NORAKER®

THE BIOGLASS® COMPANY

ActivLoss™

Bioactive Bone Substitute

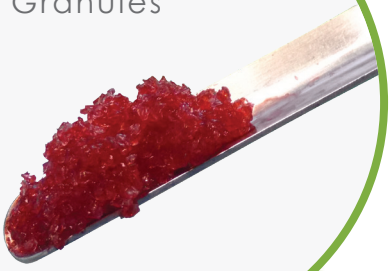
Synthetic Bone Substitute
Bioactive Glass Technology





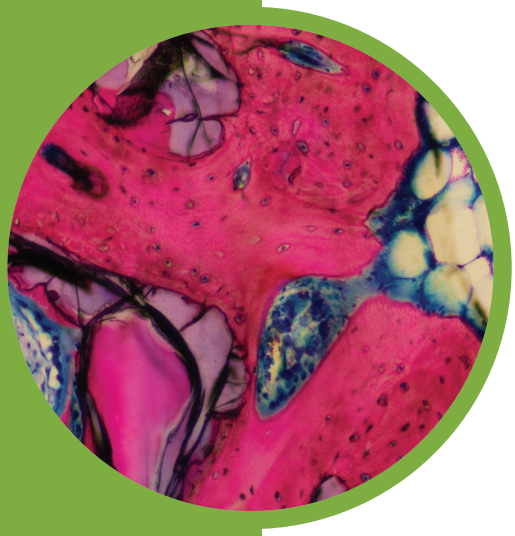
Injectable
Putty

Granules



MADE IN FRANCE

FOR TRUE BONE REGENERATION



NORAKER® has been involved in biomaterial development since 2005. It's today an innovative manufacturer of medical implants for bone regeneration, with its core technology: the **BIOACTIVE GLASS,** a synthetic bioresorbable ceramic.

Composition

Activioss™ substitutes are made of bioactive glass. This ceramic is composed of Silicium, Calcium, Sodium and Phosphorous, minerals naturally present in the human body. The natural composition allows an excellent biocompatibility. [1 2 3]

Advantages

The Bioactive glass has been classified by Dr Larry Hench as Class A bone substitute, whereas inert materials, such as hydroxyapatites or calcium phosphate, are Class B. [8]

Performances

The Bioactive glass has already proven its clinical performances: more particularly, its ability to fill a bone defect and gradually being replaced by a functional tissue. [4]

Compositional diagram for bone bonding

Biological properties according to quantity of silicium, sodium and calcium with 6% of phosphorous. [5, 9]

Activioss™

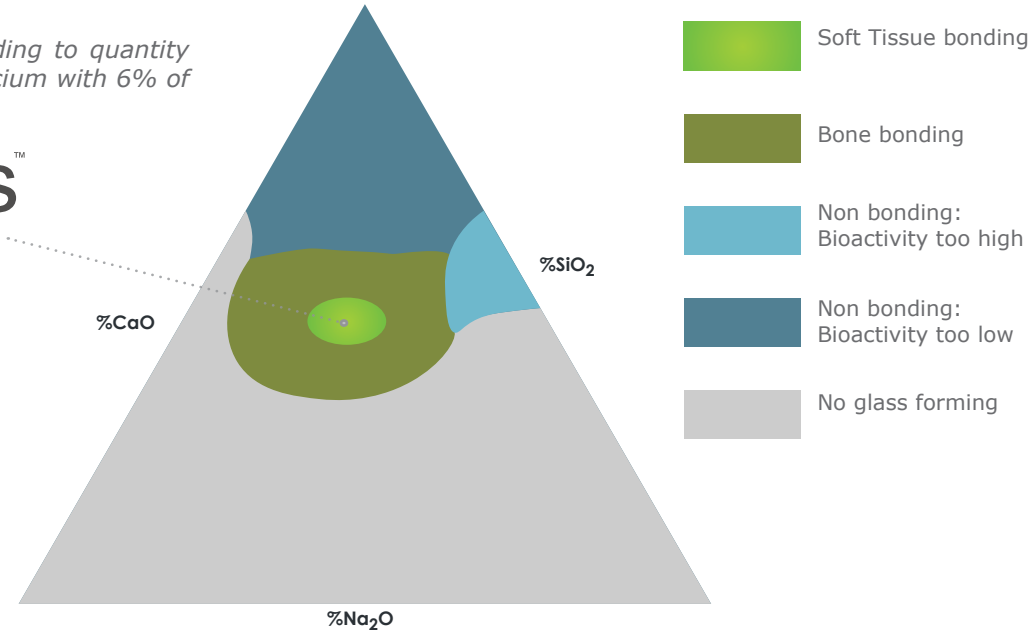
Bioactive Glass 45S5

SiO_2 : 45 %

Na_2O : 24.5 %

CaO : 24.5 %

P_2O5 : 6 %



Activioss™ range
Injectable Putty and Granules

Activioss™ Injectable Putty

Open and press !



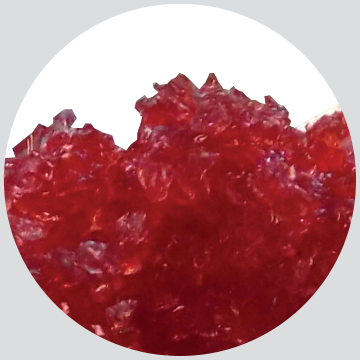
Activioss™ Granules

To mix with patient's blood, patient's bone or saline solution





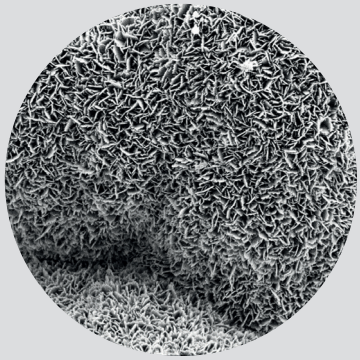
MECHANISM OF ACTION



1. Easy to use

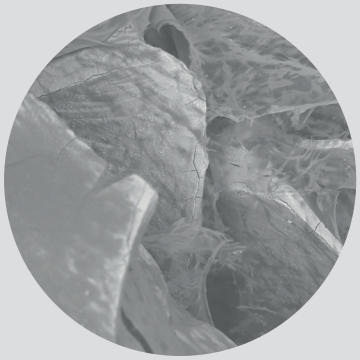
Granules: Very cohesive and hydrophilic when mixed with saline serum, patient blood or autologous bone.

Injectable Putty: Ready to use, can be injected through the syringe



2. Ionic exchanges

At 14 days: formation of an active biological mineral layer of calcium phosphate, with similar composition and structure as human bone.[1 3 5]



3. Scafold formation

At 21 days:
The increased concentration of minerals induces a carbonated hydroxyapatite layer (CHA)[2 4 6]

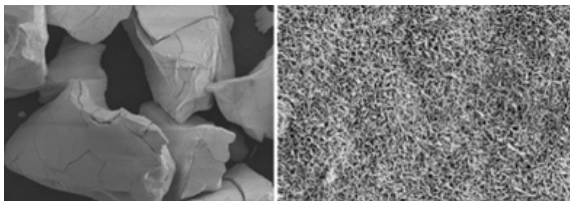
Did you know ?

Bone substitutes are classified into an Index of Bioactivity (only demonstrated by in-vitro study).[8]

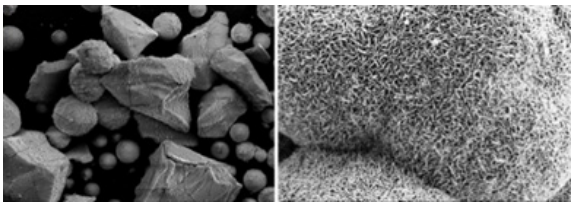
Class A	Class B
Osteoconduction + Osteoproduction	Osteoconduction
Bioactive Glass 45S5	**HA, βTCP**

Bioactivity study - In vitro evaluation for apatite-forming ability.[10] (*in vitro* study)

(a) Granules

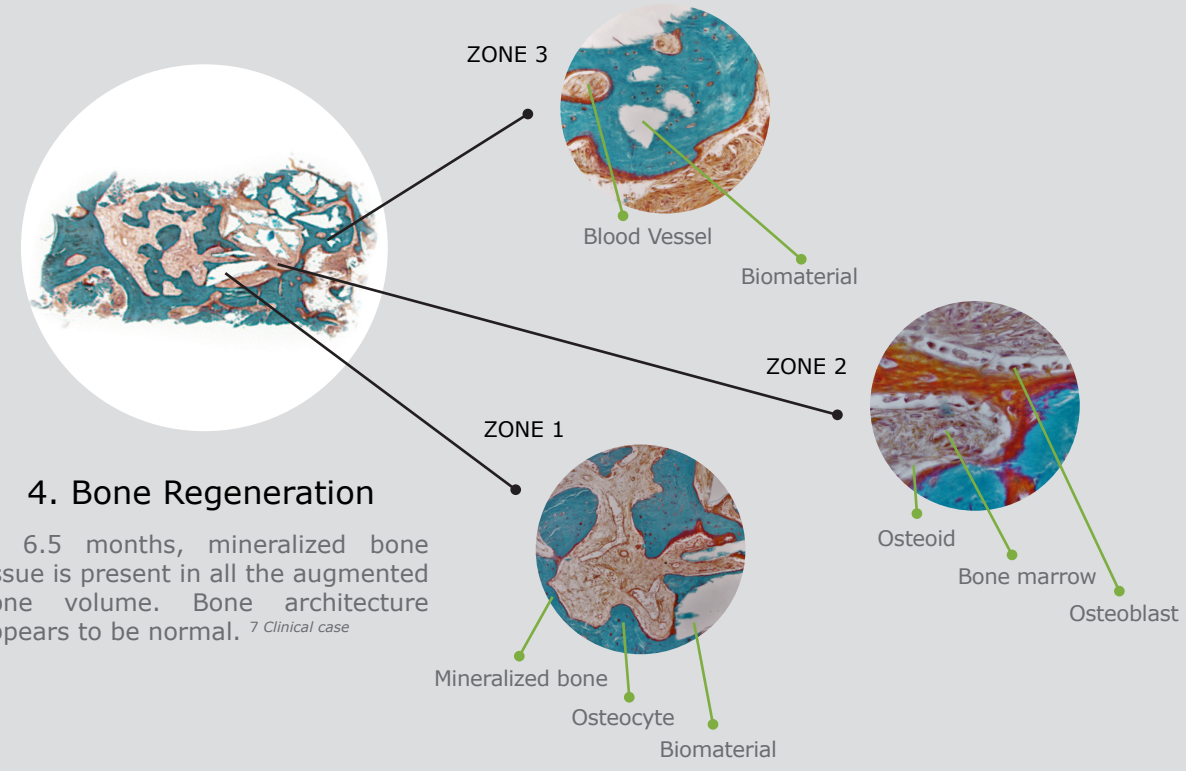


(b) Injectable Putty



SEM images of (a) Granules 05.1 and (b) Injectable Putty a magnification of x50 (left) and x10,000 (right) after 28 days of immersion inSBF (testing according to ISO 23317:2014).

The surface of the granules presents cracks at x50 and needle-like structures at x10,000. This is characteristic of hydroxipatite formation. This evaluation of apatite-forming ability on implant material in SBF is useful for evaluating its in vivo bone-bonding ability.



4. Bone Regeneration

At 6.5 months, mineralized bone tissue is present in all the augmented bone volume. Bone architecture appears to be normal. [7] *Clinical case*

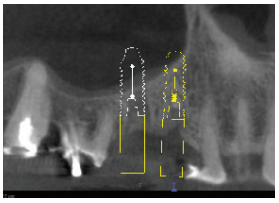
Clinical Study Results

1: Sinus bone augmentation using bioactive glass with repositioning of the bone flap. JPIO; 39:1-15. (2020) Carrotte D, Burt-Pichat B, Rizzo S, Boivin G.

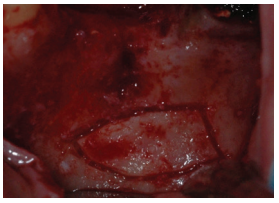
Methods – In a retrospective cases study, 52 patients that had been implanted with ActivIoss ™ granules (0.5-1mm) for sinus augmentation were selected. A total of 110 implants were placed in these patients included between August 2012 and December 2015. In this population, 58 sites were operated. The sinus augmentations were performed using the lateral access procedure. The patients having more than 3 mm crest height, underwent dental implants placement immediately after bone grafting. In the other cases, a period of 3 months minimum was required for bone reconstruction before implant placement. Implants survival rate was assessed during a 12-months follow-up. Post-operative X-rays radiographic images are used to objectify the volume filled, the correct posiionning of the implants and the integrity of the sub-sinus membrane. The implant is success is verified for the first time when screwing the prosthetic abutment. Core samples were analysed by histomorphometry, digitized microradiography and microdindention to evaluate bone quality.

Results - All patients presented good clinical outcomes. All implants were functional after a 12-months loading period. The histology analysis of the 2 explants showed that the augmented area has a normal bone structure with mineralized-bone trabeculae, bone marrow and some osteointegrated biomaterial fragments. The results that the technique combining the repositioning of the flap and the use of bioactive glass makes it possible to achieve an implant success rate of 98.2%, identical to the best results described in the literature with allografts or xenografts, and thus reduce the physical and economic stress of the patient.

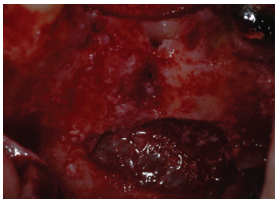


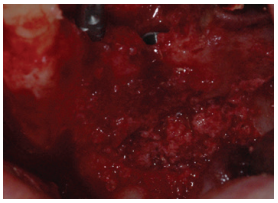


Photos 1 and 2. Project of implants in 14 and 15. Pre-operative scanner and planning of implant placement.

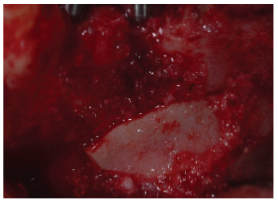


3. Cutting of the bone flap, carried out by Mectron® piezosurgery saw, is intentionally asymmetrical to facilitate its repositioning.

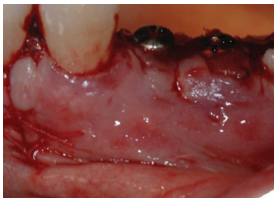




Photos 4 and 5. Bone filling is introduced via the the anterior region in the midline of the sinus, then the palatal region. The mixture of autogenous bone extracted (approximately 0.3 cc) and 1 cc of bioactive glass 45S5 (Activioss™ Noraker®, 0.5-1mm)



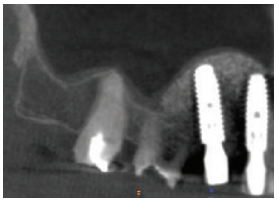
6. the bone flap is replaced and the excess material was placed onto the closed window.



7. Tight sutures are performed without tension.



8. 6 months post operative: installation of abutments.

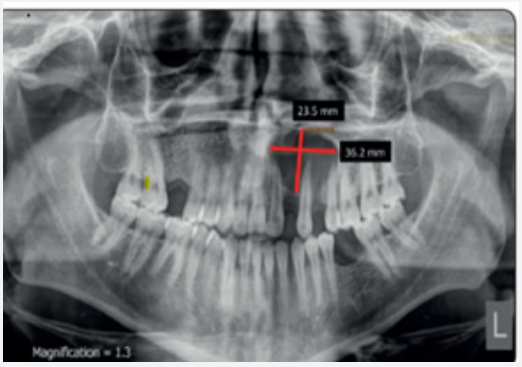


9. Postoperative tomographic image showing the reconstructed volume and the three-dimensional placement of the implant in this space.

2: Assessment of the sticky bone preparation of bioactive bone glass in grafting critical-sized surgical bony defects. Egyptian Dental Journal (2021) El-Hawary H E, Shawky M.

Method - In this randomized clinical controlled trial, 24 were divided into two equal groups for cystic bony lesions. Cystic lesions exceeding 2 x 2 cm were enucleated, and the defect was obliterated with Bioactive bone glass particles in group 1 and Bioactive glass sticky bone in group 2 (bioactive glass granules + platelet rich fibrin). Bone density was measured in grayscale units from digital panoramic radiographs immediately, at three and six months postoperatively.

Results - In group 1, the percentage of decrease in the bone density during the first three months is higher in group 1 than group 2 that was then increased by nearly the same percentage at the six months interval although statistically there is no significant difference between the two groups throughout the study period. The defects were completely filling in the 2 groups without loss of substitute. The healing went uneventful through all the cases. All the patients complained of postoperative edema and swelling on the surgical site that resolved at the end of the first postoperative week. The surgically reconstructed defects did not show postoperative infection nor wound dehiscence or graft rejection throughout the healing phase.



Preoperative orthopantomogram with the measurements of the cystic cavity

Conclusion - The two 45S5 forms have good results and the bioactive glass prepared as the sticky bone seems has better intraoperative handling and workability, better soft tissue reaction during the healing period and higher bone density values of the grafted defects than when used solely although it hasn't any radiographic statistically significant results regarding the studied parameters.

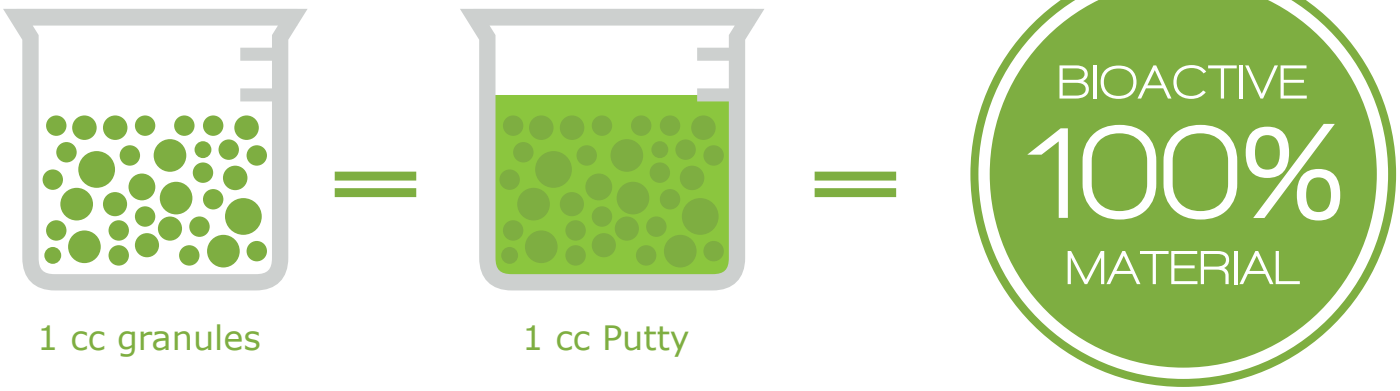
References	Granule size	Volume
Activioss™ Granules		
ACT-GM0.5	0.5 – 1.0 mm	0.5 cc
ACT-GM1		1.0 cc
ACT-GM2		2.0 cc
ACT-GL1	1.0 - 3.0 mm	1.0 cc
Activioss™ Injectable Putty		
ACT-IP1.0	0.1 mm to 0.7 mm	1.0 cc
ACT-IP2.5		2.5 cc

It is indicated in case of loss or lack of bone substance for bone defects of traumatic, pathological or surgical origin, when autologous solutions are not applicable or sufficient in dental surgery adult population.[10]



1. *Tsigkou, O. et al. Biomaterials. 2009;**30**:3542-50*
2. *Oonishi, H. et al. J. Biomed. Mater Res. 2000;**51**:37-48.*
3. *Jones, J.R. Acta Biomaterialia. 2013;**9**:4457-4486.*
4. *Xynos, I.D. et al. Calcif Tissue Int. 2000;**67**:321-9.*
5. *Hench, L.L. J. Mater Sci: Mater Med. 2006;**17**:967-978.*
6. *Jell, G. et al. J Mater Sci: Mater Med. 2006;**17**:997-1002.*
7. *Data on file at NORAKER®, clinical case.*
8. *Hench, L.L. Biomaterials 1998;**19**:1419-1423.*
9. *Data on file at NORAKER®, in vitro study.*
10. *Clinicals and technicals datas on file at NORAKER®.*

Activioss™ Granules and Activioss™ Injectable Putty bone graft substitute are class III medical devices (CE 0459), manufactured by NORAKER®.
Activioss™ products are indicated to fill bone defects. Carefully read the instructions supplied with the product.



NORAKER® is a French manufacturer specialized in the research and development of innovative products based on the 45S5 bioactive glass technology for medical applications.

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