

*BIOBvSE* being a chemically synthesized substance precludes the risk of infection and immune reactions. Over the last 20 years *BIOBvSE* has been clinically tested for a very wide range of indications. *BIOBvSE* has been licensed by the German Board of Public Health (published in the Federal Gazette Volume 43, No. 90, 17.05.1991, p. 3269) and thus the **first bioactive, resorbable bone substitute to be approved in the Germany**. *BIOBvSE* fulfills the requirements of the "ASTM F 1088-87 - TCP for surgical Implantations"; it is manufactured in accordance with GMP guidelines. There are only a few pure  $\alpha$ -tricalcium phosphates available on the market. *BIOBvSE* is a pure, inorganic  $\alpha$ -tricalcium phosphate without nonresorbable hydroxyapatite components. It exhibits excellent bioactive properties.

A special surface modification, characteristic for *BIOBvSE* leads to increased calcium elution during the initial phase of the healing process which, in turn, stimulates resorption and bone regeneration at the defect site.



Figure 1: The microporosity is visible in this enlargement

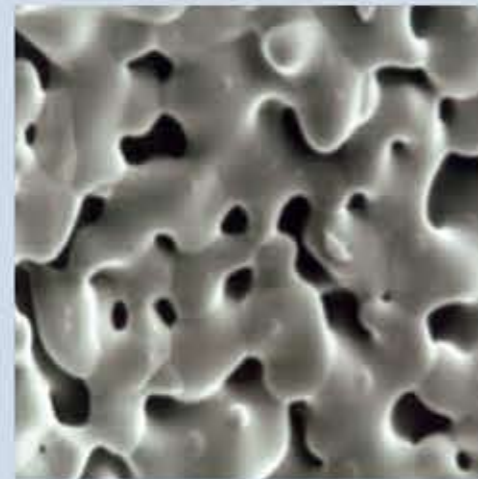


Figure 2: Microporosity in detail; pores up to approx. 5  $\mu$ m; sinter necks are discernible

#### Characteristics:

- Defect is completely filled with new bone
- No differences in the elasticity of the regenerated bone
- No complications during the healing process
- Calculable resorption time
- No decomposition of particles
- No risk of infection
- No risk of immune reactions
- No change in pH value
- Osteoconductive
- Bioactive

#### Resorption

The resorption of the substance is continually compensated for with new autologous bone. The resorption time (9 months to 2 years) is dependent on the size of the defect being treated as well as the efficacy of the metabolic processes at the implant site. After approx. 4 months the defect filled with *BIOBvSE* is ready to receive an implant.

*BIOBvSE* is a temporary bone substitute granulates which is replaced by new bone as it is resorbed. In contrast granulates based on hydroxyapatite (manufactured chemically or extracted from bovine bone), are only slightly resorbable or not at all, thus remaining in the body as an exogenous substance.

#### • Safety

*BIOBvSE* exhibits excellent recipient tissue compatibility. The material is synthetically produced so that the transmission of microbial pathogens and infections can be completely excluded.

In contrast to biological glasses *BIOBvSE* contains only chemical components normally found in human tissue or tissue fluids. These components are either incorporated by the body tissues or excreted, so that no exogenous substances remain in the body. When coming into contact with aqueous media (e.g. tissue fluid) *BIOBvSE* has a pH-value which lies within the physiological range of 7.4.

The alpha form of *BIOBvSE* was selected (sintered at high temperatures) because the compact sintered granule can be degraded by ionization/hydrolysis. The crystalline structure of  $\alpha$ -TCP, bound to the contact sites by so-called contact necks, leads to the generation of a compact sintered granule. This granule is very stable and cannot be disintegrated into particles. Therefore *BIOBvSE* can not be washed away or even removed by the lymph system. Application of *BIOBvSE* is simple and without any risk.

#### • Application

Application is simple and without risk. Moist *BIOBvSE* is easier to apply to the defect site. This can be achieved by either mixing with autologous blood or an isotonic salt solution, Antibiotics can also be included should this be necessary. *BIOBvSE* can be used as a basis for carrying osteoinductive substances.

#### • Re Sterilisation

*BIOBvSE* is radiation sterilised and therefore intended for single use. Unused *BIOBvSE* from opened bottles can be resterilised at own responsibility. For this propose, the opened original bottle is closed with the included **plastic cap with sterile paper** laid in, and subjected to steam sterilisation for **20 minutes at 121 °C**. The closure cap must only be used once.

#### • Storage life

*BIOBvSE* can be kept for 5 years in a sealed bag at room temperature.

#### • Packaging

*BIOBvSE*  $\alpha$ -pore granules are available in 1 ml and 10 ml bottles in a sterile twin pack:

KE 0021	1x1 ml	0.2 – 0.5 mm
KE 0023	1x10 ml	0.2 – 0.5 mm
KE 0025	1x1 ml	0.5 – 1.4 mm
KE 0027	1x10 ml	0.5 – 1.4 mm
KE 0028	1x1 ml	1.4 – 3.2 mm
KE 0030	1x10 ml	1.4 – 3.2 mm



Re Sterilisation Cap & Paper ▲

# Indications

*BIOBvSE* is available in different grain sizes and is suitable for a wide variety of defects. The grain size depends on the size of defect. Generally speaking, the larger defect will be need to the larger grain size. The following table indicates which grain size is to be used with which indication.

#### • Periodontology:

o Two and three wall bone defects can be used with or without membranes

#### • Implantology:

- o Defects augmentation following extraction to create an implant base
- o Elevation of sinus floor
- o Gaps between extraction socket and implant in case of immediate implant placement

#### • Surgery:

- o Defects resulting from cyst removal
- o Defects resulting from apicoectomy
- o Defects resulting from the removal of impacted teeth
- o Defects resulting from corrective osteotomies
- o All other shapes of bony craters and facial bone defects

#### Recommended Size:

##### • 0,2 to 0,5 mm:

o Two or three walled periodontal bone defects in conjunction with membranes

##### • 0,5 to 1,4 mm:

- o Augmentation of bone defects for implant therapy
- o Filling alveolar defects
- o Medium sized and small cysts
- o Apicoectomy.

##### • 1,4 to 3,2 mm:

- o Elevating the sinus floor
- o Large cysts and alveolar cavities