IngeniOs™ βHA Synthetic Bone Particles Technical Data Sheet[1]

1. CHARACTERISTICS

IngeniOs HA Synthetic Bone Particles are open-cellular, bioceramic grafting granules of non-biologic origin for bone regeneration. By use of phase-pure hydroxyapatite with an open sintering structure, a biocompatible, osteoconductive biomaterial is achieved. The material's origin and the ceramic sintering process result in a material that is free of germs and pyrogens; the potential for allergic response can be precluded.

The open cellular structure of the *IngeniOs* HA Particles generate highly porous granules, which are available in two volumes 250-1000 µm and 1000-2000 µm and serve to fill bone defects in oral and maxillofacial indications. These highly porous particles encourage ingrowth of bone. Blood components and body fluids can penetrate the material so that osseointegration and vascularization are achievable.[1]

1.1 Substance

Phase-Pure Hydroxyapatite $Ca_{10}(PO_4)_6(OH)_2$

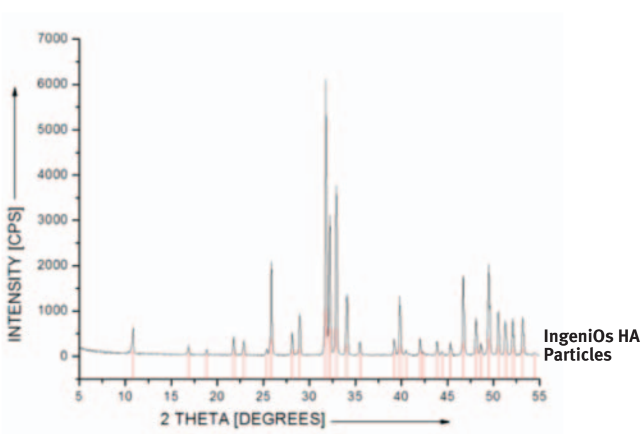

Fig. 1 *X-ray powder diffractogram of phase-pure hydroxyapatite* IngeniOs *HA Synthetic Bone Particles (5-55° 2 ϴ,0,04° resolution, measurement time 6 sec, ϴ/ϴ-diffractometer, reflection Cu-Kα, U=40 kV, I=30 mA, planar graphite monochromatic filter, scintillation counter, continuous sample rotation). The red bars mark the reflection positions of the reference file (ICDD #9-432).*

1.2 Analytic Values

Ca/P Ratio Stoichiometric: 1.67

2. POROSITY

2.1 Description Interconnected, Open-Cell

2.2 Total Porosity Up to 80%

2.3 Pore Size 250-450 µm

2.4 Trabecula Width 15-20 µm

3. LIGHT MICROSCOPY IMAGES

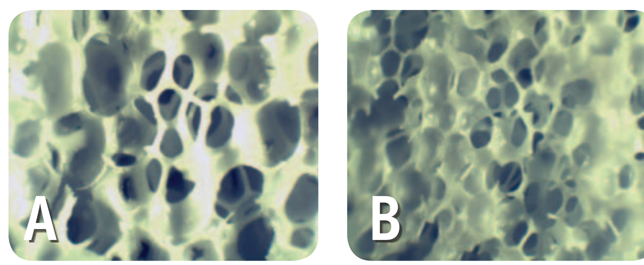

Fig. 2 *Light microscopy pictures of* IngeniOs *HA **block form**.*
The different pore sizes are shown above in Fig. 2.
After grinding, material is mixed in a 1:1 ratio.

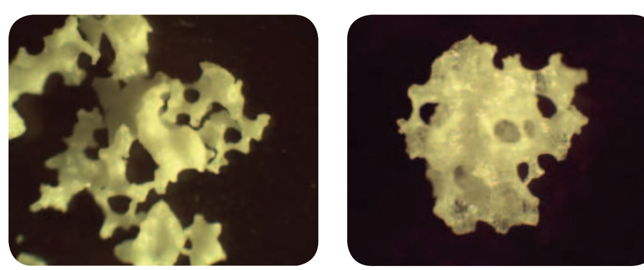

Fig. 3 *Light microscopy picture of IngeniOs HA **granules**.*
The different pore sizes are shown above in Fig. 2.
After grinding, material is mixed in a 1:1 ratio.

Through cutting and crushing, ceramic material fragments of a specified size are produced that are larger than 15-20 µm [Fig. 3]. These fragments are highly porous and spongious. Because of their irregular structure a cluster of low density and intergranular interstitial spaces is formed, which allows the ingrowth of cells, bone and blood vessels.[1]

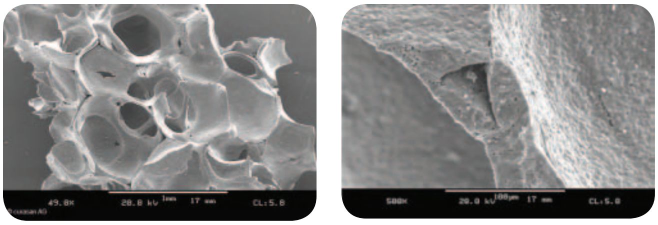

Fig. 4 *Scanning electron microscopy (SEM) pictures:* IngeniOs *HA Particles produced following the Schwartzwalder process.*

The SEM pictures [Fig. 4] show a highly porous material with web widths of 15-20 µm and an interconnecting pore system. The macro structure (i.e. the former foam structure) shows a completely spongious product. The micro structure shows small primary particles that are fused with each other. The particles do not crumble because of the regularity of the structure. All subparticles (i.e. fragments of the web) have dimensions larger than 10 µm.

4. µ-CT IMAGES

The µ-CT pictures in Fig. 5 show a highly porous pile of particles where pores as well as intergranular interstitial spaces can be seen. Bone and blood vessels have the opportunity to enter and grow into these areas to support vascularized bone growth.

In Fig. 6 the web of *IngeniOs* HA Particles are highlighted. Blue areas show voids, green areas show thin webs and X-ray areas are opaque (i.e. successive webs or accumulation of material) are marked yellow to red. Pictures B and C show structures of similar density in all areas of the pile, which indicates only slight irregularities in the pore size distribution and web widths.

The pore representation in Fig. 7 (above) shows a horizontal section through the middle of the sample. The open-cellular structure of the material is obvious and is consistent with the structure observed in the SEM pictures.

5. MANUFACTURING

Reticulated sponges (a sponge with a net like pattern) with consistent, open-cellular porosity serve as a sintering matrix. The pore size of open-cell sponges is calculated in "pore per inch" (ppi).

The HA slurry is kneaded into the regular open-cell sponges. During a thermal sintering process the open-cellular polyurethane sponge burn off residue-free, the liquid of the slurry evaporates and the ceramic particles sinter with each other. It remains a pure hydroxyapatite ceramic in form of an open-cellular sponge. With a cutting mill the open-cellular block forms are crushed to the desired particle size and materials of the different pore sizes are mixed.

Fig. 5 *µ-CT images of a granule pile of IngeniOs HA Particles*

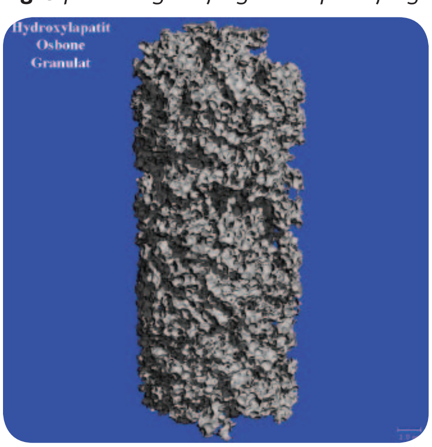

Fig. 5A *Three dimensional view.*

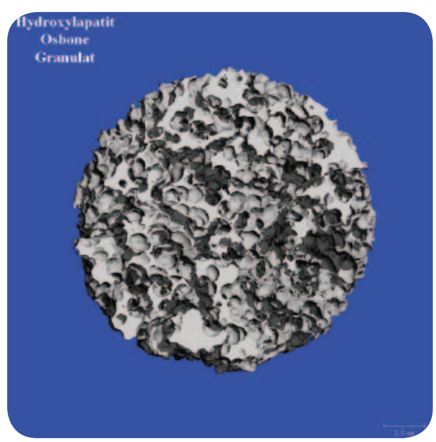

Fig. 5B *Horizontal section through the middle of the sample.*

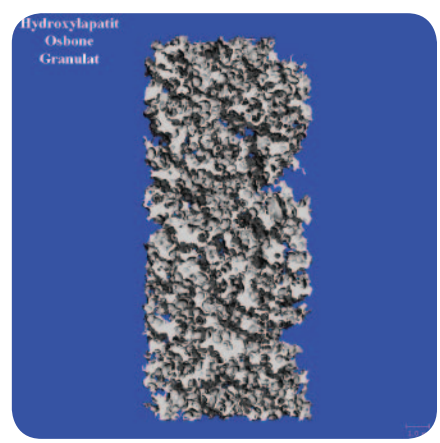

Fig. 5C *Vertical section through the middle of the sample.*

Fig. 6 *False color representation of μ-CT images of* IngeniOs *HA Particles.*

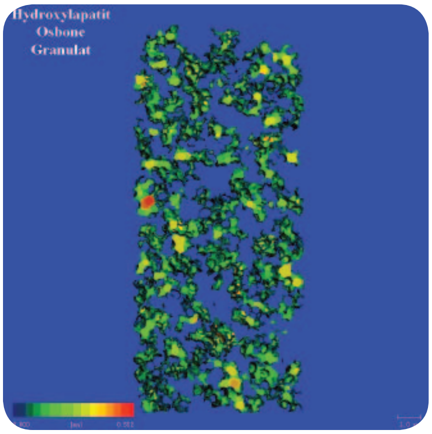

Fig. 6A *Vertical section through the middle of the sample (50 layers per 16 μm)*

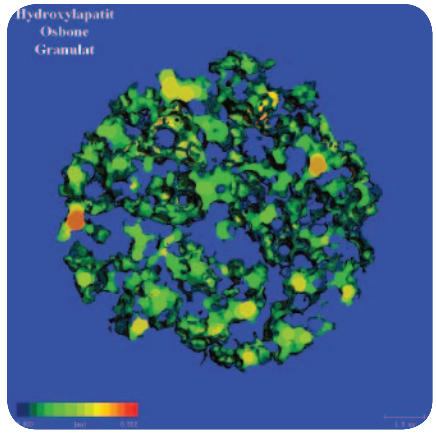

Fig. 6B *Horizontal section through the upper part of the sample (50 layers per 16 μm)*

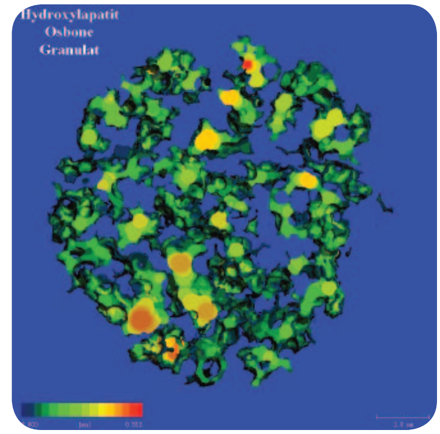

Fig. 6C *Horizontal section through the lower part of the sample (50 layers per 16 μm)*

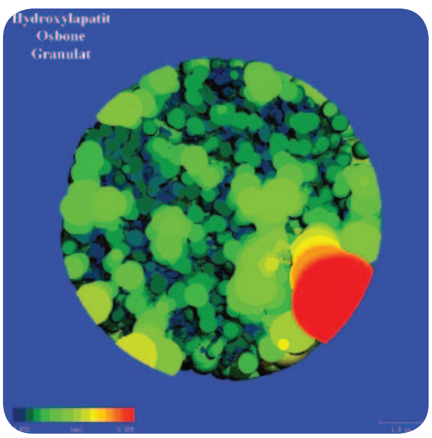

Fig. 7 *Pore representation in a granule heap.*

1. Data on file with curasan AG.