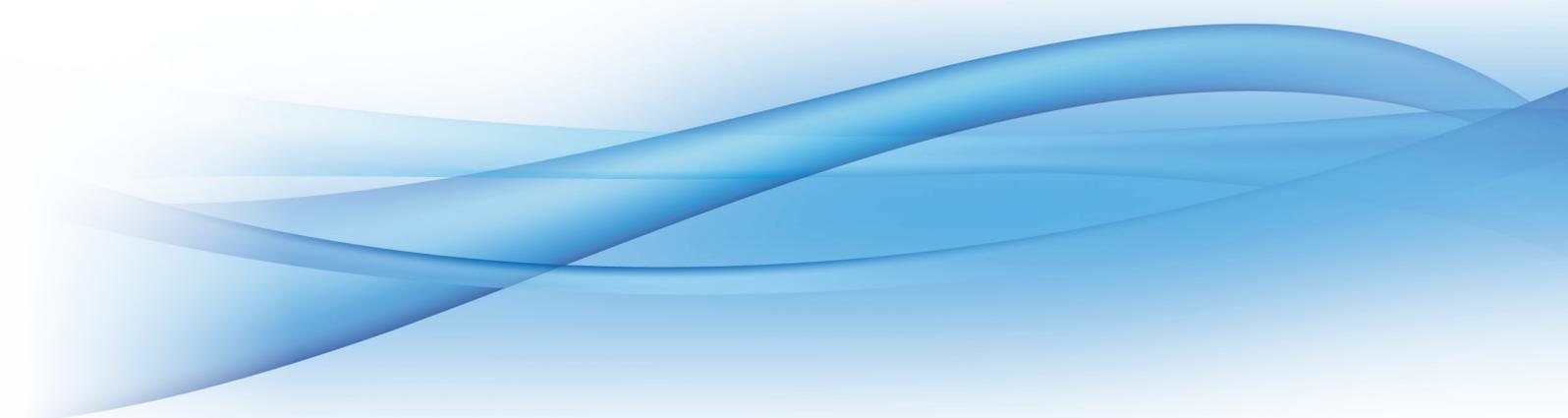

Bone regeneration material



OssaBase-HA



OssaBase-HA

- Macro and nano bone-like structure
- Excellent volume maintenance
- Low substitution rate

OssaBase-HA is a synthetic, macro- and nanoporous bone regeneration material based on hydroxyapatite with a low substitution rate. It is used for the bone regeneration of missing or lost bone tissue independently, or in combination with autologous bone tissue, blood or PRP.

OssaBase-HA features up to 83% interconnected porosity to support vascularized bone formation. Its low substitution rate helps to provide long-term graft stability and the maintenance of volume when a longer healing time is required or if re-entry to the site may be delayed. OssaBase-HA bone regeneration material offers a chemically and structurally similar, synthetic alternative to bovine-derived bone substitutes.

INDICATIONS

Orthopedics, periodontology

- Remodeling of the alveolar ridge
- Treatment of periodontal defects
- Treatment of bone defects around dental implants
- Sinus lift
- Filling of bone defects after surgical extractions to prevent alveolar atrophy
- Filling of bone defects after extirpation of cysts

Orthopedics, traumatology

- Tumor-like lesions (unicameral bone cyst, aneurysmal bone cyst, bone gangliomas, fibrous dysplasia...)
- Pathological fractures with the above-mentioned lesions
- Posttraumatic bone defects (comminuted osteoporotic fractures, compressive fractures of a long bone epiphysis)
- Benign bone

CHARACTERISTIC

In contrast to stoichiometric calcium hydroxyapatite $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ with a Ca/P molar ratio of 1.67, biological hydroxyapatites contain minor substituents in their structure (CO_3^{2-} , Cl^- , Mg^{2+} , K^+ , Na^+), and CO_3^{2-} substitutes primarily for PO_4^{3-} groups (B-type substitution) and at a minimum for OH groups (A-type substitution). The synthetic porous B-type carbonated OssaBase-HA prepared by low-temperature synthesis resembles the structure and chemical composition of the biological bone apatite and can substitute successfully nonsintered bovine apatite prepared by deproteinization of bovine bone but with the absolute elimination of risk caused by residual antigenic proteins of xenogeneic bone.

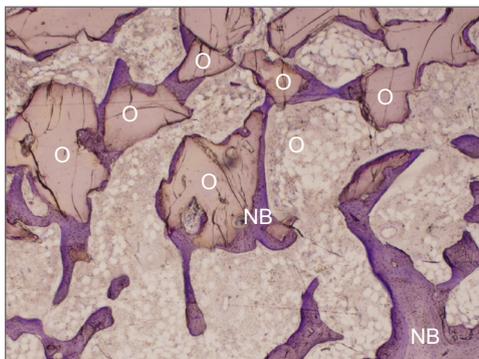
Size of granules (mm)	0.3–2.0
Size of macropores (μm)	> 100
Specific surface area (m^2/g)	78.3 (± 0.34)
Porosity (%)	83
Ca/P molar ratio	1.65
Rel CO_3^{2-} „A“ (I_{1545}/I_{1041})*	$1 \cdot 10^{-6}$
Rel CO_3^{2-} „B“ (I_{1420}/I_{1041})*	0.023

* values expressing a relative carbonate content using phosphate band at 1041 cm^{-1} as standard

ADVANTAGES OF OssaBase-HA

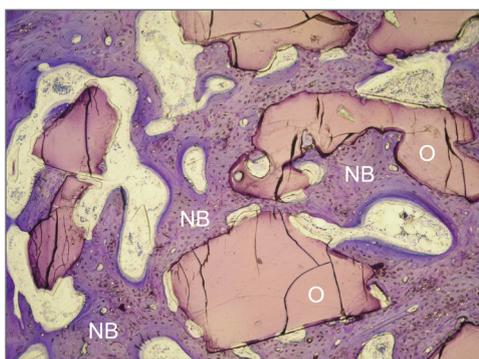
- Structure system of interconnected macro- and nanopores which mimic the structure of human bone.
- Excellent osteoconductive properties of OssaBase-HA enable predictable bone regeneration.
- Optimal non-irritating shape of polygonal macro- and nanoporous granules.
- High surface area typical for natural bone due to the network of nanopores. This nanostructure allows easy preparation by cutting instruments during later implant insertion.
- No organic porogen compounds used during manufacturing – ensures particularly high chemical and phase purity.
- Fully synthetic material – no risk of immunological reactions or pathogen transmission.
- Narrow size ranges of available granules – enough space for bone ingrowth over large distances.
- The high osteoconductivity of OssaBase-HA material is demonstrated in the pictures below.

EXCELLENT OSTEOCONDUCTIVE PROPERTIES



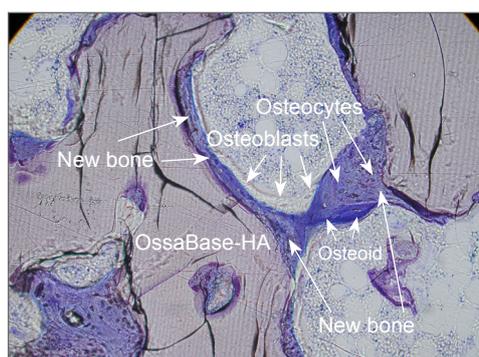
New bone formation (3 months after implantation)

New bone formation (NB) on OssaBase-HA particle surfaces (O) at the spongy site of the surgically created bone defect. (Toluidine blue staining.)



New bone formation (6 months after implantation)

Fragments of the OssaBase-HA material are tightly surrounded by vital, newly formed bone (NB), which also fills the macropores of the material (O). (Toluidine blue staining.)

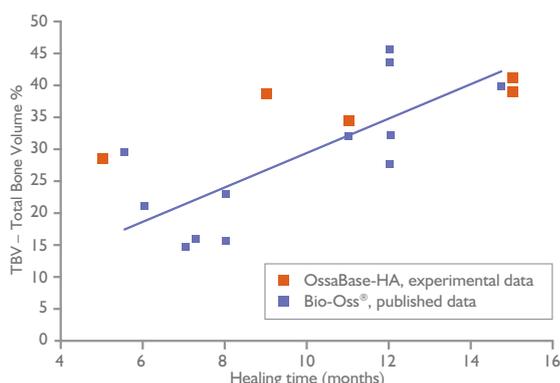


Osteoconduction in detail

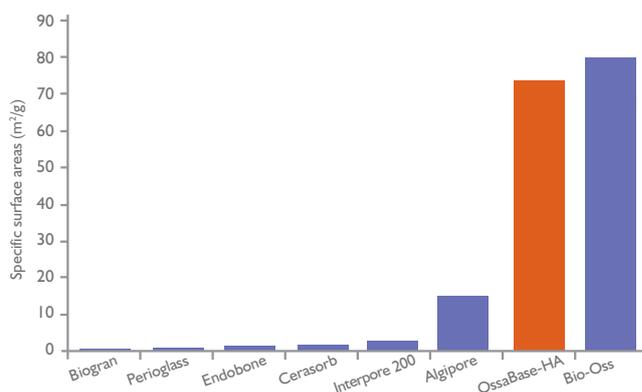
High magnification image of OssaBase-HA implant showing that new bone (NB) has formed around the implanted granules. Notice the bone bridge that connects the granules. Arrows indicate the osteoid layer at the periphery of newly formed bone. Note the central osteoid area in the case of replacing the thinner and longer bone bridge. BM = bone marrow. (Toluidine blue staining.)

COMPARISON OF EXPERIMENTAL RESULTS OF OssaBase-HA AND PUBLISHED DATA OF Bio-Oss®

The synthetic, porous B-type carbonated apatite prepared by low-temperature synthesis OssaBase-HA resembles the structure and chemical composition of the biological bone apatite and can substitute successfully for non-sintered bovine apatite prepared by the deproteinization of bovine bone (Bio-Oss®) with the advantage of the absolute elimination of risk associated with residual antigenic proteins of xenogeneic bone.



Correlation between TBV (Total Bone Volume) and healing time after grafting used in sinus elevation. The red points show experimental data of OssaBase-HA. The blue points correspond with literature data of Bio-Oss® (J. Handschel et al.: A histomorphometric meta-analysis of sinus elevation with various grafting materials, Head & Face Medicine 2009, 5: 12).



Specific surface areas of bone grafting materials (m²/g). (Weibrich, Wagner et al, Mund Kiefer GesichtsChir, 2000/OssaBase-HA Data File, LASAK Ltd.)

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OssaBase-HA – SPECIFICATION

Ref. No.	Grain size	Package
15:6	0.3–0.6 mm	0.5 ml/0.25 g
13:6	0.3–0.6 mm	1.0 ml/0.5 g
25:6	0.6–1.0 mm	0.5 ml/0.25 g
23:6	0.6–1.0 mm	1.0 ml/0.5 g
43:6	1.0–2.0 mm	1.0 ml/0.4 g
40:6	1.0–2.0 mm	2.0 ml/0.8 g

LITERATURE

In vivo behaviour of the synthetic porous hydroxyapatite prepared by low temperature processing and comparison with deproteinized bovine bone; Strnadova M., Strnad Z., Sponer P., Jirosova J., Strnad J.: Key Engineering Materials Vols. 493–494, 2012, p. 236–241.

In vivo behaviour of low-temperature calcium-deficient hydroxyapatite: comparison with deproteinised bovine bone; Sponer P., Strnadova M., Urban K.: International Orthopaedics, 2010.

A mineralogical perspective on the apatite in bone; Wopenka B., Pasteris J. D.: Materials Science and Engineering C, 25, 2005, 131–143.

Apatites in biological systems; LeGeros R. Z.: Prog Crystal Growth Charact, 1981, 4:1–45.