SEM image of an OsteoBiol® Gen-Os granule, highlighting the porosity of the material.
Magnification x30000
Source: Courtesy of Dr Ulf Nannmark, University of Göteborg, Sweden
Welcome to the OsteoBiol® world

Tissue regeneration technology: a difference that matters.

You may not immediately notice the xenogenic origin of the OsteoBiol® biomaterials, and the collagen content preserved in each granule by the Tecno® innovative biotechnology.

You may also not be aware of the excellent biocompatibility and total safety guaranteed by the Tecno® certified manufacturing process.

Not until the very moment in which you will use an OsteoBiol® grafting material in your first surgery, a unique handling sensation and clinical response from your patient.

OsteoBiol® is a complete and innovative biomaterial line: a family of products designed for each specific clinical indication.

Innovation has always required to find the limits of existing solutions, and to explore new ways to break such limits defining new quality standards.

This requires unconventional mentality and free thinking: the essential attitudes of researchers.

When Dr Giuseppi Oliva founded Tecno®, he had only one goal: develop and manufacture the best biomaterial line for bone augmentation in dentistry.

His philosophy has always been to achieve tissue regeneration respecting biological principles and laws.

These concepts, together with accurate design, pioneer technologies and meticulous quality control, have been and will be the driving force of our company.

At Tecno®, we dedicate all our energy and resources to improve hard and soft tissue regeneration: this is our only activity and focus.

Our unconditional passion for biomaterials reflects in every single product we manufacture.

And every OsteoBiol® product contains a biological added value that will create confidence in your regenerative surgery and clinical success with your patients.

Tecno® biomaterials are different, a difference that matters!

Davide Oliva MD
Managing Director
Tecnoss s.r.l.
Biomaterials Engineering

Marco Boarolo BEc
Managing Director
Tecnoss Dental s.r.l.
International Sales & Marketing

Marco Esposito DDS, PhD
Associate Professor in Biomaterials
Goteborg University, Sweden
New free APP for tablet and iPad including:

6 animations to show your patients the main GBR techniques

Information about the full range of OsteoBiol® biomaterials

Over 40 abstracts of international scientific publications

Direct access to the database of clinical videos and cases on www.osteobiol.com

This App may be too large to download over a mobile connection, or may exceed data usage limits. Wi-Fi connection recommended.
# The most complete range of bone grafting materials

**INTRODUCTION**

A significant step ahead .......................... 7  
Why xenografts? ...................................... 8  
Collagen: a key factor for clinical success .... 9  
Collagen and bone regeneration ................. 10  
From heterologous bone to biomaterial ....... 12  
Characteristics of TecnoS® process .......... 13  

**CLINICAL INDICATIONS**

**ALVEOLAR REGENERATION**

Characteristics .................................... 18  
OsteoBiol® products ............................... 19  
Case reports ....................................... 20  

**DEHISCENCES AND FENESTRATIONS**

Characteristics .................................... 24  
OsteoBiol® products ............................... 25  
Case reports ....................................... 26  

**CRESTAL ACCESS SINUS LIFT**

Characteristics .................................... 30  
OsteoBiol® products ............................... 31  
Case reports ....................................... 32  

**LATERAL ACCESS SINUS LIFT**

Characteristics .................................... 36  
OsteoBiol® products ............................... 37  
Case reports ....................................... 38  

**HORIZONTAL AND VERTICAL AUGMENTATION**

Characteristics .................................... 42  
OsteoBiol® products ............................... 43  
Case reports ....................................... 44  

**PERIODONTAL REGENERATION**

Characteristics .................................... 50  
OsteoBiol® products ............................... 51  
Case reports ....................................... 52  

**PRODUCTS**

<table>
<thead>
<tr>
<th>Bone Substitutes</th>
<th>57</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gen-O’s</td>
<td>58</td>
</tr>
<tr>
<td>mp3</td>
<td>60</td>
</tr>
<tr>
<td>Putty</td>
<td>64</td>
</tr>
<tr>
<td>Gel 40</td>
<td>68</td>
</tr>
</tbody>
</table>

**MEMBRANES AND BONE BARRIERS**

Evolution ....................................... 76  
Lamina ............................................ 78  

**SPECIFIC PRODUCTS**

Sp-Block .................. 86  
Dual-Block ................ 88  
Apatos ..................... 89  
Tablet ..................... 90  
Duo-Teck .................. 91  
Special ..................... 92  
Demar ....................... 93  

**LIVE SURGERY COURSES**

Brånenmark Osseointegration Center ....... 94  
Marseille, France ................. 95  
Lake Como Institute .......... 96  
Como, Italy ................ 97  
IV International Congress of Tissue Regeneration Madrid, Spain 97  

**CERTIFICATIONS AND LITERATURE**

From nature to man ............................ 99  
CE certificates ................................. 100  
Biocompatibility tests ..................... 101  
Gen-O’s Evolution ..................... 102  
mp3 ........................................ 103  
ISO 13485 ................................ 104  
Literature review ..................... 105  
Scientific literature ............... 106
SEM image of an OsteoBiol® Gen-Os granule: osteoblastic colonisation. Magnification x3000
Source: Courtesy of Dr Ulf Nannmark, University of Göteborg, Sweden
Research and development of biomaterials have gone through many stages, but always toward one goal: to heal bone deficit with newly-formed quality tissue in order to achieve functional recovery. All of this in the least time possible.

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.

Over the last twenty years several processes have been developed to allow the grafting of heterologous origin products in the human body without adverse reaction.

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.

Source: Courtesy of Dr Ulf Nannmark, Göteborg University, Sweden
Why xenografts?

Xenografts are the most used biomaterials worldwide

This is because:

>> tissues of origin are **extremely safe** and available in **unlimited quantities**

>> xenogenic bone surface and porosity are extremely **similar to autogenous bone**

>> there is **no need to harvest autogenous bone in extraoral sites**, with the related risk of morbidity and post-operative complications

>> sterile xenografts are **completely biocompatible** and safe

>> **no adverse reactions** after grafting deriving from biomaterial degradation

>> **easy to handle**, quick learning curve

>> collagenated xenografts **enhance osteoblasts** and osteoclasts activity

>> wide **scientific documentation**

>> **excellent clinical performance**

>> storage can be done at room temperature

>> **long shelf life** (5 years from production date)

>> **excellent price/quality ratio**

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

Marco Esposito DDS, PhD
Associate Professor in Biomaterials, Goteborg University, Sweden
Collagen: a key factor for clinical success

**INTRODUCTION**

**THE COLLAGEN FACTOR**

Tecnoss® exclusive manufacturing process is able to neutralize the antigenic components present in heterologous bone (achievement of biocompatibility) and to preserve the collagen matrix inside the granules of biomaterial.

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

These characteristics of OsteoBiol® products allow a consistent bone neo-formation and a close contact between mature neo-formed bone and biomaterial granules.

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

- It acts as a valid substrate for platelet activation and aggregation
- It serves to attract and differentiate the mesenchymal stem cells present in the bone marrow\(^2\)
- It increases the proliferation rate of the osteoblasts up to 2/3 times\(^3\)
- It stimulates the activation of the platelets, osteoblasts and osteoclasts in the tissue healing process

The presence of collagen inside each granule makes OsteoBiol® Gen-Os hydrophilic and facilitates further mixing with collagen gel (OsteoBiol® Gel 0).

This technology has permitted the development of three new versatile and innovative products: OsteoBiol® mp3, OsteoBiol® Putty and OsteoBiol® Gel 40.

Their consistency allows an ideal filling of bone defects and guarantees simple handling and fast application.

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

---


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**Composition of OsteoBiol® Gen-Os**

![Collagen and Mineral Bone Composition](image)

Source: University of Duisburg-Essen, Germany
Collagen and bone regeneration

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

The bone defect recovery occurs through the general mechanisms of tissue healing, that is, by complex dynamic mechanisms directed towards the repair of tissue function and anatomic integrity.

The discovery of the events pathway leading to tissue healing has helped to clearly identify the main actors in bone healing process; the concomitant presence of the following three components is necessary for the formation of “de novo” bone tissue:

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

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

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

>> an insoluble substrate, suitable carrier for osteoinductive signal and able to support and guide new bone tissue formation.

Sampath and Reddi (1980) demonstrated crosslinked type I collagen to be the most appropriate carrier for promoting osteoinductive signal activity.

The continuous progresses in comprehension of biological mechanisms regulating bone tissue morphogenesis can be exploited also for elaboration of natural or artificial products able to restore or maintain the function of damaged tissues and organs (tissue engineering)(1-3).

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

This important scientific evidence provides the rationale behind 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 OsteoBio® biomaterials, can draw, activate and collaborate with osteoblasts in bone rearranging and remodeling.

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

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

5. **Receiving site remodeling**
   Exogenous collagen grafting can contribute in decreasing remodeling times of immature bone tissue.

6. **Osteoconduction and guided regeneration**
   Naturally integrated with mineral component, collagen is able to increase osteoblasts proliferation rate^{5}, while as a resorbable membrane it is able to guide connective tissue regeneration.

---

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From heterologous bone to biomaterial

RESULTS OF INORGANIC CHEMICAL ANALYSES PERFORMED ON OSTEOBIO® GEN-OS

<table>
<thead>
<tr>
<th>Chemical element</th>
<th>OsteoBiol® Gen-Os (% in weight)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ca</td>
<td>25.7%</td>
</tr>
<tr>
<td>PO₄³⁻</td>
<td>35.2%</td>
</tr>
<tr>
<td>C</td>
<td>13.6%</td>
</tr>
<tr>
<td>H</td>
<td>2.2%</td>
</tr>
<tr>
<td>N</td>
<td>2.9%</td>
</tr>
<tr>
<td>O (not in PO₄³⁻)</td>
<td>20.4%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100.0%</td>
</tr>
<tr>
<td>Ca/P (n:m)</td>
<td>1.73</td>
</tr>
</tbody>
</table>

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

RESULTS OF ORGANIC CHEMICAL ANALYSES PERFORMED ON OSTEOBIO® GEN-OS

Mineral component 73.6%
Organic matrix 22.4%
Water 4.0%

“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”

A biomaterial for the reconstruction of bone defects must be biocompatible and have good handling and modeling properties; in specific clinical situations, it must also provide sufficient resistance to loading.

Tecnoss® laboratories are specialized in processing heterologous bony and collagenic tissues. OsteoBiol® bone process, in particular, has been developed to modify but maintain the original collagen matrix of heterologous tissue, in order to preserve its positive biological functions, obtaining at the same time complete biocompatibility[^1,^3].

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.

In the case of synthesized hydroxyapatite or natural bone hydroxyapatite derived from aggressive manufacturing processes osteoclastic cellular response is slow, causing extremely prolonged resorption time.

[^1]: Marco Esposito DDS, PhD
Associate Professor in Biomaterials, Goteborg University, Sweden

[^3]: Marco Esposito DDS, PhD
Associate Professor in Biomaterials, Goteborg University, Sweden
Tecnoss® 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(1).

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

Their neutralization/denaturation allows the mineral bone and collagen 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(2).

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® developed a biotechnology, able, by avoiding the high temperature ceramization phase, to preserve the structure of natural hydroxyapatite and therefore allow an osteoelastic-type remodeling of biomaterial, similar to physiological bone turnover time(3).

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

1. Absence of a foreign body response(4)
2. Gradual resorption over time
3. Stimulation and acceleration of physiological tissue healing process(5)
4. Protection of the grafting site from infection (membranes)
5. Capability of carrying medication to the surgical site
CLINICAL INDICATIONS

ALVEOLAR REGENERATION
DEHISCENCES AND FENESTRATIONS
CRESTAL ACCESS SINUS LIFT
LATERAL ACCESS SINUS LIFT
HORIZONTAL AND VERTICAL AUGMENTATION
PERIODONTAL REGENERATION

Source: Courtesy of Dr. Ulf Nannmark, Göteborg University, Sweden
Gen-Os
Collagenated heterologous cortico-cancellous bone mix | Granulometry 250-1000 µm
For information on OsteoBiol® Gen-Os see page 60

mp3
Pre-hydrated collagenated heterologous cortico-cancellous bone mix
Granulometry 600-1000 µm
For information on OsteoBiol® mp3 see page 64

Putty
Pre-hydrated collagenated heterologous cortico-cancellous bone paste
Granulometry up to 300 µm
For information on OsteoBiol® Putty see page 68

Gel 40
Pre-hydrated collagenated heterologous cortico-cancellous bone gel
Granulometry up to 300 µm
For information on OsteoBiol® Gel 40 see page 72

Sp-Block
Collagenated heterologous cancellous block
For information on OsteoBiol® Sp-Block see page 88

Evolution
Heterologous collagen membrane
For information on OsteoBiol® Evolution see page 78

Lamina
Collagenated heterologous cortical bone
For information on OsteoBiol® Lamina see page 82
"OsteoBiol® is the most complete range of biomaterials available on the market today. Our products are specifically engineered to fulfill your needs in every single clinical indication. We believe that your valuable regenerative work should not be limited to one single product adapted to all clinical indications but it should be given instead a solution thought and designed specifically for your different needs.

Each regeneration protocol is in fact different: this is why we work hard to deliver you the best solutions to help you improve your surgical procedures everyday.

Your clinical success is our only mission’’

Katia Gaetano BPharm
Production Manager
Tecnoss s.r.l.
Alveolar regeneration

Post-extractive socket preservation
Ridge preservation

Post-extractive alveolus grafted with OsteoBiol®

Source: Courtesy of Dr Roberto Rossi, Genova, Italy
DEFECT ORIGIN AND DESCRIPTION

After the loss of dental elements alveolar bone starts resorbing due to the absence of mechanical solicitation transmitted by dental roots. This physiologic resorption subsequent to tooth loss or extraction is due to both impossibility of regenerated bone to reach the pre-existing coronal level when the bone is left healing in physiologic conditions (without any biomaterial graft) and the simultaneous cortical bone remodeling process, both in coronal-apical and vestibular-lingual directions.

Lekovic and coll. demonstrated that the post-extraction bone loss is accelerated in the first 6 months, followed by a gradual turnover of the remaining bone, with as much as 40% of the alveolar height and 60% of alveolar width lost in the first 6 months. The result of this resorption often is a clinical problem able to compromise esthetic outcome and/or functional and structural aspects of restoration treatment.

The result of this resorption often is a clinical problem able to compromise esthetic outcome and/or functional and structural aspects of restoration treatment.

REGEN ERATION PROCEDURES

Socket preservation technique

The goal is the preservation of the alveolar ridge and extraction socket, in particular if patient will be rehabilitated with placement of endosseous implants. The physiologic bone resorption of alveolar ridge after tooth extraction is particularly consistent in the anterior maxilla, where the buccal plate often is extremely thin and friable.

To minimize bone resorption the first important step is the less traumatic extraction technique for tooth removal. Often this procedure is associated with socket augmentation using a variety of particulate bone graft materials with or without membrane barriers. Several studies demonstrated significantly reduced alveolar ridge dimensional changes associated with these preservation techniques.

In case of a defect involving the original buccal plate, multiple animal studies showed that these defects do not heal completely without use of grafting techniques.

Thus, in the anterior maxilla, grafting for space maintenance and ridge preservation may be beneficial.

Moreover, for situations where the periapical bone or the socket walls are not intact, bone augmentation techniques may be used to restore the original anatomy, with a particular attention to soft tissue perfect closure and graft containment, which are the main difficulties of this procedure.

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**OsteoBiol® product range**

**Tissue of origin** Collagenated heterologous cortico-cancellous bone mix
**Tissue collagen** Preserved
**Physical form** Slightly radiopaque granules
**Composition** 100% granulated mix
**Granulometry** 250-1000 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

For more information on OsteoBiol® Gen-Os see page 60

**Tissue of origin** Pre-hydrated collagenated heterologous cortico-cancellous bone paste
**Tissue collagen** Preserved + 20% additional 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

For more information on OsteoBiol® Putty see page 68

**Tissue of origin** Heterologous collagen membrane
**Tissue collagen** Preserved
**Physical form** Dried membrane with one smooth side and one micro-rough side
**Composition** 100% pericardium
**Thickness** Fine: 0.4 mm (±0.1). Standard: 0.6 mm (±0.1)
**Resorption time** Fine: approx 3 months. Standard: approx 4 months
**Packaging** Syringe: 20x20 mm, 30x30 mm, 25x35 mm (oval)

For more information on OsteoBiol® Evolution see page 78

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**PRODUCT CODES**

**Gen-Os**
- M1052FS | Vial | 0.25 g | Porcine
- M1052FE | Vial | 0.25 g | Equine
- M1005FS | Vial | 0.5 g | Porcine
- M1005FE | Vial | 0.5 g | Equine
- M1010FS | Vial | 1.0 g | Porcine
- M1010FE | Vial | 1.0 g | Equine
- M1020FS | Vial | 2.0 g | Porcine
- M1020FE | Vial | 2.0 g | Equine

**Putty**
- HPT09S | Syringe | 0.5 cc | Porcine
- HPT09E | Syringe | 0.5 cc | Equine
- HPT61S | Syringe | 1.0 cc | Porcine
- HPT61E | Syringe | 1.0 cc | Equine
- HPT35S | Syringe | 3x0.5 cc | Porcine
- HPT35E | Syringe | 3x0.5 cc | Equine
- HPT32S | Syringe | 3x0.25 cc | Porcine
- HPT32E | Syringe | 3x0.25 cc | Equine

**mp3**
- A3005FS | Syringe | 1.0 cc | Porcine
- A3005FE | Syringe | 1.0 cc | Equine
- A3015FS | Syringe | 3x0.5 cc | Porcine
- A3015FE | Syringe | 3x0.5 cc | Equine
- A3030FS | Syringe | 3x1.0 cc | Porcine
- A3030FE | Syringe | 3x1.0 cc | Equine

**Evolution**
- EV02LLE | 20x20 mm | Fine | Equine
- EV02HHE | 20x20 mm | Standard | Equine
- EV03LLE | 30x30 mm | Fine | Equine
- EV03HHE | 30x30 mm | Standard | Equine
- EVOHHE | 25x35 mm (oval) | Fine | Equine

**Tablet**
- BLE10S | 10x10x10 mm | 6 Blister | Porcine
- BLE10E | 10x10x10 mm | 6 Blister | Equine

For more information on OsteoBiol® Tablet see page 90
The entire OsteoBiol® line consists of xenografts, i.e. biomaterials deriving from heterologous bone. The Tecnoss® patented manufacturing process used to obtain these materials is able to achieve biocompatibility preserving part of the collagen matrix of the animal bone and avoiding at the same time high temperatures that would cause ceramization of the granules: the result is a unique particulate material, 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.[7]

These cortical and cancellous particles have been mixed in various proportions and granulometries with and without collagen gel, in order to develop various materials indicated for alveolar regeneration are OsteoBiol® products aimed at different clinical indications: the OsteoBiol® products: collagen gel, in order to develop various granulometries with and without collagen gel, in order to develop various granulometries with and without collagen gel.

In case of insufficient soft tissue to cover and protect the graft, an OsteoBiol® Evolution membrane is recommended.[8-10]. Evolution pericardium membranes guarantee an efficient barrier effect, favour the correct soft tissue regrowth and wound closure and do not get infected in case of exposure.

The exclusive Tecnoss® manufacturing process guarantees an exceptional malleability and plasticity,[8]; furthermore the syringe packaging gives Putty extraordinary handling properties making this product the ideal choice for incisors narrow sockets with intact walls.

OsteoBiol® Putty is a collagen gel matrix loaded for 80% of its volume with micronized cortico-cancellous bone particles (granulometry packed in a sterile vial: due to its collagen content, once hydrated with saline, it allows an excellent graft stability while its hydrophilia guarantees quick blood absorption and therefore the necessary graft vascularization. Its cortico-cancellous composition allows a progressive resorption of osteoclastic type, with in parallel a similar rate of new bone formation.[7]. These unique properties allow a very good graft volume preservation, a healthy new bony tissue and ultimately, a successful implant rehabilitation.[8].

OsteoBiol® Table 3 has also been used successfully for alveolar ridge preservation,[10] while OsteoBiol® Tablet is an anti-haemorrhagic biomaterial suitable to accelerate blood clotting in post-extractive sockets and to favour regeneration.
Case report
Alveolar ridge preservation

Sex: male | Age: 51

Fig. 1 Initial x-ray
Fig. 2 Root separation
Fig. 3 Extracted tooth
Fig. 4 Ridge preservation with OsteoBiol® mp3
Fig. 5 Grafting site protected with OsteoBiol® Evolution collagen membrane
Fig. 6 Site before grafting
Fig. 7 Site after grafting
Fig. 8 Healing and bone regeneration at 12 months
Fig. 9 Osteotomy for the insertion of the implant
Fig. 10 Thommen implant (Ø 5x12 mm)
Fig. 11 Healing of peri-implant tissues
Fig. 12 Final result

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

Bone substitute: OsteoBiol® mp3
For more information on OsteoBiol® mp3 see page 64
Membrane: OsteoBiol® Evolution
For more information on OsteoBiol® Evolution see page 78
Case report

Treatment of bone defects due to peri-implantitis

Sex: male | Age: 54

Fig. 1 Initial intraoral image: it is possible to appreciate severe inflammation of the soft tissues. The prosthesis is subjected to considerable mobility.

Fig. 2 Endoral x-ray image: the diagnosis of peri-implantitis in 3.5-3.6 zone was confirmed.

Fig. 3 Intraoral image showing the residual bone defects: in particular 3.5 site was defective of all buccal coronal half.

Fig. 4 Defects were grafted with OsteoBiol® Gen-Os.

Fig. 5 The graft was stabilized and protected by a properly shaped OsteoBiol® Evolution membrane.

Fig. 6 Soft tissues were repositioned and sutured.

Fig. 7 Intraoral image of second surgical phase (re-entry after 8 months). It is possible to appreciate a complete regeneration of pre-existent bone defects.

Fig. 8 Placement of 3 implants on the base of a monophasic protocol.

Fig. 9 Placement of titanium prosthesis abutments after 3 months from implant placement surgery: the verification of perfect implant osteointegration was performed with the resonance frequency analysis (ISQ >70).

Fig. 10 Endoral x-ray image. It is possible to proceed with “Platform Switching.”

Fig. 11 Final restoration with definitive prosthesis was completed 3 months after surgery. Picture showing the situation 12 months after surgery.

Fig. 12 Control endoral x-ray image 12 months after surgery.

Documentation provided by Dr. Roberto Cocchetto
Private practitioner in Zevio, Italy
E-mail: rcocchetto@yahoo.it

Bone substitute: OsteoBiol® Gen-Os
For more information on OsteoBiol® Gen-Os see page 60.

Membrane: OsteoBiol® Evolution
For more information on OsteoBiol® Evolution see page 78.
Dehiscences and fenestrations

Fenestration. Cortical stimulation before grafting with OsteoBiol® Gen-Os.
Source: Courtesy of Dr. Claudio Stacchi, Gorizia, Italy.
**DEFECT ORIGIN AND DESCRIPTION**

After placement of implants, there are two types of residual defects that can be treated with predictable regenerative techniques, because these defects are able to self-maintain the space necessary for regeneration. In fact, positive results have been confirmed by long-term studies both controlled\(^\text{(1-2)}\) and non controlled\(^\text{(3-4)}\), grafting different kinds of biomaterials.

Depending from their morphology, these defects can be classified as follows, according to Tinti and Parma-Benfenati clinical classification\(^\text{(5)}\):

**Fenestration:** it is a vestibular or lingual-palatal defect associated with a lack of bone thickness, creating a partial exposure of an implant which is completely surrounded by bone.

**Dehiscence:** it is a vestibular or lingual-palatal defect represented by a lack \(<50\%\) of bone thickness, resulting in the exposure of the vestibular surface of implant, starting from its head in apical direction.

**Combined defects:** if the defect is the association of both dehiscence and fenestration together, it can be defined as a combined defect.

Moreover, in the most severe cases, these combined defects can be associated with horizontal supra-crestal or extra-crestal defects, which necessitates the creation of an adequate space for bone regeneration\(^\text{(6)}\).

### REGENERATION PROCEDURES

The healing of these defects takes advantage to the principle of Guided Bone Regeneration (GBR) with the use of barrier membranes that protect and isolate the defect allowing the growth of neo-regenerated bone in sites showing insufficient bone volume.

In fact, significant more bone formation has been shown around defects protected with a barrier membrane compared with controls\(^\text{(1-3)}\).

Bio-absorbable collagen membranes are equally effective as non resorbable e-PTFE membranes, but reduce significantly the risk of complications in case of exposure since they do not get infected.

The use of pins to fix the membranes can equally effective as non resorbable e-PTFE controls with a barrier membrane compared with different biomaterials.

Regeneration (GBR) with the use of barrier membranes that protect and isolate the defect allowing the growth of neo-regenerated bone in sites showing insufficient bone volume.

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**Dehiscence:** it is a vestibular or lingual-palatal defect represented by a lack \(<50\%\) of bone thickness, resulting in the exposure of the vestibular surface of implant, starting from its head in apical direction.

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Moreover, in the most severe cases, these combined defects can be associated with horizontal supra-crestal or extra-crestal defects, which necessitates the creation of an adequate space for bone regeneration\(^\text{(6)}\).

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The use of pins to fix the membranes can equally effective as non resorbable e-PTFE controls with a barrier membrane compared with different biomaterials.

### CLINICAL INDICATIONS

**DEHISCENCES AND FENESTRATIONS**

**BIBLIOGRAPHY**

OsteoBiol® product range

**PRODUCT CODES**

**Gen-Os**
- M1052FS | 1 Vial | 0.25 g | Porcine
- M1052FE | 1 Vial | 0.25 g | Equine
- M1005FS | 1 Vial | 0.5 g | Porcine
- M1005FE | 1 Vial | 0.5 g | Equine
- M1010FS | 1 Vial | 1.0 g | Porcine
- M1010FE | 1 Vial | 1.0 g | Equine
- M1020FS | 1 Vial | 2.0 g | Porcine
- M1020FE | 1 Vial | 2.0 g | Equine

**Putty**
- HPT09S | 1 Syringe | 0.5 cc | Porcine
- HPT09E | 1 Syringe | 0.5 cc | Equine
- HPT61S | 1 Syringe | 1.0 cc | Porcine
- HPT61E | 1 Syringe | 1.0 cc | Equine
- HPT35S | 3 Syringe | 3x0.5 cc | Porcine
- HPT35E | 3 Syringe | 3x0.5 cc | Equine
- HPT32S | 3 Syringe | 3x0.25 cc | Porcine
- HPT32E | 3 Syringe | 3x0.25 cc | Equine

**mp3**
- A3005FS | 1 Syringe | 1.0 cc | Porcine
- A3005FE | 1 Syringe | 1.0 cc | Equine
- A3015FS | 3 Syringe | 3x0.5 cc | Porcine
- A3015FE | 3 Syringe | 3x0.5 cc | Equine
- A3030FS | 3 Syringe | 3x1.0 cc | Porcine
- A3030FE | 3 Syringe | 3x1.0 cc | Equine

**Evolution**
- EV02LLE | 20x20 mm | Fine | Equine
- EV02HHE | 20x20 mm | Standard | Equine
- EV03LLE | 30x30 mm | Fine | Equine
- EV03HHE | 30x30 mm | Standard | Equine
- EVO LLE | 25x35 mm (oval) | Fine | Equine
- EVO HHE | 25x35 mm (oval) | Standard | Equine

---

**Tissue of origin** Collagenated heterologous cortico-cancellous bone mix
**Physical form** Plastic consistency composed of collagen gel loaded with 80% micronized bone mix
**Granulometry** Up to 300 µm

**Putty**
**Tissue of origin** Pre-hydrated collagenated heterologous cortico-cancellous bone paste
**Physical form** Plastic consistency composed of collagen gel loaded with 80% micronized bone mix
**Granulometry** Up to 300 µm

**Evolution**
**Tissue of origin** Heterologous collagen membrane
**Physical form** Dried membrane with one smooth side and one micro-rough side
**Composition** 100% pericardium
**Thickness** Fine: 0.4 mm (±0.1), Standard: 0.6 mm (±0.1)
**Resorption time** Fine: approx 3 months, Standard: approx 4 months

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26
The entire OsteoBiol® line consists of xenografts, i.e. biomaterials deriving from heterologous bone.

The Tecnoss® patented manufacturing process used to obtain these materials is able to achieve biocompatibility preserving part of the collagen matrix of the animal bone and avoiding at the same time high temperatures that would cause ceramization of the granules: the result is a unique particulate material, 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. These cortical and cancellous particles have been mixed in various proportions and granulometries with and without collagen gel, in order to develop various products aimed at different clinical indications: the OsteoBiol® materials indicated for dehiscence regeneration are OsteoBiol® Gen-Os and OsteoBiol® Putty.

OsteoBiol® Gen-Os is a cortico-cancellous collagenated bone mix with 250-1000 µm granulometry packed in a sterile vial: due to its collagen content, once hydrated with saline, it allows an excellent graft stability while its hydrophilicity guarantees quick blood absorption and therefore the necessary graft vascularization. Its cortico-cancellous composition allows a progressive resorption of osteoclastic type, and in parallel a similar rate of new bone formation. These unique properties allow a very good graft volume preservation, a healthy new bony tissue and ultimately, a successful implant rehabilitation.

In case partially compromised bone walls, an OsteoBiol® Evolution membrane is recommended: Evolution pericardium membranes efficiently contain and stabilize the Gen-Os graft, guarantee an efficient barrier effect, favour the correct wound healing and do not get infected in case of exposure.

OsteoBiol® Putty is a collagen gel matrix loaded for 80% of its volume with micronized cortico-cancellous bone particles (granulometry up to 300 µm) packed in a sterile syringe. The exclusive Tecnoss® manufacturing process guarantees an exceptional malleability and plasticity; furthermore the syringe packaging gives Putty extraordinary handling properties making this product the ideal choice for peri implant defects with intact bone walls.

Scientific Literature on Dehiscence and Fenestration GBR with OsteoBiol® Products

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Journal of Periondontal, 2012 Oct 29, EPUB AHEAD OF PRINT
Case report
Peri-implant bone regeneration on 1.1 and 2.1

Sex: male | Age: 60

Fig. 1 OPT exam: the defect area is 1.2
Fig. 2 Clinical inspection of edentulous area 1.2
Fig. 3 Implant placed with a significant vestibular dehiscence
Fig. 4 A considerable bone resorption is evident from the occlusal view
Fig. 5 An OsteoBiol® Evolution standard membrane is fixed to the palatal bone
Fig. 6 OsteoBiol® mp3 is grafted into the defect
Fig. 7 Self-contained defect fully filled with OsteoBiol® mp3
Fig. 8 The membrane is adapted to the vestibular side and soaked with blood
Fig. 9 Suture

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Bone substitute: OsteoBiol® mp3
For more information on OsteoBiol® mp3 see page 64

Membrane: OsteoBiol® Evolution
For more information on OsteoBiol® Evolution see page 78
Case report
Treatment of peri-implant defect after post-extractive implant placement

Sex: female | Age: 32

Fig. 1 Preliminary panoramic view
Fig. 2 Digital scan shows internal root resorption of tooth 1.1
Fig. 3 Buccal view
Fig. 4 Palatal view
Fig. 5 Occlusal view after extraction
Fig. 6 Osteotomy performed
Fig. 7 Implant in place
Fig. 8 Peri-implant gap grafted with OsteoBiol® Putty
Fig. 9 Free gingival graft harvested from the palate
Fig. 10 Occlusal view
Fig. 11 Buccal view
Fig. 12 Temporary restoration in place

Documentation provided by Dr Roberto Rossi
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Bone substitute: OsteoBiol® Putty
For more information on OsteoBiol® Putty see page 68
Crestal access sinus lift performed with OsteoBiol® Gel 40

Source: Courtesy of Prof Dr Jose Louis Calvo Guirado, Murcia, Spain
CLINICAL INDICATIONS

CRESTAL ACCESS SINUS LIFT

DEFECT ORIGIN AND DESCRIPTION

After the loss of dental elements alveolar bone starts resorbing due to the absence of mechanical solicitation transmitted by dental roots. In the maxilla such bone resorption process is complicated by the maxillary sinus, a cavity which undergoes pneumatization expanding progressively into the space previously occupied by alveolar bone.

REGENERATION PROCEDURES

Athrophic maxillary alveolar bone needs regeneration in order to restore the ideal conditions for placement of endosseous implants of proper diameter and height.

In year 1996 the Consensus Conference came to the conclusion that sinus floor elevation is an effective bone restoration procedure in the upper jaw, with highly predictable results\(^1\).

The crestal access approach with osteotomes for sinus floor elevation was first published in 1994 by Summers\(^2\) and can briefly described as follows:

>> Elevation of a total thickness flap in order to expose the crestal bone; with proper osteotomes and burs the implant site is prepared and the cortical plate is fractured

>> The biomaterial is introduced and properly grafted

>> The implant is inserted and soft tissues are sutured

Through a little crestal breach and the proper use of osteotomes and hammer, the biomaterial can be pushed into the sinus cavity and, on the base of the physical principle called Pascal Law, the Schneider membrane can be elevated, due to the increase of hydraulic pressure under the membrane itself.

With this technique it is possible to simultaneously insert implants, in presence of a residual bone height of 5-6 mm and a sinus floor elevation of 4-5 mm.

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AND SIMULTANEOUS OSTEOTOME SINUS FLOOR
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IMPLANTS, 2008, 28: 283-289
OsteoBiol® product range

Tissue of origin Pre-hydrated collagenated heterologous cortical-cancellous bone gel
Tissue collagen Preserved + 40% additional collagen gel
Physical form Collagen gel type I and III loaded with 60% collagenated 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

For more information on OsteoBiol® Gel 40 see page 72

Tissue of origin Collagenated heterologous cortical-cancellous bone mix
Tissue collagen Preserved
Physical form Slightly radiopaque granules
Composition 100% granulated mix
Granulometry 250-1000 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

For more information on OsteoBiol® Gen-Os see page 60

PRODUCT CODES

| Gel 40   | | | |
|----------|-------------------------|
| 05GEL40S | 1 Syringe | 0.25 g | Porcine |
| 05GEL40E | 1 Syringe | 0.25 g | Equine |
| 15GEL40S | 3 Syringe | 3x0.5 cc | Porcine |
| 15GEL40E | 3 Syringe | 3x0.5 cc | Equine |

| Gen-Os  | | | |
|---------|-------------------------|
| M1052FS | 1 Vial | 0.25 g | Porcine |
| M1052FE | 1 Vial | 0.25 g | Equine |
| M1005FS | 1 Vial | 0.5 g | Porcine |
| M1005FE | 1 Vial | 0.5 g | Equine |
| M1010FS | 1 Vial | 1.0 g | Porcine |
| M1010FE | 1 Vial | 1.0 g | Equine |
| M1020FS | 1 Vial | 2.0 g | Porcine |
| M1020FE | 1 Vial | 2.0 g | Equine |

| Putty    | | | |
|----------|-------------------------|
| HPT09S  | 1 Syringe | 0.5 cc | Porcine |
| HPT09E  | 1 Syringe | 0.5 cc | Equine |
| HPT61S  | 1 Syringe | 1.0 cc | Porcine |
| HPT61E  | 1 Syringe | 1.0 cc | Equine |
| HPT35S  | 3 Syringe | 3x0.5 cc | Porcine |
| HPT35E  | 3 Syringe | 3x0.5 cc | Equine |
| HPT32S  | 3 Syringe | 3x0.25 cc | Porcine |
| HPT32E  | 3 Syringe | 3x0.25 cc | Equine |

For more information on OsteoBiol® Putty see page 68

Tissue of origin Pre-hydrated collagenated heterologous cortical-cancellous bone paste
Tissue collagen Preserved + 20% additional 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

For more information on OsteoBiol® Putty see page 68
The entire OsteoBiol® line consists of xenografts, i.e. biomaterials deriving from heterologous bone. The Tecnoss® patented manufacturing process used to obtain these materials is able to achieve biocompatibility preserving part of the collagen matrix of the animal bone and avoiding at the same time high temperatures that would cause ceramization of the granules: the result is a unique particulate material, 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\(^3\).

These unique properties allow a very good graft volume preservation, a healthy new bony tissue and ultimately, a successful implant rehabilitation. Gel 40 is a collagen gel matrix loaded for 60% of its volume with micronized cortico-cancellous bone particles (granulometry up to 300 µm) packed in a sterile syringe.

The exclusive Tecnoss® manufacturing process guarantees an exceptional malleability and plasticity: furthermore the syringe packaging gives Gel 40 extraordinary handling properties\(^5\) making this product the ideal choice for crestal access sinus lift (squeeze technique).

The "soft" consistency of Gel 40 is suitable to lift the Schneider membrane using the syringe pressure, reducing laceration risk to minimum and allowing a tight positioning of the biomaterial around the implant threads.
Case report
Crestal access sinus lift

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 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/biomaterial 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

Documentation provided by
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University of Murcia, Spain
E-mail: josecalvog@gmail.com

Bone substitute: OsteoBiol® Gel 40
For more information on OsteoBiol® Gel 40 see page 72
Case report
Crestal access sinus lift, x-ray analysis

Fig. 1 Initial x-ray
Fig. 2 Control x-ray before osteotomy
Fig. 3 Measuring before osteotomy
Fig. 4 Maxillary sinus lifted with OsteoBiol® Putty
Fig. 5 Implant placed in the grafted site: final x-ray
Fig. 6 Implant placed in the grafted site: final x-ray

Sex: female | Age: 43

Documentation provided by
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Bone substitute: OsteoBiol® Putty
For more information on OsteoBiol® Putty see page 68
Maxillary sinus grafted with OsteoBiol®

Source: Courtesy of Dr. Antonio Barone, Lido di Camaiore, Italy
DEFECT ORIGIN AND DESCRIPTION
After the loss of dental elements alveolar bone starts resorbing due to the absence of mechanical solicitation transmitted by dental roots.

In the maxilla such bone resorption process is complicated by the maxillary sinus, a cavity which undergoes pneumatization expanding progressively into the space previously occupied by alveolar bone.

REGENERATION PROCEDURES
Athrophic maxillary alveolar bone needs regeneration in order to restore the ideal conditions for placement of endosseous implants of proper diameter and height.

In year 1996 the Consensus Conference came to the conclusion that sinus floor elevation is an effective bone restoration procedure in the upper jaw, with highly predictable results(1).

The lateral access approach for sinus floor elevation was first published in 1980 by Boyne and James(2) and subsequently modified by other clinicians.

In brief, the operative phases of this technique are the following:

>> Elevation of a total thickness flap to uncover the anterior wall of maxillary sinus and consequent opening of a bony window in this site to uncover Schneider membrane

>> The sinus mucosa is carefully dissected and elevated. The bony wall is gently pushed inside the sinus cavity to form the roof of the graft

>> Sinus cavity is grafted with biomaterial, a resorbable membrane is applied to cover the bony window in order to protect and stabilize the graft and then soft tissues are sutured

Implants can be simultaneously placed during the sinus lift procedure(3) if at least 3-4 mm of residual crestal bone is available, essential to guarantee a good primary stability of implants.

In absence of this minimal bone height, implant placement has to be postponed a few months after sinus lift procedure (5-7 months), when sufficient new regenerated bone will guarantee stability.

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(2) BOYNE PJ, JAMES RA GRAFTING OF THE MAXILLARY SINUS FLOOR WITH AUTOGENOUS MARROW AND BONE JOURNAL OF ORAL SURGERY (1980); 38: 613-616
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OsteoBiol® product range

**Tissue of origin** Pre-hydrated collagenated heterologous cortico-cancellous bone mix
**Tissue collagen** Preserved + 10% additional 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, 3x0.5 cc, 3x1.0 cc

For more information on OsteoBiol® mp.3 see page 64

**Tissue of origin** Collagenated heterologous cortico-cancellous bone mix
**Tissue collagen** Preserved
**Physical form** Slightly radiopaque granules
**Composition** 100% granulated mix
**Granulometry** 250-1000 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

For more information on OsteoBiol® Gen-Os see page 60

**Tissue of origin** Heterologous collagen membrane
**Tissue collagen** Preserved
**Physical form** Dried membrane with one smooth side and one micro-rough side
**Composition** 100% pericardium
**Thickness** Fine: 0.4 mm (±0.1), Standard: 0.6 mm (±0.1)
**Resorption time** Fine: approx 3 months, Standard: approx 4 months
**Packaging** Fine: 20x20 mm, 30x30 mm, 25x35 mm (oval)
Standard: 20x20 mm, 30x30 mm, 25x35 mm (oval)

For more information on OsteoBiol® Evolution see page 78

**PRODUCT CODES**

**mp.3**
- A3005FS | 1 Syringe | 1.0 cc | Porcine
- A3005FE | 1 Syringe | 1.0 cc | Equine
- A3015FS | 3 Syringe | 3x0.5 cc | Porcine
- A3015FE | 3 Syringe | 3x0.5 cc | Equine
- A3030FS | 3 Syringe | 3x1.0 cc | Porcine
- A3030FE | 3 Syringe | 3x1.0 cc | Equine

**Gen-Os**
- M1005FS | 1 Vial | 0.25 g | Porcine
- M1005FE | 1 Vial | 0.25 g | Equine
- M1005FS | 1 Vial | 0.5 g | Porcine
- M1005FE | 1 Vial | 0.5 g | Equine
- M1010FS | 1 Vial | 1.0 g | Porcine
- M1010FE | 1 Vial | 1.0 g | Equine
- M1020FS | 1 Vial | 2.0 g | Porcine
- M1020FE | 1 Vial | 2.0 g | Equine

**Evolution**
- EV02LLE | 20x20 mm | Fine | Equine
- EV02HHE | 20x20 mm | Standard | Equine
- EV03LLE | 30x30 mm | Fine | Equine
- EV03HHE | 30x30 mm | Standard | Equine
- EVO-LLE | 25x35mm (oval) | Fine | Equine
- EVOHHE | 25x35mm (oval) | Standard | Equine
The entire OsteoBiol® line consists of xenografts, i.e. biomaterials deriving from heterologous bone.

The Tecnoss® patented manufacturing process used to obtain these materials is able to achieve biocompatibility preserving part of the collagen matrix of the animal bone and avoiding at the same time high temperatures that would cause ceramization of the granules: the result is a unique particulate material, 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(4).

These cortical and cancellous particles have been mixed in various proportions and granulometries with collagen gel, in order to develop various products aimed at specific clinical indications: the specific order to develops various products aimed and granulometries with collagen gel, in

mp3, a pre-hydrated cortico-cancellous bone mix with 10% collagen gel is a “ready to use” product packed in a sterile syringe: the mp3 syringe can be directly applied into the bony window without having to mix mp3 granules with saline. Due to its collagen gel content, mp3 allows an excellent graft stability while its hydrophilic guarantees quick blood absorption and therefore the necessary graft vascularization.

Its cortico-cancellous composition allows a progressive resorption of osteoclastic type, and in parallel a similar rate of new bone formation(4). These unique properties allow a very good graft volume preservation, a healthy new bony tissue and ultimately, a successful implant rehabilitation.

Another OsteoBiol® material successfully used in lateral access sinus lift is G-en-Os, a cortico-cancellous collagenated bone mix with 250-1000 µm granulometry packed in a sterile vial. G-en-Os can be grafted alone or in combination with autogenous bone(27).

For more information see page 78
Case report
Bilateral sinus lift with lateral access

Sex: female | Age: 46

Fig. 1 Preoperative panoramic x-ray image showing a severe maxillary atrophy in left posterior region

Fig. 2 Osteotomy to access the left maxillary sinus

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

Fig. 4 Intraoral image showing the left maxillary sinus filled with OsteoBiol® mp3; note also the grafting over the bucal concavity

Fig. 5 Intraoral image showing the left maxillary sinus filled with OsteoBiol® mp3

Fig. 6 A properly trimmed OsteoBiol® Special membrane was placed for left maxillary sinus antrostomy covering

Fig. 7 Postoperative panoramic X-ray image after 8 months of healing

Fig. 8 Implant placement and restoration

Fig. 9 Restoration in place

Bone substitute: OsteoBiol® mp3
Membrane: OsteoBiol® Special

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For more information on OsteoBiol® mp3 see page 64
For more information on OsteoBiol® Special see page 92
Case report
Lateral access sinus lift with simultaneous implant and horizontal augmentation

Sex: female  |  Age: 42

Fig. 1 Initial x-ray showing a 3mm residual bone
Fig. 2 Flap opening, a substantial vestibular bone resorption can be determined
Fig. 3 Antrostomy performed with Piezo surgery technique
Fig. 4 An OsteoBiol® Evolution membrane is inserted through the antrostomy to protect the Schneider membrane from grafting material
Fig. 5 Maxillary sinus grafted with OsteoBiol® mp3
Fig. 6 Immediate implant placement
Fig. 7 An OsteoBiol® Evolution membrane is stabilised with osteosynthesis screws above the antrostomy
Fig. 8 Cortical bone stimulation
Fig. 9 OsteoBiol® mp3 is grafted on the vestibular side of the defect for horizontal augmentation
Fig. 10 The OsteoBiol® Evolution membrane is stabilised into position with a transpalatal suture
Fig. 11 Final situation
Fig. 12 Post-operative x-ray

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Bone substitute: OsteoBiol® mp3
For more information on OsteoBiol® mp3 see page 64
Membrane: OsteoBiol® Evolution
For more information on OsteoBiol® Evolution see page 78
Horizontal and vertical augmentation

Two-wall defects | Ridge split technique | Inlay technique
DEFECT ORIGIN AND DESCRIPTION

Common sites for horizontal ridge augmentation are the anterior (esthetic) zone in the maxilla and the posterior area in the mandible. While traumatic tooth loss mostly affects adolescents and young adults, resulting in bone deficiencies in the anterior maxilla, mandibular bone atrophy is often found in the posterior segments in elderly people who may have long-standing narrow ridges following premature tooth loss because of endodontic or periodontal problems.

Horizontal ridge augmentation of a deficient alveolar bone site is performed either simultaneously with implant placement, or with a staged approach prior to implant insertion. Vertical augmentation of atrophic mandibles allows placement of regular implants and avoids the risk of damaging the mandibular nerve.

The main criteria to consider when choosing the procedure are the residual bone volume needed to allow correct implant positioning, the bone density needed to achieve primary implant stability, and the defect morphology of the peri-implant bone defect. In the esthetic zone, additional factors must be taken into account, such as the gingival biotype and the level of the lip line.

The classification of Cawood & Howell is currently the most comprehensive way of classifying edentulous jaws. This classification is considered the most comprehensive system at present and it is internationally recommended for standardization in reports of pre-prosthetic surgery.

REGENERATION PROCEDURES

The gold standard for rehabilitation of horizontal and/or vertical ridge defects is considered autogenous block grafts. These blocks can be harvested from intra-or extra-oral sites and they can be inserted into the recipient site with two different modalities: onlay grafts or inlay grafts.

Whatever is the applied technique, it is recommended to fill the gaps of block with a biomaterial in granules to achieve the desired volume and contour for the augmented recipient site.

In order to minimize block graft resorption, several studies suggested to protect blocks with resorbable barrier membranes.

Horizontal ridge augmentation with resorbable barrier membranes is often found in the posterior segments in elderly people who may have long-standing narrow ridges following premature tooth loss because of endodontic or periodontal problems.

Ridge splitting is an alternative technique for horizontal ridge augmentation. The surgical technique can be schematized as the alveolar widening with proper osteotomes and chisels which produces a greenstick fracture leaving the remaining periosteum attached to the bone. This periosteally pedicled buccal cortex is repositioned and a new implant bed is created.

The direction of forces by chisels should be aimed palatally to decrease the damage exerted on the fragile buccal plate. The bone can be flexed to some extent due to its elasticity.

After this preparation of receiving site and after placing the implants, the resulting gap can be covered by resorbable membrane and filled with particulate biomaterial.

The major benefit of crestal widening is that the thin alveolar bone can be utilized for implantation and the implants placed simultaneously with the bone expansion procedure.

Ongoing studies are investigating the efficacy of augmenting alveolar ridge with significant horizontal and vertical resorption, due to non-treated extraction, with particulate xenogenic biomaterials covered and stabilized by heterologous cortical bone foils properly fixed with osteosynthesis screws. To vertically regenerate the bone in the mandible, the most predictable technique is the inlay graft. The insertion of a xenogenic bone block between two segments of native bone, after an osteotomy, guarantees the supply of blood and bone cells from the two sides of the graft.
OsteoBiol® product range

**Tissue of origin** Pre-hydrated collagenated heterologous cortico-cancellous bone mix
**Tissue collagen** Preserved + 10% additional 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, 3x0.5 cc, 3x1.0 cc

For more information on OsteoBiol® mp3 see page 64

**Tissue of origin** Pre-hydrated collagenated heterologous cortico-cancellous bone paste
**Tissue collagen** Preserved + 20% additional 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

For more information on OsteoBiol® Putty see page 68

**Tissue of origin** Sp-Block: cancellous bone
**Dual-Block**: cortico-cancellous bone
**Tissue collagen** Preserved
**Physical form** Rigid dried block
**Re-entry time** About 8 months
**Packaging** Sterile blister (for dimension references see column on the right)

For more information on OsteoBiol® Sp-Block see page 87
For more information on OsteoBiol® Dual-Block see page 88

**Tissue of origin** Heterologous cortical bone
**Tissue collagen** Preserved
**Physical form** Rigid dried lamina, flexible after re-hydration
**Thickness** Standard: 2.0-4.0 mm, Medium Curved: 0.8-1.0 mm, Fine: 0.4-0.6 mm
**Resorption time** Standard: about 8 months, Medium Curved and Fine: about 6 months
**Packaging** Standard: 30x30 mm, Medium Curved: 35x35 mm, Fine: 25x25 mm, 20x40 mm, 25x35 mm (oval)

For more information on OsteoBiol® Lamina see page 82

**PRODUCT CODES**

**mp3**
A3005FS | 1 Syringe | 1.0 cc | Porcine
A3005FE | 1 Syringe | 1.0 cc | Equine
A3015FS | 3 Syringe | 3 x 0.5 cc | Porcine
A3015FE | 3 Syringe | 3 x 0.5 cc | Equine
A3030FS | 3 Syringe | 3 x 1.0 cc | Porcine
A3030FE | 3 Syringe | 3 x 1.0 cc | Equine

**Putty**
HPT09S | 1 Syringe | 0.5 cc | Porcine
HPT09E | 1 Syringe | 0.5 cc | Equine
HPT61S | 1 Syringe | 1.0 cc | Porcine
HPT61E | 1 Syringe | 1.0 cc | Equine
HPT35S | 3 Syringe | 3 x 0.5 cc | Porcine
HPT35E | 3 Syringe | 3 x 0.5 cc | Equine
HPT32S | 3 Syringe | 3 x 0.25 cc | Porcine
HPT32E | 3 Syringe | 3 x 0.25 cc | Equine

**Sp-Block**
BN0E | 10x10x10 mm | Equine
BN1E | 10x10x20 mm | Equine
BN2E | 10x20x20 mm | Equine
BN8E | 35x10x5 mm | Equine

**Dual-Block**
ST7S | 20x15x5 mm | Soft | Porcine curved
STN5S | 20x10x5 mm | Norm | Porcine curved

**Lamina**
LS03SS | 30x30 mm | Standard | Porcine
LS03SE | 30x30 mm | Standard | Equine
LS10HS | 35x35 mm | Medium Curved | Porcine
LS10HE | 35x35 mm | Medium Curved | Equine
LS25FS | 25x25 mm | Fine | Porcine
LS25FE | 25x25 mm | Fine | Equine
LS24FS | 20x40 mm | Fine | Porcine
LS24FE | 20x40 mm | Fine | Equine
LS23FS | 25x35 mm (oval) | Fine | Porcine
LS23FE | 25x35 mm (oval) | Fine | Equine

**Evolution**
EV02LLE | 20x20 mm | Fine | Equine
EV02HHE | 20x20 mm | Standard | Equine
EV03LLE | 30x30 mm | Fine | Equine
EV03HHE | 30x30 mm | Standard | Equine
EVOHHE | 25x35 mm (oval) | Standard | Equine

For more information on OsteoBiol® Evolution see page 78
OsteoBiol® products description

The entire OsteoBiol® line consists of xenografts. The Tecnoss® patented manufacturing process used to obtain these materials is able to achieve biocompatibility preserving part of the collagen matrix of the animal bone and avoiding at the same time high temperatures that would cause ceramization of the granules: the result is a unique particulate material, 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[6].

These cortical and cancellous particles have been mixed in various proportions and granulometries with collagen gel, in order to develop various products aimed at different clinical indications. The OsteoBiol® materials indicated for horizontal augmentation are OsteoBiol® mp3, OsteoBiol® Lamina and OsteoBiol® Putty and OsteoBiol® Dual-Block.

OsteoBiol® mp3, a pre-hydrated cortico-cancellous bone mix with 10% collagen gel is a “ready to use” product packed in a sterile syringe: the mp3 syringe can be directly applied into the defect without having to mix the mp3 granules with saline.

Due to its collagen gel content, mp3 allows an excellent graft stability while its hydrophilia guarantees quick blood absorption and therefore the necessary graft vascularization. Its cortico-cancellous composition allows a progressive resorption of osteoclastic type, with in parallel a similar rate of new bone formation. Used in combination with OsteoBiol® Lamina, mp3 allows a very good graft volume preservation and a healthy new bony tissue.

OsteoBiol® Sp-Block and Dual-Block are respectively cancellous and cortico-cancellous collagenated blocks. Sp-Block is indicated for mandible vertical augmentation (maximum 5mm) with inlay technique, while Dual-Block is indicated for horizontal augmentation of heavily resorbed maxilla. Whatever is the applied technique, 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, and to protect the graft with a bioresorbable membrane.

OsteoBiol® Putty is a collagen gel matrix loaded for 80% of its volume with micronized cortico-cancellous bone particles (granulometry up to 300 µm) packed in a sterile syringe.

The exclusive Tecnoss® manufacturing process guarantees an exceptional maleability and plasticity: furthermore the syringe packaging gives Putty extraordinary handling properties making this product the ideal choice for filling the gaps between implants in ridge splitting procedures[7].

An OsteoBiol® Evolution membrane is recommended to cover implants and grafted biomaterial: Evolution pericardium membranes guarantee an efficient barrier effect, favour the correct soft tissue regrowth and wound closure and do not get infected in case of exposure.

OsteoBiol® Curve Lamina and Sp-Block

OsteoBiol® Soft Lamina stabilised with titanium post

OsteoBiol® Lamina

OsteoBiol® mp3

Inlay technique with OsteoBiol® Sp-Block

OsteoBiol® Putty

OsteoBiol® mp3 | For more information see page 64

Source: Tecnoss® Dental Media Library

OsteoBiol®® products description

Due to its collagen gel content, mp3 allows an excellent graft stability while its hydrophilia guarantees quick blood absorption and therefore the necessary graft vascularization. Its cortico-cancellous composition allows a progressive resorption of osteoclastic type, with in parallel a similar rate of new bone formation. Used in combination with OsteoBiol® Lamina, mp3 allows a very good graft volume preservation and a healthy new bony tissue.

OsteoBiol®® Sp-Block and Dual-Block are respectively cancellous and cortico-cancellous collagenated blocks. Sp-Block is indicated for mandible vertical augmentation (maximum 5mm) with inlay technique, while Dual-Block is indicated for horizontal augmentation of heavily resorbed maxilla. Whatever is the applied technique, 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, and to protect the graft with a bioresorbable membrane.

OsteoBiol®® Putty is a collagen gel matrix loaded for 80% of its volume with micronized cortico-cancellous bone particles (granulometry up to 300 µm) packed in a sterile syringe.

The exclusive Tecnoss® manufacturing process guarantees an exceptional maleability and plasticity: furthermore the syringe packaging gives Putty extraordinary handling properties making this product the ideal choice for filling the gaps between implants in ridge splitting procedures[7].

An OsteoBiol®® Evolution membrane is recommended to cover implants and grafted biomaterial: Evolution pericardium membranes guarantee an efficient barrier effect, favour the correct soft tissue regrowth and wound closure and do not get infected in case of exposure.
Case report
Horizontal defect grafted with OsteoBiol® Lamina and mp3

Sex: female | Age: 45

Fig. 1 The 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 bone substitute (Osteobiol® mp3, TecnoSS).
Fig. 6 Covering the augmented area with Osteobiol Lamina
Fig. 7 Primary flap closure was achieved
Fig. 8 Digital volumetomograph six month after augmentation procedure demonstrates the amount of new bone
Fig. 9 Intraoperative view of the augmented area six months after augmentation procedure
Fig. 10 Placement of two implants
Fig. 11 Postoperative radiograph
Fig. 12 Final prosthetic reconstruction

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Bone substitute: Osteobiol® mp3
For more information on Osteobiol® mp3 see page 64
Membrane: Osteobiol® Lamina
For more information on Osteobiol® Lamina see page 82
Case report
Treatment of a failing implant case

CLINICAL INDICATIONS
HORIZONTAL AND VERTICAL AUGMENTATION

Sex: female | Age: 56

Fig. 1 Clinical situation. Implant supported restoration upper left. Teeth supported restoration upper right.

Fig. 2 Full thickness flap elevated showing implants placed partly outside the alveolar ridge.

Fig. 3 Implants are removed. Major bone loss defects can be seen.

Fig. 4 Ridge reconstructed with OsteoBiol® mp3 carefully compacted against the plate of bone.

Fig. 5 A collagen sponge is placed above the mp3 giving more stability to the material and adding volume to the soft tissues.

Fig. 6 Four months later a flap is elevated.

Fig. 7 The lateral incisor is extracted and the recreated ridge can be seen.

Fig. 8-9 The implants are placed into a very dense bone.

Fig. 10-11 Four months later a flap is elevated and abutments placed into a very stable bone (IQ Osstell between 72 and 78).

Fig. 12 Prosthetic restorations in place. Upper left and right.

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Bone substitute: OsteoBiol® mp3
For more information on OsteoBiol® mp3 see page 64.
Case report
Rehabilitation of a total superior edentulism with ridge split technique

Fig. 1 Initial endoral image, showing a total superior edentulism
Fig. 2 Pre-operative TC image showing the crestal defect width
Fig. 3 Edentulous crest expansion with ridge-split technique: insertion of depth markers
Fig. 4 Placement of 6 implants
Fig. 5 Bone deficits grafted with OsteoBiol® Putty
Fig. 6 OsteoBiol® Special membranes placed as a protection of the graft
Fig. 7 Intraoral image after 8 months from implant placement
Fig. 8 Intraoral image at second surgical phase: it is possible to appreciate the regeneration of pre-existing bone defects
Fig. 9 TC control image after 12 months from surgery: it is possible to appreciate a good preservation of crestal bone
Fig. 10 Placement of a connection bar between implants
Fig. 11 Detail of prosthesis: lingual view
Fig. 12 Final image showing a good prosthetic rehabilitation

Sex: female | Age: 58

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Bone substitute: OsteoBiol® Putty
For more information on OsteoBiol® Putty see page 68
Membrane: OsteoBiol® Special
For more information on OsteoBiol® Special see page 92
Case report
Vertical regeneration with inlay technique

Fig. 1 Pre-operatory x-ray
Fig. 2 After one horizontal and two vertical osteotomies, the bone fragment is moved towards the coronal direction
Fig. 3 Space obtained after moving the bone fragment
Fig. 4 Positioning of OsteoBiol® Sp-Block
Fig. 5 Rx post-surgery
Fig. 6 Clinical appearance of the graft during re-opening, after 3 months
Fig. 7 Preparation of implant sites
Fig. 8 Positioning of the implants
Fig. 9 Positioning of the implants
Fig. 10 Histology after 3 months*
Fig. 11 Histology detail*
Fig. 12 Histology detail*

Sex: female | Age: 60

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Bone substitute: OsteoBiol® Sp-Block
For more information on OsteoBiol® Sp-Block see page 87
Intrabony defect grafted with Osteobiol® Gen-Os

Source: Courtesy of Dr. Roberto Abundo and Dr. Giuseppe Corrente, Torino, Italy
DEFECT ORIGIN AND DESCRIPTION

According to the glossary of terms of the American Academy of Periodontology, an intrabony defect is defined as a “periodontal defect within the bone surrounded by one, two or three bony walls or combination thereof.”

Irrespective of the number and nature of the contributing factors involved, the formation of an osseous periodontal lesion is considered to be the result of an apical downgrowth of subgingival plaque with a concomitant resorption of bone within a 2mm radius from the root surface\(^1\)\(^-\)\(^2\).

The more remotely located bone structures and the root surface retain their integrity and form the anatomical boundaries of the osseous lesion.

The classification of these periodontal defects according to Goldman and Cohen\(^3\) is based on specific morphological criteria and differentiates between suprabony, intrabony and furcation defects.

Intrabony defects are defined by the apical location of the base of the pocket with respect to the residual alveolar crest.

With regard to intrabony defects, two types of defects can be recognized: intrabony defects and craters. Intrabony defects are bony defects whose intrabony component affects primarily one tooth, while in craters the defect affects two adjacent root surfaces to a similar extent.

Intrabony defects have been classified according to their morphology in terms of residual bony walls, width of the defect (or radiographic angle), and in terms of their topographic extension around the tooth. Three-wall, two-wall and one-wall defects have been defined on the basis of the number of residual alveolar bone walls. This represents the primary classification system.

REGENERTATION PROCEDURES

Bone replacement grafts remain among the most widely used therapeutic strategies for the correction of periodontal osseous intrabony defects.

Observational and controlled studies generally document improvements in clinical parameters following placement of graft materials\(^4\)\(^-\)\(^6\).

The surgical technique for treatment of not deep intrabony defects includes elevation of a full-thickness flap, with particular care in preserving the integrity of the distal margin, in order to guarantee proper blood bedewing to the receiving site.

Then, after adequate cleaning of root surface, particulate biomaterial can easily be grafted and covered with a collagen resorbable membrane, which assures protection and exclusion of epithelium tissue from the attachment apparatus to be regenerated.

After having coronally advanced the flap and suture, a periodontal dressing is generally placed to protect and favor the flap healing. Healing can be expected after 3-4 months from surgery.

In case of deep intrabony defects or when bony walls are missing, healing can be expected after 5-6 months from surgery.

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CLINICAL IMPLANT DENTISTRY AND RELATED RESEARCH, 2008, 10: 264-270
**OsteoBiol® product range**

**Gen-Os**
- **Product Codes**
  - M1052FS | 1 Vial | 0.25 g | Porcine
  - M1052FE | 1 Vial | 0.25 g | Equine
  - M1005FS | 1 Vial | 0.5 g | Porcine
  - M1005FE | 1 Vial | 0.5 g | Equine
  - M1010FS | 1 Vial | 1.0 g | Porcine
  - M1010FE | 1 Vial | 1.0 g | Equine
  - M1020FS | 1 Vial | 2.0 g | Porcine
  - M1020FE | 1 Vial | 2.0 g | Equine

**Gel 40**
- **Product Codes**
  - 05GEL40S | 1 Syringe | 0.5 cc | Porcine
  - 05GEL40E | 1 Syringe | 0.5 cc | Equine
  - 15GEL40S | 3 Syringe | 3x0.5 cc | Porcine
  - 15GEL40E | 3 Syringe | 3x0.5 cc | Equine

**Evolution**
- **Product Codes**
  - EVO2LLE | 20x20 mm | Fine | Equine
  - EVO2HHE | 20x20 mm | Standard | Equine
  - EVO3LLE | 30x30 mm | Fine | Equine
  - EVO3HHE | 30x30 mm | Standard | Equine
  - EVOHHE | 25x35 mm (oval) | Fine | Equine

**Derma**
- **Product Codes**
  - ED25FS | 1 Blister | Fine | 25x25 mm | Porcine
  - ED03SS | 1 Blister | Standard | 30x30 mm | Porcine

**For more information on OsteoBiol® Gen-Os see page 60**

**For more information on OsteoBiol® Gel 40 see page 72**

**For more information on OsteoBiol® Evolution see page 78**

**For more information on OsteoBiol® Evolution see page 93**
The entire OsteoBiol® line consists of xenografts, i.e., biomaterials deriving from heterologous bone.

The Tecnoss® patented manufacturing process used to obtain these materials is able to achieve biocompatibility preserving part of the collagen matrix of the animal bone and avoiding at the same time high temperatures that would cause ceramization of the granules: the result is a unique particulate material, 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.

These cortical and cancellous particles have been mixed in various proportions and granulometries with and without collagen gel, in order to develop various products aimed at different clinical indications: the OsteoBiol® materials indicated for intrabony defects are Gen-Os, in case of two and one wall defects, and Gel 40 in case of three wall defects.

OsteoBiol® Gel 40 is a collagen gel matrix loaded for 60% of its volume with micronized cortico-cancellous bone particles (granulometry up to 300 µm) packed in a sterile syringe.

The exclusive Tecnoss® manufacturing process guarantees an exceptional malleability and plasticity: furthermore the syringe packaging gives Gel 40 extraordinary handling properties making this product the ideal choice for periodontal defects with intact bony walls.

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

In case of partially compromised bone walls, an OsteoBiol® Evolution membrane (fine model) is recommended: Evolution pericardium membranes efficiently contain and stabilize the Gen-Os graft, guarantee an efficient barrier effect, favour the correct wound healing and do not get infected in case of exposure.

OsteoBiol® Gel 40 is a collagen gel matrix loaded for 60% of its volume with micronized cortico-cancellous bone particles (granulometry up to 300 µm) packed in a sterile syringe.

The exclusive Tecnoss® manufacturing process guarantees an exceptional malleability and plasticity: furthermore the syringe packaging gives Gel 40 extraordinary handling properties making this product the ideal choice for periodontal defects with intact bony walls.
Case report
Periodontal regeneration

Sex: female
Age: 30

Fig. 1 Pre-operative x-ray
Fig. 2 Initial clinical situation
Fig. 3 Probing intrabony defect
Fig. 4 Buccal furcation on 2.6 is also present
Fig. 5 Furcation and defect grafted with OsteoBiol® Gen-Os
Fig. 6 Completion of grafting with OsteoBiol® Gen-Os
Fig. 7 Grafting site protected with OsteoBiol® Evolution collagen membrane
Fig. 8 Collagen membrane double layer
Fig. 9 Coronally positioned flap: buccal view
Fig. 10 Sutures: palatal view
Fig. 11 Control x-ray at 12 months
Fig. 12 Clinical situation at 12 months

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Bone substitute: OsteoBiol® Gen-Os
For more information on OsteoBiol® Gen-Os see page 60
Membrane: OsteoBiol® Evolution
For more information on OsteoBiol® Evolution see page 78
Case report

Treatment of a deep intrabony defect mesial on 4.1

Sex: female | Age: 39

Fig. 1 Pre-operative endoral x-ray showing a deep intrabony defect mesial on 4.1

Fig. 2 The bone defect is 7mm deep

Fig. 3 Intraoperative image showing the two-wall defect after cleansing of radicular surfaces

Fig. 4 OsteoBiol® Gel 40

Fig. 5 Defect grafted with OsteoBiol® Gel 40

Fig. 6 A properly shaped OsteoBiol® Evolution membrane is placed to contain and protect the particulate grafting material

Fig. 7 Control endoral x-ray at the end of surgery: it is possible to appreciate the defect grafted with biomaterial

Fig. 8 Control endoral x-ray after 1 year from treatment: radiographically the biomaterial is bio-integrated with natural bone

Fig. 9 The probing depth is reduced to 2mm

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Bone substitute: OsteoBiol® Gel 40
For more information on OsteoBiol® Putty see page 72

Membrane: OsteoBiol® Evolution
For more information on OsteoBiol® Evolution see page 78
PRODUCTS

BONE SUBSTITUTES
MEMBRANES AND BARRIERS
SPECIFIC PRODUCTS

Source: Courtesy of Dr. Ulf Nannmark, Göteborg University, Sweden
Maxillary sinus lift grafted with OsteoBiol® mp 3: simultaneous implant placement and simultaneous horizontal augmentation

Source:Courtesy of Dr Rosario Scianez, Genova, Italy
OsteoBiol® bone substitutes

**HETEROLOGOUS BONE**

- Inorganic component (mineral)
- Organic component (collagen)

**CORTICAL BONE**

**CANCELLOUS BONE**

Collagenated mix

**Collagen gel**

- **Gen-Os**
  - 100% collagenated bone mix
- **mp3**
  - 90% bone mix
  - 10% Gel 0
- **Putty**
  - 80% bone mix
  - 20% Gel 0
- **Gel 40**
  - 60% bone mix
  - 40% Gel 0
- **Gel 0**
  - 100% collagen gel

**Products**

- **BONE SUBSTITUTES**

Source: Tecnoss s.r.l.
Detail of an OsteoBiol® Gen-Os granule: vascular canal entrance with evident centralised osteonic structure

Source: Courtesy of Dr Ulf Nannmark, University of Göteborg, Sweden
Characteristics | Gen-Os

**CHARACTERISTICS**
A natural replicate of autologous bone, Gen-Os conserves the same intimate structures\(^1\) (matrix and porous form) and presents a high osteoconductive activity\(^2\). It is biocompatible and bioavailable, as recognized by tests made according to the ISO 10993 method conducted at the Università degli Studi di Torino.

Gen-Os is gradually resorbable and provides support in bone neoformation helping to preserve the original graft shape and volume (osteocentric property).

Moreover, thanks to its collagen content, the product facilitates blood clotting and the subsequent invasion of repairing and regenerative cells, favouring restitution ad integrum of missing bone.

Because of its marked “hydrophilia”, it can function as a carrier for selected medications and drugs.

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

**ADVANTAGES**
Gen-Os expands up to 50% in volume after hydration with sterile saline: hydrated collagen contained in each granule also increases sensibly biomaterial adhesivity.

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**Tissue of origin**
Cortico-cancellous heterologous bone mix

**Tissue collagen**
Preserved

**Physical form**
Slightly radiopaque granules

**Composition**
100% granulated mix

**Granulometry**
250-1000 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**
- M1052FS | 1 Vial | 0.25 g | Porcine
- M1052FE | 1 Vial | 0.25 g | Equine
- M1005FS | 1 Vial | 0.5 g | Porcine
- M1005FE | 1 Vial | 0.5 g | Equine
- M1010FS | 1 Vial | 1.0 g | Porcine
- M1010FE | 1 Vial | 1.0 g | Equine
- M1020FS | 1 Vial | 2.0 g | Porcine
- M1020FE | 1 Vial | 2.0 g | Equine
Clinical indications

MAXILLARY SINUS FLOOR AUGMENTATION

For more information on LATERAL ACCESS SINUS LIFT please see page 36

INTRABONY DEFECTS

For more information on DEHISCENCES AND FENESTRATIONS please see page 24

OSTEOTOMY SINUS FLOOR AUGMENTATION

For more information on PERIODONTAL REGENERATION please see page 50

TWO-WALL DEFECTS

For more information on CRESTAL ACCESS SINUS LIFT please see page 30

SOCKET PRESERVATION

For more information on HORIZONTAL AUGMENTATION please see page 42

For more information on ALVEOLAR REGENERATION please see page 18

For more information on LATERAL ACCESS SINUS LIFT please see page 36

For more information on DEHISCENCES AND FENESTRATIONS please see page 24

For more information on PERIODONTAL REGENERATION please see page 50

For more information on HORIZONTAL AUGMENTATION please see page 42

For more information on ALVEOLAR REGENERATION please see page 18

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Crespi R, Caprare G, Gherlone E
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Clinical Implant Dentistry and Related Research, 2010 Dec 26, epub ahead of print

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Corticocancellous porcine bone in the healing of human extraction sockets: combining histomorphometry with osteoblast gene expression profiles in vivo

Scaramo A, Caramiccieti A, Asenza B, Piantelli M, Murruaga G, Piantelli A
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Casetta M, Ricci L, Iezzi G, Calasso S, Piantelli A, Perrotti V
Use of Pitressin during maxillary sinus elevation: Clinical results of 40 consecutive cases
The advantages of dual-phase biomaterials | Gen-Os

CLINICAL INDICATIONS SUMMARY

**Oral surgery:** granulomas, dentigenous cysts and ridge split.

**Periodontology:** filler of deep intrabony defects and furcations.

**Implantology:** universal filler used in treatment of dehiscences and periimplantitis, two wall defects, lateral and crestal access sinus lift. When needed Gen-Os graft can be protected with OsteoBiol® membranes or OsteoBiol® cortical laminae.

**CLINICAL INDICATIONS OVERVIEW**

A bone graft is a material used to repair a bone defect or deficiency contour and/or volume. The use of these materials in regenerative procedures is based on the assumption that they are osteoconductive i.e. serve as scaffold for new bone formation. The entire OsteoBiol® line consists of xenografts, i.e. biomaterials deriving from heterologous bone and soft tissues.

The Tecnoss® patented manufacturing process used to obtain these materials is able to achieve biocompatibility preserving part of the collagen matrix of the animal bone 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(2).

Gen-Os, a cortico-cancellous bone mix, has been the first product developed with this 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(3) 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. Gen-Os is also indicated for lateral access maxillary sinus lift(4,5,6) and dehiscence regeneration(7), always in association with Evolution membranes.

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 hydrophobic: it combines therefore extremely well with blood and is very stable once applied into the grafting site. Its cortico-cancellous composition allows a progressive resorption of osteoclastic type, with in parallel a similar rate of new bone formation(2): these unique properties allow a very good graft volume preservation, a healthy new bony tissue and ultimately, a successful implant rehabilitation.

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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 Dr Ulf Nannmark, University of Göteborg, Sweden

**Heterologous cortico-cancellous collagenated pre-hydrated bone mix**
Characteristics | mp3

**CHARACTERISTICS**

Heterologous origin biomaterial made of 600-1000 µm pre-hydrated collagenated cortico-cancellous granules, properly mixed with OsteoBiol® Gel 0. 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\(^1\), 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\(^2\), it preserves the original graft shape and volume (osteoductive property). Moreover, thanks to its collagen content, the product facilitates blood clotting and the subsequent invasion of repairing and regenerative cells.

**HANDLING**

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

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

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>mp3</th>
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<tbody>
<tr>
<td><strong>Tissue of origin</strong></td>
<td>Cortico-cancellous heterologous bone mix</td>
</tr>
<tr>
<td><strong>Tissue collagen</strong></td>
<td>Preserved plus an additional 10% OsteoBiol® Gel 0 (collagen gel)</td>
</tr>
<tr>
<td><strong>Physical form</strong></td>
<td>Pre-hydrated granules and collagen gel</td>
</tr>
<tr>
<td><strong>Composition</strong></td>
<td>90% granulated mix, 10% collagen gel</td>
</tr>
<tr>
<td><strong>Granulometry</strong></td>
<td>600-1000 µm</td>
</tr>
<tr>
<td><strong>Re-entry time</strong></td>
<td>About 5 months</td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
<td>Syringe: 1.0 cc, 3 x 0.5 cc, 3 x 1.0 cc</td>
</tr>
<tr>
<td><strong>Product codes</strong></td>
<td>A3005FS</td>
</tr>
<tr>
<td></td>
<td>A3005FE</td>
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<tr>
<td></td>
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</tbody>
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*Source: Courtesy of Dr Gianluca Reato, Mestre, Italy

*Source: Courtesy of Dr Roberto Rossi, Genova, Italy

*Source: Courtesy of Prof Antonio Barone and Prof Ugo Covani, Lido di Camaiore, Italy
Clinical indications

MAXILLARY SINUS FLOOR AUGMENTATION

For more information on
LATERAL ACCESS SINUS LIFT
see page 36

POST-EXTRACTIVE SOCKETS

For more information on
ALVEOLAR REGENERATION
see page 18

TWO-WALL DEFECTS

For more information on
HORIZONTAL AUGMENTATION
see page 42

“For many years Doctors enjoyed the superb clinical performances offered by the universal granulated product Osteobiol® Gen-O s and a common technique was to mix Gen-O s with additional collagen gel (Osteobiol® Gel 0).

After many years of research Tecnoss® was able to introduce a revolutionary product, collagenated, pre-hydrated and ready-to-use, offering unprecedented clinical performances and unique handling properties”

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

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TISSUE CHANGES OF EXTRACTION SOCKETS IN HUMANS: A COMPARISON OF SPONTANEOUS HEALING VS. RIDGE PRESERVATION WITH SECONDARY SOFT TISSUE HEALING
CLINICAL ORAL IMPLANTS RESEARCH, 2012 JUL 12, EPUB AHEAD OF PRINT
Ultimate performance and handling

CLINICAL INDICATIONS SUMMARY

Oral surgery and implantology: thanks to its particular formulation and granulometry, mp3 is ideal for grafting in surgical procedures of maxillary sinus lift with lateral access(1,2).

A membrane OsteoBiol® Evolution or OsteoBiol® Special is recommended to cover the antrostomy.

CLINICAL INDICATIONS OVERVIEW

A bone graft is a material used to repair a bone defect or deficiency contour and/or volume.

The use of these materials in regenerative procedures is based on the assumption that they are osteoconductive i.e. serve as scaffold for new bone formation.

The entire OsteoBiol® line consists of xenografts, i.e. biomaterials deriving from heterologous bone and soft tissues.

The Tecnoss® patented manufacturing process used to obtain these materials is able to achieve biocompatibility preserving part of the collagen matrix of the animal bone 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(3).

mp3 main indication is lateral access maxillary sinus lift(2,3), always in association with Evolution membranes: the mp3 syringe can be directly applied into the bony window without having to mix the mp3 granules with saline. Due to its collagen gel content, mp3 allows an excellent graft stability while its hydrophilia guarantees quick blood absorption and therefore the necessary graft vascularization.

mp3 has also been successfully used in combination with Evolution membranes for alveolar ridge preservation(4): the application of this biomaterial limits significantly 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 is indicated for horizontal augmentation (two wall defects) in combination with autogenous bone blocks(5) or with OsteoBiol® Lamina(6): its cortico-cancellous composition allows a progressive resorption of osteoclastic type, and in parallel a similar rate of new bone formation(5). These unique properties allow a very good graft volume preservation, a healthy new bony tissue and ultimately, a successful implant rehabilitation.

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Part of a biopsy showing newly formed bone after treatment with Osteobiol® Putty. Biopsies were taken 5 weeks after implantation in rabbit maxillae. The smaller granules are totally covered by newly formed bone and seams of osteoblasts are recorded almost at all bone surfaces. Both the marrow spaces and bone are fully nurtured by neovessels. Htx-eosine.

Original magnification x20

Source: Histology by Dr Ulf Nannmark, University of Göteborg, Sweden
CHARACTERISTICS

Putty is a bone paste with at least 80% micronized heterologous bone (granulometry up to 300 µm) and collagen gel (OsteoBiol® Gel 0). 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. 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.
**PRODUCTS**

**BONE SUBSTITUTES**

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**Tissue of origin**
Cortico-cancellous heterologous bone mix

**Tissue collagen**
Preserved plus an additional 20% OsteoBiol® Gel 0 (collagen gel)

**Physical form**
Rustic 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
- HPT61S | 1 Syringe | 1.0 cc | Porcine
- HPT61E | 1 Syringe | 1.0 cc | Equine
- HPT35S | 3 Syringe | 3x0.5 cc | Porcine
- HPT35E | 3 Syringe | 3x0.5 cc | Equine
- HPT32S | 3 Syringe | 3x0.25 cc | Porcine
- HPT32E | 3 Syringe | 3x0.25 cc | Equine

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*Source: Courtesy of Dr Ulf Nannmark, University of Göteborg, Sweden*
Clinical indications

**POST-EXTRACTIVE SOCKETS**

For more information on **ALVEOLAR REGENERATION**
see page 18

**OSTEOTOMY SINUS FLOOR AUGMENTATION**

For more information on **PERI-IMPLANT LESIONS**
see page 30

**OSTEOTOMY SINUS FLOOR AUGMENTATION**

For more information on **DEHISCENCES AND FENESTRATIONS**
see page 24

**RIDING SPLIT**

For more information on **HORIZONTAL AUGMENTATION**
see page 42

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MINERVA STOMATOLOGICA, 2005 JUN;54(6):351-62

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JOURNAL OF ORAL IMPLANTOLOGY, 2010 JUN 16

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Engineered for peri-implant lesions

CLINICAL INDICATIONS SUMMARY

Implantology: versatile alveolar filler to preserve crestal volume and in immediate post-extractive implants where it facilitates primary stability; ideal for the treatment of peri-implantitis and in ridge split procedures.

In crestal access sinus lift, Putty can be used alone or in association with Gen-Os to facilitate insertion.

Oral surgery: ideal filler after dental extractions, granulomas, dentigenous cysts.

CLINICAL INDICATIONS OVERVIEW

The exclusive Tecnoss® manufacturing process guarantees an exceptional malleability and plasticity. Furthermore, the new syringe packaging gives Putty extraordinary handling properties making this product the ideal choice for post-extractive sockets, 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® manufacturing process avoids granules ceramization, allowing a progressive resorption of the biomaterial and, at the same time, a significant new-bone formation rate.

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.

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 this condition: for example post-extractive sockets and inside the bone crest when ridge-split technique is adopted.

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Part of a biopsy showing newly formed bone after treatment with OsteoBiol® Gel 40. Biopsies were taken 5 weeks after implantation in rabbit maxillae. Hematoxylin-eosine. Original magnification x20.

Gel 40
Heterologous cortico-cancellous collagenated pre-hydrated bone gel

Source: Histology by Dr. Ulf Nannmark, University of Göteborg, Sweden
Characteristics | Gel 40

**Characteristics**
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 µm). 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 lipophila 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.
Clinical indications

**OSTEOTOME**

**SINUS FLOOR AUGMENTATION**

For more information on **CRESTAL ACCESS SINUS LIFT** see page 30

**OSTEOTOME**

**DEFECTS AND GINGIVAL RECESSIONS**

For more information on **PERIODONTAL REGENERATION** see page 50

**INTRABONY**

**GEL 40**

**OSTEOBON**

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CLINICAL IMPLANT DENTISTRY AND RELATED RESEARCH, 2010 OCT 26 EPUB

SANTAGATA M, GUARNIERI L, RAUSO R, TARRARO G  
immediate loading of dental implant after sinus floor elevation with osteotome technique: a clinical report and preliminary radiographic results  
JOURNAL OF ORAL IMPLANTOLOGY, 2010 DEC; 36(6); 485-489

Source: Tecnoss® Dental Media Library
A unique heterologous bone gel

CLINICAL INDICATIONS SUMMARY

Maxillary sinus lift with crestal access; treatment of 3-wall periodontal defects and gingival recessions; it can also be used mixed with OsteoBiol® Gen-Os as graft stabilizer.

CLINICAL INDICATIONS OVERVIEW

The exclusive Tecnoss® manufacturing process guarantees an exceptional malleability and plasticity: furthermore the syringe packaging gives Gel 40 extraordinary handling properties making this product the ideal choice for crestal access sinus lift, deep and narrow peri-implant defects, three-wall intrabony defects and, in combination with Evolution membranes, for gingival recessions.

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.

Gel 40 “soft” consistency also guarantees an easy and healthy soft-tissue healing.

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Buccal Bone Augmentation Around Immediate Implants With and Without Flap Elevation: A Modified Approach

(2) BARONE A, CORNELINI R, CIAGLIA R, COVANI U
Implant Placement in Fresh Extractions Sockets and Simultaneous Osteotome Sinus Floor Elevation: A Case Series

(3) CARDARO P, D. CARDARO POU G
Healing of Gingival Recession Using a Collagen Membrane with a Demineralized Xenograft: A Randomized Controlled Clinical Trial

(4) NANNMARK U, AZARMIDRI
Short Communication: Collaginated Cortico-Cancellous Porcine Bone Grafts. A Study in Rabbit Maxillary Defects
Clinical Implant Dentistry and Related Research, Epub 2010
OsteoBiol® membranes and barriers

**MEMBRANES**

**Evolution**
- Heterologous pericardium

**Special**
- Heterologous pericardium

**Duo-Teck**
- Lyophilised equine collagen felt + bone

**Derma**
- Porcine derma

**Lamina**
- Cortical bone

**BARRIERS**

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

Translucent dried membrane

Dried membrane covered with micronized bone

Dried membrane

Rigid dried lamina, flexible after re-hydration

Intrabony defect graft protected by OsteoBiol® Evolution
Source: Courtesy of Dr. Roberto Abundo and Dr. Giuseppe Ceneto, Torino, Italy
For more information on OsteoBiol® Evolution see page 78

OsteoBiol® Special protecting the Schneider membrane before grafting
Source: Courtesy of Dr. Concezio Marcelli, Legnano, Italy
For more information on OsteoBiol® Special see page 92

OsteoBiol® Duo-Teck grafted
Source: Courtesy of Dr. Atef Ismail Mohamed, Cairo, Egypt
For more information on OsteoBiol® Duo-Teck see page 91

OsteoBiol® Derma grafted in lateral sinus wall
Source: Courtesy of Dr. Antonio J. Murillo Rodriguez, Eibar, Spain
For more information on OsteoBiol® Derma see page 93

OsteoBiol® Lamina for the covering of a host perforated augmented area
Source: Courtesy of Prof. Dr. Hannes Wachtel and Dr. Tobias Thalmaier, Munich, Germany
For more information on OsteoBiol® Lamina see page 82

SEM image showing collagenic matrix of OsteoBiol® membranes
Source: Courtesy of Nobil Biotech, Magenta, Italy
For more information on OsteoBiol® see page 78
### Membranes and Barriers

#### Membranes

<table>
<thead>
<tr>
<th>Product</th>
<th>Size</th>
<th>Thickness</th>
<th>Estimated Resorption Time</th>
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</thead>
<tbody>
<tr>
<td>Evolution Standard</td>
<td>20x20, 30x30, 25x35</td>
<td>[Bars]</td>
<td>[Bars]</td>
</tr>
<tr>
<td>Evolution Fine</td>
<td>20x20, 30x30, 25x35</td>
<td>[Bars]</td>
<td>[Bars]</td>
</tr>
<tr>
<td>Special</td>
<td>20x20, 30x30</td>
<td>[Bars]</td>
<td>[Bars]</td>
</tr>
<tr>
<td>Duo-Teck</td>
<td>20x20</td>
<td>[Bars]</td>
<td>[Bars]</td>
</tr>
<tr>
<td>Derma Standard</td>
<td>30x30</td>
<td>[Bars]</td>
<td>[Bars]</td>
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<tr>
<td>Derma Fine</td>
<td>25x25</td>
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</tbody>
</table>

#### Bone Barriers

<table>
<thead>
<tr>
<th>Product</th>
<th>Size</th>
<th>Thickness</th>
<th>Estimated Re-entry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lamina Fine</td>
<td>25x25, 20x40, 25x35</td>
<td>[Bars]</td>
<td>[Bars]</td>
</tr>
<tr>
<td>Curved Lamina</td>
<td>35x35 curved</td>
<td>[Bars]</td>
<td>[Bars]</td>
</tr>
<tr>
<td>Lamina Standard</td>
<td>30x30</td>
<td>[Bars]</td>
<td>[Bars]</td>
</tr>
</tbody>
</table>

Source: Tecnoss® s.r.l.
SEM image showing collagenic matrix of Osteobiol® Evolution
Source: Courtesy of Nobil Bio Ricerche, Villafranca d’Asti, Italy
Obtained from mesenchymal tissue (heterologous pericardium) the Evolution membrane is completely resorbable. Its structure is made of dense collagen fibers of high consistency and of extraordinary resistance that offer the specialist surgeon:

- the maximum adaptability to bone tissue and soft tissues
- an easy and secure suturability to nearby tissues
- the best membrane/bone and membrane/periosteum interface
- stability and prolonged protection of the underlying graft

**HANDLING**

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.

N.B.: 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.

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**Characteristics | Evolution**

**Tissue of origin**
Heterologous pericardium

**Tissue collagen**
Preserved

**Physical form**
Dried membrane with one smooth side and one micro-rough side

**Composition**
100% pericardium

**Thickness**
- Fine: 0.4 mm (±0.1 mm)
- Standard: 0.6 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
- EV03LLE | 30x30 mm | Fine | Equine
- EV03HHE | 30x30 mm | Standard | Equine
- EVO LLE | 25x35 mm (oval) | Fine | Equine
- EVO HHE | 25x35 mm (oval) | Standard | Equine
Clinical indications

MAXILLARY SINUS FLOOR AUGMENTATION

For more information on LATERAL ACCESS SINUS LIFT see page 36

For more information on INLAY TECHNIQUE see page 42

INTRABONY DEFECTS

For more information on PERIODONTAL REGENERATION see page 50

Post-Extracitive Sockets

For more information on DEHISCENCES AND FENESTRATIONS see page 24

For more information on ALVEOLAR REGENERATION see page 18

Two-Wall Defects

For more information on HORIZONTAL AUGMENTATION see page 42

For more information on VERTICAL AUGMENTATION see page 42

PERI-IMPLANT LESIONS

For more information on LATERAL ACCESS SINUS LIFT see page 36

For more information on DEHISCENCES AND FENESTRATIONS see page 24

For more information on ALVEOLAR REGENERATION see page 18

INLAY TECHNIQUE

SCIENTIFIC PUBLICATIONS ON OSTEOBIOLO® EVOLUTION

COVANI U, BARONE A, CORELLI R, CRESPI R

CLINICAL OUTCOME OF IMPLANTS PLACED IMMEDIATELY AFTER IMPLANT REMOVAL


BARONE A, RICCI M, CABO GUARDO J L, COVANI U

BONE REMODELLING AFTER REGENERATIVE PROCEDURES AROUND IMPLANTS PLACED IN FRESH EXTRACTION SOCKETS: AN EXPERIMENTAL STUDY IN BEAGLE DOGS


COVANI U, CORELLI R, BARONE A

BUCCAL BONE AUGMENTATION AROUND IMMEDIATE IMPLANTS WITH AND WITHOUT FLAP ELEVATION: A MODIFIED APPROACH

I N T E R N A T I O N A L J O U R N A L O F O R A L A N D M A X I L L O F A C I A L R E S E A R C H , 2 0 0 8 S E P 2 0 C T 2 0(3):441-6

SCARAVINO A, MATTIELLI A, Perrotti V, MANZONI L, IIEZG G

MAXILLARY SINUS AUGMENTATION IN HUMANS USING CORTICAL PORCINE BONE: A HISTOLOGICAL AND HISTOMORPHOMETRICAL EVALUATION AFTER 4 AND 6 MONTHS


BARONE A, OLANDO B, CABO GUARDO J L, MARCONCINI S, DORCH G, COVANI U

A RANDOMIZED CLINICAL TRIAL TO EVALUATE AND COMPARE IMPLANTS PLACED IN AUGMENTED VS. NON-AUGMENTED EXTRACTION SOCKETS. A 3-YEAR EVALUATION

J O U R N A L O F P E R I O D O N T O L O G Y , 2 0 1 1 D E C 5, E P U B A H E A D O F P R I N T

SLOTTI C, LINOFORI N, NUVI NARI A K

SURGICAL RECONSTRUCTION OF PERI-IMPLANT BONE DEFECTS WITH PREHYDRATED AND COLLAGENATED PORCINE BONE AND COLLAGEN BARRIERS: CASE PRESENTATION

C D I R R , 2 0 1 1 D E C 6, E P U B A H E A D O F P R I N T


ULTRASTRUCTURAL STUDY BY BACKSCATTERED ELECTRON IMAGING AND D ELEMENTAL MICRANALYSIS OF BONE-TO-BIOMATERIAL INTERFACE AND MINERAL DIGESTION OF PORCINE XENOGRAFTS USED IN MAXILLARY SINUS FLOOR ELEVATION


ESPOSITO M, CANNIZZARO G, SOARDI E, PISTILLI R, PIATTELLI M, CORVIN O, FELICE P

POSTERIOR ATROPHIC JAWS REHABILITATED WITH PROSTHESSES SUPPORTED BY 6 MM-LONG, 4 MM-WIDE IMPLANTS OR BY LONGER IMPLANTS IN AUGMENTED BONE: PRELIMINARY RESULTS FROM A PILOT RANDOMISED CONTROLLED TRIAL


FELICE P, PIANA L, CHECCHI L, PISTILLI R, PELLIERINO G

VERTICAL RIDGE AUGMENTATION OF THE ATROPHIC POSTERIOR MANDELE WITH A 2-STEP INLAY TECHNIQUE: A CASE REPORT

I M P L A N T D E N T I S T R Y , 2 0 1 2 J U N 2 1(3):190-5

BARONE A, RICCI M, TONELLI P, SANTINI S, COVANI U

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

C L I N I C A L I M P L A N T R E S E A R C H , 2 0 1 2 J U L 12, E P U B A H E A D O F P R I N T

CASSETTA M, RICCI C L, IIEZG G, CALASSO S, MATTIELLI A, PERROTTI V

USE OF PEZOSURGERY® IN POSTERIOR MAXILLARY SINEUS ELEVATION: CLINICAL RESULTS OF 40 CONSECUTIVE CASES


BARONE A, RICCI M, BASSI P R, NAHRMARK U, LARSSON T A, COVANI U, BARONE A

A 6-MONTH HISTOLOGICAL ANALYSIS ON MAXILLARY SINUS AUGMENTATION WITH AND WITHOUT USE OF COLLAGEN MEMBRANES OVER THE OSTEOMY WINDOW RANDOMIZED CONTROLLED CLINICAL TRIAL

C L I N I C A L I M P L A N T R E S E A R C H , 2 0 1 3 J U N 2 4(4):6, E P U B 2 0 1 3 D E C 12
The natural Evolution of collagen membranes

**CLINICAL INDICATIONS SUMMARY**

**Oral surgery and traumatology:** the standard model is always recommended in case of large regenerations with risks of exposure.

**Implantology:** ideal for covering antrostomy and for protection of two wall defects graft.

**Periodontology:** protection of grafted intrabony defects when flaps suture presents risks of exposure and as space maker in gingival recessions (fine model).

Besides an eutrophic effect, Evolution membranes provide grafting site stabilization as well as long lasting protection against external agents.

**CLINICAL INDICATIONS OVERVIEW**

Evolution is obtained from mesenchymal tissue (heterologous pericardium) and is completely resorbable.

Experimental studies have shown histological evidence of the prolonged barrier effect of this membrane, which lasts at least eight weeks(1).

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.

This property is particularly important in case of regeneration of large posterior sockets, when flaps cannot completely cover the graft(2).

In lateral access sinus lift Evolution membranes are indicated to cover antrostomy (standard model)(3,4,5) and to protect the sinus membrane from cutting risk due to graft pressure (fine model or OsteoBiol® Special, see page 92).

Evolution is also ideal to protect peri-implant regenerations(6) and periodontal grafts.

Finally Evolution fine has been successfully used in combination with OsteoBiol® Gel 40 for the treatment of gingival recessions(7).

![Grafting site stabilized with OsteoBiol® Evolution](Image)

Source:Courtesy of Dr Giuseppe Fama, Pesugia, Italy

![Grafting site protected with OsteoBiol® Evolution](Image)

Source: Courtesy of Dr Roberto Ross, Genoa, Italy

![Intrabony defect graft protected by OsteoBiol® Evolution](Image)

Source: Courtesy of Dr R.A. Bundo and Dr R. Comente, Torino, Italy

![Intrabony defect covered by OsteoBiol® Evolution](Image)

Source: Courtesy of Dr Roberto Ross, Genoa, Italy

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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, Göteborg University, Sweden
**Characteristics | Lamina**

**OsteoBiol®** Lamina is made of cortical bone of heterologous origin produced with an exclusive Tecnoss® process that avoids the ceramization 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® 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®** Lamina can be shaped with sterile scissors until the desired size is reached, then it must be hydrated for 5/10 minutes in sterile physiological solution.

Once it acquires the desired plasticity, it must be adapted to the grafting site; it should always be immobilized either with titanium microscrews or sutured (fine model) directly to the surrounding tissues with a triangular section non-traumatic needle.

**OsteoBiol® Curved Lamina** should not be hydrated but can also be shaped with sterile scissors, and must be fixed 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.

---

**Characteristics | Lamina**

**Tissue of origin**

Cortical bone

**Tissue collagen**

Preserved

**Physical form**

Rigid dried lamina, flexible after re-hydration

**Composition**

100% cortical bone

**Thickness**

Fine: 0.4-0.6 mm
Medium Curved: 0.8-1.0 mm
Standard: 2-4 mm

**Estimated re-entry time**

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

**Packaging**

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

**Product codes**

LS25FS | 25x25 mm | Fine | Porcine
LS25FE | 25x25 mm | Fine | Equine
LS24FS | 20x40 mm | Fine | Porcine
LS24FE | 20x40 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
LS03SE | 30x30 mm | Standard | Equine
Clinical indications

TWO-WALL DEFECTS

For more information on HORIZONTAL AUGMENTATION see page 42

SCIENTIFIC PUBLICATIONS ON OSTEIBOL® LAMINA

RINNA C, UN G, SARDELLA A, CASINO N, REALE G
ORBITAL FLOOR RESTORATION
JOURNAL OF CRANIOFACIAL SURGERY, 2005 NOV 16(6) 968-72

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REMOVAL, AFTER 7 YEARS, OF AN IMPLANT DISPLACED INTO THE MAXILLARY SINUS. A CLINICAL AND HISTOLOGIC CASE REPORT
JOURNAL OF OSSEOINTEGRATION, 2009

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REMOVAL, AFTER 7 YEARS, OF AN IMPLANT DISPLACED INTO THE MAXILLARY SINUS. A CLINICAL AND HISTOLOGIC CASE REPORT
JOURNAL OF OSSEOINTEGRATION, 2009

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REMOVAL, AFTER 7 YEARS, OF AN IMPLANT DISPLACED INTO THE MAXILLARY SINUS. A CLINICAL AND HISTOLOGIC CASE REPORT
JOURNAL OF OSSEOINTEGRATION, 2009

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OPHTHALMIC PLASTIC AND RECONSTRUCTIVE SURGERY, 2009; 25(2)

GRENGA PL, REALE G, FORESTA E, MUSTAZZA MC
MEDIAL ORBITAL WALL RECONSTRUCTION WITH SWINE BONE CORTEX
THE JOURNAL OF CRANIOFACIAL SURGERY, 2009; 20(3)

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A COLLAGENATED PORCINE BONE SUBSTITUTE FOR AUGMENTATION AT NEOSS IMPLANT SITES: A PROSPECTIVE 1-YEAR MULTICENTER CASE SERIES STUDY WITH HISTOLOGY CLINICAL IMPLANT DENTISTRY AND RELATED RESEARCH, 2010 OCT 26 EPUB

HINZE M, VREUNCK L, THALMIR T, WACHTER H, BLOZ W
ZYGOMATIC IMPLANT PLACEMENT IN CONJUNCTION WITH SINUS BONE GRAFTING: THE "EXTENDED SINUS ELEVATION TECHNIQUE": A CASE-COHORT STUDY
ORAL AND CRANIOFACIAL TISSUE ENGINEERING 2011; 1:188-197

FESTA VM, ADDABBO E, LAINO L, FEMIANO F, RULLO R
PORCINE-DERIVED XENOGRAFT COMBINED WITH A SOFT CORtical MEMBRANE VERSUS EXTRACTION ALONE FOR IMPLANT SITE DEVELOPMENT: A CLINICAL STUDY IN HUMANS CLINICAL IMPLANT DENTISTRY AND RELATED RESEARCH, 2011 NOV 14, EPUB AHEAD OF PRINT

WEINLÄNDER M, KRENNMAIR G
AUGMENTATION IN ENORALER WEICH- UND HARTGEWEBE CHIRURGIE, 04 2012

Source: Tecnoss Dental Media Library
A unique cortical bone barrier

CLINICAL INDICATIONS SUMMARY

**Oral surgery and Traumatology:** stabilization and protection of large regenerations with risks of exposure, where it perfectly adapts itself both to the underlying bone and to the soft tissues.

**Implantology:** ideal for protection and stabilization of two-wall defect grafts or peri-implant regenerations in esthetic areas. Fine model is also indicated for covering antrostomy.

The Fine model after hydration become flexible and can be adapted to the defect morphology creating, once fixed with osteosynthesis screws, a semi-rigid covering to the underlying graft. This property is particularly useful when it is necessary to obtain a space making effect in esthetic areas, as well as in horizontal augmentation of two-wall defects.

**Laminae** can also be used for orbital floor restoration.

**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 of ridges with compromised cortical plate.

**Horizontal defect grafted with OsteoBiol® Lamina stabilized with a titanium post and osteosynthesis screws**

**Clinical application of OsteoBiol® Curved Lamina in horizontal augmentation**

**Fixation of OsteoBiol® cortical Lamina with titanium pins**

**Source:** Courtesy of Prof Dr Hannes Wachtel and Dr Tobias Thalmair, Munich, Germany
Products
Membranes and Barriers

PRODUCTIONs

- The products are made of cortical bone of heterologous origin which undergoes a process of superficial decalcification, nevertheless maintaining the typical consistency of the Fine model after hydration become flexible and can be adapted to the defect morphology creating, once fixated with osteosynthesis screws, a semi-rigid covering to the space making effect in esthetic areas, as well as in horizontal augmentation of two wall wall.

- This property is particularly useful when it is necessary to obtain a space making effect in esthetic areas, as well as in horizontal augmentation of two wall.

- thickness and can be directly grafted without hydration: it is particularly indicated in association with Osteobiol® mp3 for regeneration.

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With a titanium post and osteosynthesis screws.
Specific products

Specially engineered solutions for specific clinical indications

Source: Courtesy of Dr Ulf Nannmark, University of Göteborg, Sweden
Collagenated cancellous blocks

CHARACTERISTICS

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: thanks to its rigid consistency it is able to maintain in time 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 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 which must be accurately decorticated in order to guarantee maximum contact; the block must always be fixed with osteosynthesis microscrews and should be protected with a resorbable barrier (Evolution membrane).

SCIENTIFIC PUBLICATIONS ON OSTEOBIOl® SP-BLOCK

SCARANO A, CARINCI F, ASSENZA B, PIATTELLI M, MURMURA G, PIATTELLI A
VERTICAL RIDGE AUGMENTATION OF ATROPHIC POSTERIOR MANDIBLE USING AN INLAY TECHNIQUE WITH A XENOGRAFT WITHOUT MINISCREWS AND MINIPLATES: CASE SERIES
CLINICAL ORAL IMPLANTS RESEARCH, 2011 OCT; 22(10):1125-30

ESPOSITO M, CANNIZZARO G, SOARDI E, PISTILLI R, PIATTELLI M, CORDUENO V, FELICE P
POSTERIOR ATROPHIC JAWS REHABILITATED WITH PROSTHESSES SUPPORTED BY 6 MM-LONG, 4 MM-WIDE IMPLANTS OR BY LONGER IMPLANTS IN AUGMENTED BONE: PRELIMINARY RESULTS FROM A PILOT RANDOMISED CONTROLLED TRIAL

FELICE P, PIANA L, CHECCHI L, PISTILLI R, PELLEGRINO G
VERTICAL RIDGE AUGMENTATION OF THE ATROPHIC POSTERIOR MANDIBLE WITH A 2-STAGE INLAY TECHNIQUE: A CASE REPORT
IMPLANT DENTISTRY, 2012 JUN;21(3):190-5

Tissue of origin
Cancellous block

Tissue collagen
Preserved

Physical form
Rigid dried block

Composition
100% cancellous bone

Re-entry time
About 8 months, variable depending on characteristics and irradiation grade of grafting site and on clinical conditions of patient

Packaging
Sterile blister

Product codes
BN0E | 1 Blister | 10x10x10 mm | Equine
BN1E | 1 Blister | 10x10x20 mm | Equine
BN2E | 1 Blister | 10x20x20 mm | Equine
BN8E | 1 Blister | 35x10x5 mm | Equine

SEM image of OsteoBiol® cancellous block
Source: Courtesy of Dr Ulf Nannmark, University of Göteborg, Sweden

OsteoBiol® Sp-Block hydrated with patient’s blood
Source: Tecnoss® Dental Media Library

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

**Collagenated cortico-cancellous blocks**

**CHARACTERISTICS**

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

**HANDLING**

Dual-Block must be hydrated before use for 5/10 minutes with sterile lukewarm physiological solution or with antibiotics. Afterwards, the block can be adapted to the receiving site which must be accurately decorticated in order to guarantee maximum contact and the block should be always fixed with osteosynthesis microscrews.

Dual-Block is indicated for heavily resorbed maxilla horizontal augmentation. Whatever is the applied technique, 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.

**Tissue of origin**
Cortico-cancellous bone

**Tissue collagen**
Preserved

**Physical form**
Rigid dried block

**Composition**
100% Cortico-cancellous bone

**Re-entry time**
About 8 months, variable depending on characteristics and irritation grade of grafting site and on clinical conditions of patient

**Packaging**
Sterile blister

**Product codes**
STS7S | 20x15x5 mm | Soft | Porcine curved
STN5S | 20x10x5 mm | Norm | Porcine curved

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

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

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

**OsteoBiol® Dual-Block grafted with onlay technique**
Source: Tecnoss® Dental Media Library
Apatos is a biomaterial of heterologous origin with characteristics similar to mineralized human bone; it can therefore be used as an alternative to autologous bone. The natural microporous consistency of Apatos facilitates the formation of new bone tissue in bone defect area, accelerating the process. Apatos nanocrystalline hydroxyapatite is available in cancellous, 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.

CLINICAL INDICATIONS
Oral surgery: granulomas, dentigenous cysts and ridge split.
Implantology: universal filler used in treatment of dehiscences and peri-implantitis, two wall defects, lateral and crestal access sinus lift. In particular Apatos Cortical is characterized by a very long resorption time, guaranteeing optimal preservation of the graft volume. When needed, Apatos graft can be protected with OsteoBiol® Evolution membrane or soft cortical Lamina.

SCIENTIFIC PUBLICATIONS ON OSTEOBIO® APATOS
BARONE A, AMERI S, COVANI U
IMMEDIATE POSTEXTRACTION IMPLANTS: TREATMENT OF RESIDUAL PERI-IMPLANT DEFECTS. A RETROSPECTIVE ANALYSIS
EUROPEAN JOURNAL OF IMPLANT PROSTHODONTICS, 2006, 2: 99-106
ORSINI G, SCARANO A, PIATTELLI M, PICCIRILLI M, CAPUTTI S, PIATTELLI A
HISTOLOGIC AND ULTRASTRUCTURAL ANALYSIS OF REGENERATED BONE IN MAXILLARY SINUS AUGMENTATION USING A PORCINE BONE-DERIVED BIOMATERIAL
JOURNAL OF PERIODONTAL RESEARCH, 2007 DEC; 42(6):189-98
SCARANO A, PIATTELLI A, ASSEBIA B, QUARANTA A, PERROTTI V, PIATTELLI M, IEZZI G
PORCINE BONE USED IN SINUS AUGMENTATION PROCEDURES: A 5-YEAR RETROSPECTIVE CLINICAL EVALUATION
JOURNAL OF ORAL AND MAXILLOFACIAL SURGERY, 2010 AUG; 68(8):1869-73
SCARANO A, PIATTELLI A, PERROTTI V, MANzano N, IEZZI G
MAXILLARY SINUS AUGMENTATION IN HUMANS USING CORTICAL PORCINE BONE: A HISTOLOGICAL AND HISTOMORPHOMETRICAL EVALUATION AFTER 4 AND 6 MONTHS
CLINICAL IMPLANT DENTISTRY AND RELATED RESEARCH, 2011 MAR; 13(1):13-18
IEZZI G, DEGIDI M, PIATTELLI A, MANzano C, SCARANO A, SHIBLI JA, PERROTTI V
COMPARATIVE HISTOLOGICAL RESULTS OF DIFFERENT BIOMATERIALS USED IN SINUS AUGMENTATION PROCEDURES: A HUMAN STUDY AT 6 MONTHS
CLINICAL ORAL IMPLANT RESEARCH, 2011 NOV 2, EPUB AHEAD OF PRINT

Tissue of origin
Apatos Mix: Cortico-cancellous heterologous bone mix
Apatos Cortical: Heterologous cortical bone

Tissue collagen
Degraded

Physical form
Radioopaque granules of mineral hydroxyapatite

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

Granulometry
600-1000 µm

Re-entry time
About 3 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 | 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
OsteoBiol® Tablet

Engineered for haemorrhagic patients

CHARACTERISTICS
Thanks to its composition (micronized heterologous bone granules aggregated with collagen), besides functioning as a socket filling material, OsteoBiol® Tablet can also provide an immediate and constant anti-inflammatory and antihaemorrhagic action.

Tablet can thus be considered the first choice material after dental extractions and oral surgery in subjects with haemorrhagic predisposition (diabetics, people with heart disease treated with anticoagulants, people with low platelet counts): in these cases, the block acts as a uniform sealant of the cavity walls even without stitching the flaps.

HANDLING
After debridement of the receiving site, directly place the block in the bone cavity to be filled. Once soaked with blood, its plastic consistency allows a perfect adaptation to the post-extractive cavity.

Due to this plasticity, Tablet antihaemorrhagic blocks are not resistant to loading and compression of grafting sites: these conditions must therefore be avoided and the suturing of the alveolar margins is recommended.

CLINICAL INDICATIONS
Traumatology, Dentistry and wherever fast and prolonged antihaemorrhagic action is needed; Tablet provides also a scaffold function in order to avoid the collapse of the alveolar walls after dental extractions, with consequent both vertical and horizontal bone loss.
Granules-coated collagen felt

CHARACTERISTICS
Made of lyophilized collagen of equine origin, biocompatible and quickly resorbable.

Duo-Teck 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
Once it acquires the desired plasticity, it can be easily placed in the grafting site with the micronized bone film side in contact with graft and the smooth side in contact with soft tissues: this allows a perfect adhesion to the tissue around bone defect.

CLINICAL INDICATIONS
Oral Surgery and Implantology: 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 lateral access sinus floor augmentation procedure, in order to avoid accidental lesions caused by grafting material. It can also be used for closure of antrostomy, before replacement of the muco-gingival flap.

SCIENTIFIC PUBLICATIONS ON OSTEOBIO® DUO-TECK

Granules-coated collagen felt

Tissue of origin
Equine lyophilized 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 µm

Thickness
About 1 mm

Estimated resorption time
About 15 days

Packaging
20x20 mm

Product codes
DT020 | 1 Blister | 20x20 mm | Equine
Engineered to protect hard tissue grafts and soft tissues

CHARACTERISTICS
Obtained from extra fine mesenchymal tissues (pericardium of heterologous origin) using an exclusive Tecnoss® 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
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

Periodontology: the Special membrane can be used as a separator of bone and soft tissues in treatment of gingival recessions.

Implantology: protection of the sinus membrane before insertion of grafting material, closing of sinus membrane perforations, protection of grafts placed in post-extractive sockets.

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
EM02LS | 1 Blister | 20x20 mm | Porcine
EM02LE | 1 Blister | 20x20 mm | Equine
EM03LS | 1 Blister | 30x30 mm | Porcine
EM03LE | 1 Blister | 30x30 mm | Equine
Porcine derma

CHARACTERISTICS

Obtained from derma of porcine origin, using an exclusive Tecnoss® process, Derma membranes are gradually integrated with the autologous soft tissues. 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 15 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.

If this is not possible, the membrane can be stitched with envelope sutures which bridle it with the gingival flaps.

N.B.: if Derma membrane, for any reason, shows dehiscences (for example in the secondary tearing of flaps) it must absolutely not be removed, because its plasticity and consistency is such as to allow it to achieve a complete second intention healing of the wound, because of the physiological sliding of the flaps.

CLINICAL INDICATIONS

Oral Surgery and Traumatology: stabilization and protection of large regenerations with risk of exposure.

Implantology: protection of two wall defects graft, soft tissue augmentation.

Periodontology: space making below thin biotype tissues (fine model).

Tissue of origin
Porcine derma

Tissue collagen
Preserved

Physical form
Dried membrane

Composition
100% derma

Thickness
Fine: 0.8-1.0 mm
Standard: 1.0-2.0 mm

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

Packaging
Fine: 25x25 mm
Standard: 30x30 mm

Product codes
ED25FS | 1 Blister | Fine | 25x25 mm | Porcine
EDO35S | 1 Blister | Std | 30x30 mm | Porcine

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

OsteoBiol® Derma grafted in a case of horizontal augmentation
Source: Courtesy of Dr Antonio J. Murillo Rodriguez, Elbas, Spain
Live surgery courses and congresses
Advanced concepts in implant dentistry. Treatment of Complex Cases: Simplification, Reproducibility, Reliability

ABSTRACT
A unique experience giving the participants an insight to hard and soft tissue management, advanced grafting techniques, the science and evidence behind short and narrow implants in various cases (from simple tooth to full arch rehabilitation).

TRAINING CENTER DESCRIPTION
The Brånemark Osseointegration Center (BOC) was founded in Gothenburg in 1989. Since then its mission is to provide treatment for patients with severe oral, maxillofacial impediments.

PROGRAM
Live surgeries of complex cases performed by Dr. Palacci with comments from Prof. Nannmark; short lectures and discussions in between live surgeries. The main topics will be:
- Case analysis
- Precision in implant positioning
- Sinus elevation, onlay augmentation, ridge augmentation
- The use of short and narrow implants
- Surgical and prosthetic aspects
Social dinner on Thursday evening.

LECTURERS
Dr. Patrick Palacci, DDS
>> Head of the Brånemark Osseointegration Center Marseille (France) working in very tight relationship with Professor Per-Ingvar Brånemark
>> Developer of several techniques in relation with optimal implant positioning, papilla regeneration technique and esthetic implant dentistry
>> Speaker to scientific meetings all around the world and author of numerous scientific articles

Dr. Ulf Nannmark, DDS, PhD
>> Associate Professor at the Göteborg University (Sweden) working in close collaboration with PI Brånemark in developing different methods in osseointegration rehabilitation
>> Working in private practice as well as developing methods for bone regeneration
>> Author of more than 100 scientific articles and book chapters
>> Speaker at scientific meetings all around the world

Location
Brånemark Osseointegration Center
8-10 Rue Fargès
13008 Marseille
France

Date
16th-17th May 2013

Duration
Thursday and Friday

Participants
Minimum 10, maximum 25

Cost
€ 2000 (price includes local taxes)

Registration
Send an email to edu@tecnoss-dental.com to receive an Enrolment Form.

Please do not book flights or hotels until the course is confirmed.

Registration Deadline
15th April 2013

Course language
English

Nearest airport
Marseille (MRS)
An evidence-based educational path in maxillary sinus augmentation: the lateral approach

ABSTRACT

There are many patients with atrophic posterior maxillas requesting fixed prostheses. When the residual bone height is below 4 mm sinus lift procedures remain the most viable therapeutic options. This two-day course will present sinus elevation techniques and possible alternatives to sinus elevation therapy from pre-surgical planning to prosthetic restoration. The scientific program will be supported by multiple video presentations, one interactive session, live surgery and hands-on workshop on sinus models.

TRAINING CENTER

The Lake Como Institute boasts internationally recognized professionals in the field of Implant Dentistry and experts in all the other disciplines of modern dentistry. The Institute mission is to deliver meticulous diagnosis, treatment and comprehensive management of complex cases. A team of highly dedicated professionals work in close collaboration to achieve the best possible outcome for the patient.

PROGRAM

Day 1 - 09,00/18,30
Theoretical session
- Sinus lift procedure: the scientific evidence
- Basic about graft materials and membranes
- Presurgical diagnosis, indications and contraindications
- Lateral window technique: surgical procedure and video sessions
- Crestal approach: surgical procedure and video sessions
- Treatment of complications

Live surgery
- Treatment of complications

Day 2 - 09,00/13,00
Workshop
- Hands-on models for conventional lateral window technique
- Hands-on models for piezoelectric technique

LECTURERS

Dr. Tiziano Testori, MD, DDS, FICD
- Assistant Clinical Professor and Head of the Section of Implant Dentistry and Oral Rehabilitation, School of Dentistry, I.R.C.C.S. Galeazzi Institute, University of Milan, Italy
- Member of the Editorial Board of: The International Journal of Oral and Maxillofacial Implants (IJOI) and European Journal of Oral Implantology (EJOI)
- Author of 72 scientific publications in peer reviewed journals

Dr. Marco Esposito, DDS, PhD
- Associate Professor in Biomaterials with the Sahlgrenska Academy at Göteborg University, Sweden
- Editor in Chief of the European Journal of Oral Implantology (EJOI) and Associate Editor of the Cochrane Oral Health Group
- Author of more than 180 scientific publications in international peer-reviewed journals

Dr. Matteo Invernizzi, DDS
- DDS degree from University of Ferrara (Italy)
- Senior lecturer at Lake Como Institute® Advanced Implant Training Center

Location
Lake Como Institute
Via Rubini 22 - 22010 Como, Italy
info@lakecomoinstitute.com
www.lakecomoinstitute.com

Date
Friday Sept 6th, 2013 | h 09,00-18,30
Saturday Sept 7th, 2013 | h 09,00-13,00

Hospitality
Friday lunch and dinner included

Participants
Maximum 25 participants

Cost
Early registration fee: before March 31, 2013 € 1.200 (VAT included)
Regular fee: after March 31, 2013 € 1.400 (VAT included)

Course management office
Tecnoss Dental s.r.l.
Ms. Francesca Mosena
Ph +39 011- 9682823
dedu@tecnoss-dental.com

Course language
English

Nearest airport
Milano Malpensa (MXP)
The International Congress of Tissue Regeneration
Bone, Biomaterials & Beyond

**PROGRAM**

**INTRODUCTION**

The International Congress of Tissue Regeneration is at its 5th edition, thanks to the participation and collaboration of several Universities and speakers from all Europe.

It is a high level meeting for dentistry, with 10 lectures where the speakers will show their clinical cases, giving the chance to the audience to share their experience and knowledge in the field of regeneration, allowing discussions about the new improvements in the management of soft and hard tissues.

The program of the Congress is divided in two distinct parts: Friday will be dedicated to the Spanish-speaking audience, with oral communications of graduated and PhD students as well as clinical sessions only in Spanish language.

Main lectures will take place on Saturday, with simultaneous translations from Spanish to English and viceversa.

President of the Congress will be Prof. Juan Manuel Aragoneses Lamas, Director of the Department of Dentistry, Universidad Europea de Madrid, Spain.

**Location**
NH Eurobuilding
C/ Padre Damián, 23
28036 Madrid, Spain

**Date**
October 4th - 5th, 2013

**Hospitality**
Coffee breaks and OsteoBiol® material included (1 mp3 + 1 Gen-Os)

**Cost**
€ 140 (VAT included)

**Registration office**
Osteógenos S.R.L.
congreso@osteogenos.com
Tel. +34 902 01 34 33 | +34 91 413 37 14

Further information on:
www.osteogenos.com/congreso

**Course language**
Spanish (Oct. 4th) - English and Spanish (Oct. 5th)

**Nearest airport**
Madrid-Barajas (MAD)
CERTIFICATIONS AND LITERATURE

CE CERTIFICATES
LABORATORY TESTS
ISO 13485
LITERATURE REVIEW
SCIENTIFIC LITERATURE
From nature to man

Tecnoss® develops and produces biomaterials of animal origin to obtain Medical Devices of new conception, providing a valid and innovating aid to the surgeon and a clinical benefit to the patient.

Materials are manufactured with an innovative technology that conditions animal tissues in order to neutralize the antigenic components present in animal bony tissues (achievement of biocompatibility) and allows development of products unique in their kind, capable of satisfying every surgical need.

OsteoBiol® biomaterials provide excellent healing results thanks to an active colonization of the receiving site by patient’s cells and therefore favor the process of restitutio ad integrum of injured tissues.

Tecnoss® obtains its products from raw materials that derive from animals whose tissues have been evaluated as suitable for human intake and come from suppliers controlled by SSV.

The biological matrix from which the OsteoBiol® Medical Devices product line is derived has been subjected to ISO 10993 certification, that is a series of biological and histocompatibility tests carried out on both animal and human tissues showing the perfect and complete bioavailability and biocompatibility of the products.

Clinical studies with histological reports published on international scientific journals confirm results achieved and therefore the quality of the production.

OsteoBiol® biomaterials are manufactured in conformity with 93/42/EEC (D.Lgs 47/97 and next modifications), European rule. Italian Istituto Superiore di Sanità (ISS) is the Notified Body (0373) for CE mark of Tecnoss® Medical Devices.

All OsteoBiol® Products are sterile and for single use. Sterilization is performed with gamma rays and is periodically checked; expiration date is 60 months from date of sterilization.
Annex III | Porcine and Equine Bone Matrix
Source: Tecnoss srl

Annex V | Porcine and Equine Membranes
Source: Tecnoss srl

Annex III | Equine Felts
Source: Tecnoss srl

Annex V | Porcine and Equine Bone Matrix
Source: Tecnoss srl

Annex V | Porcine and Equine Membranes
Source: Tecnoss srl

Annex V | Equine Felts
Source: Tecnoss srl
DIRECWORKS CONTACT CYTOTOXICITY

AIM: cytotoxic potential evaluation of OsteoBiol® Gen-0s grafting material

MATERIALS AND METHODS

The direct contact cytotoxicity test was performed on a culture of cells grown in a medium containing 0.2 mg/gm weight/volume ratio. The assay sample was incubated for 72 hours at 37°C ± 1°C temperature. 2ml extract was incubated with cultured N CTC L929 cells for a period of 48 hours in incubator at 37°C ± 1°C temperature, with CO2 atmosphere in air.

RESULTS

After 24 hours of incubation, no cytotoxic reaction is detectable in cultured treated cells; in fact there is no presence of both cells lacking intra- and extracellular granulomas and areas characterized by wide cellular lesions (reactivity grade: 0.0).

CONCLUSIONS

As stated in UNI EN ISO 10993: 5, 2000 rule, OsteoBiol® Gen-0s study material must be considered as NON CYTOTOXIC.

DELAYED HYPERSENSITIVITY

AIM: sensitizing effects analysis of OsteoBiol® Gen-0s grafting material

MATERIALS AND METHODS

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

Induction phase | During induction phase the group of 10 treated guinea-pigs was inoculated with 3 couples (0.1 ml 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 the study material was inoculated (vegetable oil or saline) and in the 3rd injection the study material was inoculated (vegetable oil or saline). 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/a of intradermal injection. The challenge phase begins 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 the 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-0s study material must be considered as NON SENSITIZING.

INTRACUTANEOUS REACTIVITY

AIM: local toxic effects evaluation of OsteoBiol® Gen-0s 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/l 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-0s study material satisfies the assay conditions, in fact all LOCAL TOXIC EFFECTS were ABSENT, as stated in UNI EN ISO 10993:10:2002 rule.

SYSTEMIC TOXICITY

AIM: toxic systemic effects evaluation of OsteoBiol® Gen-0s grafting material

MATERIALS AND METHODS

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

RESULTS

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

CONCLUSIONS

On the base of results obtained, interpreted as stated in UNI EN ISO 10993:11:1997 rule, OsteoBiol® Gen-0s grafting material can be considered as NON TOXIC.

SALMONELLA TYPHIMURIUM REVERSION

AIM: mutagenesis effects analysis of OsteoBiol® Gen-0s grafting material

MATERIALS AND METHODS

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

RESULTS

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

CONCLUSIONS

As stated in ISO 10993-11:1993 rule, OsteoBiol® Gen-0s study material was NON MUTAGENIC, both in presence or absence of metabolic activation.
Biocompatibility tests | Evolution

DIRECT CONTACT CYTOTOXICITY

AIM: cytotoxic potential evaluation of OsteoBiol® Evolution resorbable membrane

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

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

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

DELAYED HYPERSENSITIVITY

AIM: sensitizing effects analysis of OsteoBiol® Evolution resorbable membrane

MATERIALS AND METHODS
2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 6cm²/ml surface/volume ratio. Each assay sample was incubated for 72 hours at 37°C ± 1°C temperature. 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 a 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.

INTRACUTANEOUS REACTIVITY TEST

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

MATERIALS AND METHODS
A intracutaneous reactivity assay on rabbit was performed. 2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 6cm²/ml surface/volume ratio. Each assay sample was inoculated 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 a observation period, no signs of erythema, oedema and eschars were detected in treated rabbits.

CONCLUSIONS
OsteoBiol® Evolution resorbable membrane must be defined as NON SENSITIZING.

SYSTEMIC TOXICITY TEST

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

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

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

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

SALMONELLA TYPHIMURIUM REVERSION

AIM: mutagenesis effects analysis of OsteoBiol® Evolution resorbable membrane

MATERIALS AND METHODS
Salmonella typhimurium assay (reversion of mutation) was performed on 5 mutant strains of Salmonella typhimurium (TA1535, TA1537, TA100, TA102). The mutagenic activity of study material was defined by the computation of revertant colonies of control cultures. This activity was evaluated both in presence or absence of an enzymatic system of metabolic activation with the method of direct incorporation into plate. For the assay, 2 eluates of study material were prepared using saline or DMSO as extraction liquids. The extracts were obtained under static conditions by dipping the study material in saline or DMSO to reach a 6cm²/ml surface/volume ratio.

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.
DIRECT CONTACT CYTOTOXICITY

AIM: cytotoxic potential evaluation of OsteoBiol® mp3 grafting material

MATERIALS AND METHODS

The cytotoxicity direct contact test was performed on a confluent NCTC L929 (Mammal fibroblasts ATCC CCL1 NCTC Clone L929) cell culture in exponential phase of growth. The test product was applied to the monolayer of NCTC L929 and was incubated at 37°C ± 1°C in CO₂ atmosphere for 24 hours. After 24 hours of incubation the cells cultures were observed to evaluate the biological reactivity (cell degeneration and malformations).

RESULTS

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

CONCLUSIONS

On the basis of the results, interpreted according to EN ISO 10993-5:2009, the test product must be considered NON CYTO TOXIC.

DELAYED HYPERSENSITIVITY

AIM: hypersensitivity effects evaluation of OsteoBiol® mp3 grafting material

MATERIALS AND METHODS

Two extracts of the test product were prepared both in vegetable oil and in physiological solution in order to perform the tests for delayed-type hypersensitivity. The extracts of the test product were performed by submerging the test sample into both solvents. Then the test sample was incubated for 24 hours at a temperature of 37°C ± 1°C in dynamic conditions. Each extract was intracutaneously injected in albino rabbits. All animals have been observed at 24, 48 and 72 hours for injection. For evaluated each toxic symptom and macroscopic 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.

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 a temperature of 37°C ± 1°C in dynamic conditions. Each extract was intracutaneously injected in albino rabbits. All animals have been observed at 24, 48 and 72 hours for injection.

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.

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 a temperature of 37°C ± 1°C in dynamic conditions. An extract of test device in physiological solution was intravenously 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 toxic 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.
ISO TUV 13485 quality certificate

CERTIFICATES
ISO 13485

REGULATIONS ON MANUFACTURING PROCESS

UNI EN ISO 13485:2012
Medical devices - Quality management systems - Requirements for regulatory purposes

DIRETTIVA 93/42/CEE and relative amendments

UNI CEI EN ISO 14971:2009
“Application of risk management to medical devices”

UNI EN ISO 10993-1:2004
“Biological evaluation to medical devices. Part 1: Evaluation and testing”

UNI EN ISO 22442:2008 [1-2-3]
“Animal tissues and their derivatives utilized in the manufacture of medical devices”

UNI EN ISO 11137-1:2006
“Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices”

UNI EN ISO 11137-2:2006
“Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose”

UNI EN 556-1:2002
“Sterilization of medical devices. Requirements for medical devices to be designated “STERILE”. Requirements for terminally sterilized medical devices”

UNI CEI EN ISO 15223-1:2012
“Medical devices - symbols to be used with medical device labels, labelling and information to be supplied - part 1: general requirements”

MEDDEV 2.12-1 rev 6
Guidelines on a medical devices vigilance - 2009
Clinical summary of literature on OsteoBiol® biomaterials

Xenografts are the most widely used and scientifically documented biomaterials for bone regeneration in dentistry. The OsteoBiol® xenograft line (Tecnoss®, Coazza, Italy) includes different types of collagenated bone substitutes and membranes, of porcine and equine origin.

A study by Figueiredo et al. (JBM 2009) investigated the physiochemical characterization of several biomaterials used in dentistry, comparing them with human bone. An OsteoBiol® collagenated cortico-cancellous porcine bone particulate material (CCPB) was included in this comparative analysis, using the following parameters: particle size, porosity, real density, specific surface area, infrared spectroscopy, X-ray diffraction. In particular, the real density of CCPB is extremely similar to natural human bone, due to the collagen content. Infrared spectra of OsteoBiol® particles and natural human bone are also very similar, although they have different origins, whereas calcified human bone, hydroxyapatite and anorganic bovine bone have different FTIR spectra. Similar observations can be made analyzing the XRD spectra, that demonstrate once more the similarity between natural human bone and CCPB: these patterns represent the dual-phase composition of both natural human bone and OsteoBiol®, consisting in hydroxyapatite (sharp peaks) and collagen (broad band). These differences, in chemical nature and phase composition, between anorganic and collagenated biomaterials are expected to affect the performance of these materials after in vivo implantation.

The biocompatibility of porcine bone substitutes has been tested in vitro by Tribbiani et al. (JIP 2007) using PDL-MSC’s: cellular colonization and proliferation was evident on porcine bone granules, with no signs of infection in culture cell medium. PDL-MSCs cells were able to differentiate in osteoblasts in vitro and after 30 days of induction, cells were separated from substrate and able to organize themselves as a single nodule englobing all porcine bone particles.

An experimental study by Nannmark and Sennery (CIDRR, 2008) investigated in vivo the bone tissue response to dry CCPB vs. pre-hydrated CCPB mixed with collagen gel. The histological analysis showed no significant difference between the two bone substitutes, with new bone formation directly on the particles. The new bone area increased progressively both in test and control sites, while the residual biomaterial area decreased progressively due to osteoclastic resorption. The collagen membrane used to protect both grafts fulfilled its function and was well integrated with the overlying soft tissues. The study demonstrated that porcine bone exhibits good biocompatibility and osteoconductive properties and is resorbed by surface osteoclasts.

A second experimental study was conducted by Calvo et al. (CIDRR, 2011), who verified the biocompatibility of the material and its resorption 4 months after the placement in rabbits’ tibiae: the gifted material acted as a scaffold for bone cells, leading to progressive increases in bone regrowth in and around the xenograft. Osteointegration of the grafts was investigated by Scarano et al. (CIDRR, 2011) who analyzed histologically and histomorphometrically samples of bone taken from sinuses grafted with CCPB after 4 and 6 months: with these analyses it was possible to confirm that gifted biomaterial particles were surrounded by newly formed bone, with no signs of inflammatory reactions and no gaps at the bone-biomaterial interface.

A comparison between different materials was made by Ramirez-Fernandez et al. (COIR, 2011) who implanted of xenografts of bovine and porcine origin in rabbits. After 4 months measurements revealed that both materials are osteoconductive and do not interfere with normal reparative bone processes, while collagenized porcine granules were more resorbable than bovine grafts with similar granulometry.

Clinical studies investigated the efficacy of porcine biomaterials on alveolar ridge preservation after tooth extraction. Cardaropoli D. and G. (PRD, 2008) grafted CCPB in posterior teeth post-extractive sockets: 85% of the initial crestal width has been preserved using this procedure, while with spontaneous healing a 50% reduction of buccolingual width after 12 months has been reported in a previous study (PRD, 2003, 23: 313-323). The results of the investigation promote the use of a porcine bone substitute to fill the postextraction site of posterior teeth to avoid alveolar bone loss.

A second clinical study by Barone et al. (JP, 2008) compares the use of pre-hydrated CCPB with spontaneous socket healing to verify if the biomaterial grafted contributes to reduce horizontal and vertical ridge reduction. The grafted material reduced significantly both vertical and horizontal bone loss, while histomorphometric analysis showed a higher amount of trabecular bone in grafted sites compared to extraction alone control sites.

Crespi et al. (JOMI, 2011) confirmed the biocompatibility and high osteoconductivity of CCPB in a split mouth study for alveolar regeneration by means of histomorphometries and osteoblast-specific gene expression.

Several clinical studies investigated the effects of porcine bone in maxillary sinus floor elevation. The first study by Barone et al. (JOMI, 2005) reports a histologic and histomorphometric comparison at 5 months of maxillary bone regenerated via lateral approach with 100% autogenous bone (control) vs. a mixture of 50% autogenous bone and 50% CCPB (test). No significant differences in new bone percentages were observed in biopsies from control and test sites: CCPB particles were well integrated and in complete continuity with the new bone tissue formations. No evidence of inflammatory infiltrate, necrosis, or foreign body reaction was observed in any of the test biopsies. CCPB was not completely resorbed at 5 months, but the particles were well integrated and in complete continuity with the new bone tissue formations.
Orsini at al. (JOP, 2006) performed a histomorphometric analysis at 5 months of maxillary bone regenerated with 100% porcine cortical bone. Light microscopy (LM) and transmission electron microscopy (TEM) observations were also made. LM showed that most particles were surrounded by newly formed bone, with no evidence of acute inflammatory infiltrate. Newly formed bone area was 38% ± 2.8% while residual graft area was 31% ± 1.6%. New bone in contact with cortical porcine bone particles presented all phases of bone formation, and showed features similar to the pre-existing osseous tissue, thus indicating the biocompatible properties of this graft.

Barone et al. (COIR, 2008) reports the use of 100% pre-hydrated CCPB in lateral access sinus lift (26 sinuses) using a collagen membrane to cover the bony window. All patients had uneventful healing and no signs or symptoms of maxillary sinus disease were observed after the augmentation surgical procedures.

In JPRD (2008), Barone et al., JPRD 2008 investigated the effect of CCBP gel in crestal access sinus lift procedures and dehiscence regeneration. The biomaterial was introduced into receptor site after sinus floor fracture with last osteotome, and pressed into fractured sinus floor area. One of 12 implants failed during the first 6 weeks, due to abscess; all remaining implants were successful at 6 months and showed no signs of mobility, pain, suppuration or absence of peri-implant radiolucency. No implants failed after definitive prosthetic rehabilitation, while bone augmentation into sinus floor was 4.2 mm ± 1.4 mm and remained stable after 18 months.

Regeneration of dehiscences with porcine derived biomaterials has been investigated in two studies: in the first study Covani et al. (JP, 2006) evaluated the clinical success at 12 months of implants placed immediately after explantation of failed implants, regenerating all dehiscences or peri-implant bone defects larger than 2 mm with CCPB and collagen membranes. Cortico-cancellous porcine particles were used to prevent the collapse of the membrane and maintain space beneath the membrane for bone regeneration: no residual bone defects were observed after implants sites were probed at second stage surgery, and all implants were asymptomatic and not mobile.

The second study by the same authors (JOMI, 2008) evaluated buccal bone regeneration around implants placed immediately after extraction with flap elevation (control group) and without flap (test group). All dehiscences were grafted with CCPB gel and collagen membranes and clinical success was assessed at 6 months using three parameters: DIB (distance between implant shoulder and first bone-implant contact) - ISQ (implant stability quotient) and DIC (distance between implant shoulder and crestal bone at the midbuccal aspect). All grafting procedures were successfully carried out as planned without any complications, and post-surgical healing phase was uneventful for all patients. No peri-implant bone defect was observed at second stage surgery after 6 months, while the neck of 1 of the implants from the flapless group was covered with regenerated bone. Slotte et al. (CIDRR, 2011) placed CCPB into peri-implant bone lesions and observed the results after 12 months of healing, when the favorable properties of the particles in enhancing regeneration in that type of defect was evident.

In conclusion, the OsteoBiol® collagenated porcine bone substitutes and collagen membranes have shown positive clinical and biological results in all the scientific articles reviewed in this summary. These biomaterials can therefore be considered as predictable and effective medical devices for the regeneration of bone defects in dentistry.

Antonio Barone
DDS, PhD, MSc
"Tecnoss®" Dental is constantly investing a considerable budget in clinical and experimental studies in order to continuously improve the scientific knowledge on OsteoBiol® products.

Marco Baorolo, BSc, Managing Director and Scientific Coordinator
Tecnoss® Dental s.r.l.

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**Scientific literature**

- **Histology at 3 months. Human mandible grafted with osteobio®-Sp-Block**
  
  **Source**: Courtesy of Dr. F. Feligia, Bologna, Italy. Histology by Prof. Nannmark, University of Göteborg, Sweden.


2. CASSETTA M, CALASSO S, VD ZGAAI D. DELL’AQUILA D. REHABILITATION OF ATROPHIC ALVEOLAR CRESTS WITH CYLINDRICAL SANDBLASTED AND ACID ETCHED IMPLANTS: A PILOT STUDY. EUR J OF IMPLANT PROSTHODONTICS, 2005;31:133-144


10. TRUBIANI D, NICHOLLS BJ. RESORPTION PATTERN OF A PORCINE-DERIVED BONE SUBSTITUTE. J ORAL AND MAXILLOFACIAL IMPLANTS, 2008; OCT: 28(5):469-77


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## Product Codes

**OsteoBiol®**

**Product Codes**

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