NORAKER®

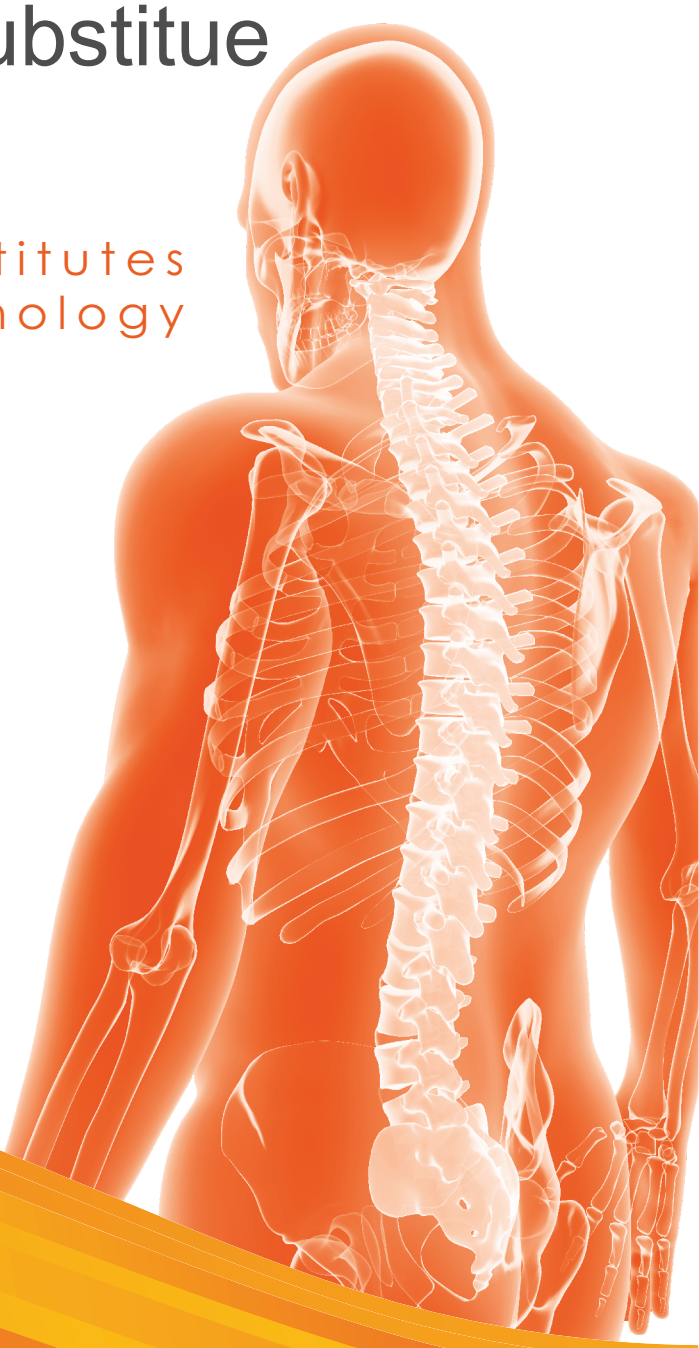
THE BIOGLASS® COMPANY

# GlassBone™

## Bioactive Bone Substitue

Synthetic Bone Substitutes
Bioactive Glass Technology





CERTIFIED MDR EU 2017/745

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

GlassBone™ 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 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]

## INDICATIONS AND TARGET POPULATION

Loss or lack of bone substance for bone defects of traumatic, pathological, or surgical origin when autologous solutions are not applicable or sufficient. Glassbone is a synthetic, bioactive, and absorbable device for filling, reconstruction and/or fusion of bone defects or gaps in the sketetal system in children and adult populations.

## Compositional diagram for bone bonding

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

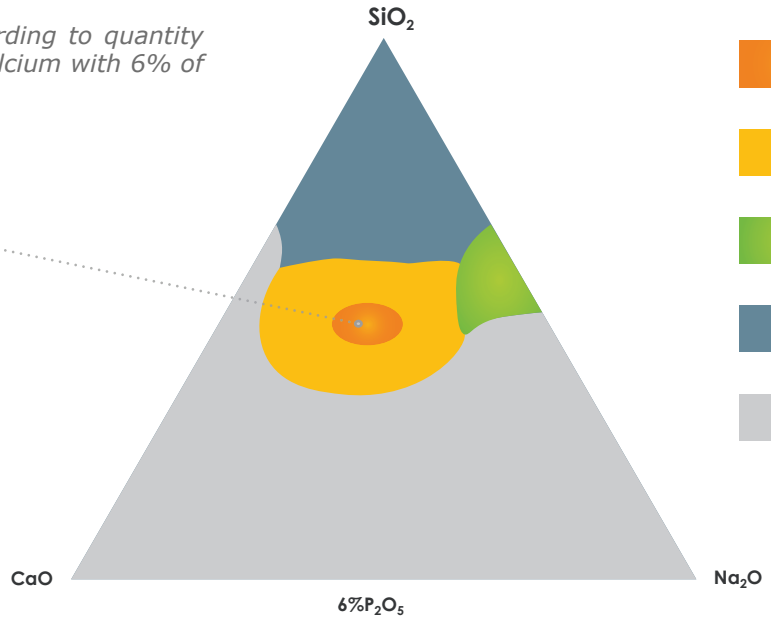
GlassBone™
Bioactive glass 45S5

$SiO_2$ : 45%

$Na_2O$ : 24.5 %

CaO : 24.5 %

$P_2O5$ : 6 %




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

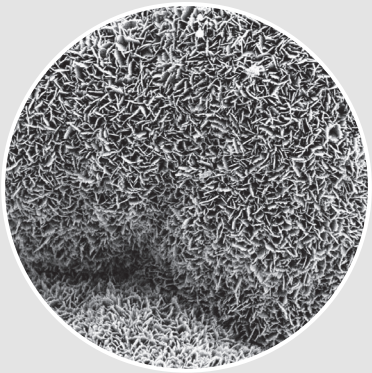
| Indication | Performance achieved | Benefits | Risk |
|---|---|---|---|
| Fusion or reconstruction of deformities and degenerative diseases in spine | 92% fusion minimum at 12 months | Improvement of patient quality of life<br>No bone harvest | No complication related to GlassBone G or IP identified |
| Filling after surgical bone defect (donor sites after removal of autograft, trepanation, ...) | 100% filling at 12 months | Improvement of patient quality of life | No complication related to GlassBone G or IP identified |

# MECHANISM OF ACTION

## 1. Easy to use

*Granules:* very cohesive and hydrophylic 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]

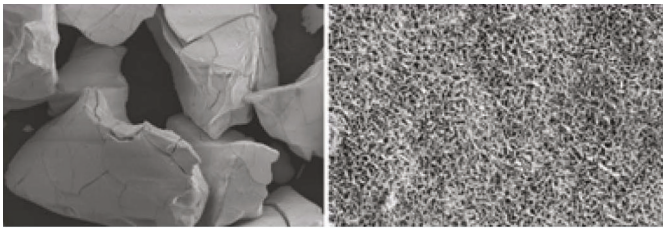
## Did you know?

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

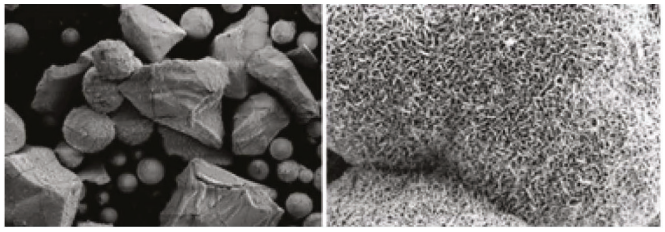
| Class A | Class B |
|---|---|
| Osteoconduction + Osteoproduction | Osteoconduction |
| **Bioactive Glass 45S5** | HA, βTCP |

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

**(a) GlassBone™ Granules**

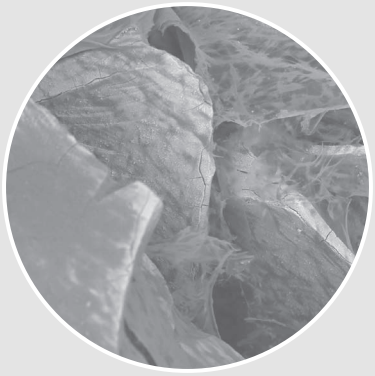


**(b) GlassBone™ Injectable Putty**



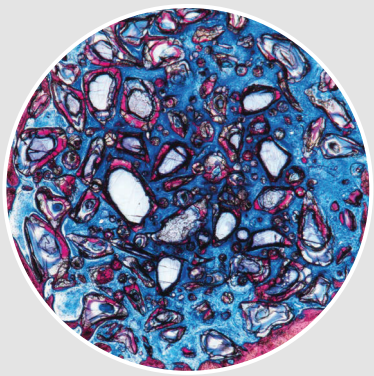
SEM images of (a) GlassBone™ Granules 05.1 and (b) GlassBone™ Injectable Putty a magnification of x50 (left) and X 10,000 (right) after 28 days of immersion in SBF (testing according to ISO 23317:2014).

The surface of the granules presents cracks at x50 and needle-like structures at X 10,000. This is characteristic of hydroxyapatite formation. This evaluation of apatite-forming ability on implant material in SBF is useful for evaluating its in vivo bone-bonding ability.



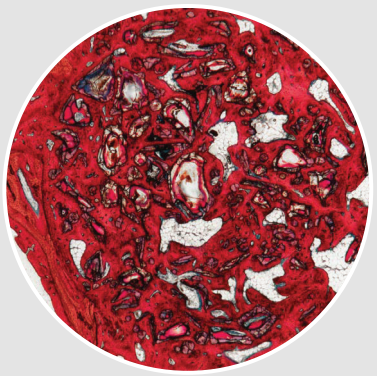
### 3. Scaffold formation

At 21 days:
The increased concentration of minerals induces a carbonated hydroxyapatite layer (CHA). [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

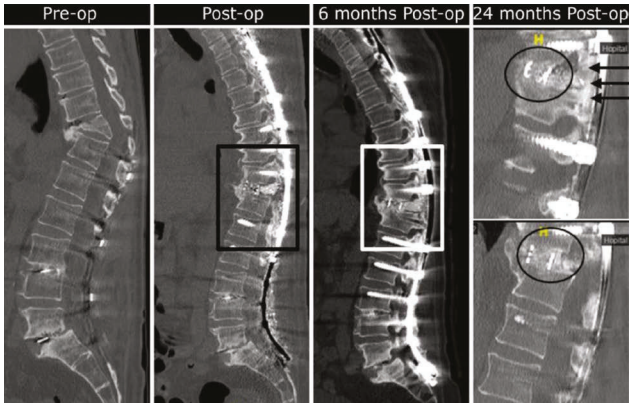
## 1_ Clinical and radiographic evaluation of bioactive glass in posterolateral cervical or lumbar spinal fusion. *European Journal of Orthopaedic Surgery & Traumatology (2019)*

Barrey C, Broussolle T

METHOD: *Retrospective case series. 30 consecutive patients with indications for a posterolateral spinal fusion procedure were operated. Appropriate decompressive surgery was performed with subsequent fixation using posterior instrumentation as appropriate and filled with bioactive glass. GlassBone™ Granules (1 – 3.15 mm) were mixed with local autograft harvested from the surgical site and blood. The clinical evaluation includes pain evaluation and patient satisfaction, and the fusion was evaluated with CT scans at 6 months for cervical procedure and 12 months for lumbar procedure (T-L-S).*

RESULTS: *Radiographic imaging demonstrated excellent fusion rates (93%) at final follow-up, equivalent to the outcomes reported in the literature for autogenous bone, with excellent bone bridging and no spinal implant loosening. Only two cases of non-union were encountered. Additionally, 90% of the patients demonstrated recovery at 1 year after surgery with a pain reduction of 60%.*

CONCLUSION: *the results suggest that the 45S5 bioactive glass may be an interesting alternative option to autologous graft, in terms of safety and bone fusion efficiency.*




Patient was operated by VCR (vertebral column resection) to treat PJK (proximal junctional kyphosis). The granules are visible immediately after surgery along the instrumentation. At 2 years after surgery, a bone bridging is clearly visible inside the vertebral cage and through the disc space.

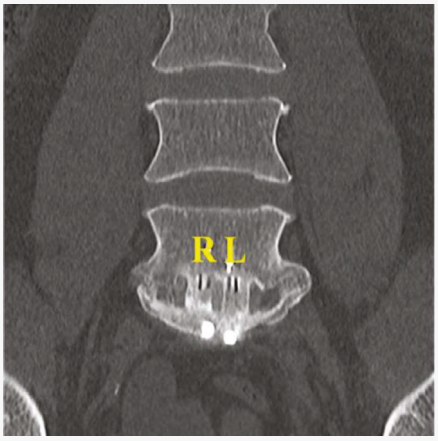
## 2_ Bioactive glass grants equivalent or better fusion compared to autologous iliac crest bone for ALIF. *Spine (2022)*

Szadkowski M, Bahroun S, Aleksic I , Kerckhove M V, Ramos-Pascual S, Saffarini M , Fière V, d'Astorg H

METHODS: *Consecutive series of 40 patients (58 levels) that underwent single-level (L5-S1 only) or two-level (L4-L5 and L5-S1) ALIF were assessed. Intervertebral cages had one chamber filled with bioactive glass (GlassBone™ Injectable Putty) and the other with autologous iliac crest bone. CT scans were graded using the Bridwell classification. Patients were clinically evaluated; complications and reoperations were noted.*

RESULTS: *At a follow-up of 14±4 months, chambers filled with bioactive glass had Bridwell grade I at 30 levels (52%), grade II at 26 levels (45%), and grade III at 2 levels (3%), compared to chambers filled with autologous bone which had Bridwell grade I at 23 levels (40%), grade II at 33 levels (57%), and grade III at 2 levels (3%) (p=0.416). The two patients with Bridwell grade III at both chambers of the L4-L5 cages required reoperation using posterior instrumentation. There were two postoperative complications (one hematoma, one radiculopathy), neither of which required reoperation.*

CONCLUSION: *For ALIF at L5-S1 or L4-L5, bioactive glass grants equivalent or better fusion compared to autologous iliac crest bone. The findings of this study suggest that for patients undergoing ALIF, bioactive glass can be used as a substitute to autologous iliac crest bone; thus, avoiding increased operative time and blood loss, as well as donor site morbidity.*



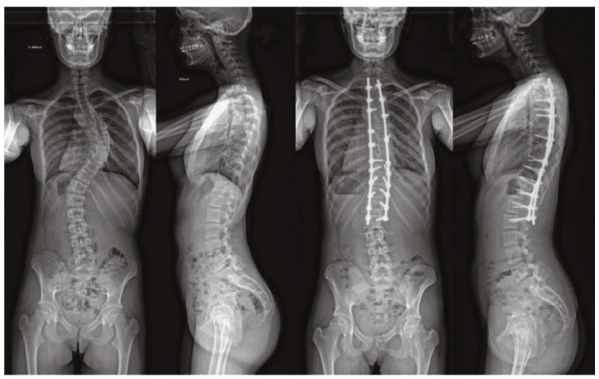

Frontal CT scan of a patient with fusion of Bridwell grade I1 in both the chamber filled with bioactive glass (R) and the chamber filled with autologous bone (L)in both the chamber filled with bioactive glass (R) and the chamber filled with autologous bone (L)in both the chamber filled with bioactive glass (R) and the chamber filled with autologous bone (L).

## 3_ Safety and Efficacy of Stand-Alone Bioactive Glass Injectable Putty or Granules in Posterior Vertebral Fusion for Adolescent Idiopathic and Non-Idiopathic Scoliosis. *Children (2023)*

Courvoisier A, Maximin M-C, Baroncini A.

METHODS: *A retrospective study was conducted including 43 patients with scoliosis and requirement of posterior fusion posterior instrumentation. 18 patients underwent surgery using GlassBone™ Granules (GB-G 1-3mm) and 25 using GlassBone™ Injectable Putty (GB-IP). The aim is to evaluate and compare the post-operative safety and efficiency of bioactive glass 45S5 putty and granules in posterior spine fusion. Each patient's last follow-up was performed at 24 months and included clinical and radiological evaluations.*

RESULTS: *Four of all operated patients (GB-G and Putty) experienced adverse events. 2 patients (4.7%) had surgical site infection which was treated with revision and cleaning, and 1 patient had an extended stay in the intensive care unit (2.3%). About fusion, at the latest follow-up, bony fusion was documented in all patients (100%). Cobb angle measurements reflected a significant reduction in spinal deformity. No significant loss of correction occurred between the immediate post-operative examination and the 24-months. There was no sign of non-union, screw loosening, implant displacement or rod breakage.*



Pre-and post-operative full-spine coronal and sagittal X-rays illustrating a typical long construct for posterior fusion to correct a deformity.

CONCLUSION: *No significant difference between GB-G and GB-IP. The clinical and radiographic results showed the performance and safety of bioactive glass.*

| 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-IP1.5 | 0.1 - 0.7 mm | 1.5 cc |
| GB-IP2.5 | 0.1 - 0.7 mm | 2.5 cc |
| GB-IP5.0 | 0.1 - 0.7 mm | 5.0 cc |
| GB-IP6 | 0.1 - 0.7 mm | 6.0 cc |
| GB-IP10* | 0.1 - 0.7 mm | 10.0 cc |

* Not available for France

Loss or lack of bone substance for bone defects of traumatic, pathological or surgical origin when autologous solutions are not applicable or sufficient in orthopedics, neurosurgery, cranio maxillo facial and otorhinolaryngology surgery in children and adult population.

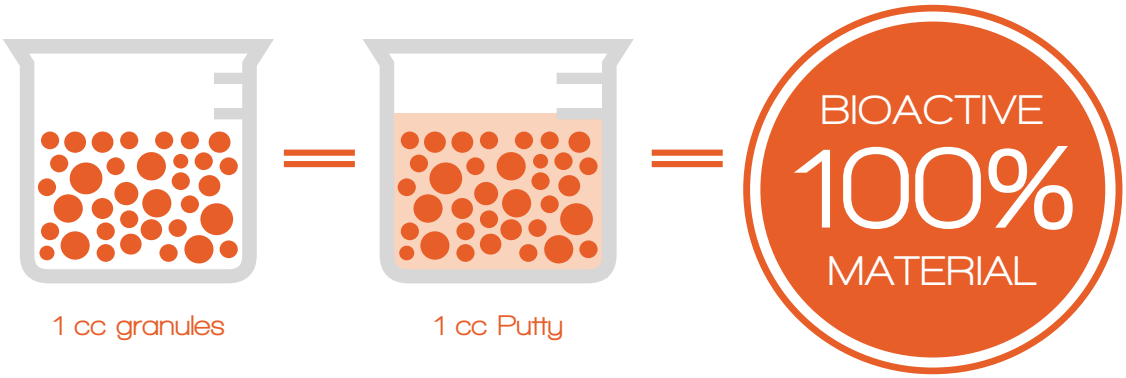
Main indications:

- ORTHOPAEDIC SURGERY
- SPINAL SURGERY
- CMF / ENT 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, 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®, study on sheep.*
8. *Hench, L.L. 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.*
*Carefully read the instructions supplied with the product.*




Brochure GlassBone EN 06-2025

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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