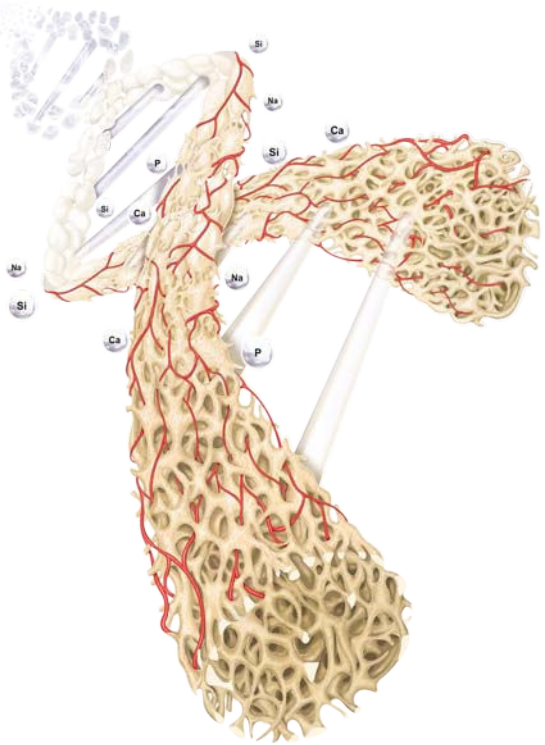
NORAKER®

THE BIOGLASS® COMPANY

GlassBone®

Bioactive Bone Substitute

Synthetic Bone Substitutes
Bioactive Glass Technology

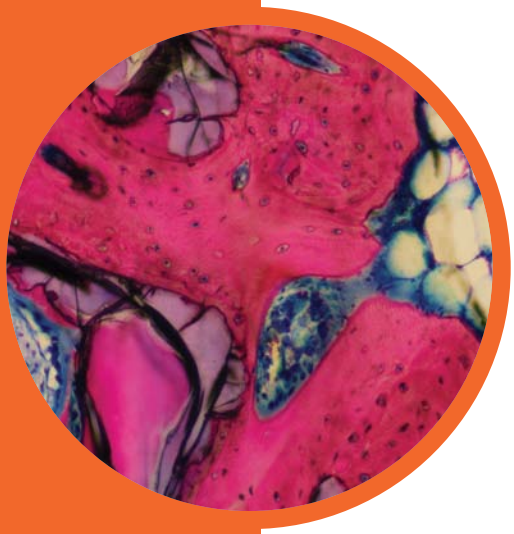


Injectable Putty

Granules

MADE IN FRANCE

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 Glassbone® Granules and Glassbone® 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]

Advantages

The Bioactive glass has been classified by Dr Larry Hench Class A bonesubstitute, 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

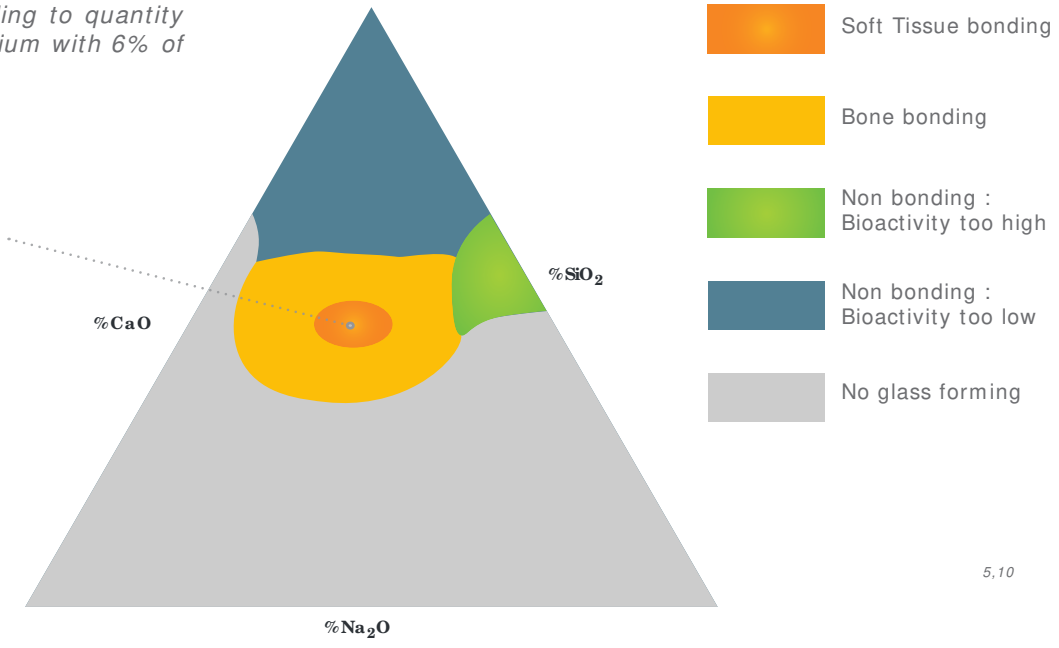
Biological properties according to quantity of silicium, sodium and calcium with 6% of phosphorous. [5, 10]

GlassBone®
Bioactive glass 45S5

SiO_2 : 45%

Na_2O : 24.5 %

CaO : 24.5 %



5,10

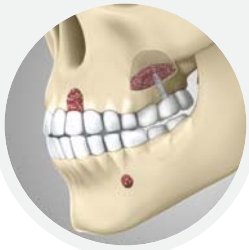
Glassbone® range :
Injectable Putty and Granules

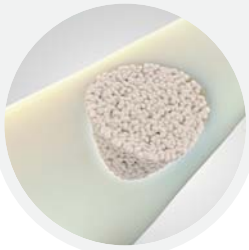
GlassBone®
Injectable Putty

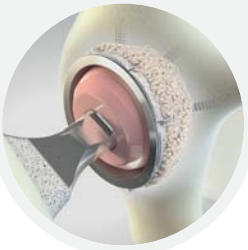
Open & Press!

GlassBone®
Granules

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





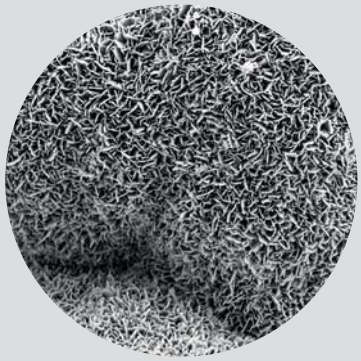


MECHANISM OF ACTION

1. Easy to use

Granules: very cohesive and hydrophylic when mixed with serum, blood or autologous bone.

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



2. Ionic exchanges

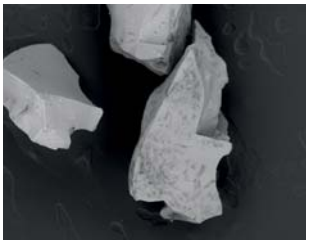
At 14 days: formation of an active biological mineral layer of calcium phosphate, with similar composition and structure as human bone. [1, 3, 5]

Did you know?

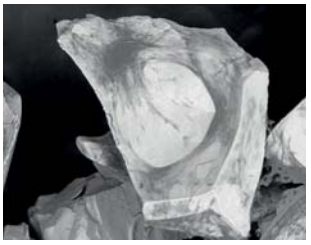
Bone substitutes are classified into an Index of Bioactivity. [8]

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

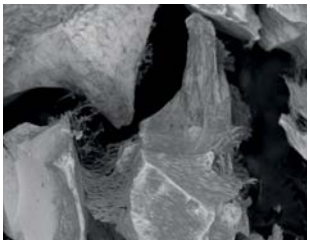
Adhesion and Proliferation of mesenchymal stem cells hMSC on Glassbone®. [10] (*in vitro* study)



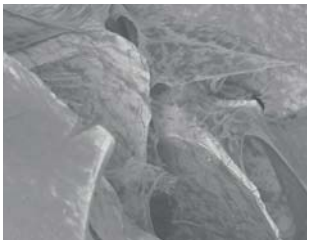
SEM image - Day 2
Stem cells adhesion on the surface of Glassbone® (dark dots)



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



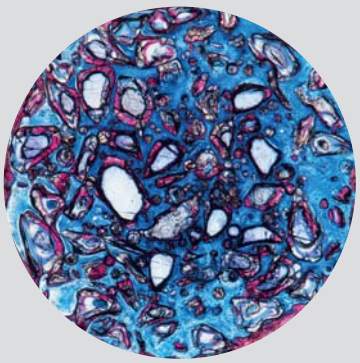
SEM image - Day 14
Extracellular matrix and natural hydroxyapatite in formation



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

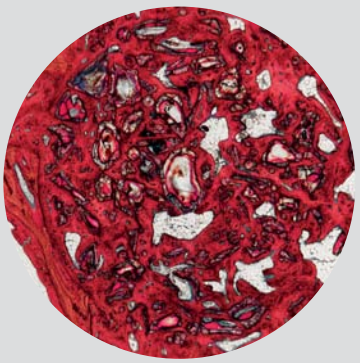
3. Activation phase

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]



4. Bone Regeneration

At 4 weeks:
Fibrous collagenous tissue (blue) is spread in the defect and surrounds the bone substitute. A centripetal bone neoformation (dark pink) is already observed. [7] (*In vivo* study)

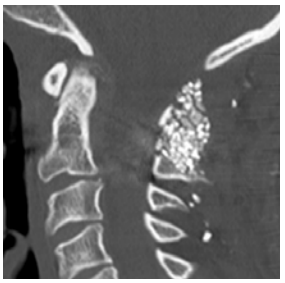


At 12 weeks:
New bone (dark pink) is present in most of the initial defect, with adipocytic bone marrow, an indicator of mature trabecular bone. [7] (*In vivo* study)

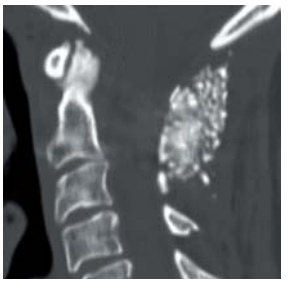
Clinical Results Examples

1: Clinical and radiographic evaluation of bioactive glass in posterior cervical and lumbar spinal fusion*.

In this retrospective study, 30 patients with degenerative and traumatic pathologies of the cervical or lumbar spine underwent spinal fusion using a bioactive glass synthetic bone graft substitute (Glassbone®, Noraker, Lyon-Villeurbanne, France). Pain was assessed by VAS score and graft union by 1-to-1 postoperative radiographic images. Multilevel fusions accounted for the majority of the cohort (43% of patients with more than seven levels treated). Radiographic images showed excellent fusion rates (93%) at last follow-up, equivalent to results reported in the literature for autogenous bone, with excellent bone bypass and no loosening of the spinal implant. Only two cases of non-union were encountered. For 90% of the patients, a recovery at 1 year after surgery was shown with a reduction in pain of 60%. These results suggest that the 45S5 bioactive glass may be an interesting alternative to autologous grafting, in terms of safety and efficiency of bone fusion.



CT scan Post op

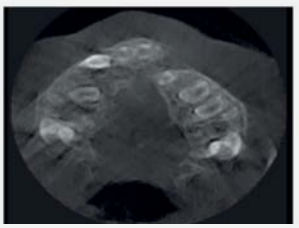


CT scan at 1 year follow up

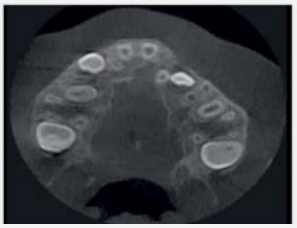
*Extract from the article: Barrey C et Broussolle T. Clinical and radiographic evaluation of bioactive glass in posterior cervical and lumbar spinal fusion (2019). European Journal of Orthopaedic Surgery & Traumatology.

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

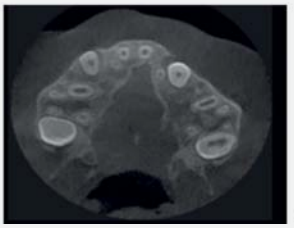
In a prospective study conducted from July 2015 to April 2016 on patients with unilateral or bilateral cleft lip, maxillo-palate, 11 patients including 5 boys and 6 girls underwent gingivoperiostoplasty. The autologous iliac bone harvest has been replaced by the synthetic substitute Glassbone granules. 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 4.6 mm left alveolar cleft



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.

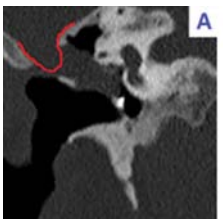
One year postoperatively, the CBCT performed on a patient confirmed a mature bone bridge with the same density as the adjacent jawbone and complete resorption of the bone substitute (see imaging).

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.

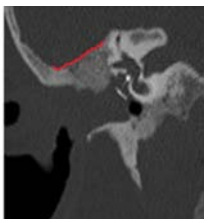
3: Mastoid obliterations with 45S5 Bioglass filling – University Hospital Lyon Sud - France

Retrospective study which covers 42 patients, mean age 49,8 years old, who had undergone obliteration of mastoid or/and epitympanic cavity filled with 45S5 bioactive glass 45S5 bone graft between, November 2017 to January 2019. Microscopic examinations showed dry well-healed tympanic membranes and external auditory canals for 95.2% of the patients after 1 year. Inner ear injuries after obliteration were not observed, comparing pre and post-operative bone conduction audiometry (p value 0.457). One-year postoperative radiological assessments did not reveal any silent implantation of cholesteatoma or residual disease. Two patients presented an inflammatory reaction on the T2WI sequence.

Mastoid and epitympanic obliterations subsequently filled with 45S5 bioactive glass is option in cholesteatoma surgery.



Coronal view of CT-scan of a cholesteatoma recurrence complicated with meningocele,



5th day postoperative CT scan, note the position of meninges after obliteration.

Bioactive Bone Substitutes		
References	**Granule size**	**Volume**
Glassbone® Granules		
GB05.1/05-U	0.5 – 1.0 mm	0.5 cc
GB05.1/1-U	0.5 – 1.0 mm	1.0 cc
GB05.1/5	0.5 – 1.0 mm	5.0 cc
GB1.3/1-U	1.0 – 3.0 mm	1.0 cc
GB1.3/5	1.0 – 3.0 mm	5.0 cc
GB1.3/10	1.0 – 3.0 mm	10.0 cc
GB1.3/16	1.0 – 3.0 mm	16.0 cc
Glassbone® Injectable Putty		
GB-IP1.0	0.1 - 0.7 mm	1.0 cc
GB-IP2.5	0.1 - 0.7 mm	2.5 cc
GB-IP5.0	0.1 - 0.7 mm	5.0 cc
GB-IP10 *	0.1 - 0.7 mm	10.0 cc

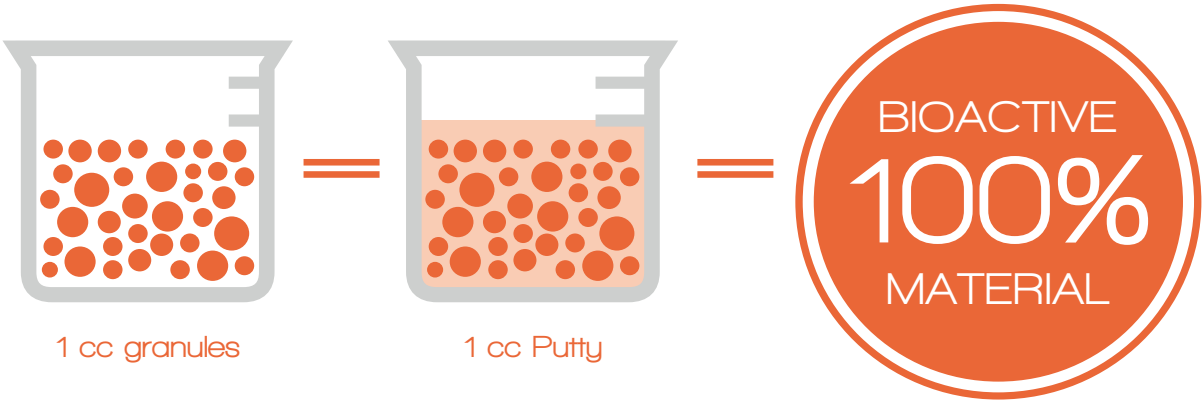
* Not available for France

Glassbone® is intended for bone substitution to fill, rebuild, fuse bone defects, when autologous solutions are not applicable or sufficient, pending the regeneration of the bone. [9]
Main indications :

- ORTHOPAEDIC SURGERY
- SPINAL SURGERY
- CMF / ENT SURGERY
- DENTAL SURGERY

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, ID. et al. Calcif Tissue Int. 2000;**67**:321-9.*
5. *Hench, LL 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®, study on sheep.*
8. *Hench, LL Biomaterials 1998;**19**:1419-1423.*
9. *Clinicals and technicals datas on file at NORAKER®.*
10. *Datas on file at NORAKER® : In vitro study*

Glassbone®, bone graft substitutes are medical devices class III (CE 0459), manufactured by NORAKER®.
Glassbone® 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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