NORAKER

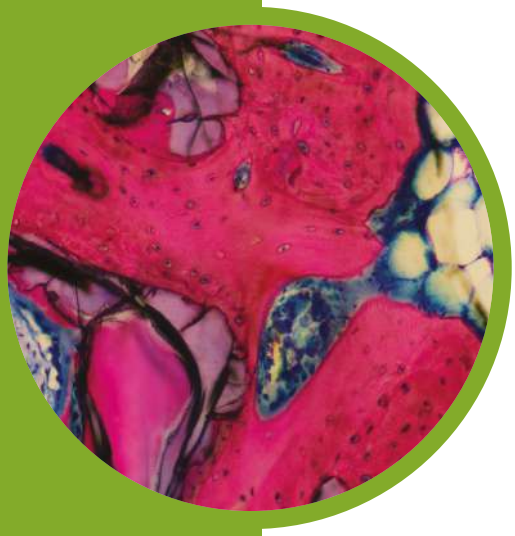
INNOVATIVE BIOMATERIALS

Activioss™

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 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

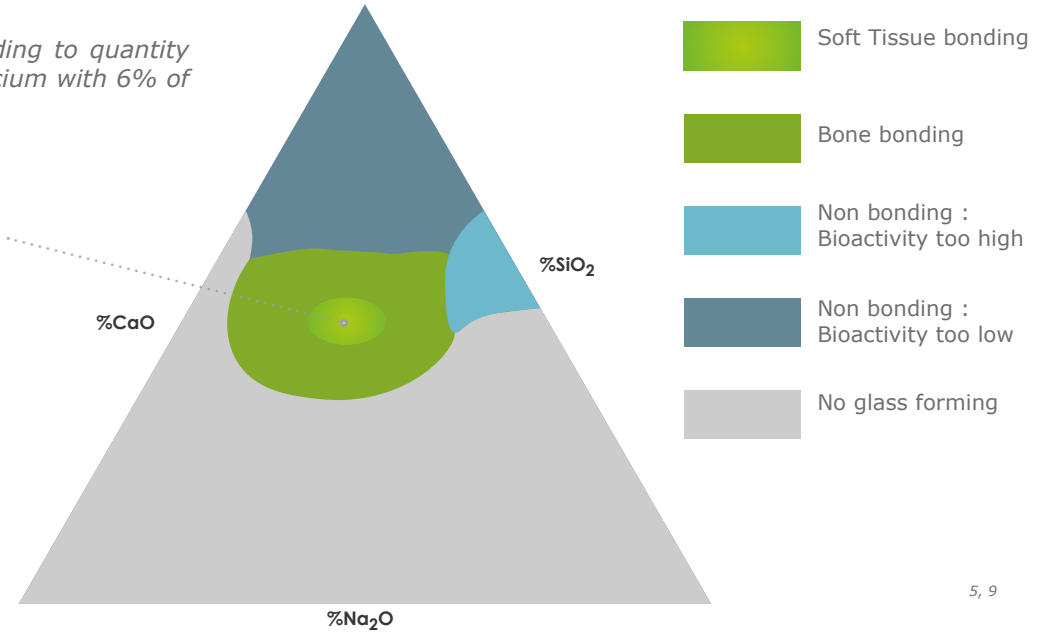
Biological properties according to quantity of silicium, sodium and calcium with 6% of phosphorous. [5, 9]

Activioss™
Verre bioactif 45S5

SiO_2 : 45%

Na_2O : 24.5 %

CaO : 24.5 %



[5, 9]

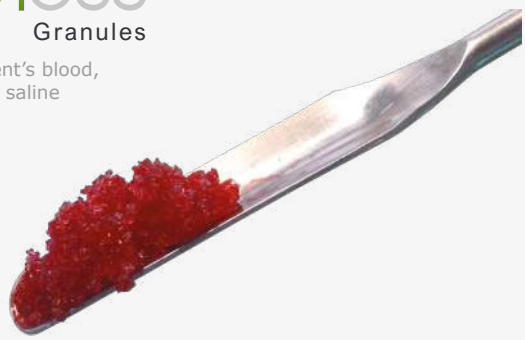
Activioss™ range :
Injectable Putty and Granules

Activioss™
Injectable Putty

Open and press !

Activioss™
Granules

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

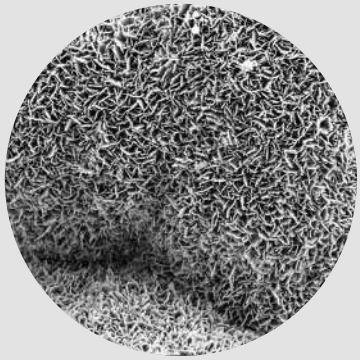


MECHANISM OF ACTION

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

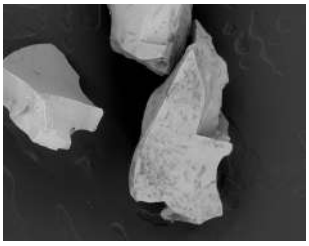
At 21 days:
The increased concentration of minerals improves the differenciation and proliferation of osteoblasts in the defect; and starts the formation of the extra-cellular matrix of collagen. [2 4 6]

Did you know?

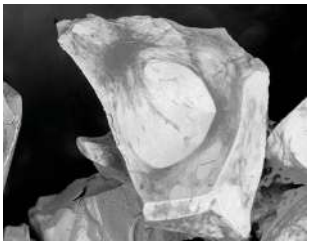
Bone substitutes are classified into an Index of Bioactivity.[8]

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

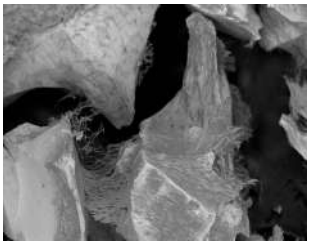
Adhesion and Proliferation of mesenchymal stem cells hMSC on Activioss™.[9] (*in vitro* study)



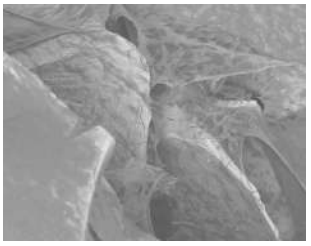
SEM Image - Day 2
Stem cells adhesion on the surface of Activioss™ (dark dots)



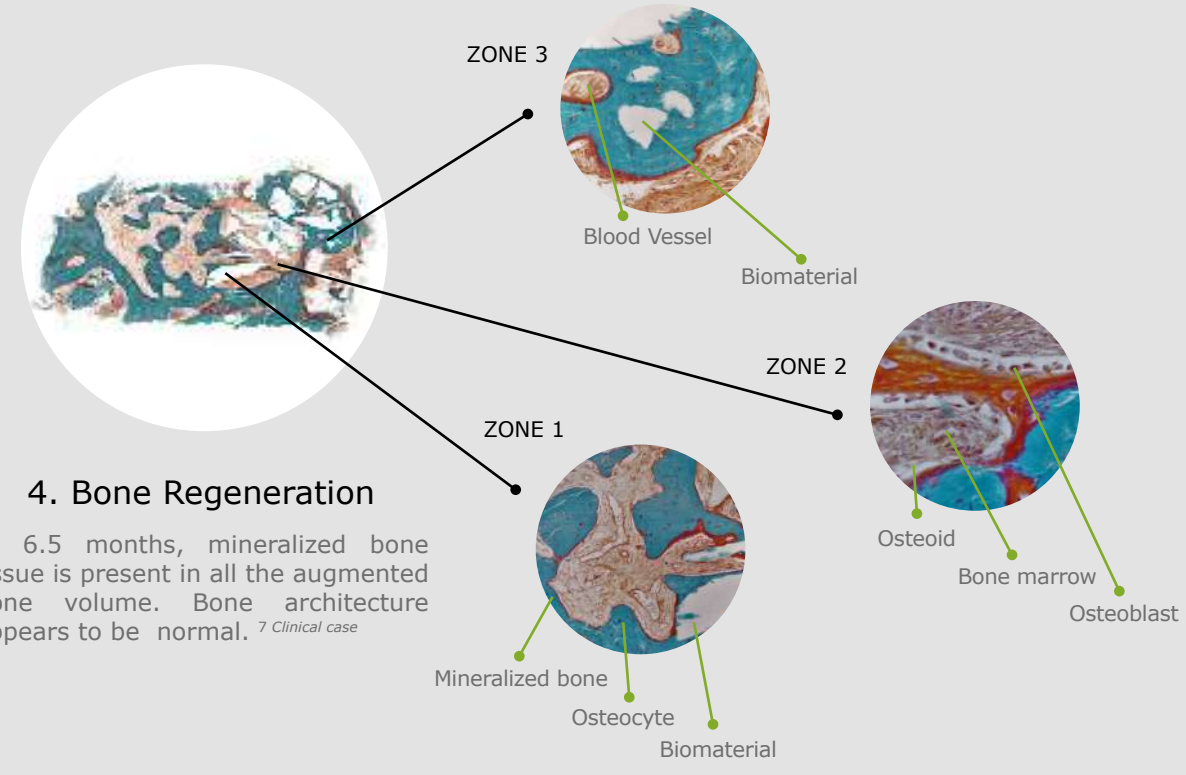
SEM Image - Day 7
Multiplication and differentiation of the stem cells (dark spider web)



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 Cases

1: Implant dehiscence, Dr D. Carrotte, private practice in Villeurbanne Lyon (69)

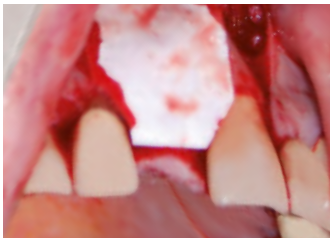
1. Gingival healing after tooth extraction.

2. Bone crest after flap opening and cortical stimulation.

3. Fenestration to neck implant, on 5 mm

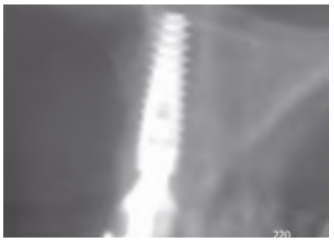
4. Recovery of the apparent grooves with drilling bone.

5. Placement of the Activioss™ bone substitute, in relation with autologous bone.



6. Defect's recovery with Activioss™ Membrane, 20x30 mm, reshaped for this site.

7. Final view with stitchings.



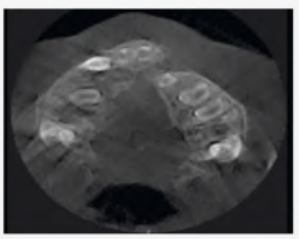
8. 3 months scanner. Highlight of the bone graft, on the vestibular face of the implant.

9. Gingiva scalopping at 3 months, due to the connection of the temporary crown «direct implant».

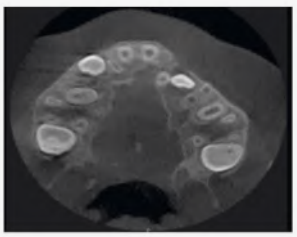
10. Clinical results at 6 months, with natural adjacent tooth mimetism and papilla's maturation.

2: Ginvivoperiostoplasty Dr M-E Gatibelza, CHU Sud Rennes

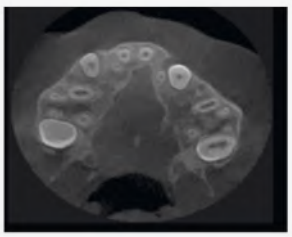
This case is a 9-years-old female, with an alveolar left cleft of 4,6mm, confirmed on cone-beam. Gingivoperiostoplasty was realized in ambulatory, with 1cc of Activioss™ Granules mixed with 0,5cc of patient's blood. School could start again 1 week after surgery, and sports 1 month after. Clinical follow up at 1 month and 1 year showed good gingival continuity, stable bone volume, no persistent palate or alveolar fistula. Radio follow up at 6 months with cone beam showed progressive integration of the bone substitute. At 1 year follow up, cone beam confirmed a mature bone bridge with same density as adjacent maxillaire and complete resorption of Activioss™.



a ConeBeam before surgery



b ConeBeam at 6 months follow up



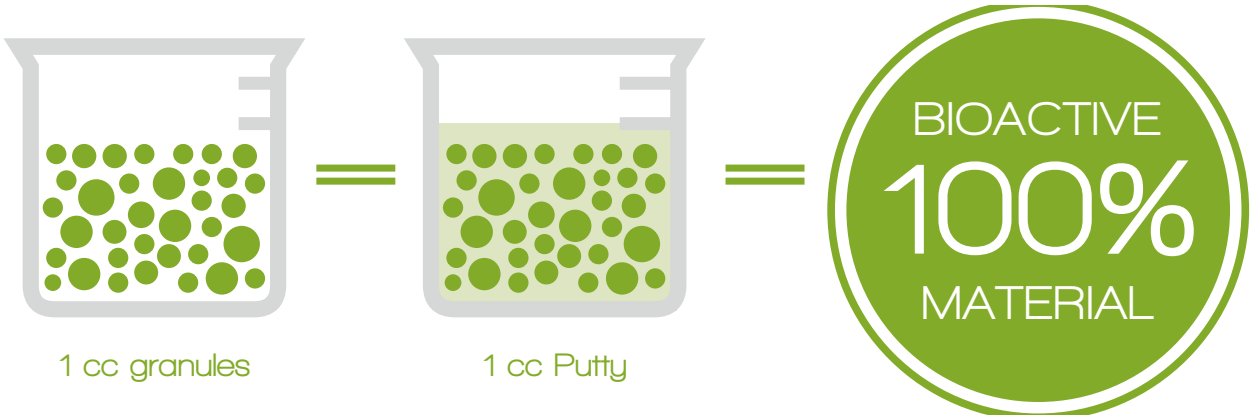
c ConeBeam at 1 year follow up

References	Granule size	Volume ≈ weight
Activioss™ Granules Osteostimulative granules for the bone regeneration.		
ACT-GS0.5 S	0.04 – 0.5 mm	0.5 cc
ACT-GS1.0 S	0.04 – 0.5 mm	1.0 cc
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 Osteostimualtive Injectable paste for bone remodling.		
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 IN CASE OF LOSS OR LACK OF BONE SUBSTANCE FOR BONE DEFECTS OF TRAUMATIC, PATHOLOGICAL OR SURGICAL ORIGIN, IN DENTAL 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, manufactured by NORAKER.
Activioss™ products are indicated for filling bone defects. Read the instructions for used.
Last update : 2019/04



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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