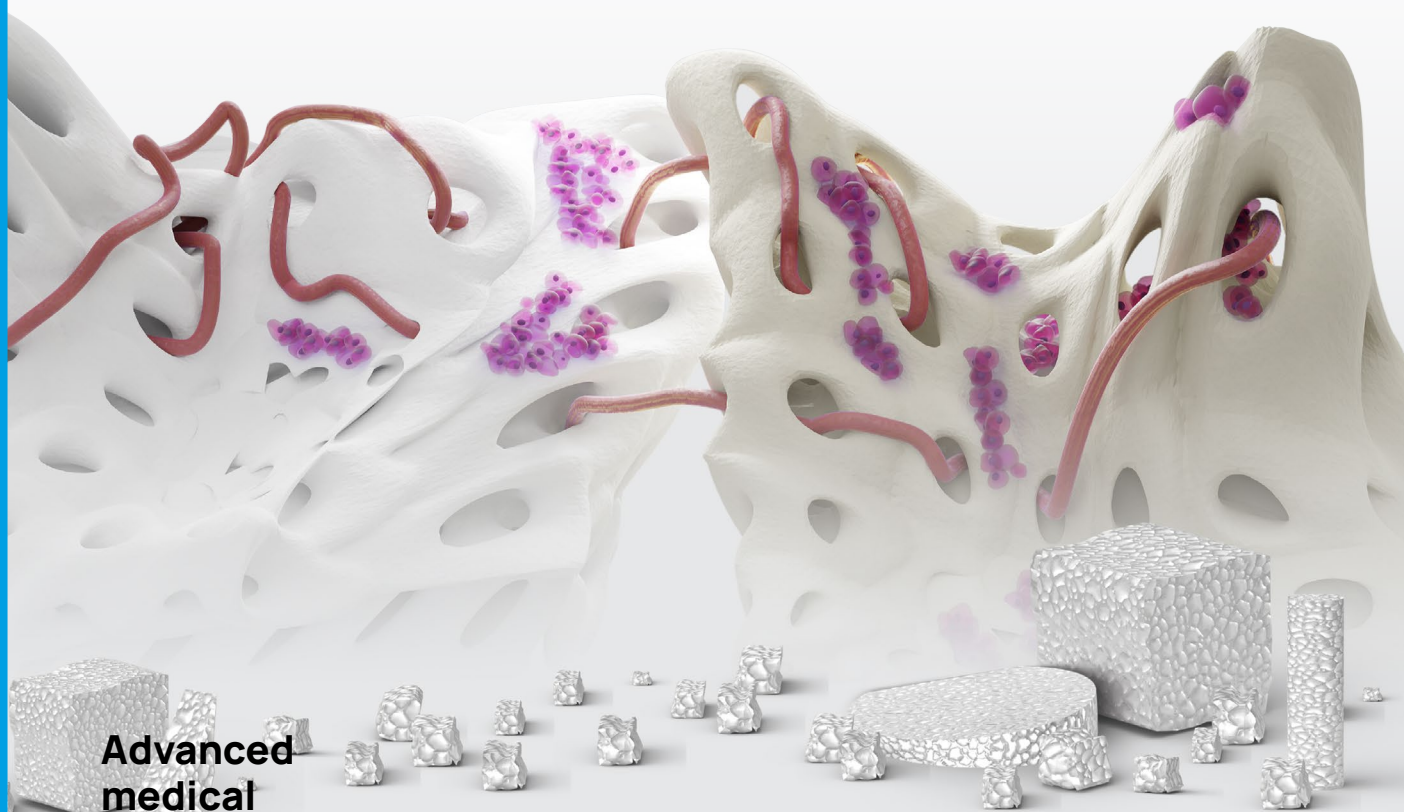


OSSYLBONE™

Biomimetic bone substitute



Advanced
medical
devices

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OSSYLBONE™

Biomimetic bone substitute



table of contents

Introduction	
Biomimetic material.....	4
Biphasic three-dimensional structures	
Biphasic three-dimensional structures	8
Case studies	10
Hydroxyapatite non-setting paste	
Hydroxyapatite non-setting paste	12
Case studies	14
Setting paste with chitosan	
Setting paste with chitosan	16
Case studies	18
Offer	
Ossylbone™ Portfolio.....	20
Ossylbone™ Application.....	22

INTRODUCTION

OSSYLBONE™ BIOMIMETIC MATERIAL

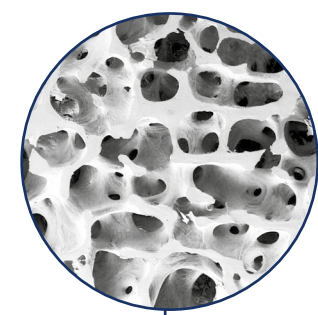
- High biological activity
- Replaced by natural bone
- Applied in one-step surgery
- No risk of contamination by prions, viruses and bacteria
- No risk of immunological conflict
- Optimal resorption time

- SAFE**
No risk of contamination by pathogens and immunological conflict
- BIOMIMETIC**
Designed to reflect the parameters of bone and to support natural healing process
- BIOACTIVE**
Naturally stimulates material-bone tissue binding followed by bone growth
- BIODEGRADABLE**
Completely resorbed and replaced by a regenerating bone
- BIOCOMPATIBLE**
Ensures a biologically correct response of surrounding tissues



INTRODUCTION

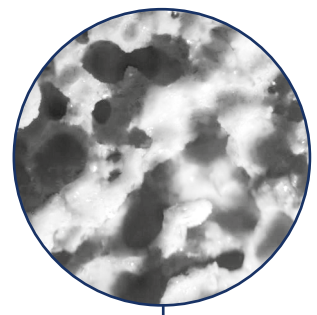
OSSYLBONE™ BIOMIMETIC MATERIAL



BONE TISSUE
Porosity: 50-90%¹
Pores:

- up to 1000 μm^2
- micro- and macropores
- open, interconnected

Main component: hydroxyapatite



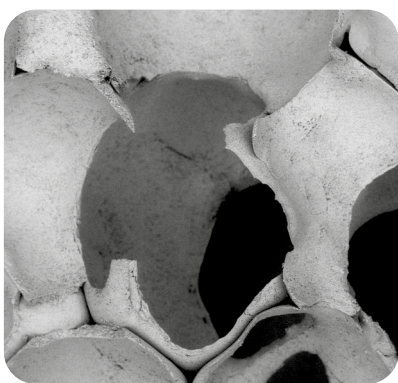
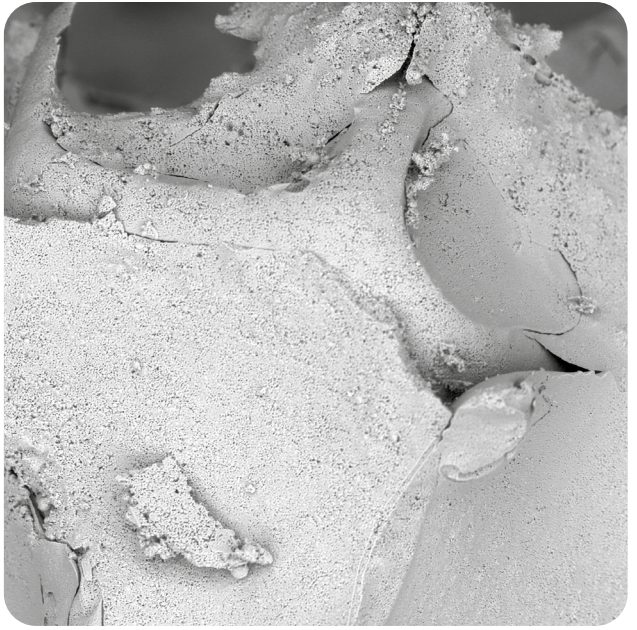
OSSYLBONE™
Porosity: 50-80%
Pores:

- micropores ($< 20 \mu\text{m}$)
- macropores (200-500 μm)
- open, interconnected

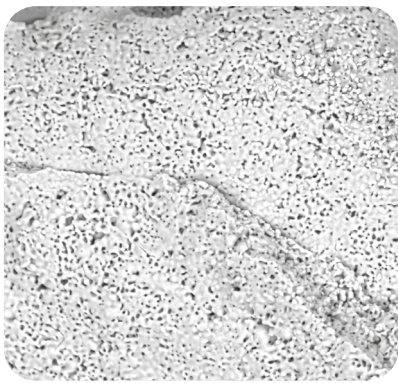
Main component: hydroxyapatite with tricalcium phosphate



OSTEOCONDUCTIVITY
Bone tissue can effectively grow on the surface of biomaterial and into its open pores.



OSTEOINTEGRATION
Biomaterial creates natural and permanent connection with bone tissue.



ANATOMIC STRUCTURE
Optimal pores structure and size support accelerated vascularization of the biomaterial, and thus enable faster regeneration.



BIPHASIC THREE-DIMENSIONAL STRUCTURES

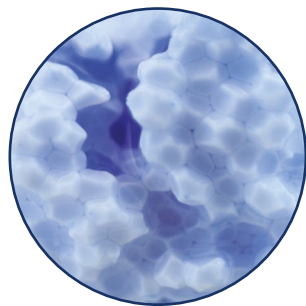


**75% Hydroxyapatite (HAp) +
25% Tricalcium phosphate (β -TCP)**

Compressive strength >5 MPa

Resorption time - over 6 months^{3, 4}

Biphasic composition provides an optimal balance between the rate of graft resorption and the rate of bone ingrowth

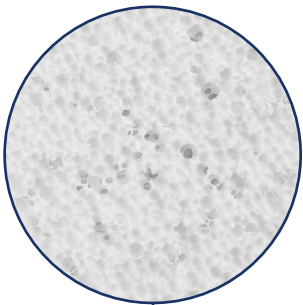


Visualization was made with dye

Biomimetic Ossylbone™ biphasic 3D structures are hydrophilic and exhibit high absorbency, so they can be used in combination with patient blood, blood derived products, saline or hyaluronic acid⁵.

Biomimetic Ossylbone™ biphasic 3D structures:

- create optimal conditions for the reconstruction of new bone at the defect site,
- provide optimal scaffold with high porosity and adequate mechanical strength,
- stimulate new bone growth at the defect site,
- allow the growth and proper vascularization of bone tissue,
- are gradually resorbed and replaced by newly formed bone tissue.



BIPHASIC THREE-DIMENSIONAL STRUCTURES

CASE STUDIES

Orthopedics and traumatology

DIAGNOSIS

A 60-year-old female with a pseudoarthrosis and a bilateral fracture femur.

TREATMENT

Femur opening osteotomy was performed. Two biphasic Ossylbone™ wedges (10-14 mm) were placed in the bone defect. The defect was secured with plates and screws.



Before surgery



After surgery

RESULTS

After 6 months no complications were found.

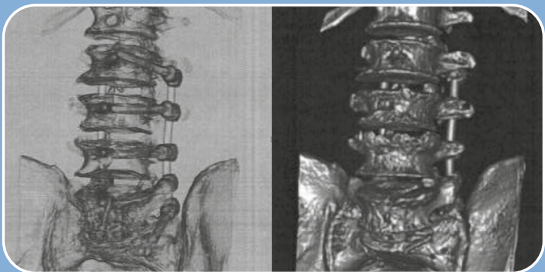
Spinal surgery

DIAGNOSIS

56-year-old male with multi-segmental spinal canal stenosis, hypertrophy L3-S1 and osteochondrosis L5/S1.

TREATMENT

Anterior fusion with pillar-SA cage L5/S1 was performed. Ossylbone™ granules were implanted to treat stenosis.



After surgery

RESULTS

After 1 month, no signs of complications and no migration of the bone substitute were reported.

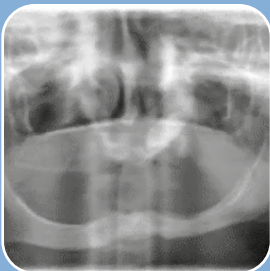
Dental surgery

DIAGNOSIS

Patient with missing teeth

TREATMENT

Dental implants were implanted/inserted, the bone defect was filled with Ossylbone™ granules mixed with the patient's blood.



Before surgery



After surgery

RESULTS

There were no infections or complications after implantation. Correct healing process and advanced bone growth were found. The product turned out to be ideal for the described application.

HYDROXYAPATITE NON-SETTING PASTE



100% nano-hydroxyapatite (n-HAp)

Ossylbone™ biomimetic hydroxyapatite non-setting paste is a bone substitute which consists of hydroxyapatite nanoparticles suspended in water.

Ossylbone™ hydroxyapatite non-setting paste is suitable bone substitute for filling difficult to access bone defects. Due to its unique properties, paste acts as a temporary osteoconductive scaffold for bone tissue reconstruction in sites where complete biomaterial resorption is required.



ENHANCED BONE TISSUE REGENERATION DUE TO UNIQUE NANO-STRUCTURE

Ossylbone™ hydroxyapatite non-setting paste creates an ideal environment for the growth of bones. Nanoscale structure mimics nanostructure of human bone mineral, enhancing osteointegration of the biomaterial after the application in place of bone defect⁹.

UNIQUE STRUCTURE

Hydroxyapatite nanoparticles suspended in water, allow for spontaneous and effective formation of bone tissue around the nano-hydroxyapatite crystals through promoting adhesion and proliferation of osteoblasts and deposition of minerals containing calcium.

HANDINESS

Ossylbone™ hydroxyapatite non-setting paste is available in pre-filled, ready-to-use syringe. The product doesn't have a fixed setting time, so it can be freely use in various stages of the procedure¹⁰.



HYDROXYAPATITE NON-SETTING PASTE CASE STUDIES

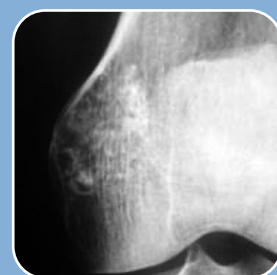
Orthopedics and traumatology

DIAGNOSIS

45-year-old female with pain in anterior knee and changes in bone structure.

TREATMENT

The injury was removed and bone defect was filled with Ossylbone™ hydroxyapatite non-setting paste.



Before surgery



After surgery

RESULTS

After 3 weeks, good cicatrisation and minor pain discomfort were noticed and after 3 months progressive bone neoformation was observed. After 12 months the bone substitute was completely resorbed and an optimal and complete growth of new bone was demonstrated.

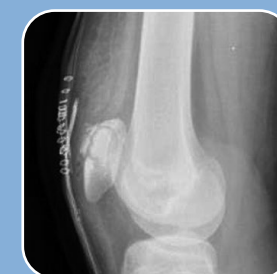
Spinal surgery

DIAGNOSIS

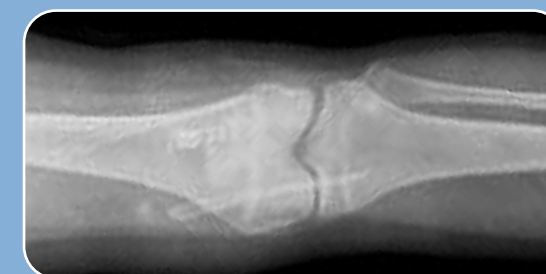
15-year-old female with knee aneurysmal bone cystic.

TREATMENT

Knee aneurysmal bone cystic was subjected curettage and the tumour was resected. Bone void of approximately 8 cc was filled with Ossylbone™ hydroxyapatite non-setting paste (bone substitute implanted in contact with cancellous tissue).



Before surgery



After surgery

RESULTS

After the operation, no signs of infection or complications were reported, normal cicatrisation was observed. After 12 months, the space occupied by the cyst was filled by newly formed bone and consolidated without the presence of area with bone graft present visible under the radiographs.

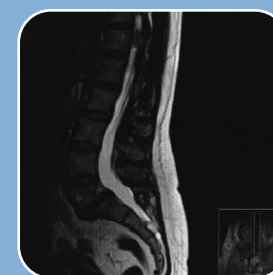
Spinal surgery

DIAGNOSIS

L5-S1 grade II Listhesis in 45-year-old female.

TREATMENT

The surgery procedure of laminectomy (L5) together with transpedicular screws fixation (L4, L5, S1), posterior lumbar interbody fusion (L5-S1) and listhesis reduction were performed. The interbody cage was filled with 5 cc of Ossylbone™ hydroxyapatite non-setting paste impregnated with autologous bone marrow (bone substitute was implanted in contact with cancellous tissue).



Before surgery



After surgery

RESULTS

After 11 months, no signs of infection or complications were reported. Total implant resorption and new bone growth occurred.

SETTING PASTE WITH CHITOSAN



Setting paste is available in two different forms - in syringe or with spatula.

Ossylbone™ Setting paste is a moldable material based on calcium phosphates and chitosan, setting to final hydroxyapatite composition.

Setting paste with chitosan is appropriate for use as a bone substitute in cases where immediate mechanical stabilization with simultaneous filling of the bone defect is required, allowing bone reconstruction.

Ossylbone™ setting paste with chitosan

- Supports immediate defect site stabilization and promotes reconstruction of initial bone volume
- Shows good bone adhesion
- Is moldable and can be formed into any shape before application
- No volume reduction after solidification
- Setting reaction is not accompanied by material shrinkage or temperature rise
- Has a physiological pH
- Setting completely at the defect site
- Visible on X-rays

5. FINAL PRODUCT

100% hydroxyapatite - component of the bone mineral phase
Compressive strength >4 MPa
Resorption time over 6 months

3. INITIAL SETTING

Initial setting time 8 min

4. COMPLETE SETTING

Entire setting in bone defect

1. PREPARATION

Mix 2-5 min until a homogenous mass is obtained

2. APPLICATION

Formation, injection or application with spatula

CHITOSAN

Improves paste-bone adhesion
Accelerates new bone formation
Is mucoadhesive*
Improves material plasticity
Has antibacterial⁶,
anti-inflammatory, analgesic
and hemostatic properties⁷

* Improves adhesion of biological material, in particular, osteoblasts, to the implant surface. This property clinically directly translates into faster growth of regenerated bone⁸.

SETTING PASTE WITH CHITOSAN

CASE STUDIES

Orthopedics and traumatology

DIAGNOSIS

39-year-old male with left calcaneus fracture.

TREATMENT

The fracture was treated with osteosynthesis using a plate. Bone defect was filled with Ossylbone™ calcium phosphate setting paste with chitosan.



Before surgery



After surgery

RESULTS

13 months after surgery, no signs of complications was reported. Significant implant resorption and new bone formation were observed. No migration of the bone substitute was noticed.

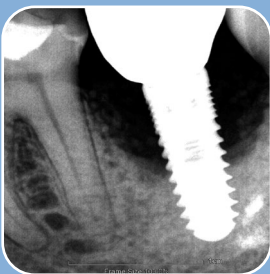
Dental surgery

DIAGNOSIS

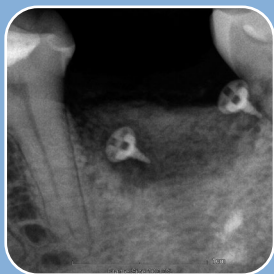
48-year-old female with diagnosed vertical atrophy of the alveolar in the area of tooth 36, resulting from an infection around the implant. Tooth implants were implanted.

TREATMENT

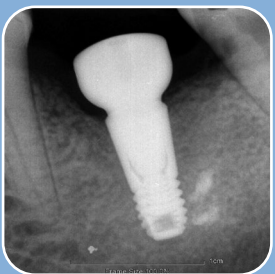
The implant was removed, and then the bone was cleaned of infected granulation tissue. The bone defect was replaced with Ossylbone™ setting paste. Finally, a membrane was pinned and sewn to the treatment site for stabilization.



Before surgery



After surgery



After 4 months

AFTER 4 MONTHS

4 months after the surgery, no inflammation was demonstrated, but very good healing and reconstruction of bone tissue were noted.

8 MONTHS AFTER SURGERY

Control visit after 8 months showed no bone resorption and no inflammation. Healing and bone regeneration as well as implant osseointegration were successful.

PORTFOLIO OSSYLBONE™

Biphasic three-dimensional structures

IRREGULAR GRANULES

Product option	Ref. number	Product option	Ref. number
0.5-1 mm – 0.5 g	OSB.GN405	2-4 mm – 15 cc	OSB.G020415
0.5-1 mm – 1 g	OSB.GN410	2-4 mm – 20 cc	OSB.G020420
0.5-1 mm – 2 g	OSB.GN420	2-4 mm – 30 cc	OSB.G020430
1-2 mm – 0.5 g	OSB.GN505	4-6 mm – 2.5 cc	OSB.G0406025
1-2 mm – 1 g	OSB.GN510	4-6 mm – 5 cc	OSB.G040605
1-2 mm – 2 g	OSB.GN520	4-6 mm – 10 cc	OSB.G040610
2-4 mm – 2.5 cc	OSB.G0204025	4-6 mm – 15 cc	OSB.G040615
2-4 mm – 5 cc	OSB.G020405	4-6 mm – 20 cc	OSB.G040620
2-4 mm – 10 cc	OSB.G020410	4-6 mm – 30 cc	OSB.G040630



BLOCKS

Product option	Ref. number
30x20x12 mm – 1 pc	OSB.B3020121
15x15x20 mm – 1 pc	OSB.B1515201
15x15x30 mm – 1 pc	OSB.B1515301
10x10x20 mm – 1 pc	OSB.B1010201
10x10x5 mm – 1 pc	OSB.B1010051
10x30x5 mm – 1 pc	OSB.B1030051
10x30x10 mm – 1 pc	OSB.B1030101



CYLINDERS

Product option	Ref. number
25x9.5 mm – 1 pc	OSB.CY250951
25x10.5 mm – 1 pc	OSB.CY251051
25x12.5 mm – 1 pc	OSB.CY251251
25x15 mm – 1 pc	OSB.CY251501



SEMI-CIRCULAR WEDGES TYPE 3

Product option	Ref. number
35x25 mm – 7° – 1 pc	OSB.W33525041
35x25 mm – 10° – 1 pc	OSB.W33525061
35x25 mm – 13° – 1 pc	OSB.W33525081



WEDGES

Product option	Ref. number
20x15x8 mm – 1 pc	OSB.C2015081
20x15x10 mm – 1 pc	OSB.C2015101
20x15x12 mm – 1 pc	OSB.C2015121



HYDROXYAPATITE NON-SETTING PASTE

Product option	Ref. number
1 cc	OSB.NIBS011
3 cc	OSB.NIBS031
5 cc	OSB.NIBS051



SETTING PASTE WITH CHITOSAN APPLIED BY SPATULA

Product option	Ref. number
2 g	OSB.CMT2
10 g	OSB.CMT10
20 g	OSB.CMT20



INJECTABLE SETTING PASTE WITH CHITOSAN

Product option	Ref. number
10 g	OSB.SCMT10-P
20 g	OSB.SCMT20-P



OSSYLBONE™ APPLICATION

Orthopedics and traumatology

Indication/ Product	Treatment of fracture with bone loss	Treatment of pseudoarthrosis	Bone defects filling	Arthrodesis (joint ossification)	Filling bone defects after osteotomies	Filling bone defects after removal of benign tumors	Filling bone defects after removal of cysts	Craniofacial bones and skull reconstruction	Filling defects of bone marrow
Biphasic blocks									
Biphasic irregular granules									
Biphasic cylinders									
Biphasic wedges									
Semi-circular biphasic wedges									
Hydroxyapatite non-setting paste									
Setting paste with chitosan applied by spatula									
Injectable setting paste with chitosan									

Spinal surgery

Indication/ Product	Narrowed intervertebral spaces filling in spondylolisthesis	Spinal stenosis	Disc herniation	Spinal fusion	Posterolateral spinal fusion	Filling spinal spaces in discopathy	Spinal fracture treatment	Spinal defects filling in cervical spondylosis	Cervical spine myelopathy	Filling odontoid fractures
Biphasic irregular granules										
Hydroxyapatite non-setting paste										

Dental surgery

Indication/ Product	Bone filling during implantation	Tooth socket filling	Bone defects filling after periimplantitis	Sinus lifting	Alveolar ridge and maxillofacial bone defects filling	Periodontal hard tissue regeneration	Bone defects filling after apical root amputation	Endodontics	Filling the alveolus
Biphasic blocks									
Biphasic irregular granules									
Setting paste with chitosan									
Hydroxyapatite non-setting paste									



Advanced medical devices

Global marketing

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references