called contact necks, a compact sinter grain, which is very stable against particular degradation and can therefore not be washed away in small particles, forms the defect site or is even excreted via the lymphatic system.

## DURABILITY

BioBASE is available in 2 ml, 5 ml and 10 ml vials. BioBASE 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:**

BioBASE	2 ml	0.5 – 1.4 mm	KE 04.0002.014
BioBASE	5 ml	1.4 – 3.2 mm	KE 04.0005.032
BioBASE	5 ml	3.2 – 5.0 mm	KE 04.0005.050
BioBASE	5 ml	5.0 – 8.0 mm	KE 04.0005.080
BioBASE	10 ml	1.4 – 3.2 mm	KE 04.00010.032
BioBASE	10 ml	3.2 – 5.0 mm	KE 04.00010.050
BioBASE	10 ml	5.0 – 8.0 mm	KE 04.00010.080



We are indebted to Dr. med. Bruno Schweigert for his assistance.

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**Ordering:** [www.biovision.de/en/order](http://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

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