BonAlive® putty composition

- **Bioactive glass:** 53% SiO_2, 23% Na_2O, 20% CaO, 4% P_2O_5
- **Synthetic binder:** Polyethylene glycols (PEGs) and glycerol

Small applicator

Ref. No	Unit size
16110	1 cc
16120	2.5 cc

Large applicator

Ref. No	Unit size
16130	5 cc
16140	10 cc

Medical education

Product website

References

1. Molecular basis for action of bioactive glasses as bone graft substitute. Välimäki VV, Aro HT. Scand J Surg. 2006;95(2):95-102.
2. Histomorphometric and molecular biologic comparison of bioactive glass granules and autogenous bone grafts in augmentation of bone defect healing. Virolainen P, Heikkilä J, Yli-Urpo A, Vuorio E, Aro HT. J Biomed Mater Res. 1997;35A(1):9-17.
3. A prospective randomized 14-year follow-up study of bioactive glass and autogenous bone as bone graft substitutes in benign bone tumors. Lindfors NC, Koski I, Heikkilä JT, Mattila K, Aho AJ. J Biomed Mater Res. 2010;94B(1):157-164.
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5. Posterolateral spondylodesis using bioactive glass S53P4 and autogenous bone in instrumented unstable lumbar spine burst fractures - A prospective 10-year follow- up study. Rantakokko J, Frantzén J, Heinänen J, Kajander S, Kotilainen E, Gullichsen E, Lindfors N. Scan J Surg. 2012;101(1):66-71.
6. Instrumented spondylodesis in degenerative spondylolisthesis with bioactive glass and autologous bone. A prospective 11-year follow-up. Frantzén J, Rantakokko J, Aro H, Heinänen J, Kajander S, Koski I, Gullichsen E, Kotilainen E, Lindfors N. J Spinal Disorder Tech. 2011;24(7):455-461.

Manufacturer

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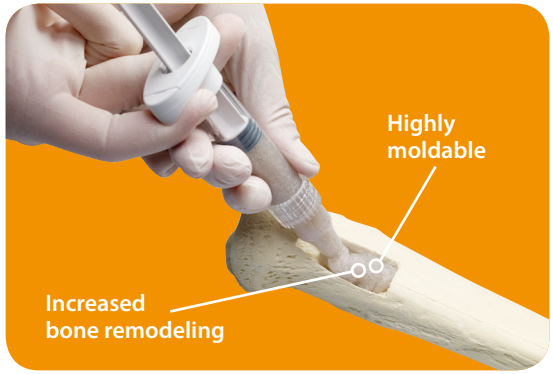
Distributor

91616/1

BonAlive® putty

Product brief | *Trauma & Spine*



BonAlive® putty

BonAlive® putty is an easy-to-use and highly moldable biomaterial for bone regeneration.

BonAlive® putty contains bioactive glass S53P4 that is osteoconductive and osteostimulative*, which means that it has been proven to activate genes responsible for bone formation in osteogenic cells[1,2]. This is seen by the promotion of osteogenic cells to increase the remodeling rate of bone.

Indication

- Filling of bony voids and gaps

BonAlive® BIOMATERIALS LTD

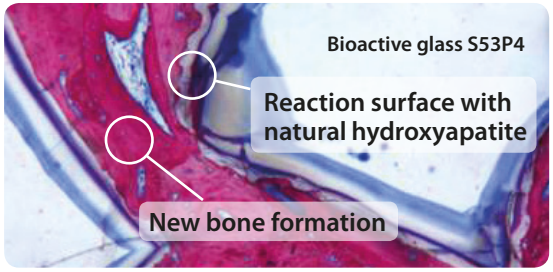
**non-osteoinductive*

What is BonAlive® putty?

BonAlive® putty** is a CE-marked, class III medical device made of bioactive glass S53P4 (BonAlive® granules) and a water-soluble synthetic binder. The synthetic binder is a blend of polyethylene glycols (PEGs) and glycerol that acts as a temporary binding agent for the bioactive glass. After implantation the binder is absorbed within a few days leaving behind only the bioactive glass thus permitting tissue infiltration between the granules to facilitate the regeneration of bone.

Histological findings

In a preclinical rabbit study, the histological findings 8 weeks after BonAlive® putty implantation were that new bone is formed already in an early stage. The grafted area was highly vascularized with dense bone formation and periosteal growth.



Clinical evidence

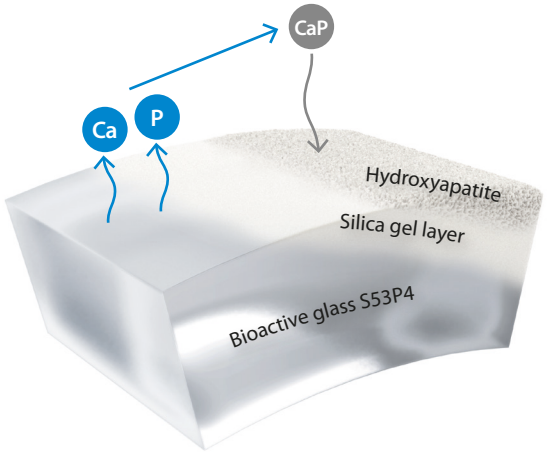
The clinical use of moldable BonAlive® putty is supported by several clinical trials that have been conducted with bioactive glass S53P4 in orthopedic[3], trauma[4] and spine surgery[5,6].

***BonAlive® putty has not been verified to inhibit bacterial growth*

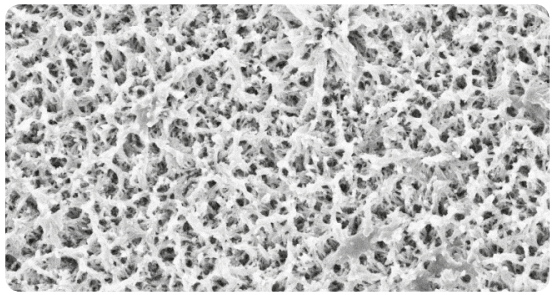
Bone regeneration cascade

In contact with body fluids bioactive glass works by leaching out ions leading to the development of a silica gel layer on the bioactive glass. The silica gel layer attracts the Ca and P that has been released from the granules. The precipitated CaP crystallizes to natural hydroxyapatite, which is similar to the mineral component of bone. The newly formed natural surface will promote bone bonding and osteointegration.

Formation of natural hydroxyapatite



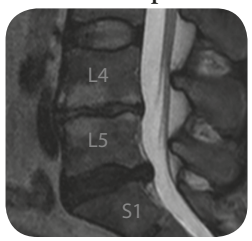
The natural hydroxyapatite layer on the bioactive glass surface is presented in this scanning electron microscopy (SEM) image (10 000x magnification).



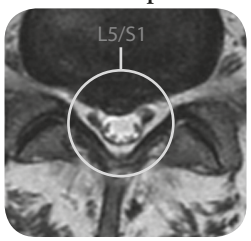
MIS fusion in the degenerative spine

Patient: 45-year old female suffered from an L5/S1 disc herniation in 2006 and was treated conservatively. Low back pain increased after a fall on ice. MRI images showed disc degeneration at levels L4/5 and L5/S1 with a residual herniation L5/S1, Modic I/II endplate changes were observed.

Pre-op



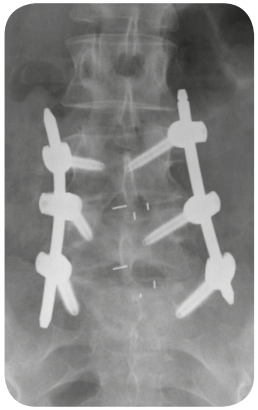
Pre-op



Operation: An L4/5 and L5/S1 minimally invasive transpedicular fusion with TLIF cages was performed using image guided surgery. The cages were filled with BonAlive® putty (2cc) and autograft. In addition, a posterolateral fusion was performed on the right side with autograft mixed with BonAlive® putty (8cc). Intraoperative 3D images were taken to verify implant location and follow up was at 3 months and 12 months with plain X-rays.

12 months post-op

Clinical outcome: At 3-month post-op the patient was free from medications and was able to walk 12 km. At 12 months the control X-rays showed that the screws, rods and cages where unchanged and there was no signs of loosening. The bony fusion was successfully developing.



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