NORAKER®

THE BIOGLASS® COMPANY

BiologicGlass™

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

BiologicGlass™ 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. BiologicGlass™ 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]

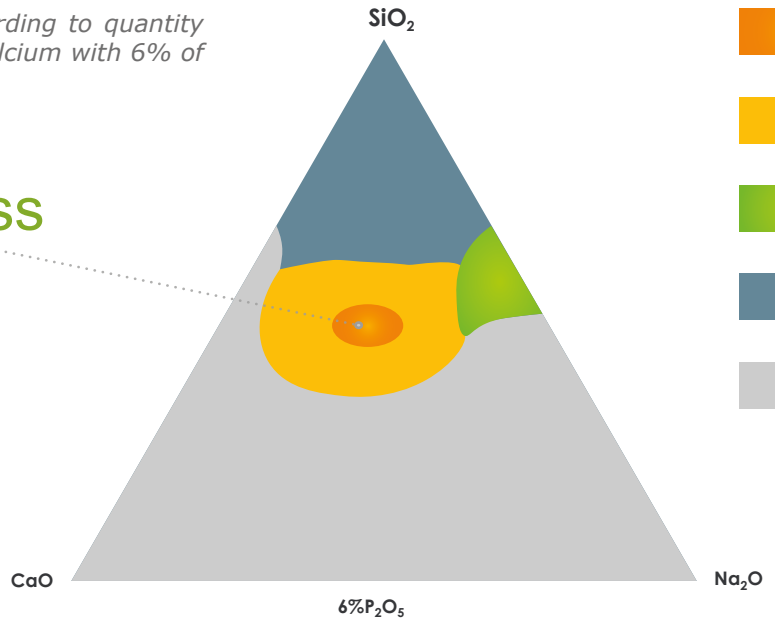
BiologicGlass
Bioactive glass 45S5

SiO_2 : 45%

Na_2O : 24.5 %

CaO : 24.5 %

P_2O5 : 6 %



5,10

BiologicGlass™ range : Injectable Putty and Granules

BiologicGlass™ Injectable Putty

Open & Press!

BiologicGlass™ Granules

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

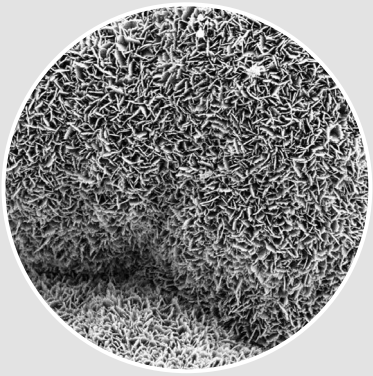
Indication	Performance achieved	Benefits	Risk
Filling after surgical bone: defect (donor sites after removal of autograft, trepanation, ...)	100% filing at 12 months	Improvement of patient quality of life. No bone harvest	No complication related to BiologicGlass™ G or IP identified
Filling after removal of cholesteatoma	100% filing at 12 months	Improvement of patient quality of life. No bone harvest	No complication related to BiologicGlass™ G or IP identified
Filling and reconstruction due to maxilla and periodontium pathologies	More 80% reconstruction at 12 months	Improvement of patient quality of life. No bone harvest	No complication related to BiologicGlass™ 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?

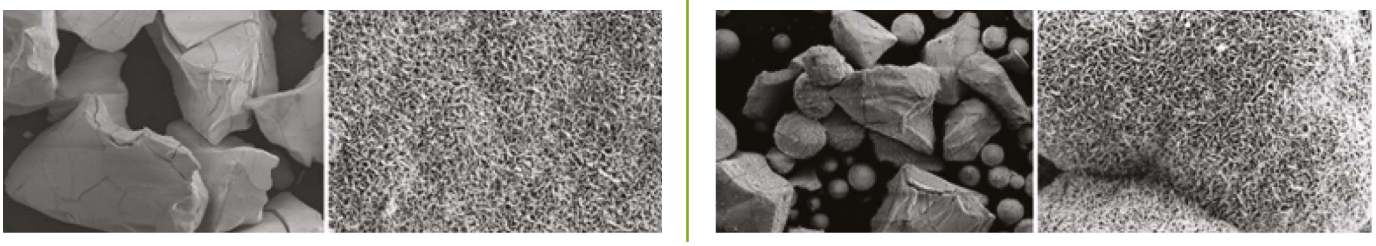
Bone substitutes are classified into an Index of Bioactivity (only demonstrated by in-vitro study).[8]

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) BiologicGlass™ Granules

(b) BiologicGlass™ Injectable Putty

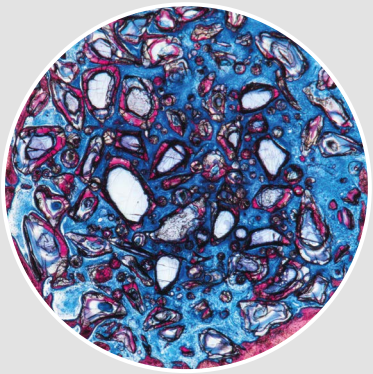


SEM images of (a) BiologicGlass™ Granules 05.1 and (b) BiologicGlass™ Injectable Putty a magnification of x50 (left) and X 10,000 (right) after 28 days of immersion in SBF (testing according to ISO 23317:2014).

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.

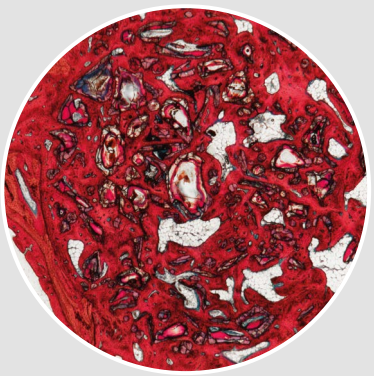
3. Scaffold formation

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

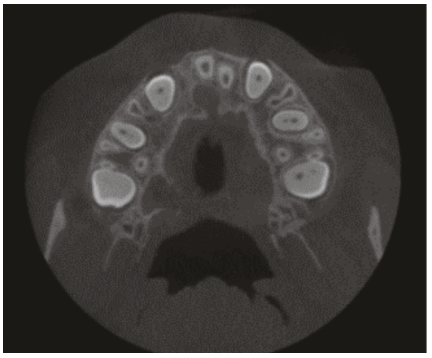
1_ Bioactive glass 45S5 ceramic for alveolar cleft reconstruction, about 58 cases. *Journal of Cranio-Maxillo-Facial Surgery (2018).*

Graillon N, Degardin N, Foletti JM, Seiler M, Alessandrini M, Gallucci A. J Craniomaxillofac Surg.

METHODS: *In this clinical case series, 58 patients aged 3 to 15 years (7.6 years on average) was included who has undergone a unilateral or bilateral alveolar cleft. The alveolar cleft was grafted with 0.5 to 2 cc of GlassBone™ (size: 0.5 - 1mm) depending on the volume of the graft. The patients underwent clinical assessment preoperatively, at 1 month, 6 months, and 1 year; imaging check-up via dental panoramic radiography preoperatively, postoperatively, at 1 year and every two years; and maxillary CBCT preoperatively and at 1 year. The safety and performance of bioactive glass have been evaluated. The resorption of the material has not been studied.*

RESULTS: *Hospitalization, social eviction and antalgic consumption were reduced. Bone continuity was achieved in 63.8% of the cases. Bilateral cleft and dental agenesia increased grafting failure. In the subgroup of 25 patients with isolated unilateral cleft without dental agenesis, 80% had bone continuity at one year. We noted 10.3% of alveolar fistula recurrence.*

CONCLUSION: *The use of GlassBone™ in alveolar grafts simplifies the surgery procedure and the postoperative management, and ensures satisfactory mucosal healing, tooth eruption and bone continuity in two thirds of the followed grafts.*



Maxillary CBCT 1 year after the right alveolar bone grafting using GlassBone™ showing an alveolar bone continuity.

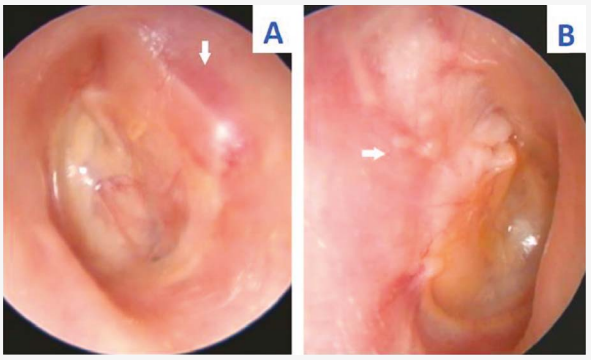
2_ Tolerance and safety of 45S5 bioactive glass used in obliteration procedures during middle ear surgery: Preliminary results. *Am J Otolaryngol (2020)*

Al Tamami N, Bawazeerb N, Fieux M, Zaouche S, Tringali S

METHOD: *Retrospective study of 42 patients who had undergone obliteration of mastoid or/and epitympanic cavity with 45S5 bioactive glass between, November 2017 to January 2019. Data from clinical follow ups, audiological assessment, CT-scan and MRI were analyzed.*

RESULTS: *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 by comparing pre and post-operative bone conduction audiometry (p value 0.457). No facial palsy was reported post-operatively. One-year postoperative radiological assessments did not reveal any silent implantation of cholesteatoma or residual disease. There was no extrusion of bioactive glass material.*

CONCLUSION: *Mastoid and epitympanic obliterations with 45S5 bioactive glass seem to be a tolerable and safe option in cholesteatoma surgery with favorable outcomes.*



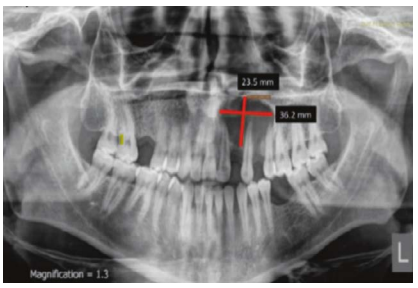
Otoscopic examinations after 1-year postoperative showing the result of obliteration using 45S5 Bioactive Glass. Note the reconstructed attic with a cartilage (white arrow).
A: An example of a left ear. B: An example of a right ear.

3_ 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 statistical significant results regarding the studied parameters.*

Bioactive Bone Substitutes		
References	**Granule size**	**Volume**
BiologicGlass™ Granules		
XBG-GM0.5	0.5 – 1.0 mm	0.5 cc
XBG-GM1.0	0.5 – 1.0 mm	1.0 cc
XBG-GM5	0.5 – 1.0 mm	5.0 cc
XBG-GL1.0	1.0 – 3.0 mm	1.0 cc
XBG-GL5	1.0 – 3.0 mm	5.0 cc
XBG-GL10	1.0 – 3.0 mm	10.0 cc
XBG-GL16	1.0 – 3.0 mm	16.0 cc
BiologicGlass™ Injectable Putty		
XBG-IP1.0	0.1 - 0.7 mm	1.0 cc
XBG-IP1.5	0.1 - 0.7 mm	1.5 cc
XBG-IP2.5	0.1 - 0.7 mm	2.5 cc
XBG-IP5.0	0.1 - 0.7 mm	5.0 cc
XBG-IP6.0	0.1 - 0.7 mm	6.0 cc
XBG-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 orthopaedics, neurosurgery, cranio maxillo facial and otorhinolaryngology surgery in children and adult population.

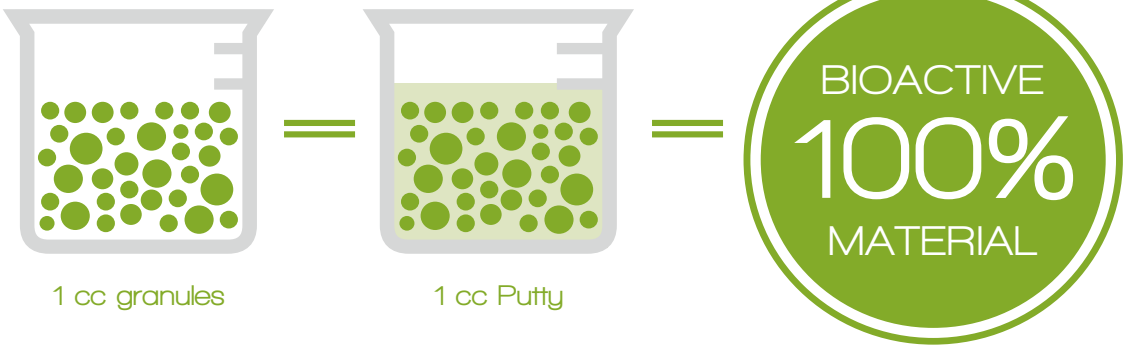
Main indications:

- ORTHOPAEDIC SURGERY
- SPINAL SURGERY
- CMF / ENT SURGERY

BiologicGlass™

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*

BiologicGlass™, bone graft substitutes are medical devices class III (CE 0459), manufactured by NORAKER®.
BiologicGlass™ 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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Brochure BiologicGlass EN 05-2025