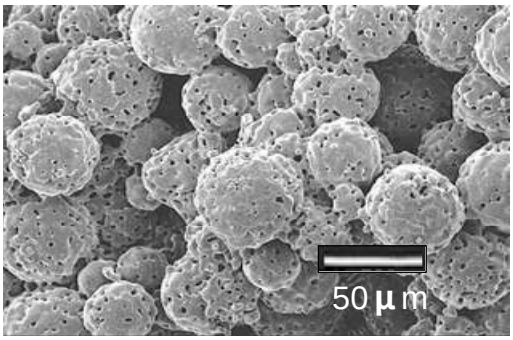
Product Information

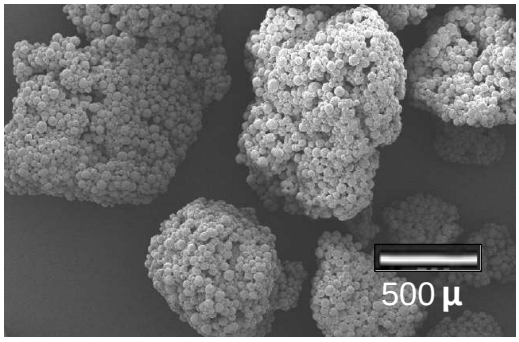
ArrowBone

- **Pure phase tricalcium phosphate bone grafting material that is completely resorbable, while simultaneously enabling new bone formation.**

- **Its unique osteoconductive granule structure with open micro- and macropores allows faster replacement by newly formed autogenous bone.**



SEM image of a granule
(taken at an original magnification of × 50)



A higher magnification SEM image of a granule
(taken at an original magnification of × 500)

Roles of bone grafting material:

1. **Osteoconductivity:**
   The material is biocompatible and serves as a scaffold for new bone formation generated from the surrounding existing bone.

2. **Space maintenance capability and physical strength:**
   Capability of maintaining space in the scaffold for new bone formation.

3. **Bioactivity:**
   Capability of promoting new bone formation (including bone healing).

From the viewpoint of osteoconductivity, space maintenance capability, and bioactivity, ArrowBone tricalcium phosphate (TCP) is very suitable bone grafting material.

Bone Grafting with ArrowBone

- ArrowBones are bone grafting materials that have excellent biocompatibility and higher bioresorbability, which have been achieved using our own proprietary manufacturing method.
- ArrowBone-α is made of very pure α-tricalcium phosphate granule ceramics with a unique micro- and macropore structure.
- ArrowBone-β is made of very pure β-tricalcium phosphate granule ceramics with a unique micro- and macropore structure.

Advanced Features of ArrowBone

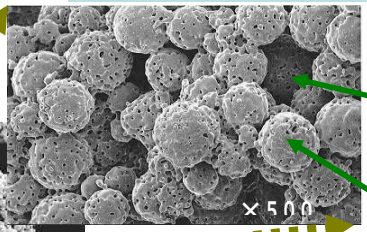
- Single-phase ceramic granules of very pure tricalcium phosphate
- The osteoconductive scaffold stimulates cellular activity as a result of its excellent biocompatibility and higher osteoconductivity
- The unique granule structure with open micro- and macropores provides space for cells to function and promotes attachment, proliferation, and differentiation
- Vascularization in macropores and subsequent new bone regeneration, degradation, and resorption occur in balance and bone substitution results.
- Due to its unique micro- and macroporous structure, new bone tissue forms in pores and better initial fixation is expected. In addition, as blood clots tend to get tangled when implanting the material, it allows for easier implantation surgery.
- Due to our high-purity chemical synthesis materials, potential infection risks associated with bone substitutes of biological origin are avoided.

Scientific Studies

● *Granule Structure of ArrowBone*

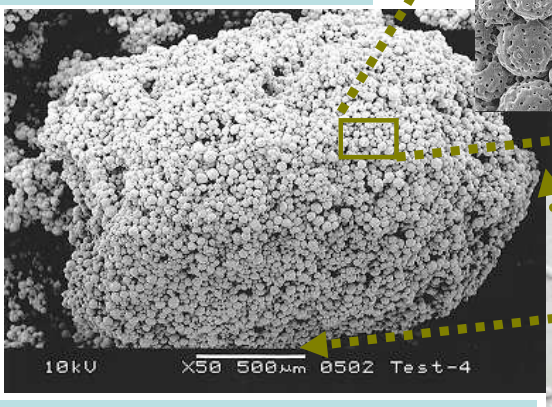
SEM image (original magnification of x 500)

SEM image (original magnification of x 50)



Interconnecting pores of the granules

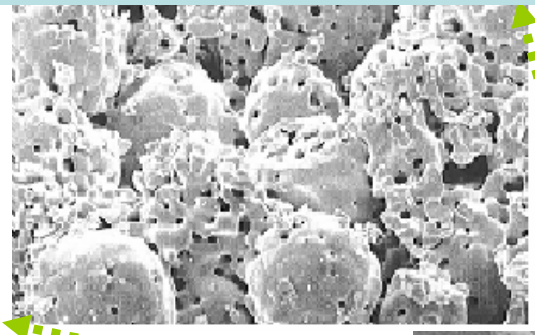
Surface micropores



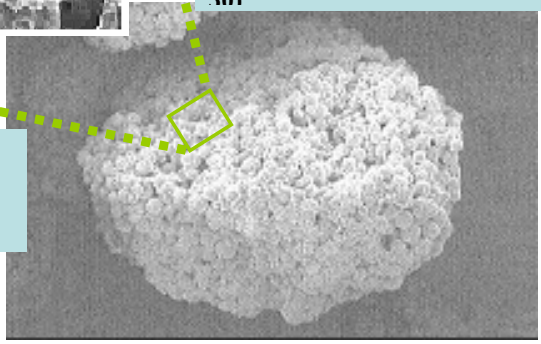
The SEM photograph showing the interconnecting open macro- and micropores.

Granules

A cross-sectional view of granules by SEM image (taken at an original magnification of x 500)



A cross-sectional view of granules by SEM image (taken at an original magnification of x 50)



Micropores are even observed in the inner parts of the granules, which results in a greater surface

● Property of α-TCP

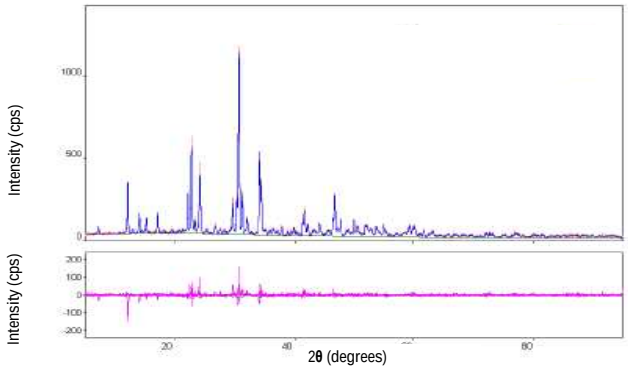
- Chemical Formula：Ca3(PO4)2
- Cas Number：7758-87-4
- Ca/P mole ratio：1.50 as a stoichiometric composition of tricalciumphosphate
- Crystallographic texture：Single-phase ceramic of α-tricalciumphosphate
- Form：Open porous granule structure
- Granule size：250-1000μ m
- Porosity：75%
- Hydrophilicity：Excellent
- Biocompatibility： Excellent

● Property of β-TCP

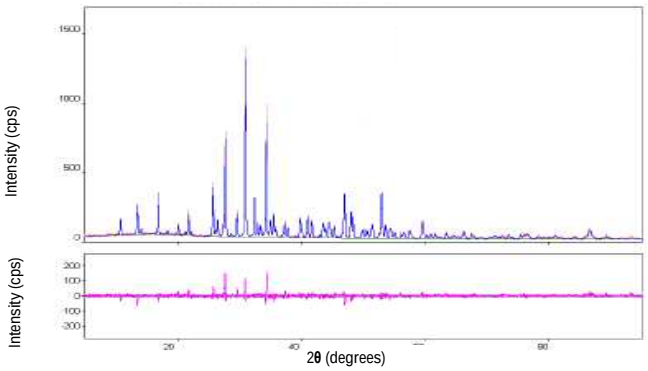
- Chemical Formula：Ca3(PO4)2
- Cas Number：7758-87-4
- Ca/P mole ratio：1.50 as a stoichiometric composition of tricalciumphosphate
- Crystallographic texture：Single-phase ceramic of β-tricalciumphosphate
- Form：Open porous granule structure
- Granule size：250-1000μ m
- Porosity：75%
- Hydrophilicity：Excellent
- Biocompatibility：Excellent

X-ray Diffraction Profile

● ArrowBone-α (α-TCP)

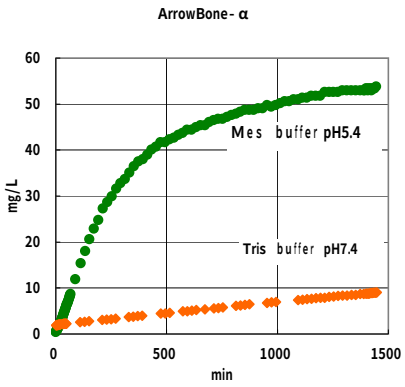


● ArrowBone-β (β-TCP)

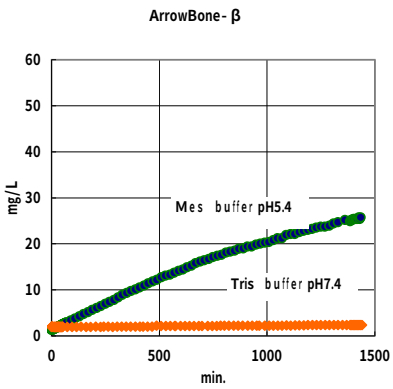


Dissolution Test

● ArrowBone-α (α-TCP)



● ArrowBone-β (β-TCP)

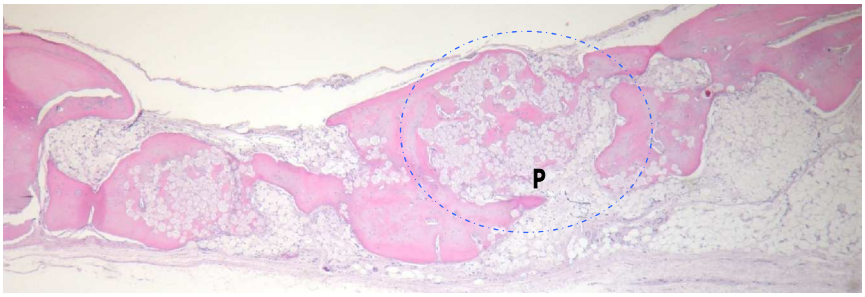


Dissolution rate differences and biodegradation rate:
Compared to β-TCP, since the resorption of α-TCP is faster, it is expected that the use of ArrowBone-β, which is resorbed more slowly than ArrowBone-α, will bring about good clinical results in cases where the blood supply is insufficient and a long healing time is needed.

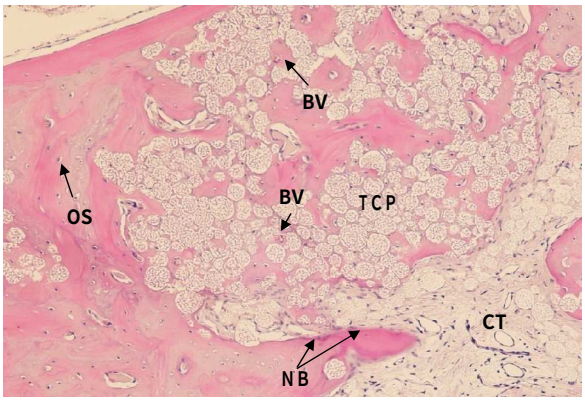
Clinical Studies

Animal Implantation Test :

Histological observations of ArrowBone-α particles 8 weeks after filling cranial bone defects prepared in white rabbits.



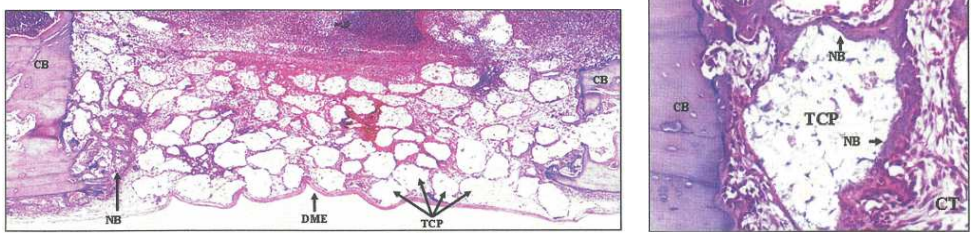
Original magnification of P site x 100
NB: New bone
CT: Connective tissue
OS: Osteocyte
TCP: Remnants of α-TCP particles



The in-growth of newly formed bone and the vascularization in α-TCP particles (TCP) were observed.

Study of Bone Grafting using our TCP Granule Material (1)

Source: Hidemichi Kihara. Makoto Shiota, Yasuo Yamashita, Shohei Kasugai. : Biodegradation Process of α-TCP Particles and New Bone Formation in a Rabbit Cranial Defect Model, J Biomed Mater Res B: Appl Biomater 79(2): 284-291, 2006.



a b

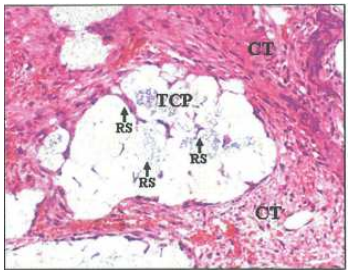


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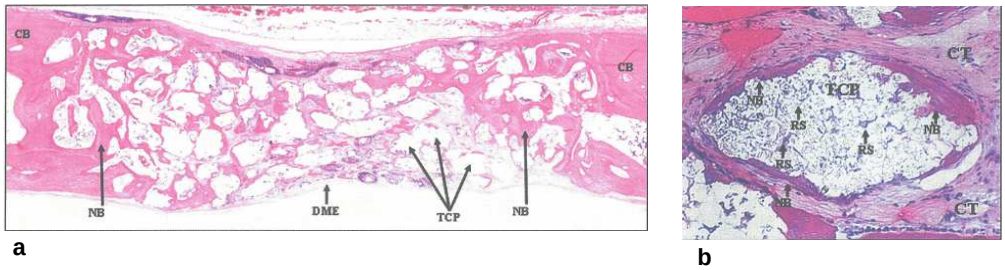
Figure 2. (a) Hematoxylin-eosin staining of the entire defect in the experimental group at 1 week. The defect was compactly filled with α-TCP particles (TCP). Connective tissue and numerous capillaries were present among α-TCP particles. DME, dura mater encephalon; CB, cranial bone; NB, new bone. (Original magnification ×10). (b) Hematoxylin-eosin staining of α-TCP near the defect wall at 1 week. New bone (NB) was observed on the surface of α-TCP particles (TCP). CB, cranial bone; FC, fibrous connective tissue. (Original magnification ×100). (c) Hematoxylin-eosin staining of α-TCP at the center of the defect at 1 week. A reticulate structure (RS) was observed inside the α-TCP particles. TCP, α-TCP; CT, connective tissue. (Original magnification ×50).

Microscopic view of a cross-section of a defect 1 week after implantation
Connective tissue and numerous capillaries are seen among the alpha-TCP granules. Near the defect wall, newly formed bone is observed around the surface of the alpha-TCP granules and some of the alpha-TCP granules and the defect wall are partially connected with newly formed bone.



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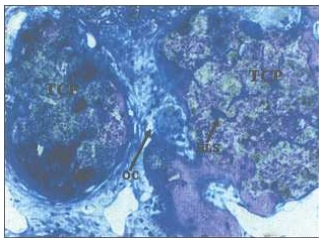

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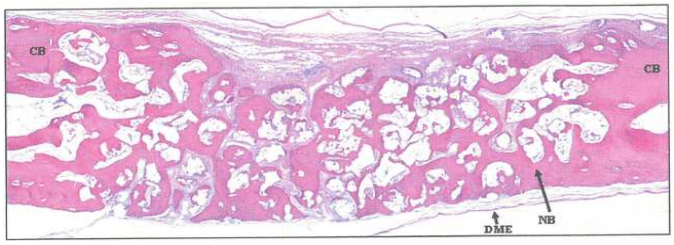
Figure 4. (a) Hematoxylin-eosin staining of the entire defect in the experimental group at 4 weeks. The defect was almost completely filled with α-TCP particles and the center space of the defect was maintained. DME, dura mater encephalon; CB, cranial bone; TCP, α-TCP; NB, new bone. (Original magnification ×10). (b) Hematoxylin-eosin staining of α-TCP within the center of the defect in decalcified specimens at 4 weeks. New bone (NB) was observed on α-TCP particles' surface and a reticulate structure (RS) was observed inside α-TCP particles (TCP). CT, connective tissue. (Original magnification ×50). (c) Toluidine blue staining of α-TCP in nondecalcified specimens at 4 weeks. Reticulate immature bone or bone-like structures (BLS) were present in α-TCP particles (TCP) and a few osteoclasts (OC) were observed surrounding the α-TCP particles. (Original magnification ×100).

Microscopic view of a cross-section of a defect 4 weeks after implantation
The defect space is maintained, even in the center of the defect. The connective tissues first observed at 1 week are reduced, and new bone in direct contact with the surface of the alpha-TCP particles is observed among the alpha-TCP granules, even in the center of the defect. This demonstrates the good osteoconduction of the alpha-TCP granules. Near the defect wall, most of the alpha-TCP granules are enclosed in new bone and have become smaller. In non-decalcified specimens, reticulate immature bone or bone-like structures surround the alpha-TCP particles and a few osteoclasts are observed surrounding the alpha-TCP particles.



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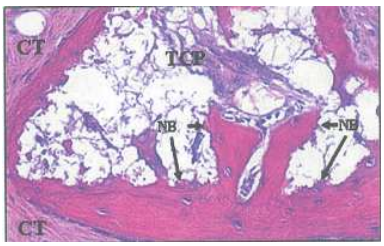

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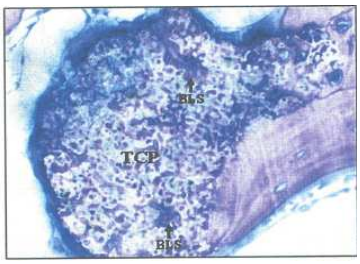


c

Figure 6. (a) Hematoxylin-eosin staining of the entire defect in the experimental group at 8 weeks. The overall defect's space was maintained by α-TCP particles and new bone (NB). DME, dura mater encephalon; CB, cranial bone. (Original magnification ×10). (b) Hematoxylin-eosin staining of α-TCP in the center of the defect in decalcified specimens at 8 weeks. New bone (NB) was observed around α-TCP particles (TCP) and in a deeper area of α-TCP particles. (Original magnification ×50). (c) Toluidine blue staining of α-TCP in nondecalcified specimens at 8 weeks. In α-TCP particles (TCP), reticulate new bone or bone-like structures (BLS) were observed. (Original magnification ×100).

Microscopic view of a cross-section of a defect 8 weeks after implantation
The entire defect is filled with new bone and residual alpha-TCP particles, which are in the process of being replaced by new bone, even in the center of the defect. The connective tissue among the alpha-TCP particles is reduced more than at 4 weeks, and new bone substitution has progressed. Reticulate new bone or bone-like structures are observed in the alpha-TCP particles in non-decalcified specimens.

Most of the alpha-TCP particles near the defect wall have lost their original shape and become smaller. At some distance from the defect wall, the alpha-TCP particles have various forms; some have a concave surface into which new bone has entered and other particles have been deeply invaded by new bone.

In non-decalcified specimens, the alpha-TCP particles are smaller than at 4 weeks and the boundary between the alpha-TCP particles and surrounding new bone is indistinct, resulting from the progressive collapse of alpha-TCP particles.

Study of Bone Grafting using our TCP Granule Material (2)

Source: Yamada M, Shiota M, Yamashita Y, Kasugai S. : Histological and Histomorphometrical Comparative Study of the Degradation and Osteoconductive Characteristics of alpha-and beta-Tricalcium Phosphate in Block Grafts. J Biomed Mater Res B Appl Biomater 2007;82(1):139-48.

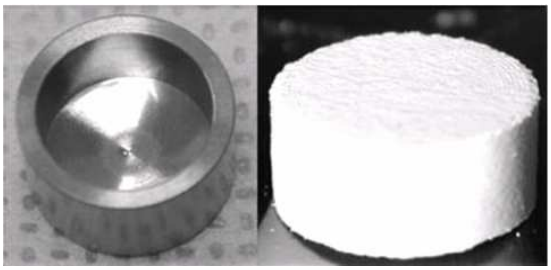


Figure 1. Commercial pure titanium chamber (left) and tricalciumphosphate porous block used in this study.

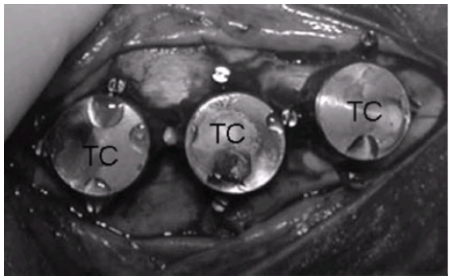
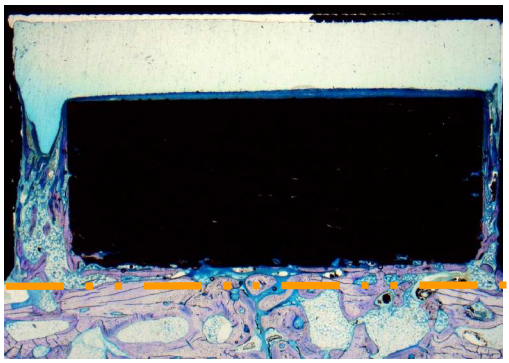
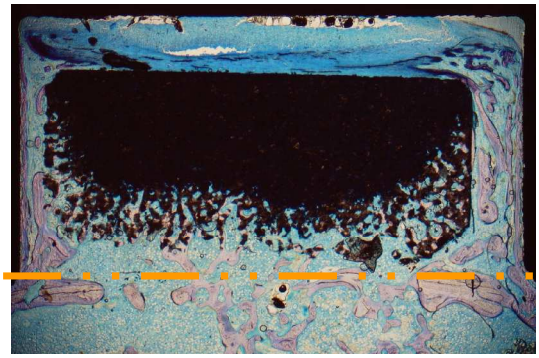


Figure 2. Ti-chambers (TC) were placed and attached to the bone with dental adhesive resin cement involving fixing screws.

- **Higher initial solubility than β-TCP**
- **Residual α-TCP particles surrounded by newly formed bone**
- **The degradation of α-TCP seemed to be aligned with bone formation**

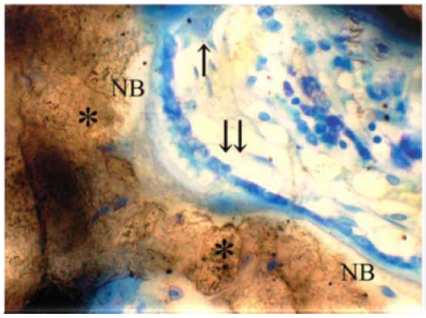


8w β-TCP Block



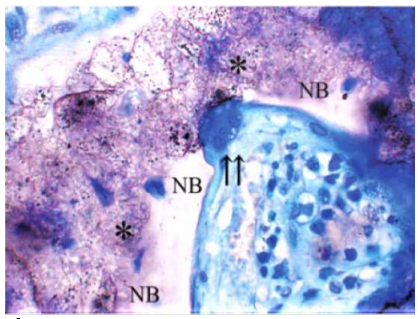
8w α-TCP Block

- **New bone originating from the defect wall has invaded the block of TCP, both the alpha- and beta-TCP, from the boundary between the block and defect wall.**
- **The difference in the degradation of alpha- and beta-TCP observed *in vivo* is reflected directly by the difference in the solubilities of alpha- and beta-TCP.**



a

α-TCP group at 8 weeks at high magnification (original magnification x 50). Osteoblasts (double arrow) are visible on the surface of newly formed bone (NB) surrounding TCP particles (asterisk). Arrow shows multinuclear giant cell.

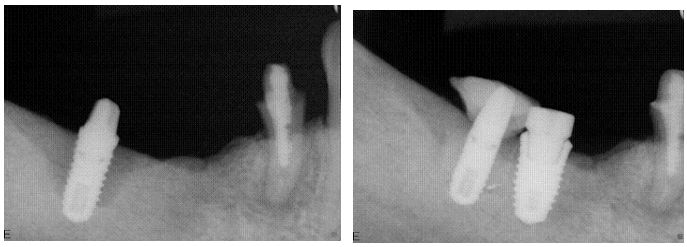


b

α-TCP group at 8 weeks at high magnification (original magnification x 50).
Both newly formed bone (NB) and α-TCP particles (asterisk) are absorbed by osteoclast-like cell (double arrow).

Clinical Evidence

Peri-Implantitis



Before

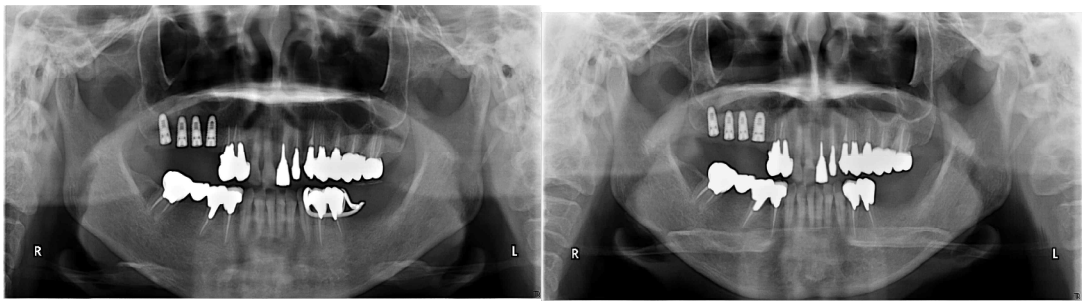
After

Extraction Site

Before

After

Crest Augmentation



Before

After

Indications / Use

- **Augmentation or reconstructive procedure of the alveolar ridge.**
- **Filling of intrabony periodontal defects.**
- **Filling of defects after root resection, apicoectomy, and cystectomy.**
- **Filing of extraction sockets to enhance preservation of the alveolar ridge.**
- **Elevation of the maxillary sinus floor.**
- **After preparing the bone grafting site, fill the device into the site in combination with patient blood.**
- **In order to ensure the formation of new bone, the product should be placed in direct contact with well-vascularized bone tissue (a selective osteoplasty of adjacent cortical bone may be necessary).**

ArrowBone

Pure Phase Tricalcium Phosphate

- **Kihara H, Shiota M, Yamashita Y, Kasugai S. : Biodegradation Process of alpha-TCP Particles and New Bone Formation in a Rabbit Cranial Defect Model. J Biomed Mater Res B Appl Biomater 2006;79(2):284-91.**
- **Yamada M, Shiota M, Yamashita Y, Kasugai S. : Histological and Histomorphometrical Comparative Study of the Degradation and Osteoconductive Characteristics of alpha-and beta-Tricalcium Phosphate in Block Grafts. J Biomed Mater Res B Appl Biomater 2007; 82(1):139-48.**

For more detail, please see :

http://www.interscience.wiley.com/jpages/1549-3296