B-OstIN®
Maximizing OsteoINtegration

Uses & Presentations

1. Bone void filler
2. Tibia Plateau Fracture
3. Distal Radius Fracture
4. Vertebral Fracture
5. Spinal Fusion
6. Cavity filling in spine
7. Calcaneus Fracture

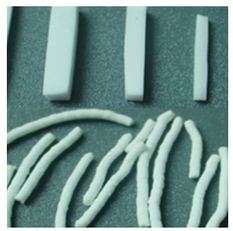
Instruction for use

- B-OstIN implants may be used with or without mixing with patient's own blood or with autogenous cancellous bone or bone marrow aspirate.
- B-OstIN implants should be placed in direct contact with cancellous bone.
- B-OstIN (block and rod) is recommended to be trimmed to an appropriate size with sharp blade and shaped with a bone file to achieve a snug fit. It is suggested that the shaped surfaces be smooth and free from exessive loose particles before implantation.
- Gap or cavity should be properly filled. Overfill should be avoided.
- Once B-OstIN is implanted, it is recommended not to use suction or any local washing / diluting material for fear of loss/migration of B-OstIN from the implanted site.
- B-OstIN implant may be fixed wherever practically possible with periosteal sutures to decrease the risk of migration.

Product Presentation

Granules

SIZE (mm)	VOLUME (cc)
0.5 - 1.0	1, 3, 5
1.0 - 3.0	3, 5, 10, 15, 20
3.0 - 5.0	5, 10, 15, 20, 30



Rod

DIA (mm)	LENGTH (mm)
8	12
8	14
10	14
10	16
12	16
12	18

Block

DIMENSIONS
5 mm x 5 mm x 10 mm
12 mm x 12 mm x 10 mm
20 mm x 20 mm x 10 mm
10 mm x 10 mm x 35 mm
10 mm x 10 mm x 45 mm

** References : On Basic Healthcare File*

Basic Healthcare
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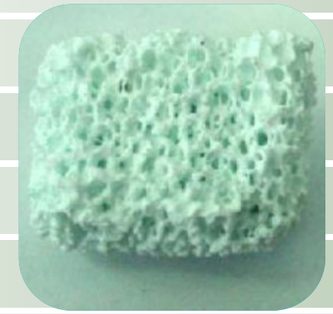

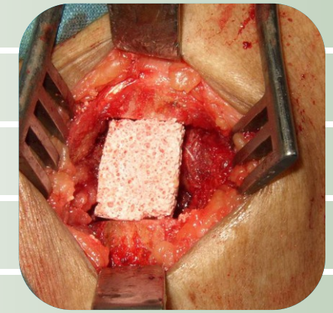

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B-OstIN

Maximizing OsteoINtegration

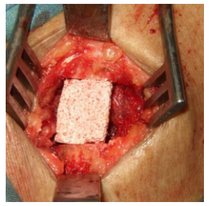
B-OstIN is biocompatible synthetic Calcium phosphosilicate compound combining the osteoconductive properties of HAP with osteostimulating properties of silica. B-OstIN has excellent tissue bonding properties due to the presence of silanol radical which promotes the precipitation of hydroxyl-carbonate apatite (HAC) on its surface in addition silanol has ability to stimulate active bone growth.

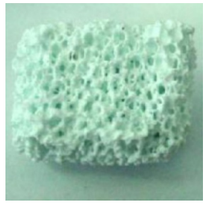
Product integrity of B-OstIN is strengthened by stringent adherence to quality standards (applicable ISO and ASTM standards) that ensures the standard composition of bio composite ceramic for implant. Biocompatibility of B-OstIN has been tested as per ISO 10993 specification.

B-OstIN is described as bioactive silica layer over a porous backbone of poly crystalline hydroxyapatite ceramic. This structure enhance the surface bonding properties of B-OstIN. The Toxicological evaluation shows that B-OstIN is not hemolytic, shows no cytotoxicity and is biocompatible in subcutaneous soft tissue without causing any adverse effect.

Apart from hydroxapatite, the elemental composition of silica is 17% silicon, 53% calcium and 30% phosphorous. Ratio of HAP and silica is tuned so as to get optimum in vivo activity and resorption rate. This feature allows us to customize the product for specific applications / surgeries. One such application is recovery of iliac crest defect.

B-OstIN blocks were studied in the reconstruction of iliac crest defects in twenty three patients. Donor site pain is significantly reduced with B-OstIN. The radiological evaluation covered the parameter like incorporation, dissolution, fragmentation and migration of B-OstIN. The study concluded that the use of composite blocks was a complication saving procedure because it prevented donor site pain, local hematoma, fracture of remaining iliac bone and cosmetic problems.





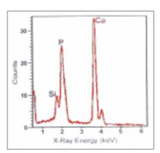
FEATURES

- Biocompatibility, bioactivity, osteoconductivity of B-OstIN adheres to standard bone graft material.
- B-OstIN has enhanced bioresorption rate. B-OstIN resorb fully within 1 year.
- B-OstIN is osteostimulating due to silica content.
- B-OstIN has excellent surface bonding property not only with bone but also with soft tissue.
- Compressive strength of B-OstIN is 10 MPa which is similar to that of cancellous bone.
- B-OstIN is non immunogenic so no risk of disease transmission.
- B-OstIN is easy to shape so can be cut in to desired shape.

Chemical Characterization

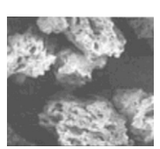
X-RAY DIFFRACTION

X-Ray diffraction pattern showing peaks of phosphate, calcium and silicate.



SCANNING ELECTRON MICROSCOPY

The pore sizes of B-OstIN granules are in the ranges 100-200 microns



PRODUCT STABILITY

B-OstIN does not show any physical and chemical change either by irradiation (12 hr) or by heat treatment (450°c)

TRACE ELEMENT ANALYSIS

The amount of heavy element found in B-OstIN to below the maximum allowed concentration ensuring purity of the material.

Element	MAC in ppm	B-OstIN (HABG)
As	3	< 1ppm
Cd	5	< 1ppm
Hg	5	< 1ppm
Pb	30	< 1ppm

CHEMICAL ANALYSIS

Calcium and phosphate were estimated by spectrophotometry, and silica by gravimetry.

Si as SiO2 - 17 + 3%

Ca as CaO - 53 + 3%

P as P205 - 30 + 3%

Toxological Evaluation

HAEMOLYSIS TEST

The percentage of haemolysis by B-OstIN is less than 5% in fresh potassium oxalate anticoagulated rabbit blood and hence calculated as non haemolytic.

CYTOTOXICITY TEST

B-OstIN in contact with L929 cells for 24 hr does not produce any cytotoxic effect

SUBCUTANEOUS IMPLANTATION TEST

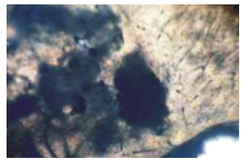
Following results are obtain when B-OstIN is placed in contact with tissue for 12 weeks

- Cell Necrosis, Plasma cells, Eosinophils, Neutrophils, Haemorhage, Fatty infiltration, and Oedema were not present
- Lymphocyte and calcification were present in moderate amount
- Macrophages, giant cells, fibrocyte and fibroplasias are present in apparent quantity

IN VIVO ANIMAL STUDIES

The Induction of bone ingrowth in rabbits by B-OstIN of a period interest of 3 and 6 months.

After 3 months

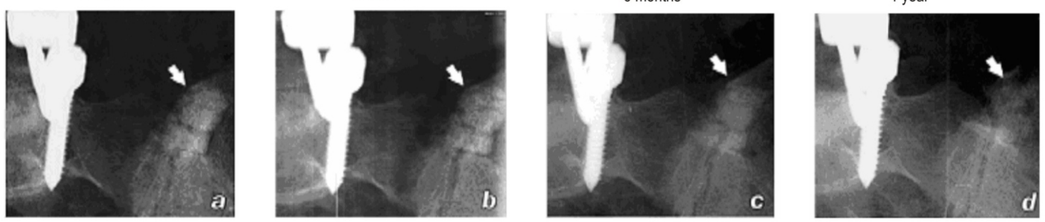


After 6 months

Clinical Studies

X-rays of patient after implantation of B-OstIN block in iliac crest after bone extraction for autograft

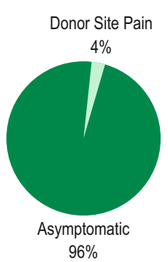
B-OstIN block integrate with the host bone within one year



The position of the implant is marked by the arrow.

CLINICAL OUTCOMES

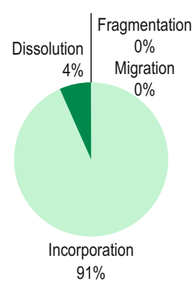
Patient evaluated by the visual anologue scale for pain proves incident of long term donor site pain in iliac crest reconstruction with B-OstIN is only 4% which is very remarkable as compared to historical data.



RADIOLOGICAL OUTCOMES

No clinical complication like haemotoma, infection fracture, visceral prolapse or neuroma formation.

B-OstIN showed 91% incorporation proving excellent acceptability of B-OstIN.



** Data on Basic Healthcare File.*

** Study Duration : 1 year*