NORAKER®

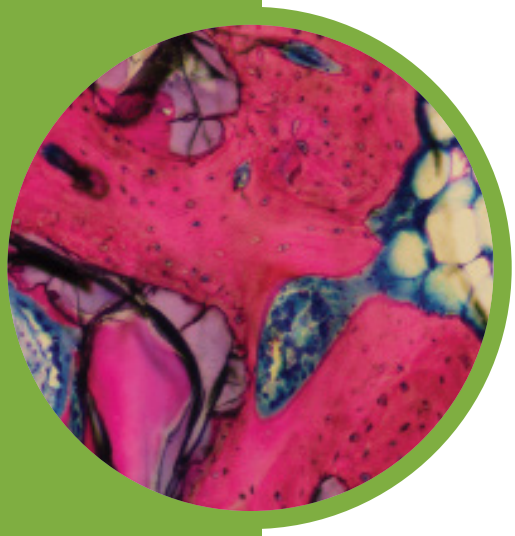
THE BIOGLASS® COMPANY

ActivLoss®

Bioactive Bone Substitute

Synthetic Bone Substitutes
Bioactive Glass Technology

BIOMATERIALS 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

The bone substitutes Activioss® Granules and Activioss® Putty 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]

Avantages

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 functionnal tissue. [4]

Compositional diagram for bone bonding

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

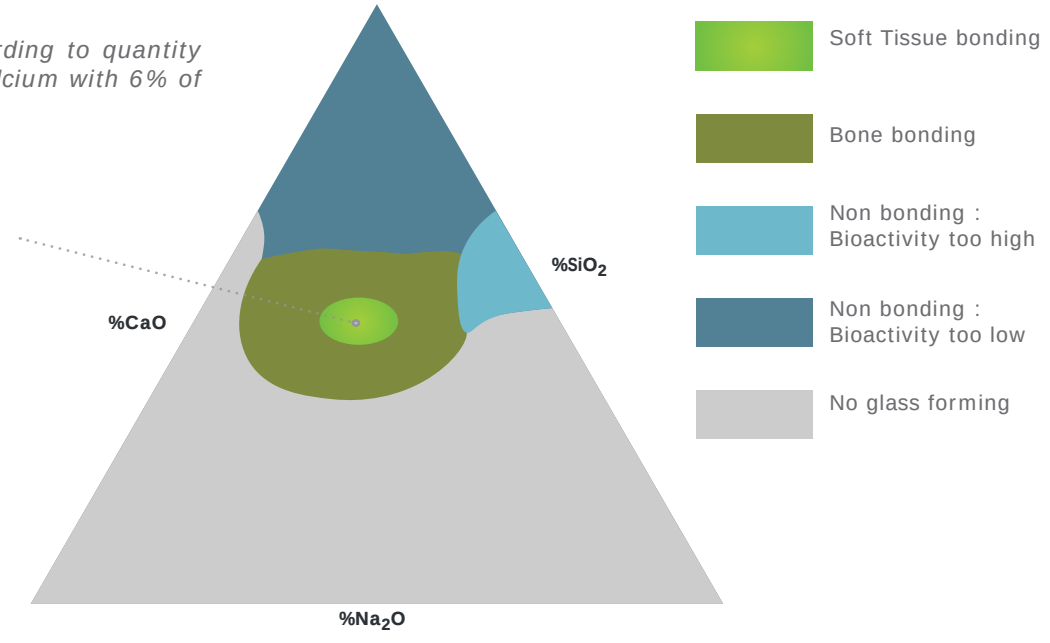
ActivIoss®

Bioactive Glass 45S5

SiO_2 : 45%

Na_2O : 24.5 %

CaO : 24.5 %



Activioss® range :
Injectable Putty and Granules

ActivIoss®
Injectable Putty

Open and press !

ActivIoss®
Granules

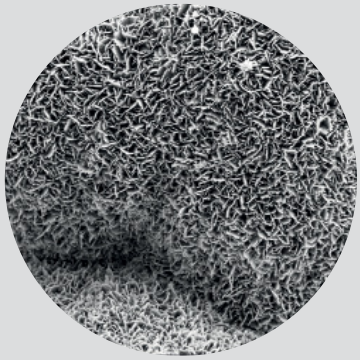
To mix with patient's blood, patient's bone or saline solution

MECHANISM OF ACTION

1. Easy to use

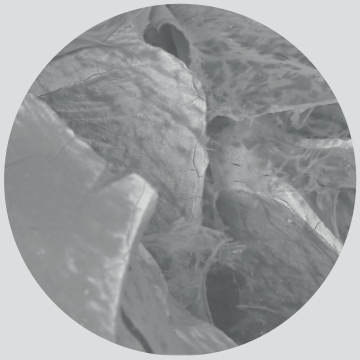
Granules: Very cohesive and hydrophilic when mixed with serum, blood or autologous bone.

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. Activation phase

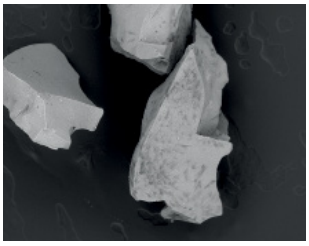
At 21 days:
The increased concentration of minerals improves the differenciation and proliferation of osteoblasts in the defect; and starts the formation of the extra-cellular matrix of collagen. [2 4 6]

Did you know?

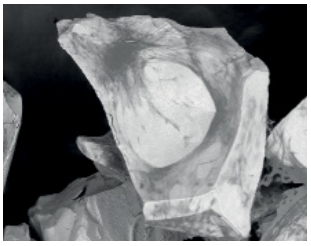
Bone substitutes are classified into an Index of Bioactivity.[8]

Class A	Class B
Matrix for the bone colonization + Stimulation of stem cells	Matrix for the bone colonization
Bioactive Glass 45S5	HA, βTCP

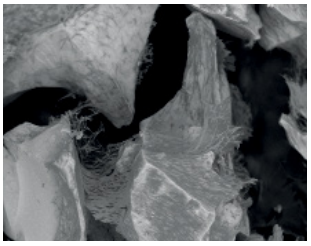
Adhesion and Proliferation of mesenchymal stem cells hMSC on Activioss®.[9] (*in vitro* study)



SEM Image - Day 2
Stem cells adhesion on the surface of Activioss® (dark dots)

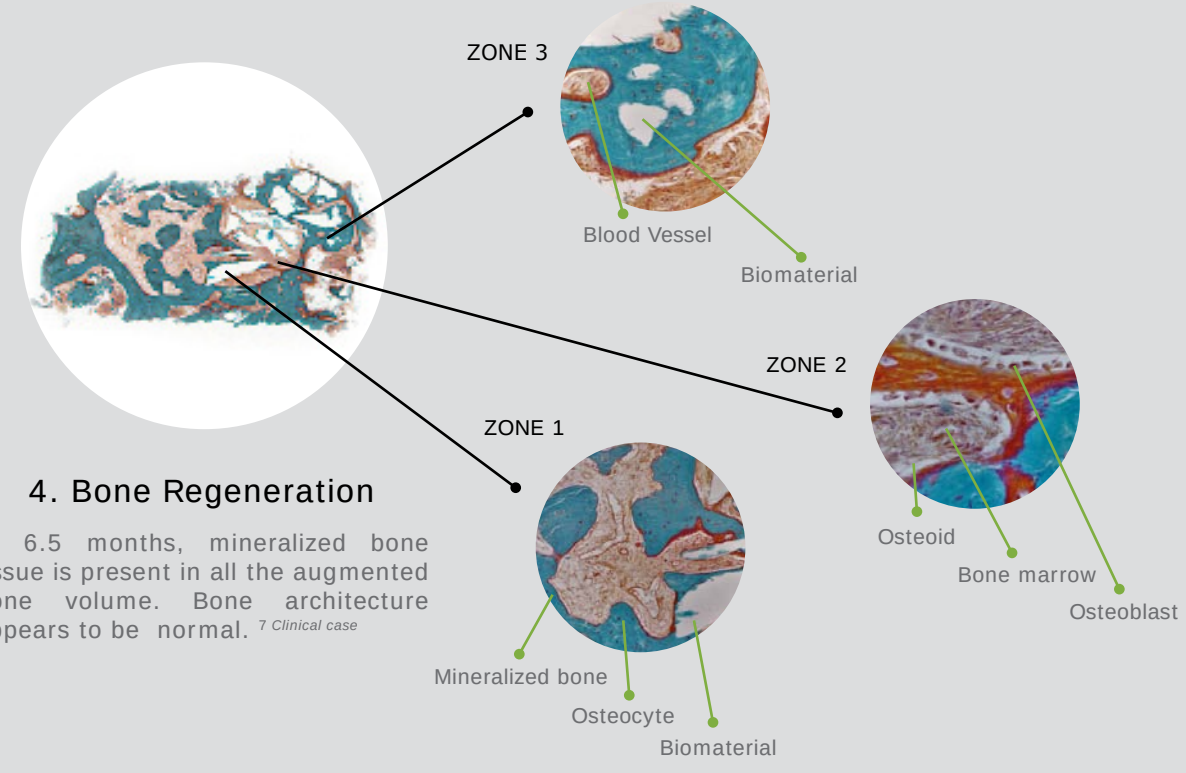


SEM Image - Day 7
Multiplication and differentiation of the stem cells (dark spider web)



SEM Image - Day 14
Extracellular matrix and natural hydroxyapatite in formation

SEM Image - Day 21
Dense extracellular matrix; cells differentiated in osteoblasts



4. Bone Regeneration

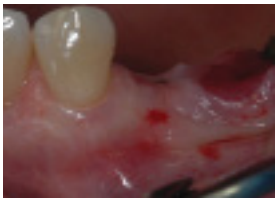
At 6.5 months, mineralized bone tissue is present in all the augmented bone volume. Bone architecture appears to be normal. [7] *Clinical case*

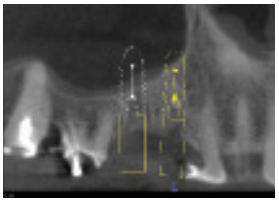
Clinical Results Examples

1: Sinusal bone augmentation using bioactive glass and bone flap repositioning Baly Private clinic Villeurbanne - France

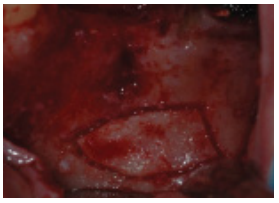
A retrospective study evaluated the success rate of implantation after sub-sinusian bone augmentation performed by the modified Tatum technique with repositioning of the bone flap and using the bioactive glass 45S5 (Activioss®) as a bone substitute. The surgical technique is described in an iconographic case: Fifty-eight consecutive cases in fifty-eight patients have been operated with this technique. One hundred eleven dental implants were placed either directly during bone augmentation surgery or on a delayed basis for the cases with residual bone too resorbed. The patient cohort was followed for 12 to 52 months postoperatively with an evaluation of survival implant at 12 months. Post-operative X-ray radiographic images are used to objectify the volume filled, the correct positioning of the implants and the integrity of the sub-sinus membrane. The implant success is verified for the first time when screwing the prosthetic abutment. Core samples were analyzed by histomorphometry, digitized microradiography and microindentation to evaluate bone quality. For the cases of deferred implantations

The results of this study show that the technique combining the repositioning of the bone flap and the use of bioactive glass makes it possible to achieve implant success rates of over 98%, identical to the best results described in the literature with allografts or xenografts and thus reduce the physical and economic stress of the patient.

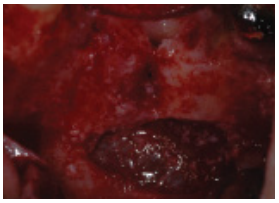


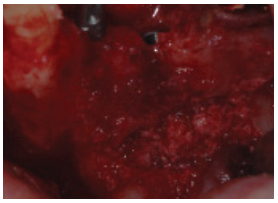


Photos 1 and 2. Project of implants in 14 and 15. Pre-operative scanner and planning of implant placement.

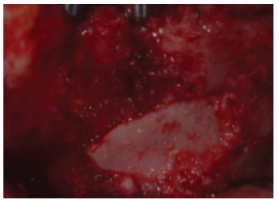


3. Cutting of the bone flap, carried out by Mectron® piezosurgery saw, is intentionally asymmetrical to facilitate its repositioning.

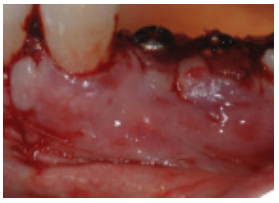




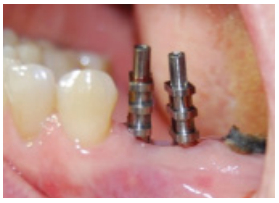
Photos 4 and 5. Bone filling is introduced via the the anterior region in the midline of the sinus, then the palatal region. The mixture of autogenous bone extracted (approximately 0.3 cc) and 1 cc of bioactive glass 45S5 (Activioss® Noraker®, 0.5-1mm)



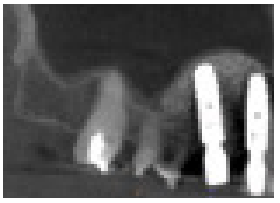
6. the bone flap is replaced and the excess material was placed onto the closed window.



7. Tight sutures are performed without tension.



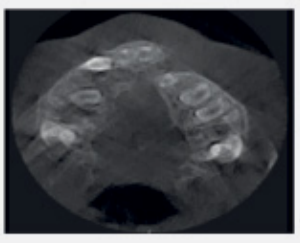
8. 6 months post operative: installation of abutments.



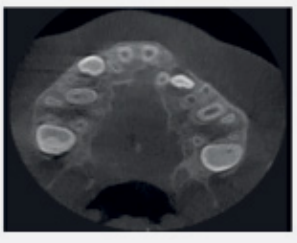
9. Postoperative tomographic image showing the reconstructed volume and the three-dimensional placement of the implant in this space.

2: Gingivoperiostoplasty with bone substitute graft. Rennes University Hospital - France

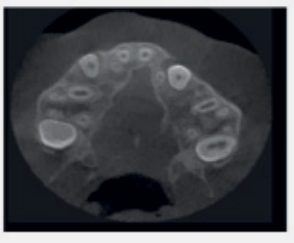
In a prospective study conducted from July 2015 to April 2016 on patients with unilateral or bilateral cleft lip, maxillo-palate, 11 patients including 5 boys and 6 girls underwent gingivoperiostoplasty. The autologous iliac bone harvest has been replaced by the synthetic substitute Glassbone granules. There were 9 unilateral and 2 bilateral clefts. The mean age was 9 years [5-16]. Hospitalization was outpatient in 10 cases. Nine patients had simple consequences, with well relieved pain and the endo-oral examination found healthy gingiva. Mild gingival inflammation was found in two cases without local infectiousness. The substitute was well integrated, not mobile and not painful on palpation. Normal eating was resumed after two weeks, school after three days and sport after two weeks.



a ConeBeam before surgery



b ConeBeam at 6 months follow up



c ConeBeam at 1 year follow up

At 6 months, radiological control by Conebeam of 4 patients showed good filling of the bony cleft with more symmetrical labial and nasal relief and good integration of the substitute.

One year postoperatively, the CBCT performed on a patient confirmed a mature bone bridge with the same density as the adjacent jawbone and complete resorption of the bone substitute (see imaging).

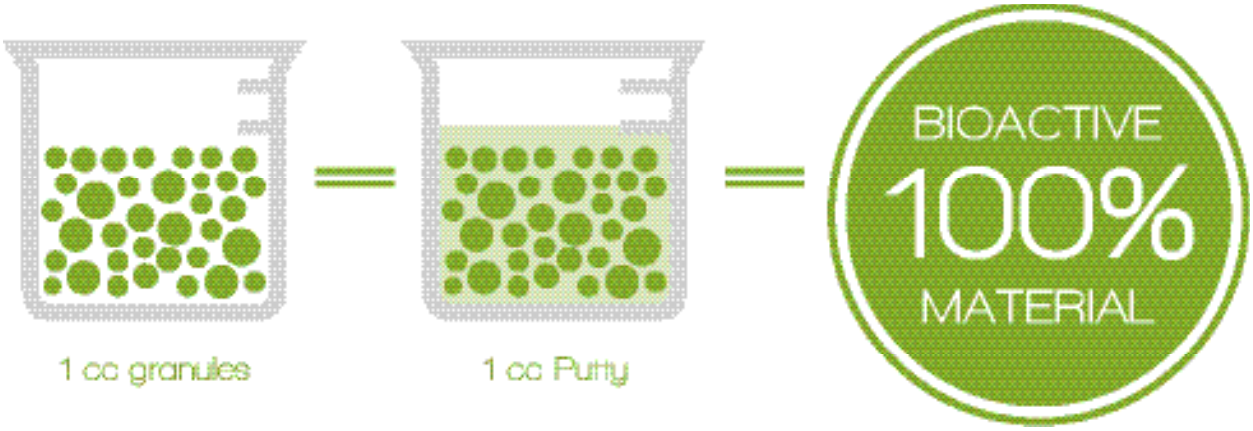
Glassbone® grafting during gingivoperiostoplasty is a simple, reliable, inexpensive and reproducible technique. It has low morbidity. Additional long-term studies would confirm the encouraging results of this technique and offer it as an alternative to autologous bone grafting taken from the iliac crest.

References		Granule size	Volume
Activioss® Granules			
ACT-GM0.5	M	0.5 – 1.0 mm	0.5 cc
ACT-GM1.0	M	0.5 – 1.0 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 adults and children (oral surgery only) in case of loss or lack of bone substance for bone defects of traumatic, pathological or surgical origin, in dental/ oral surgery when autologous solutions are not applicable or sufficient.[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 substitutes are medical devices class III (CE 0459), manufactured by NORAKER®.
Activioss® products are indicated to fill bone defects. Read the instructions supplied with the product for complete information on indications, cons-indications, warnings and precautions, and adverse effects.
Last update : 10/2020



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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