

NORAKER®
THE BIOGLASS® COMPANY

ActivLoss®

Resorbable synthetic
bilayer membrane

*Patented Jet-Spraying technology:
Full barrier effect during 4 weeks, and
complete resorption in 6 months*

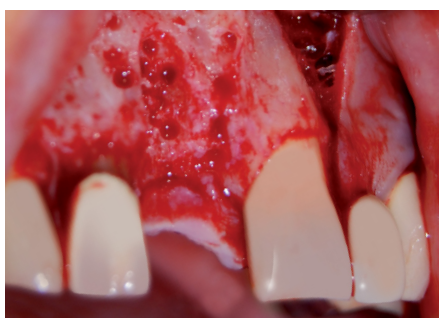


Clinical Results Examples

Implant Dehiscence Baly Private clinic Villeurbanne - France



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.

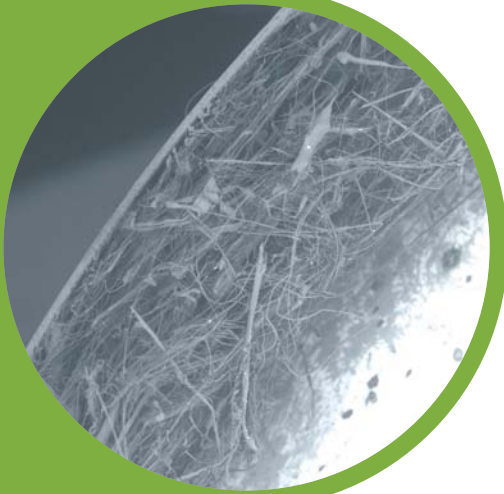
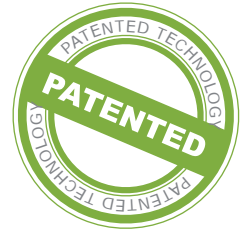


9. Gingiva scalloping at 3 months, due to the connection of the temporary crown «direct implant».



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

UNIQUE JET-SPRAYING TECHNOLOGY



Activioss® Membrane is produced by a patented Jet-Spraying technology, which confers it a bilayer structure, with a thick and smooth layer to prevent connective tissue invagination and to ensure mechanical resistance, and a rough biomimetic layer to support osteoblastic cells colonization and to promote full bone regeneration. ¹

What is Activioss® Membrane?

Activioss® is a resorbable bilayer synthetic membrane, with a biomimetic structure to promote full bone regeneration. Its synthetic property induces reliable characteristics, in terms of fabrication, in order to ensure predictable and reproducible results. ¹

What does it consist of?

Activioss® Membrane is made of synthetic polymer: the choice of this material ensures an excellent biocompatibility and an optimal resorption, allowing hard and soft tissues regeneration. ^{1 2 3}

What is it used for ?

Activioss® Membrane is indicated in Guided Bone Regeneration and Guided Tissue Regeneration. The isolation of the bone defect, combined with the bone filling Activioss® Granule offers a 100% synthetic solution.

What makes it different?

Resistant and supple, setting up Activioss® Membrane is easy, and allows the blood clot maintain, favoring tissue healing.

The Jet-Spraying technology is a French patented technology, allowing manufacturing a bilayer membrane, with a rough biomimetic structure. This nano-fibrillar layer has a 10 µm porosity, to allow blood vessels and bone cells development between the fibers. ¹

The thick and smooth layer has been developed to ensure a full barrier effect during the 4 first critical weeks for gingival tissues healing. Moreover, the Jet-Spraying technology and the polymer selection allowed developing a membrane with a good physiological tolerance, to allow a 6 months degradation, with a gradual and controlled process. ^{1 2 3}

Tissue engineering is the science which, using biological mechanisms and biomaterials, stimulates deficient tissue regeneration. NORAKER® is involved in biomaterial development with the aim of becoming an innovative player in the field of tissue engineering.

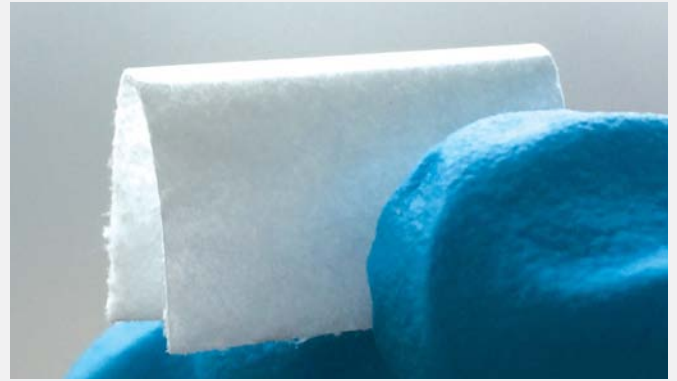
The future of medicine is heading towards regenerative medicine.

Handling experience

Blood clot maintain

Mechanical properties of Activioss® membrane make it flexible and resistant. It can be cut, repositioned, sutured, without sticking to the instrumentation. ²

Membrane's resistance and the intact full barrier effect during 4 weeks are essential factors to maintain the blood clot and the filled volume, and to optimize bone regeneration. ^{2 4}

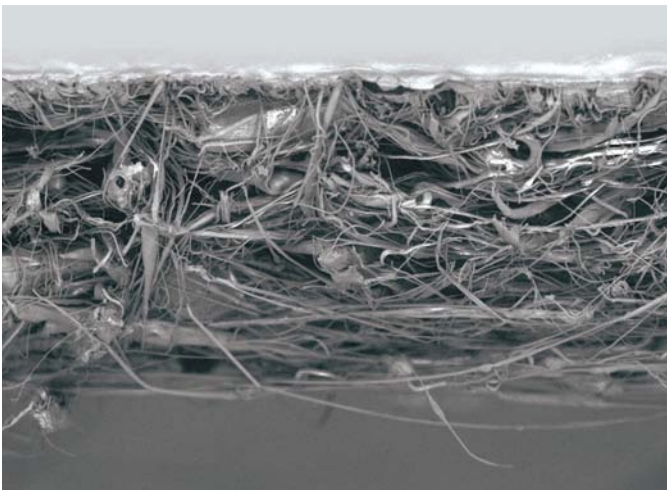


Activioss® Membrane is both supple and flexible, adaptable to bone defects, ensuring bone regeneration results.

Full barrier effect during 4 weeks

Biomimetic bilayer structure

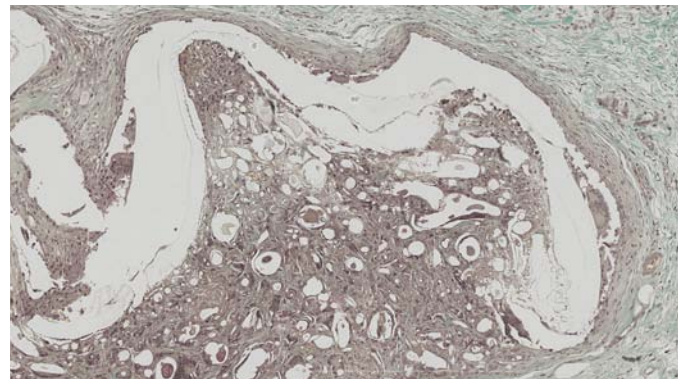
During the first 4 weeks, the membrane's thick layer preserves its integrity to ensure the barrier effect during the critical step of gingival tissue healing. It avoids soft tissues invagination in bone defect, while stabilizing the blood clot. ^{1 2 4}



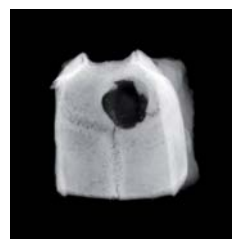
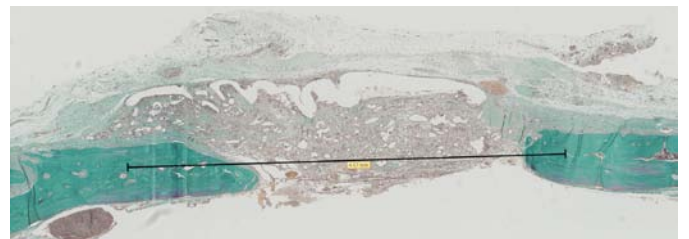
Activioss® Membrane - Biomimetic bilayer structure (SEM 1000x)

The rough biomimetic layer is made of entangled fibers with a 10 µm porosity, facilitating the passage of blood vessels and bone cells. ^{1 2}

The association with a bioactive bone substitute and the presence of bone remodeling actors promotes bone tissue regeneration.



Subcutaneous histological study, at 4 weeks:
The thick layer (in white) remains intact, no adipose tissue infiltration was observed. No signs of inflammation or infection were observed. Cell colonization is observed on the rough layer after 4 weeks.*



In-vivo study at 4 weeks:
The bilayer structure of Activioss® membrane is still present, with a good healing. A centripetal bone healing can be observed on the radiography at 4 weeks.*

Did you know?

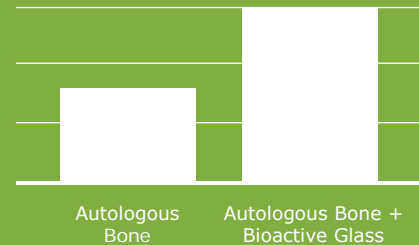
Activioss® Membrane meets the need of tissue healing, isolating the filling site during the first 4 weeks, necessary for epithelial tissues healing. This temporary occlusion promotes the recruitment of players needed for bone regeneration, supported by the presence of a bioactive bone substitute as Activioss® Granules.

The combination with a bioactive bone substitute and autologous bone speeds up full bone regeneration two-fold. ^{5 6 *}

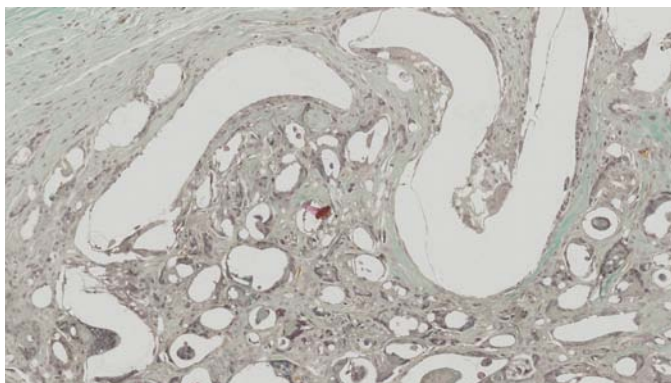
During membrane's resorption time, maintaining the blood clot and the bone volume are essential points for optimal bone regeneration.



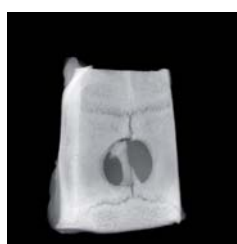
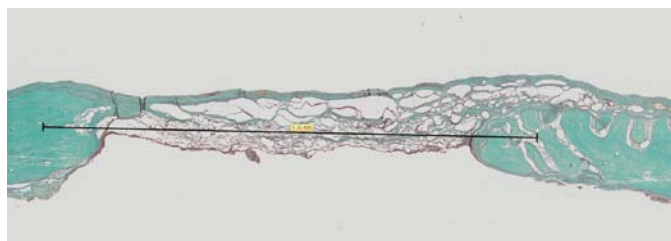
% Bone Growth



Slow and controlled resorption in 6 months



Subcutaneous histological study, at 8 weeks: The thick layer (in white) of Activioss® membrane is still apparent, but with multiples lysis.*



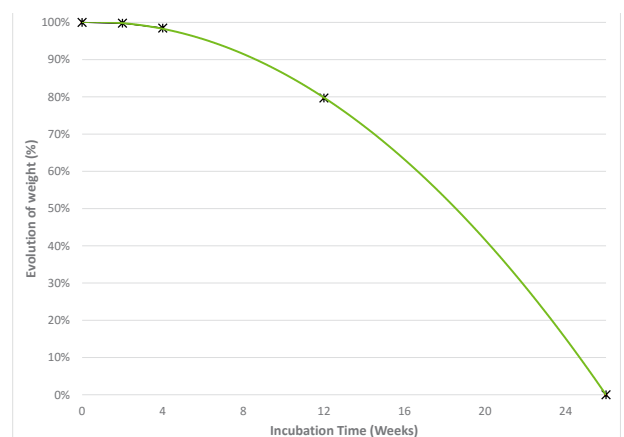
In-vivo study at 8 weeks: Activioss® membrane confirms its capacity to isolate the defect and to lead bone regeneration (in green). A bone bond is present on the radiography, in a critical size defect.

Bioresorbable

From the first weeks, the Activioss® Membrane's rough layer will degrade by hydrolysis of the polymer chains. Gradually, the fibers break up, allowing blood vessels and bone cells to induce bone regeneration. ²

After 8 weeks, the thick and smooth layer lyses in multiple points, to be finally fully absorbed by the organism at 4 and 8 weeks. ²

The Activioss® Membrane resorption is complete after 6 months (Graphic 1). This slow and controlled resorption, combined with a bioactive bone substitute, favors a quality bone regeneration. ²



Graphic 1: Barrier effect and resorption. Activioss® Membrane is stable during the first 4 weeks, and gradually degraded in a 6 months period. ^{2 *}

The resorbable bilayer synthetic Activioss® Membrane is indicated in Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR), in periodontal and implant surgery:

- Sinus floor elevation
- Extraction socket
- Periodontal treatments
- Bone augmentation
- Bony dehiscence and apical fenestration



References		Dimensions
Resorbable Bilayer Synthetic Membrane Biomimetic tissue engineered matrix for GTR and GBR		
ACT-MS1520	S	15 x 20 mm
ACT-MM2030	M	20 x 30 mm
ACT-ML3040	L	30 x 40 mm

References

1. Hoornaert A., Layrolle P., Sohier J. Membrane de régénération osseuse et procédé de formation d'une membrane de régénération osseuse. EP2404627, 2010.
2. Hoornaert A., Arros C., Heymann M-A, Layrolle P., Biocompatibility, resorption and biofunctionality of a new synthetic biodegradable membrane for guided bone regeneration. Biomedical Materials, 2016, Revised article submitted on April 29, 2016
3. Kulkarni RK, Pani KC, Neuman C, Leonard F. Polylactic acid for surgical implants. Archives of Surgery 1966;93:839-843.
4. Retzepe M, Donos N. Guided Bone Regeneration: biological principle and therapeutic applications. Clin. Oral Impl. Res. 21 (2010) 567-76.
5. Leal AI, Caridade SG, Ma J, Yu N, Gomes ME, Reis RL, et al. Asymmetric PDLLA membranes containing Bioglass® for guided tissue regeneration: characterization and in vitro biological behavior. Dent. Mater. 29 (2013) 427-36.
6. Oonishi, H. and al. Quantitative comparison of bone growth behavior in granules of Bioglass, A-W glass ceramic and hydroxyapatite. J Biomed Mater Res. John Wiley & Sons, Inc., 2000, Vol. 51.

Activioss® Membrane, manufactured by Biomedical Tissues, and Activioss® Granule, manufactured by NORAKER®, are medical devices of class III – CE 0459. Activioss® Membrane is a resorbable bilayer synthetic membrane, used in periodontal and implant surgery. Activioss® Granule is a biomaterial of bone substitution, indicated in bone defect filling. Read carefully the instructions before use.

* These study results do not prevail of human results.

NORAKER® is a French manufacturer specialized in the research and development of innovative products based on 45S5 bioactive glass for medical applications.

60 Av. Rockefeller
69008 Lyon
France

Tél : +33 (0)4 78 93 30 92
Fax : +33 (0)4 72 35 94 37

contact@noraker.com

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