# ShefaBone SCPC

## Silica-Calcium Phosphate Composite (SCPC)

**Synthetic Resorbable Porous Bioactive Granules for Bone Graft**


Shefabone SCPC is a new, US patented, resorbable osteoconductive bone graft material made of bioactive silica-calcium phosphate ceramic [1, 2]. SCPC is engineered with unique interconnected porosity and crystalline structure to enhance new bone formation and graft material resorption [3-5]. After implantation, the SCPC develops a carbonate hydroxyapatite surface layer, similar to the mineral phase of bone which facilitates osteoblasts attachment and new bone deposition on the surface of SCPC. There is no fibrous encapsulation or immune reaction against SCPC. The porosity of SCPC facilitates penetration of bone cells and blood vessels inside the particles leading to formation of vascularized new bone within the particles. Bone formation in the inner pores and on the outer surface of SCPC particles accelerates regeneration of functioning bone made by the patient own cells. The newly formed bone undergoes remodeling exactly like host bone. As the SCPC resorbs, bone cells deposit new bone that fully replaces the graft material. **SCPC has successfully passed all ISO 10993-1 biocompatibility tests and showed complete absence of sensitization, irritation, systemic toxicity, and genotoxicity.**

ShefaBone

ShefaBone is a synthetic resorbable osteoconductive bone graft composed of silicon oxide

## What are the ingredients of SCPC?

The SCPC composition combines oxides of Si, Na, Ca and P needed to promote new bone formation [1, 2]. The oxides of SCPC are packed together in a unique crystalline structure made of ß-Rhenanite (NaCaPO4) and α-Cristobalite (SiO2). It has been shown that b -NaCaPO4 has the most effect on the differentiation of human bone–derived cells, inducing mRNA and protein expression of osteopontin, osteocalcin, osteonectin, and bone sialoprotein, suggesting later osteoblast differentiation [7]. The silica phase of SCPC facilitates guided bone cell growth and mineralized bone matrix formation [1, 2]. Therefore, the combination of silicate to sodium calcium phosphate in SCPC structure synergistically facilitates a superior biocompatibility, nonimmunogenity, osteoconductivity and new bone tissue formation.

## Advantages

**Bioactive:** Stimulates bone cell function and tissue formation

**Osteoconductive:** Enhance bone cells differentiation and direct bone deposition on the material surface.

**Porous:** Allows rapid bone formation, vascularization and graft material resorption

**Resorbable:** Allows complete bone regeneration as the body fully resorbs the graft material.

**Handling:** Easy to apply, SCPC particles stay in place inside the defect and do not migrate or diffuse.

**Biocompatability:** Nontoxic, non-immunogenic and do not elicit any rejection reaction

**Efficiency:** Minimizes the need for autogenous bone in large defects after tumor resection

**Radiopacity:** SCPC is radiopaque in X-ray radiograph which makes it easy to follow the progress in bone healing and graft material resorption.

## Indications For Use

ShefaBone SCPC Resorbable Bioactive granules are used as a bone filling material in orthopedic and maxillofacial surgeries. Typical uses include:

- **Cystic cavities**
- **Periodontal / infrabony defects**
- **Ridge augmentation (sinusotomy, osteotomy, cystectomy)**
- **Extraction sites (ridge maintenance/augmentation, implant preparation/placement)**
- **Sinus lifts**
- **Oral and maxillofacial augmentation**

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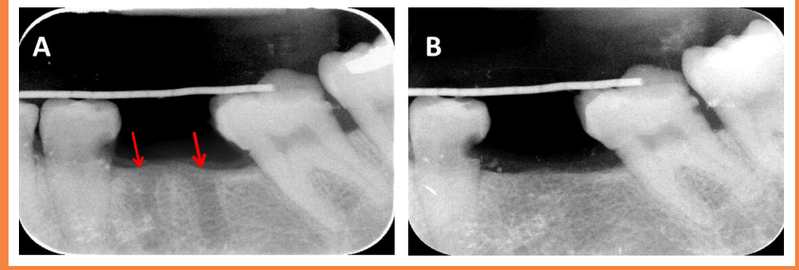
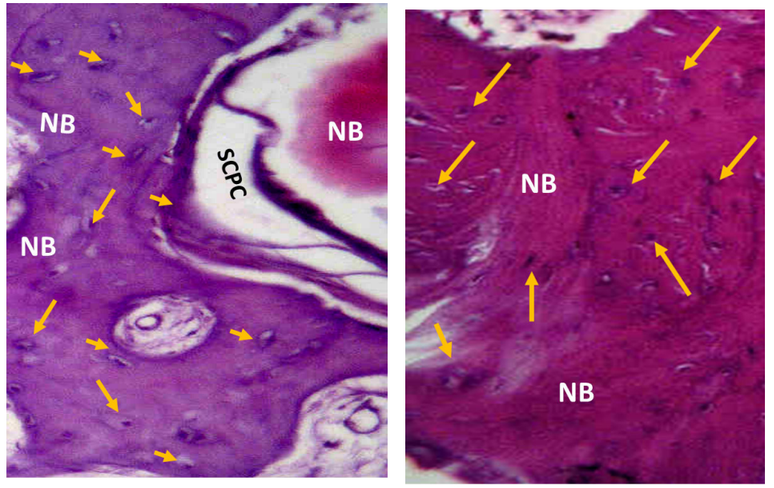



***X-ray radiographs showing: (A) immediate postoperative image of the extraction sockets (red arrows) and (B) after 6 month, the SCPC granules were resorbed and replaced by new bone which has comparable radio-opacity to the host bone.***




***Histology analysis of bone biopsy taken from the core of extraction sockets grafted with SCPC (for 6 months). Areas of mature bone with osteocytes (arrows) and Haversian system are seen. A small remnant of SCPC (left image) can be seen surrounded by new mature bone. (H&E; magnification 100X).***

# Administration

These instructions are intended as guidelines for the use of ShefaBone SCPC as a part of established surgical techniques. They are not intended to replace or change standard procedures for treatment of bone defects involving bone grafting and internal fixation. The seal on the vial should be carefully removed to avoid spillage. ShefaBone SCPC granules can be mixed with the patient's blood or sterile saline using a disposable dappen dish cup and subsequently delivered to the defect site with a spatula. Allow material to hydrate in the bone defect. Gently pack the particles and do not over fill. The granules in the bone defect can be covered by the soft tissue and suture or a resorbable collagen plug (RCP), or tape (RCT), can be cut to size and compressed in place as a dressing (cover the SCPC particles inside the socket or bone defect). Criss-cross and/or mattress sutures are placed. Allow to heal completely.

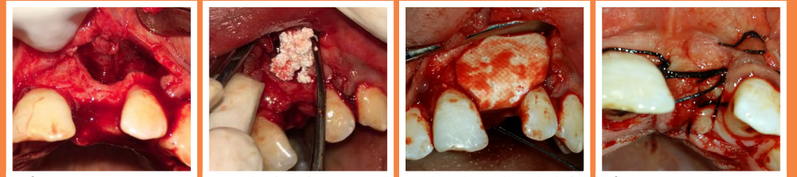



***Figure 1. Illustration of filling extraction socket with SCPC bone graft.***

**CONTENT PER VIAL:** Each vial contains 1 cc of resorbable porous bioactive SCPC granules.

**STERILIZATION:** STERILE R

Sterilized by Gamma radiation. Contents are sterile if unopened and undamaged.

**SINGLE USE ONLY.**

Do not attempt to re-sterilize or re-use

**CONTRAINDICATIONS**

ShefaBone SCPC should not be used in patients in which general oral surgery is not advisable.

**CAUTION**

℞ Only. ShefaBone SCPC is intended for use on the order of a physician or dentist.

**PRECAUTIONS**

ShefaBone SCPC should not be used outside its intended indications. Underlying oral pathological conditions, such as infections, should be controlled or eliminated prior to implementation of ShefaBone SCPC. Care should be exercised to avoid salivary contamination. ShefaBone SCPC vial is for Single Use Only. Reuse of products that are labeled for single use may result in product contamination, patient infection and/or failure of the device to perform as intended. Standard postoperative practices for the treatment and rehabilitation associated with bone grafting must be strictly followed.

**WARNINGS**

1. Content of package is sterile unless opened or damaged. Do not use if package is opened or damaged or if expiration date has been exceeded
2. Dose is SINGLE USE ONLY. Do not attempt to re-sterilize or re-use.
3. SCPC does not possess sufficient mechanical strength to support load bearing defects prior to hard tissue ingrowth. In cases of fracture fixation or where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.
4. SCPC is intended for use by clinician familiar with bone grafting and internal/external fixation techniques.
5. SCPC must not be used to gain screw purchase or to stabilize screw placement.
6. Not intended for immediate load-bearing (allow approximately 16 weeks for substantial bone reconstruction)
7. Do not overfill defects
8. Do not leave defect open
9. Do not compromise blood supply to the defect area
10. The device should be secured to prevent motion and migration, use in areas where the graft can be adequately contained

# Why is SCPC better than other silicate bioactive glass (BG) bone grafting materials?

SCPC is a new, resorbable, porous, bioactive silica-calcium phosphate composite (SCPC) that has the ability to stimulate rapid bone generation and resorb when grafted in large bone defects. To enhance bioactivity and resorbability, ion substitution and formation of solid solution were induced in the crystalline phases. Thus, the entire structure of SCPC contains, ion substituted silica and calcium phosphate modified with Na and/or silica. These crystalline phases will synergistically enhance bioactivity and resorbability of the material. The role of silica is two folds: silica substitution in the calcium phosphate mineral regulates its resorption and enhances bone bioactivity property. Second, the silica surface, which was not incorporated in the calcium phosphate, nucleates the precipitation of a carbonated hydroxyapatite layer on the SCPC surface known to stimulate bone cell attachment, differentiation, and tissue formation. Histological analyses showed that the bioactivity and resorpability of SCPC is superior to those of bioactive glass (Figure 2). Bioactive glass forms a carbonate hydroxyapatite layer on the top of a silica-rich layer. The silica rich layer slows down BG dissolution by inhibiting Ca, P and Si ion diffusion from the glass bulk into the surface [6]. The implication for the slow rate of dissolution of BG is the slow rate of resorption in vivo. On the other hand, the porous structure of SCPC enhances the continuous resorption of the graft material inside bone defects [1-5].

While the resorption and bioactivity of bioactive glass is limited by ion diffusion from the glass bulk to the surface, the resorption and bioactivity of the SCPC do not depend on the bulk composition. The modified calcium phosphate phases can work as a weak binder for the modified silica phases and offer sites for preferential dissolution and resorption.

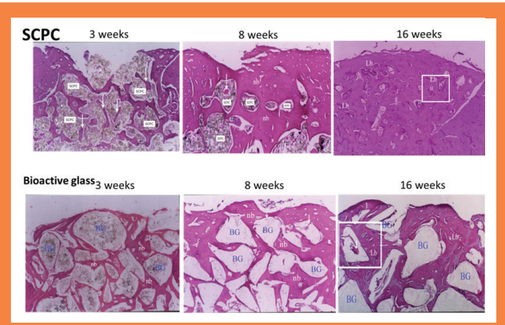



***Figure 2.** Histology analysis of a rabbit femoral critical size bone defect grafted with SCPC or bioactive glass (BG) granules for 3, 8 and 16 weeks. A successful regeneration of the cortical bone and SCPC graft resorption was observed after 16 weeks. The newly formed bone completely remodeled to a mature lamellar bone showing restoration of the Haversian systems (H). On the other hand, BG particles occupied close to 50% of the bone defect area after 16 weeks due to the slow rate of resorption. (H&E staining, original magnification x40).*

X-ray radiography confirmed the histology analyses and showed the resorption of SCPC graft and restoration of the continuity of the cortical bone after 16 weeks of implantation (Fig. 3). For defects grafted with BG granules, X-ray radiography showed restoration of the continuity of the cortical defect however, the presence of significant amount of BG particles in the defect is evident after 16 weeks.

***Figure 3.** X-ray radiography of rabbit femoral bone defect grafted with (a) SCPC granules and (b) BG granules 16 weeks postoperative. SCPC-grafted defect showed complete restoration of the cortical continuity and graft material resorption. On the other hand, significant amount of BG granules remained un-resorbed in the defect after the same time period.*





# Why is SCPC better than other calcium phosphate bone grafting materials?

Tricalcium phosphate (Ca3 [PO4]2, TCP Whitlockite), and hydroxyapatite [Ca10(PO4)6(OH)2] (HA) are the material most widely used as bone substitute. Although evidence of bone growth in porous and dense HA particulates is widespread, the bone conductive effect is limited [8]. Often at a distance away from the bone defect wall, these particulates are encapsulated by fibrous tissue. TCP is more biodegradable than HA; however, its presence elicits a foreign body response [9]. The main calcium phosphate phase in SCPC is NaCaPO4 which possesses a higher potency than TCP and the other calcium phosphates, thereby promoting osteogenesis and bone matrix calcification [7]. The incorporation of silicate in SCPC structure is considered a major advantage over bone grafts made of calcium phosphate ceramics due to its important role in the upregulation of osteoblastic cells and development of osteoid and mineralized skeleton [10].

Biological bone grafts such as cadaver bone or from patients sources have many limitations related to rejection reaction due to genetic difference or disease transmission. With SCPC being a synthetic resorbable bioactive bone graft there is no need to address issues related to problems involving allergic reactions or the potential risks of infection transmission from materials like bovine bone, processed bone matrix or cadaveric demineralized freeze-dried bone allograft.

# References:


1. El-Ghannam A. "Resorbable, Porous, Silica-Calcium Phosphate Bioactive Composite For Improved Synthetic Graft Resorbability and Tissue Regeneration", US patent number 8168208B1 (2012)
2. El-Ghannam A., "Resorbable, Porous, Silica-Calcium Phosphate Bioactive Composite For Improved Synthetic Graft Resorbability and Tissue Regeneration", US patent No. 7,223,414B1 (2007)
3. Fahmy RA, Mahmoud N, Soliman S, Nouh SR, Cunningham L, El-Ghannam A., Acceleration of Alveolar Ridge Augmentation Using a Low Dose of rhBMP2 Loaded on a Resorbable Bioactive Ceramic, J Oral Maxillofac Surg. 2015 Dec;73(12):2257-72.
4. Mohanad Al-Sabbagh, John Burt, Ahmed Barakat, Ahmad Kutkut and Ahmed El-Ghannam, "Alveolar Ridge Preservation Using Resorbable Bioactive Ceramic Composite: A histological Study", Journal of the International Academy of Periodontology, Journal of the International Academy of Periodontology 15/3:91-98 (2013)
5. Ahmed El-Ghannam, "Advanced Bioceramic Composite for Bone Tissue Engineering: Design Principles and Structure-Bioactivity Relationship", Journal of Biomedical Materials Research, 1;69A(3):490-501 (2004)
6. L.L. Hench "Bioceramcis: From Concepts to Clinic" J. Amer. Ceram Soc., 74[7] (1991).
7. R. M. Knotts, S. Jalota, S.B. Bhaduri and A. C. Tas. "Synthesis of Rhenanite (B-NaCaPO4)-Apatititc calcium phosphate biphasics for skeletal repair". Advances in bioceramics and porous ceramics, Ceramics Engineering and Science Proceedings, editors: R Narayan and P. Colombo, John Wiley & Sons publication, vol 29, issue 7, p. 152, 2008.
8. Schepers E, de Clercq M, Ducheyne P, Kempeneers R. Bioactive glass particulate material as a filler for bone lesions. J Oral Rehabil 1991; 18:439–445.
9. Eggli PS, Muller W, Schenk RK. Porous hydroxyapatite and tricalcium phosphate cylinders with two different pore size ranges implanted in the cancellous bone of rabbits. Clin Orthop 1988; 232:127–137.
10. R. Jugdaohsingh, Silicon and Bone Health, J Nutr Health Aging, 2007 ; 11(2): 99–110


# How to Order:

To place an order please visit
www.shefabone.com
or call 704-793-4488.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