Bonalive® Orthopedics granules
(composition by weight)

- 53 % SiO_2
- 20 % CaO
- 23 % Na_2O
- 4 % P_2O_5

Small Applicator

Ref. No	Granule size	Unit size
14120	0.5-0.8 mm (small)	2.5 cc

Large Applicator

Ref. No	Granule size	Unit size
14130	0.5-0.8 mm (small)	5 cc
14330	1.0-2.0 mm (large)	5 cc
14340	1.0-2.0 mm (large)	10 cc

Indications for Use

Bonalive® Orthopedics granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Bonalive® Orthopedics granules is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product contains a bone void filler that resorbs and is replaced with bone during the healing process. When used in the extremities and pelvis, Bonalive® Orthopedics granules is intended to be used alone.

Contraindications

Bonalive® Orthopedics granules should not be applied:

• To replace structures that are subject to strong mechanical stress;

• In patients that have received or are to receive chemo-therapy or radiation therapy at or near the implant site; or

• In patients with known allergy to bioactive glass.

Complications

Possible complications are the same as to be expected of autogenous bone grafting procedures and general complications that may arise from anesthesia and/or surgery.

TriMed Inc.

For the past 25 years, TriMed has contributed a number of revolutionary solutions to the field of orthopaedics for the treatment of problematic and complex injuries. By interacting with surgeons around the world and through various on-going educational programs, TriMed continues to improve orthopaedic treatment for patients. TriMed is an ISO 13485:2016 certified medical device company headquartered in Santa Clarita, California.

DISTRIBUTOR:

TriMed®

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Bonalive Biomaterials Ltd

As the world seeks better solutions for bone healing, the Bonalive S53P4 bioactive glass technology represents a new standard in patient care. Evolving at the intersection of technology and human biology, Bonalive biomaterials are transforming the future of healthcare focusing explicitly on complex surgery. With one of the most evidence-based technologies in the industry, Bonalive creates a smarter future for healthcare. Bonalive is an ISO 13485:2016 certified medical device company with its headquarters in Finland.

MANUFACTURER:

bonalive

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Federal law restricts this device to sale by or on the order of a physician or a licensed practitioner.

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LC-72-B02 Rev. A 24 NOV 2020
8-100389

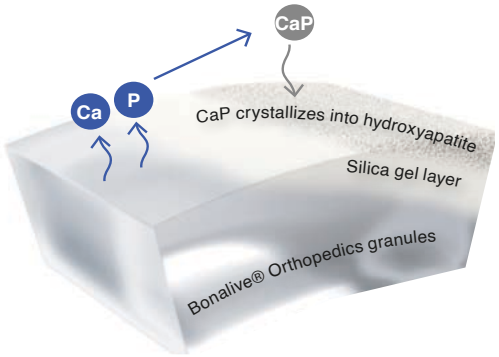
TriMed®

Bonalive® Orthopedics granules

Bonalive® Orthopedics granules (S53P4 bioactive glass) is an FDA cleared medical device that is used in surgical procedures to regenerate bone.

Bone Regeneration and Remodeling

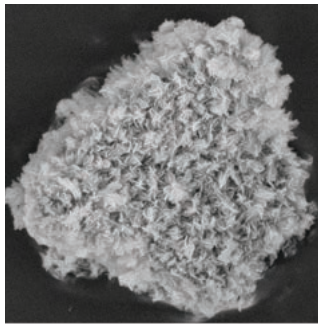
Bonalive® Orthopedics granules (S53P4 bioactive glass) is an osteoconductive biomaterial characterized by its ability to attach firmly to living tissue. S53P4 bioactive glass resorbs and promotes new bone formation in the implanted area.



In an aqueous solution (e.g. body fluids), bioactive glass works by leaching out ions and developing a silica-gel layer that acts as a template for a calcium phosphate (CaP) precipitation. The CaP crystallizes to hydroxyapatite, which resembles the mineral phase of natural bone in its chemical composition and structure, thus enabling bonding of the bioactive glass to the surrounding bone.

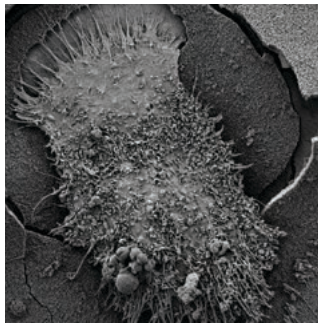
Literature

S53P4 bioactive glass has been studied for several decades and more than 200 peer-reviewed publications have been published.



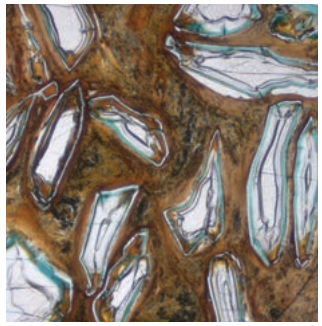
Courtesy of Bonalive Biomaterials Ltd

Natural hydroxyapatite layer formed on S53P4 bioactive glass granule 72 hours after exposure to an aqueous solution.



Courtesy of Maastricht UMC+, The Netherlands

The SEM (scanning electronic microscopy) image shows the osteoclast activity on the surface of the S53P4 bioactive glass.



Courtesy of Päijät-Häme Central Hospital, Finland

Histological image 3 months after S53P4 bioactive glass granules implantation (human biopsy).

Non-union in the Distal Tibia

Patient: 72-year-old male, supramalleolar osteotomy was performed. Fracture of the plate 5 months post-op. 7 months post-op there was swelling, pain and reddening with diagnosis of tibial osteomyelitis (non-union).

Bacterial culture: *Staphylococcus epidermidis*

Complication: Persistance of infection and new bacteria encountered. Three further revisions with debridement and implantation of antibiotic releasing PMMA beads.

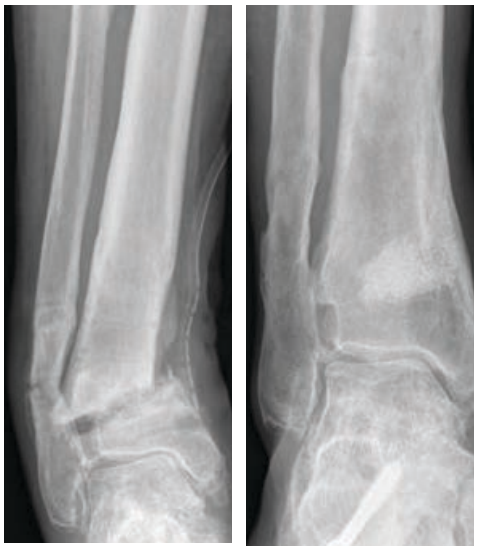
Bacterial culture: *Enterococcus faecalis* and *Staphylococcus caprae*

Operation: Revision surgery 10 months after initial osteotomy. Removal of all infected tissue and implantation of 20 cc S53P4 bioactive glass.

Final clinical outcome: Complete integration of S53P4 bioactive glass into the bone structure and full consolidation could be observed at 2 years post-op.

7 months after injury

2 years post-op



Courtesy of BG Klinikum Duisburg, Germany