

## 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 Nannmark, University of Goteborg, Sweden Active resorption by osteoclasts of a particle of prehydrated and collagenated

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Source: Courtesy of Prof Ult Nam

LM image of an OsteoBiol Lamina hydrated with blood: vascularisation enhanced by the presence of the original vascular canals Source: Courtesy of Prof Ulf Nannmark, University of Göteborg, Sweden Part of a biopsy showing newly formed bone after treatment with OsteoBiol® Putty. Htx-cosine, Magnification x20 Source: Histology by Prof Ulf Nannmark, University of Göleborg, 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.I.



## THE OSTEOBIOL® DUAL-PHASE HETEROLOGOUS BONE MATRIX

OsteoBiol<sup>®</sup> is the family of biomaterials produced by Tecnoss<sup>®</sup> for the dental and maxillo-facial surgeons.

In each OsteoBiol<sup>®</sup> granule, besides its mineral phase, the Tecnoss<sup>®</sup> 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<sup>®</sup> bone matrix avoids ceramization, maintaining a chemical composition extremely similar to autogenous bone, and therefore gradually resorbable and replaceable by newly formed bone.

SEM image of an OsteoBiol® Gen-Os® granule: osteoblastic colonisation. Magnification x3000 Source: Courtesy of Prof Ulf Nannmark, University of Göteborg, Sweden 1

## **HIGH BIOCOMPATIBILITY**

The chemical structure of each OsteoBiol<sup>®</sup> dual-phase granule, its ideal porosity and collagen content, make it a valid scaffold and substrate for osteoblasts anchorage, proliferation and new bone apposition.



Part of a biopsy showing newly formed bone inside and around a particle of OsteoBiol® 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<sup>®</sup> 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<sup>®</sup> granules, which are partially but significantly replaced by vital bone at re-entry time.



## **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<sup>®</sup> granules allows an adequate colonization of the grafting site by new vessels, and is therefore a positive and significant factor within the regenerative process.



## THE ROLE OF COLLAGEN

Collagen favours MSC differentiation and enhances osteoblasts proliferation: it is considered as the ideal substrate for bone forming cells. OsteoBiol<sup>®</sup> 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.



# A SPECIFIC PRODUCT FOR EVERY CLINICAL INDICATION

OsteoBiol<sup>®</sup> 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 10 years of clinical research: you will experience that today it is finally possible to achieve predictable clinical success without the availability limitations of autogenous bone.



## **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 is the greatest reward for any surgeon and fulfillment of our company mission.

## **OsteoBiol® products vs clinical indications**

	<b>Gen-Os<sup>®</sup></b> Collagenated heterologous cortico-cancellous bone mix Granulometry 250-1000 μm For information on OsteoBiol <sup>®</sup> Gen-Os <sup>®</sup> see page 22	<b>Pre-hydrated collagenated heterologous</b> cortico-cancellous bone mix Granulometry 600-1000 μm For information on OsteoBiol® mp3 <sup>®</sup> see page 30	<b>Putty</b> Pre-hydrated collagenated heterologous cortico-cancellous bone paste Granulometry up to 300 μm For information on OsteoBiol® Putty see page 34	<b>Gel 40</b> Pre-hydrated collagenated heterologous cortico-cancellous bone gel Granulometry up to 300 µm For information on OsteoBiol® Gel 40 see page 38
ALVEOLAR REGENERATION	-00	100	~~~~	
MAXILLARY SINUS LIFT				CRESTAL ACCESS ONLY
PERI-IMPLANT DEFECTS	NI CONTRACTOR		IF DEFECT WALLS	
HORIZONTAL AUGMENTATION			ACTIVE PROFILE	
VERTICAL AUGMENTATION INLAY TECHNIQUE		IN ASSOCIATION		
PERIODONTAL REGENERATION	N			3-WALL DEFECTS
SOFT TISSUE AUGMENTATION				



Cortico-cancellous and cortical bone Granulometry 600-1000  $\mu$ m For information on OsteoBiol® Apatos see page 42

#### **Sp-Block**

Collagenated heterologous cancellous block For information on OsteoBiol® *Sp-Block* see page 48

#### **Evolution**

Heterologous collagen membrane For information on OsteoBiol® Evolution see page 54

#### Lamina

Collagenated heterologous cortical bone For information on OsteoBiol® Lamina see page 62

#### Derma

Collagen dermal matrix For information on OsteoBiol® Derma see page 58



## **BONE SUBSTITUTES**

















### **OsteoBiol® bone substitutes**



Bone substitutes

Blocks

Membranes

Clinical cases

Innovation

Certifications

Literature



Bone augmentation using OsteoBiol® Gen-Os® after the removal of a cyst Source: Courtesy of Dr Uri Arny, Israel



Periodontal regeneration with OsteoBiol® Gen-Os® Source: Courtesy of Dr Sergio Matos, Coimbra, Portugal











## The advantages of a dual-phase biomaterial

**Collagenated heterologous cortico-cancellous bone mix** 



**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

 $\begin{array}{c} 250\text{-}1000\,\mu\text{m} \\ \text{M}1052\text{FS} & | 1 \,\text{Vial} & | 0.25 \,\text{g} & | \text{ Porcine} \\ \text{M}1052\text{FE} & | 1 \,\text{Vial} & | 0.25 \,\text{g} & | \text{ Equine} \\ \text{M}1005\text{FS} & | 1 \,\text{Vial} & | 0.5 \,\text{g} & | \text{ Porcine} \\ \text{M}1005\text{FE} & | 1 \,\text{Vial} & | 0.5 \,\text{g} & | \text{ Equine} \\ \text{M}1010\text{FS} & | 1 \,\text{Vial} & | 1.0 \,\text{g} & | \text{ Porcine} \\ \text{M}1010\text{FE} & | 1 \,\text{Vial} & | 1.0 \,\text{g} & | \text{ Equine} \\ \text{M}1020\text{FS} & | 1 \,\text{Vial} & | 2.0 \,\text{g} & | \text{ Porcine} \\ \text{M}1020\text{FE} & | 1 \,\text{Vial} & | 2.0 \,\text{g} & | \text{ Equine} \\ \end{array}$ 

1000-2000 μm M0210FS | 1 Vial | 1.0 g | Porcine

**GMDN code** 38746

#### **Characteristics and handling**

#### CHARACTERISTICS

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

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<sup>(5)</sup>, it can function as a carrier for selected medications and drugs<sup>(6)</sup>.

#### HANDLING

Gen-Os<sup>®</sup> must always be hydrated and thoroughly mixed with *TSV Gel* or a few drops of sterile physiological solution to activate its collagen matrix and to enhance its adhesivity; it can also be mixed with patient's blood. If necessary it can as well be mixed with the drug selected for surgery.

#### ADVANTAGES

Gen-Os<sup>®</sup> expands up to 50% in volume after hydration with sterile saline: hydrated collagen contained in each granule also increases sensibly the biomaterial adhesivity.



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



Source: Tecnoss® Dental Media Library

#### **Clinical Indications**

Gen-Os<sup>®</sup>, 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<sup>(7)</sup> 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<sup>(8)</sup>. Gen-Os<sup>®</sup> is also indicated

for lateral access maxillary sinus lift<sup>(4,9)</sup>

and dehiscence regeneration<sup>(10)</sup>, always

Ongoing studies are also proving its

effectiveness in periodontal regeneration

of deep intrabony defects. Due to its

collagen content, once hydrated

Gen-Os® becomes very sticky and

hydrophylic<sup>(5)</sup>: 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<sup>(2)</sup>: these unique

properties allow a very good graft

volume preservation, a healthy new

bony tissue and ultimately, a successful

implant rehabilitation.

with

Evolution

association

in

membranes.

free animated videos on OsteoBiol<sup>®</sup> APP



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**DEHISCENCES AND FENESTRATIONS** peri-implant lesions case reports on page 76



**CRESTAL ACCESS SINUS LIFT** osteotome technique case reports on page 78



**ALVEOLAR REGENERATION** socket preservation case reports on page 73

25

Additional case reports on osteobiol.com



LATERAL ACCESS SINUS LIFT maxillary sinus floor augmentation



PERIODONTAL REGENERATION



**HORIZONTAL AUGMENTATION** case reports on page 83



case reports on page 80

intrabony defects case reports on page 88

For further information see the complete literature on p. 110









# TSV Gel





## The resorbable solution for ideal graft stability

Thermosensitive resorbable gel for graft stabilization



#### **Composition** Heterologous type I and III collagen gel Thermogelling synthetic biocompatible copolymer

**Physical form** LV phase at <8°C Gel viscosity at >13°C

#### **Packaging** Syringe: 0.5 cc, 1.0 cc

Available only in combination with OsteoBiol® Gen-Os® 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 and handling**

#### CHARACTERISTICS

The purpose of this product is to provide mechanical stability to bone substitutes and barrier membranes.

OsteoBiol<sup>®</sup> *TSV Gel* is sterilized by Gamma irradiation and is radiotransparent. It contains Heterologous type I and III collagen gel with polyunsaturated fat acids diluted in aqueous solution containing a biocompatible synthetic copolymer that gives OsteoBiol<sup>®</sup> *TSV Gel* thermo-reversible and thermo-gelling properties. At low temperature  $(+4^{\circ}C)$ 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

OsteoBiol<sup>®</sup> *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 OsteoBiol<sup>®</sup> *Gen-Os*<sup>®</sup> or to apply on OsteoBiol<sup>®</sup> membranes.

At room temperature, the product remains at LV phase for few minutes, whereas once in situ its viscosity quickly increases with body temperature. OsteoBiol<sup>®</sup> *TSV Gel* in LV phase can be used instead of saline for hydrating and mixing with OsteoBiol<sup>®</sup> *Gen-Os*<sup>®</sup>. The result will be a sticky mixture easy to place and extremely stable once in situ. OsteoBiol<sup>®</sup> *TSV Gel* can also be applied to the rough side of the OsteoBiol<sup>®</sup> *Evolution* membrane to stabilize it during graft covering and whilst suturing.



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

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



Source: Tecnoss® Dental Media Library



28

#### **Clinical Indications**

free animated videos on OsteoBiol<sup>®</sup> APP Coogle play App Store

# Blocks

Membranes

#### **OsteoBiol® TSV Gel GELIFICATION KINETICS**



Source: Politecnico di Torino, Italy

The graph shows the effect of temperature change on 3 OsteoBiol® 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 OsteoBiol® TSV Gel is gel-like. It does not harden but keeps a soft consistency that allows the mixture with Gen-Os<sup>®</sup> granules. Thanks to the hydrophilic properties of Gen-Os<sup>®</sup>, the mixture becomes a sticky, stable conglomerate that can easily be placed in the defect site. OsteoBiol® TSV Gel is biocompatible and rapidly resorbed.

**ALVEOLAR REGENERATION** socket preservation case reports on page 73



**DEHISCENCES AND FENESTRATIONS** peri-implant lesions case reports on page 76



PERIODONTAL REGENERATION intrabony defects case reports on page 88



**HORIZONTAL AUGMENTATION** two-wall defects case reports on page 83

OsteoBiol® TSV Gel can be used in GBR procedures together with OsteoBiol® bone substitutes and membranes to enhance graft stability. The viscosity reached by OsteoBiol® TSV Gel at body temperature improves significantly the stability of Gen-Os® 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.

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





OsteoBiol® mp3® extruded directly from the syringe Source: Courtesy of Dr Gianluca Reato, Mestre (VE), Italy













## **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

**Re-entry time** About 5 months

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

#### **Product codes**

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

#### GMDN code

38746

#### **Characteristics and handling**

#### **CHARACTERISTICS**

Heterologous origin biomaterial made of 600-1000  $\mu$ m 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 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<sup>(1)</sup>, and can be used as an alternative to autologous bone.

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

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

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

#### HANDLING

*mp3*<sup>®</sup> 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: Tecnoss® Dental Media Library

#### **Clinical Indications**

The Tecnoss<sup>®</sup> patented manufacturing process used to obtain OsteoBiol<sup>®</sup> materials is able to achieve biocompatibility preserving part of the collagen matrix of the animal bone<sup>(6)</sup> and avoiding at the same time high temperatures that would cause ceramization of the granules: the result is a unique biomaterial, consisting of mineral component and organic matrix, with a porous surface extremely similar to autogenous bone and able to resorb progressively while new bone formation takes place<sup>(2)</sup>.

*mp3*<sup>®</sup>, a pre-hydrated cortico-cancellous bone mix with 10% collagen gel, has been developed with this innovative biotechnology and is a "ready-to-use" product.

*mp3*<sup>®</sup> main indication is lateral access maxillary sinus lift<sup>(3,7,8)</sup>, always in association with *Evolution* membranes, recommended to cover the antrostomy: the *mp3*<sup>®</sup> syringe can be directly applied into the bony window without having to mix the *mp3*<sup>®</sup> granules with saline.

Due to its collagen gel content,  $mp3^{(B)}$ allows an excellent graft stability while its hydrophilia guarantees quick blood absorption and therefore the necessary graft vascularization.  $mp3^{(B)}$  has also been successfully used in combination with *Evolution* membranes for alveolar ridge preservation<sup>(9)</sup>: 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.

Finally, mp3<sup>®</sup> is also indicated for

horizontal augmentation (two wall defects) in combination with autogenous bone blocks<sup>(10)</sup> or with OsteoBiol<sup>®</sup> Lamina<sup>(11)</sup>: its cortico-cancellous composition allows a progressive resorption of osteoclastic type, and in parallel a similar rate of new bone formation<sup>(2)</sup>.

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



mp3<sup>®</sup> grafted after the removal of a cyst Source: Courtesy of Prof Antonio J. Murillo Rodriguez, Eibar, Spain



**Ridge preservation with OsteoBiol® mp3®** Source: Courtesy of Dr Roberto Rossi, Genova, Italy



App Store

free animated videos

on OsteoBiol<sup>®</sup> APP

Google play

LATERAL ACCESS SINUS LIFT maxillary sinus floor augmentation case reports on page 80



ALVEOLAR REGENERATION post-extractive sockets case reports on page 73



HORIZONTAL AUGMENTATION two-wall defects case reports on page 83

Additional case reports on osteobiol.com

33

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For further information see the complete literature on p. 110





Horizontal augmentation performed with OsteoBiol® Putty Source: Courtesy of Prof Antonio J Murillo Rodriguez, Eibar, Spain









## **Engineered for peri-implant defects**

Pre-hydrated collagenated heterologous cortico-cancellous bone paste



#### **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: 0.5 cc, 1.0 cc, 3x0.5 cc, 3x0.25 cc

#### Product codes

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 Wide tip HPT61S | 1 Syringe | 1.0 cc | Porcine HPT61E | 1 Syringe | 1.0 cc | Equine

GMDN code

38746

#### **Characteristics and handling**

#### **CHARACTERISTICS**

Putty is a bone paste with at least 80% micronized heterologous bone (granulometry up to 300  $\mu$ m) and collagen gel. It is made with an exclusive process that provides the product with exceptional malleability and plasticity, making it easy to apply in sockets and 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<sup>(1)</sup>. 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: Tecnoss® Dental Media Library
## **Clinical Indications**

The exclusive Tecnoss<sup>®</sup> manufacturing process guarantees an exceptional malleability and plasticity: furthermore the syringe provides Putty extraordinary handling properties making this product the ideal choice for post-extractive sockets<sup>(2)</sup>, self-contained peri-implant defects and all defects that present a self-contained cavity. Thanks to the collagen component, Putty facilitates blood clotting and the subsequent invasion of repairing and regenerative cells. Furthermore, the Tecnoss<sup>®</sup> manufacturing process avoids granules ceramization, allowing a progressive resorption of the biomaterial and, at the same time, a significant new-bone formation rate<sup>(3)</sup>. 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<sup>(4,5)</sup>.

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 self contained defects where the surrounding walls guarantee such condition: for example post-extractive sockets and inside the bone crest when ridge-split technique is adopted<sup>(6)</sup>.







Fenestration grafted with OsteoBiol® Putty. Grafting site protected with OsteoBiol® Evolution membrane Source: Courtesy of Dr Atef Ismail Mohamed, Cairo, Egypt



App Store

free animated videos

on OsteoBiol<sup>®</sup> APP

Google play

**ALVEOLAR REGENERATION** post-extractive sockets case reports on page 73



**DEHISCENCES AND FENESTRATIONS** peri-implant defects case reports on page 76



**HORIZONTAL AUGMENTATION** ridae split case reports on page 83

Additional case reports on osteobiol.com

37

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For further information see the complete literature on p. 110

Bone substitutes



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







# **Gel 40**





## A unique heterologous bone gel

**Collagenated heterologous cortico-cancellous bone mix** 



**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 and handling**

#### **CHARACTERISTICS**

Gel 40 is made of a collagen matrix (type I and III) obtained using exclusive Tecnoss® process, loaded for 60% of its volume with micronized heterologous bone (granulometry up to 300  $\mu$ m). The product is in a gel state at temperatures below 30° C; at higher temperatures the viscosity is reduced and Gel 40 can be mixed with hydrosoluble and/or liposoluble drugs. 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. Placed on site *Gel 40* combines with blood, contributing to the fast and compact formation of primary blood clot.



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: Tecnoss® Dental Media Library

## **Clinical Indications**

The exclusive Tecnoss<sup>®</sup> manufacturing process quarantees 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<sup>(1,2)</sup>, deep and narrow peri-implant defects<sup>(3)</sup>, three-wall intrabony defects and, in combination with Evolution membranes, for gingival recessions<sup>(4)</sup>. Thanks to the collagen component, Gel 40 facilitates blood clotting and the subsequent invasion of repairing and regenerative cells. 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<sup>(5)</sup>. Gel 40 "soft" consistency also guarantees an easy and healthy soft-tissues healing.



Crestal access sinus lift with OsteoBiol® Gel 40 Source: Tecnoss® Dental Media Library



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on OsteoBiol<sup>®</sup> APP

Google play

**PERIODONTAL REGENERATION** intrabony defects and gingival recessions case reports on page 88



**CRESTAL ACCESS SINUS LIFT** crestal sinus floor augmentation case reports on page 78

Additional case reports on osteobiol.com



SERIES

Blocks

Membranes HEALING OF GINGIVAL RECESSIONS USING A COLLAGEN MEMBRANE WITH A DEMINERALIZED XENOGRAFT: A RANDOMIZED INT J PERIODONTICS RESTORATIVE DENT, 2009 FEB;29(1):59-67

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Clinical cases















## Microcrystalline hydroxyapatite

Heterologous cortico-cancellous and cortical bone



#### **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

#### 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**

 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
 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

GMDN code

38746

## **Characteristics and handling**

#### **CHARACTERISTICS**

Apatos is a biocompatible<sup>(1)</sup>, biomaterial of osteoconductive<sup>(2)</sup> heterologous origin with characteristics similar to mineralized human bone $^{(3,4)}$ ; it can therefore be used as an alternative to autologous The bone. natural microporous consistency of Apatos facilitates the formation of new bone tissue in bone defect area<sup>(5)</sup>, 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; 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: Tecnoss® Dental Media Library

## **Clinical Indications**

Apatos is a universal filler, that can be used to treat peri-implant defects and two-wall defects<sup>(6,7)</sup>. Because of its granulometry, Apatos cannot be used in narrow defects, but it fits well in big sockets, e.g. after molar extractions<sup>(8)</sup>. Both types of sinus lift (with crestal or lateral access)<sup>(4,9)</sup> can be performed with Apatos as bone substitute, as well as surgeries for horizontal regenerations.

Apatos Cortical is characterized by a very long resorption time, guaranteeing optimal preservation of the graft volume.

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



LATERAL ACCESS SINUS LIFT maxillary sinus floor augmentation case reports on page 80



**ALVEOLAR REGENERATION** socket preservation case reports on page 73



HORIZONTAL AUGMENTATION two-wall defects case reports on page 83







**DEHISCENCES AND FENESTRATIONS** peri-implant grafting case reports on page 76



**CRESTAL ACCESS SINUS LIFT** osteotome sinus floor augmentation case reports on page 78



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# BLOCKS

















## **OsteoBiol® bone blocks**



SEM image of OsteoBiol® Sp-Block. Magnification 25x. Source: Courtesy of Prof Dr José L Calvo Guirado, Murcia, Spain For more information on OsteoBiol® Sp-Block see page 48





SEM image of OsteoBiol® Dual-Block. Magnification 20x. Source: Politecnico di Torino, Italy For more information on OsteoBiol® Dual-Block see page 48





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





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







**Highly osteoconductive properties** 





## Dual-Block

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



**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 irroration grade of grafting site and on clinical conditions of patient

#### Packaging

Sterile blister

#### Product codes

BN0E | 10x10x10 mm | Equine BN1E | 10x10x20 mm | Equine BN2E | 10x20x20 mm | Equine BN8E | 35x10x5 mm | Equine

GMDN code

38746

## **Characteristics, handling and clinical indications**

free animated videos on OsteoBiol<sup>®</sup> APP

Google play

App Store

**CHARACTERISTICS** 

*Sp-Block* is a cancellous block of xenogenic bone produced with an exclusive Tecnoss® process which avoids ceramization of the hydroxyapatite crystals, thus accelerating physiological resorption. *Sp-Block* supports new bone formation<sup>(1,2)</sup>: 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<sup>(3,4,5)</sup>, 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 and to stabilize the augmented area with mini-plates and screws.



SEM image of OsteoBiol<sup>®</sup> cancellous block Source: Courtesy of Prof Ulf Nannmark, University of Göteborg, Sweden

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VERTICAL AUGMENTATION inlay technique case reports on page 86

Additional case reports on osteobiol.com

## Characteristics, handling and clinical indications



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<sup>(1)</sup>, the graft offers an adequate support for tissue recostruction 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 be always fixed with microscrews osteosynthesis 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.

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

#### OsteoBiol® Dual-Block Source: Tecnoss® Dental Media Library

case reports on page 83

**HORIZONTAL AUGMENTATION** 

onlay technique

## Literature

**Physical form** Rigid dried block

Cortico-cancellous bone

**Tissue collagen** 

Preserved

Composition Collagenated cortico-cancellous bone

#### **Re-entry time**

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

Packaging Sterile blister

#### STS7S | 20x15x5 mm | Soft | Porcine curved STN5S| 20x10x5 mm | Norm | Porcine curved

GMDN code 38746



free animated videos

App Store

on OsteoBiol<sup>®</sup> APP

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## MEMBRANES AND BARRIERS

















## **OsteoBiol®** membranes and barriers

**MEMBRANES** BARRIERS **Duo-Teck Evolution Special** Lamina Derma Porcine derma Cortical bone Heterologous Heterologous Lyophilised equine mesenchymal tissue pericardium collagen felt + bone **Translucent Dried membrane** Semi-rigid dried **Dried membrane with one** Dried smooth side and one dried covered with lamina, flexible membrane micro-rough side membrane micronized bone after re-hydration OsteoBiol® Derma grafted on lateral sinus Intrabony defect graft protected by OsteoBiol® Special protecting the Schneider OsteoBiol® Duo-Teck grafted OsteoBiol® Lamina for the covering of a OsteoBiol® Evolution membrane before grafting Source: Courtesy of Dr Atef Ismail Mohamed, Cairo, horizontally augmented area wall Source: Courtesy of Dr Roberto Abundo and Dr Source: Courtesy of Prof Antonio J. Murillo Rodriguez, Source: Courtesy of Dr Donato Frattini, Legnano, Italy Egypt For more inf Source: Courtesy of Prof Dr Hannes Wachtel and Dr Source: Courtesy of Profile Profile Tobias Thalmair, Munich, Germany Giuseppe Corrente, Torino, Italy on OsteoBiol® Speci on on OsteoBiol® Duo-Teck Eibar, Spain For more tion on OsteoBiol® Evolution tion on OsteoBiol® Dermo see page 66 For more info see page 66 For more info see page 58 see page 62 see page 54

Literature





Periodontal defect treated with OsteoBiol<sup>®</sup> Gen-Os<sup>®</sup> and covered with Evolution Source: Courtesy of Prof Małgorzata Pietruska, Białystok, Poland





# Evolution





## The natural Evolution of collagen membranes

Heterologous mesenchymal tissue



**Tissue of origin** Heterologous mesenchymal tissue

Tissue collagen Preserved

#### **Physical form**

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

#### Thickness

Fine: 0.3 mm (±0.1 mm) Standard: 0.5 mm (±0.1 mm)

#### **Estimated resorption time** Fine: about 3 months

Standard: about 4 months

**Packaging** 20x20 mm, 30x30 mm, 25x35 mm (oval)

#### **Product codes**

EV02LLE | 20x20 mm | Fine | Equine EV02HHE | 20x20 mm | Standard | Equine EM02HS | 20x20 mm | Standard | Porcine EV03LLE | 30x30 mm | Fine | Equine EV03HHE | 30x30 mm | Standard | Equine EM03HS | 30x30 mm | Standard | Porcine EVOLLE | 25x35 mm (oval) | Fine | Equine EM00HS | 25x35 mm (oval) | Standard | Porcine

GMDN code

38746

## **Characteristics and handling**

#### CHARACTERISTICS

Obtained from heterologous mesenchymal tissue, the *Evolution* membrane is gradually resorbable<sup>(1)</sup>. 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 membraneperiosteum interface

• stability and prolonged protection of the underlying graft<sup>(1)</sup>

#### 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<sup>(3,4,5)</sup>.



**SEM image of the rough side of an OsteoBiol® Evolution membrane** Source: Courtesy of Prof Dr José L Calvo Guirado, Murcia, Spain



Source: Tecnoss® Dental Media Library

## **Clinical Indications**

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<sup>(1)</sup>, protecting the graft from external agents. The dense collagenic matrix of Evolution protects the graft from infection in case of accidental exposure: the membrane itself will also not be infected, allowing second intention healing $^{(3,4)}$ .

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

In lateral access sinus lift Evolution membranes are indicated to cover antrostomy (standard model)<sup>(6,7,8)</sup> and to protect the sinus membrane from cutting risk due to graft pressure (fine model or OsteoBiol<sup>®</sup> Special)<sup>(9)</sup>.

Evolution is also ideal to protect regenerations<sup>(10)</sup> and peri-implant periodontal grafts. Furthermore, Evolution fine has been successfully used in combination with OsteoBiol® Gel 40 for the treatment of gingival recessions<sup>(2)</sup> and to protect Sp-Block in vertical augmentation with inlay technique<sup>(11)</sup>.

LATERAL ACCESS SINUS LIFT maxillary sinus floor augmentation case reports on page 80



PERIODONTAL REGENERATION intrabony defects case reports on page 88



**HORIZONTAL AUGMENTATION** two-wall defects case reports on page 83



App Store

free animated videos

on OsteoBiol<sup>®</sup> APP

Set Kin Google play

**DEHISCENCES AND FENESTRATIONS** peri-implant lesions case reports on page 76



**ALVEOLAR REGENERATION** graft protection case reports on page 73



**VERTICAL AUGMENTATION** inlay technique case reports on page 86

57

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INT J PERIODONTICS RESTORATIVE DENT, 2013 MAR;33(2):159-66

For further information see the complete literature on p. 106

Blocks

Clinical cases

Literature



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













## A xenogenic graft for soft tissue augmentation

**Collagen dermal matrix** 



**Tissue of origin** Porcine derma

Tissue collagen Preserved

**Physical form** Dried membrane

**Composition** 100% derma

#### Thickness

Fine: 0.9 mm (±0.1 mm) Standard: 2.0 mm (±0.2 mm)

**Estimated resorption time** Fine: about 3 months Standard: about 4 months

**Packaging** Fine: 25x25 mm Standard: 7x5 mm, 15x5 mm, 30x30 mm

#### **Product codes**

ED21FS | 12x8 mm | Fine | Porcine ED25FS | 25x25 mm | Fine | Porcine ED03SS | 30x30 mm | Standard | Porcine ED75SS | 7x5 mm | Standard | Porcine ED15SS | 15x5 mm | Standard | Porcine

GMDN code

38746

## **Characteristics and handling**

#### CHARACTERISTICS

Obtained from derma of porcine origin, using an exclusive Tecnoss<sup>®</sup> process, *Derma* membranes are gradually integrated with the autologous soft tissues<sup>(1)</sup>. Their strong consistency and resistance allow a perfect stabilization and a prolonged protection of underlying graft in large 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 hydrated for 5 minutes in sterile lukewarm physiological solution. 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<sup>®</sup> Derma Source: Politecnico di Torino, Italy



**SEM image of Derma collagen fibers** Source: Courtesy of Dr Kai R. Fischer, University of Witten/Herdecke, Germany



Source: Tecnoss® Dental Media Library

## **Clinical Indications**

Derma membrane is a collagen resorbable barrier to protect and stabilize bone grafting materials; only in this specific indication it can be used also in open healing 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 to improve the quality of keratinized tissues<sup>(2)</sup>.

Mild gingival recessions<sup>(3)</sup> 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.





Derma grafted to treat gingival recession and healing after 1 year Source: Courtesy of Dr Magda Mensi, Brescia, Italy



SOFT TISSUE AUGMENTATION soft tissue improvement case reports on page 90



PERIODONTAL REGENERATION gingival recessions case reports on page 88



ALVEOLAR REGENERATION graft protection case reports on page 73

Additional case reports on osteobiol.com

61

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Bone substitutes



Horizontal defect grafted with OsteoBiol<sup>®</sup> 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





# Lamina





## A unique cortical bone barrier

Heterologous collagenated cortical bone



**Tissue of origin** Cortical bone

**Tissue collagen** Preserved

**Physical form** Semi-rigid dried lamina, flexible after re-hydration

**Composition** 100% cortical bone

#### Thickness

Fine: 0.5 mm (±0.1 mm) Medium Curved: 1.0 mm (±0.1 mm) Standard: 3 mm (±1 mm)

#### Estimated re-entry time

Fine: about 5 months Medium Curved: about 6 months Standard: about 8 months

#### Packaging

Fine: 25x25 mm, 25x35 mm (oval) Medium Curved: 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 | Porcine LS10HE | 35x35 mm | Curved | Equine LS03SS | 30x30 mm | Standard | Porcine LS24LS | 20x40 mm | Medium | Porcine

GMDN code 38746

## **Characteristics and handling**

#### **CHARACTERISTICS**

OsteoBiol<sup>®</sup> Lamina is made of cortical bone of heterologous origin produced with an exclusive Tecnoss<sup>®</sup> process that ceramization avoids the of hydroxyapatite crystals, thus accelerating 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. OsteoBiol<sup>®</sup> Curved Lamina has a semi-rigid consistency and can be grafted without hydration, provided that it is previously shaped to fit the defect morphology.

#### HANDLING

OsteoBiol<sup>®</sup> Lamina can be shaped with sterile scissors until the desired size is reached, then it must be hydrated for 3/5 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.

OsteoBiol<sup>®</sup> Curved Lamina should not be hydrated 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 OsteoBiol® Lamina** Source: Courtesy of Prof José L Calvo Guirado, Murcia, Spain



Source: Tecnoss® Dental Media Library

## **Clinical Indications**

Cortical Laminas are made of cortical bone of heterologous origin which undergoes a process of superficial decalcification, nevertheless maintaining the typical consistency of the bone tissue from which it originates.

The fine model becomes flexible after hydration and can be shaped<sup>(1)</sup> and adapted to the defect morphology creating, once fixated with osteosynthesis screws, a semi-rigid covering to the underlying graft<sup>(2)</sup>. This property is particularly useful when it is necessary to obtain a space making effect in esthetic areas<sup>(3)</sup>, as well as in horizontal augmentation<sup>(4)</sup> of two wall defects and antrostomy covering in lateral access sinus lift procedures<sup>(5,6,7)</sup>. Lamina can also be used in regenerations with risks of exposure and for orbital floor restoration<sup>(1,8,9)</sup>. The Curved Lamina has a 0.8-1.0 mm thickness and can be directly grafted without hydration: it is particularly indicated in association with OsteoBiol® mp3® for regeneration of ridges with compromised cortical plate.







OsteoBiol® Lamina positioning Source: Tecnoss® Dental Media Library



HORIZONTAL AUGMENTATION

two-wall defects

case reports on page 83

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Certifications

Literature

65



OsteoBiol\* Special protecting the Schneider membrane before grafting Source: Courtesy of Dr Donato Frattini, Legnano (MI), Italy



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











**Engineered to protect hard and soft tissue grafts** 







**Granules-coated collagen felt** 



**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

**Packaging** 20x20 mm, 30x30 mm

#### **Product codes**

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

**GMDN code** 38746

## **Characteristics, handling and clinical indications**

#### **CHARACTERISTICS**

Obtained from extra fine pericardium of heterologous origin, using an exclusive Tecnoss<sup>®</sup> 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 can be also 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 88



LATERAL ACCESS SINUS LIFT Schneider membrane protection case reports on page 80

## Characteristics, handling and clinical indications

#### **CHARACTERISTICS**

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

It 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<sup>(1)</sup>, in order to avoid accidental lesions caused by grafting material. It can be also used for closure of antrostomy, before replacement of the muco-gingival flap.

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JOURNAL OF ORAL IMPLANTOLOGY, 2010 DEC; 36(6):485-489



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



LATERAL ACCESS SINUS LIFT maxillary sinus floor augmentation case reports on page 80



**DEHISCENCES AND FENESTRATIONS** peri-implant lesions case reports on page 76



**Tissue of origin** Equine lyophilised collagen felt and equine bone

**Tissue collagen** Preserved

**Physical form** Dried membrane covered with micronized bone

Composition Collagen felt and bone granules

Granulometry Up to  $300 \,\mu m$ 

Thickness With granules coating: 0.2 mm  $(\pm 0.1 \text{ mm})$ Collagen felt only: 0.15 mm ( $\pm 0.05$  mm)

**Estimated resorption time** 

About 15 days

Packaging 20x20 mm, 25x25 mm

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

**GMDN** code 38746

Clinical cases

Innovation

## 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 leads to less risk of morbidity and reduce treatment time.

Readers will enjoy a comprehensive atlas providing some practical advise 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 lezzi

### 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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## **CLINICAL CASES**
















# **Case report** Ridge preservation











Fig. 6



### **ALVEOLAR REGENERATION**

Sex: female | Age: 49 Fig. 1 Preoperative image

and bony tissue are evident

the bone defect

14 threads

with PP 5/0

vestibular side

vertical defect

Fig. 12 Periapical x-ray

Fig. 2 After the extraction, the deficit of soft tissue

Fig. 3 Intraoperative image: vertical defect in 2.4 Fig. 4 Implant placement in 2.3 and 2.5, close to

Fig. 5 Implant placement in 2.4, with exposure of

Fig. 7 Placement of OsteoBiol® Cortical Lamina to

Fig. 6 Treatment of the defect with OsteoBiol®

Fig. 9 Primary closure of the wound from the

Fig. 10 Detail of the treated area at 8 months

Fig. 11 Complete bone regeneration of the

Apatos mixed with autologous bone

avoid the collapse of the vertical defect Fig. 8 Detail (occlusal view) of the bone regeneration with Apatos and Lamina and suture

Documentation provided by

Bone substitute: OsteoBiol® Apatos For more information on OsteoBiol® Apatos see page 42

Barrier: OsteoBiol® Lamina For more information on OsteoBiol® Lamina see page 62





Fig. 4



Fig. 7



Fig. 8

Fig. 5



Prof Antonio J Murillo Rodriguez Eibar, Spain email: dr.murillo@clinicairazabal.com www.clinicairazabal.com

#### **ALVEOLAR REGENERATION**

## **Case report** Ridge bone volumetric reconstruction with mp3<sup>®</sup>

#### 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*<sup>®</sup> 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

Documentation provided by Prof **Antonio Barone** DDS, PhD, MSc University of Pisa, Italy e-mail: barosurg@gmail.com













Fig. 2



Fig. 5





Fig. 3



Fig. 6



# Case report Alveolar ridge preservation











Fig. 9

#### **ALVEOLAR REGENERATION**

Fig. 2 Soft tissues collapse after tooth extraction

Fig. 3-4 Graft with OsteoBiol® Gen-Os® and PRP Fig. 5 Socket seal with fibrin and PRP sponge

Fig. 7 Implant positioning with flapless technique

Sex: female | Age: 21 Fig. 1 Initial situation

Fig. 6 Provisional tooth

Fig. 8-9 Final result

Blocks

Bone substitute: OsteoBiol® Gen-Os® For more information on OsteoBiol<sup>®</sup> Gen-Os<sup>®</sup> see page 22





Fig. 8

Documentation provided by Dr Roberto Rossi

e-mail: drrossi@mac.com

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

75

Fig. 4



#### **DEHISCENCES AND FENESTRATIONS**

Case report Regeneration of a fenestration defect

Sex: male | Age: 34

Fig. 1 Preoperative image

**Fig. 2** Placement of the implants, where it is possible to observe a fenestration defect

Fig. 3 Defect treated with OsteoBiol® Putty

Fig. 4 Creation of a pocket for the introduction of more OsteoBiol<sup>®</sup> Putty to fill the defect

Fig. 5 Surgical re-entry, where it is possible to observe the bone regeneration







76



Fig. 3

Documentation provided by Prof Antonio J Murillo Rodriguez Eibar, Spain email: dr.murillo@clinicairazabal.com www.clinicairazabal.com





## **Case report** Peri-implant bone regeneration









#### **DEHISCENCES AND FENESTRATIONS**

Fig. 2 Clinical inspection of edentulous area 1.2

Fig. 3 Implant placed with a significant vestibular

Fig. 4 A considerable bone resorption is evident

**Fig. 6** OsteoBiol<sup>®</sup> *mp3*<sup>®</sup> is grafted into the defect Fig. 7 Self-contained defect fully filled with

Fig. 8 The membrane is adapted to the vestibular

Fig. 1 OPT exam: the defect area is 1.2

Fig. 5 An OsteoBiol® Evolution standard membrane is fixed to the palatal bone

Fig. 10 OPT exam with implant in 1.2

Sex: male | Age: 60

from the occlusal view

OsteoBiol® mp3®

Fig. 9 Suture

side and soaked with blood

dehiscence

Blocks

MD - DDS Private Practitioner in Perugia, Italy Implant and Oral Surgery Director - Eiffel Medical Center, Budapest, Hungary e-mail: pino@famadental.com www.famadental.com

Bone substitute: OsteoBiol® mp3® For more information on OsteoBiol® mp3 see page 30

Membrane: OsteoBiol® Evolution For more information on OsteoBiol® Evolution see page 54



Fig. 4



Fig. 7



Fig. 9

Fig. 6

Fig. 10

77

Documentation provided by Dr. Giuseppe Famà

#### **CRESTAL ACCESS SINUS LIFT**

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 OsteoBiol<sup>®</sup> Gel 40

Fig. 7 Post-operative x-ray

Fig. 8 Control x-ray at 12 months

# Case report Sinus lift with crestal access



Fig. 4





Fig. 2



Documentation provided by Dr **Roberto Rossi** M.Sc.D. in Periodontology, Genova, Italy e-mail: drrossi@mac.com

Bone substitute: OsteoBiol® Gel 40 For more information on OsteoBiol® Gel 40 see page 38





# **Case report** Crestal access sinus lift on three sites







Fig. 3







Documentation provided by Prof Dr José L Calvo Guirado University of Murcia, Spain e-mail: josecalvog@gmail.com

Bone substitute: OsteoBiol® Gel 40 For more information on OsteoBiol® Gel 40 see page 38

# **CRESTAL ACCESS SINUS LIFT**

Blocks

Membranes

Clinical cases

#### Sex: male | Age: 45

Fig. 1 Pre-operative panoramic x-ray

Fig. 2 Initial situation, the three missing teeth will be replaced by three single prothesis

Fig. 3 Flap opening and crest exposure, an horizontal defect is also present

Fig. 4 Osteotomy is performed on the three sites

Fig. 5 Maxillary sinus floor lifted with OsteoBiol® Gel 40

Fig. 6 Grafting has been completed and implants can now be inserted

Fig. 7 Three implants placed into position

Fig. 8 A mix of autologous bone and OsteoBiol® Gel 40 is prepared

Fig. 9 The bone/biomaterials mixture is grafted on the vestibular side of the defect to complete the horizontal augmentation

Fig. 10 Flaps are repositioned and sutured

Fig. 11 Post-operative panoramic x-ray

Fig. 12 Final situation

Innovation



Fig. 4









Fig. 11

Fig. 5

79



#### LATERAL ACCESS SINUS LIFT

# Case report Bilateral sinus lift with lateral access

#### Sex: female | Age: 48

**Fig. 1** Initial x-ray OPT image showing a severe maxillary atrophy in the posterior region

Fig. 2 Pre-operative intraoral image, right sector

Fig. 3 Osteotomy to access the right maxillary sinus

**Fig. 4** Intraoral image showing the right maxillary sinus filled with OsteoBiol® *mp3*<sup>®</sup>

Fig. 5 Suture of mucoperiosteal flap

Fig. 6 Osteotomy to access the left maxillary sinus

Fig. 7 Intraoral image showing the left maxillary sinus filled with OsteoBiol<sup>®</sup>  $mp3^{®}$ 

**Fig. 8** A properly shaped OsteoBiol<sup>®</sup> Special membrane was placed as left maxillary sinus antrostomy covering

Fig. 9 X-ray image after 8 months from sinus lift surgery





Fig. 2



Fig. 5



Fig. 6



Fig. 8



Documentation provided by

Prof **Antonio Barone** DDS, PhD, MSc University of Pisa, Italy e-mail: barosurg@gmail.com

e-mail: covani@covani.it

Prof **Ugo Covani** MD, DDS

Membrane: OsteoBiol<sup>®</sup> Special For more information on OsteoBiol<sup>®</sup> Special see page 66

Fig. 9

Fig. 4

Fig. 7

80

# Case report Sinus lift with lateral access and treatment of horizontal defect









Fig. 6



Fig. 9

#### LATERAL ACCESS SINUS LIFT

Blocks

Membranes

Clinical cases

#### Sex: female | Age: 46

Fig. 1 Pre-operative radiograph showing insufficient residual bone height in the left maxillar quadrant

Fig. 2 Osteotomy to access the maxillary sinus. Note the buccal concavity of the maxilla showing a horizontal bone defect

Fig. 3 Autogenous bone collected with a bone scraper from the tuberosity and anterior wall of the maxilla

Fig. 4 Grafting of the buccal concavity with autogenous bone and insertion of OsteoBiol® Apatos in the sinus

Fig. 5 Grafting with OsteoBiol<sup>®</sup> mp3<sup>®</sup>, overlaying the previous biomaterial and the autogenous bone

Fig. 6 Placement of an OsteoBiol® Evolution collagen membrane covering the sinus window in two layers

Fig. 7 Post-operative x-ray

Fig. 8 Post-operative x-ray showing the rehabilitation 15 months after the sinus lift and 9 months after implant placement (delayed placement)

Fig. 9 Final restoration in place

Documentation provided by Dr Bruno Negri Alicante, Spain e-mail: brunonegri2000@yahoo.com Prof Dr José L Calvo Guirado Murcia, Spain e-mail: josecalvog@gmail.com

Bone substitute: OsteoBiol® mp3® For more information on OsteoBiol® mp3® see page 30

Bone substitute: OsteoBiol® Apatos For more information on OsteoBiol® Apatos see page 42

Membrane: OsteoBiol® Evolution For more information on OsteoBiol® Evolution see page 54

Fig. 1



Fig. 7



Fig. 8



Innovation

#### LATERAL ACCESS SINUS LIFT

# Case report Lateral access sinus lift with simultaneous implant and horizontal augmentation

#### 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<sup>®</sup> *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<sup>®</sup> *Evolution* membrane is stabilized with osteosynthesis screws above the antrostomy

Fig. 8 Cortical bone stimulation

**Fig. 9** OsteoBiol<sup>®</sup>  $mp3^{®}$  is grafted on the vestibular side of the defect for horizontal augmentation

**Fig. 10** The OsteoBiol<sup>®</sup> Evolution membrane is stabilised into position with a transpalatal suture

Fig. 11 Final situation

Fig. 12 Post-operative x-ray

Documentation provided by Dr **Rosario Sentineri** Private practitioner in Genova, Italy e-mail: rosario.sentineri@gmail.com

Bone substitute: **OsteoBiol® mp3®** For more information on OsteoBiol® mp3® see page 30

Membrane: OsteoBiol<sup>®</sup> Evolution For more information on OsteoBiol<sup>®</sup> Evolution see page 54





Fig. 2



Fig. 5



Fig. 8



Fig. 11



Fig. 3



Fig. 6





Fig. 10 82

Fig. 4

## **Case report** Horizontal defect grafted with OsteoBiol<sup>®</sup> Lamina and mp3<sup>®</sup>











Fig. 6





Fig. 12

#### HORIZONTAL AUGMENTATION

Blocks

Membranes

Clinical cases

#### 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<sup>®</sup> mp3<sup>®</sup>

Fig. 6 Covering the augmented area with OsteoBiol<sup>®</sup> 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

Innovation



Barrier: OsteoBiol® Lamina





Fig. 4



83

Documentation provided by Prof Dr Hannes Wachtel Dr Tobias Thalmair Private Institute for Periodontology and Implantology, Munich, Germany

Email: hannes@wachtel.biz

Bone substitute: OsteoBiol® mp3® For more information on OsteoBiol® mp3® see page 30

For more information on OsteoBiol® Lamina see page 62







#### HORIZONTAL AUGMENTATION

## **Case report** Extensive horizontal augmentation with mp3<sup>®</sup> graft and Lamina

#### 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. 8

Fig. 5





Fig. 3



Fig. 6



Fig. 9

Documentation provided by Prof **Michael Weinländer** Wien, Austria e-mail: office@drweinlaender.at

Bone substitute: **OsteoBiol®** mp3® For more information on OsteoBiol® mp3® see page 30

Barrier: OsteoBiol® Lamina For more information on OsteoBiol® Lamina see page 62

# Case report Horizontal regeneration in the aesthetic area









Fig. 6



#### **HORIZONTAL / VERTICAL** AUGMENTATION

# 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<sup>®</sup> mp3<sup>®</sup> is compacted around the screw

Fig. 6 Ridge is recreated, compacting the mp3<sup>®</sup>. 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

Bone substitutes

Blocks

Membranes

Clinical cases

Innovation

Documentation provided by Dr Patrick Palacci Brånemark Osseointegration Center Marseille, France e-mail: patrick@palacci.com

85

Bone substitute: OsteoBiol® mp3® For more information on OsteoBiol® mp3® see page 30













Fig. 4

Fig. 11



#### VERTICAL AUGMENTATION

### **Case report** Vertical bone regeneration of the frontal mandible

#### 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<sup>®</sup> 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 Uneventfully 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

Documentation provided by Dr Miha Kočar Ljubljana, Slovenia e-mail: mihakocar@yahoo.com

Bone substitute: OsteoBiol® Sp-Block For more information on OsteoBiol<sup>®</sup> Sp-Block see page 48

Bone substitute: OsteoBiol® Gen-Os® For more information on OsteoBiol<sup>®</sup> Gen-Os see page 22

Membrane: OsteoBiol® Evolution For more information on OsteoBiol® Evolution see page 54











86





Fig. 2



Fig. 5















## **Case report** Vertical regeneration with inlay technique in the posterior mandible







Fig. 3

Fig. 6





VERTICAL AUGMENTATION

Blocks

Membranes

Clinical cases

#### 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

Innovation

Documentation provided by Dr Pietro Felice Prof Roberto Pistilli University of Bologna, Italy E-mail: pietro.felice@unibo.it

\*Prof **Ulf Nannmark** University of Göteborg, Sweden

Bone substitute: OsteoBiol® Sp-Block For more information on OsteoBiol® Sp-Block see page 48



Fig. 11

Fig. 7

Fig. 4







Fig. 12

87



#### **PERIODONTAL REGENERATION**

Sex: male | Age: 47

Fig. 1 Pre-operative x-ray: 4-mm defect

Fig. 2 Pocket probing depth (PPD) 6 mm

Fig. 3 Flap elevation

Fig. 4 Intrabony defect

Fig. 5 Treatment with OsteoBiol® Gen-Os®

Fig. 6 Covering with OsteoBiol® Evolution

Fig. 7 Double sling suture

Fig. 8 Double sling suture - Occlusal view

Fig. 9 Healing after 1 week

Fig. 10 CAL gain of 3 mm after 9 months

Fig. 11 PPD 3 mm after 1 year

Fig. 12 X-ray after 1 year







Fig. 5



Fig. 4

Fig. 7

Fig. 10

88





Fig. 8



Fig. 11



Fig. 3



Fig. 6



Fig. 9





Documentation provided by Dr Sergio Matos Coimbra, Portugal e-mail: sergiomatos1@sapo.pt

Bone substitute: **OsteoBiol® Gen-Os®** For more information on OsteoBiol® Gen-Os® see page 22

Membrane: OsteoBiol® Evolution For more information on OsteoBiol® Evolution see page 54

# Case report Periodontal regeneration in the aesthetic area

## **Case report** Treatment of a periodontal defect in the anterior mandible

Blocks



Fig. 1 Severe loss of attachment

Fig. 2 Pocket probing depth (PPD) 10 mm

Fig. 3 Intrabony 2-walls defect, 5 mm

Fig. 4 OsteoBiol® Gen-Os® graft covered with an Evolution membrane

Fig. 5 36-months follow up

Fig. 6 Attachment gain and regeneration of the intrabony defect

# Fig. 2





Documentation provided by Dr Roberto Rossi M.Sc.D. in Periodontology, Genova, Italy e-mail: drrossi@mac.com

Bone substitute: OsteoBiol® Gen-Os® For more information on OsteoBiol® Gen-Os® see page 22

Membrane: OsteoBiol® Evolution For more information on OsteoBiol® Evolution see page 54

Fig. 1

Fig. 3

Fig. 6

89

#### SOFT TISSUE AUGMENTATION

# Case report Gingival recession grafted with Derma

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. 4

Fig. 7

Fig. 10

90





Fig. 3



Fig. 5





Fig. 9



Documentation provided by Assist Prof Rok Gašperšič Ljubljana, Slovenia e-mail: rok.gaspersic@mf.uni-lj.si



# **Case report** Soft tissue augmentation at time of second stage











Fig. 4









#### SOFT TISSUE AUGMENTATION

Blocks

Membranes

#### 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

Clinical cases

Prof Stefan Fickl Associate Professor Department of Periodontology, Julius-Maximilians-University, Würzburg, Germany email: fickl\_s@ukw.de

Documentation provided by

Soft tissue: OsteoBiol® Derma For more information on OsteoBiol® Derma see page 58

# Bone, Biomaterials & Beyond

Educational website

**BBB.education** is providing dental education to members from over 40 countries and is supported by a team of world renowned clinicians and researchers.

**BBB.education** is delivering information on high quality courses and webinars to dental professionals in order to meet their growing educational needs, focusing on the most advanced biomaterials and surgical techniques.

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# BBB International Symposia



Madrid



Düsseldorf

# **BBB Webinars**



Dr Patrick Palacci Prof Ulf Nannmark

Sinus elevation and immediate implant placement in severely resorbed maxilla by using *mp3* and a compacting technique



Prof Stefan Fickl Prof Antonio Barone

Soft tissue grafting - established techniques and new materials

# BBB Events



Marseille



Dr Giuseppe Verdino Dual-Block technique



Dr Roberto Rossi

Vertical and horizontal ridge augmentation with Cortical Lamina technique

# INNOVATION

# Tecnoss<sup>®</sup> bone vs human bone

Studies and researches have demonstrated that gold standard in bone regeneration is autologous bone<sup>(1,2)</sup>.

It is also well known, though, what disadvantages are related to the harvesting and grafting of autogenous  $bone^{(3,4)}$ .

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<sup>(5)</sup>.

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<sup>(6,7)</sup>.

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<sup>(8)</sup>.



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CLIN ORAL IMPLANTS RES, 2014 MAY 26 EPUB AHEAD OF PRINT

Certifications



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 postoperatory 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

# Bone substitutes

Clinical cases

# Characteristics of Tecnoss® process

Tecnoss<sup>®</sup> has developed treatment manufacturing processes of various animal species connective tissues, allowing to obtain the biocompatibility of these tissues, preserving at the same time their collagen matrix<sup>(1)</sup>.

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<sup>(2)</sup>. The basic research for development of OsteoBiol® 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, Tecnoss<sup>®</sup> developed a biotechnology able, by avoiding the high temperature ceramization phase, to preserve the structure of natural hydroxyapatite and therefore allow an osteoclastic-type remodeling of biomaterial, similar to physiological bone turnover time<sup>(3)</sup>.

Thanks to this innovative technology, the OsteoBiol<sup>®</sup> line has the following important characteristics:

1. Absence of a foreign body response<sup>(4)</sup>

2. Gradual resorption over time $^{(3,5)}$ 

3. Stimulation and acceleration of physiological tissue healing  $\ensuremath{\mathsf{process}}^{(6)}$ 

4. Protection of the grafting site from infection (membranes) $^{(7,8)}$ 

5. Capability of carrying medication to the surgical site  $\ensuremath{^{(9)}}$ 

![](_page_96_Picture_16.jpeg)

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PHYSICOCHEMICAL CHARACTERIZATION OF BIOMATERIALS COMMONLY USED IN DENTISTRY AS BONE SUBSTITUTES -COMPARISON WITH HUMAN BONE

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OSTEOBIOL® INFLUENCES OSTEOGENIC DIFFERENTIATION OF ADIPOSE DERIVED STEM CELLS EUR J INFLAMMAT, 2011, VOL. 9, NO. 3(S), 103-107

(6) HSU FY, CHUEH SC, WANG YJ MICROSPHERES OF HYDROXYAPATITE/RECONSTITUTED COLLAGEN AS SUPPORTS FOR OSTEOBLAST CELL GROWTH BIOMATERIALS 1999, 20:1931-1936 **Collagen: a key factor for clinical success** 

Tecnoss<sup>®</sup> 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<sup>(1)</sup>.

These characteristics of OsteoBiol® products allow a consistent bone neo-formation and a close contact between mature neo-formed bone and biomaterial granules<sup>(2-4)</sup>.

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

• it acts as a valid substrate for platelet activation and aggregation

 $\bullet$  it serves to attract and differentiate the mesenchymal stem cells present in the bone  $marrow^{(5)}$ 

• it increases the proliferation rate of the

osteoblasts up to 2/3 times<sup>(6)</sup>

• it stimulates the activation of the platelets, osteoblasts and osteoclasts in the tissue healing process

The presence of collagen inside each granule makes OsteoBiol<sup>®</sup> *Gen-Os*<sup>®</sup> 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<sup>®</sup> 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®

![](_page_97_Figure_26.jpeg)

Source: University of Duisburg-Essen, Germany

![](_page_97_Picture_28.jpeg)

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-B (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)<sup>(1-3)</sup>.

In vitro studies demonstrated that heterologous collagen is able to induce differentiation of mesenchymal osteoprogenitor stem cells into osteoblasts<sup>(4)</sup>, 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 OsteoBiol® 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 OsteoBiol<sup>®</sup> 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<sup>(4,5)</sup>.

#### 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<sup>(5)</sup> while as a resorbable membrane it is able to guide connective tissue regeneration.

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(5) BRUNELLI G, SOLLAZZO V, CARINCI F, PALMIERI A, GIRARDI A, MONGUZZI R **OSTEOBIOL® INFLUENCES OSTEOGENIC DIFFERENTIATION** 

OF ADIPOSE DERIVED STEM CELLS EUR J INFLAMMAT, 2011, VOL. 9, NO. 3(S), 103-107

Bone substitutes

Blocks

Membranes

![](_page_98_Picture_33.jpeg)

REGENERATION

Alveolar bone

CELLS

Certifications

periodontal ligament cementum

# From heterologous bone to biomaterial

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

![](_page_99_Figure_2.jpeg)

**OSTEOBIOL® GEN-OS®** 

RESULTS OF ORGANIC CHEMICAL ANALYSES PERFORMED ON

"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

Inorganic chemical analyses results

Source: University of Duisbura-Essen, Germany

![](_page_99_Picture_9.jpeg)

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<sup>®</sup> 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<sup>(1,2)</sup>. 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<sup>®</sup> 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.

(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

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CLIN IMPLANT DENT RELAT RES. 2008 DEC:10(4):264-70. EPUB 2008 JAN 30

"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

![](_page_100_Picture_2.jpeg)

# CERTIFICATIONS

# **Certifications** CE certificates

![](_page_102_Picture_1.jpeg)

Annex V | Porcine and Equine Bone Matrix Source: Tecnoss<sup>®</sup> s.r.l.

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![](_page_102_Picture_11.jpeg)

Annex III | Porcine and Equine Membranes Source: Tecnoss<sup>®</sup> s.r.l.

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Annex V | Porcine and Equine Membranes Source: Tecnoss<sup>®</sup> s.r.l.

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Annex III | Equine Felts Source: Tecnoss<sup>®</sup> s.r.l.

![](_page_102_Picture_29.jpeg)

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Annex V | Equine Felts Source: Tecnoss<sup>®</sup> s.r.l.

![](_page_102_Picture_31.jpeg)

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 10<sup>th</sup> March 2005).

![](_page_103_Picture_1.jpeg)

# **Biocompatibility test Gen-Os®**

#### 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  $37^{\circ}C \pm 1^{\circ}C$  temperature. Then, 2ml extract was incubated with cultured NCTC L929 cells for a period of 48 hours in incubator at  $37^{\circ}C \pm 1^{\circ}C$  temperature, with CO<sub>2</sub> 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-cytoplasmatic 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  $37^{\circ}C \pm 1^{\circ}C$  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

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 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  $37^{\circ}$ C  $\pm 1^{\circ}$ 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  $37^{\circ}C \pm 1^{\circ}C$  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 CO<sub>2</sub> 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.

#### **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  $6 \text{cm}^2/\text{ml}$ surface/volume ratio. Each assay sample was incubated for 72 hours at  $37^\circ\text{C} \pm 1^\circ\text{C}$  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  $6 \, \mathrm{cm^2/ml}$  surface/volume ratio. Each assay sample was incubated for 72 hours at  $37^\circ\mathrm{C} \pm 1^\circ\mathrm{C}$  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.

#### **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  $\delta \operatorname{cm}^2/\operatorname{nl}$  surface/volume ratio. Each assay sample was incubated for 72 hours at  $37^{\circ}C \pm 1^{\circ}C$  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.

#### 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  $\delta \rm cm^2/ml$  surface/volume ratio. Each assay sample was incubated for 72 hours at 37°C  $\pm 1^\circ \rm C$  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. Blocks

# **Biocompatibility test** mp3<sup>®</sup>

#### **DIRECT CONTACT CYTOTOXICITY**

AIM: cytotoxic potential evaluation of OsteoBiol\*  $mp3^{\circ}$  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  $\pm$ 1°C in CO<sub>2</sub> atmosphere for 24 hours. After 24 hours of incubation the cells cultures were observed to evaluate the biological reactivity (cell degeneration and malformations).

#### RESULTS

aml 100

90

80

70

60

50

40

30

20

1 500

20

200

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 hypersensivity. 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 auinea pias 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  $37^{\circ}C \pm 1^{\circ}C$  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  $\pm$ 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  $37^{\circ}$ C  $\pm 1^{\circ}$ 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 controlateral 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.

# UNI EN ISO 13485 KIWA CERMET quality certificate

![](_page_106_Picture_1.jpeg)

Società con socio unico, soggetta all'attività di direzione e coordinam di Kiwa Italia Holding Sri Via Cadriano, 23 40057 Granarolo dell'Emilia (BO) Tel +39.051.459.3.111 Fax +39.051.763.382 E-mail info@kiwacermet.it www.kiwaconnet.it

CERMET

![](_page_106_Picture_4.jpeg)

2007-01-15 2015-12-23 Last modification date 2019-01-14

Quality Management System Certificate ISO 13485:2012

We certify that the Quality Management System of the Organization:

#### **TECNOSS S.r.I.**

Is in compliance with the standard UNI CEI EN ISO 13485:2012 for the following

Manufacturing of bone substitutes, membranes and collagen felts for bone and

![](_page_106_Picture_11.jpeg)

Maintenance of the certification is subject to annual survey and dependent upon the observance of Kiwa Cermet Italia contractual requirements

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![](_page_106_Picture_16.jpeg)

#### **REGULATIONS ON MANUFACTURING** PROCESS

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DIRETTIVA 93/42/CEE and relative amendments

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MEDDEV 2.12-1 rev 8 Guidelines on a medical devices vigilance - 2013

# Membranes

Bone substitutes

Blocks

![](_page_107_Picture_0.jpeg)

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# LITERATURE



Histology at 3 months. Human mandible grafted with OsteoBiol<sup>®</sup> Sp-Block Source: Courtesy of Dr P Felice, Bologna, Italy. Histology by Prof U Nannmark, University of Göteborg, Sweden

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Clinical cases

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**TISSUE CHANGES OF EXTRACTION SOCKETS IN HUMANS: A COMPARISON OF SPONTANEOUS HEALING VS. RIDGE PRESERVATION WITH** SECONDARY SOFT TISSUE HEALING

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**USE OF PIEZOSURGERY DURING MAXILLARY SINUS ELEVATION: CLINICAL RESULTS OF 40 CONSECUTIVE CASES** 

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65 | RODRIGUEZ JG, ELDIBANY RM VERTICAL SPLITTING OF THE MANDIBULAR BODY AS AN ALTERNATIVE TO INFERIOR ALVEOLAR NERVE

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INT J ORAL MAXILLOFAC SURG, 2013 SEP;42(9):1060-6

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COMPARISON OF A XENOGENEIC 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 APP. 2013 AUG

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#### A NEW OPTION FOR THE RECONSTRUCTION OF ORBITAL FLOOR DEFECTS WITH HETEROLOGOUS CORTICAL BONE

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CARBON, JULY 2016, VOLUME 103, PAGES 291–298 AVAILABLE ONLINE 14 MARCH 2016

GRANULES

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Membranes

113

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INDEX

PRODUCIS	18	INNOVATION
BONE SUBSTITUTES	20	Tecnoss® bone vs hu
Gen-Os®	22	Why xenografts?
TSV Gel	26	Characteristics of Teo
mp3®	30	Collagen: a key fact
Putty	34	Collagen and bone i
Gel 40	38	From heterologous b
Apatos	42	
BLOCKS	46	CERTIFICATIONS
Sp-Block, Dual-Block	48	CE certificates
MEMBRANES AND BARRIERS	52	Biocompatibility tests
Evolution	54	Gen-Os®
Derma	58	Evolution
Lamina	62	mp3®
Special, Duo-Teck	66	UNI EN ISO 13485
CLINICAL CASES	72	LITERATURE
ALVEOLAR REGENERATION	73	
DEHISCENCES AND FENESTRATIONS	76	INDEX
CRESTAL ACCESS SINUS LIFT	78	
LATERAL ACCESS SINUS LIFT	80	PRODUCT CODES
HORIZONTAL AUGMENTATION	83	
VERTICAL AUGMENTATION	86	
PERIODONTAL REGENERATION	88	
SOFT TISSUE AUGMENTATION	90	

INNOVATION	94
Tecnoss® bone vs human bone	95
Why xenografts?	96
Characteristics of Tecnoss® process	97
Collagen: a key factor for clinical success	98
Collagen and bone regeneration	99
From heterologous bone to biomaterial	100
CERTIFICATIONS	102
CE certificates	103
Biocompatibility tests	
Gen-Os®	104
Evolution	105
mp3®	106
UNI EN ISO 13485	107
LITERATURE	110

114

115



PRODUCT	PACKAGING	ТҮРЕ	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	
TSV Gel	1 Syringe	GEL	0.5 g	TSV005S	TSV005E
TSV Gel	1 Syringe	GEL	1.0 g	TSV010S	TSV010E
mp3®	1 Syringe	BONE MIX	1.0 сс	A3005FS	A3005FE
mp3®	3 Syringes	BONE MIX	3х0.25 сс (0.75 сс)	A3075FS	
mp3®	3 Syringes	BONE MIX	3x0.5 cc (1.5 cc)	A3015FS	A3015FE
mp3®	3 Syringes	BONE MIX	3х1.0 сс (3.0 сс)	A3030FS	A3030FE
Putty	1 Svrinae	BONE PASTE	0.5 cc	HPT09S	HPT09E
Putty	1 Syringe wide tip	BONE PASTE	1.0 сс	HPT61S	HPT61E
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
Gel 40	1 Svringe	BONE GEL	0.5 cc	05GEL40S	05GEL40E
Gel 40	3 Syringes	BONE GEL	3x0.5 cc (1.5 cc)	15GEL40S	15GEL40E
MEMBRANES AND BARRIE	RS				
Evolution	1 Blister	DRIED / FINE	20x20x (0.3) mm		EV0211E
Evolution	1 Blister	DRIED / FINE	30x30x (0.3) mm		EV03LLE
Evolution	1 Blister	DRIED / FINE	Oval 25x35x (0.3) mm		EVOLLE
Evolution	1 Blister	DRIED / STANDARD	20x20x (0.5) mm	EM02HS	EV02HHE
Evolution	1 Blister	DRIED / STANDARD	30x30x (0.5) mm	EM03HS	EV03HHE
Evolution	1 Blister	DRIED / STANDARD	Oval 25x35x (0.5) mm	EMOOHS	
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 / STANDARD	30x30x (3.0) mm	LS03SS	
Semi Soft Cortical Lamina	1 Blister	DRIED / MEDIUM	20x40x (1.0) mm	LS24LS	
Curved Lamina	1 Blister	DRIED / MEDIUM	35x35x (1.0) mm	LS10HS	LS10HE
SPECIFIC PRODUCTS					
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	
Sp-Block	1 Blister	DRIED BLOCK / NORM	10x10x10 mm		BNOE
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	
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 Blietor		20x20x (0.2) mm		DT020
Duo-Teck	6 Blietor		25x25x (0.15) mm		DTN625
Dorma	1 Blister		12282 (0.0) mm	ED01EC	DIRUZJ
Derma	1 Blister		25v25v (0.9) mm	ED21F3 ED25FS	
Derma	1 Blistor		7x5x (2,0) mm	ED2515	
Derma	1 Blietor	DRIED / STANDARD	15x5x (2.0) mm	ED/ 535	
Derma	1 Blister	DRIED / STANDARD	30x30x (2.0) mm	ED 1355	
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