



OsteoBiol[®]
by TecnoSS

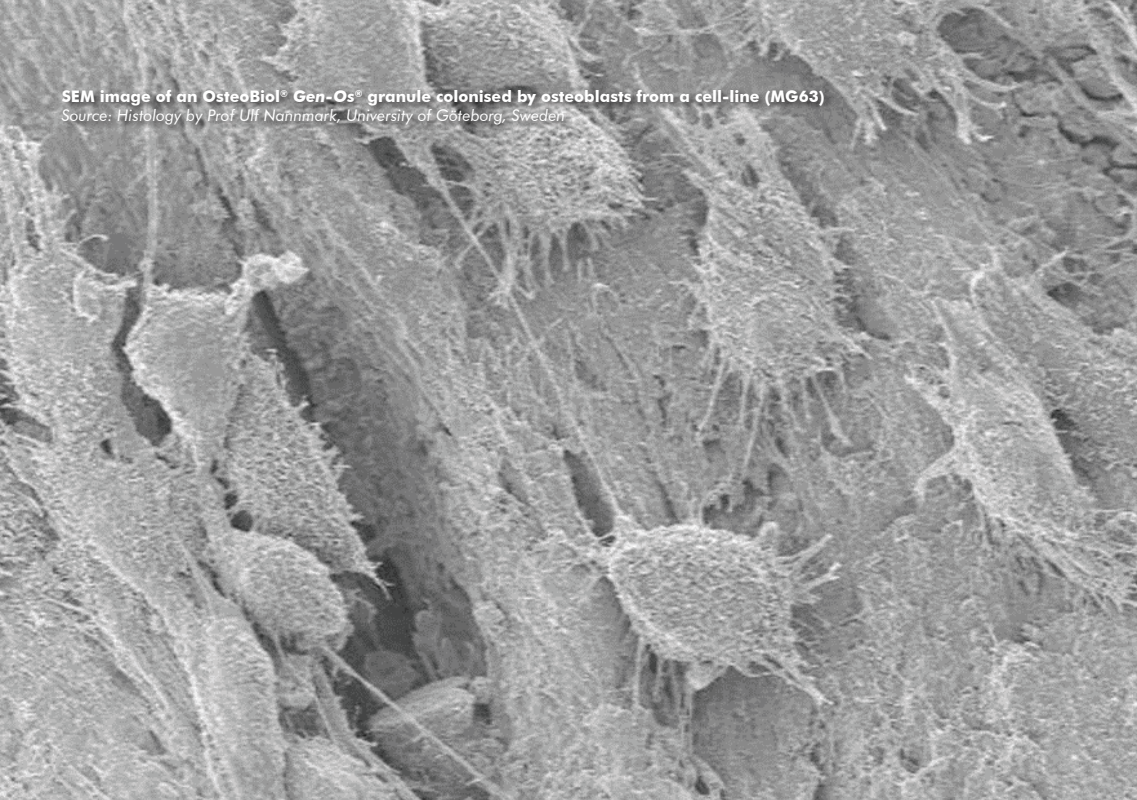
Bone Grafting Materials

REGENERATION SCIENCE

INSPIRED BY NATURE

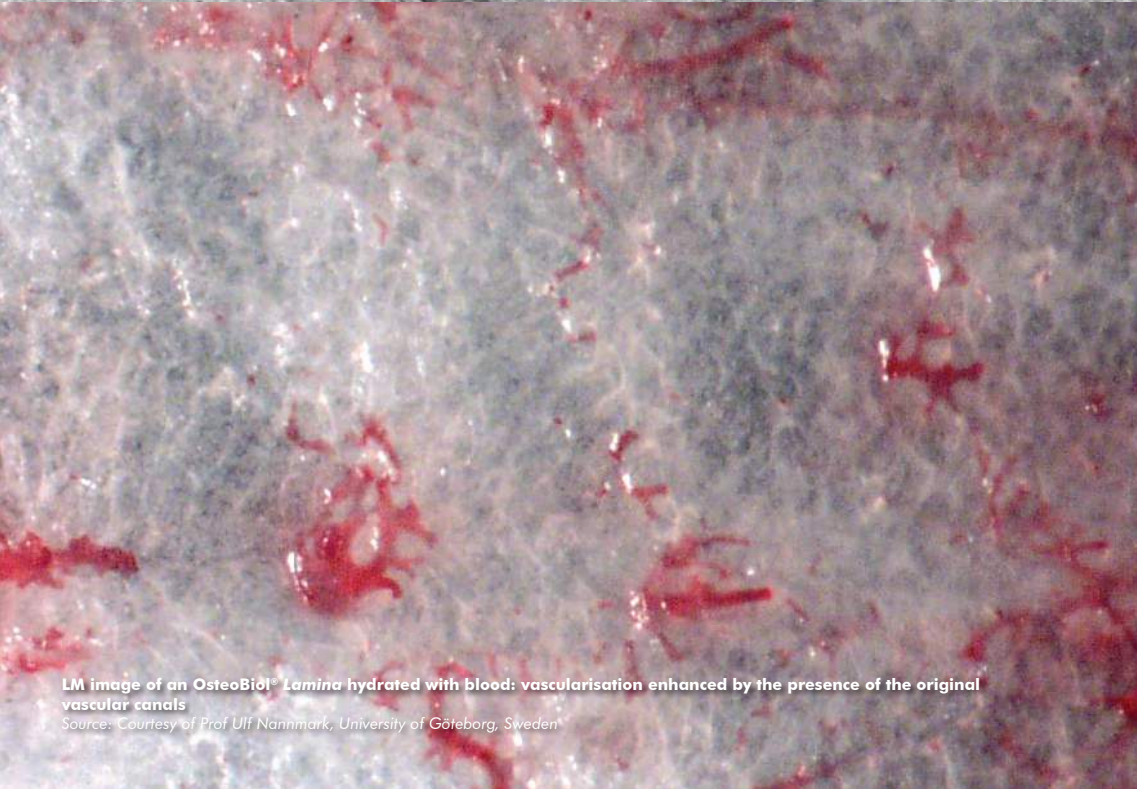
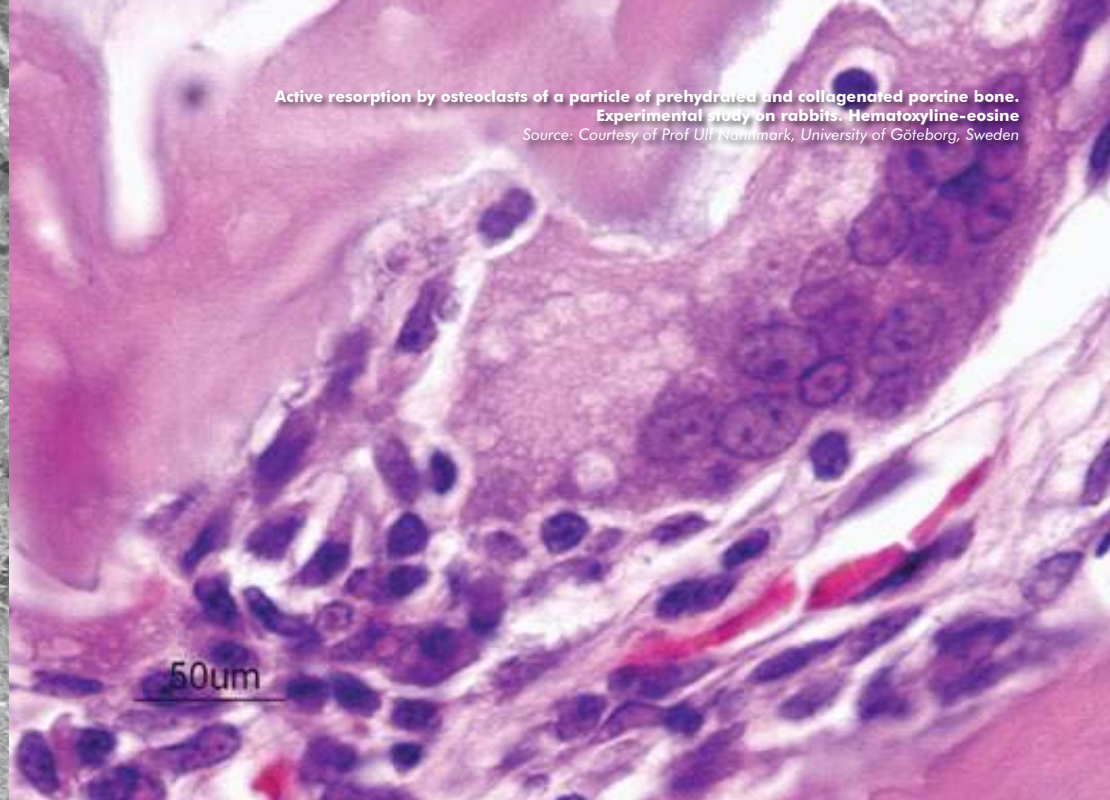
SEM image of an OsteoBiol® Gen-Os® granule colonised by osteoblasts from a cell-line (MG63)

Source: Histology by Prof Ulf Nånmark, University of Göteborg, Sweden



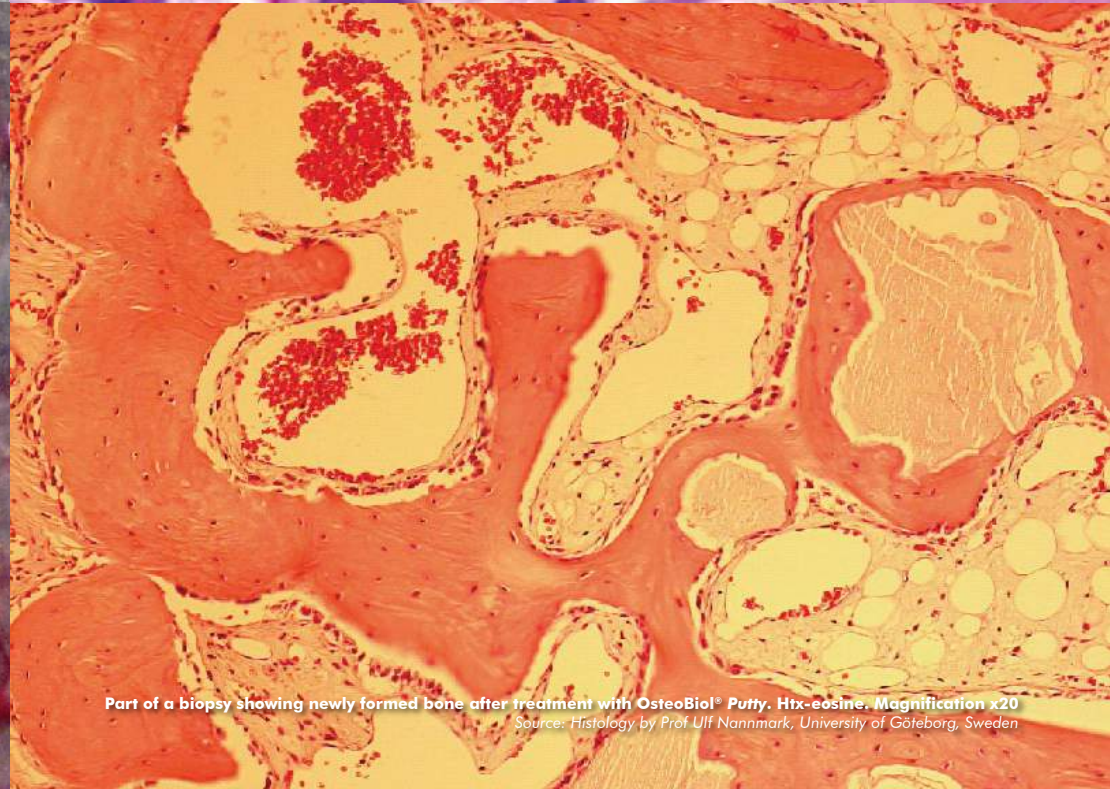
Active resorption by osteoclasts of a particle of prehydrated and collagenated porcine bone. Experimental study on rabbits. Hematoxyline-eosine

Source: Courtesy of Prof Ulf Nånmark, University of Göteborg, Sweden



LM image of an OsteoBiol® Lamina hydrated with blood: vascularisation enhanced by the presence of the original vascular canals

Source: Courtesy of Prof Ulf Nånmark, University of Göteborg, Sweden



Part of a biopsy showing newly formed bone after treatment with OsteoBiol® Putty. Htx-eosine. Magnification x20

Source: Histology by Prof Ulf Nånmark, University of Göteborg, Sweden

OUR MISSION

«To produce a xenogenic bone substitute as similar as possible to autogenous bone»

Giuseppe Oliva MD
R&D Director
Tecnoss S.r.l.



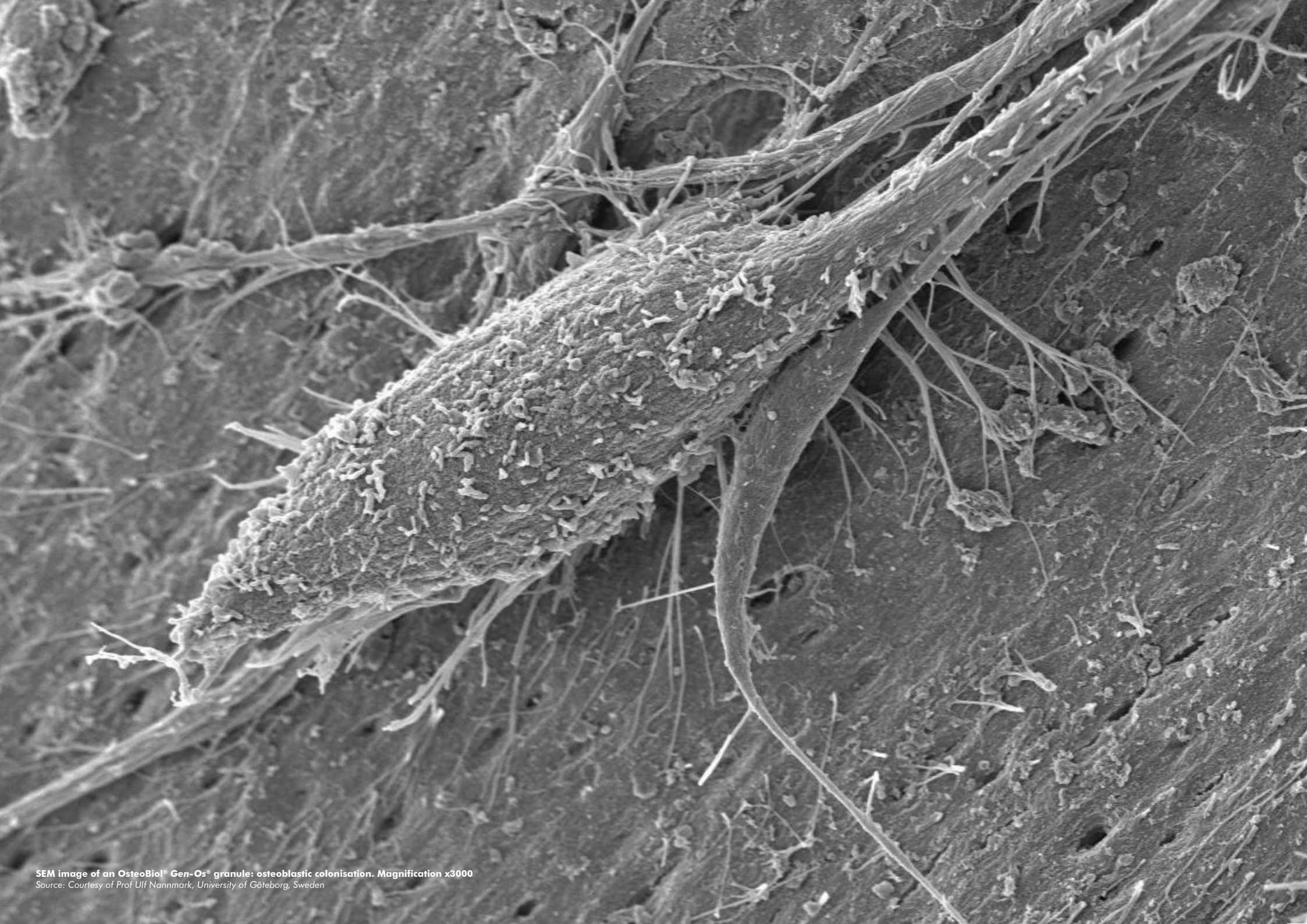
THE OSTEObIOL® DUAL-PHASE HETEROLOGOUS BONE MATRIX

OsteoBiol® is the family of biomaterials produced by Tecnos® for the dental and maxillo-facial surgeons.

In each OsteoBiol® granule, besides its mineral phase, the Tecnos® process retains the xenogenic collagen phase with its precious biological properties, making it biocompatible and ideal for grafting and augmentation purposes.

Avoiding high process temperatures, the OsteoBiol® bone matrix prevents ceramization, maintaining a chemical composition extremely similar to autogenous bone⁽¹⁾, and therefore gradually resorbable and replaceable by newly formed bone.

(1) Figueiredo M, Henriques J, Martins G, Guerra F, Judas F, Figueiredo H
Physicochemical characterization of biomaterials commonly used in dentistry as bone substitutes - comparison with human bone
Journal of Biomedical Materials Research Part B: Applied Biomaterials, 2010 Feb; 92(2):409-19



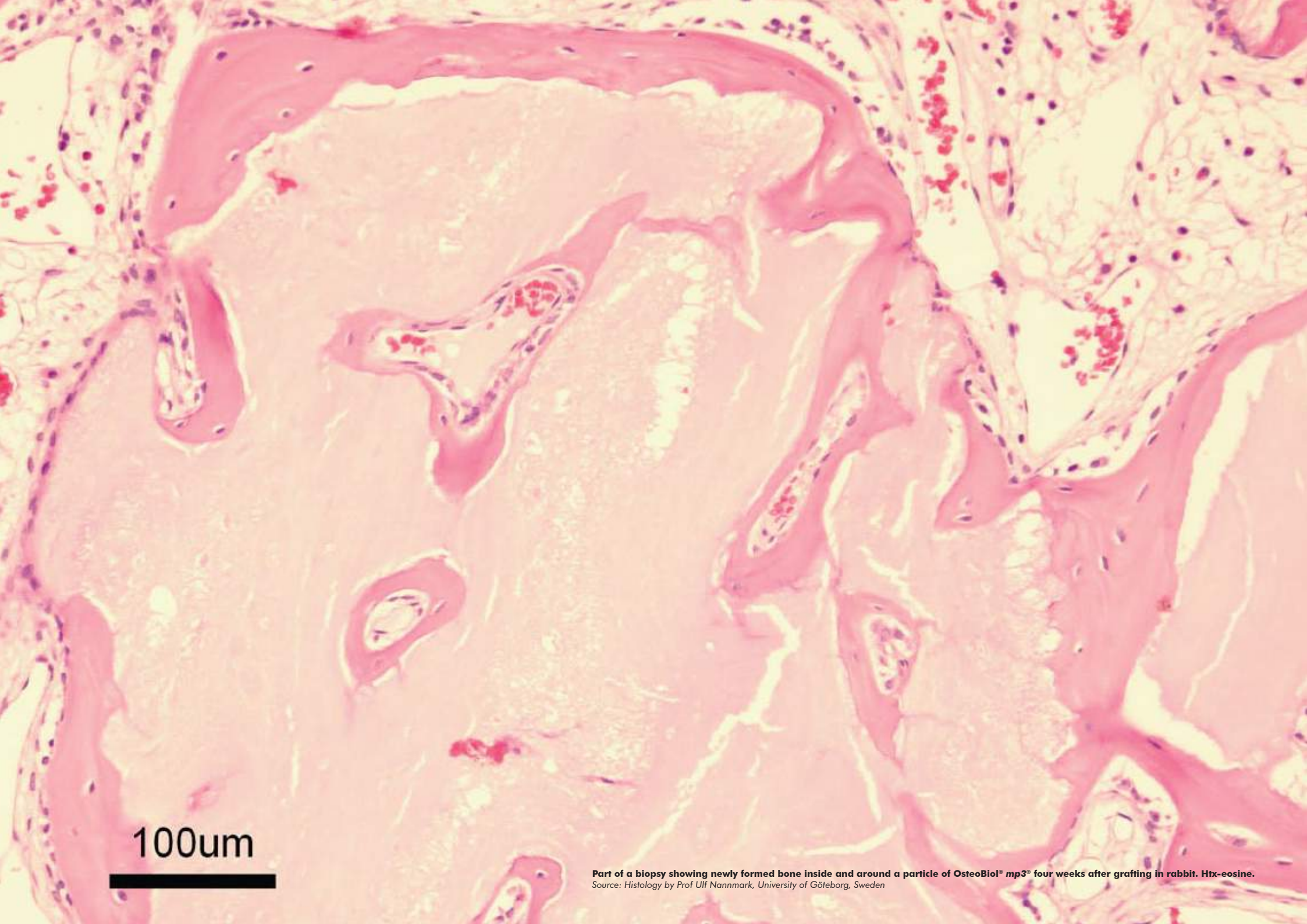
SEM image of an OsteoBiol® Gen-Os® granule: osteoblastic colonisation. Magnification x3000
Source: Courtesy of Prof Ulf Nannmark, University of Göteborg, Sweden

HIGH BIOCOMPATIBILITY

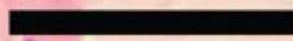
The chemical structure of each OsteoBiol[®] dual-phase granule, its ideal porosity and collagen content, make it a valid scaffold and substrate for osteoblasts anchorage, proliferation and new bone apposition⁽²⁾.

(2) Nannmark U, Sennerby L

The bone tissue responses to prehydrated and collagenated cortico-cancellous porcine bone grafts: a study in rabbit maxillary defects
Clinical Implant Dentistry and Related Research, 2008 Dec;10(4):264-70



100um



Part of a biopsy showing newly formed bone inside and around a particle of OsteoBio® mp3® four weeks after grafting in rabbit. Htx-eosine.
Source: Histology by Prof Ulf Nannmark, University of Göteborg, Sweden

GRADUAL RESORPTION

Autogenous bone is gradually replaced by newly formed bone: similarly, the OsteoBiol® bone matrix allows progressive osteoclastic resorption, with simultaneous new bone apposition.

Cells receive nutrients from newly formed vessels, that are able to colonize adequately the grafted site.

New bone grows in and around the OsteoBiol® granules⁽³⁾, which are partially but significantly replaced by vital bone at re-entry time.

(3) Giuliani A, Iezzi G, Mazzoni S, Piattelli A, Perrotti V, Barone A

Regenerative properties of collagenated porcine bone grafts in human maxilla: demonstrative study of the kinetics by synchrotron radiation microtomography and light microscopy
Clinical Oral Investigations, 2018 Jan;22(1):505-513

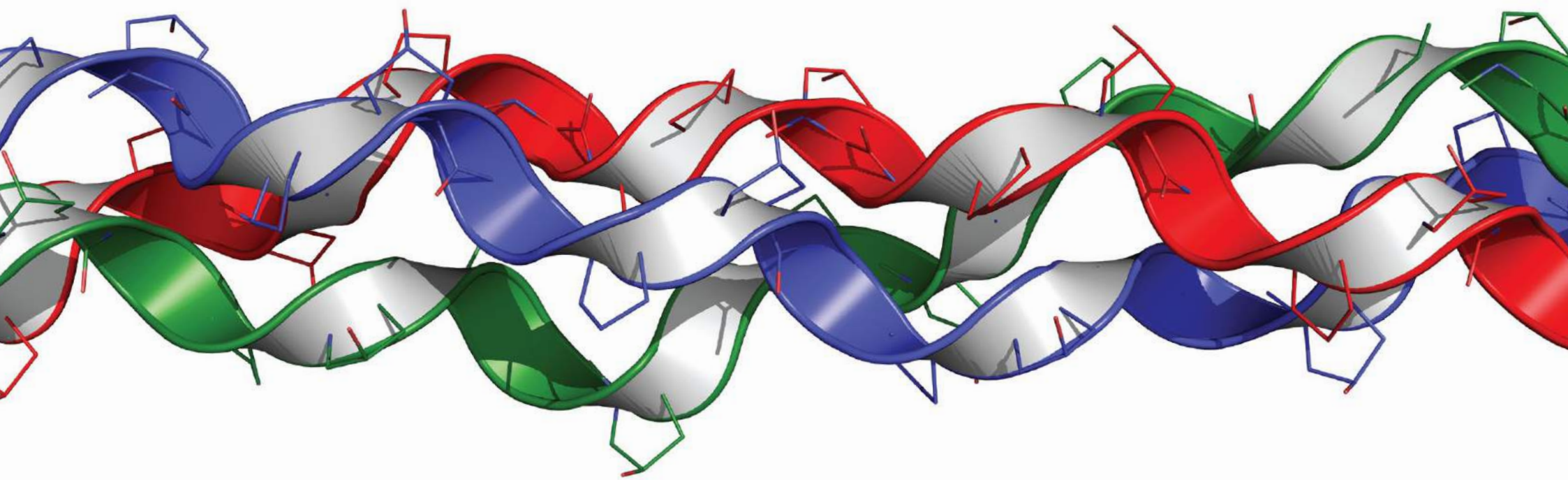


VASCULARIZATION IS THE KEY FOR CLINICAL SUCCESS

Dual-phase biomaterials are progressively resorbed by osteoclasts and replaced by new vital bone produced by osteoblasts, similarly to autogenous bone grafts. Both types of cells live thanks to blood supply, which is critical and essential for the success of any bone regeneration procedure.

The progressive resorption of OsteoBiol[®] granules allows an adequate colonization of the grafting site by new vessels, and is therefore a positive and significant factor within the regenerative process⁽⁴⁾.

(4) Rombouts C, Jeanneau C, Camilleri J, Laurent P, About I
Characterization and angiogenic potential of xenogeneic bone grafting materials: Role of periodontal ligament cells
Dental Materials Journal, 2016 Dec 1;35(6):900-907

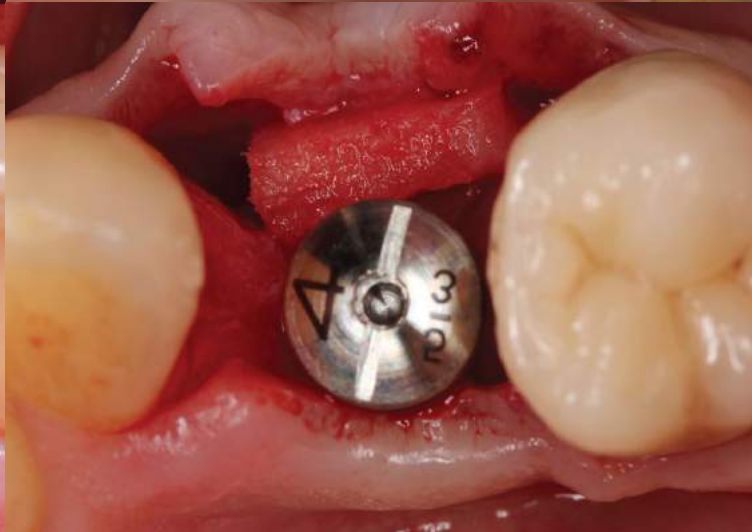
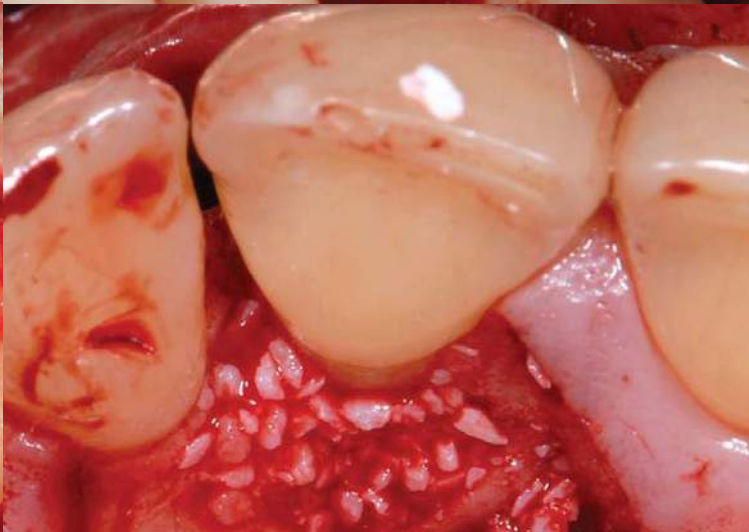
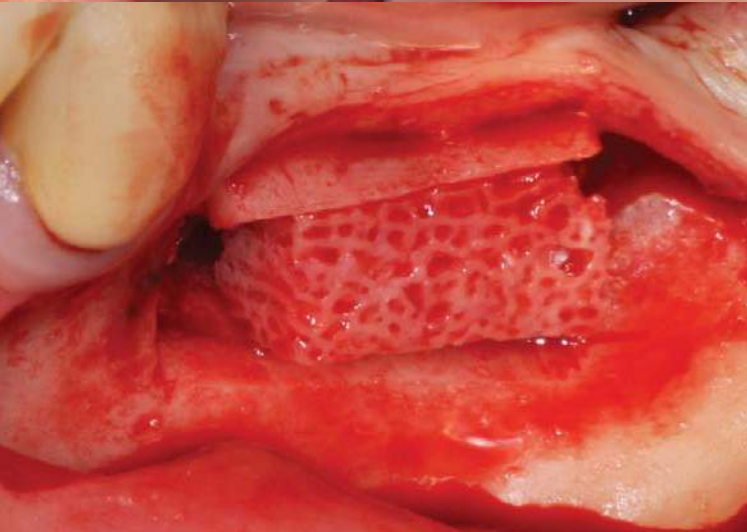
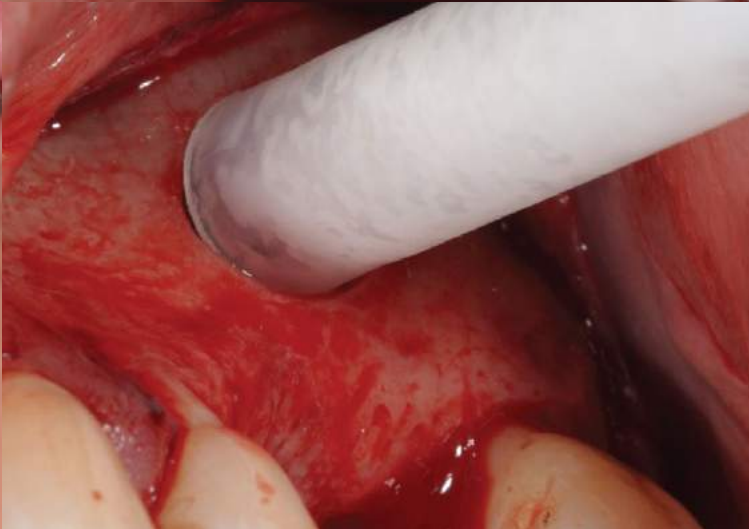
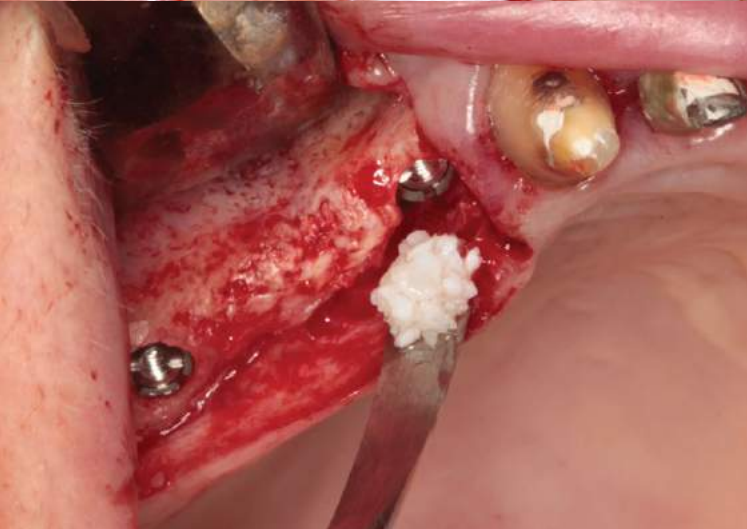
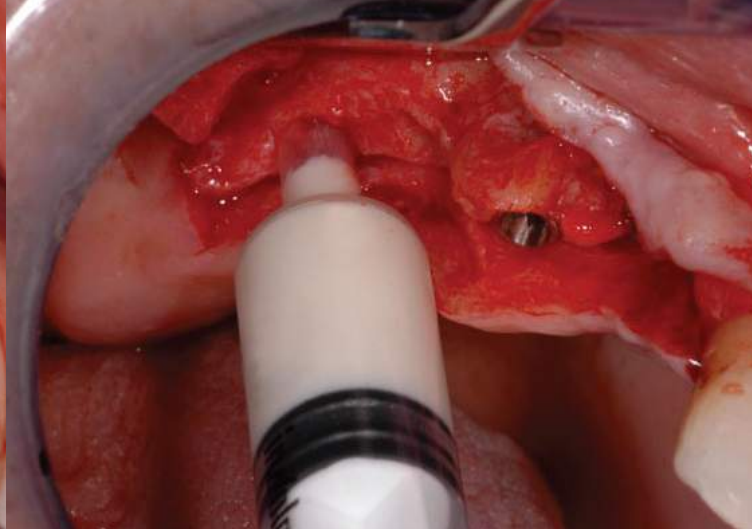


THE ROLE OF COLLAGEN

Collagen favours MSC differentiation and enhances osteoblasts proliferation⁽⁵⁾: it is considered as the ideal substrate for bone forming cells. OsteoBiol[®] dual-phase particulate bone substitutes contain approximately 22% collagen.

Furthermore, collagen gel mixed with dual-phase collagenated granules packed in syringes improves the handling and the stability of the graft, reducing also operatory time and risk of contamination.

(5) Brunelli G, Sollazzo V, Carinci F, Palmieri A, Girardi A, Monguzzi R
OsteoBiol[®] influences osteogenic differentiation of adipose derived stem cells
European Journal of Inflammation, 2011, Vol. 9, no. 3 (S), 103-107



A SPECIFIC PRODUCT FOR EVERY CLINICAL INDICATION

OsteoBiol® is not only a marvellous collagenated bone matrix: it is a complete family of biomaterials specifically designed for bone and soft tissue augmentation in dentistry. For every clinical indication a dedicated product has been developed, with the goal of providing the best handling, the ideal granulometry and consistency, and finally optimal regenerative results in adequate re-entry time.

Enjoy one of the widest and most complete product ranges, with the security and support of 15 years of clinical research: you will experience that today it is finally possible to achieve predictable clinical success⁽⁶⁾ without the availability limitations of autogenous bone.

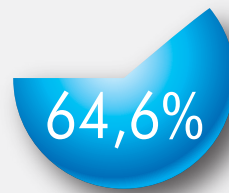
(6) Checchi V, Felice P, Zucchelli G, Barausse C, Piattelli M, Pistilli R, Grandi G, Esposito M

Wide diameter immediate post-extractive implants vs delayed placement of normal-diameter implants in preserved sockets in the molar region: 1-year post-loading outcome of a randomised controlled trial
European Journal of Oral Implantology, 2017;10(3):263-278

OsteoBiol® and natural human bone have the same density and very similar physico-chemical properties

Figueiredo et al. J Biomed Mater Res B: Appl Biomater, 2010 Feb; 92(2):409-19

Mineral content



Gen-Os®



Natural Human Bone

Figueiredo et al. J Biomed Mater Res B: Appl Biomater, 2010 Feb; 92(2):409-19

Gen-Os® has a higher angiogenic potential compared to anorganic xenografts

Rombouts et al. Dent mater J, 2016 Dec 1;35(6):900-907

New bone

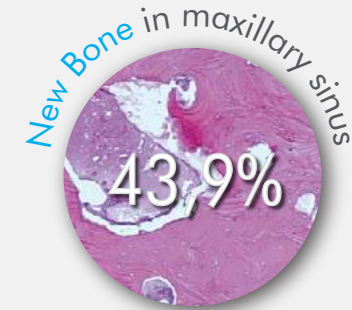


In regenerated sockets after 12 months

Giuliani et al. Clin Oral Investig, 2018 Jan;22(1):505-513

In ridge preservation collagenated biomaterials show significant smaller volume reduction and basal area shrinkage compared to slowly resorbable xenografts

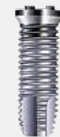
Barone et al. Clin Oral Implants Res, 2016 Nov;27(11):E105-E115



New Bone in maxillary sinus augmentation after 6 months

Barone et al. Clin Impl Dent Rel Res, 2012 Jun;14(3):373-9

Implant Success Rate



95,4%

in preserved sockets after 12 months from loading

Cecchi et al. Eur J Oral Implantol, 2017;10(3):263-278

OsteoBiol® bone matrix promotes osteoblast differentiation and bone regeneration

Brunelli et al. Eur J Inflamm, 2011, Vol. 9, no. 3 (S), 103-107

OsteoBiol® bone scaffolds absorb growth factors secreted by MSCs and improve bone tissue repair

Mijiritsky et al. Materials, 2017 Sep 8;10(9)

KEY SCIENTIFIC DATA

Over 120 articles have been published on peer-reviewed journals during the last 15 years, proving with in-vitro, experimental and clinical studies the outstanding biological properties and clinical performance of the OsteoBiol[®] collagenated biomaterials.



PATIENTS FIRST

Combining the best skills and the best materials, within the limits and guidelines provided by scientific evidence, is the key for clinical success: however let us all remember that the patients are and will always be the center of all our attentions.

Meeting their expectations, helping them to recover function and aesthetics with long term success^(7,8) is the greatest reward for any surgeon and fulfillment of our company mission.

(7) Barone A, Orlando B, Tonelli P, Covani U

Survival rate for implants placed in the posterior maxilla with and without sinus augmentation: a comparative cohort study
Journal of Periodontology, 2011 Feb; 82(2):219-26

(8) Scarano A, Piattelli A, Assenza B, Quaranta A, Perrotti V, Piattelli M, Iezzi G

Porcine bone used in sinus augmentation procedures: a 5-year retrospective clinical evaluation
Journal of Oral and Maxillofacial Surgery, 2010 Aug;68(8):1869-73

OsteoBiol® products vs clinical indications

Gen-Os®

Collagenated heterologous cortico-cancellous bone mix
 Granulometry 250-1000 µm
 For information on OsteoBiol® Gen-Os® see page 24

mp3®

Pre-hydrated collagenated heterologous cortico-cancellous bone mix
 Granulometry 600-1000 µm
 For information on OsteoBiol® mp3® see page 32

Putty

Pre-hydrated collagenated heterologous cortico-cancellous bone paste
 Granulometry up to 300 µm
 For information on OsteoBiol® Putty see page 36

Gel 40

Pre-hydrated collagenated heterologous cortico-cancellous bone gel
 Granulometry up to 300 µm
 For information on OsteoBiol® Gel 40 see page 40

ALVEOLAR REGENERATION



IN ASSOCIATION



WITH TSV GEL



MAXILLARY SINUS LIFT



CRESTAL ACCESS ONLY



PERI-IMPLANT DEFECTS



IF DEFECT WALLS



ARE PRESERVED

HORIZONTAL AUGMENTATION



IN ASSOCIATION



IN ASSOCIATION



WITH LAMINA AND TSV GEL

WITH LAMINA

IN ASSOCIATION

VERTICAL AUGMENTATION

INLAY TECHNIQUE



WITH SP-BLOCK

PERIODONTAL REGENERATION



3-WALL DEFECTS



SOFT TISSUE AUGMENTATION

Apatos

Cortico-cancellous and cortical bone
Granulometry 600-1000 μm
For information on OsteoBio[®] Apatos
see page 44

Sp-Block

Collagenated heterologous
cancellous block
For information on OsteoBio[®] Sp-Block
see page 50

Evolution

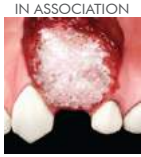
Heterologous collagen membrane
For information on OsteoBio[®] Evolution
see page 58

Lamina

Collagenated heterologous cortical bone
For information on OsteoBio[®] Lamina
see page 66

Derma

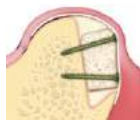
Collagen dermal matrix
For information on OsteoBio[®] Derma
see page 62



WITH TSV GEL



IN ASSOCIATION

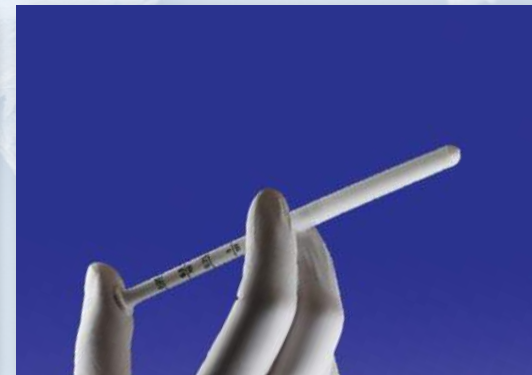
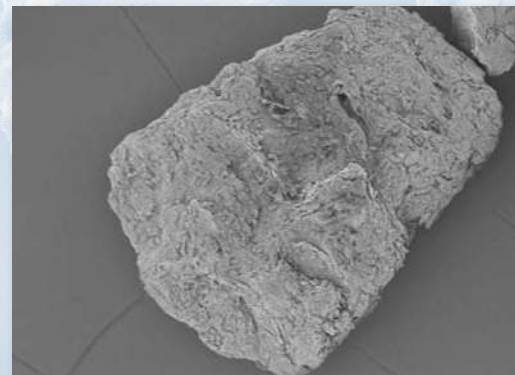
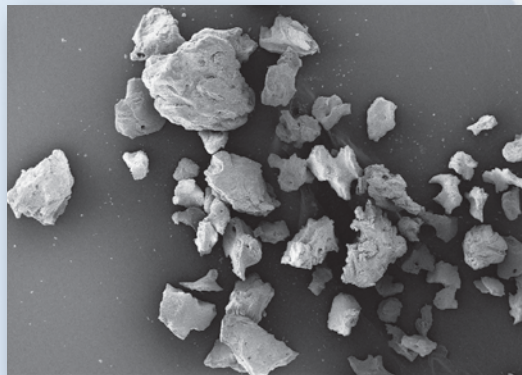
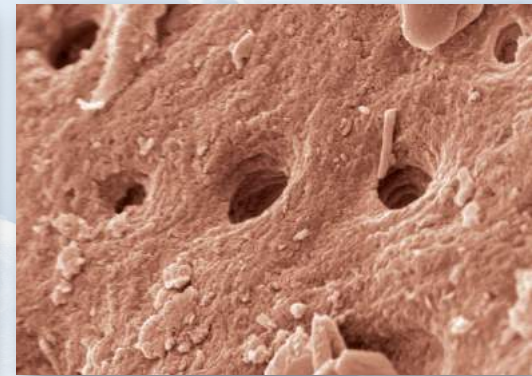
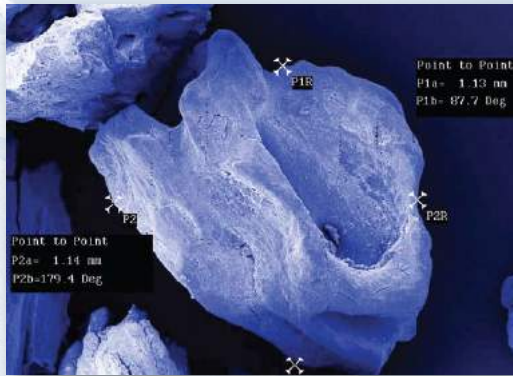


BONE LAYER TECHNIQUE

WITH LAMINA AND TSV GEL

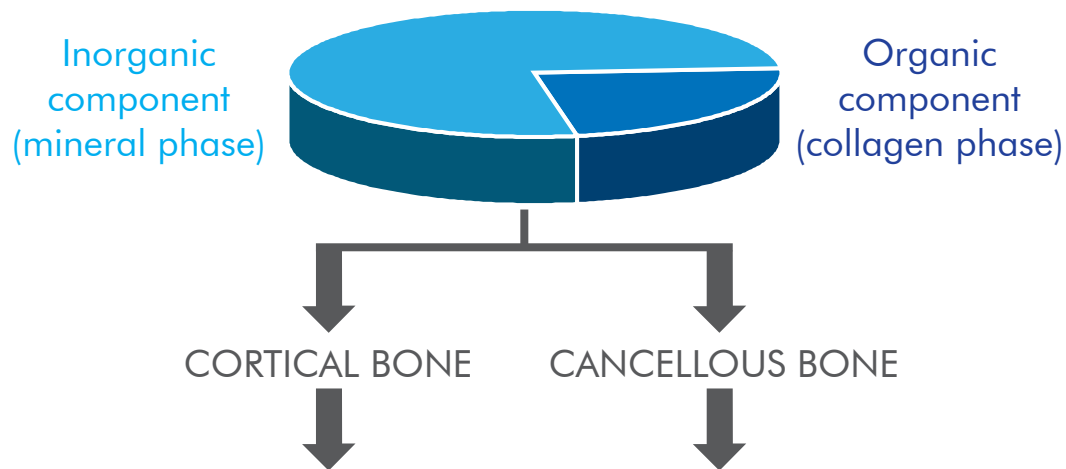


BONE SUBSTITUTES



OsteoBiol® bone substitutes

HETEROLOGOUS BONE



Collagenated mix

Collagen gel

Apatos Cortical

cortical bone

Gen-Os®

mp3®

Putty

Gel 40

Apatos Mix

100% collagenated bone mix

90% collagenated bone mix

80% collagenated bone mix

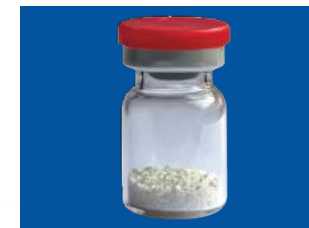
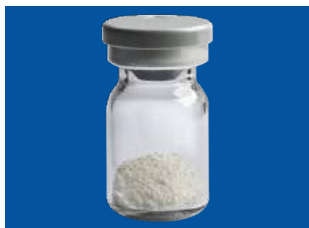
60% collagenated bone mix

cortico-cancellous bone mix

10% collagen gel

20% collagen gel

40% collagen gel



Heterologous cortico-cancellous collagenated bone mix

Heterologous cortico-cancellous collagenated pre-hydrated bone mix

Heterologous cortico-cancellous collagenated pre-hydrated bone paste

Heterologous cortico-cancellous collagenated pre-hydrated bone gel

Heterologous microcrystalline hydroxyapatite

For more information on OsteoBiol® Gen-Os® see page 24

For more information on OsteoBiol® mp3® see page 32

For more information on OsteoBiol® Putty see page 36

For more information on OsteoBiol® Gel 40 see page 40

For more information on OsteoBiol® Apatos see page 44

Blocks

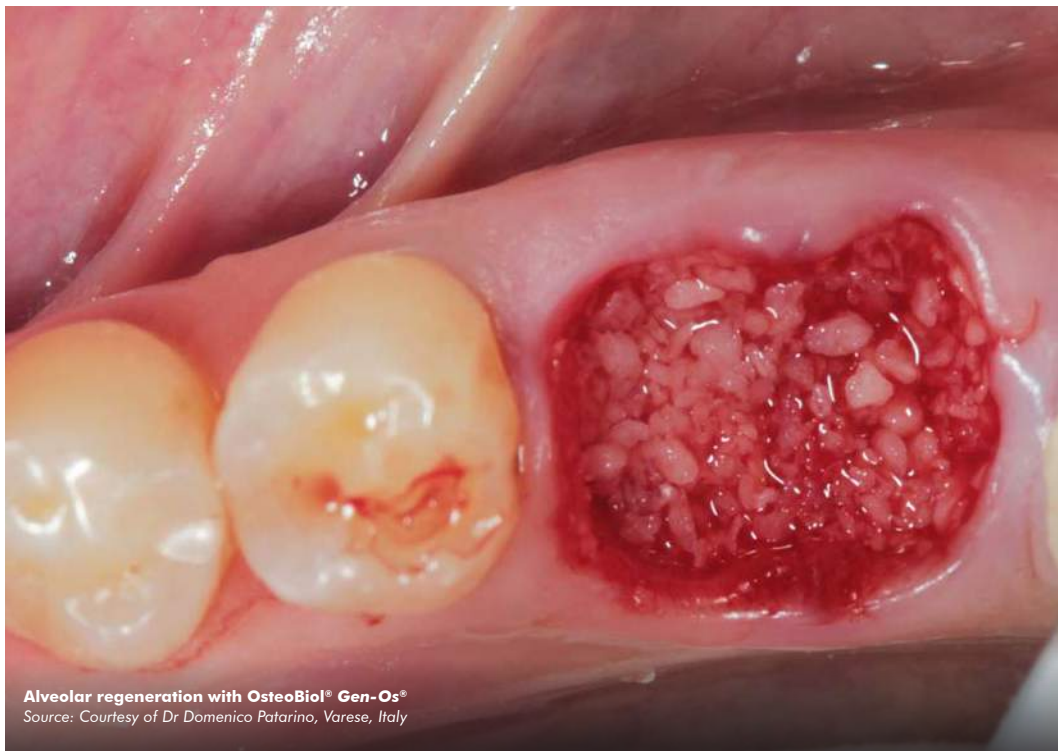
Membranes

Clinical cases

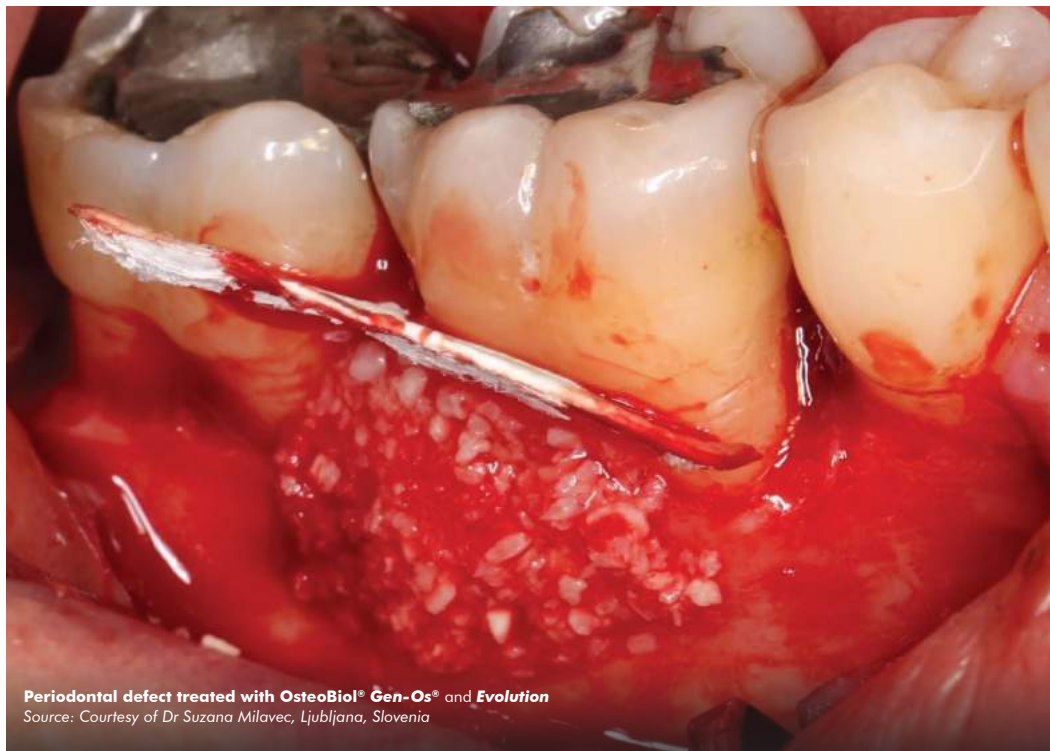
Innovation

Certifications

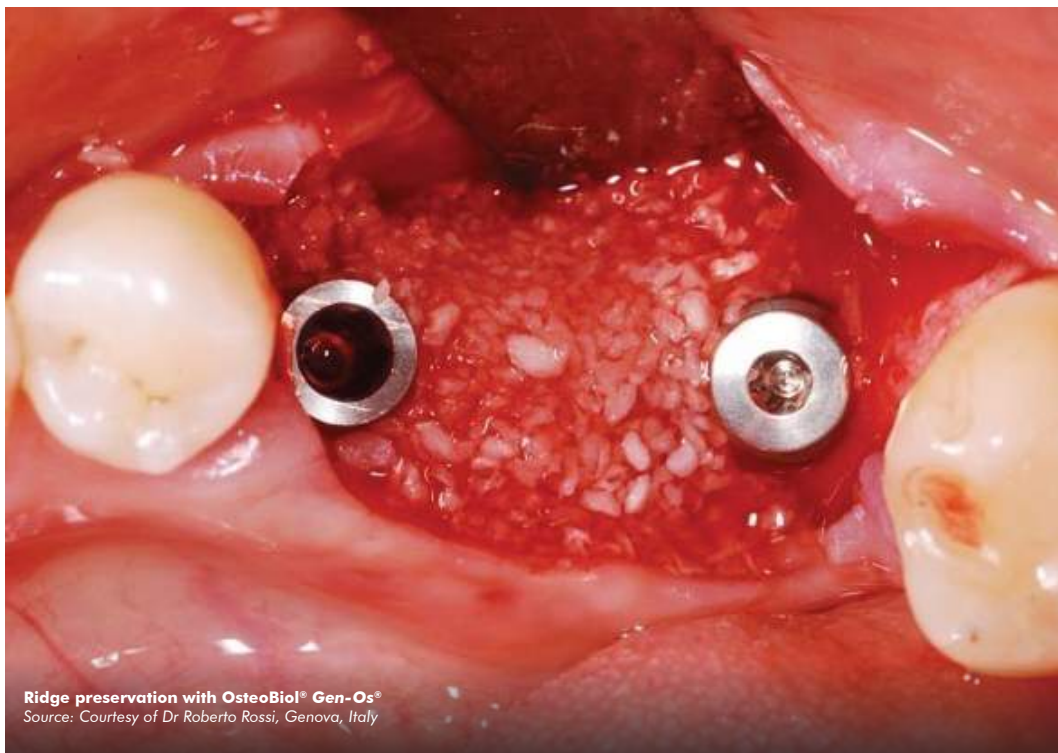
Literature



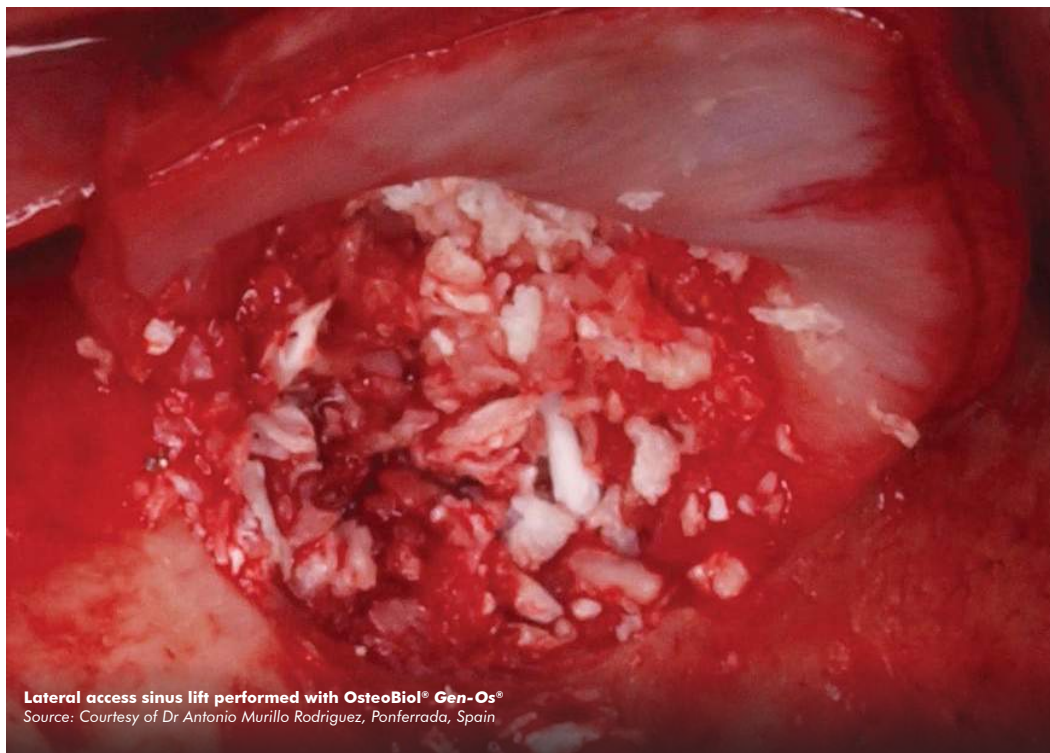
Alveolar regeneration with OsteoBiol® Gen-Os®
Source: Courtesy of Dr Domenico Patarino, Varese, Italy



Periodontal defect treated with OsteoBiol® Gen-Os® and Evolution
Source: Courtesy of Dr Suzana Milavec, Ljubljana, Slovenia



Ridge preservation with OsteoBiol® Gen-Os®
Source: Courtesy of Dr Roberto Rossi, Genova, Italy



Lateral access sinus lift performed with OsteoBiol® Gen-Os®
Source: Courtesy of Dr Antonio Murillo Rodriguez, Ponferrada, Spain

Gen-Os®



The advantages of a dual-phase biomaterial
Collagenated heterologous cortico-cancellous bone mix

Characteristics and handling



Tissue of origin

Cortico-cancellous heterologous bone mix

Tissue collagen

Preserved

Physical form

Slightly radiopaque granules

Composition

100% granulated mix

Granulometry

250-1000 μm

1000-2000 μm

Re-entry time

4/5 months, depending on grafting site characteristics

Packaging

Vial: 0.25 g, 0.5 g, 1.0 g, 2.0 g

Product codes

250-1000 μm

M1052FS | 1 Vial | 0.25 g | Porcine

M1052FE | 1 Vial | 0.25 g | Equine

M1005FS | 1 Vial | 0.5 g | Porcine

M1005FE | 1 Vial | 0.5 g | Equine

M1010FS | 1 Vial | 1.0 g | Porcine

M1010FE | 1 Vial | 1.0 g | Equine

M1020FS | 1 Vial | 2.0 g | Porcine

M1020FE | 1 Vial | 2.0 g | Equine

1000-2000 μm

M0210FS | 1 Vial | 1.0 g | Porcine

M0220FS | 1 Vial | 2.0 g | Porcine

GMDN code

38746

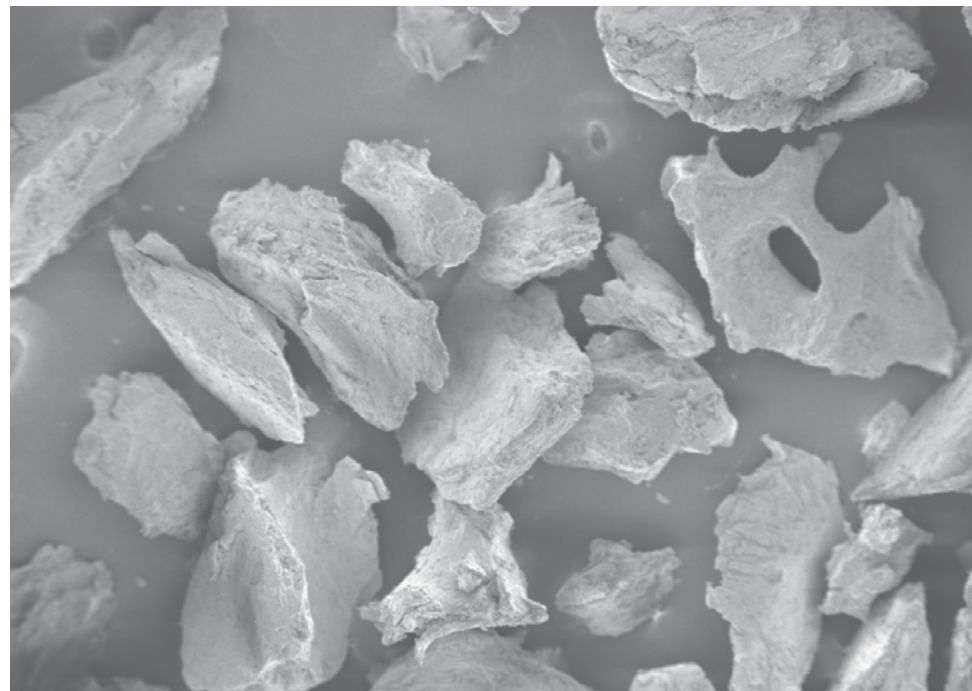
CHARACTERISTICS

A natural replicate of autologous bone, Gen-Os[®] conserves the same intimate structures⁽¹⁾ (matrix and porous form) and presents highly osteoconductive properties^(2,3). It is biocompatible and bioavailable, as recognized by tests made according to the ISO 10993 method conducted at Eurofins Biolab. Gen-Os[®] is gradually resorbable and provides support in bone neoformation helping to preserve the original graft shape and volume⁽⁴⁾.

Moreover, thanks to its collagen content, the product facilitates blood clotting and the subsequent invasion of repairing and regenerative cells, favouring restitutio ad integrum of missing bone. Because of its marked hydrophilia⁽⁵⁾, it can function as a carrier for selected medications and drugs⁽⁶⁾ and it is ideal to mix with GFs⁽⁷⁾.

HANDLING

Gen-Os[®] must always be hydrated and thoroughly mixed with either a few drops of sterile physiological solution (or patient's blood) to activate its collagen matrix and to enhance its adhesivity or with TSV Gel to increase graft stability in not self-contained defects. If necessary it can as well be mixed with the drug selected for surgery.



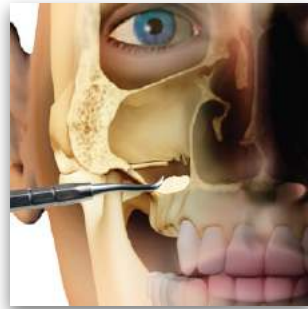
SEM image of OsteoBiol[®] Gen-Os[®] granules. Magnif. x50
Source: Courtesy of Prof Ulf Nannmark, University of Göteborg, Sweden



Source: Tecnos[®] Dental Media Library

Clinical Indications

Gen-Os[®], a cortico-cancellous bone mix, has been the first product developed with the TecnoSS[®] innovative biotechnology and, due to its universal use, still is today the most demanded from the market. Gen-Os[®] has been successfully used and documented for alveolar ridge preservation⁽⁸⁾ in combination with *Evolution* membranes: the application of this biomaterial limits significantly the alveolar ridge width reduction that would naturally occur with spontaneous healing, preserving thus the alveolar ridge volume and allowing a correct second stage implant placement⁽⁹⁾. Gen-Os[®] is also indicated for lateral access maxillary sinus lift⁽³⁾ and dehiscence regeneration⁽¹⁰⁾, always in association with *Evolution* membranes. Gen-Os[®] is as well effective in periodontal regeneration of deep infrabony defects⁽¹¹⁾. Due to its collagen content, once hydrated Gen-Os[®] becomes very sticky and hydrophilic⁽⁵⁾: it combines therefore extremely well with blood and is very stable once applied into the grafting site. Its cortico-cancellous composition allows a progressive resorption of osteoclastic type, with in parallel a similar rate of new bone formation⁽²⁾: these unique properties allow a very good graft volume preservation, a healthy and well vascularized⁽¹²⁾ new bony tissue and, ultimately, a successful implant rehabilitation.



LATERAL ACCESS SINUS LIFT
maxillary sinus floor augmentation
case reports on page 84



PERIODONTAL REGENERATION
infrabony defects
case reports on page 92



HORIZONTAL AUGMENTATION
two-wall defects
case reports on page 87

free animated videos
on OsteoBio[®] APP



DEHISCENCES AND FENESTRATIONS
peri-implant lesions
case reports on page 80



CRESTAL ACCESS SINUS LIFT
osteotome technique
case reports on page 82



ALVEOLAR REGENERATION
socket preservation
case reports on page 77

Additional case reports on osteobiol.com

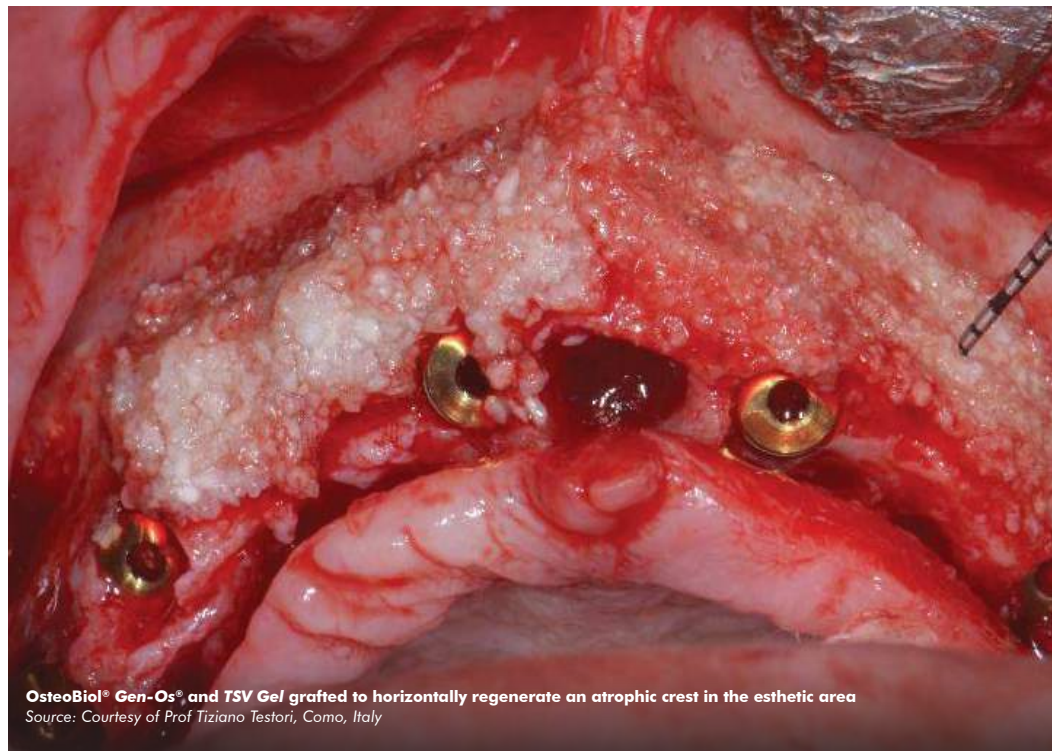
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J BIOMED MATER RES B APPL BIOMATER, 2010 FEB; 92(2):409-19
- (2) NANNMARK U, SENNERBY L
THE BONE TISSUE RESPONSES TO PREHYDRATED AND COLLAGENATED CORTICO-CANCELLOUS PORCINE BONE GRAFTS: A STUDY IN RABBIT MAXILLARY DEFECTS
CLIN IMPLANT DENT RELAT RES, 2008 DEC;10(4):264-70
- (3) CASSETTA M, PERROTTI V, CALASSO S, PIATTELLI A, SINJARI B, IEZZI G
BONE FORMATION IN SINUS AUGMENTATION PROCEDURES USING AUTOLOGOUS BONE, PORCINE BONE, AND A 50 : 50 MIXTURE: A HUMAN CLINICAL AND HISTOLOGICAL EVALUATION AT 2 MONTHS
CLIN ORAL IMPLANTS RES, 2015 OCT;26(10):1180-4
- (4) CARDAROPOLI D, CARDAROPOLI G
PRESERVATION OF THE POSTEXTRACTION ALVEOLAR RIDGE: A CLINICAL AND HISTOLOGIC STUDY
INT J PERIODONTICS RESTORATIVE DENT, 2008 OCT; 28(5):469-77
- (5) FIGUEIREDO A, COIMBRA P, CABRITA A, GUERRA F, FIGUEIREDO M
COMPARISON OF A XENOGENIC AND AN ALLOPLASTIC MATERIAL USED IN DENTAL IMPLANTS IN TERMS OF PHYSICO-CHEMICAL CHARACTERISTICS AND IN VIVO INFLAMMATORY RESPONSE
MATER SCI ENG C MATER BIOL APPL, 2013 AUG 1;33(6):3506-13
- (6) FISCHER KR, STAVROPOULOS A, CALVO GUIRADO JL, SCHNEIDER D, FICKL S
INFLUENCE OF LOCAL ADMINISTRATION OF PAMIDRONATE ON EXTRACTION SOCKET HEALING - A HISTOMORPHOMETRIC PROOF-OF-PRINCIPLE PRE-CLINICAL IN VIVO EVALUATION
CLIN ORAL IMPLANTS RES, 2015 OCT;26(10):1135-42
- (7) MIJIRITSKY E, FERRONI L, GARDIN C, BRESSAN E, ZANETTE G, PIATTELLI A, ZAVAN B
PORCINE BONE SCAFFOLDS ADSORB GROWTH FACTORS SECRETED BY MSCS AND IMPROVE BONE TISSUE REPAIR
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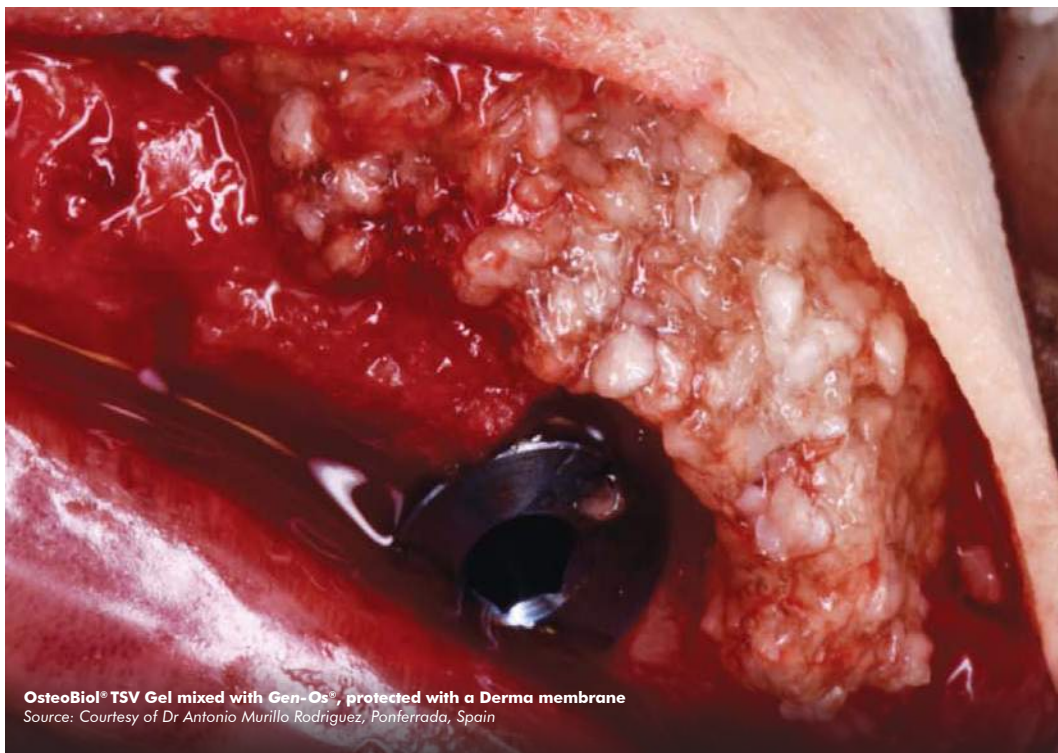
For further information see the complete literature on p. 114



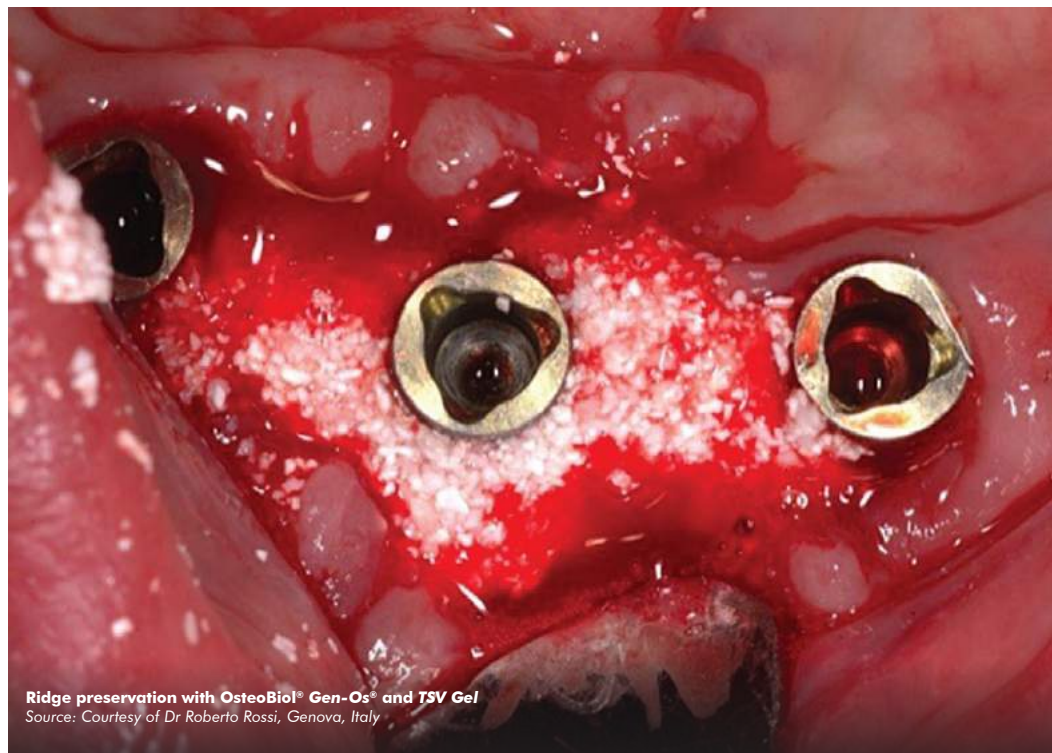
Vestibular bone regeneration with OsteoBiol® Gen-Os® and TSV Gel
Source: Courtesy of Prof Tiziano Testori, Como, Italy



OsteoBiol® Gen-Os® and TSV Gel grafted to horizontally regenerate an atrophic crest in the esthetic area
Source: Courtesy of Prof Tiziano Testori, Como, Italy



OsteoBiol® TSV Gel mixed with Gen-Os®, protected with a Derma membrane
Source: Courtesy of Dr Antonio Murillo Rodriguez, Ponferrada, Spain



Ridge preservation with OsteoBiol® Gen-Os® and TSV Gel
Source: Courtesy of Dr Roberto Rossi, Genova, Italy

TSV Gel



The resorbable solution for ideal graft stability
Thermosensitive resorbable gel for graft stabilization

Characteristics and handling



Composition

Heterologous type I and III collagen gel
Thermogelling synthetic biocompatible copolymer

Physical form

LV phase at $+4^{\circ}\text{C}$
Gel viscosity at >math>+13^{\circ}\text{C}</math>

Packaging

Syringe: 0.5 cc, 1.0 cc

Available only in combination with OsteoBio® Gen-Os® and Apatos
0.5 g, 1.0 g

Product codes

TSV005S | 1 Syringe | 0.5 cc | Porcine
TSV005E | 1 Syringe | 0.5 cc | Equine
TSV010S | 1 Syringe | 1.0 cc | Porcine
TSV010E | 1 Syringe | 1.0 cc | Equine

GMDN code

38746



CHARACTERISTICS

The purpose of *TSV Gel* is to provide mechanical stability to bone substitutes and barrier membranes.

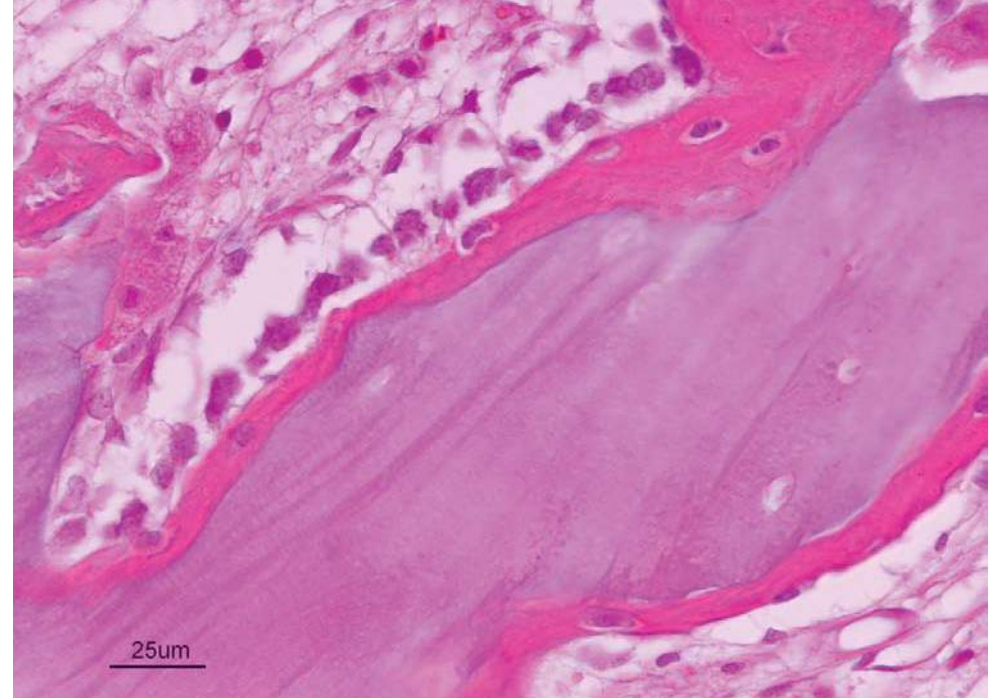
TSV Gel is sterilized by Gamma irradiation and is radio-transparent. It contains heterologous type I and III collagen gel with polyunsaturated fat acids diluted in aqueous solution containing a biocompatible synthetic copolymer that gives *TSV Gel* thermo-reversible and thermo-gelling properties. At low temperature (+4°C) the gel is relatively flowable and easy to mix and manipulate with graft but becomes more viscous when *in situ* and exposed to body temperature.

HANDLING

TSV Gel must be refrigerated for at least 20 minutes at +4°C before use, in order to reach the low viscosity (LV) phase, which makes it easier to mix with *Gen-Os®* or *Apatos*.

At room temperature, the product remains at LV phase for few minutes, whereas once *in situ* its viscosity quickly increases with body temperature. *TSV Gel* in LV phase can be used instead of saline for hydrating and mixing with *Gen-Os®* or *Apatos*. The result will be a sticky mixture easy to place and extremely stable once *in situ*.

TSV Gel can also be applied to the rough side of the *Evolution* membrane to stabilize it during graft covering and whilst suturing.

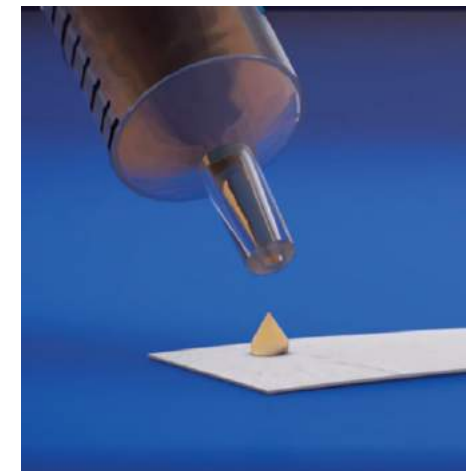


Part of a biopsy showing newly formed bone around a particle of OsteoBio® Gen-Os® mixed with OsteoBio® TSV Gel two weeks after grafting in rabbit. Htx-eosine.

Source: courtesy of Prof Ulf Nannmark, University of Göteborg, Sweden



Source: Tecnos® Dental Media Library



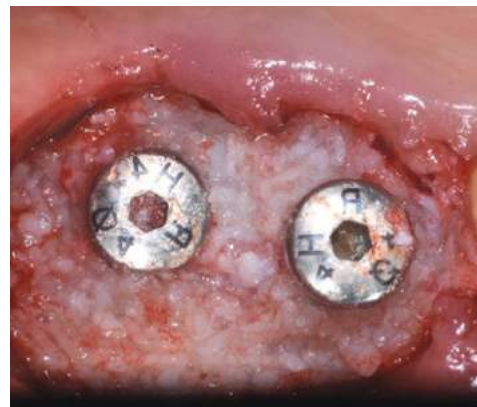
Source: Tecnos® Dental Media Library

Clinical Indications

TSV Gel can be used in GBR procedures together with OsteoBiol® bone substitutes and membranes to enhance graft stability. The viscosity reached by TSV Gel at body temperature improves significantly the stability of Gen-Os® or Apatos granules and it is particularly beneficial in cases where there is little bony support around the defect i.e. lateral augmentation, sockets with a compromised buccal wall, dehiscences and periodontal two and one wall defects.

Additionally, the viscosity of OsteoBiol® TSV Gel improves the stability and handling of Evolution membranes, particularly during the delicate phase of flap closure.

TSV Gel can also be used as a cicatrizing agent for the treatment of cutaneous and mucosal lesions.



Peri-implant defect treated with OsteoBiol® Gen-Os® mixed with TSV Gel

Source: Courtesy of Dr Roberto Rossi, Genova, Italy



DEHISCENCES AND FENESTRATIONS
peri-implant lesions
case reports on page 80



PERIODONTAL REGENERATION
intrabony defects
case reports on page 92



HORIZONTAL AUGMENTATION
two-wall defects
case reports on page 87

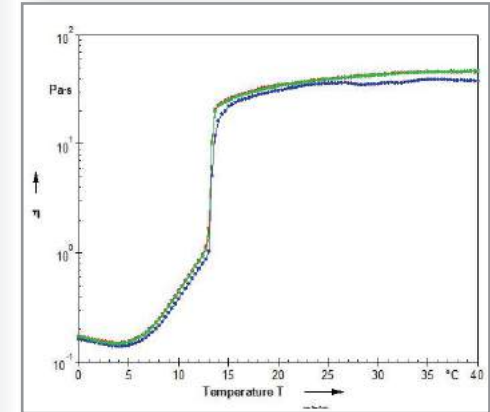


ALVEOLAR REGENERATION
socket preservation
case reports on page 77

free animated videos
on OsteoBiol® APP



OsteoBiol® TSV Gel GELIFICATION KINETICS



Source: Politecnico di Torino, Italy

The graph shows the effect of temperature change on 3 TSV Gel samples.

As temperature increases from 0°C (1°C/min), the viscosity of the gel reaches its minimum at 4°C.

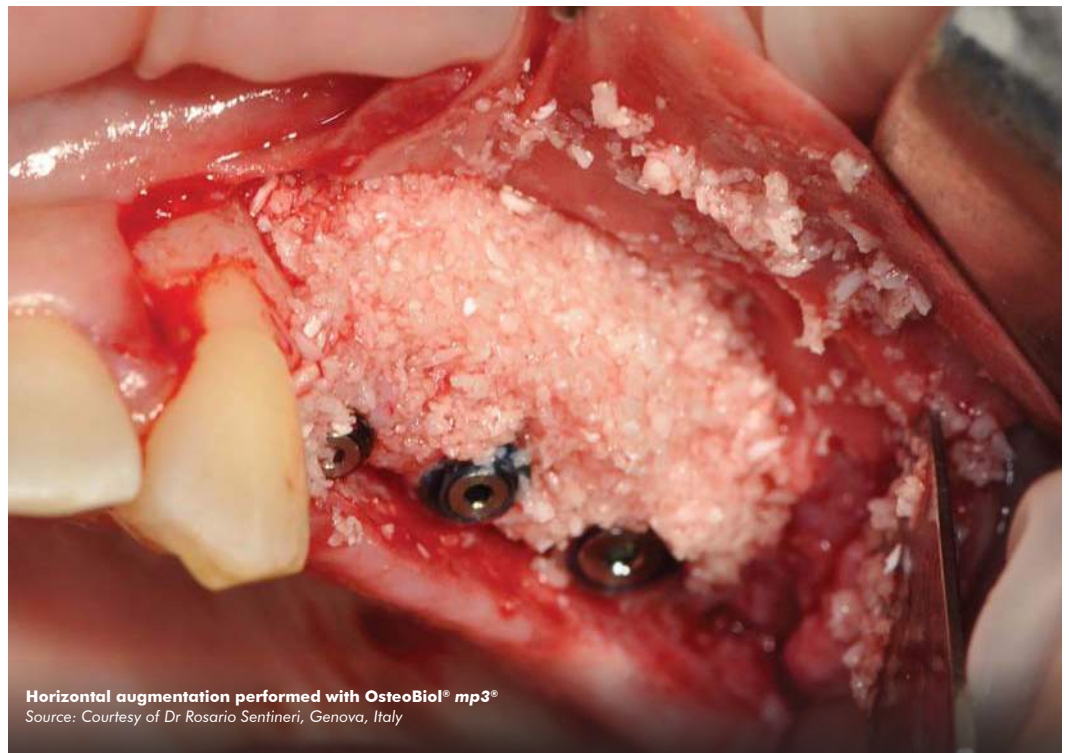
It then increases rapidly until it plateaus at 13°C. At room and body temperature TSV Gel is gel-like. It does not harden but keeps a soft consistency that allows the mixture with Gen-Os® or Apatos granules. Thanks to the hydrophilic properties of OsteoBiol® bone substitutes, the mixture becomes a sticky, stable conglomerate that can easily be placed in the defect site.

TSV Gel is biocompatible and rapidly resorbed.

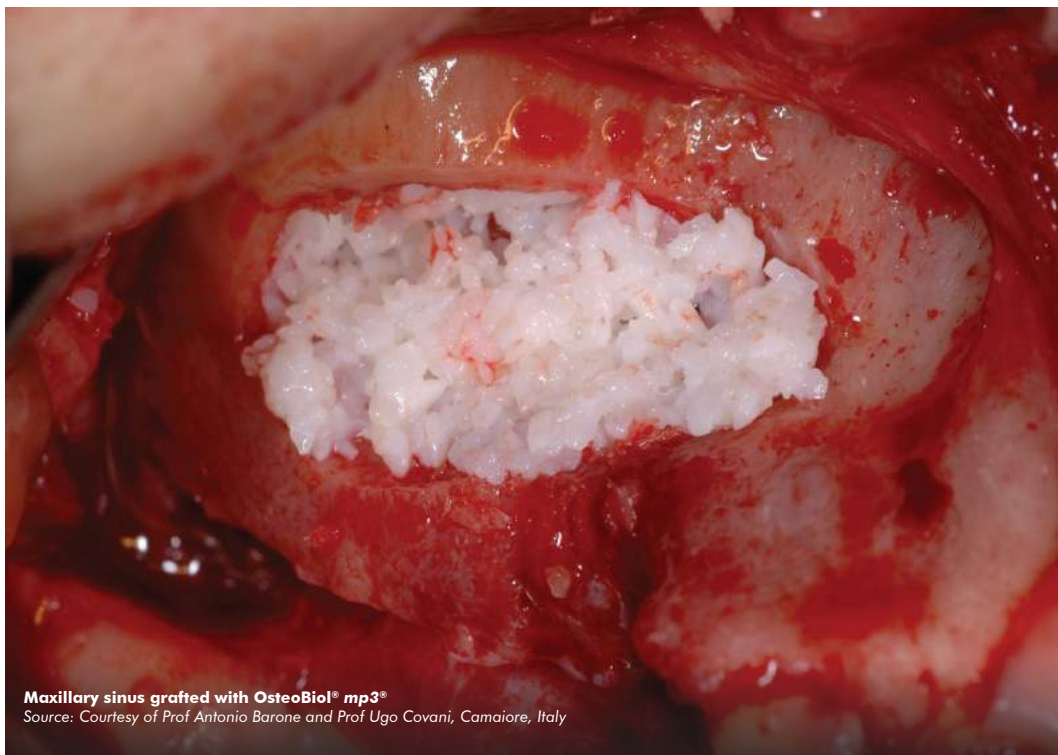
Additional case reports on osteobiol.com



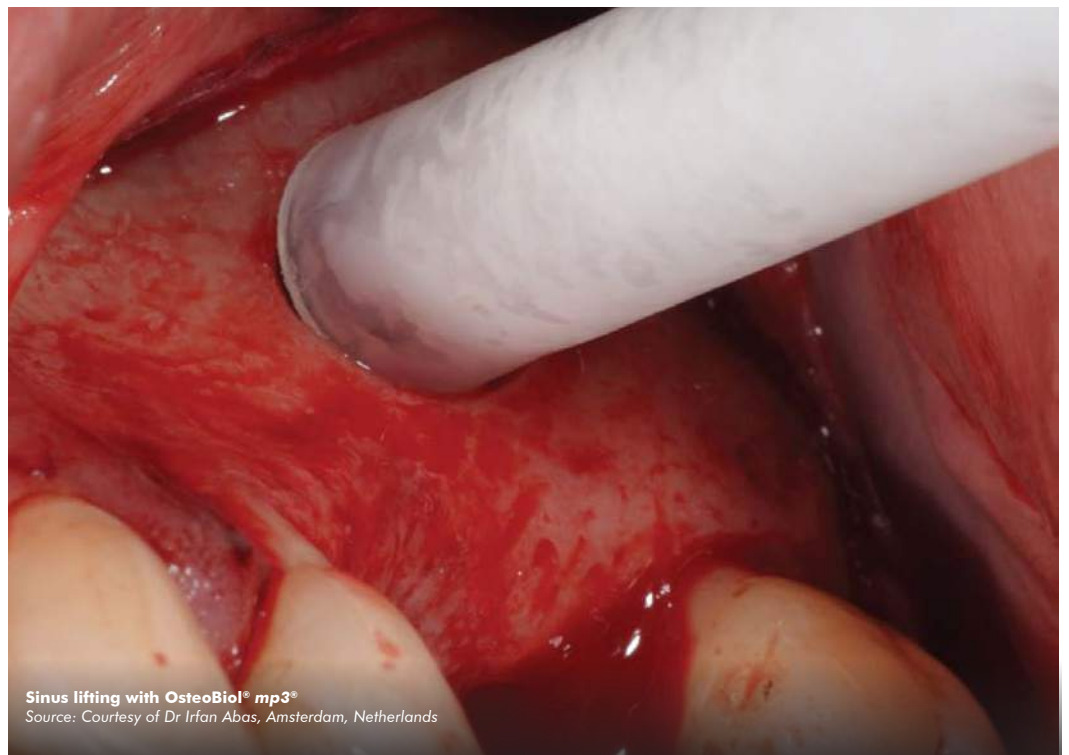
Ridge reconstructed with OsteoBiol® mp3®
Source: Courtesy of Dr Patrick Palacci, Marseille, France



Horizontal augmentation performed with OsteoBiol® mp3®
Source: Courtesy of Dr Rosario Sentineri, Genova, Italy

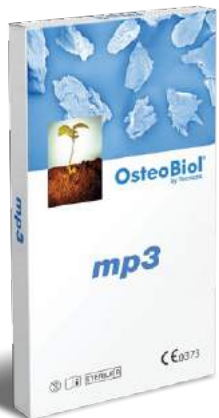


Maxillary sinus grafted with OsteoBiol® mp3®
Source: Courtesy of Prof Antonio Barone and Prof Ugo Covani, Camaiore, Italy



Sinus lifting with OsteoBiol® mp3®
Source: Courtesy of Dr Irfan Abas, Amsterdam, Netherlands

mp3[®]



Ultimate performance and handling
Pre-hydrated collagenated heterologous cortico-cancellous bone mix



Tissue of origin

Cortico-cancellous heterologous bone mix

Tissue collagen

Preserved plus an additional 10% collagen gel

Physical form

Pre-hydrated granules and collagen gel

Composition

90% granulated mix, 10% collagen gel

Granulometry

600-1000 μm

1000-2000 μm

Re-entry time

About 5 months

Packaging

Syringe: 0.5 cc, 1.0 cc, 3x0.25 cc, 3x0.5 cc, 3x1.0 cc

Wide tip syringe: 2.0 cc

Product codes

600-1000 μm

A3095FS | 1 Syringe | 0.5 cc | Porcine

A3095FE | 1 Syringe | 0.5 cc | Equine

A3005FS | 1 Syringe | 1.0 cc | Porcine

A3005FE | 1 Syringe | 1.0 cc | Equine

A3075FS | 3 Syringes | 3x0.25 cc | Porcine

A3015FS | 3 Syringes | 3x0.5 cc | Porcine

A3015FE | 3 Syringes | 3x0.5 cc | Equine

A3030FS | 3 Syringes | 3x1.0 cc | Porcine

A3030FE | 3 Syringes | 3x1.0 cc | Equine

A3010FS | 1 Wide tip syringe | 2.0 cc | Porcine

A3010FE | 1 Wide tip syringe | 2.0 cc | Equine

1000-2000 μm

A3210FS | 1 Wide tip syringe | 2.0 cc | Porcine

A3210FE | 1 Wide tip syringe | 2.0 cc | Equine

GMDN code

38746

Characteristics and handling

CHARACTERISTICS

Heterologous origin biomaterial made of 600-1000 μm or 1000-2000 μm pre-hydrated collagenated cortico-cancellous granules, properly mixed with collagen gel. Thus, it is possible both skipping the hydration phase and decreasing the risk of accidental exposure of the material to pathogens during manipulation and grafting phases; furthermore, the syringe is flexible and ideal to simplify grafting in the receiving site.

The granules are endowed with characteristics very similar to human mineral bone, and can be used as an alternative to autologous bone.

Their natural micro-porous consistency facilitates new bone tissue formation⁽¹⁾ in defect sites and accelerates the regeneration process.

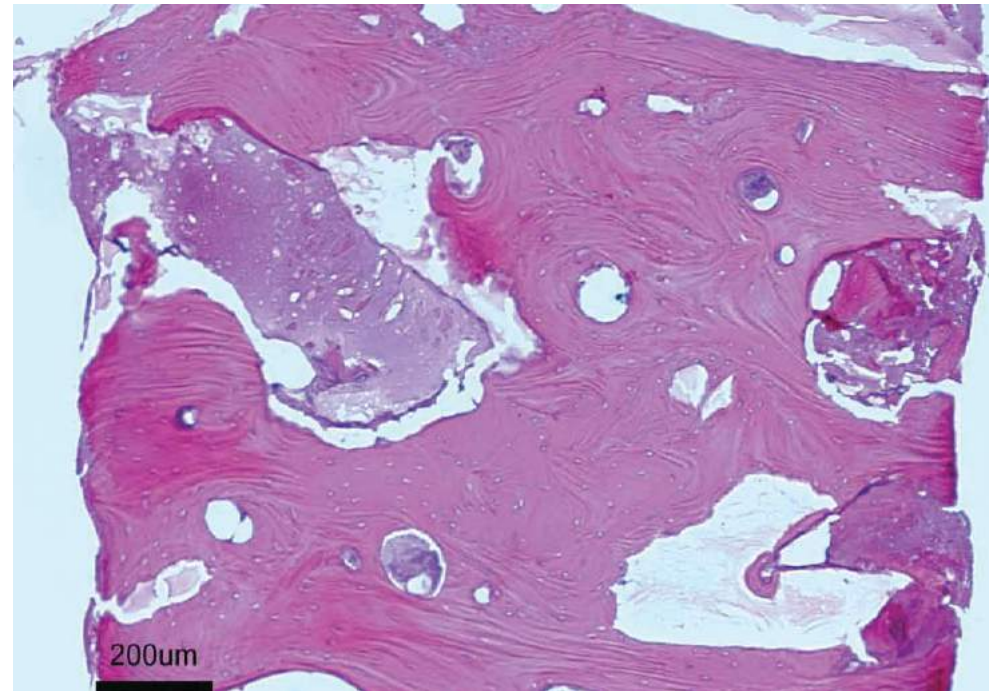
Gradually resorbable^(2,3), it preserves the original graft shape and volume (osteoconductive property)^(4,5).

Moreover, thanks to its collagen content, the product facilitates blood clotting and the subsequent invasion of repairing and regenerative cells.

HANDLING

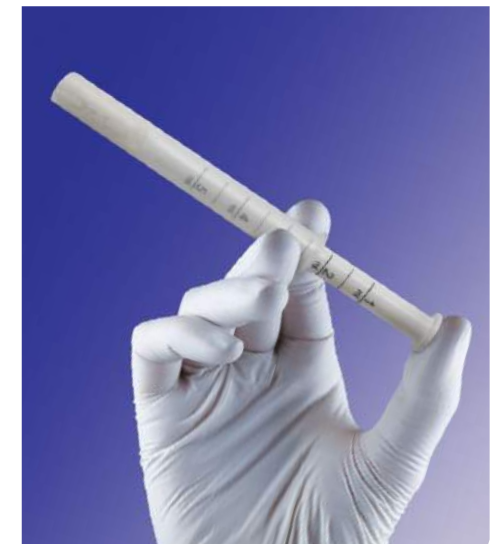
mp3[®] is available in ready-to-use syringes and can be easily grafted avoiding the hydration and manipulation phases.

After adapting the material to the defect shape, it is necessary to remove non-stable residues before proceeding to soft tissue suture.



Histology on maxillary sinus biopsy taken at 24 months. 48% new bone formation, 13% residual granules

Source: Biopsy by Dr Roberto Rossi, Genova, Italy. Histology by Prof Ulf Nannmark, University of Göteborg, Sweden



Source: Tecnos[®] Dental Media Library

Clinical Indications

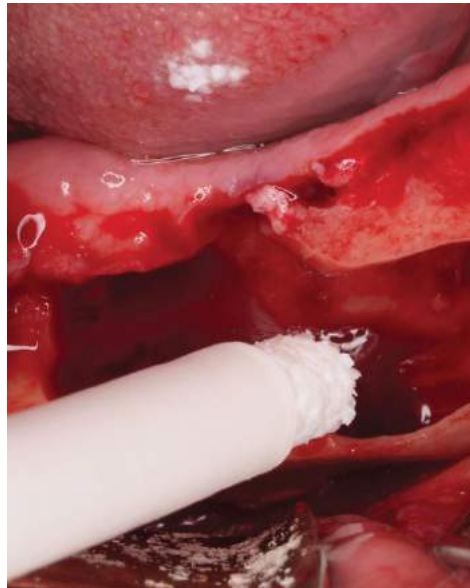
mp3® is a pre-hydrated cortico-cancellous bone mix with 10% collagen gel. It has been developed with this innovative biotechnology and is a “ready-to-use” product.

mp3® main indication is lateral access maxillary sinus lift^(1,6), always in association with *Evolution* membranes, recommended to cover the antrotomy: the mp3® syringe can be directly applied into the bony window without having to mix the mp3® granules with saline.

Due to its collagen gel content, mp3® allows an excellent graft stability while its hydrophilia guarantees quick blood absorption and therefore the necessary graft vascularization. mp3® has also been successfully used in combination with *Evolution* membranes for alveolar ridge preservation^(3,7,8): the application of this biomaterial significantly limits the alveolar ridge width and height reduction that would naturally occur with spontaneous healing, preserving thus the alveolar ridge volume and allowing a correct second stage implant placement. mp3® is also indicated for horizontal augmentation (two wall defects) in combination with autogenous bone blocks or with OsteoBiol® *Lamina*^(9,10): its cortico-cancellous composition allows a progressive resorption of osteoclastic type, and in parallel a similar rate of new bone formation⁽²⁾.

These unique properties allow a very good graft volume preservation⁽¹¹⁾, a healthy new bony tissue and ultimately, a successful implant rehabilitation.

Finally, mp3® can also be used as filler of bone defects after trauma, reconstruction or corrections in non-load-bearing indications in maxillofacial surgery.



OsteoBiol® mp3® grafted after the removal of a cyst
Source: Courtesy of Dr Antonio Murillo Rodriguez, Ponferrada, Spain



Periodontal defect grafted with OsteoBiol® mp3®
Source: Courtesy of Dr Gerd Körner, Bielefeld, Germany

free animated videos
on OsteoBiol® APP



LATERAL ACCESS SINUS LIFT
maxillary sinus floor augmentation
case reports on page 84



ALVEOLAR REGENERATION
post-extractive sockets
case reports on page 77



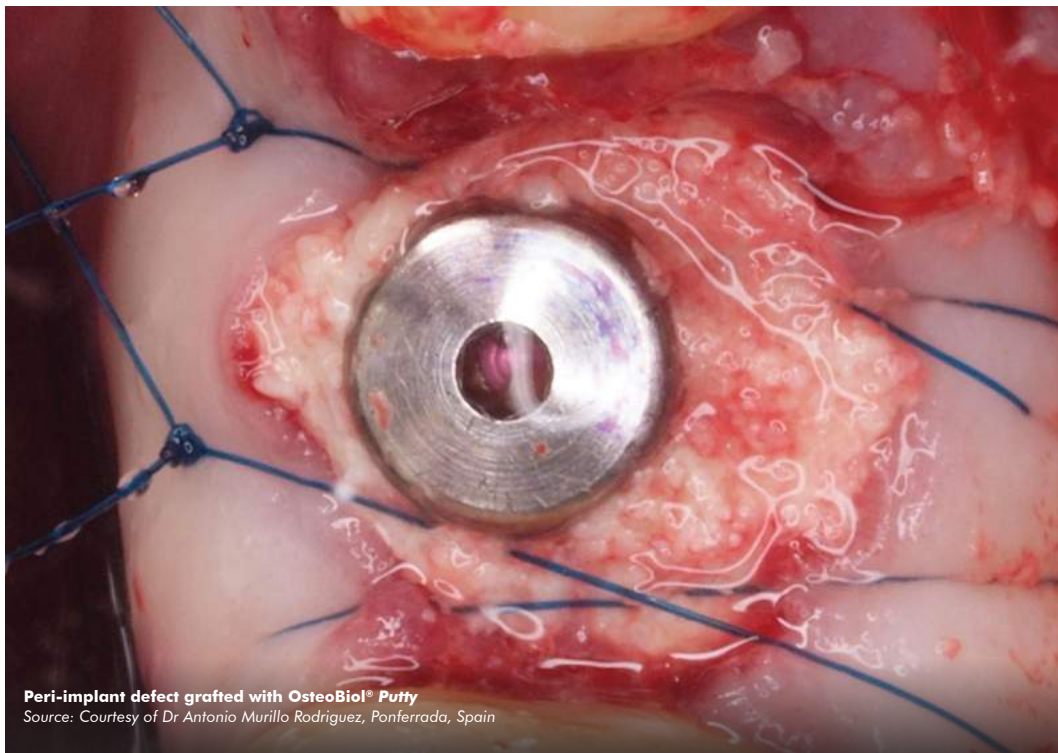
HORIZONTAL AUGMENTATION
two-wall defects
case reports on page 87

Additional case reports on osteobiol.com

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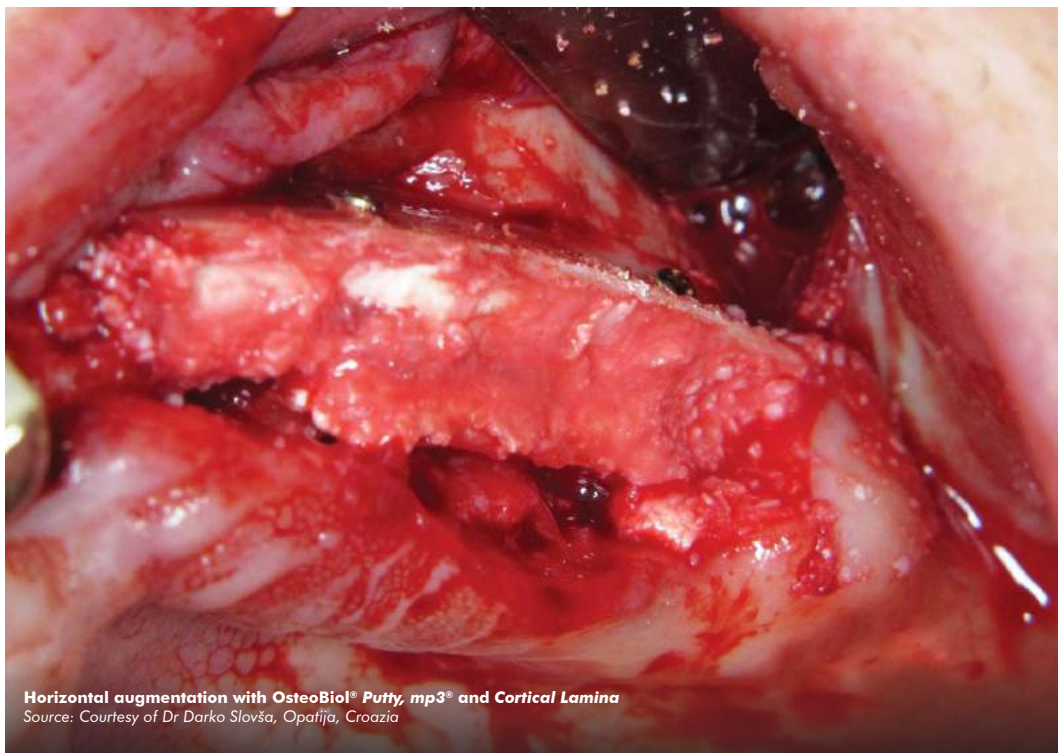
For further information see the complete literature on p. 114



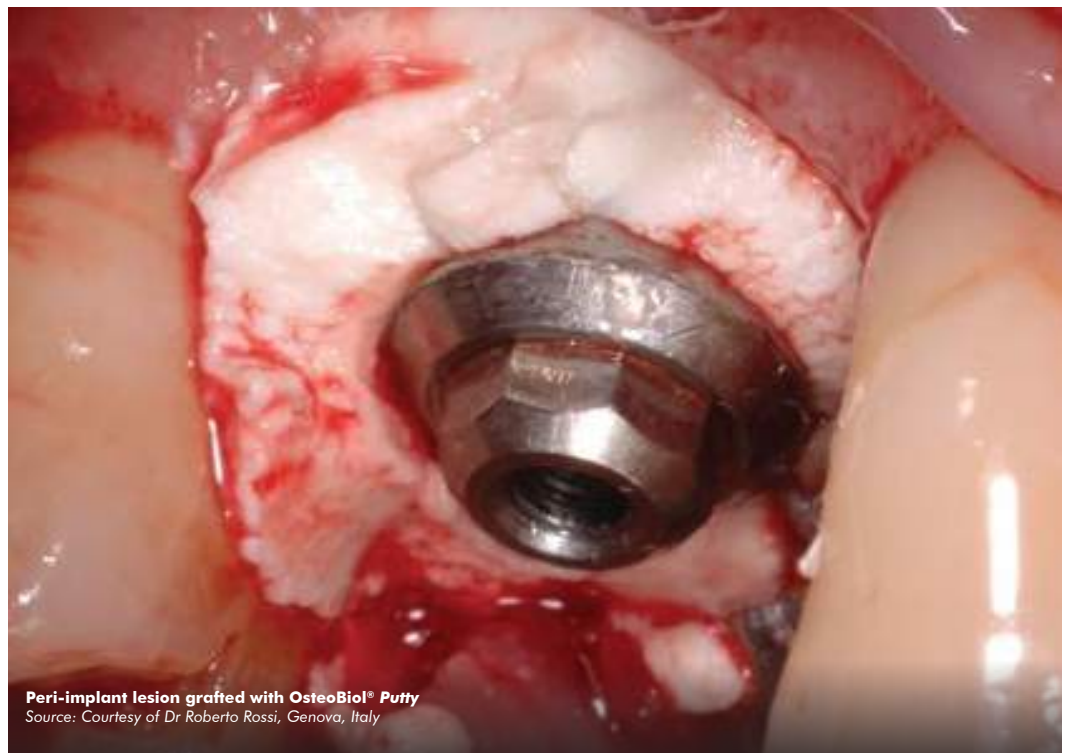
Peri-implant defect grafted with OsteoBiol® Putty
Source: Courtesy of Dr Antonio Murillo Rodriguez, Ponferrada, Spain



Bone Layer technique performed with OsteoBiol® Putty
Source: Courtesy of Dr Michele Antonio Lopez, Rome, Italy



Horizontal augmentation with OsteoBiol® Putty, mp3® and Cortical Lamina
Source: Courtesy of Dr Darko Slovša, Opatija, Croatia



Peri-implant lesion grafted with OsteoBiol® Putty
Source: Courtesy of Dr Roberto Rossi, Genova, Italy

Putty



Engineered for peri-implant defects
Pre-hydrated collagenated heterologous cortico-cancellous bone paste

Characteristics and handling



Tissue of origin

Cortico-cancellous heterologous bone mix

Tissue collagen

Preserved plus an additional 20% collagen gel

Physical form

Plastic consistency composed of collagen gel loaded with 80% micronized bone mix

Composition

80% granulated mix, 20% collagen gel

Granulometry

Up to 300 μm

Re-entry time

About 4 months

Packaging

Syringe: 0.25 cc, 0.5 cc, 3x0.5 cc, 3x0.25 cc
Wide tip syringe: 1.0 cc

Product codes

HPT52S	1 Syringe	0.25 cc	Porcine
HPT09S	1 Syringe	0.5 cc	Porcine
HPT09E	1 Syringe	0.5 cc	Equine
HPT35S	3 Syringes	3x0.5 cc	Porcine
HPT35E	3 Syringes	3x0.5 cc	Equine
HPT32S	3 Syringes	3x0.25 cc	Porcine
HPT32E	3 Syringes	3x0.25 cc	Equine

HPT61S	1 Wide tip syringe	1.0 cc	Porcine
HPT61E	1 Wide tip syringe	1.0 cc	Equine

GMDN code

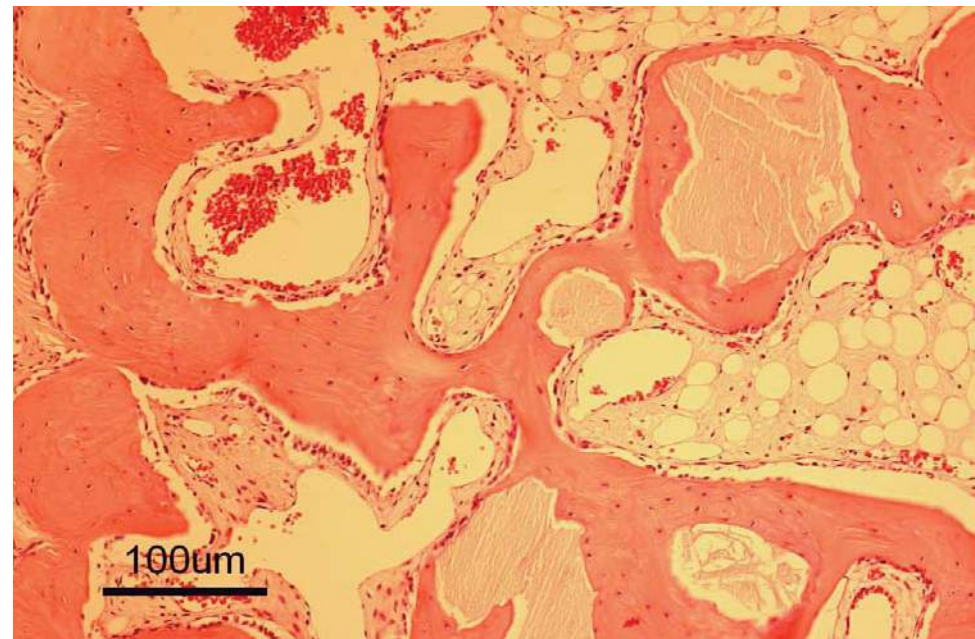
38746

CHARACTERISTICS

Putty is a bone paste with at least 80% micronized heterologous bone (granulometry up to 300 μm) and collagen gel. It is made with an exclusive process that provides the product with exceptional malleability and plasticity, making it easy to apply peri-implant defects with walls. Thanks to its collagen component, the product facilitates blood clotting and the subsequent invasion of repairing and regenerative cells, showing an osteoconductive behaviour⁽¹⁾. Successful grafting needs complete stability of the biomaterial: for this reason *Putty* must be used only in cavities able to firmly contain it. Therefore, *Putty* must not be grafted in two wall defects or in lateral access sinus lift procedures.

HANDLING

Inject the product and adapt it to defect morphology without compression; any non stable residue must be removed before soft tissue suture. An *Evolution* membrane is recommended to protect *Putty* grafted in peri-implant defects.



Part of a biopsy showing newly formed bone after treatment with OsteoBiol® Putty

Source: Histology by Prof Ulf Nannmark, University of Göteborg, Sweden

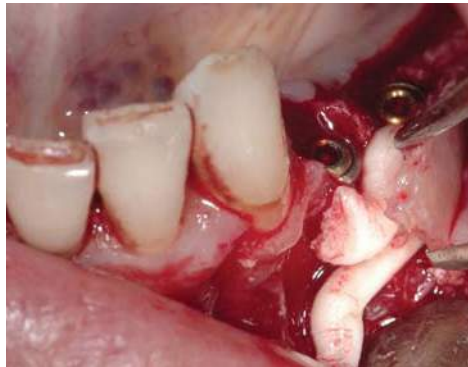


Source: Tecnos® Dental Media Library

Clinical Indications

The extraordinary handling properties of *Putty* syringe make this product the ideal choice for self-contained peri-implant defects⁽²⁾ and all small defects that present a self-contained cavity. Furthermore, the TecnoSS[®] manufacturing process avoids granules ceramization, allowing a progressive resorption of the biomaterial and, at the same time, a significant new-bone formation rate⁽³⁾. *Putty*'s "soft" consistency also guarantees an easy and healthy soft-tissues healing. Thanks to these unique characteristics, *Putty* is particularly indicated for peri-implant defects regeneration: following immediate post-extractive implants placement, *Putty* can be injected between the defect walls and the implant, guaranteeing a perfect filling of the entire defect volume⁽⁴⁾.

The product versatility also makes *Putty* the ideal solution when bone tissue has been lost due to peri-implantitis as long as the containing walls are present. In fact, the primary condition for gaining a successful regeneration is to achieve the biomaterial initial stability. Therefore, *Putty* must be used only in defects where the surrounding walls guarantee such condition: for example inside the bone crest when ridge-split technique is adopted⁽⁵⁾, or with horizontally resorbed crests, in association with OsteoBiol[®] Lamina (Bone Layer technique)⁽⁶⁾. *Putty* is also an ideal filler after removal of granulomas and dentogenous cysts.



Bone Layer technique with OsteoBiol[®] Lamina and Putty
Source: Courtesy of Dr Michele Antonio Lopez, Roma, Italy

free animated videos
on OsteoBiol[®] APP



DEHISCENCES AND FENESTRATIONS
peri-implant defects
case reports on page 80



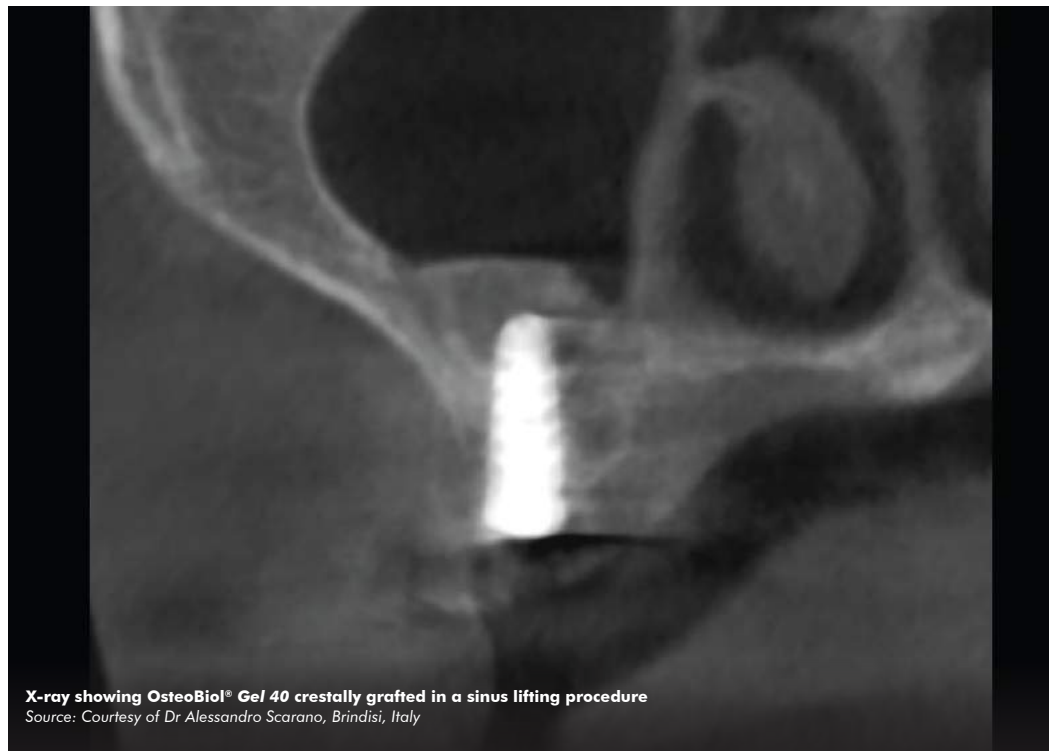
HORIZONTAL AUGMENTATION
ridge split
case reports on page 87

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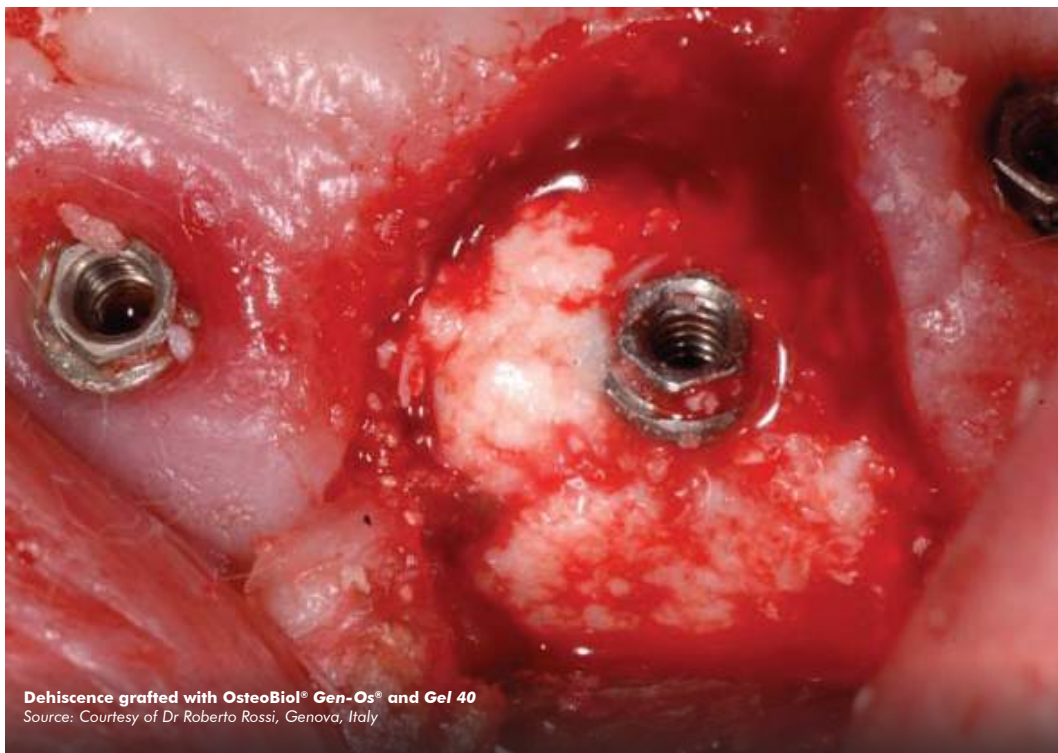
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THE USE OF RESORBABLE CORTICAL LAMINA AND MICRONIZED COLLAGENATED BONE IN THE REGENERATION OF ATROPHIC CRESTAL RIDGES: A SURGICAL TECHNIQUE. CASE SERIES
J BIOL REGUL HOMEOST AGENTS, 2016 APR-JUN;30(2 SUPPL 1):81-85



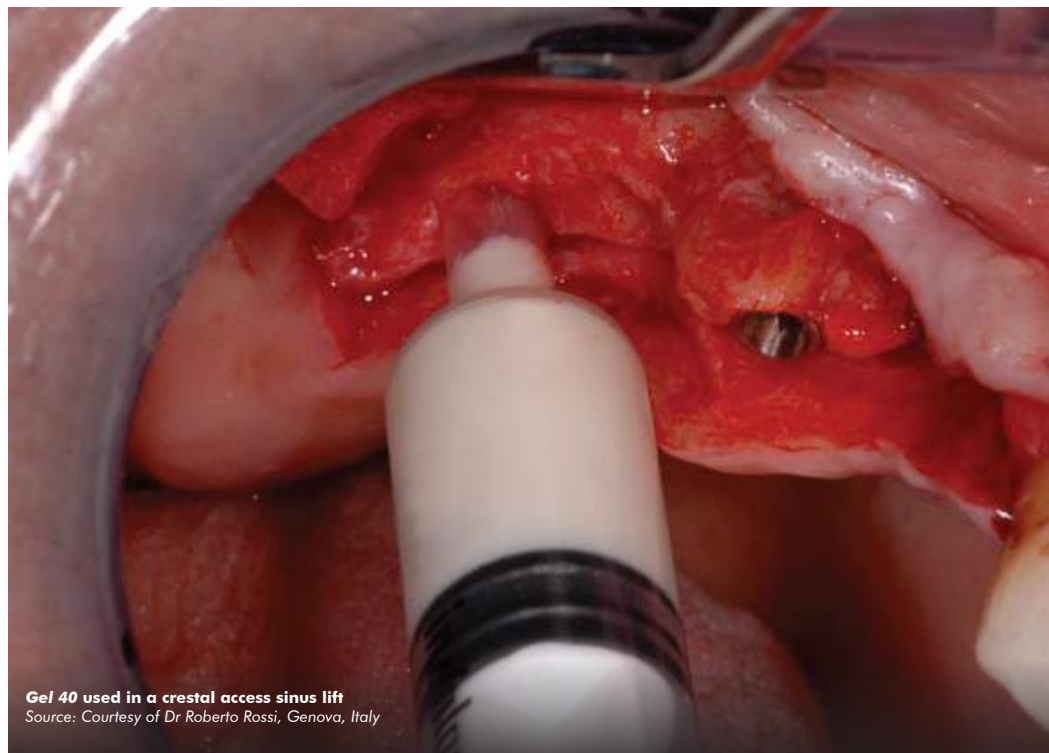
Intrabony defect grafted with OsteoBiol® Gel 40
Source: Courtesy of Dr Walter Rao, Pavia, Italy



X-ray showing OsteoBiol® Gel 40 crestally grafted in a sinus lifting procedure
Source: Courtesy of Dr Alessandro Scarano, Brindisi, Italy



Dehiscence grafted with OsteoBiol® Gen-Os® and Gel 40
Source: Courtesy of Dr Roberto Rossi, Genova, Italy



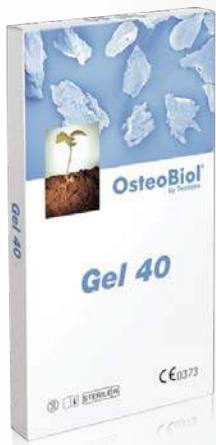
Gel 40 used in a crestal access sinus lift
Source: Courtesy of Dr Roberto Rossi, Genova, Italy

Gel 40



A unique heterologous bone gel
Collagenated heterologous cortico-cancellous bone mix

Characteristics and handling



Tissue of origin

Cortico-cancellous heterologous bone mix

Tissue collagen

Preserved plus an additional 40% collagen gel

Physical form

Collagen gel type I and III loaded with 60% bone mix

Composition

60% granulated mix, 40% collagen gel

Granulometry

Up to 300 μm

Re-entry time

About 4 months

Packaging

Syringe: 0.5 cc, 3x0.5 cc

Product codes

05GEL40S | 1 Syringe | 0.5 cc | Porcine
05GEL40E | 1 Syringe | 0.5 cc | Equine
15GEL40S | 3 Syringes | 3x0.5 cc | Porcine
15GEL40E | 3 Syringes | 3x0.5 cc | Equine

GMDN code

38746

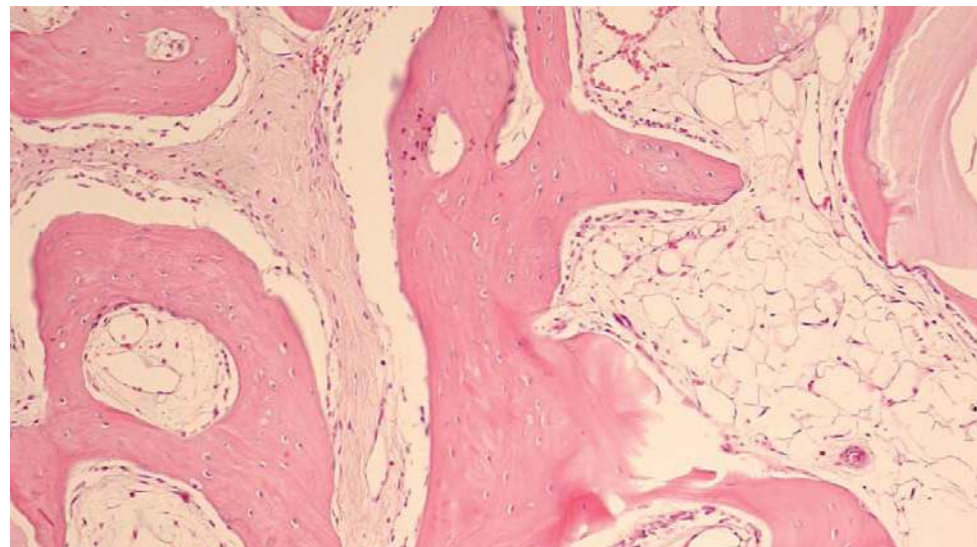
CHARACTERISTICS

Gel 40 is made of a collagen matrix (type I and III) obtained using an exclusive Tecnos[®] process, loaded for 60% of its volume with micronized heterologous bone (granulometry up to 300 μm). Thanks to its collagen component, Gel 40 facilitates the formation of primary blood clot and the subsequent invasion of repairing and regenerative cells; moreover, the cortico-cancellous component provides the necessary scaffold function.

The collagen gel component contained in Gel 40 is rapidly and totally resorbed; it is also endowed with exceptional anti-inflammatory, eutrophic and cicatrizing properties. This lipophilia is due mainly to a percentage of polyunsaturated fatty acids of the oleic-linoleic series (to which Omega 3 also belongs) directly derived from the raw material. Such components possess a valuable antioxidant action on the free radicals and therefore aid tissue regeneration.

HANDLING

The distinctive characteristics of viscosity and density of Gel 40 facilitate the handling of the product by the operator, providing a glue-like support. If viscosity is excessive, add a few drops of sterile lukewarm saline and then re-mix thoroughly to obtain the desired density.



Part of a biopsy showing newly formed bone after treatment with OsteoBiol[®] Gel 40. Biopsies were taken 5 weeks after implantation in rabbit maxillae. Htx-eosine. Original magnification x20
Source: Histology by Prof Ulf Nannmark, University of Göteborg, Sweden



Source: Tecnos[®] Dental Media Library

Clinical Indications

The exclusive Tecnos[®] manufacturing process guarantees an exceptional malleability and plasticity: furthermore, the syringe packaging provides Gel 40 extraordinary handling properties making this product the ideal choice for crestal access sinus lift^(1,2), deep and narrow peri-implant defects⁽³⁾, three-wall intrabony defects and, in combination with *Evolution* membranes, for treating gingival recessions⁽⁴⁾.

Furthermore, the Tecnos[®] manufacturing process avoids granules ceramization, allowing a progressive resorption of the biomaterial and, at the same time, a significant new-bone formation rate^(5,6).

Gel 40 "soft" consistency also guarantees an easy and healthy soft-tissues healing.



Crestal access sinus lift with OsteoBiol[®] Gel 40
Source: Tecnos[®] Dental Media Library

free animated videos
on OsteoBiol[®] APP



PERIODONTAL REGENERATION

intrabony defects and gingival recessions
case reports on page 92



CRESTAL ACCESS SINUS LIFT

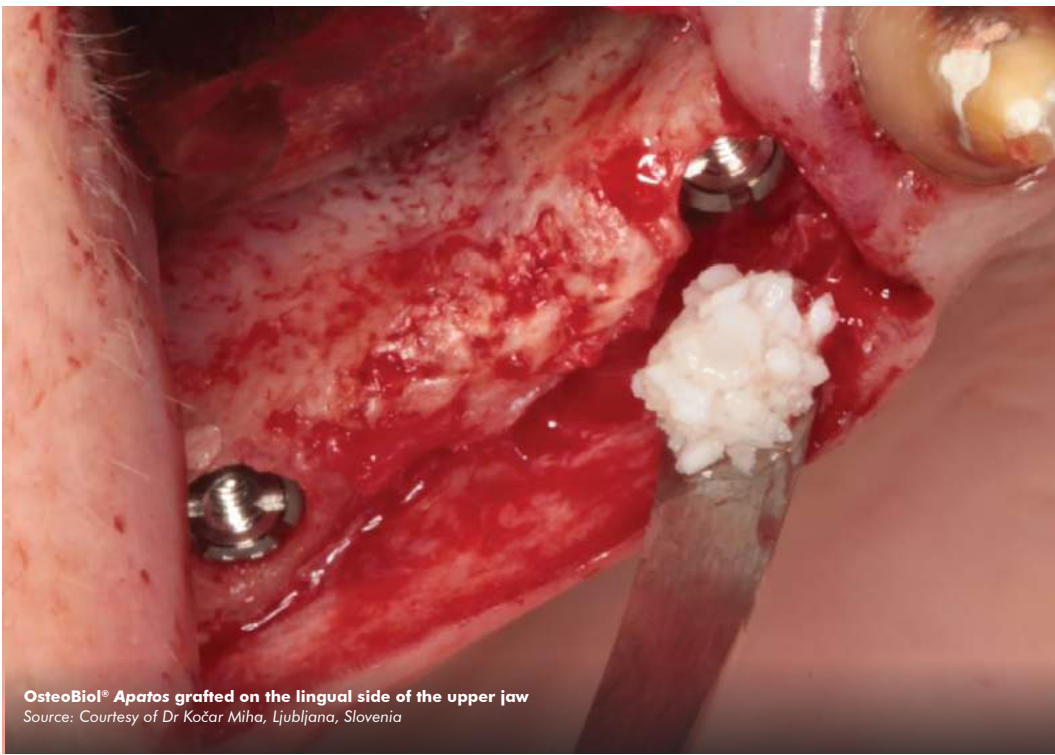
crestal sinus floor augmentation
case reports on page 82

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DENTISTRY, 2015, 5:2

Additional case reports on osteobiol.com

For further information see the complete literature on p. 114



Apatos



Microcrystalline hydroxyapatite

Heterologous cortico-cancellous and cortical bone

Characteristics and handling



Tissue of origin

Apatos Mix: cortico-cancellous heterologous bone mix
Apatos Cortical: heterologous cortical bone

Tissue collagen

Degraded

Physical form

Radiopaque granules of mineral hydroxyapatite

Composition

Apatos Mix: 100% cortico-cancellous mix
Apatos Cortical: 100% cortical bone

Granulometry

600-1000 μm
1000-2000 μm

Re-entry time

About 5 months

Packaging

Mix | Vial: 0.5 g, 1.0 g, 2.0 g
Cortical | Vial: 0.5 g, 1.0 g

Product codes

600-1000 μm
Mix | A1005FS | 1 Vial | 0.5 g | Porcine
Mix | A1005FE | 1 Vial | 0.5 g | Equine
Mix | A1010FS | 1 Vial | 1.0 g | Porcine
Mix | A1010FE | 1 Vial | 1.0 g | Equine
Mix | A1020FS | 1 Vial | 2.0 g | Porcine
Mix | A1020FE | 1 Vial | 2.0 g | Equine
Cortical | AC1005FS | 1 Vial | 0.5 g | Porcine
Cortical | AC1010FS | 1 Vial | 1.0 g | Porcine
1000-2000 μm
Mix | A0210FS | 1 Vial | 1.0 g | Porcine
Mix | A0210FE | 1 Vial | 1.0 g | Equine

GMDN code

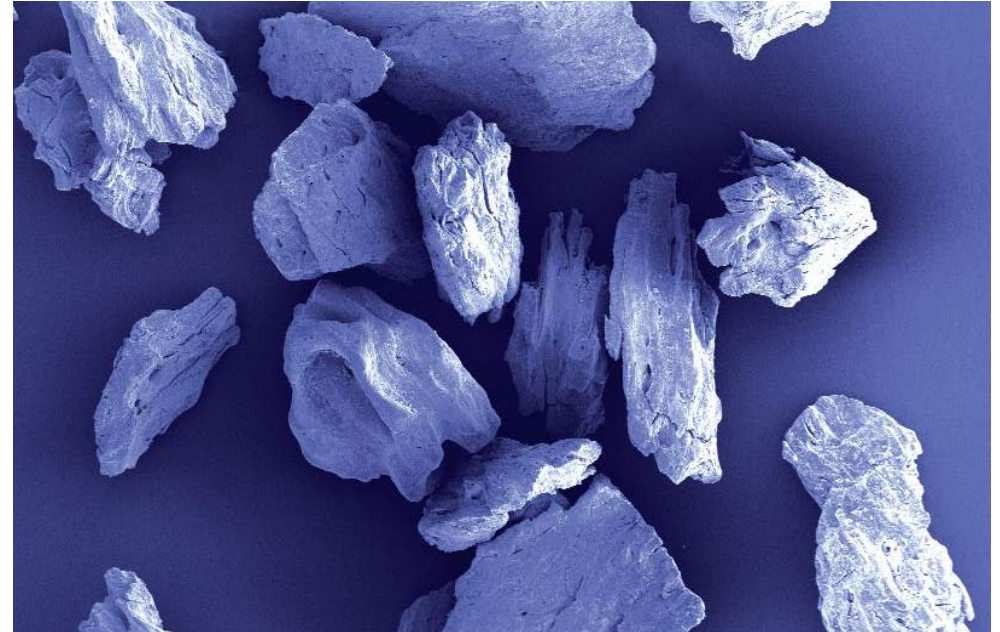
38746

CHARACTERISTICS

Apatos is a biocompatible^(1,2), osteoconductive^(3,4) biomaterial of heterologous origin with characteristics similar to mineralized human bone⁽⁵⁾; it can therefore be used as an alternative to autologous bone. The natural microporous consistency of Apatos facilitates the formation of new bone tissue in bone defect area⁽⁶⁾, accelerating the process. Apatos microcrystalline hydroxyapatite is available in cortical and mixed granules.

HANDLING

Apatos must always be hydrated and thoroughly mixed with a few drops of sterile saline or with *TSV Gel* to increase graft stability in not self-contained defects; it can also be mixed with patient's blood. Finally it can be mixed if necessary with the drug selected for surgery; the mixture thus obtained should be positioned with a sterile spatula or syringe for biomaterials.



SEM image of OsteoBiol® Apatos, cancellous granules

Source: Courtesy of Prof Ulf Nannmark, University of Göteborg, Sweden



Source: Tecnos® Dental Media Library

Clinical Indications

Apatos is a universal filler, that can be used to treat peri-implant defects and two-wall defects^(7,8). Because of its granulometry, Apatos cannot be used in narrow defects, but it fits well in big sockets, e.g. after molar extractions⁽⁹⁾. Both types of sinus lift (with crestal or lateral access)^(2,10) can be performed with Apatos as bone substitute, as well as surgeries for horizontal regenerations. Finally, Apatos can be used as filler of large maxillofacial bone defects, reconstruction or corrections in non-load-bearing indications.

Apatos Cortical is characterized by a very long resorption time⁽¹¹⁾, guaranteeing adequate preservation of the grafted volume.

When needed, Apatos grafts can be protected with OsteoBiol® Evolution membrane or stabilized with Cortical Lamina.



Sinus grafting with OsteoBiol® Apatos
Source: Courtesy of Dr. Antonio Murillo Rodriguez, Ponferrada, Spain



LATERAL ACCESS SINUS LIFT
maxillary sinus floor augmentation
case reports on page 84



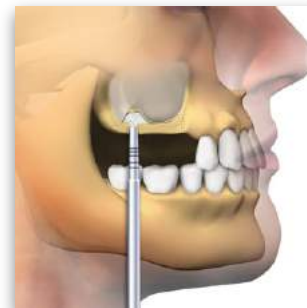
ALVEOLAR REGENERATION
socket preservation
case reports on page 77



HORIZONTAL AUGMENTATION
two-wall defects
case reports on page 87



DEHISCENCES AND FENESTRATIONS
peri-implant grafting
case reports on page 80



CRESTAL ACCESS SINUS LIFT
osteotome sinus floor augmentation
case reports on page 82

free animated videos
on OsteoBiol® APP



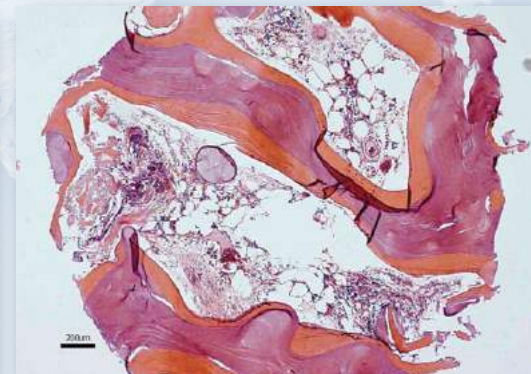
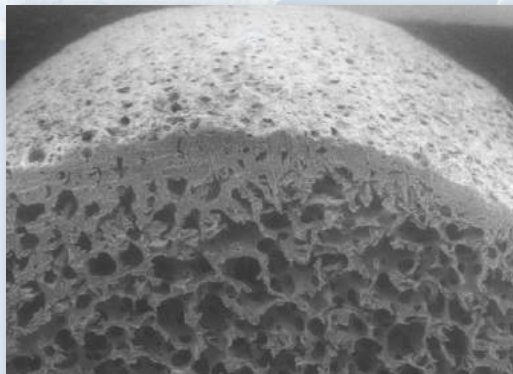
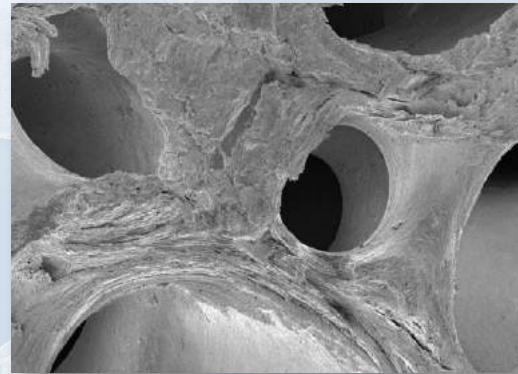
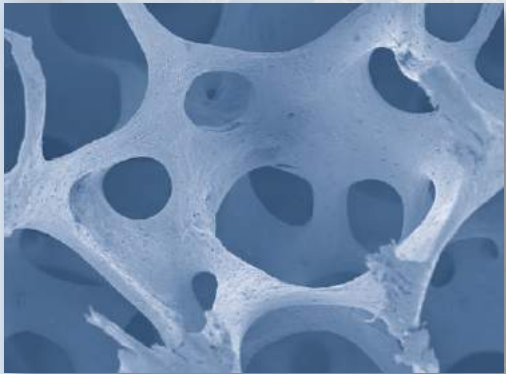
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Additional case reports on osteobiol.com

For further information see the complete literature on p. 114

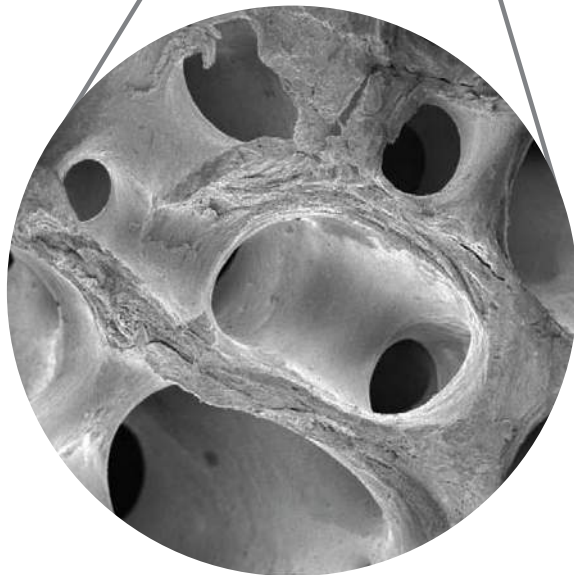
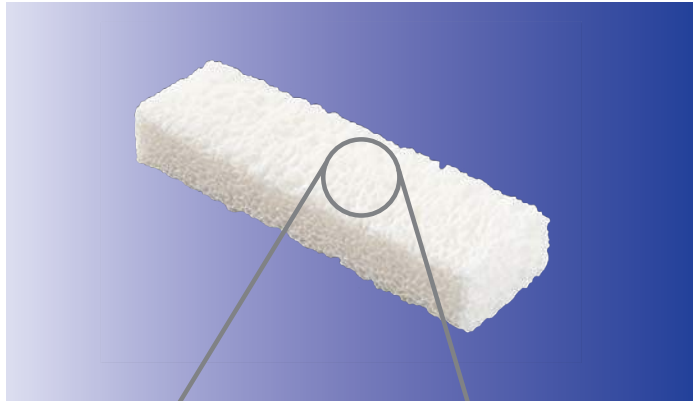
BLOCKS



OsteoBiol® bone blocks

Sp-Block

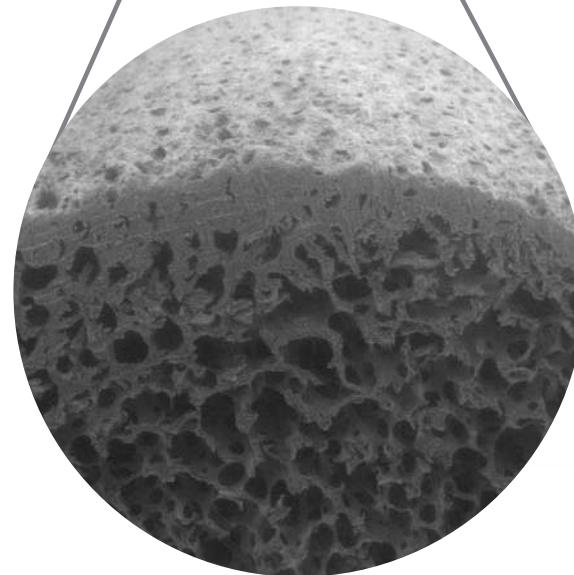
collagenated cancellous bone



SEM image of OsteoBiol® Sp-Block. Magnification 200x.
Source: Politecnico di Torino, Italy
For more information on OsteoBiol® Sp-Block see page 50

Dual-Block

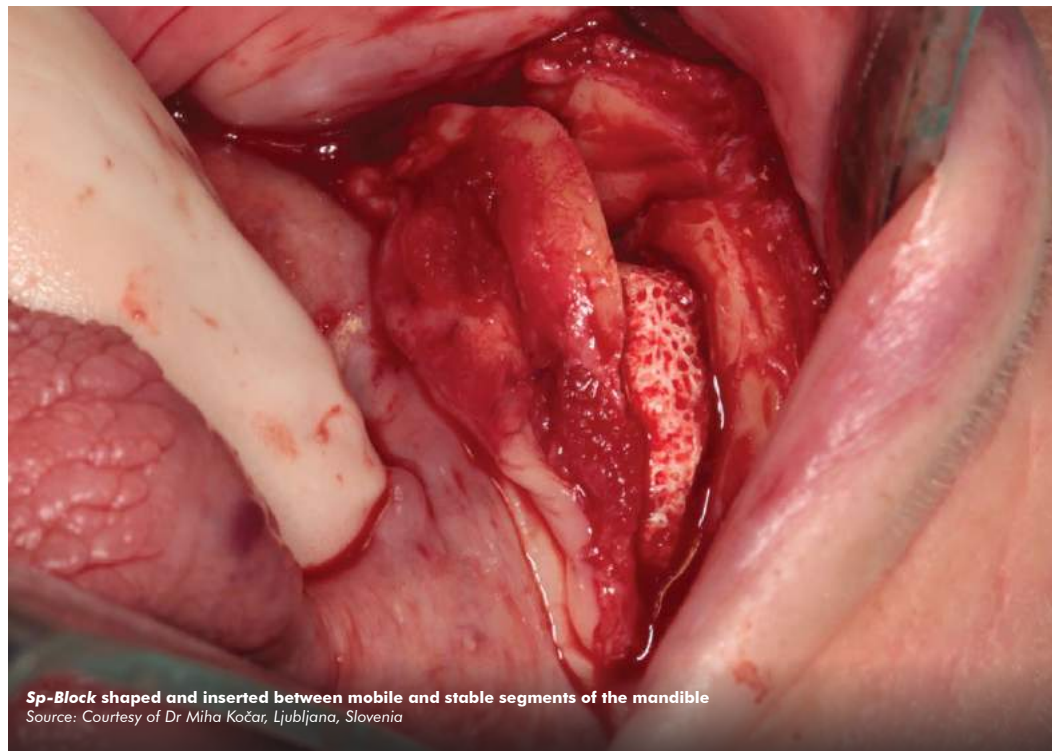
collagenated cortico-cancellous bone



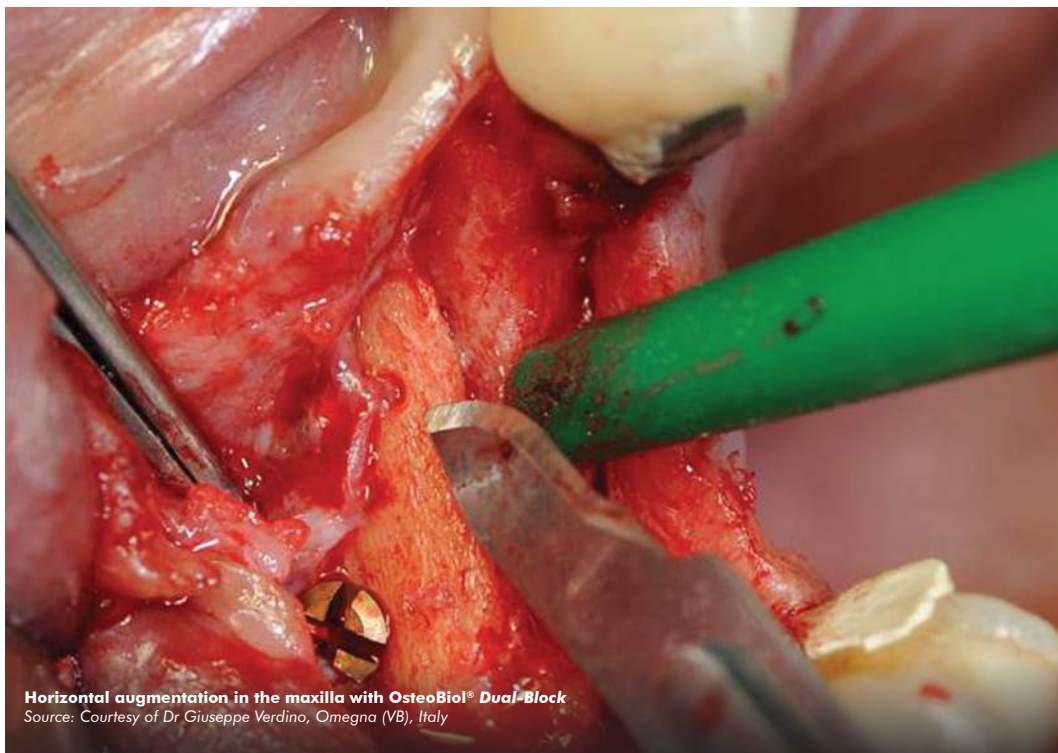
SEM image of OsteoBiol® Dual-Block. Magnification 20x.
Source: Politecnico di Torino, Italy
For more information on OsteoBiol® Dual-Block see page 50



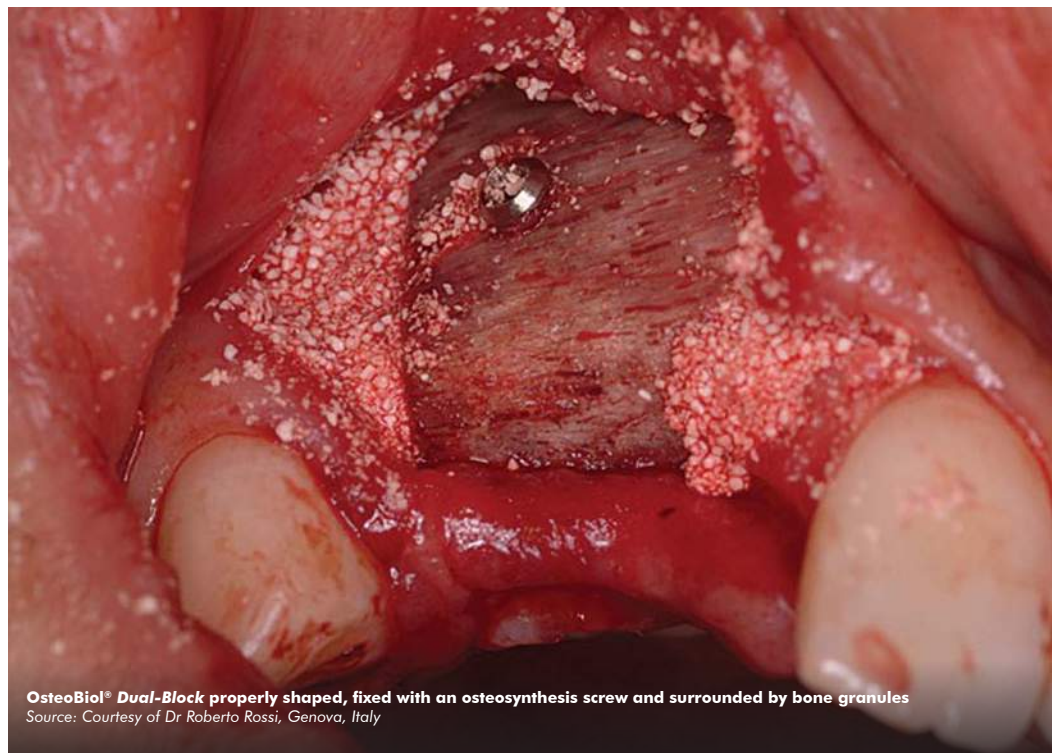
Inlay technique with OsteoBiol® Sp-Block
Source: Courtesy of Dr Pietro Felice, Bologna, Italy



Sp-Block shaped and inserted between mobile and stable segments of the mandible
Source: Courtesy of Dr Miha Kočar, Ljubljana, Slovenia



Horizontal augmentation in the maxilla with OsteoBiol® Dual-Block
Source: Courtesy of Dr Giuseppe Verdino, Omegna (VB), Italy



OsteoBiol® Dual-Block properly shaped, fixed with an osteosynthesis screw and surrounded by bone granules
Source: Courtesy of Dr Roberto Rossi, Genova, Italy

Sp-Block

**Cancellous block for the
inlay technique in the mandible**



Highly osteoconductive properties



Dual-Block

**Cortico-cancellous scaffold for
horizontal augmentation in the maxilla**



Characteristics, handling and clinical indications

free animated videos
on OsteoBiol® APP



CHARACTERISTICS

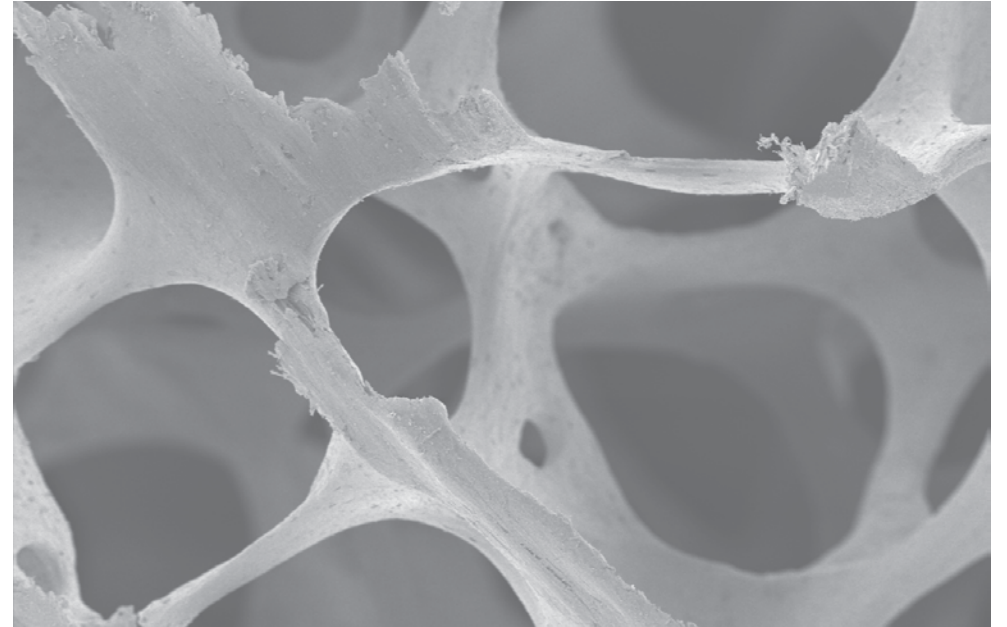
Sp-Block is a cancellous block of xenogenic bone produced with an exclusive Tecnos[®] process which avoids ceramization of the hydroxyapatite crystals, thus accelerating physiological resorption. *Sp-Block* supports new bone formation^(1,2): thanks to its rigid consistency it is able to maintain the original graft volume, which is particularly important in case of large regenerations. Moreover, its collagen content facilitates blood clotting and the subsequent invasion of regenerative and repairing cells, favoring the *restitutio ad integrum* of missing bone.

HANDLING

Sp-Block must be hydrated before use for 5/10 minutes with sterile lukewarm physiological solution or with antibiotics. Afterwards, it can be adapted to the receiving site; the block must always be fixed with osteosynthesis microscrews and should be protected with a resorbable membrane (*Evolution*).

CLINICAL INDICATIONS

Sp-Block is indicated in cases where a vertical gain in posterior mandible is required⁽³⁻⁵⁾, to achieve an augmentation of maximum 5 mm, by means of the inlay technique. It is recommended to fill the gaps around the block with a biomaterial in granules, to stabilize the augmented area with mini-plates and screws and to cover it with an *Evolution* membrane.



SEM image of OsteoBiol® cancellous block

Source: Courtesy of Prof Ulf Nannmark, University of Göteborg, Sweden

Tissue of origin

Cancellous bone

Tissue collagen

Preserved

Physical form

Rigid dried block

Composition

Collagenated cancellous bone

Re-entry time

About 8 months, variable depending on characteristics and irradiation grade of grafting site and on clinical conditions of the patient

Packaging

Sterile blister

Product codes

BNOE | 10x10x10 mm | Equine
BN1E | 10x10x20 mm | Equine
BN2E | 10x20x20 mm | Equine
BN8E | 35x10x5 mm | Equine

GMDN code

38746

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J CRANIO-MAXILLOFAC, 2017 SEP;45(9):1438-1447



VERTICAL AUGMENTATION
inlay technique
case reports on page 90

Additional case reports on osteobiol.com



CHARACTERISTICS

Dual-Block is a cortico-cancellous block of xenogenic bone with osteoconductive characteristics. It can be used when the regeneration of big volumes is needed: thanks to the collagen content that promotes blood clotting and migration of regenerative and repairing cells⁽¹⁾, the graft offers an adequate support for tissue reconstruction and is gradually resorbed, while new bone is produced by osteoblasts.

HANDLING

Dual-Block must be hydrated before use with sterile lukewarm physiological solution or with antibiotics (5/10 minutes for Soft version; up to 40 minutes for Norm version). Afterwards, the block can be adapted to the receiving site which must be accurately decorticated in order to guarantee maximum contact; the block should always be fixed with osteosynthesis microscrews and protected with *Evolution* membrane.

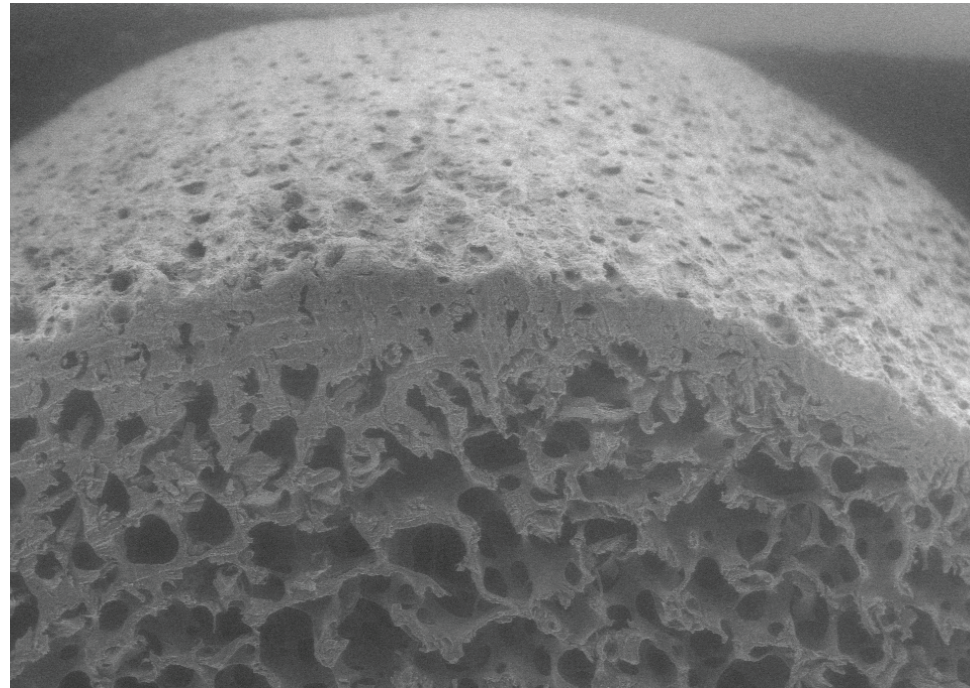
CLINICAL INDICATIONS

Dual-Block can be grafted with the onlay technique only to augment horizontally heavily resorbed maxilla.

It is recommended to fill the gaps around the block with a biomaterial in granules to achieve the desired volume and contour of the augmented recipient site.

BIBLIOGRAPHY

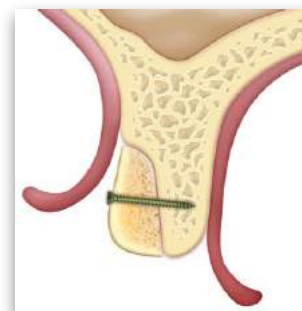
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J PERIODONTAL RES, 2016 Feb;51(1):112-24



SEM image of OsteoBiol® *Dual-Block*
Source: Politecnico di Torino, Italy



OsteoBiol® *Dual-Block*
Source: TecnoSS® Dental Media Library



HORIZONTAL AUGMENTATION
onlay technique
case reports on page 87



Tissue of origin

Cortico-cancellous bone

Tissue collagen

Preserved

Physical form

Rigid dried block

Composition

Collagenated cortico-cancellous bone

Re-entry time

About 8 months, variable depending on characteristics and irradiation grade of grafting site and on clinical conditions of the patient

Packaging

Sterile blister

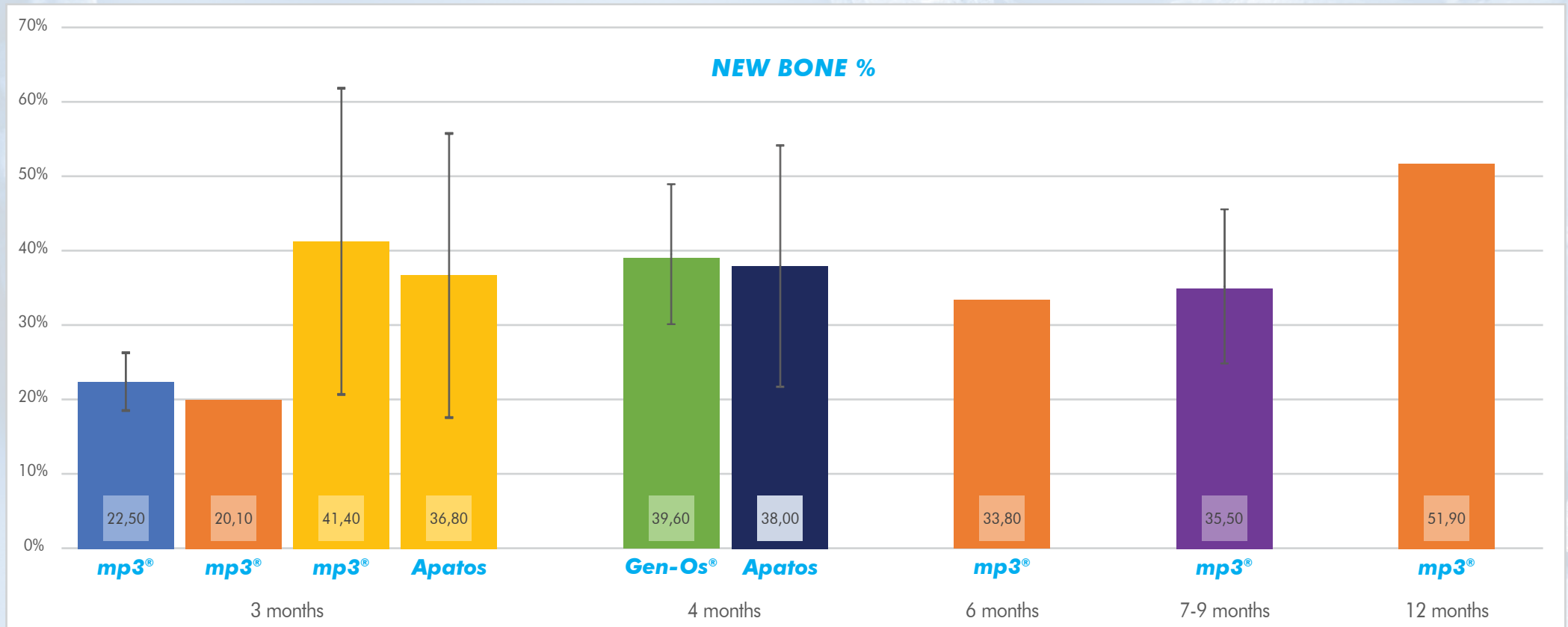
Product codes

ST57S | 20x15x5 mm | Soft | Porcine curved
STN5S | 20x10x5 mm | Norm | Porcine curved

GMDN code

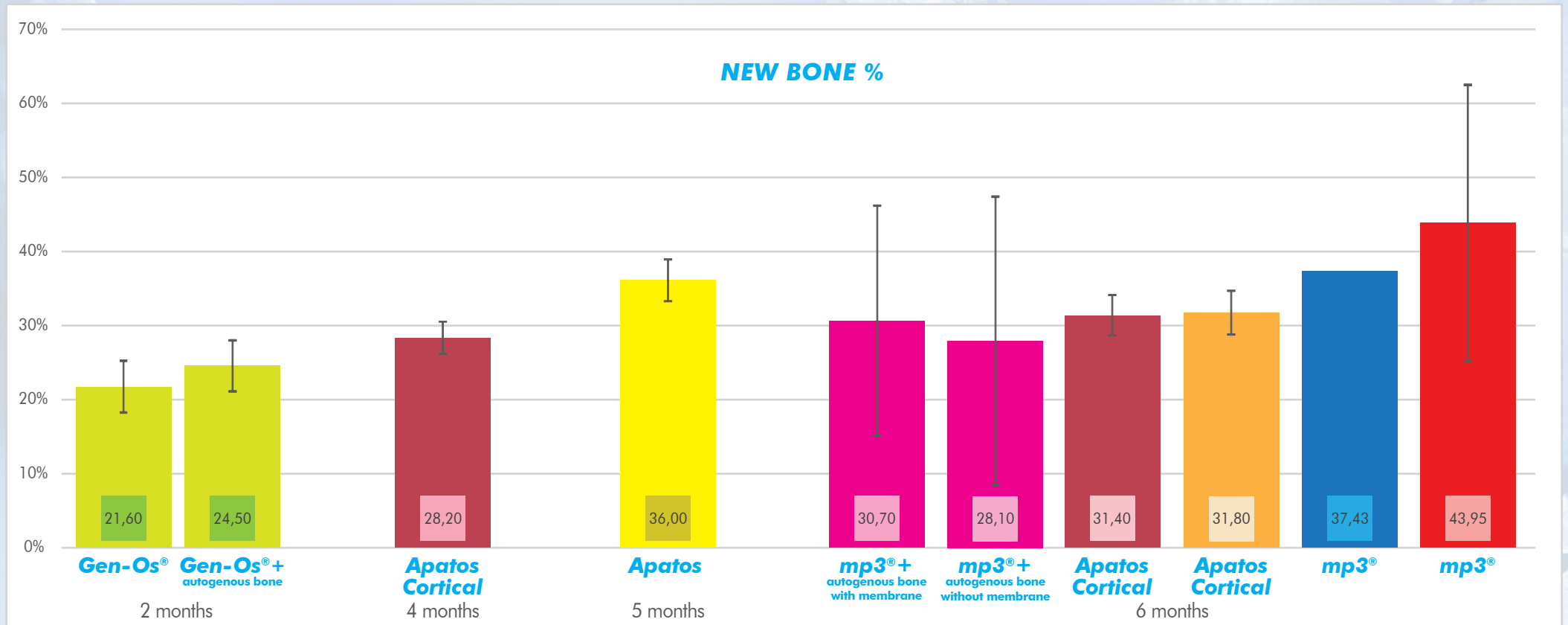
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Key scientific data: histological results in alveolar regeneration



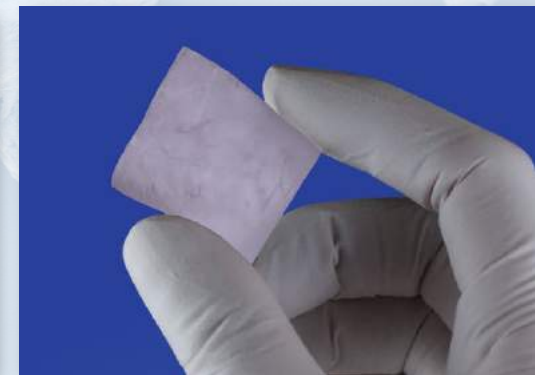
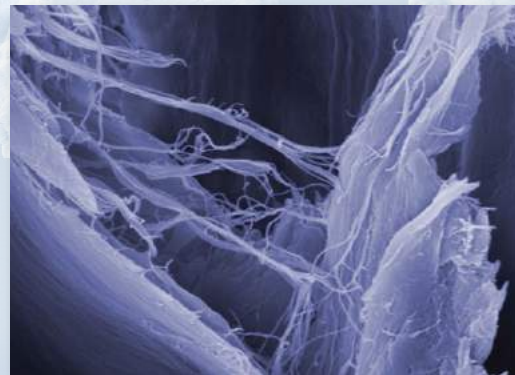
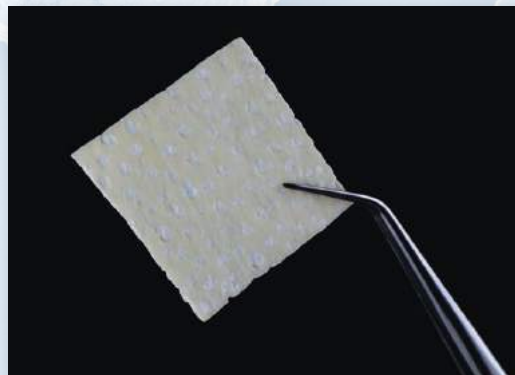
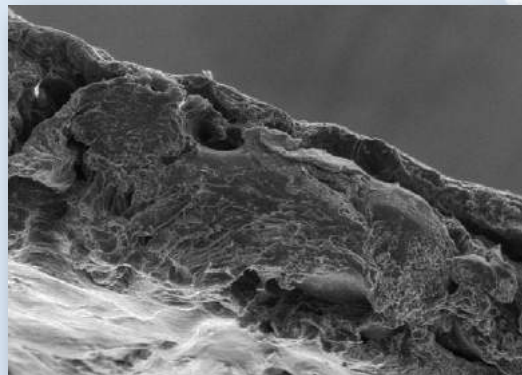
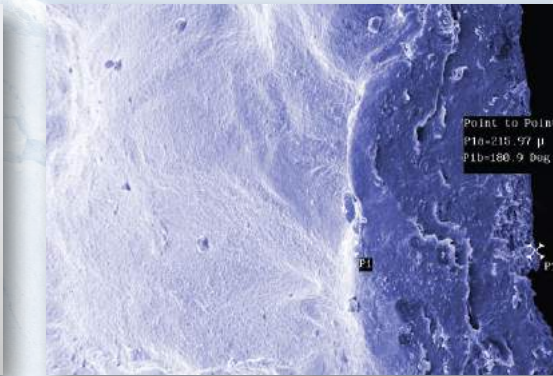
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Clinical Oral Implants Research, 2015 Jul;26(7):806-13
- **B)** Giuliani A et al. - **Regenerative properties of collagenated porcine bone grafts in human maxilla: demonstrative study of the kinetics by synchrotron radiation microtomography and light microscopy**
Clinical Oral Investigations, 2018 Jan;22(1):505-513
- **C)** Barone A et al. - **Clinical and histological changes after ridge preservation with two xenografts: preliminary results from a multicenter randomized controlled clinical trial**
Journal of Clinical Periodontology, 2017 Feb;44(2):204-214
- **E)** Crespi R et al. - **Corticocancellous porcine bone in the healing of human extraction sockets: combining histomorphometry with osteoblast gene expression profiles in vivo**
Int Journal of Oral and Maxillofacial Implants, 2011 Jul - Aug; 26(4):866-72
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- **G)** Barone A et al. - **Xenograft versus extraction alone for ridge preservation after tooth removal: a clinical and histomorphometric study**
Journal of Periodontology, 2008 Aug; 79(8):1370-7

Key scientific data: histological results in sinus lift



- **A)** Cassetta M et al. - **Bone formation in sinus augmentation procedures using autologous bone, porcine bone, and a 50 : 50 mixture: a human clinical and histological evaluation at 2 months**
Clinical Oral Implants Research, 2015 Oct;26(10):1180-4
- **B)** Scarano A et al. - **Maxillary sinus augmentation in humans using cortical porcine bone: a histological and histomorphometrical evaluation after 4 and 6 months**
Clinical Implant Dentistry and Related Research, 2011 Mar; 13(1):13-18
- **C)** Orsini G et al. - **Histologic and ultrastructural analysis of regenerated bone in maxillary sinus augmentation using a porcine bone-derived biomaterial**
Journal of Periodontology, 2006 Dec; 77(12):1984-90
- **D)** Barone A et al. - **A 6-month histological analysis on maxillary sinus augmentation with and without use of collagen membranes over the osteotomy window: randomized clinical trial**
Clinical Oral Implants Research, 2013 Jan; 24(1):1-6
- **E)** Iezzi G et al. - **Comparative histological results of different biomaterials used in sinus augmentation procedures: a human study at 6 months**
Clinical Oral Implants Research, 2012 Dec;23(12):1369-76
- **F)** Silvestri M et al. - **Simultaneous sinus augmentation with implant placement: histomorphometric comparison of two different grafting materials. A multicenter double-blind prospective randomized controlled clinical trial**
Int Journal of Oral and Maxillofacial Implants, 2013 Mar-Apr; 28(2):543-9
- **G)** Barone A et al. - **Maxillary sinus augmentation using prehydrated corticocancellous porcine bone: histomorphometric evaluation after 6 months**
Clinical Implant Dentistry and Related Research, 2012 Jun;14(3):373-9

MEMBRANES AND BARRIERS



OsteoBiol® membranes and barriers

MEMBRANES

BARRIERS

Evolution

Heterologous mesenchymal tissue



Dried membrane with one smooth side and one micro-rough side



Periodontal defect covered with OsteoBiol® Evolution
Source: Courtesy of Dr Roberto Rossi, Genova, Italy
For more information on OsteoBiol® Evolution see page 58

Derma

Porcine derma



Dried membrane



Soft tissue augmentation with OsteoBiol® Derma
Source: Courtesy of Dr Stefan Fickl, Würzburg, Germany
For more information on OsteoBiol® Derma see page 62

Special

Heterologous pericardium



Translucent dried membrane



OsteoBiol® Special protecting the Schneider membrane before grafting
Source: Courtesy of Dr Donato Frattini, Legnano, Italy
For more information on OsteoBiol® Special see page 70

Duo-Teck

Lyophilised equine collagen felt + bone



Dried membrane covered with micronized bone



OsteoBiol® Duo-Teck grafted
Source: Courtesy of Dr Atef Ismail Mohamed, Cairo, Egypt
For more information on OsteoBiol® Duo-Teck see page 70

Lamina

Cortical bone

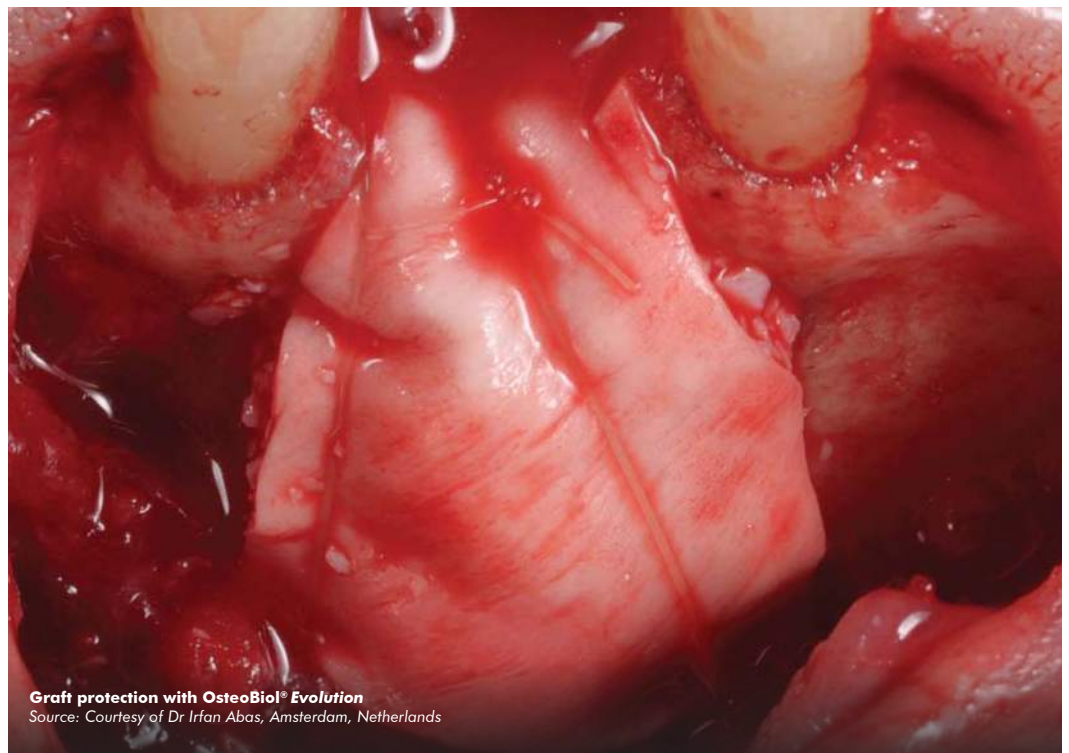
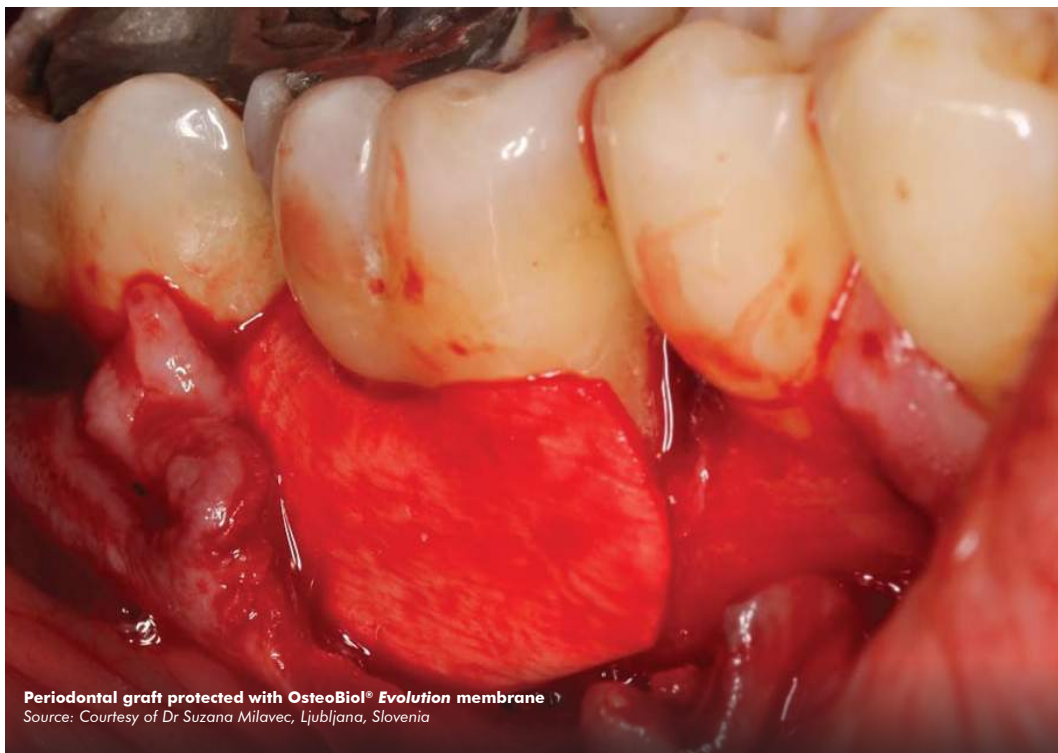
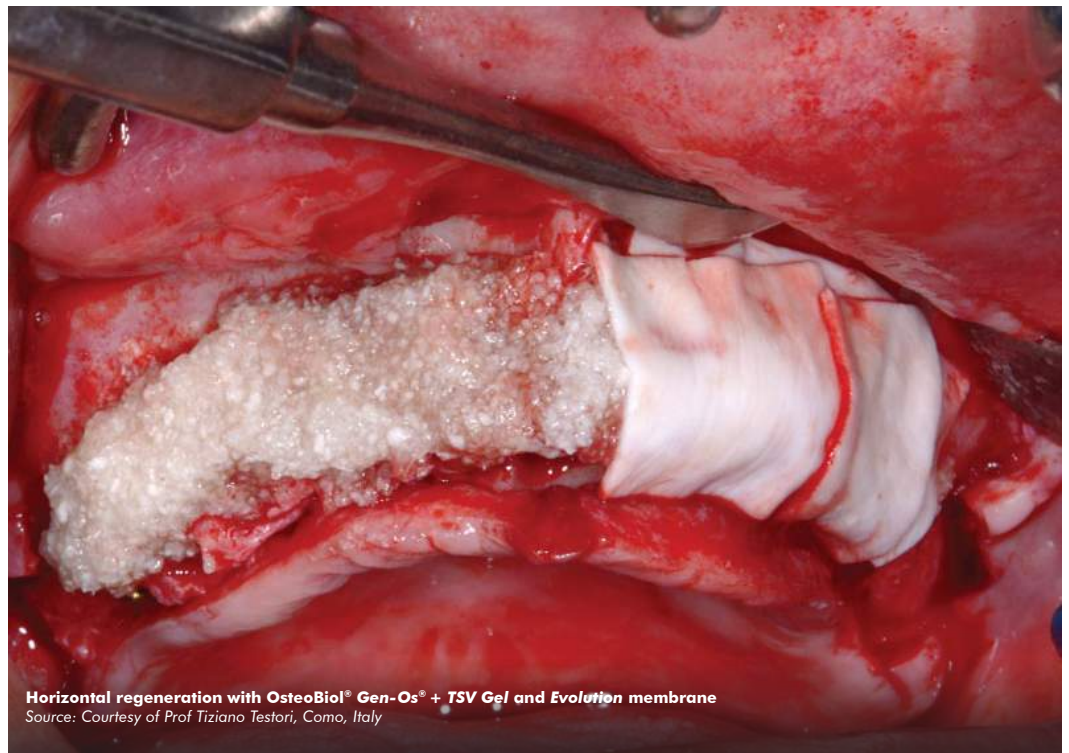
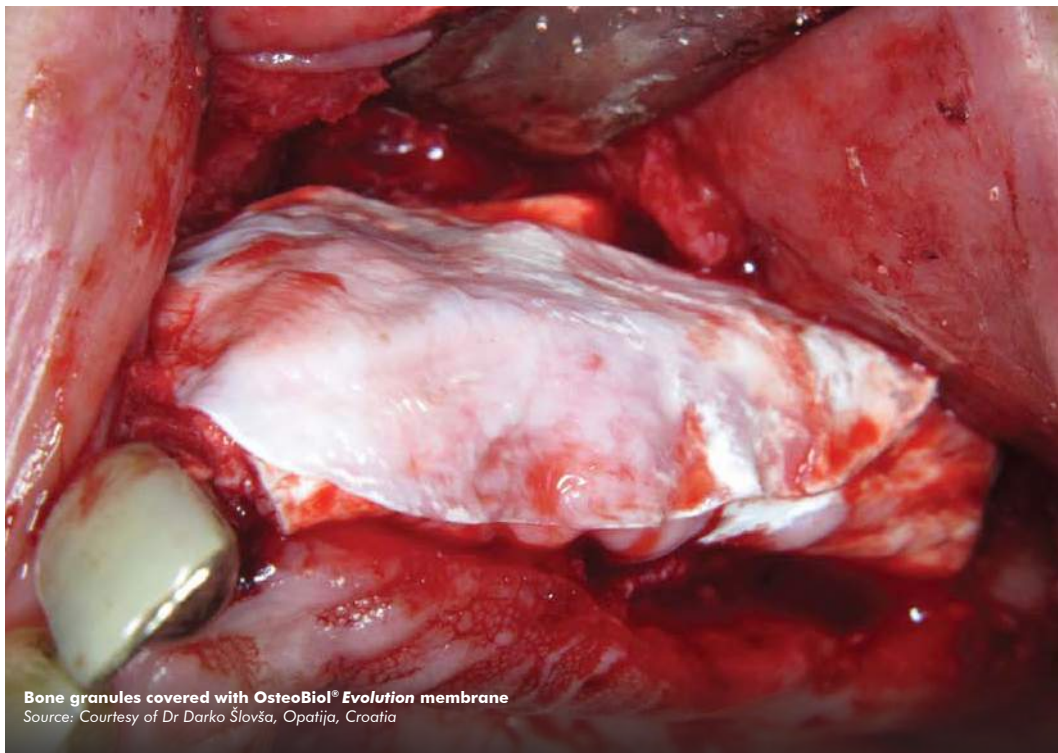


Semi-rigid dried lamina, flexible after re-hydration

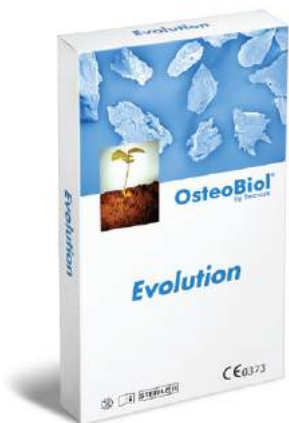


OsteoBiol® Lamina for the covering of a horizontally augmented area
Source: Courtesy of Prof Dr Hannes Wachtel and Dr Tobias Thalmeier, Munich, Germany
For more information on OsteoBiol® Lamina see page 66

SEM image showing collagenic matrix of OsteoBiol® membranes
Source: Courtesy of Nobil Bio Ricerche, Villafranca d'Asti, Italy



Evolution



The natural Evolution of collagen membranes
Heterologous mesenchymal tissue

Characteristics and handling



Tissue of origin

Heterologous mesenchymal tissue

Tissue collagen

Preserved

Physical form

Dried membrane with one smooth side and one micro-rough side

Thickness

X-Fine: 0.2 mm (± 0.1 mm)

Fine: 0.3 mm (± 0.1 mm)

Standard: 0.5 mm (± 0.1 mm)

Estimated resorption time

X-Fine: about 2 months

Fine: about 3 months

Standard: about 4 months

Size

20x20 mm, 30x30 mm, 25x35 mm (oval), 40x40 mm, 80x60 mm

Product codes

EM02XS	20x20 mm	X-Fine	Porcine
EM03XS	30x30 mm	X-Fine	Porcine
EV02LLE	20x20 mm	Fine	Equine
EV03LLE	30x30 mm	Fine	Equine
EVOLLE	25x35 mm (oval)	Fine	Equine
EV04LLE	40x40 mm	Fine	Equine
EV06LLE	80x60 mm	Fine	Equine
EV02HHE	20x20 mm	Standard	Equine
EM02HS	20x20 mm	Standard	Porcine
EV03HHE	30x30 mm	Standard	Equine
EM03HS	30x30 mm	Standard	Porcine
EM00HS	25x35 mm (oval)	Standard	Porcine

GMDN code

38746

CHARACTERISTICS

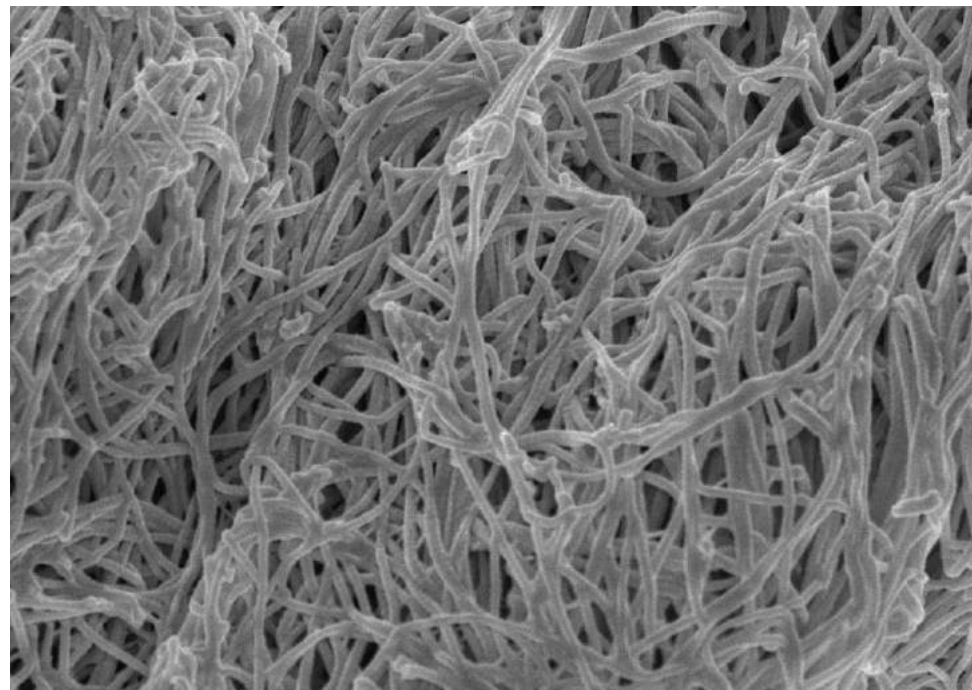
Obtained from heterologous mesenchymal tissue, the *Evolution* membrane is gradually resorbable⁽¹⁾. Its structure is made of dense collagen fibers of high consistency and of extraordinary resistance that offer the specialist surgeon:

- maximum adaptability to bone tissue and soft tissues
- easy and secure suturability to nearby tissues
- best membrane-bone and membrane-periosteum interface
- stability and prolonged protection of the underlying graft
- clot stabilization and isolation⁽²⁾

HANDLING

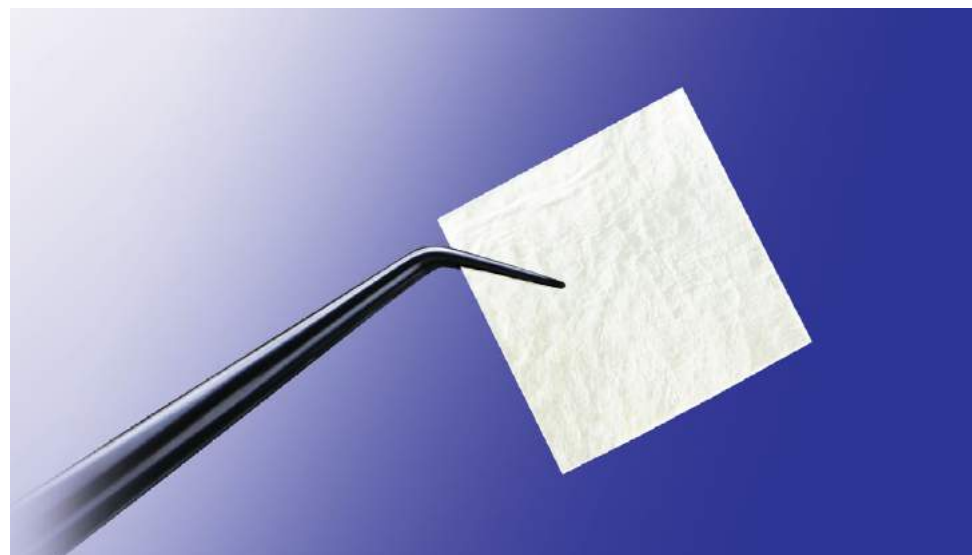
The membrane can be shaped with sterile scissors until the desired size is reached; unless the grafting site is already bleeding, the membrane should be rehydrated with lukewarm physiological solution. Once it acquires the desired plasticity, it must be adapted to the grafting site.

NB: in case of accidental exposure, the dense collagenic matrix of *Evolution* protects the graft from infection; the membrane itself will also not be infected, allowing second intention healing⁽³⁻⁵⁾.



SEM image of an OsteoBiol® Evolution standard membrane

Source: Politecnico di Torino, Italy



Source: Tecoss® Dental Media Library



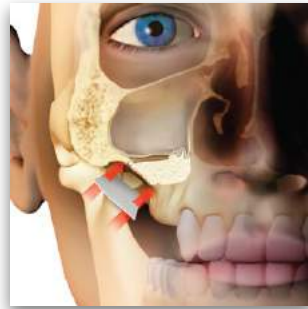
Evolution is obtained from heterologous mesenchymal tissue and is completely resorbable. Experimental studies have shown histological evidence of the prolonged barrier effect of this membrane, which lasts at least eight weeks⁽¹⁾, protecting the graft from external agents.

This property is particularly important in case of flapless regeneration⁽³⁾ of large posterior sockets⁽⁵⁾: in these cases, the standard model is recommended.

In lateral access sinus lift *Evolution* membranes are indicated to cover antrostomy (standard model)^(6,7) and to protect the sinus membrane from cutting risk due to graft pressure (fine model)⁽⁸⁾.

Evolution is also ideal to protect peri-implant regenerations⁽⁹⁾ and periodontal grafts. Furthermore, *Evolution* fine has been successfully used for the treatment periodontal defects⁽¹⁰⁾ and to protect *Sp-Block* in vertical augmentation with inlay technique⁽¹¹⁾.

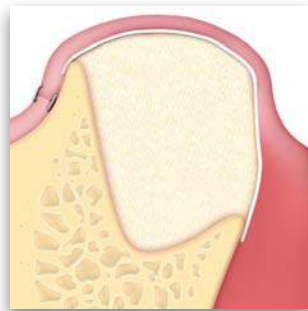
In oral surgery and traumatology, *Evolution* is always recommended in case of large regeneration with risks of exposure.



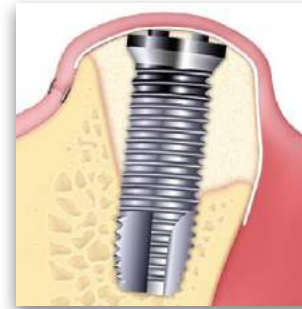
LATERAL ACCESS SINUS LIFT
maxillary sinus floor augmentation
case reports on page 84



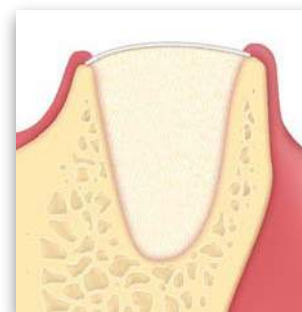
PERIODONTAL REGENERATION
intra-bony defects
case reports on page 92



HORIZONTAL AUGMENTATION
two-wall defects
case reports on page 87



DEHISCENCES AND FENESTRATIONS
peri-implant lesions
case reports on page 80



ALVEOLAR REGENERATION
graft protection
case reports on page 77



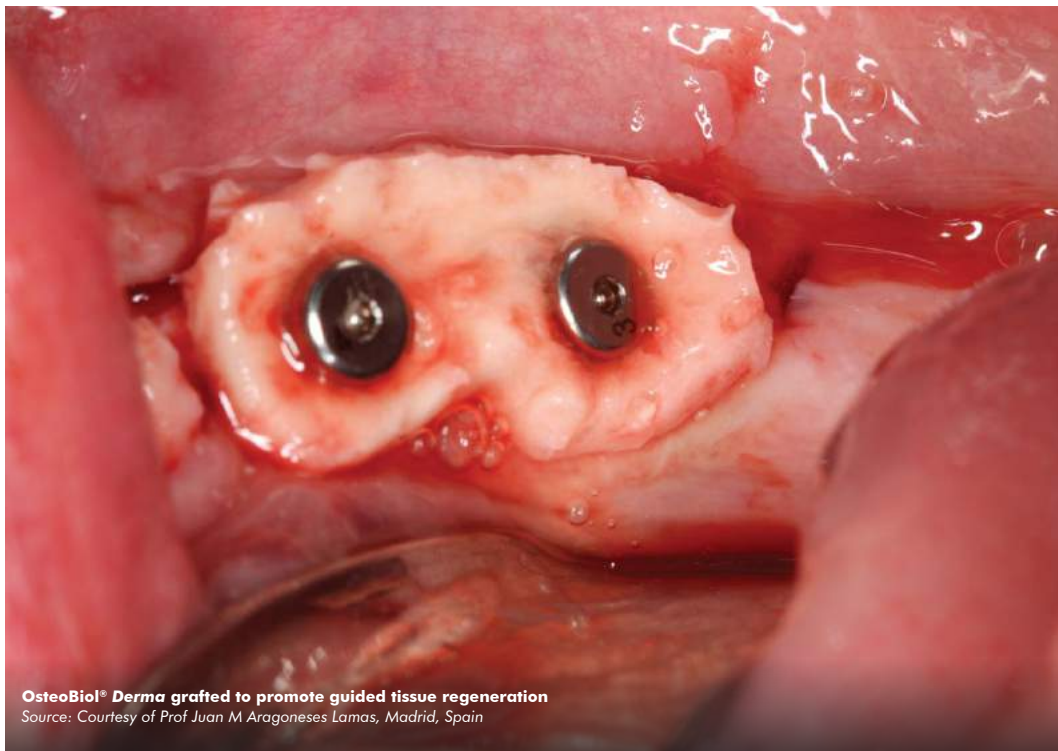
VERTICAL AUGMENTATION
inlay technique
case reports on page 90

Additional case reports on osteobiol.com

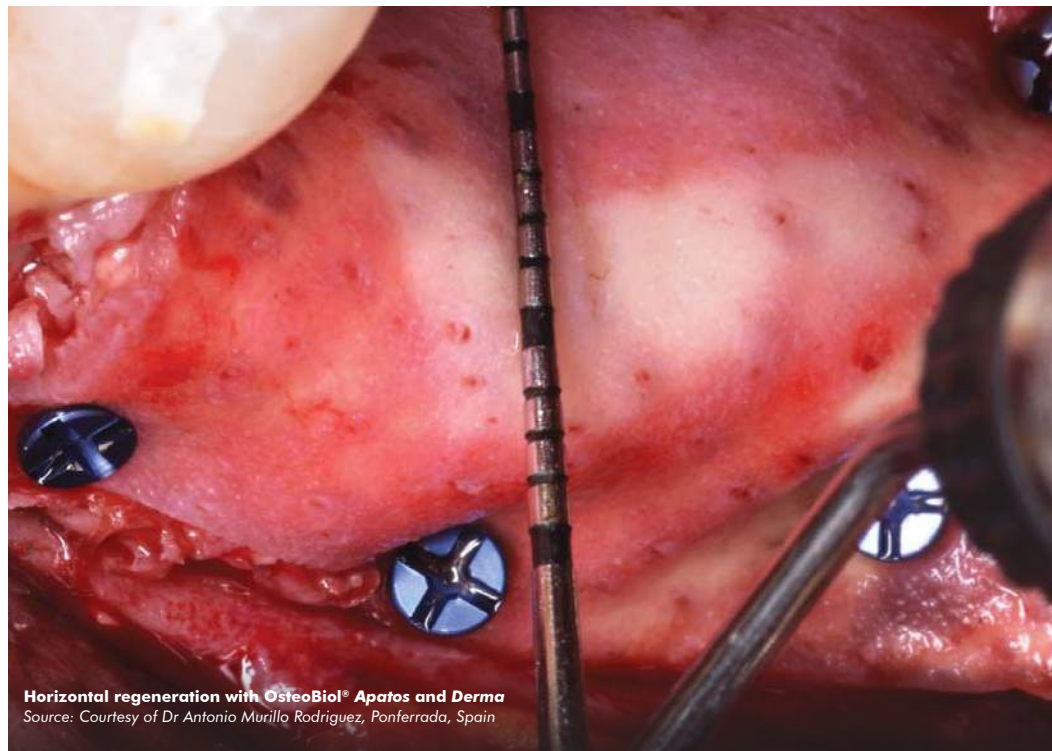
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MAXILLARY SINUS AUGMENTATION IN HUMANS USING CORTICAL PORCINE BONE: A HISTOLOGICAL AND HISTOMORPHOMETRIC EVALUATION AFTER 4 AND 6 MONTHS
CLIN IMPLANT DENT RELAT RES, 2011 MAR; 13(1):13-18
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VERTICAL RIDGE AUGMENTATION OF ATROPHIC POSTERIOR MANDIBLE WITH AN INLAY TECHNIQUE AND CANCELLOUS EQUINE BONE BLOCK: A CASE REPORT
INT J PERIODONTICS RESTORATIVE DENT, 2013 MAR;33(2):159-66

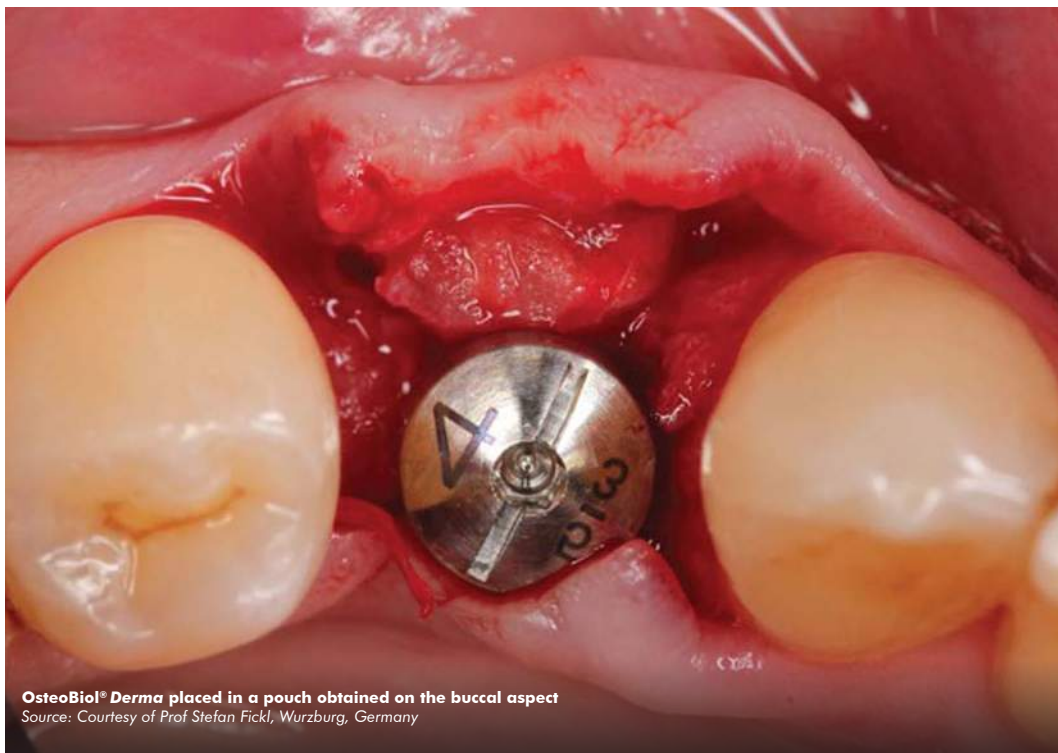
For further information see the complete literature on p. 114



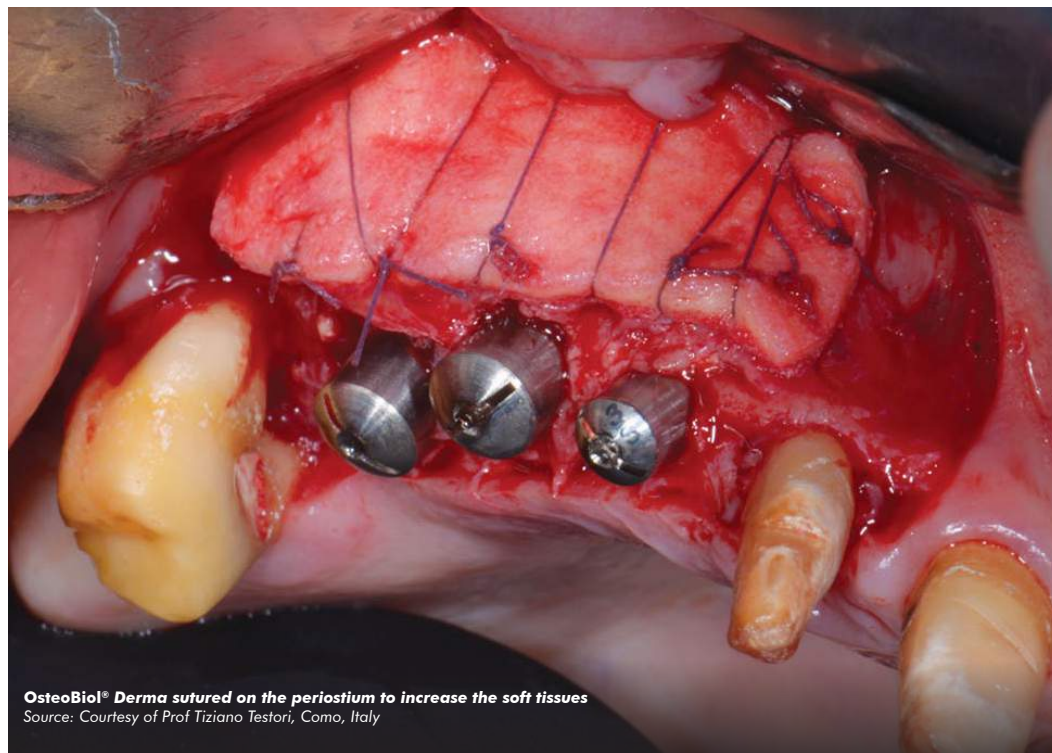
OsteoBiol® Derma grafted to promote guided tissue regeneration
Source: Courtesy of Prof Juan M Aragonese Lamas, Madrid, Spain



Horizontal regeneration with OsteoBiol® Apatos and Derma
Source: Courtesy of Dr Antonio Murillo Rodriguez, Ponferrada, Spain

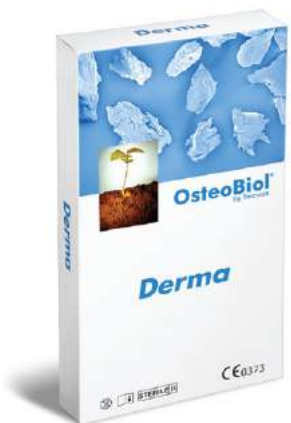


OsteoBiol® Derma placed in a pouch obtained on the buccal aspect
Source: Courtesy of Prof Stefan Fickl, Würzburg, Germany



OsteoBiol® Derma sutured on the periostium to increase the soft tissues
Source: Courtesy of Prof Tiziano Testori, Como, Italy

Derma



A xenogenic graft for soft tissue augmentation
Collagen dermal matrix

Characteristics and handling



Tissue of origin

Porcine derma

Tissue collagen

Preserved

Physical form

Dried membrane

Composition

100% derma

Thickness

X-Fine: 0.6 mm (± 0.1 mm)

Fine: 0.9 mm (± 0.1 mm)

Standard: 2.0 mm (± 0.2 mm)

Estimated resorption time

X-Fine: about 1 month

Fine: about 3 months

Standard: about 5 months

Size

X-Fine: 20x20 mm

Fine: 25x25 mm, 12x8 mm, 50x50 mm

Standard: 15x5 mm, 30x30 mm, 50x50 mm

Product codes

ED02LS | 20x20 mm | X-Fine | Porcine

ED21FS | 12x8 mm | Fine | Porcine

ED25FS | 25x25 mm | Fine | Porcine

ED05FS | 50x50 mm | Fine | Porcine

ED03SS | 30x30 mm | Standard | Porcine

ED15SS | 15x5 mm | Standard | Porcine

ED05SS | 50x50 mm | Standard | Porcine

GMDN code

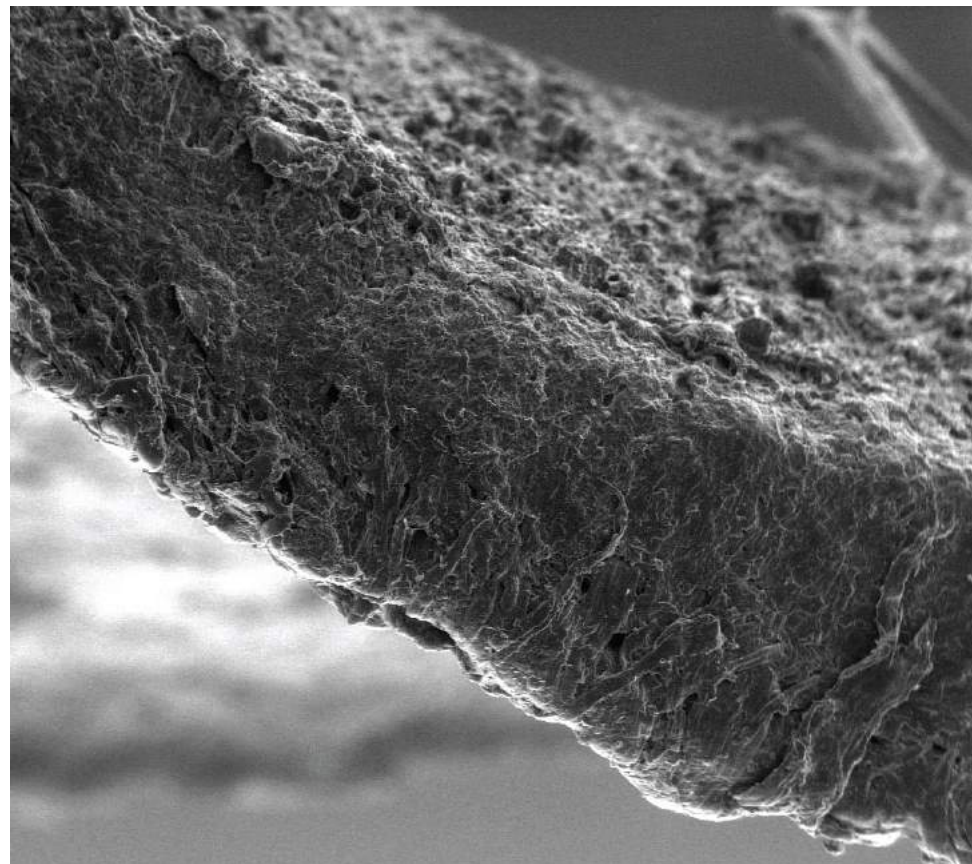
38746

CHARACTERISTICS

Obtained from derma of porcine origin, using an exclusive Tecnos[®] process that preserves the natural collagen fibers⁽¹⁾, *Derma* membranes are gradually integrated⁽²⁾ with the autologous soft tissues. Their strong consistency and resistance allow a perfect stabilization and a prolonged protection of underlying graft⁽³⁾ in socket regeneration procedures, together with a strong barrier action to guide the growth of epithelium and preventing its invagination.

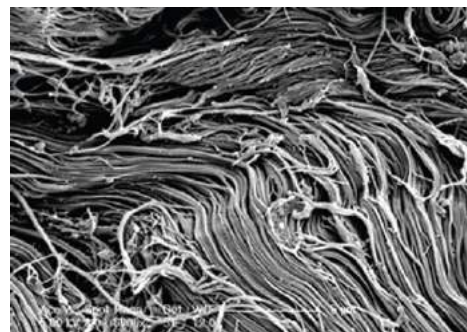
HANDLING

Derma membrane can be shaped with scissors until the desired size is reached; then it must be thoroughly hydrated in sterile lukewarm physiological solution until the desired consistency is obtained. Once it acquires the desired plasticity, it must be adapted to the grafting site. It is always recommendable to prepare a pocket with an elevator in order to stabilize the membrane in the site after stitching the flaps.



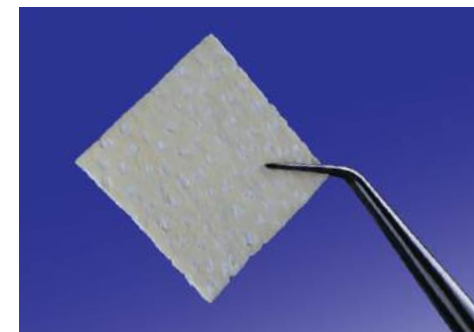
SEM image of OsteoBiol[®] *Derma*

Source: Politecnico di Torino, Italy



SEM image of *Derma* collagen fibers

Source: Courtesy of Dr Kai R. Fischer, Wurzburg, Germany



Source: Tecnos[®] Dental Media Library

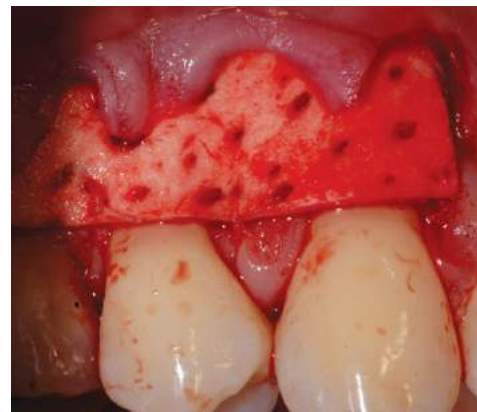
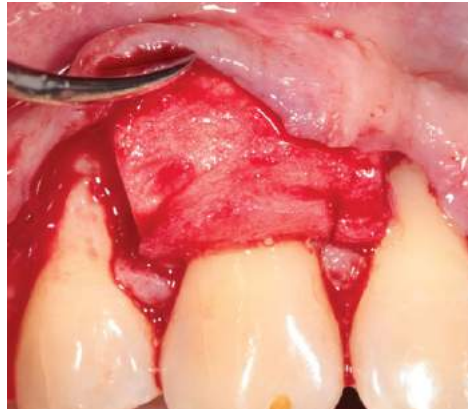
Clinical Indications

Derma membrane is a collagen resorbable barrier useful to protect and stabilize bone grafting materials; only in this specific indication it can be used also in open healing⁽³⁾ situations due to its perfect tissue integration characteristics.

If a residual band of keratinized tissue is still present around teeth or implants, *Derma* membrane can be used as an alternative to connective tissue graft⁽²⁾ to improve the quality of keratinized tissues⁽⁴⁾.

Mild gingival recessions⁽⁵⁾ can be treated with *Derma* to avoid patient morbidity and discomfort due to connective tissue graft harvesting. It is recommended to leave *Derma* membrane completely covered by the coronally advanced flap and to avoid membrane exposure. A properly shaped *Derma* membrane with rounded edges is also indicated for the tunnel technique⁽⁵⁾.

In oral surgery and traumatology *Derma* is indicated in the stabilization and protection of large regeneration with risks of exposure.



OsteoBiol® *Derma* shaped for a gingival recession treatment
Source: Courtesy of Dr Roberto Rossi, Genova, Italy

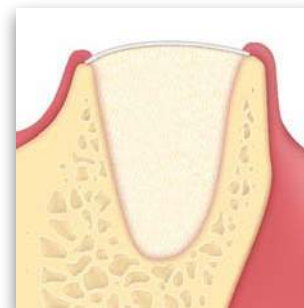
Gingival recession treated with OsteoBiol® *Derma*
Source: Courtesy of Dr Domenico Patarino, Varese, Italy



SOFT TISSUE AUGMENTATION
soft tissue improvement
case reports on page 94



PERIODONTAL REGENERATION
gingival recessions
case reports on page 92



ALVEOLAR REGENERATION
graft protection
case reports on page 77

Additional case reports on osteobiol.com

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BIOMED MATER, 2017 SEP 13;12(5):055005

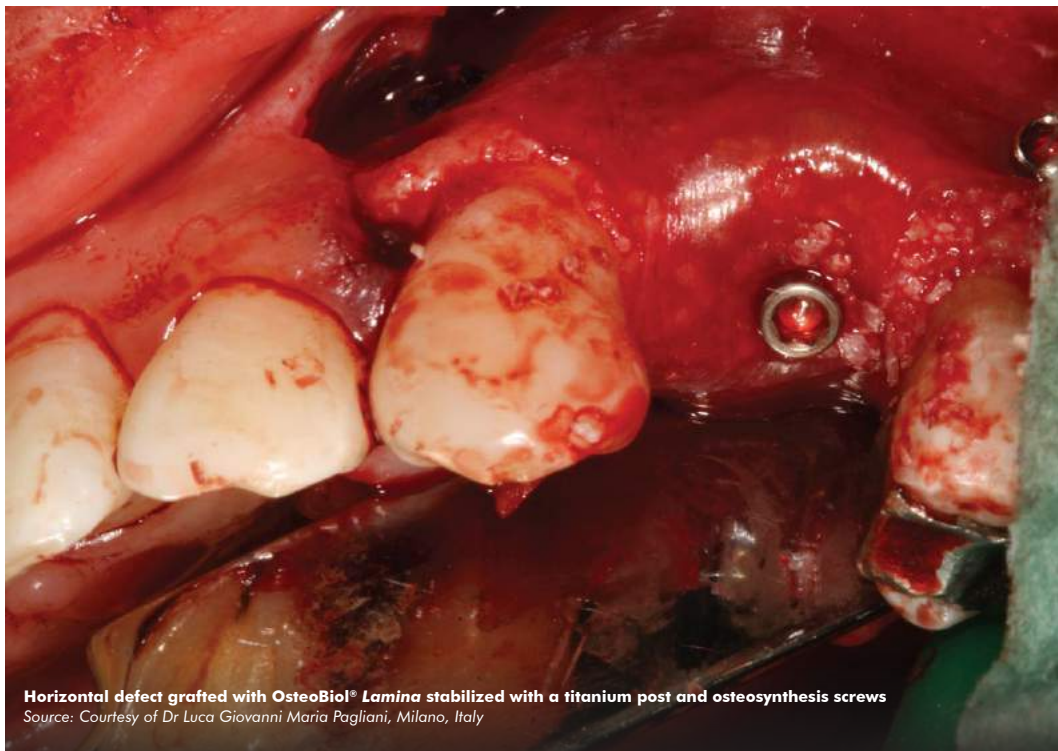
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PORCINE DERMAL MATRIX IN THE TREATMENT OF DEHISCENCE-TYPE DEFECTS – AN EXPERIMENTAL SPLIT-MOUTH ANIMAL TRIAL
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EUR J ORAL IMPLANTOL, 2016;9(3):263-275

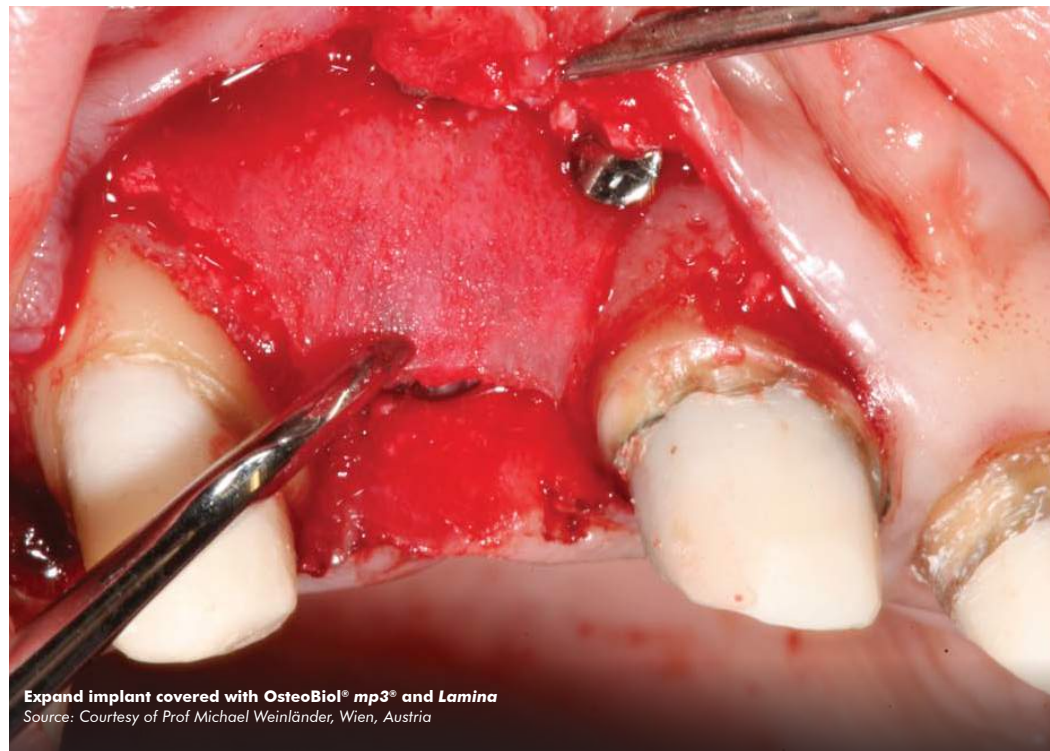
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QUINTESSENCE INT, 2014 NOV-DEC;45(10):853-60

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PORCINE DERMAL MATRIX FOR COVERING OF RECESSION TYPE DEFECTS: A CASE SERIES
QUINTESSENCE INT, 2013;44(3):243-6

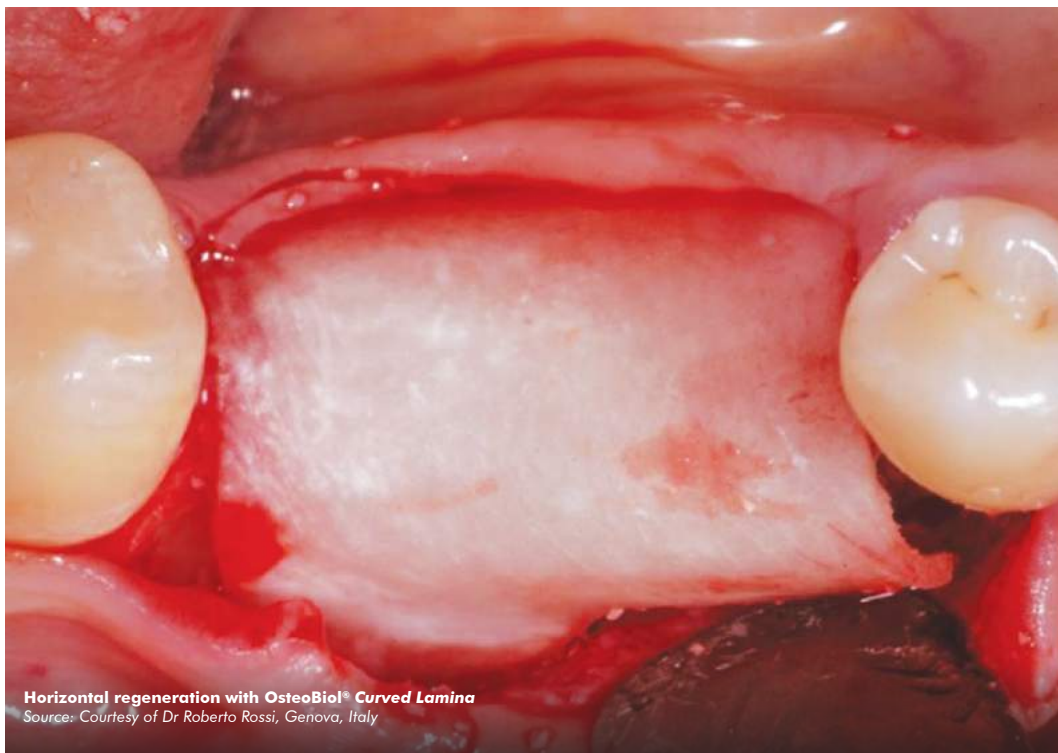
For further information see the complete literature on p. 114



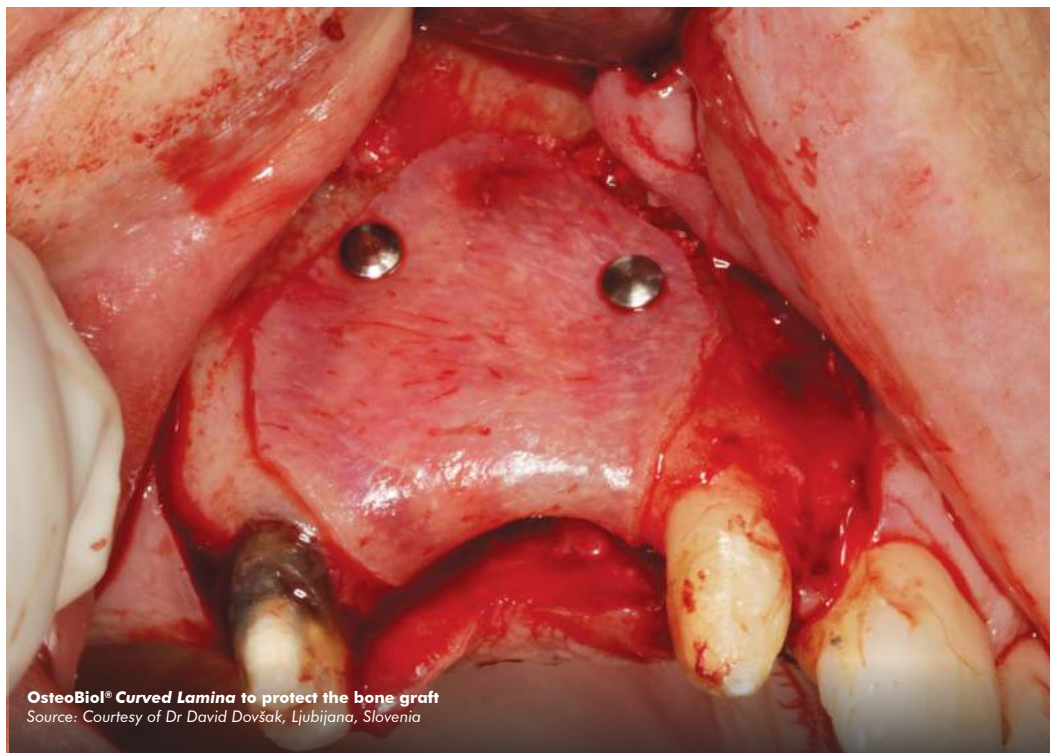
Horizontal defect grafted with OsteoBioL® Lamina stabilized with a titanium post and osteosynthesis screws
Source: Courtesy of Dr Luca Giovanni Maria Pagliani, Milano, Italy



Expand implant covered with OsteoBioL® mp3® and Lamina
Source: Courtesy of Prof Michael Weinländer, Wien, Austria

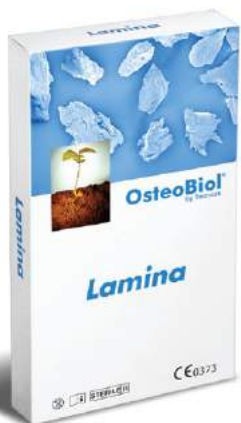


Horizontal regeneration with OsteoBioL® Curved Lamina
Source: Courtesy of Dr Roberto Rossi, Genova, Italy



OsteoBioL® Curved Lamina to protect the bone graft
Source: Courtesy of Dr David Dovšak, Ljubijana, Slovenia

Lamina



A unique cortical bone barrier
Heterologous collagenated cortical bone

Characteristics and handling



Tissue of origin

Cortical bone

Tissue collagen

Preserved

Physical form

Lamina: Semi-rigid dried lamina, flexible after re-hydration
Semi Soft Lamina: Rigid dried lamina, flexible after re-hydration

Composition

100% cortical bone

Thickness

Fine: 0.5 mm (± 0.1 mm)
Medium: 1.0 mm (± 0.1 mm)
Semi Soft: 1.0 mm (± 0.1 mm)
Standard: 3.0 mm (± 1 mm)

Estimated re-entry time

Fine: about 5 months
Medium: about 6 months
Semi Soft: about 8 months
Standard: about 8 months

Size

Fine: 25x25 mm, 25x35 mm (oval)
Medium: 35x35 mm (Curved), 20x40 mm
Semi Soft: 35x35 mm
Standard: 30x30 mm

Product codes

LS25FS | 25x25 mm | Fine | Porcine
LS25FE | 25x25 mm | Fine | Equine
LS23FS | 25x35 mm (Oval) | Fine | Porcine
LS23FE | 25x35 mm (Oval) | Fine | Equine
LS10HS | 35x35 mm (Curved) | Medium | Porcine
LS10HE | 35x35 mm (Curved) | Medium | Equine
LS35LS | 35x35 mm (Semi Soft) | Medium | Porcine
LS35LE | 35x35 mm (Semi Soft) | Medium | Equine
LS24LS | 20x40 mm | Medium | Porcine
LS03SS | 30x30 mm | Standard | Porcine

GMDN code

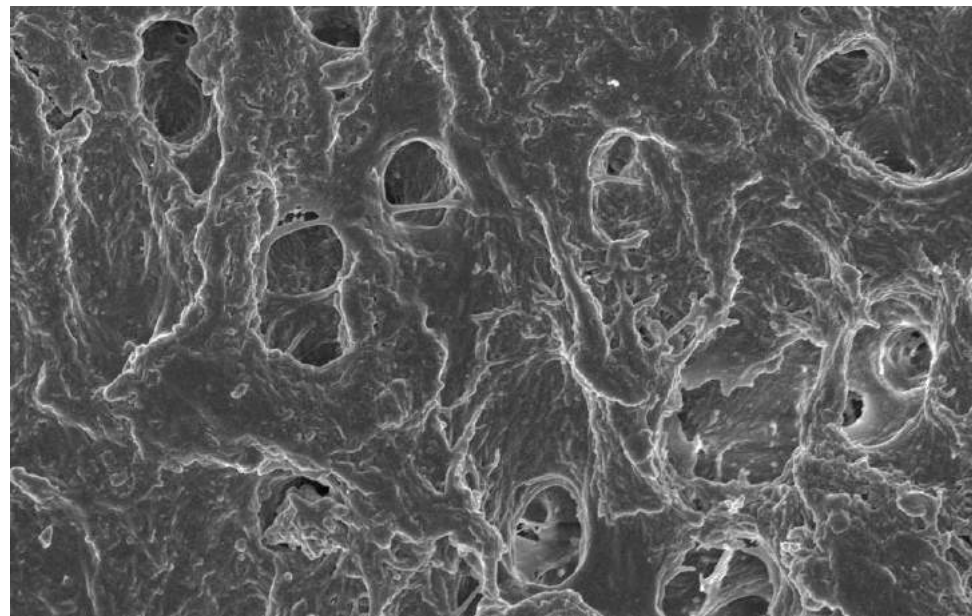
38746

CHARACTERISTICS

Lamina is made of cortical bone of heterologous origin produced with an exclusive TecnoSS® process that avoids the ceramization of hydroxyapatite crystals, thus allowing physiological resorption. After a process of superficial decalcification, it acquires an elastic consistency, nevertheless maintaining the typical compactness of the bone tissue from which it originates; the margins are soft in order not to cause micro traumas to the surrounding tissues. Curved Lamina has a semi-rigid consistency and can be grafted without hydration, provided that it is previously shaped to fit the defect morphology. Semi Soft Lamina undergoes a process of superficial semi-decalcification (50% vs Lamina) therefore increasing its consistency, typical of the cortical bone tissue.

HANDLING

Lamina can be shaped with sterile scissors until the desired size is reached, then it must be hydrated for 5/10 minutes in sterile physiological solution. Once it acquires the desired plasticity, it must be adapted to the grafting site; it should always be immobilized either with titanium microscrews or sutured (fine model) directly to the surrounding tissues with a triangular section non-traumatic needle. Curved Lamina should not be hydrated in order to maintain its tenting effect but can also be shaped with sterile scissors, and must be fixated with osteosynthesis screws. In case of exposure, Lamina should only be removed if there is a clear suprainfection, because its consistency is such as to allow it to achieve a complete second intention healing of the wound.



SEM image of OsteoBioLamina

Source: Politecnico di Torino, Italy



Source: TecnoSS® Dental Media Library

Clinical Indications

Lamina becomes flexible after hydration and can be shaped⁽¹⁾ and adapted to the defect morphology creating, once fixated with osteosynthesis screws, a semi-rigid covering to the underlying graft⁽²⁻⁴⁾. This property is particularly useful when it is necessary to obtain a space making effect in aesthetic areas, as well as in horizontal augmentation^(4,5) of two wall defects and anrostomy covering in lateral access sinus lift procedures^(3,6). *Lamina* can also be used in regenerations with risks of exposure. *Curved Lamina* has a 0.8-1.0 mm thickness and can be directly grafted without hydration⁽⁷⁾; it is particularly indicated in association with *mp3*[®] for regeneration of ridges with compromised cortical plate⁽¹⁾.

Semi Soft Lamina is indicated for orbital floor and wall reconstruction⁽⁸⁻¹⁰⁾ after trauma in non-load-bearing indications, unless used in combination with appropriate osteosynthesis fixation.

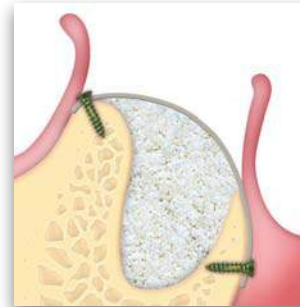


OsteoBiol[®] Lamina positioning
Source: Tecnos[®] Dental Media Library



Bone Layer technique with OsteoBiol[®] Lamina
Source: Courtesy of Dr Michele Antonio Lopez, Rome, Italy

free animated videos
on OsteoBiol[®] APP



HORIZONTAL AUGMENTATION
two-wall defects
case reports on page 87



HORIZONTAL AUGMENTATION
bone-layer technique



ORBITAL FLOOR RESTORATION

BIBLIOGRAPHY

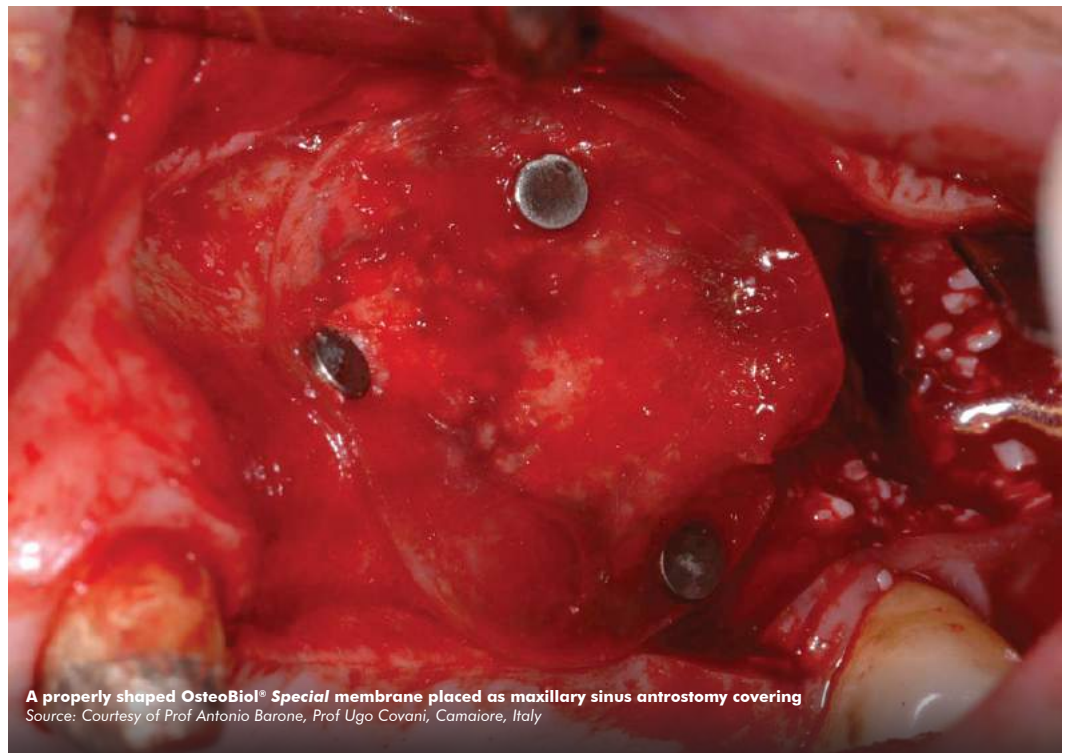
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Additional case reports on osteobiol.com

For further information see the complete literature on p. 114



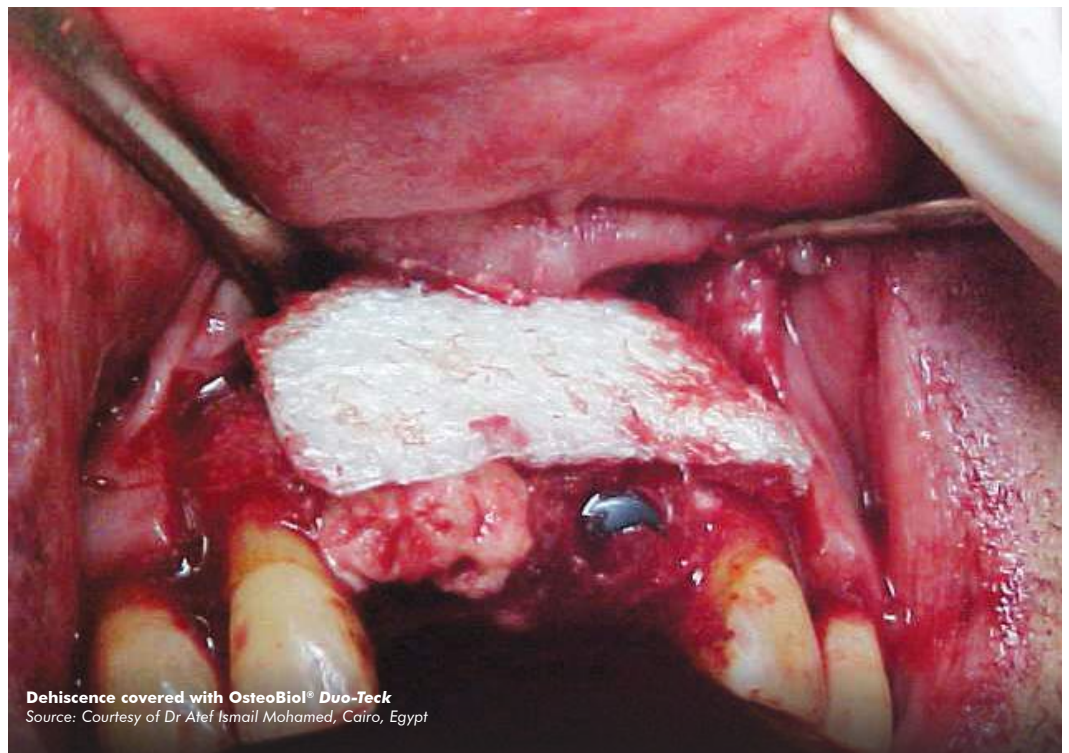
OsteoBiol® Special protecting the Schneider membrane before grafting
Source: Courtesy of Dr Donato Frattini, Legnano, Italy



A properly shaped OsteoBiol® Special membrane placed as maxillary sinus antrostomy covering
Source: Courtesy of Prof Antonio Barone, Prof Ugo Covani, Camaiore, Italy



Maxillary sinus lift filled with OsteoBiol® Gen-Os® and antrostomy covering with OsteoBiol® Duo-Teck
Source: Courtesy of Dr Antonio Murillo Rodriguez, Ponferrada, Spain



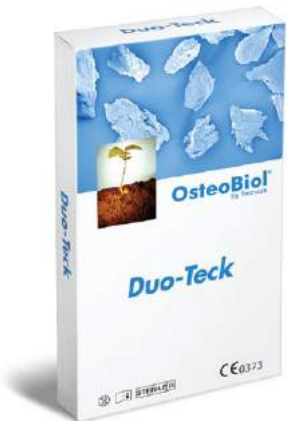
Dehiscence covered with OsteoBiol® Duo-Teck
Source: Courtesy of Dr Atef Ismail Mohamed, Cairo, Egypt

Special

A translucent membrane to separate bone and soft tissues



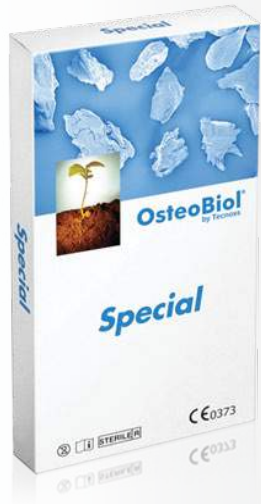
Engineered to protect hard and soft tissue grafts



Duo-Teck

Collagen felt

Characteristics, handling and clinical indications



Tissue of origin

Heterologous pericardium

Tissue collagen

Preserved

Physical form

Translucent dried membrane

Composition

100% pericardium

Thickness

Extra-fine: 0.2 mm

Resorption time

About 40 days

Size

20x20 mm, 30x30 mm

Product codes

EM02LE | 20x20 mm | Equine
EM03LE | 30x30 mm | Equine

GMDN code

38746

CHARACTERISTICS

Obtained from extra fine pericardium of heterologous origin, using an exclusive Tecross® process, the dried *Special* membranes are completely resorbable. Once hydrated, they become translucent and flexible, guiding the growth of epithelium and preventing its invagination: their action favors therefore an optimal regeneration of the underlying bone tissue.

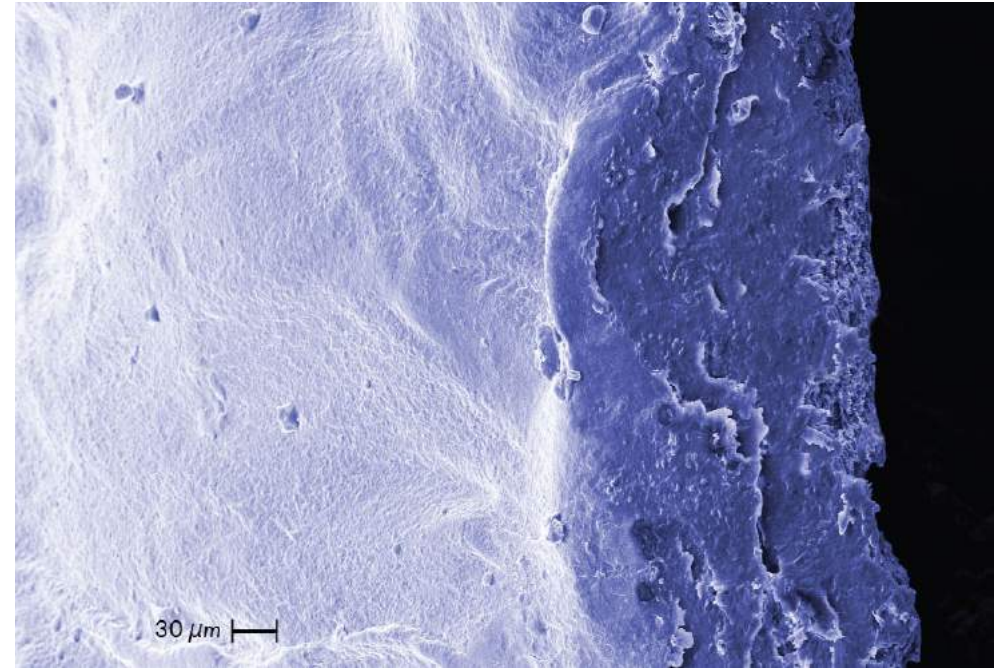
HANDLING

The membrane can be shaped with sterile scissors until the desired size is reached; it must then be rehydrated with lukewarm physiological solution. Once it acquires the desired plasticity, it must be adapted to the grafting site. It is recommended to prepare a pocket with an elevator in order to stabilize the membrane in the site after stitching the flaps. If this is not possible, the membrane can be stabilized with envelope sutures which bridle it with the gingival flaps.

CLINICAL INDICATIONS

In periodontology, the *Special* membrane can be used as a separator of bone and soft tissues in treatment of gingival recessions.

Special can be used to protect the sinus membrane before the insertion of the grafting material, to close sinus membrane perforations. Grafts placed in post-extractive sockets with closed healing procedure can also be protected with this membrane.



SEM images of OsteoBiol® Special

Source: Courtesy of Nobil Bio Ricerche, Villafranca d'Asti, Italy



PERIODONTAL REGENERATION
intrabony defects
case reports on page 92



LATERAL ACCESS SINUS LIFT
Schneider membrane protection
case reports on page 84

Characteristics, handling and clinical indications

CHARACTERISTICS

Duo-Teck is made of lyophilized collagen of equine origin, biocompatible and quickly resorbable.

The model DT020 differs from other membranes as it is coated on one side with a film of micronized bone, also of equine origin: this coating increases its consistency and stability, allowing good protection of grafts together with a correct repositioning of soft tissues.

HANDLING

Duo-Teck can be easily placed directly in the grafting site with the micronized bone film side in contact with the graft and the smooth side in contact with the soft tissues.

CLINICAL INDICATIONS

Duo-Teck is indicated in all those cases where a "soft" separation between tissues of different consistency is necessary. Duo-Teck can be used to protect the maxillary sinus membrane in sinus floor augmentation procedures⁽¹⁾, in order to avoid accidental lesions caused by grafting material. It can also be used for closure of antrostomy, before replacement of the muco-gingival flap.

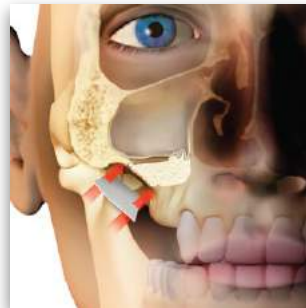
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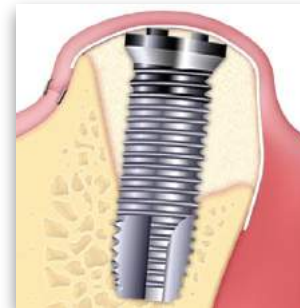
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SEM image of OsteoBiol® Duo-Teck
Source: Politecnico di Torino, Italy



LATERAL ACCESS SINUS LIFT
maxillary sinus floor augmentation
case reports on page 84



DEHISCENCES AND FENESTRATIONS
peri-implant lesions
case reports on page 80



Bone
substitutes

Blocks

Membranes

Clinical
cases

Innovation

Certifications

Literature

Tissue of origin

Equine lyophilised collagen felt and equine bone (DT020)
Equine lyophilised collagen felt (DTN625)

Tissue collagen

Preserved

Physical form

Dried membrane covered with micronized bone (DT020)
Dried membrane (DTN625)

Composition

Collagen felt and bone granules (DT020)
Collagen felt (DTN625)

Granulometry

Up to 300 μm (DT020)

Thickness

With granules coating: 1.0 mm (± 0.1 mm)
Collagen felt only: 0.2 mm (± 0.05 mm)

Estimated resorption time

About 15 days

Size

20x20 mm (DT020)
25x25 mm (DTN625)

Product codes

With granules coating
DT020 | 1 Blister | 20x20 mm | Equine
Collagen felt only
DTN625 | 6 Blisters | 25x25 mm | Equine

GMDN code

38746

Success through innovation:

Products launch



Gen-Os®



Apatos



Gel 40



Special



Lamina



Sp-Block



Dual-Block



Derma

Year

2000

2001

2002

2003

2004

2005

2006

2007

2008

2009

Worldwide distribution countries

1

2

8

12

19

28

41

Publications on international journals

1

4

9

12

19

26

history of the **OsteoBiol[®]** brand by Tecross



Putty



Duo-Teck



Evolution



mp3[®]



TSV Gel



CLINICAL CASES

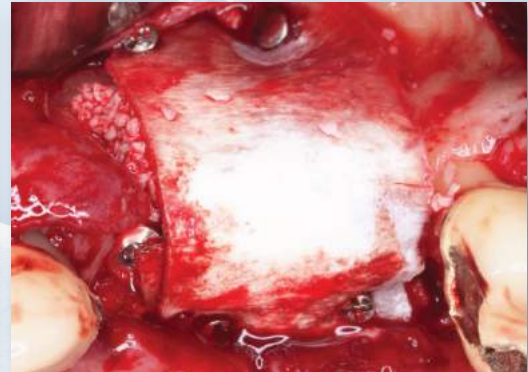
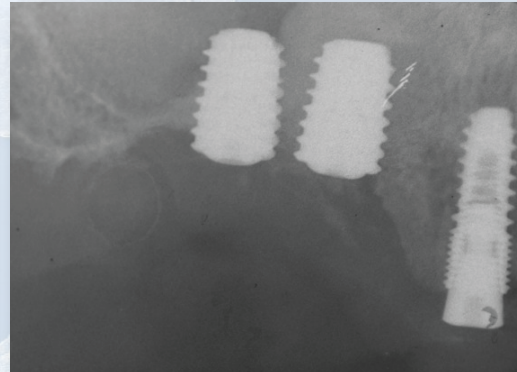
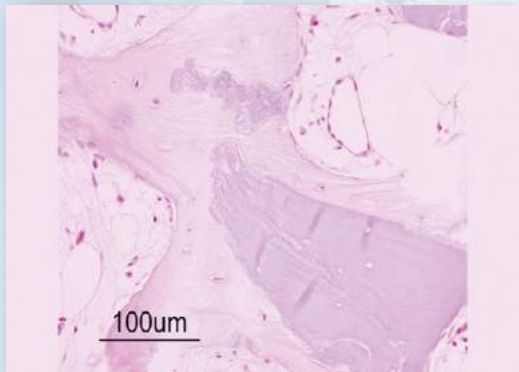




Fig. 1



Fig. 2



Fig. 3

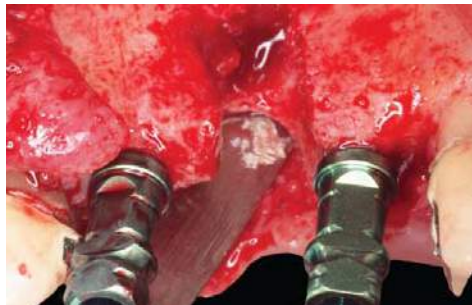


Fig. 4

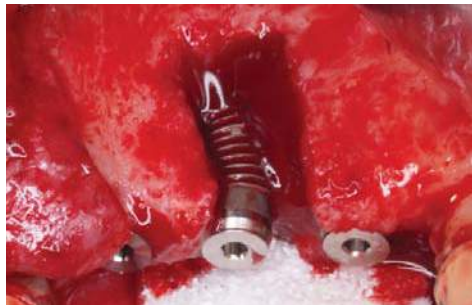


Fig. 5



Fig. 6



Fig. 7

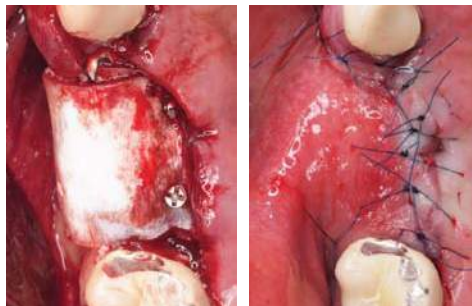


Fig. 8

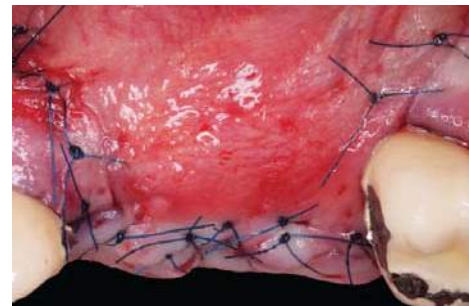


Fig. 9



Fig. 10

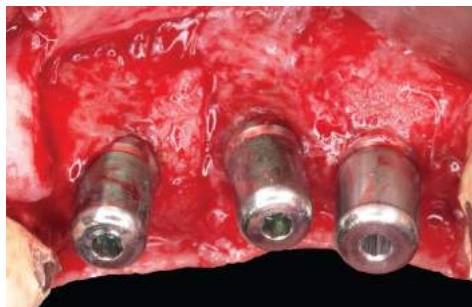


Fig. 11



Fig. 12

Sex: **female** | Age: **49**

Fig. 1 Preoperative image

Fig. 2 After the extraction, the deficit of soft tissue and bony tissue are evident

Fig. 3 Intraoperative image: vertical defect in 2.4

Fig. 4 Implant placement in 2.3 and 2.5, close to the bone defect

Fig. 5 Implant placement in 2.4, with exposure of 14 threads

Fig. 6 Treatment of the defect with OsteoBiol® Apatos mixed with autologous bone

Fig. 7 Placement of OsteoBiol® Cortical Lamina to avoid the collapse of the vertical defect

Fig. 8 Detail (occlusal view) of the bone regeneration with Apatos and Lamina and suture with PP 5/0

Fig. 9 Primary closure of the wound from the vestibular side

Fig. 10 Detail of the treated area at 8 months

Fig. 11 Complete bone regeneration of the vertical defect

Fig. 12 Periapical x-ray

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Bone substitute: **OsteoBiol® Apatos**
[For more information on OsteoBiol® Apatos see page 44](#)

Barrier: **OsteoBiol® Lamina**
[For more information on OsteoBiol® Lamina see page 66](#)

Sex: female | Age: 47

Fig. 1 X-ray of the first upper premolar showing a periapical bone loss

Fig. 2 Clinical intra-operative view showing the large alveolar bone deficit around the upper premolar

Fig. 3 Clinical intra-operative view showing the bone deficit after tooth extraction

Fig. 4 Clinical intra-operative view during the mp3® grafting stage

Fig. 5 Primary soft tissue closure of the muco-periosteal flap after its coronal positioning

Fig. 6 Occlusal view of the soft tissue healing 6 months after the intervention

Fig. 7 Vestibular view of the soft tissue healing 6 months after the intervention

Fig. 8 Vestibular view of the implant positioned in the regenerated bone

Fig. 9 Occlusal view of the implant positioned in the regenerated bone. Note how the correct hard tissue profile has been regenerated in order to support the soft tissues

Fig. 10 Clinical view showing the final prosthetic rehabilitation 3 months after the implant positioning



Fig. 1

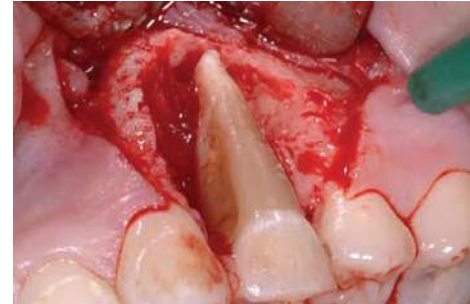


Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6



Fig. 7



Fig. 8



Fig. 9



Fig. 10

Documentation provided by
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Bone substitute: **OsteoBiol® mp3®**
 For more information on **OsteoBiol® mp3®** see page 32



Fig. 1



Fig. 2

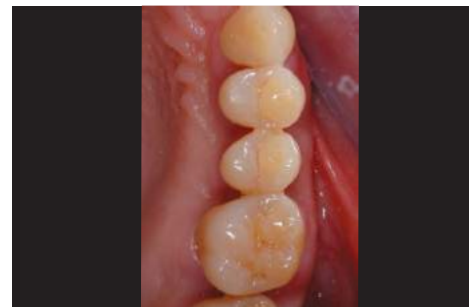


Fig. 3



Fig. 4



Fig. 5



Fig. 6



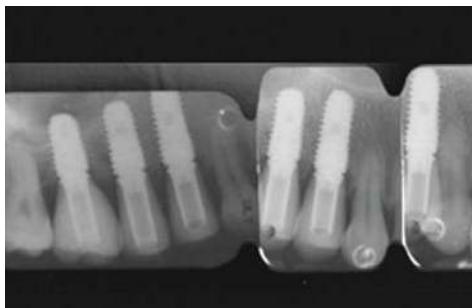
Fig. 7



Fig. 8



Fig. 9



Sex: **female** | Age: **34**

Fig. 1 Initial situation

Fig. 2 Pre-op x-ray

Fig. 3 Occlusal view

Fig. 4 Sockets after the extraction

Fig. 5 Sockets filled with OsteoBiol® mp3®

Fig. 6 Provisional prosthetic to protect the graft

Fig. 7 Mucotomy before the guided surgery procedure

Fig. 8 Guided implant surgery (at 6 months)

Fig. 9 Implants positioned

Fig. 10 Final restoration

Fig. 11 X-ray after 8 years

Fig. 12 Clinical situation after 8 years

Documentation provided by

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M.Sc.D. in Periodontology, Genova, Italy

e-mail: drrossi@mac.com

Bone substitute: **OsteoBiol® mp3®**
For more information on OsteoBiol® mp3® see page 32

Sex: female | Age: 41

Fig. 1 Initial situation

Fig. 2 OsteoBiol® Gen-Os® grafted to treat the peri-implant defect

Fig. 3 Graft protection with OsteoBiol® Derma

Fig. 4 Final situation showing the regenerated bone

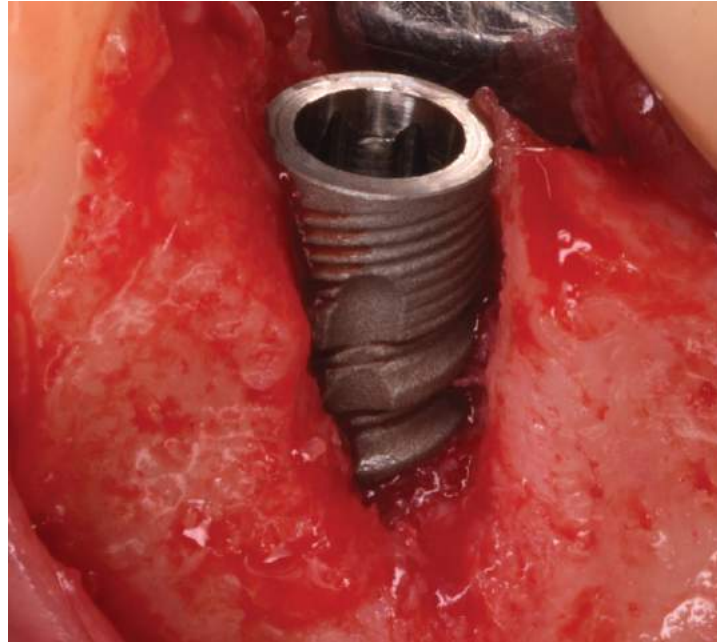


Fig. 1

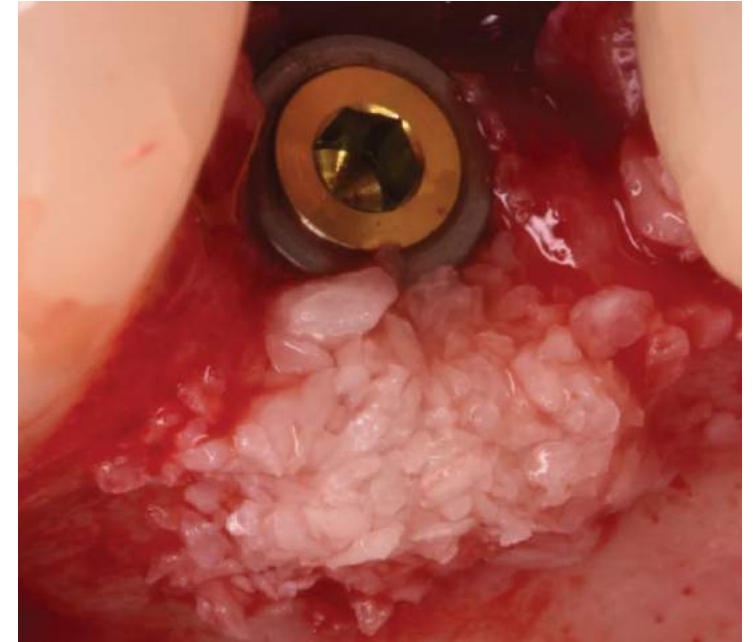


Fig. 2

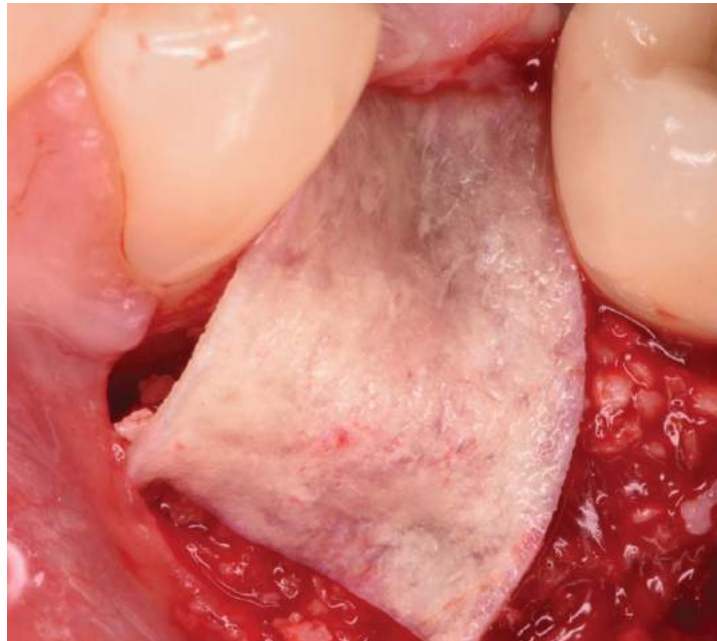


Fig. 3



Fig. 4

Documentation provided by
Dr **Antonio Murillo Rodriguez**
Ponferrada, Spain
email: dr_murillorodriguez@yahoo.es

Bone substitute: **OsteoBiol® Gen Os®**
For more information on OsteoBiol® Gen Os® see page 24
Membrane: **OsteoBiol® Derma**
For more information on OsteoBiol® Derma see page 62



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6

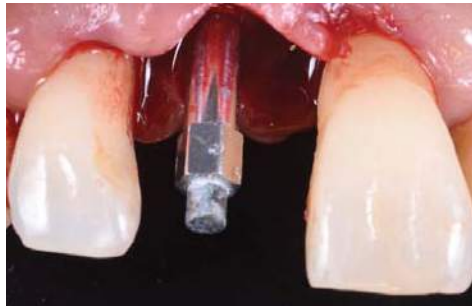


Fig. 7



Fig. 8

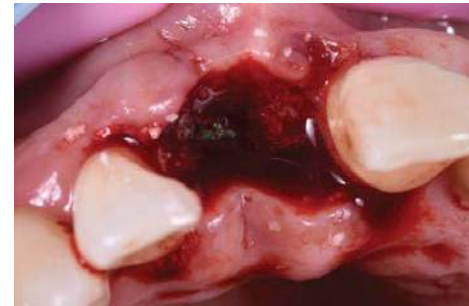


Fig. 9



Fig. 10



Fig. 11



Fig. 12

Sex: **female** | Age: **50**

Fig. 1 Initial clinical situation

Fig. 2 Initial x-ray

Fig. 3 Flap opening

Fig. 4 Flap opening

Fig. 5 Implant insertion

Fig. 6 Implant insertion (occlusal view)

Fig. 7 Check of the alignment

Fig. 8 OsteoBiol Gen-Os® mixed with TSV Gel

Fig. 9 OsteoBiol Gen-Os® + TSV Gel grafting in the defect site

Fig. 10 Flap suture and measurement of the horizontal width

Fig. 11 Post-operative x-ray

Fig. 12 Final result

Documentation provided by
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e-mail: drrossi@mac.com

Bone substitute: **OsteoBiol® Gen-Os® + TSV Gel**
For more information on OsteoBiol® Gen-Os® see page 24
For more information on OsteoBiol® TSV Gel see page 28

Sex: male | Age: 60

Fig. 1 Sinus imaging with TC

Fig. 2 3D image of the area

Fig. 3-4 Dental scans

Fig. 5 Preparation of the grafting sites

Fig. 6 Crestal access sinus lift with OsteoBio[®] Gel 40

Fig. 7 Post-operative x-ray

Fig. 8 Control x-ray at 12 months

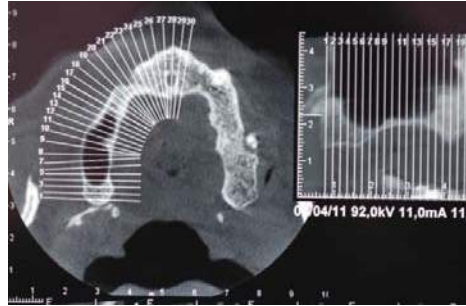


Fig. 1

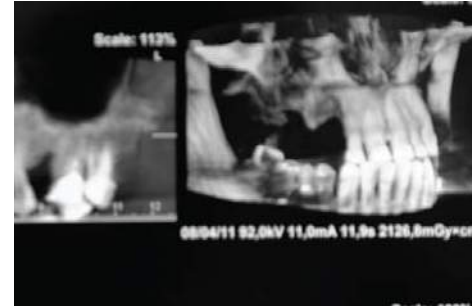


Fig. 2

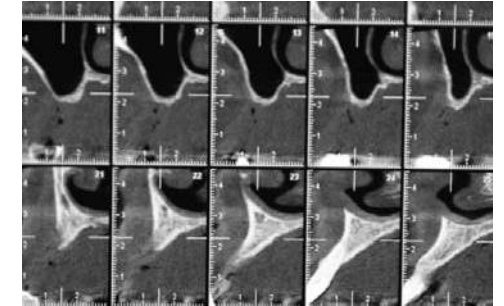


Fig. 3

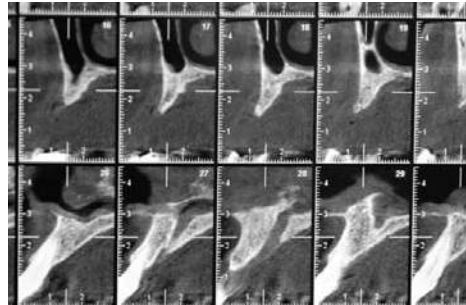


Fig. 4



Fig. 5

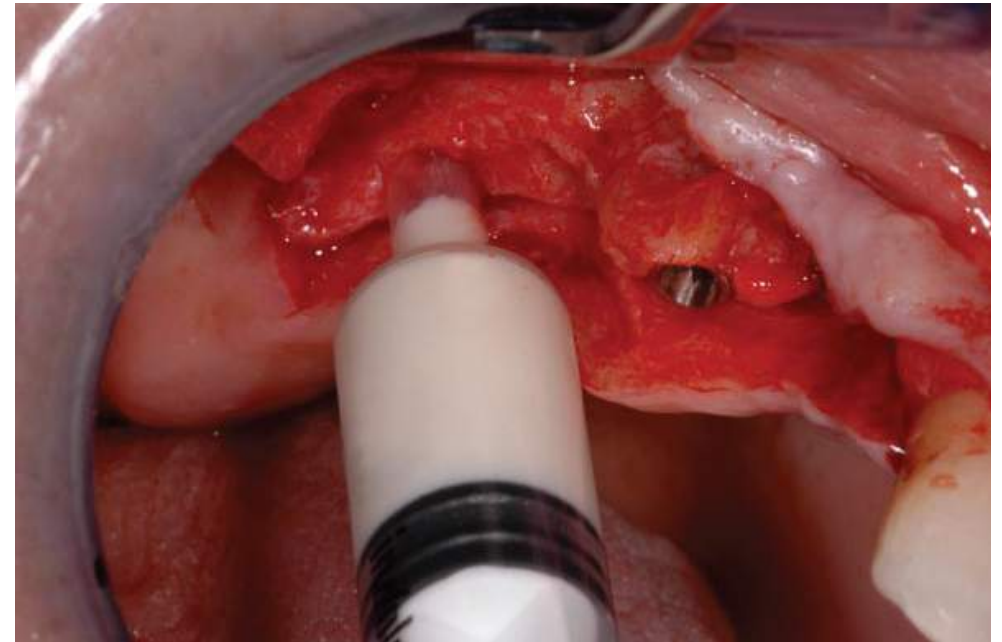


Fig. 6

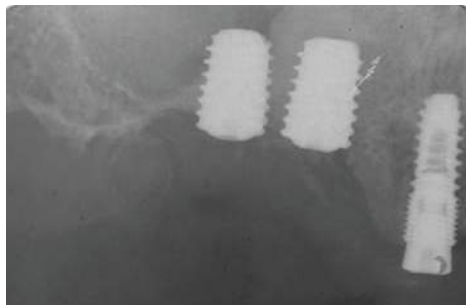


Fig. 7

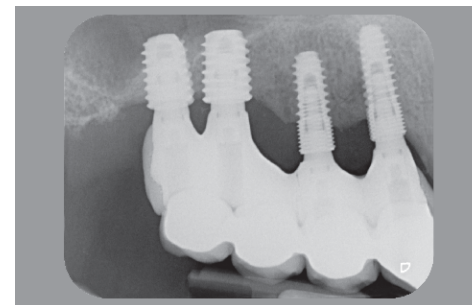


Fig. 8

Documentation provided by
 Dr **Roberto Rossi**
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 e-mail: drrossi@mac.com

Bone substitute: **OsteoBio[®] Gel 40**
 For more information on OsteoBio[®] Gel 40 see page 40

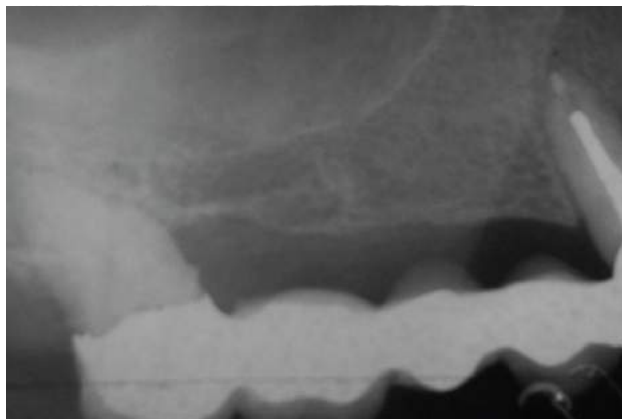


Fig. 1



Fig. 2

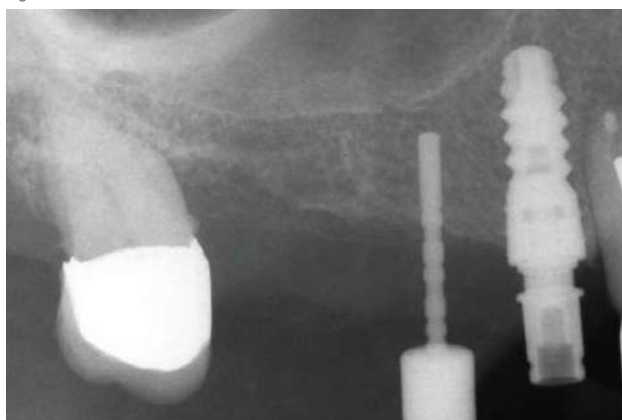


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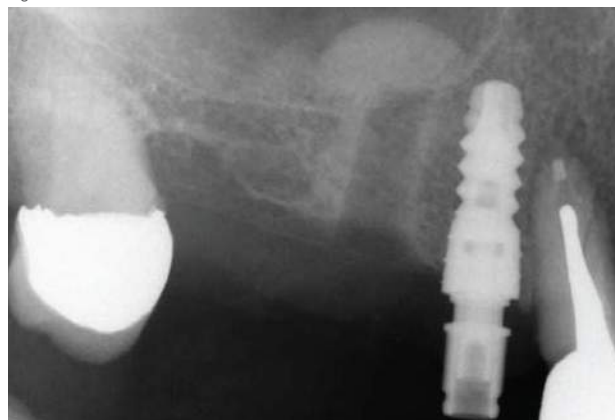


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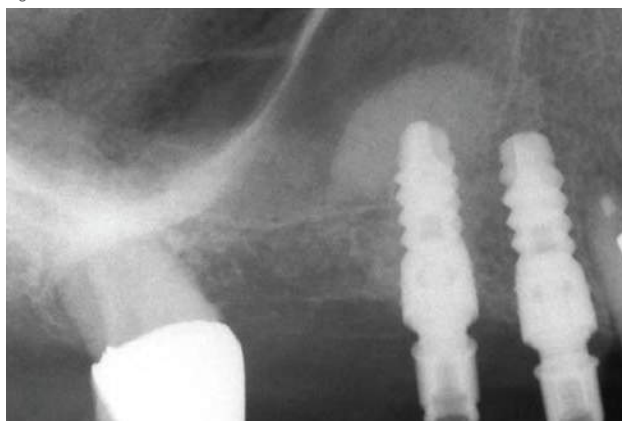


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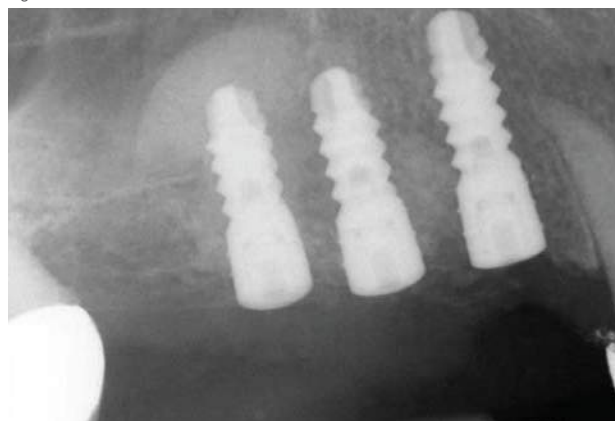


Fig. 6

Sex: **female** | Age: **43**

Fig. 1 Initial x-ray

Fig. 2 Control x-ray before osteotomy

Fig. 3 Measuring before osteotomy

Fig. 4 Maxillary sinus lifted with OsteoBiol® Putty

Fig. 5 Implant placed in the grafted site: final x-ray

Fig. 6 Implant placed in the grafted site: final x-ray

Documentation provided by
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Bone substitute: **OsteoBiol® Putty**
For more information on OsteoBiol® Putty see page 36

Sex: male | Age: 52

Fig. 1 Initial x-ray. Teeth 2.5 and 2.6 missing for 2 years, residual bone height is 3-5 mm below the maxillary sinus

Fig. 2 Flap opening

Fig. 3 Antrostomy opening and lifting

Fig. 4 Antrostomy opening and lifting

Fig. 5 Lifting of the intact Schneider membrane

Fig. 6 Direction indicators

Fig. 7 Sinus grafting with OsteoBio[®] mp3[®]

Fig. 8 Implants in situ

Fig. 9 Bone packing

Fig. 10 Graft protection with OsteoBio[®] Evolution

Fig. 11 Sutures

Fig. 12 Final x-ray



Fig. 1

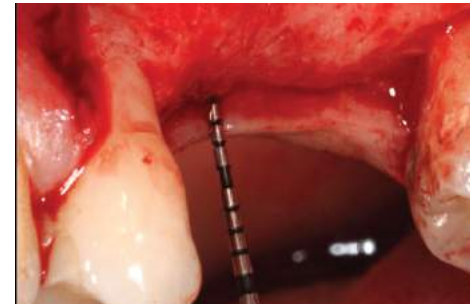


Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6



Fig. 7



Fig. 8



Fig. 9



Fig. 10



Fig. 11



Fig. 12

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Bone substitute: **OsteoBio[®] mp3[®]**

[For more information on OsteoBio[®] mp3[®] see page 32](#)

Membrane: **OsteoBio[®] Evolution**

[For more information on OsteoBio[®] Evolution see page 58](#)

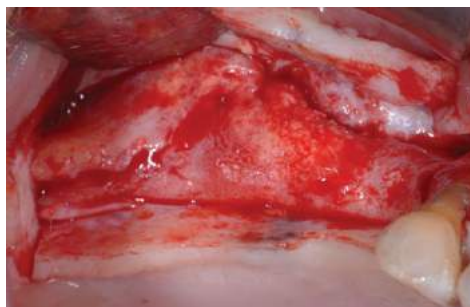


Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6



Fig. 7



Fig. 8



Fig. 9

Sex: **male**

Fig. 1 Flap opening

Fig. 2 Osteotomy

Fig. 3 Schneider membrane protection with OsteoBiol® Evolution (fine model)

Fig. 4 OsteoBiol® mp3® grafting inside the maxillary sinus

Fig. 5 Implant insertion

Fig. 6 Grafting and packing of OsteoBiol® mp3® to support the maxillary contour

Fig. 7 OsteoBiol® Evolution to protect the bone graft

Fig. 8 Flap closure

Fig. 9 Sutures

Bone
substitutes

Blocks

Membranes

Clinical
cases

Innovation

Certifications

Literature

Documentation provided by
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Bone substitute: **OsteoBiol® mp3®**
For more information on OsteoBiol® mp3® see page 32
Membrane: **OsteoBiol® Evolution**
For more information on OsteoBiol® Evolution see page 58

Sex: female | Age: 42

Fig. 1 Initial x-ray showing a 3 mm in height residual bone

Fig. 2 Flap opening, a substantial vestibular bone resorption can be determined

Fig. 3 Antrostomy performed with Piezosurgery technique

Fig. 4 A OsteoBiol® Evolution membrane is inserted through the antrostomy to protect the Schneider membrane from the grafting material

Fig. 5 Maxillary sinus grafted with OsteoBiol® mp3®

Fig. 6 Immediate implant placement

Fig. 7 An OsteoBiol® Evolution membrane is stabilized with osteosynthesis screws above the antrostomy

Fig. 8 Cortical bone stimulation

Fig. 9 OsteoBiol® mp3® is grafted on the vestibular side of the defect for horizontal augmentation

Fig. 10 The OsteoBiol® Evolution membrane is stabilised into position with a transpalatal suture

Fig. 11 Final situation

Fig. 12 Post-operative x-ray

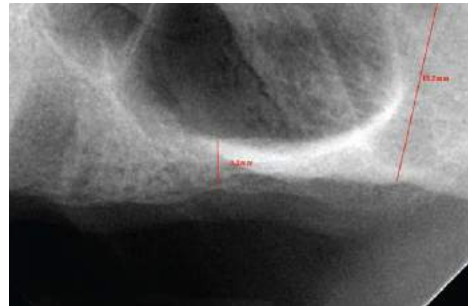


Fig. 1



Fig. 2

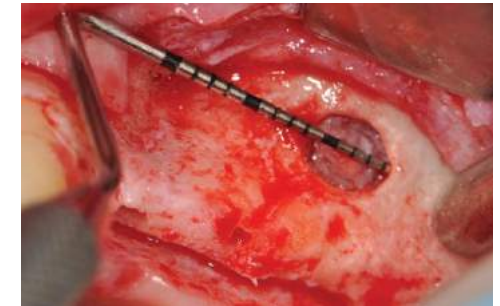


Fig. 3



Fig. 4



Fig. 5

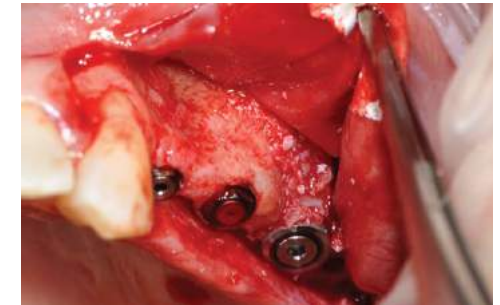


Fig. 6

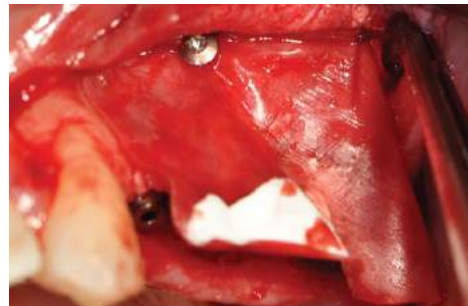


Fig. 7



Fig. 8



Fig. 9



Fig. 10

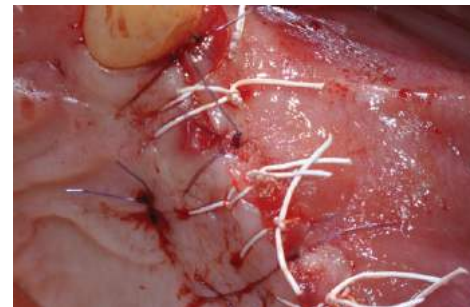


Fig. 11

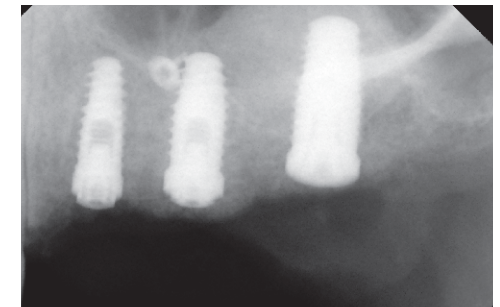


Fig. 12

Documentation provided by
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Bone substitute: **OsteoBiol® mp3®**
 For more information on OsteoBiol® mp3® see page 32

Membrane: **OsteoBiol® Evolution**
 For more information on OsteoBiol® Evolution see page 58

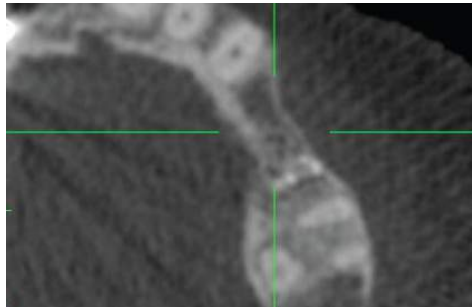


Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5

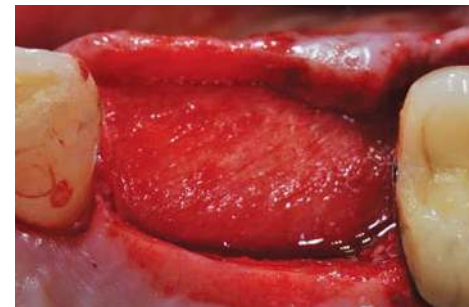


Fig. 6



Fig. 7

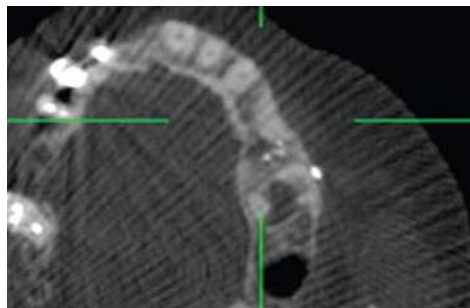


Fig. 8



Fig. 9

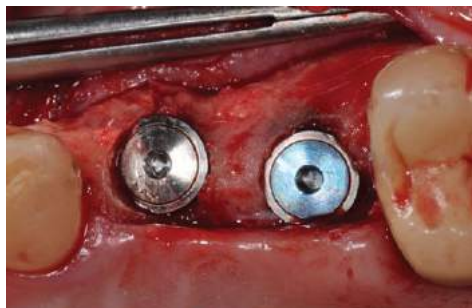


Fig. 10

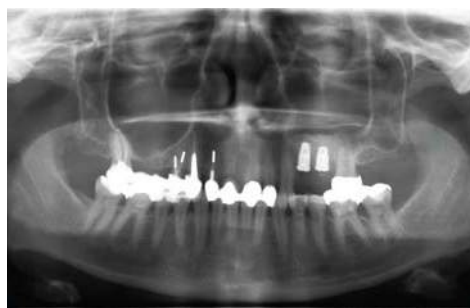


Fig. 11



Fig. 12

Sex: **female** | Age: **45**

Fig. 1 Preoperative cone beam scan

Fig. 2 Alveolar ridge presenting an inadequate width for implant placement

Fig. 3 Intraoperative view demonstrating the alveolar defect. Due to the limited vertical and horizontal dimension the elevation of the sinus has been performed

Fig. 4 Fixation of OsteoBiol® Cortical Lamina with titanium pins performed prior to ridge augmentation

Fig. 5 Reconstruction of the alveolar ridge with OsteoBiol® mp3®

Fig. 6 Covering the augmented area with OsteoBiol® Lamina

Fig. 7 Primary flap closure was achieved

Fig. 8 Digital volume tomography 6 months after augmentation procedure demonstrates the amount of new bone

Fig. 9 Intraoperative view of the augmented area six months after augmentation procedure

Fig. 10 Placement of two implants

Fig. 11 Postoperative radiograph

Fig. 12 Final prosthetic reconstruction

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Bone substitute: **OsteoBiol® mp3®**
For more information on OsteoBiol® mp3® see page 32

Barrier: **OsteoBiol® Lamina**
For more information on OsteoBiol® Lamina see page 66

Sex: **female** | Age: **33**

Fig. 1-2 At preoperative planning with a DVT the thin alveolar ridge in the area 1.2 is visible

Fig. 3 Pre-operative clinical view of the buccal alveolar atrophy

Fig. 4 Intra-operative view of a 3,4 mm implant with a "bone bridge" in the area of the implant head and the main part of the implant body outside of the bony envelope

Fig. 5 GBR Type covering of the exposed implant area with a *OsteoBiol*[®] *Lamina* and *mp3*[®]; the *Lamina* is fixated with pins

Fig. 6 View of the augmented area 6 months post augmentation

Fig. 7-8 Healing abutment, uncovering with partially inverted CTG procedure to additionally augment the buccal soft tissue

Fig. 9 Final result with cemented full porcelain crowns on the neighboring teeth and a full porcelain screwed on crown on 1.2

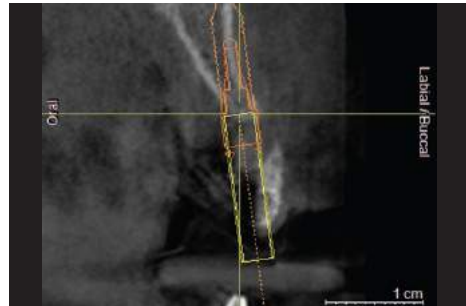


Fig. 1

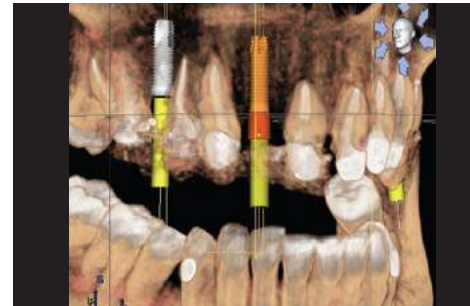


Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6



Fig. 7



Fig. 8



Fig. 9

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Bone substitute: **OsteoBiol[®] mp3[®]**
 For more information on **OsteoBiol[®] mp3[®]** see page 32

Barrier: **OsteoBiol[®] Lamina**
 For more information on **OsteoBiol[®] Lamina** see page 66



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6



Fig. 7



Fig. 8



Fig. 9



Fig. 10

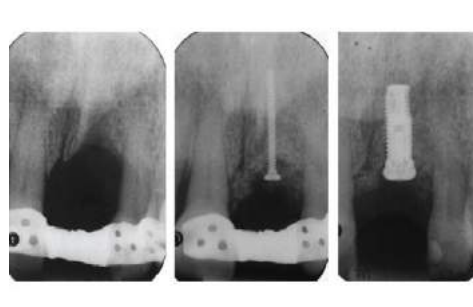


Fig. 11



Fig. 12

Sex: **female** | Age: **46**

Fig. 1 Infected upper central incisor being extracted

Fig. 2 Inflamed tissues and major bone loss

Fig. 3 A flap is elevated, horizontal vertical ridge loss

Fig. 4 A fixation screw is vertically placed in the alveolus

Fig. 5 OsteoBiol® mp3® is compacted around the screw

Fig. 6 Ridge is recreated, compacting the mp3®. A collagen membrane is placed above the mp3® reconstruction

Fig. 7 Clinical view 4 months later. Dense bone recreated

Fig. 8 Fixation screw is removed

Fig. 9 A Brånemark implant NP is inserted

Fig. 10 See the bone level allowing optimal implant positioning

Fig. 11 Radiographs before the fixation screw, implant in place

Fig. 12 4 months later: second step surgery healing abutment is placed

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Bone substitute: **OsteoBiol® mp3®**
For more information on OsteoBiol® mp3® see page 32

Sex: female | Age: 58

Fig. 1 Seriously resorbed alveolar ridge at the time of first surgical intervention

Fig. 2 Semicircular osteotomy performed with diamond circular saw in general anesthesia

Fig. 3 Osteotomy of lingual compact bone completed with chisel in order to avoid damaging of lingual periostium. The mobile segment of residual ridge was covered with soft tissue to give appropriate blood supply

Fig. 4 OsteoBiol® Sp-Block reshaped and inserted between mobile and stable segment of mandible

Fig. 5 Mobile segment fixed with two mini plates. Gaps were also filled with Sp-Block particles, obtained by mincing

Fig. 6 Unevenly healed wound 10 days after surgical intervention

Fig. 7 Re-entry due to implantation 6 months after augmentation with Sp-Block under local anesthesia. Vital bone with incorporated xenograft was found. Mini-plates with all screws were on the same place

Fig. 8 Insertion of two implants (regions 4.2, 3.2). Minimal dehiscence was detected at region 4.2

Fig. 9 Dehiscence at region 4.2 grafted with OsteoBiol® Gen-Os® and covered with OsteoBiol® Evolution

Fig. 10 Suprastructures for supporting denture with stable mucosa 7 months after implantation and 3 months after healing abutment positioning

Fig. 11 Rehabilitation with removable denture on both jaws

Fig. 12 OPT 13 months after augmentation and 7 months after implantation. Both implants with prosthetical suprastructure show stable peri-implant bone

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Bone substitute: **OsteoBiol® Sp-Block**
 For more information on OsteoBiol® Sp-Block see page 50

Bone substitute: **OsteoBiol® Gen-Os®**
 For more information on OsteoBiol® Gen-Os® see page 24

Membrane: **OsteoBiol® Evolution**
 For more information on OsteoBiol® Evolution see page 58



Fig. 1

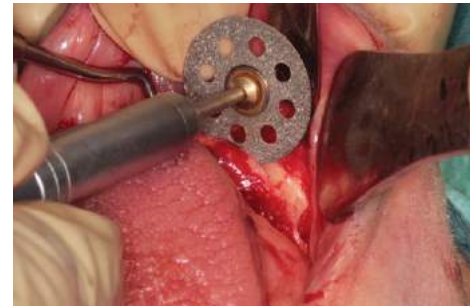


Fig. 2

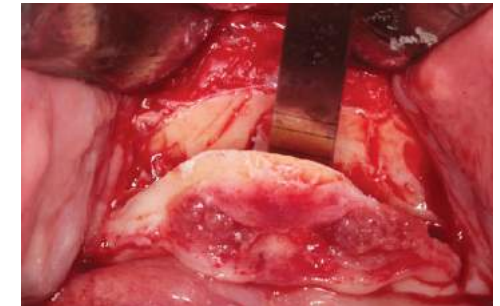


Fig. 3

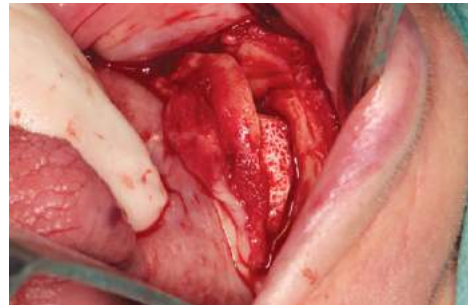


Fig. 4



Fig. 5



Fig. 6



Fig. 7



Fig. 8



Fig. 9



Fig. 10
90



Fig. 11

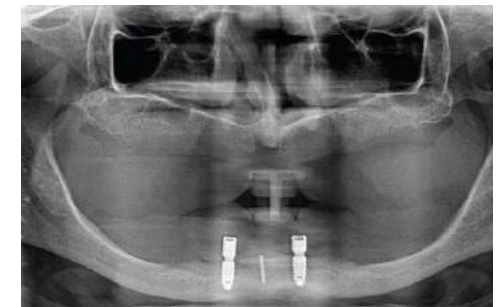


Fig. 12

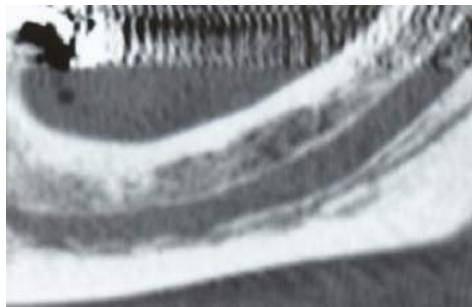


Fig. 1

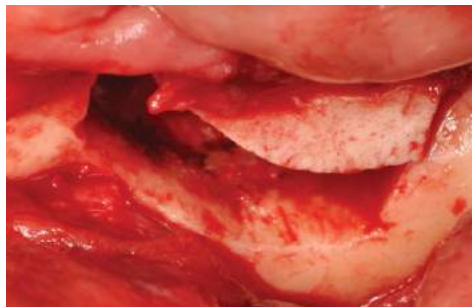


Fig. 2

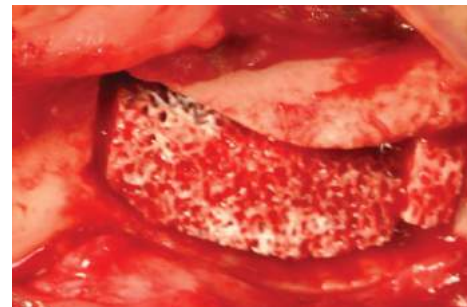


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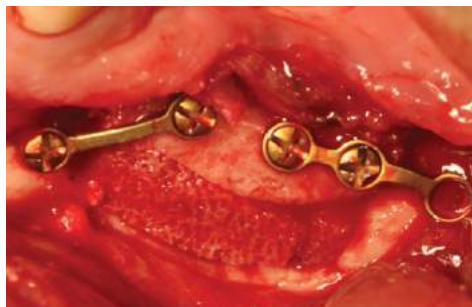


Fig. 4



Fig. 5



Fig. 6



Fig. 7

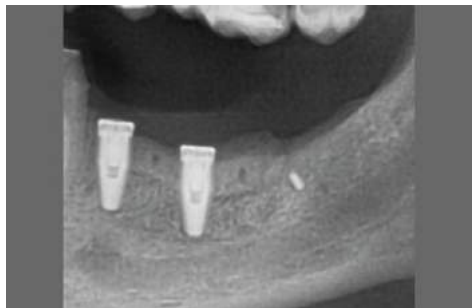


Fig. 8



Fig. 9



Fig. 10

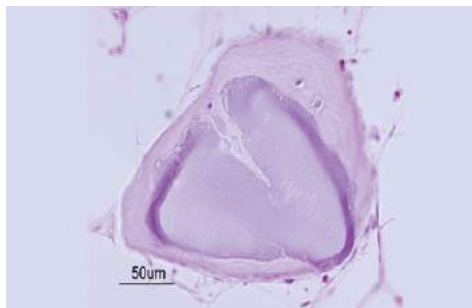


Fig. 11

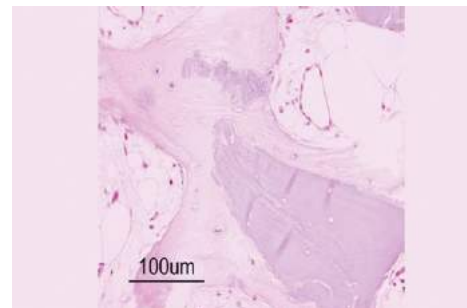


Fig. 12

Sex: **female** | Age: **60**

Fig. 1 Computed tomography scans taken before the augmentation procedure

Fig. 2 The cranial segment is moved upward and raised to the level of the alveolar crest

Fig. 3 Placement of a cancellous equine bone block as an interpositional graft

Fig. 4 Fixation of the graft with miniplates

Fig. 5 Postoperative panoramic radiographs showing the interpositional bone graft in the mandible

Fig. 6 Reopening during second-stage surgery after 3 months of healing

Fig. 7 Bone core retrieved for histological evaluation using a trephine with a 2 mm internal diameter

Fig. 8-9 Panoramic and intraoral x-rays taken 4 months after implant placement

Fig. 10 The provisional prosthesis delivered 4 months after implant placement

Fig. 11-12 Histology detail*. It is possible to notice the tight connection between biomaterial and the newly formed bone

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Bone substitute: **OsteoBio[®] Sp-Block**
For more information on OsteoBio[®] Sp-Block see page 50

Sex: male | Age: 39

Fig. 1 Pre-op clinical situation

Fig. 2 Periodontal defect

Fig. 3 Occlusal view of the defect

Fig. 4 PrefGel conditioning

Fig. 5-6 OsteoBiol® mp3® grafting

Fig. 7 OsteoBiol® Lamina to protect the graft

Fig. 8 Occlusal view

Fig. 9 Preparation for a soft tissue graft after 4 months

Fig. 10 Connective tissue graft

Fig. 11 Pre-op and post-op x-rays at 20 months

Fig. 12 Clinical result at 20 months



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5

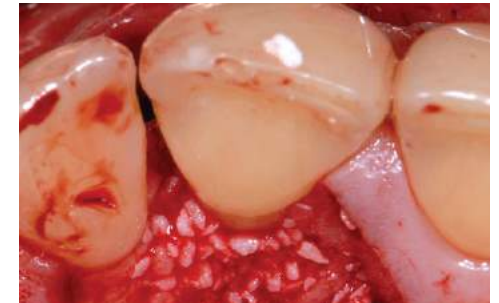


Fig. 6



Fig. 7



Fig. 8

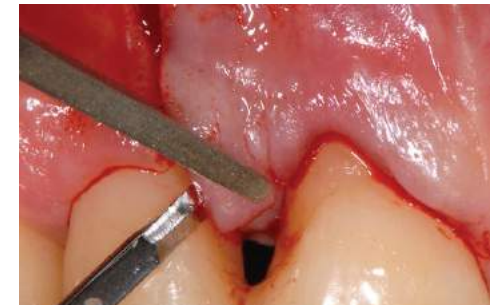


Fig. 9



Fig. 10

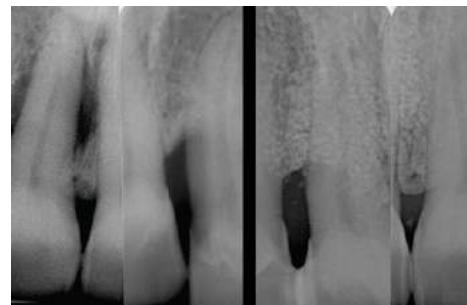


Fig. 11



Fig. 12

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Bone substitute: **OsteoBiol® mp3®**
 For more information on **OsteoBiol® mp3®** see page 32

Membrane: **OsteoBiol® Lamina**
 For more information on **OsteoBiol® Lamina** see page 66

Case report Treatment of a periodontal defect in the anterior mandible

PERIODONTAL REGENERATION

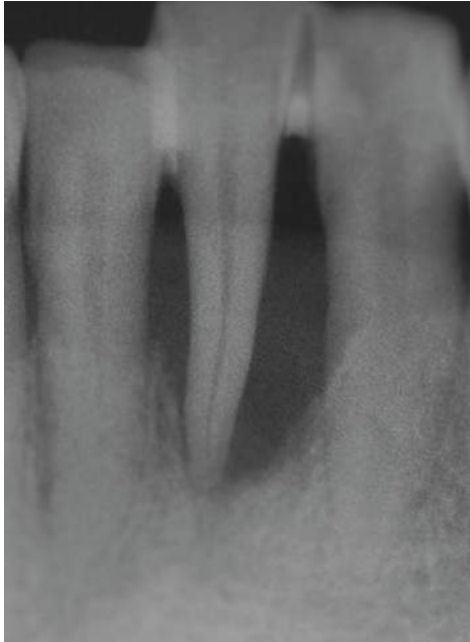


Fig. 1



Fig. 2

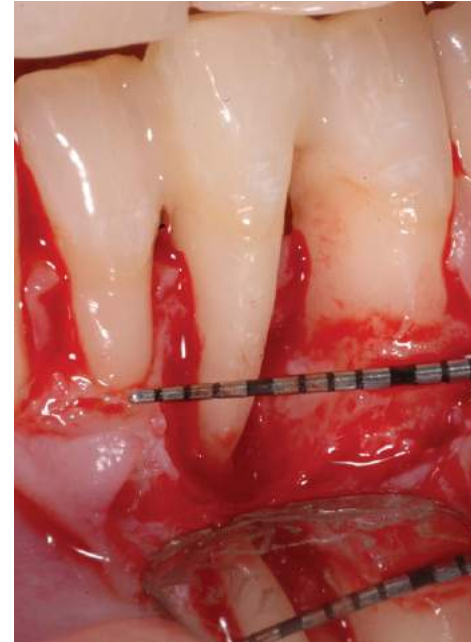


Fig. 3



Fig. 4



Fig. 5

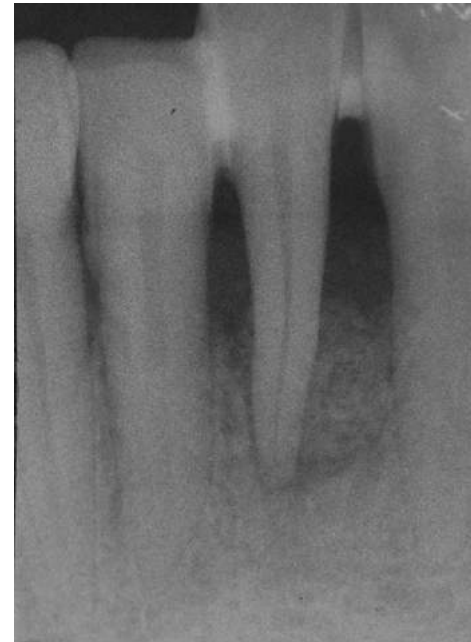


Fig. 6

Sex: **female** | Age: **34**

Fig. 1 Severe loss of attachment

Fig. 2 Pocket probing depth (PPD) 10 mm

Fig. 3-4 Intrabony defect

Fig. 5 Defect grafted with OsteoBiol® Gen-Os®, later covered with OsteoBiol® Evolution

Fig. 6 Attachment gain of 5 mm and regeneration of the intrabony defect after 12 months

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Bone substitute: **OsteoBiol® Gen-Os®**
For more information on OsteoBiol® Gen-Os® see page 24

Membrane: **OsteoBiol® Evolution**
For more information on OsteoBiol® Evolution see page 58

Bone
substitutes

Blocks

Membranes

Clinical
cases

Innovation

Certifications

Literature

Sex: female | Age: 55

Fig. 1-2 Multiple recessions and erosions in the lower arch

Fig. 3-5 Correction of the enamel defects

Fig. 6 Split flap

Fig. 7-9 Suturing of the OsteoBiol® *Derma* membrane

Fig. 10 Flap closure and healing

Fig. 11 Two weeks

Fig. 12 Three months



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6



Fig. 7



Fig. 8



Fig. 9



Fig. 10



Fig. 11



Fig. 12

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Soft tissue: **OsteoBiol® *Derma***
 For more information on **OsteoBiol® *Derma*** see page 62



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5



Fig. 6



Fig. 7



Fig. 8

Sex: **female** | Age: **65**

Fig. 1 At time of second stage a volume deficit is clearly visible

Fig. 2 Following a crestal incision, the implant is exposed

Fig. 3 A pouch is obtained on the buccal aspect and OsteoBioL® Derma is placed

Fig. 4 Two double interrupted sutures are used to close the tissue around the healing abutment

Fig. 5 Healing after 7 days presents uneventful

Fig. 6 At time of final impression an increase of tissue volume is visible

Fig. 7 Occlusal view showing that the dermal matrix is clinically fully integrated into the surrounding tissue

Fig. 8 Final reconstruction with a screw retained prosthesis

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Soft tissue: **OsteoBioL® Derma**

For more information on OsteoBioL® Derma see page 62

Bone, Biomaterials & Beyond

Prof Antonio Barone, Prof Ulf Nannmark

CONTENTS

The introduction of osseointegrated dental implants soon 50 years ago has indeed revolutionized dentistry.

The scientific evaluation of their use has shown good and increasingly successful treatment outcomes.

A prerequisite though is the availability of sufficient bone volumes to ensure integration and acceptable aesthetic results.

In this book various surgical techniques, using different augmentation materials, are described and explained.

The aim has been to highlight minimally invasive surgical techniques, which lead to less risk of morbidity and reduce treatment time.

Readers will enjoy a comprehensive atlas providing some practical advice for every day surgical practice based on solid scientific evidence.



CHAPTERS

CHAPTER 1

An Introduction to Guided Bone Regeneration

Ugo Covani, Massimiliano Ricci, Simone Marconcini

CHAPTER 2

Bone Tissue Reactions to Bone Substitutes

Lars Sennerby, Ulf Nannmark

CHAPTER 3

Periodontal Regeneration

Roberto Rossi, Maria Gabriella Grusovin, Tobias Thalmair, Hannes Wachtel

CHAPTER 4

Fresh Extraction Socket Management

Antonio Barone, Adriano Piattelli, José Luis Calvo-Guirado, Fortunato Alfonsi, Bruno Negri, Giovanna Iezzi

CHAPTER 5

Maxillary Sinus Augmentation

Paolo Martegani, Ferdinando D'Avenia, Maurizio Silvestri, Sanjiv Kanagaraja

CHAPTER 6

The Bone Lamina Technique: A Novel Approach To Bone Augmentation

Hannes Wachtel, Christian Helf, Tobias Thalmair

CHAPTER 7

Reconstruction of Horizontal Ridge Defects

Arndt Happe, Christer Slotte

CHAPTER 8

The Inlay Technique in the Treatment of Posterior Mandibular Atrophy

Pietro Felice, Roberto Pistilli, Carlo Barausse

CHAPTER 9

Soft Tissue Augmentation

Stefan Fickl

CHAPTER 10

Surgical Treatment of Peri-Implant Bone Lesions

Christer Slotte

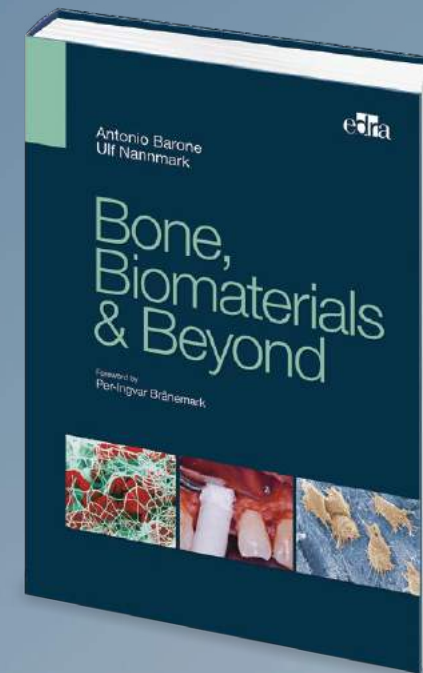
CHAPTER 11

Treatment of Extreme Cases

Patrick Palacci

Conclusions

Antonio Barone, Ulf Nannmark



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INNOVATION

A close-up photograph of a scientist wearing a white lab coat, a white surgical cap, and a white face mask. The scientist is looking through the eyepieces of a white and black microscope. The background is a blurred laboratory setting with various pieces of equipment. The word "INNOVATION" is overlaid in large, bold, blue capital letters on the left side of the image.

Tecnoss® bone vs human bone

Studies and researches have demonstrated that gold standard in bone regeneration is autologous bone^(1,2).

It is also well known, though, what disadvantages are related to the harvesting and grafting of autogenous bone⁽²⁻⁴⁾.

The goal of bone regeneration is to heal bone deficits with newly-formed quality tissue, in order to achieve a functional recovery and esthetics. To obtain these results, hundreds of studies have been conducted about the clinical performance of biomaterials. The examination of clinical results and the commercial diffusion of various kinds of products developed by the biomedical industry show a

clear superiority of products of natural origin over those of synthetic derivation.

The structure of animal bone is morphologically more similar to human bone than any synthesized product, the latter presenting a morphological pattern and properties artificially created, which differ in various ways from the structure of natural bone⁽⁵⁾.

Over the last thirty years several processes have been developed to allow the grafting of heterologous

origin products in the human body without adverse reaction⁽⁶⁻⁸⁾.

The first products developed through these technologies have shown encouraging clinical results, even if made of bone mineral matrix only.

The OsteoBiol® new generation of biomaterials, thanks to a revolutionary technology, goes beyond the simple role of aiding natural bone regrowth by stimulating and accelerating contact osteogenesis, with a behaviour similar to that of autogenous bone^(9,10).



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CLIN ORAL IMPLANTS RES, 2015 OCT;26(10):1180-4

Why xenografts?

“The ideal bone substitute should be easy to handle and should not be resorbed too fast via an inflammatory process or induce adverse reactions”

Marco Esposito DDS, PhD
Associate Professor in Biomaterials,
University of Göteborg, Sweden

Xenografts are the most used biomaterials worldwide.

This is because:

- tissues of origin are extremely safe and available in unlimited quantities
- xenogenic bone surface and porosity are extremely similar to autogenous bone
- there is no need to harvest autogenous bone in extraoral sites, with the related risk of morbidity and post-operative complications
- sterile xenografts are completely biocompatible and safe
- no adverse reactions after grafting deriving from biomaterial degradation
- easy to handle, quick learning curve
- collagenated xenografts enhance osteoblasts and osteoclasts activity
- wide scientific documentation
- excellent clinical performance
- storage can be done at room temperature
- long shelf life (5 years from production date)
- excellent price/quality ratio

“Xenografts offer a reliable if not better alternative to autogenous bone in practically all indications when used in conjunction with dental implants or in periodontal therapy. There is more evidence supporting the use of xenografts than other types of bone substitutes”

Marco Esposito DDS, PhD
Associate Professor in Biomaterials,
University of Göteborg, Sweden

Characteristics of Tecnos® process

Tecnos® has developed treatment manufacturing processes of tissues from various animal species, allowing to obtain the biocompatibility of these tissues, preserving at the same time their collagen matrix⁽¹⁾.

The protein components of animal tissues are determinant to make every individual unique. They activate the cells of the immune system of the receiving organism by interacting with receptors of the Major Histocompatibility Complex (MHC).

Their neutralization/denaturation allows collagen mineral bone matrix to be transferred from animal to man without any dangerous adverse reaction outbreak.

Successful Guided Bone Regeneration (GBR) depends both on stimulation of tissues involved in new bone formation and on the characteristics of grafted biomaterials, which can determine the quality of bone/graft interface. The basic research for development of OsteoBio® product line has thus been driven by the

ideal biomaterial concept: a material with the highest affinity to the new endogenous bone.

To pursue this aim, Tecnos® developed a biotechnology able to preserve the structure of the natural hydroxyapatite by avoiding the high temperature ceramization phase, therefore allowing a bone turnover time of the grafted site similar to the one of the physiologic natural process⁽²⁾.

Thanks to this innovative technology, the OsteoBio® line has the following important characteristics:

1. Cell growth support and differentiation⁽³⁾
2. Absence of a foreign body response^(4,5)
3. Gradual resorption over time^(2,6)
4. Stimulation of the physiological tissue regeneration process⁽⁷⁾
5. Protection of the grafting site from infection (membranes)^(5,8)
6. Capability of carrying medication to the surgical site⁽⁹⁾
7. Absorption and release over time of growth factors⁽¹⁰⁾



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Collagen: a key factor for clinical success

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Tecnoss[®] exclusive manufacturing process is able to neutralize the antigenic components present in heterologous bone with achievement of biocompatibility and preservation of the collagen matrix inside the granules of biomaterial.

Moreover, the molecular structure of natural hydroxyapatite is not significantly altered thanks to the limited maximum process temperature⁽¹⁾.

These characteristics of OsteoBiol[®] products allow a consistent bone neo-formation and a close contact between mature neo-formed bone and biomaterial granules⁽²⁻⁵⁾.

Collagen has a key role in bone regeneration process in that:

- it acts as a valid substrate for platelet activation and aggregation
- it serves to attract and differentiate the mesenchymal stem cells present in the bone marrow⁽⁶⁾

- it increases the proliferation rate of the osteoblasts up to 2/3 times⁽⁷⁾

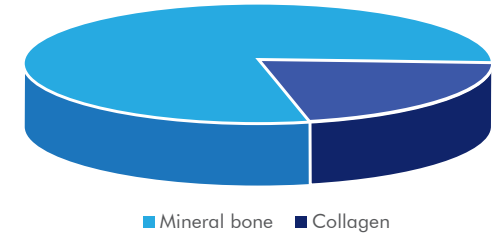
- it stimulates the activation of the platelets, osteoblasts and osteoclasts in the bone healing process⁽⁸⁾.

The presence of collagen inside each granule makes OsteoBiol[®] Gen-Os[®] hydrophilic and facilitates further mixing with collagen gel.

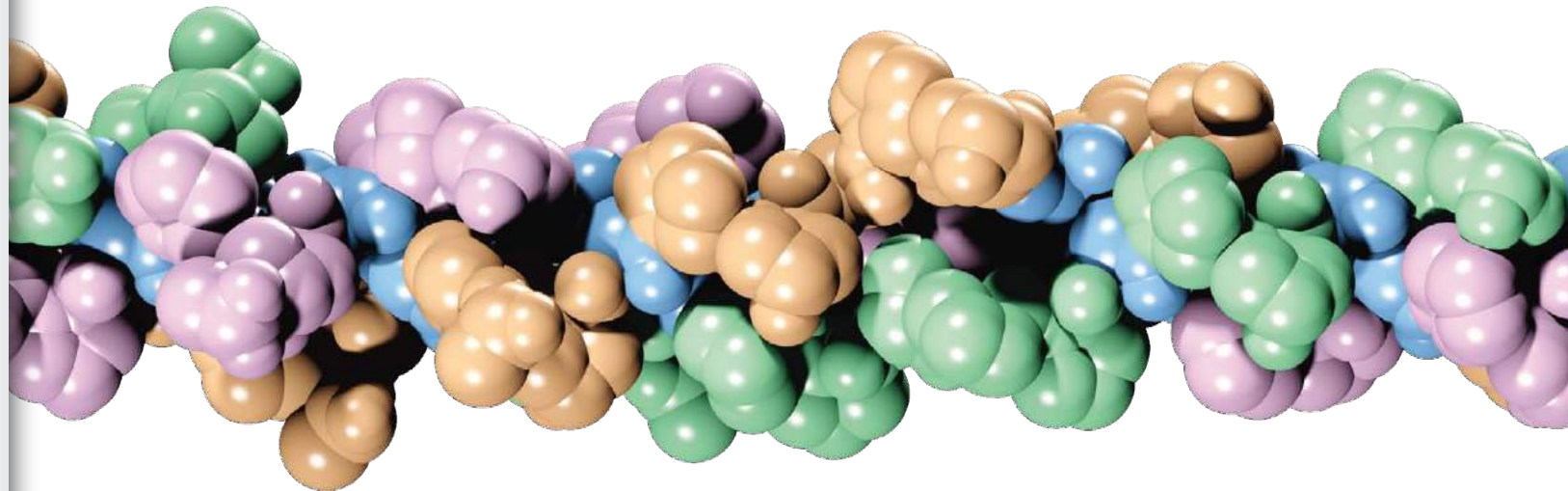
This technology has permitted the development of three versatile and innovative products: OsteoBiol[®] mp3[®], OsteoBiol[®] Putty and OsteoBiol[®] Gel 40. Their consistency allows an ideal filling of bone defects and guarantees simple handling and fast application.

The OsteoBiol[®] new generation of biomaterials, thanks to a revolutionary technology, goes beyond the simple role of aiding natural bone regrowth by stimulating and accelerating this vital physiological process.

Composition of **OsteoBiol[®] Gen-Os[®]**



Source: University of Duisburg-Essen, Germany



Guided bone regeneration (GBR) is necessary to treat bone deficits due to lesions or bacterial infections.

The bone defect recovery occurs through the general mechanisms of tissue healing, that is, by complex dynamic mechanisms directed towards the repair of tissue function and anatomic integrity. The discovery of the events pathway leading to tissue healing has helped to clearly identify the main actors in bone healing process; the concomitant presence of the following three components is necessary for the formation of “*de novo*” bone tissue:

- the platelets represent the principal actors during the first phase of the healing process, when, subsequent to a lesion, an initial deposition of fibrin and the formation of blood clot take place. This phase is characterized by significant activation of the chemical signals mediated by cytokines and growth factors.

In fact, the primary post-haemorrhagic clot formation process through platelet aggregation and lysis causes the release of both the coagulation cascade factors and growth factors, such as PDGF, IGF 1, IGF 2 and VEGF which are known for their activating effect on osteoblasts and osteoclasts, and TGF- β (Bone Morphogenetic Proteins belong to this superfamily) which starts bony callus formation.

- the osteoblastic precursors deriving from bone marrow mesenchymal stem cells are responsible, after cell differentiation in osteoblasts, for the second phase of the healing process (enchondral and/or intramembranous ossification) thanks to the synthesis of collagen and other components of the

extracellular matrix.

- an insoluble substrate, suitable carrier for osteoinductive signal and able to support and guide new bone tissue formation. Sampath and Reddi (1980) demonstrated crosslinked type I collagen to be the most appropriate carrier for promoting osteoinductive signal activity. The continuous progresses in comprehension of biological mechanisms regulating bone tissue morphogenesis can be exploited also for elaboration of natural or artificial products able to restore or maintain the function of damaged tissues and organs (tissue engineering)⁽¹⁻³⁾.

In vitro studies demonstrated that heterologous collagen is able to induce differentiation of mesenchymal osteoprogenitor stem cells into osteoblasts⁽⁴⁾, and that association of collagen type I with a scaffold of hydroxyapatite significantly enhances osteoblasts proliferation rate.

This important scientific evidence provides the rationale behind OsteoBioI[®] product line: a complete series of biomaterials with collagen base.

Collagen, in addition to its well-known structural action carried on connective tissues, is endowed with the following important properties, useful in tissue reparation processes:

1. Haemostasis

Collagen is able to activate the receptors present on cellular membranes of platelets, responsible for their aggregation and lysis process; moreover, during the first week, it reinforces the action of fibrin in the formation of the primary clot, and then, in the second week, it replaces the

function of fibrin.

2. Debridement

Collagen has a chemotactic action on monocyte/macrophage cell lines, from which osteoclasts derive; these cells, through their action on mineral component resorption of both bone tissue and OsteoBioI[®] biomaterials, can draw, activate and collaborate with osteoblasts in bone rearranging and remodeling.

3. Angiogenesis

The drawn monocytes/macrophages, in their turn, stimulate both osteoblastic activity and angiogenesis process in grafting site.

4. Osteoblastic activity

Collagen, binding to fibronectin, promotes the anchorage of mesenchymal stem progenitors, on which it exerts its chemotactic action, and induces differentiation into osteoblasts^(4,5).

5. Receiving site remodeling

Exogenous collagen grafting can contribute in decreasing remodeling times of immature bone tissue.

6. Osteoconduction and guided regeneration

Naturally integrated with mineral component, collagen is able to increase osteoblasts proliferation rate while as a resorbable membrane it is able to guide connective tissue regeneration.

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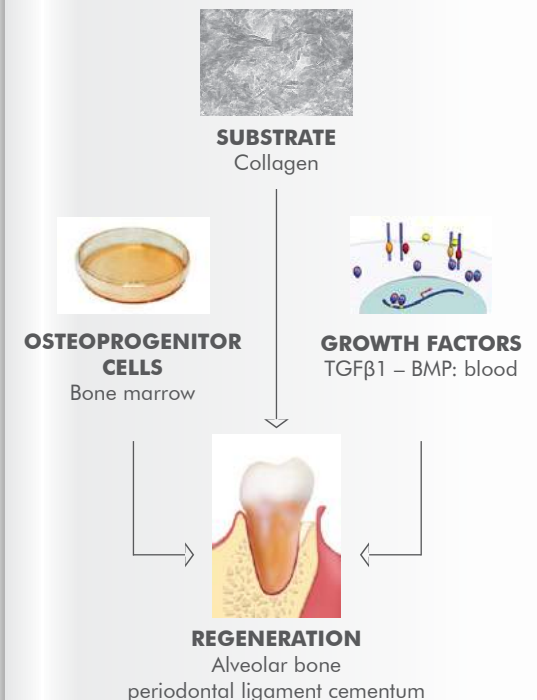
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From heterologous bone to biomaterial

RESULTS OF **INORGANIC** CHEMICAL ANALYSES PERFORMED ON OSTEObIOL® GEN-OS®

Chemical element	OsteoBiol® Gen-OS® (% in weight)
Ca	25.7%
PO ₄ ³⁻	35.2%
C	13.6%
H	2.2%
N	2.9%
O (not in PO ₄ ³⁻)	20.4%
TOTAL	100.0%
Ca/P (n:n)	1.73

Inorganic chemical analyses results
Source: University of Duisburg-Essen, Germany



Mineral component
73.6%

Organic matrix
22.4%

Water 4.0%

RESULTS OF **ORGANIC** CHEMICAL ANALYSES PERFORMED ON OSTEObIOL® GEN-OS®



"The separated proteins (one lane) were fractionated in ten portions and analysed with nano-LC-ESI MS/MS. In the fractions 1-5 in the range from 20-200kDa we found **ONLY COLLAGEN**. In the fractions 6-10 we identify **NO PROTEIN**"

Organic chemical analyses results
Source: Proteome Factory, Germany

A biomaterial for the reconstruction of bone defects must be biocompatible and have good handling and modeling properties; in specific clinical situations, it must also provide sufficient resistance to loading. TecnoSS® laboratories are specialized in processing heterologous bony and collagenic tissues. OsteoBiol® bone process, in particular, has been developed to modify but maintain the original collagen matrix of heterologous tissue, in order to preserve its positive biological functions, obtaining at the same time complete biocompatibility^(1,2). Most biomaterials are inert products that do not interfere, or rather, do not take

part in the physiology of bone remodeling: since they have been developed according to the sole concept of biocompatibility, their function is limited only to preservation of the graft volume (scaffold). The concept of biocompatibility by itself has an essential purpose in the implant of permanent prosthetic elements inside the human body, but it is extremely restrictive in case of materials used for bone reconstruction. OsteoBiol® biomaterials, being gradually resorbed and replaced by abundant newly formed bone over time, create the ideal conditions for the osseointegration of dental implants at re-entry.

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CLIN IMPLANT DENT RELAT RES, 2008 DEC;10(4):264-70.



OsteoBiol®: the most complete products range



The extensive OsteoBiol® range of products are engineered to help surgeons making the right decision when it comes to choose the perfect product for a specific clinical indication, both in dental and maxillofacial surgery.

Tecnoss® development of new products or improvement of existing ones, have a focus on supporting the technical capabilities of the practitioner to improve both intraoperative techniques and clinical results.

Specialists and researchers share their experience, blending clinical background and hands-on experience with the most advanced bio-technologies: the main goal is to obtain a specific solution to satisfy each clinical need.

OsteoBiol® collagenated grafting materials contribute to mineral deposition, vascular ingrowth and growth factor binding, thus providing a favourable environment for bone regeneration. The scientific literature has demonstrated that OsteoBiol® bone matrix is similar to human bone, and it has been reported in humans to be osteoconductive, well integrated in the host site and partially resorbed after 5-6 months, with no signs of adverse reaction.

CERTIFICATIONS



Certifications CE certificates



Annex II | Porcine and Equine Bone Matrix
Source: TecnoSS® s.r.l.



Annex II | Porcine and Equine Membranes
Source: TecnoSS® s.r.l.



Annex II | Equine Felts
Source: TecnoSS® s.r.l.



Annex II | Full Quality Assurance System
Source: TecnoSS® s.r.l.

Bone
substitutes

Blocks

Membranes

Clinical
cases

Innovation

Certifications

Literature

Biocompatibility test Gen-Os®

In order to analyze the biocompatibility of OsteoBiol® grafting materials, a battery of in vitro and animal tests was performed at Biolab S.p.A laboratory (Vimodrone, Milano, Italy), in conformity with Good Laboratory Practice (GLP – certification number 158/245/05; Ministry of Health Decree 10th March 2005).



DIRECT CONTACT CYTOTOXICITY

AIM: cytotoxic potential evaluation of OsteoBiol® Gen-Os® grafting material

MATERIALS AND METHODS

The direct contact cytotoxicity test was performed on a culture at confluence of murine fibroblasts belonging to NCTC L929 clone (Lgc Promochem, Teddington, Middlesex, UK) in exponential growth phase. An eluate with culture Medium was prepared, by dipping the study material in culture Medium to obtain a 0,2g/ml weight/volume ratio. The assay sample was incubated for 72 hours at 37°C ±1°C temperature. Then, 2ml extract was incubated with cultured NCTC L929 cells for a period of 48 hours in incubator at 37°C ±1°C temperature, with CO₂ atmosphere in air.

RESULTS

After 24 hours of incubation, no cytotoxic reaction is detectable in cultured treated cells; in fact there is no presence of both cells lacking intra-cytoplasmic granulations and areas characterized by wide cellular lysis (reactivity grade: 0.00).

CONCLUSIONS

As stated in UNI EN ISO 10993: 5, 2000 rule, OsteoBiol® Gen-Os® study material must be considered as NON CYTOTOXIC.

DELAYED HYPERSENSITIVITY

AIM: sensitizing effects analysis of OsteoBiol® Gen-Os® grafting material

MATERIALS AND METHODS

2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 0.2g/ml weight/volume ratio. Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 15 guinea-pigs were used for each eluate analysis, whom 10 were treated with each study material extract and 5 as controls. Cutaneous sensitization assay is characterized by an induction phase and by a challenge phase.

Induction phase | During induction phase the group of 10 treated guinea-pigs was inoculated with 3 couples (0,1ml each) of intradermal injections as follows:

1°: Complete Freund Adjuvant (FCA) in deionized water (1:1 ratio)

2°: study material eluate

3°: study material eluate + FCA (1:1 ratio).

5 control guinea-pigs received the same injection couples as treated group, but in the 2nd injection only extraction liquid was inoculated (vegetable oil and saline) and in the 3rd injection extraction liquid + FCA (1:1 ratio). After 6 days from intradermal injection in both treated and control animals, a topical application through massage of 0.5ml Sodium Lauryl Sulfate at 10%. After 7 days from intradermal injection, on the skin of 10 treated animals the study material extract was applied in a volume of 0.5ml/animal for a incubation period of 48 hours. The same treatment was performed in the control group, using the respective extraction liquid.

Challenge phase | After 21 days from the beginning of treatment, on all treated and control animals the challenge phase was induced, by applying on the right side of their back 0.5ml of study material extract and on their left side the respective extraction liquid (vegetable oil or saline). The bandages were left in site for 24 hours. After 24 and 48 hours from bandages removal all reactions of both treated and control animals were evaluated.

RESULTS

No reactions of erythema and/or oedema were detectable in both treated and control animals.

CONCLUSIONS

On the base of results obtained, interpreted as stated in UNI EN ISO 10993-10:2002 rule, OsteoBiol® Gen-Os® study material must be defined as NON SENSITIZING.

INTRACUTANEOUS REACTIVITY

AIM: local toxic effects evaluation of OsteoBiol® Gen-Os® grafting material

MATERIALS AND METHODS

An intracutaneous reactivity assay on rabbit was performed. 2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 0.2g/ml weight/volume ratio. Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 0.2ml of each extract was subcutaneously injected in 3 rabbits to evaluate macroscopic signs of cutaneous irritation such as erythema, oedema and eschars.

RESULTS

During all observation period, no signs of erythema, oedema and eschars were detected in treated rabbits.

CONCLUSIONS

OsteoBiol® Gen-Os® study material satisfies the assay conditions, in fact all LOCAL TOXIC EFFECTS were ABSENT, as stated in UNI EN ISO 10993-10:2004 rule.

SYSTEMIC TOXICITY

AIM: toxic systemic effects evaluation of OsteoBiol® Gen-Os® grafting material

MATERIALS AND METHODS

2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 0.2g/ml weight/volume ratio. Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 50mg/Kg of saline extract was subcutaneously injected in a group of 5 mice and 50mg/Kg of vegetable oil extract was intra-peritoneally administered to a group of 5 mice. All noticed symptoms in treated animals during the following 72 hours of observation were surveyed and registered.

RESULTS

None of mice treated with saline or vegetable oil extracts from study material showed toxic symptoms.

CONCLUSIONS

On the base of results obtained, interpreted as stated in UNI EN ISO 10993-11:1997 rule, OsteoBiol® Gen-Os® grafting material can be considered as NON TOXIC.

SALMONELLA TYPHIMURIUM REVERSION

AIM: mutagenesis effects analysis of OsteoBiol® Gen-Os® grafting material

MATERIALS AND METHODS

Salmonella typhimurium assay (reversion of mutation) was performed on 5 mutant strains of Salmonella typhimurium (TA1535, TA1537, TA98, TA100, TA102). The mutagenic activity of study material was defined by the computation of revertant colonies of test cultures in comparison with the number of revertant colonies of control cultures. This activity was evaluated both in presence or absence of an enzymatic system of metabolic activation with the method of direct incorporation into plate. For the assay, 2 eluates of study material were prepared using saline or DMSO as extraction liquids. The extracts were obtained under static conditions by dipping the study material in saline or DMSO to reach a 0.2g/ml weight/volume ratio. Each assay sample was incubated for 72 hours at 37°C ±1°C temperature.

RESULTS

The analysis performed on test strains (incubation with study material eluates) about genetic characteristics demonstrated the maintenance of required genetic characters. Moreover, the study material extracts were both non toxic nor harmful on bacteria used for assays.

CONCLUSIONS

As stated in ISO 10993-11:1993 rule, OsteoBiol® Gen-Os® study material was NON MUTAGENIC, both in presence or absence of metabolic activation.

DIRECT CONTACT CYTOTOXICITY

AIM: cytotoxic potential evaluation of OsteoBiol® Evolution resorbable membrane

MATERIALS AND METHODS

The direct contact cytotoxicity test was performed on a culture at confluence of murine fibroblasts belonging to NCTC L929 clone (Lgc Promochem) in exponential growth phase. The study material was incubated with cultured NCTC L929 cells in monolayer for a period of 24 hours in incubator at 37°C ±1°C temperature, with CO₂ atmosphere in air. After 24 hours incubation, the cell culture was observed to evaluate biological reactivity.

RESULTS

After 24 hours of direct contact in cultured treated cells, no areas, under or surrounding the material, was deformed and/or degenerated (reactivity grade: 0.00).

CONCLUSIONS

As stated in UNI EN ISO 10993: 5, 2000 rule, OsteoBiol® Evolution resorbable membrane must be considered as NON CYTOTOXIC.

DELAYED HYPERSENSITIVITY

AIM: sensitizing effects analysis of OsteoBiol® Evolution resorbable membrane

MATERIALS AND METHODS

2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 6cm²/ml surface/volume ratio. Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 15 guinea-pigs were used for each eluate analysis, whom 10 were treated with each study material extract and 5 as controls. Cutaneous sensitization assay is characterized by an induction phase and by a challenge phase.

Induction phase | During induction phase the group of 10 treated guinea-pigs was inoculated with 3 couples (0.1ml each) of intradermal injections as follows:

1°: Complete Freund Adjuvant (FCA) in deionized water (1:1 ratio)

2°: study material eluate

3°: study material eluate + FCA (1:1 ratio)

5 control guinea-pigs received the same injection couples as treated group, but in the 2nd injection only extraction liquid was inoculated (vegetable oil and saline) and in the 3rd injection extraction liquid + FCA (1:1 ratio). After 6 days from intradermal injection in both treated and control animals, a topical application through massage of 0.5ml Sodium Lauryl Sulfate at 10%. After 7 days from intradermal injection, on the skin of 10 treated animals the study material extract was applied in a volume of 0.5ml/animal for a incubation period of 48 hours. The same treatment was performed in the control group, using the respective extraction liquid.

Challenge phase | After 21 days from the beginning of treatment, on all treated and control animals the challenge phase was induced, by applying on the right side of their back 0.5ml of study material extract and on their left side the respective extraction liquid (vegetable oil or saline). The bandages were left in site for 24 hours. After 24 and 48 hours from bandages removal all reactions of both treated and control animals were evaluated.

RESULTS

No reactions of erythema and/or oedema were detectable in both treated and control animals.

CONCLUSIONS

On the base of results obtained, interpreted as stated in UNI EN ISO 10993-10:2002 rule, OsteoBiol® Evolution resorbable membrane must be defined as NON SENSITIZING.

INTRACUTANEOUS REACTIVITY TEST

AIM: local toxic effects evaluation of OsteoBiol® Evolution resorbable membrane

MATERIALS AND METHODS

A intracutaneous reactivity assay on rabbit was performed. 2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 6cm²/ml surface/volume ratio. Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 0.2ml of each extract were subcutaneously injected in 3 rabbits to evaluate macroscopic signs of cutaneous irritation such as erythema, oedema and eschars.

RESULTS

During all observation period, no signs of erythema, oedema and eschars were detected in treated rabbits.

CONCLUSIONS

OsteoBiol® Evolution resorbable membrane satisfies the assay conditions, in fact all LOCAL TOXIC EFFECTS were ABSENT, as stated in UNI EN ISO 10993-10:2004 rule.

SYSTEMIC TOXICITY TEST

AIM: systemic toxicity effects evaluation of OsteoBiol® Evolution resorbable membrane

MATERIALS AND METHODS

2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 6cm²/ml surface/volume ratio. Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 50mg/Kg of saline extract was subcutaneously injected in a group of 5 mice and 50mg/Kg of vegetable oil extract was intra-peritoneally administered to a group of 5 mice. All noticed symptoms in treated animals during the following 72 hours of observation were surveyed and registered.

RESULTS

None of mice treated with saline or vegetable oil extracts from study membrane showed toxic symptoms.

CONCLUSIONS

On the base of results obtained, interpreted as stated in UNI EN ISO 10993-11:1997 rule, OsteoBiol® Evolution resorbable membrane can be considered as NON TOXIC.

SALMONELLA TYPHIMURIUM REVERSION

AIM: mutagenesis effects analysis of OsteoBiol® Evolution resorbable membrane

MATERIALS AND METHODS

Salmonella typhimurium assay (reversion of mutation) was performed on 5 mutant strains of Salmonella typhimurium (TA1535, TA1537, TA98, TA100, TA102). The mutagenic activity of study material was defined by the computation of revertant colonies of test cultures in comparison with the number of revertant colonies of control cultures. This activity was evaluated both in presence or absence of an enzymatic system of metabolic activation with the method of direct incorporation into plate. For the assay, 2 eluates of study material were prepared using saline or DMSO as extraction liquids. The extracts were obtained under static conditions by dipping the study material in saline or DMSO to reach a 6cm²/ml surface/volume ratio. Each assay sample was incubated for 72 hours at 37°C ±1°C temperature.

RESULTS

The analysis performed on test strains (incubation with study material eluates) about genetic characteristics demonstrated the maintenance of required genetic characters. Moreover, the study material extracts were both non toxic nor harmful on bacteria used for assays.

CONCLUSIONS

As stated in ISO 10993-11:1993 rule, OsteoBiol® Evolution resorbable membrane was NON MUTAGENIC, both in presence or absence of metabolic activation.

Biocompatibility test mp3®

DIRECT CONTACT CYTOTOXICITY

AIM: cytotoxic potential evaluation of OsteoBiol® mp3® grafting material

MATERIALS AND METHODS

The cytotoxicity direct contact test was performed on a confluent NCTC L929 (Mammal fibroblasts ATCC CCL1 NCTC Clone L929) cell culture in exponential phase of growth.

The test product was applied to the monolayer of NCTC L929 and was incubated at 37°C ±1°C in CO₂ atmosphere for 24 hours. After 24 hours of incubation the cells cultures were observed to evaluate the biological reactivity (cell degeneration and malformations).

RESULTS

After 24hrs of contact, in the cells treated with test product no detectable malformed or degenerated zone around or under specimen was observed (reactivity grade 0).

CONCLUSIONS

On the basis of the results, interpreted according to EN ISO 10993-5:2009, the test product must be considered NOT CYTOTOXIC.

DELAYED HYPERSENSITIVITY

AIM: hypersensitivity effects evaluation of OsteoBiol® mp3® grafting material

MATERIALS AND METHODS

Two extracts of the test product were prepared both in vegetable oil and in physiological solution in order to perform the tests for delayed-type hypersensitivity. The extracts of the test product were performed by submerging the test sample into both solvents. Then the test sample was incubated for 72 hours at temperature of 37°C ±1°C in dynamic conditions. For each extract guinea pigs were used. The test is characterized by an induction phase and challenge phase. In induction phase, the guinea pigs were treated with intradermal injections. 6 days after the beginning of treatment on the all animals, a topical application was performed. After 7 days from the intradermal injections, the extracts of test product were applied. The application lasted 48 hours. The same treatment was performed on control guinea pigs using only extraction liquid. The challenge phase, 21 days after the beginning of treatment, was performed applying by an occlusive patch on all the animals about 1ml of the extract on the left side and about 1ml of the solvent on the right side. The patch was left on for 24 hours. 48 and 72 hours after the beginning of this phase, the tested animals and the control animals were observed. No abnormalities were observed in the animals used as treated and as control. On the basis of the results, interpreted according to EN ISO 10993-10:2002, the test product can be considered NON SENSITIZING.

RESULTS

No abnormalities were observed in the animals used as treated and as control.

CONCLUSIONS

On the basis of the results, interpreted according to EN ISO 10993-10:2002, the test product can be considered NON SENSITIZING.

INTRACUTANEOUS REACTIVITY

AIM: local toxic effects evaluation of OsteoBiol® mp3® grafting material

MATERIALS AND METHODS

An intracutaneous reactivity assay on albino rabbit was performed. Two extracts of test product were prepared using physiological solution and vegetable oil as liquid of extraction. The extracts of the test product were performed by submerging the test sample into both solvents. Then the test sample was incubated for 72 hours at temperature of 37°C ±1°C in dynamic conditions. Each extract were intracutaneously injected in albino rabbits. All animals have been observed at 24, 48 and 72 hours for injection for evaluated each toxic symptom and macroscopical skin reactions, as erythema, oedema and eschar.

RESULTS

During the study, all the treated sites showed no sign of erythema nor sign of oedema. All the control sites showed no sign of erythema nor sign of oedema.

CONCLUSIONS

On the basis of the results, interpreted according to EN ISO 10993-10:2002, the test product SATISFIES the requirements of the test.

SALMONELLA TYPHIMURIUM REVERSE MUTATION

AIM: mutagenesis effects evaluation of OsteoBiol® mp3® grafting material

MATERIALS AND METHODS

The test was performed on five mutant strains of Salmonella typhimurium (TA1535, TA1537, TA98, TA100, TA102). The mutagenic activity of the test sample was determined by comparing number of reverting colonies with the number of the reverting organisms in the control cultures. The extracts of the test product were performed by submerging the test sample into physiological solution and DMSO. Then the sample was incubated for 72 hours at temperature of 37°C ±1°C in dynamic conditions.

RESULTS

No increase in the number of revertant colonies per plate in any strain with or without metabolic activation system was detected.

CONCLUSIONS

On the basis of results, evaluated according to EN ISO 10993-3:2003, the test product, undergone to Ames test, is NON-MUTAGENIC either in the presence or absence of metabolic activation.

SYSTEMIC TOXICITY

AIM: systemic toxic effects evaluation of OsteoBiol® mp3® grafting material

MATERIALS AND METHODS

In the acute systemic toxicity test two extracts of test device were prepared using physiological solution and vegetable oil as liquid of extraction. The extracts of the test product were performed by submerging the test sample into both solvents. Then the test sample was incubated for 72 hours at temperature of 37°C ±1°C in dynamic conditions. An extract of test device in physiological solution was intravenous injected in a group of mice and other extract in vegetable oil was intraperitoneally injected in other group of mice. All animals were observed immediately after injection and after 4, 24, 48 and 72 hours for evaluated each symptom as tremors, convulsions, tachycardia, etc.

RESULTS

In none of the treated animals toxic signs or symptoms were observed.

CONCLUSIONS

On the basis of the results, interpreted according to EN ISO 10993-11:2006, the test product must be considered NON TOXIC.

IN BONE IMPLANT

AIM: osteogenesis activity evaluation of OsteoBiol® mp3® grafting material

MATERIALS AND METHODS

In bone implant test, the test samples were implanted in three sites of right femur of 4 white rabbits; USP Reference Standard Negative Control Plastic were implanted in three sites of the contralateral side. Animals were sacrificed after 4 and 12 weeks. At the end of the study, histopathology of the implanted sites (for each animal 1 treated site and 1 control site) were performed.

RESULTS

After 4 weeks the bone holes treated with the test sample showed an active neo-osteogenesis. After 12 weeks the treated bone holes were completely closed.



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Medical devices – Quality management systems – Requirements for regulatory purposes

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LATERAL ACCESS SINUS LIFT

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Laura Ricci
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Adriano Pignelli
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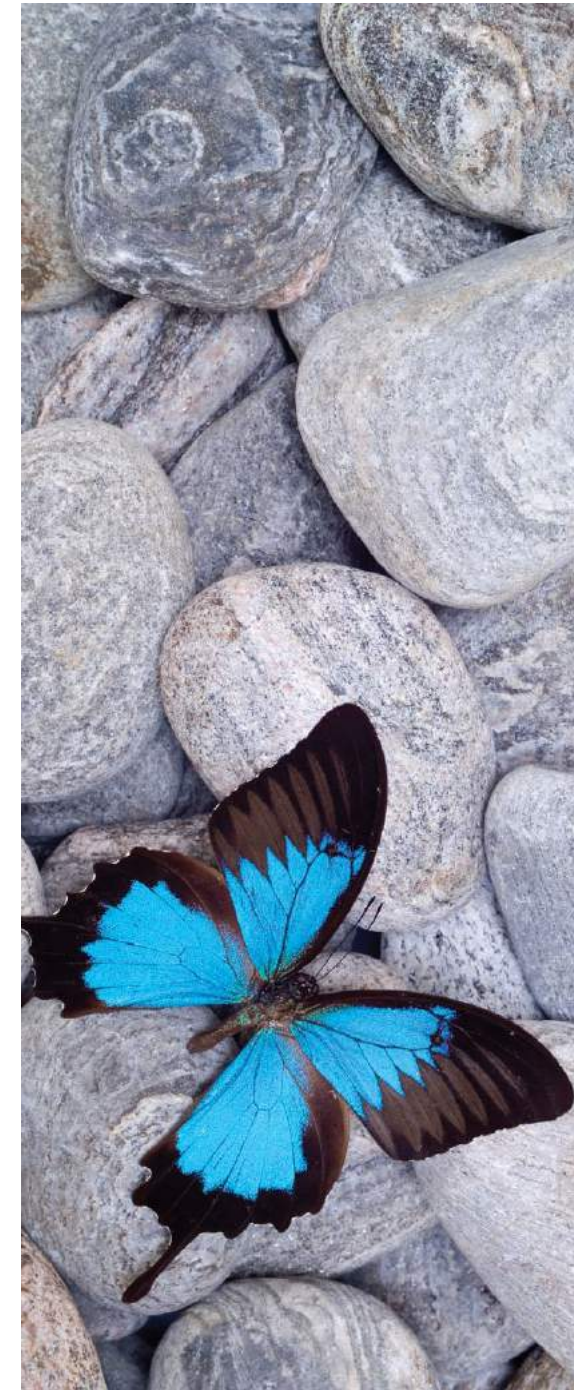
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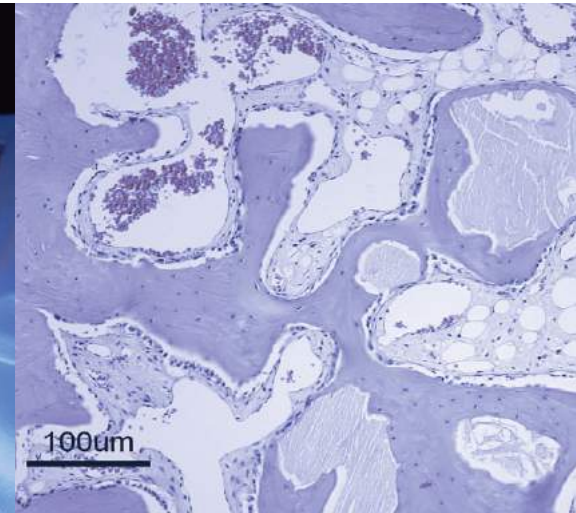
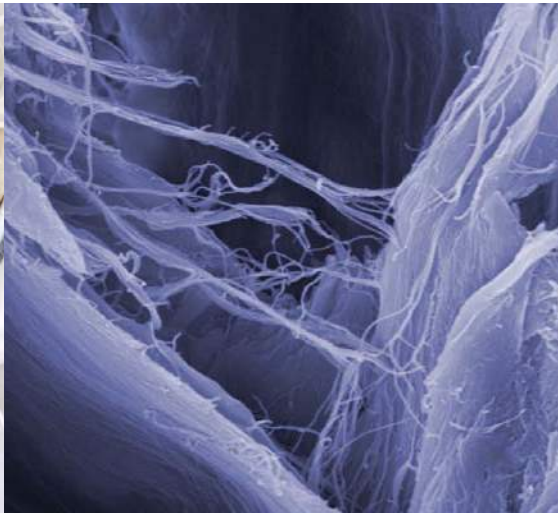
PRODUCT	PACKAGING	TYPE	SIZE	PORCINE CODE	EQUINE CODE
BONE SUBSTITUTES					
Gen-Os®	1 Vial	DRIED GRANULES	0.25 g	M1052FS	M1052FE
Gen-Os®	1 Vial	DRIED GRANULES	0.5 g	M1005FS	M1005FE
Gen-Os®	1 Vial	DRIED GRANULES	1.0 g	M1010FS	M1010FE
Gen-Os®	1 Vial	DRIED GRANULES	2.0 g	M1020FS	M1020FE
Gen-Os® 1000-2000	1 Vial	DRIED GRANULES	1.0 g	M0210FS	
Gen-Os® 1000-2000	1 Vial	DRIED GRANULES	2.0 g	M0220FS	
TSV Gel	1 Syringe	Thermo GEL	0.5 g	TSV005S <small>in kit with M1005FS or A1005FS</small>	TSV005E <small>in kit with M1005FE or A1005FE</small>
TSV Gel	1 Syringe	GEL	1.0 g	TSV010S <small>in kit with M1010FS or A1010FS</small>	TSV010E <small>in kit with M1010FE or A1010FE</small>
mp3®	1 Syringe	BONE MIX	0.5 cc	A3095FS	A3095FE
mp3®	1 Syringe	BONE MIX	1.0 cc	A3005FS	A3005FE
mp3®	3 Syringes	BONE MIX	3x0.25 cc (0.75 cc)	A3075FS	
mp3®	3 Syringes	BONE MIX	3x0.5 cc (1.5 cc)	A3015FS	A3015FE
mp3®	3 Syringes	BONE MIX	3x1.0 cc (3.0 cc)	A3030FS	A3030FE
mp3®	1 Syringe (wide tip)	BONE MIX	2.0 cc	A3010FS	A3010FE
mp3® 1000-2000	1 Syringe (wide tip)	BONE MIX	2.0 cc	A3210FS	A3210FE
Putty	1 Syringe	BONE PASTE	0.25 cc	HPT52S	
Putty	1 Syringe	BONE PASTE	0.5 cc	HPT09S	HPT09E
Putty	3 Syringes	BONE PASTE	3x0.25 cc (0.75 cc)	HPT32S	HPT32E
Putty	3 Syringes	BONE PASTE	3x0.5 cc (1.5 cc)	HPT35S	HPT35E
Putty	1 Syringe (wide tip)	BONE PASTE	1.0 cc	HPT61S	HPT61E
Gel 40	1 Syringe	BONE GEL	0.5 cc	05GEL40S	05GEL40E
Gel 40	3 Syringes	BONE GEL	3x0.5 cc (1.5 cc)	15GEL40S	15GEL40E
Apatos Mix	1 Vial	DRIED GRANULES	0.5 g	A1005FS	A1005FE
Apatos Mix	1 Vial	DRIED GRANULES	1.0 g	A1010FS	A1010FE
Apatos Mix	1 Vial	DRIED GRANULES	2.0 g	A1020FS	A1020FE
Apatos Cortical	1 Vial	DRIED GRANULES	0.5 g	AC1005FS	
Apatos Cortical	1 Vial	DRIED GRANULES	1.0 g	AC1010FS	
Apatos Mix 1000-2000	1 Vial	DRIED GRANULES	1.0 g	A0210FS	A0210FE

PRODUCT	PACKAGING	TYPE	SIZE	PORCINE CODE	EQUINE CODE
BLOCKS					
Sp-Block	1 Blister	DRIED BLOCK / NORM	10x10x10 mm		BN0E
Sp-Block	1 Blister	DRIED BLOCK / NORM	10x10x20 mm		BN1E
Sp-Block	1 Blister	DRIED BLOCK / NORM	10x20x20 mm		BN2E
Sp-Block	1 Blister	DRIED BLOCK / NORM	35x10x5 mm		BN8E
Dual-Block CURVED	1 Blister	DRIED BLOCK / SOFT	20x15x5 mm	STS7S	
Dual-Block CURVED	1 Blister	DRIED BLOCK / NORM	20x10x5 mm	STN5S	
MEMBRANES AND BARRIERS					
Evolution	1 Blister	DRIED / X-FINE	20x20x (0.2) mm	EM02XS	
Evolution	1 Blister	DRIED / X-FINE	30x30x (0.2) mm	EM03XS	
Evolution	1 Blister	DRIED / FINE	20x20x (0.4) mm		EV02LLE
Evolution	1 Blister	DRIED / FINE	30x30x (0.4) mm		EV03LLE
Evolution	1 Blister	DRIED / FINE	Oval 25x35x (0.4) mm		EVOLLE
Evolution	1 Blister	DRIED / FINE	40x40x (0.5) mm		EV04LLE
Evolution	1 Blister	DRIED / FINE	80x60x (0.4) mm		EV06LLE
Evolution	1 Blister	DRIED / STANDARD	20x20x (0.6) mm	EM02HS	EV02HHE
Evolution	1 Blister	DRIED / STANDARD	30x30x (0.6) mm	EM03HS	EV03HHE
Evolution	1 Blister	DRIED / STANDARD	Oval 25x35x (0.6) mm	EM00HS	
Derma	1 Blister	DRIED / X-FINE	20x20x (0.6) mm	ED02LS	
Derma	1 Blister	DRIED / FINE	Oval 12x8x (0.9) mm	ED21FS	
Derma	1 Blister	DRIED / FINE	25x25x (1.0) mm	ED25FS	
Derma	1 Blister	DRIED / FINE	50x50x (1.0) mm	ED05FS	
Derma	1 Blister	DRIED / STANDARD	15x5x (2.0) mm	ED15SS	
Derma	1 Blister	DRIED / STANDARD	30x30x (2.0) mm	ED03SS	
Derma	1 Blister	DRIED / STANDARD	50x50x (2.0) mm	ED05SS	
Soft Cortical Lamina	1 Blister	DRIED / FINE	25x25x (0.5) mm	LS25FS	LS25FE
Soft Cortical Lamina	1 Blister	DRIED / FINE	Oval 25x35x (0.5) mm	LS23FS	LS23FE
Soft Cortical Lamina	1 Blister	DRIED / MEDIUM	20x40x (1.0) mm	LS24LS	
Curved Lamina	1 Blister	DRIED / MEDIUM	35x35x (0.9) mm	LS10HS	LS10HE
Soft Cortical Lamina	1 Blister	DRIED / SEMI-SOFT	35x35x (1.0) mm	LS35LS	
Soft Cortical Lamina	1 Blister	DRIED / STANDARD	30x30x (2.0) mm	LS03SS	LS03SE
Special	1 Blister	DRIED / X-FINE	20x20x (0.2) mm		EM02LE
Special	1 Blister	DRIED / X-FINE	30x30x (0.2) mm		EM03LE
Duo-Teck	1 Blister	DRIED	20x20x (1.0) mm		DT020
Duo-Teck	6 Blister	DRIED FELT	25x25x (0.2) mm		DTN625





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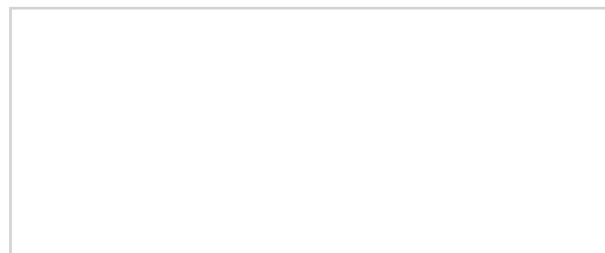
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