OsteoBiol®

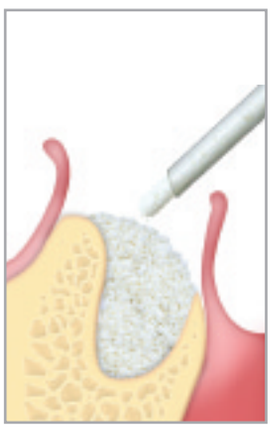
REGENERATION SCIENCE

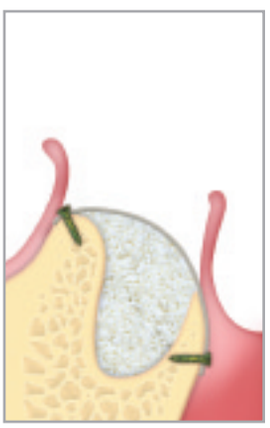
INSPIRED BY NATURE

Bone Grafting Materials

New Putty packaging in syringe

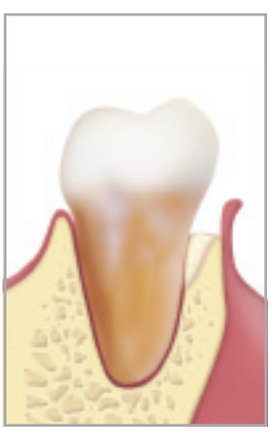
Pag. 17





New Curved Cortical Lamina

Pag. 24



New 0.25 gr. Gen-Os packaging

Pag. 14

Journal of Periodontology, 2008, 79: 1370-1377.

International Journal of Periodontics and Restorative Dentistry, 2008, 28: 283-289

Clinical Oral Implants Research, 2008, 19: 511-515

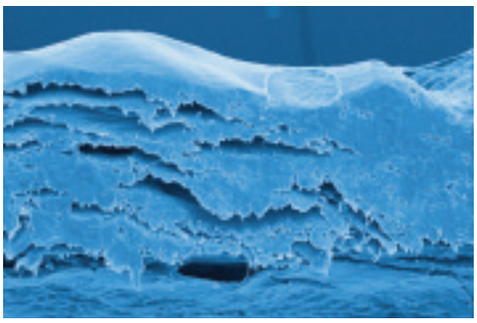
International Journal of Periodontics and Restorative Dentistry, 2008, 28:469-477

Clinical Implant Dentistry and Related Research, 2008, 10: 264-270

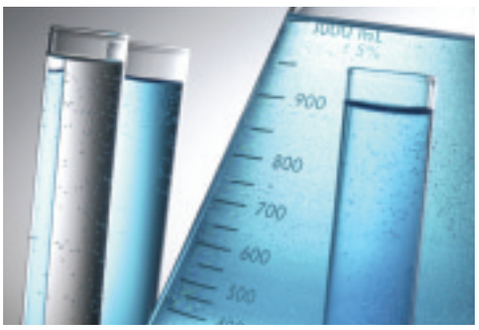
Journal of Immunopathology and Pharmacology, 2007, 20: 89-93

New publications

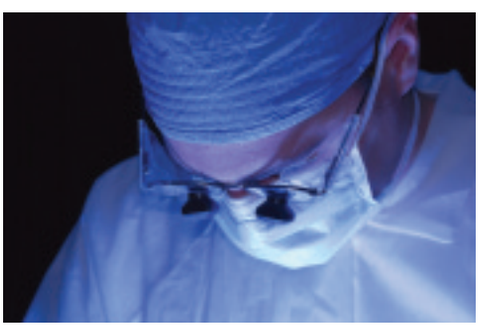
Pag. 33



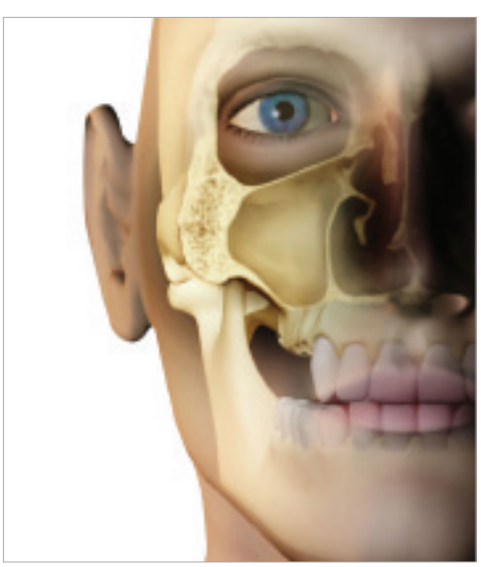
Introduction



Product Specifications



Publications and Case Reports

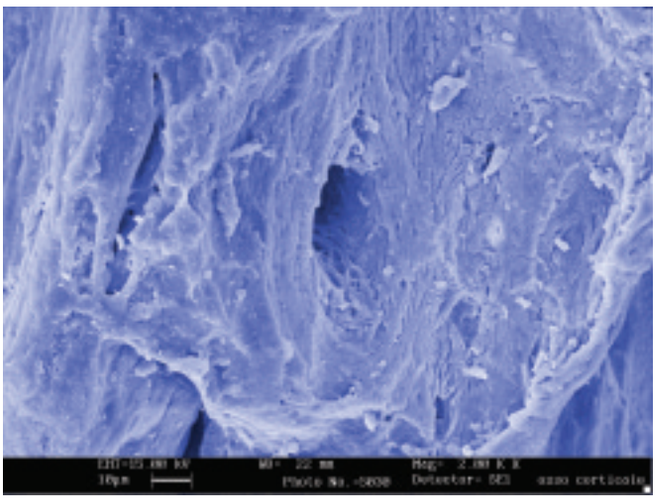


Certifications and Laboratory Analyses

Nature provides all the necessary elements for bone regeneration

Our aim is to accelerate and guide this process

A natural bone matrix



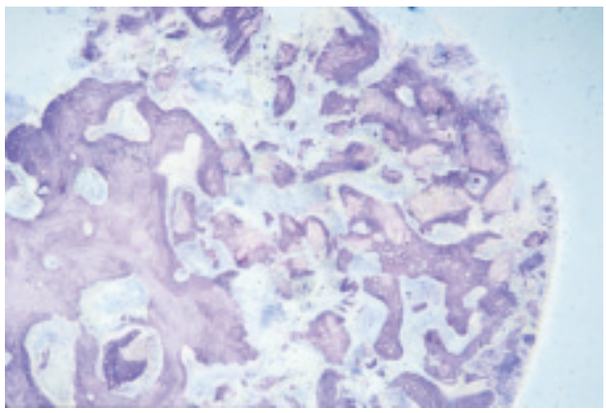
Detail of a Gen-Os granule:
vascular canal entrance with evident centralized osteonic structure.

Source: Nobil Bioricerche (Italy)

10 years of scientific research

A revolutionary innovation

A significant step ahead

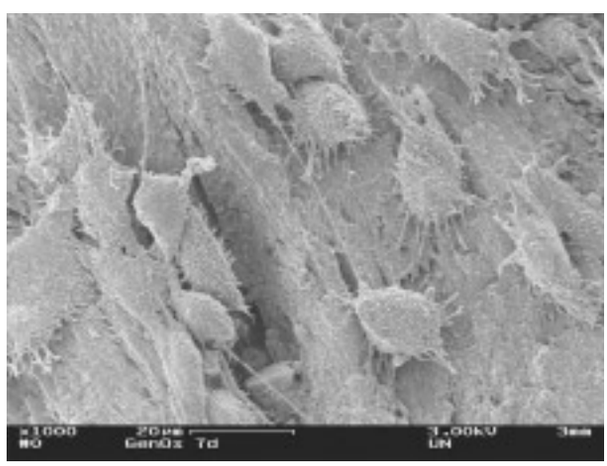


Research and development of biomaterials has gone through many stages, but always toward one goal: to heal bone deficit with newly-formed quality tissue in order to achieve functional recovery.

All of this in the least time possible.

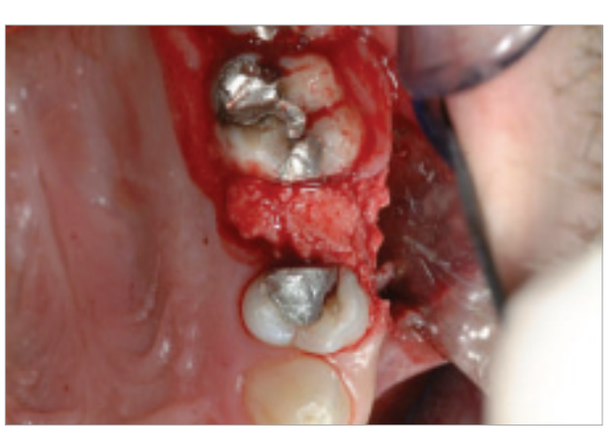
The examination of clinical results and the commercial diffusion of various kinds of products developed by the biomedical industry show a clear superiority of products of natural origin over those of synthetic derivation.

The structure of animal bone is morphologically more similar to human bone than any synthesized product.



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

Courtesy of Dr. U. Nannmark, Göteborg University, Sweden.



Alveolar post-extractive filling with OsteoBiol Putty.

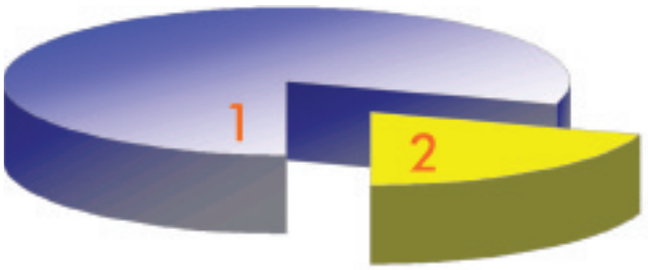
Over the last twenty years several processes have been developed to allow the grafting of heterologous origin products in the human body without adverse reaction.

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 this vital physiological process.

Collagen: a key factor for clinical success

COMPOSITION OF GEN-OS



MINERAL BONE (1) - COLLAGEN (2)

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 biomaterial granules.

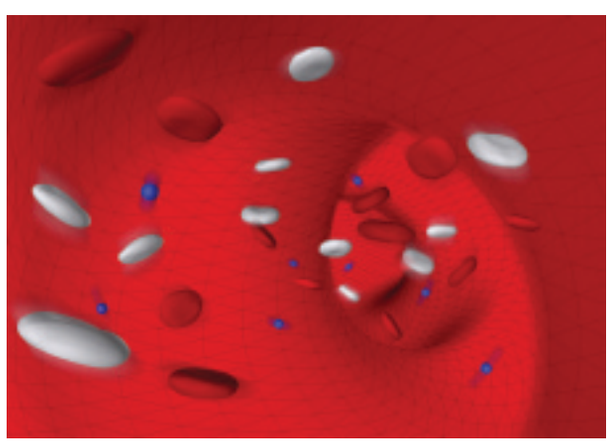
Moreover, the molecular structure of natural hydroxyapatite is not significantly altered thanks to the limited maximum process temperature.

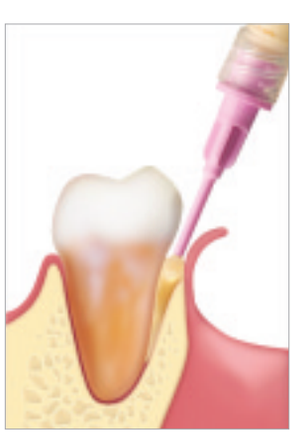
These characteristics of OsteoBiol products allow a consistent bone neo-formation and a close contact between mature neo-formed bone and biomaterial granules.

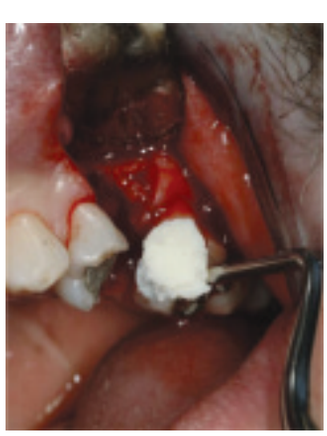
Collagen has a key role in bone regeneration process in that:

a) it acts as a valid substrate for platelet activation and aggregation
b) it serves to attract and differentiate the mesenchymal stem cells present in the bone marrow (1)
c) it increases the proliferation rate of the osteoblasts up to 2/3 times (2)
d) it stimulates the activation of the platelets, osteoblasts and osteoclasts in the tissue healing process

1) Salasznyk RM, et al. Journal of Biomedicine and Biotechnology (2004), 1: 24-34
2) Hsu FY, et al. Biomaterials (1999), 20: 1931-1936







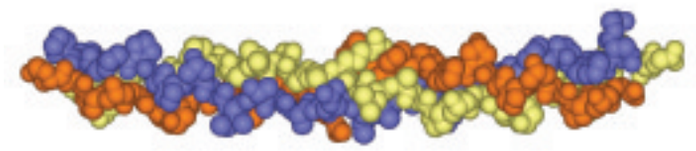
The presence of collagen inside each granule makes OsteoBiol Gen-Os hydrophilic and facilitates further mixing with collagen gel (Gel 0).

This technology has permitted the development of two new versatile and innovative products: Putty and Gel 40.

Their plastic consistency is ideal for filling three wall bone defects and guarantees simple handling and fast application.

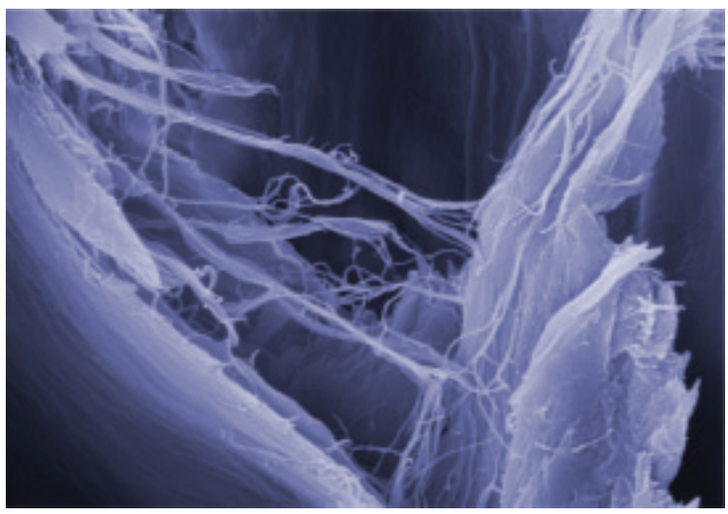
Collagen and bone regeneration

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



Graphic representation of collagen triple helix.

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 is known for its activating effect on osteoblasts and osteoclasts, and TGF-ß (Bone Morphogenetic Proteins belong to this superfamily) which starts bony callus formation.

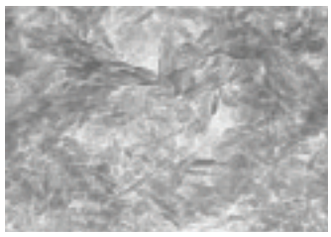
>> the ***osteoblastic precursors*** deriving from bone marrow mesenchymal stem cells are responsible, after cell differentiation in osteoblasts, for the second phase of the healing process (enchondral and/or intermembrous ossification) thanks to the synthesis of collagen and other components of the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

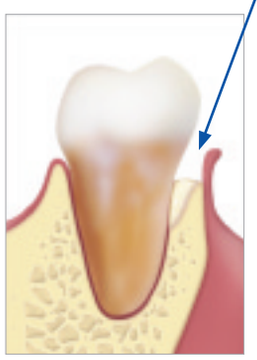
The continuous progresses in comprehension of biological mechanisms regulating bone tissue morphogenesis can be exploited also for elaboration of natural or artificial products able to restore or maintain the function of damaged tissues and organs (tissue engineering) (1, 2, 3).

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 (5).

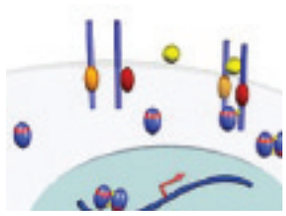


SUBSTRATE:
collagen

OSTEOPROGENITOR CELLS:
bone marrow



REGENERATION:
alveolar bone
periodontal ligament
cementum



GROWTH FACTORS TGFβ1 – BMP:
blood

Key elements for tissue and bone regneration (Nakashima N. et al., 2003, modified; 3).

SUBSTRATE: TEM image of OsteoBiol Gen-Os granule, in which it is possible to appreciate the collagen fibers.

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 receptor present on cellular membranes of platelets, responsible for their aggregation and lysis process; moreover, during the first week, it reinforces the action of fibrin in the formation of the primary clot, and then, in the second week, it replaces the function of fibrin.

2. Debridement: collagen has a chemotactic action on monocyte/macrophage cell lines, from which osteoclasts derive; these cells, through their action on mineral component resorption of both bone tissue and OsteoBiol 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. Receiving site remodeling: exogenous collagen grafting can contribute in decreasing remodeling times of immature bone tissue.

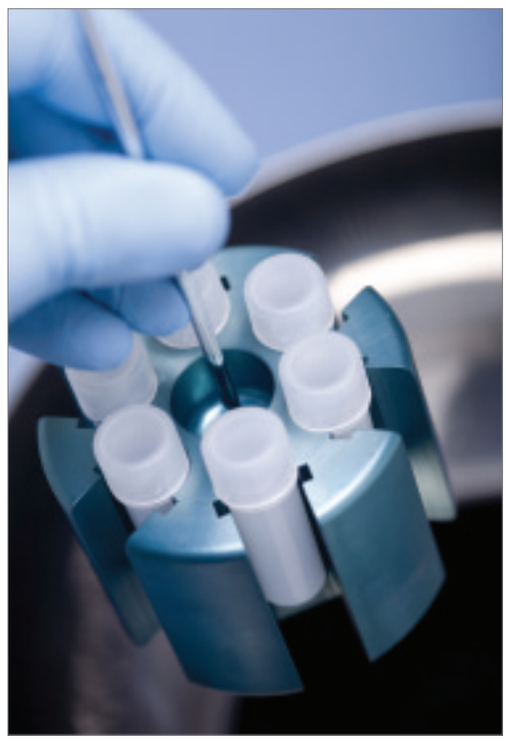
6. Osteoconduction and guided regeneration: naturally integrated with mineral component, collagen is able to increase osteoblasts proliferation rate (5), while as a resorbable membrane it is able to guide connective tissue regeneration.

Therefore all collagenated biomaterials of OsteoBiol product line provide the natural substrate for correct bone tissue regeneration and repair, facilitating and accelerating the physiological regeneration process and allowing optimal results within a reasonable period of time.

1) Griffith LG, Naughton G. Science (2002); 295: 1009-14
2) Reddi AH. Tissue Eng (2000); 6: 351-59
3) Nakashima N, Reddi AH. Nature Biotechnology (2003); 9: 1025-32
4) Salasznyk RM, et al. Journal of Biomedicine and Biotechnology (2004), 1: 24-34
5) Hsu FY, et al. Biomaterials (1999), 20: 1931-36

From heterologous bone to biomaterial

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).

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.

CHARACTERISTICS OF TECNOSS PROCESS

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.

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.

1) Trubiani O, et al. Journal of Immunopathology and Pharmacology (2007); 20: 89-93

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 osteoclastic-type remodeling of biomaterial, similar to physiological bone turnover time (1).

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

1. absence of a foreign body response
2. gradual resorption over time
3. stimulation and acceleration of physiological tissue healing process
4. protection of the grafting site from infection (membranes)
5. capability of carrying medication to the surgical site.

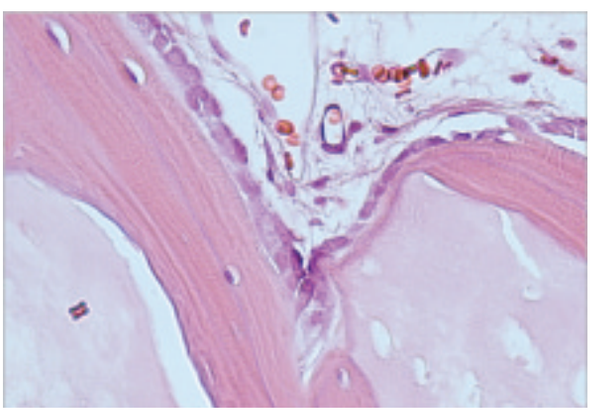


Image showing bone formation on collagenated porcine bone granules (OsteoBiol Gen-Os) 2 weeks after implantation in a rabbit. In the lower left and right corners granules can be seen. These granules are covered by newly formed bone and a seam of osteoblasts. Osteocytes in lacunae are visible in the newly formed bone. Close to the osteoblastic seam, both feeding microvessels and a venule can be seen.
Staining hematoxyline-eosine. Original magnification x40.

Courtesy of Drs U. Nannmark and L. Sennerby, Göteborg University, Sweden.

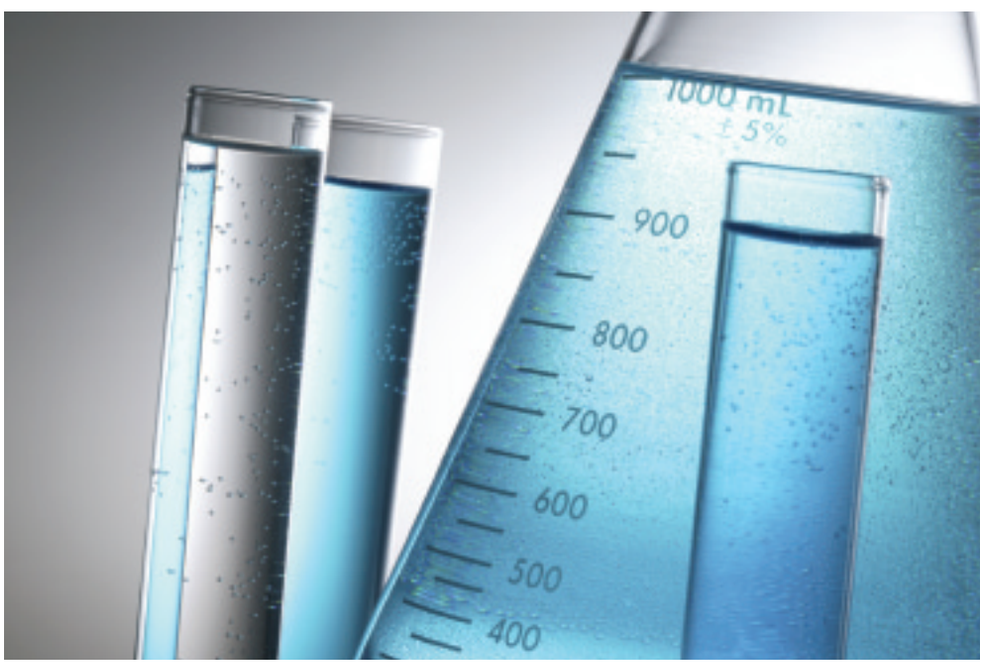
Results of chemical analyses performed on OsteoBiol Gen-Os (University of Duisburg-Essen, Germany):

Chemical element	**OsteoBiol Gen-Os (% in weight)**
Ca	25.7%
PO_4^{3-}	35.2%
C	13.6%
H	2.2%
N	2.9%
O (not in PO_4^{3-})	20.4%
TOTAL	**100%**
Ca/P (n:n)	1.73

Sample	**Water**	**Organic matrix**	**Mineral component**
OsteoBiol Gen-Os	4.0%	22.4%	73.6%

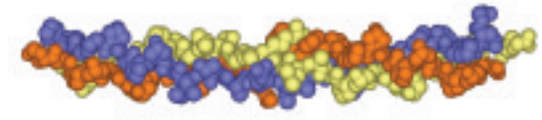
1) Nannmark U, Sennerby L. Clinical Implant Dentistry and Related Research (2008) Dec; 10(4):264-70.

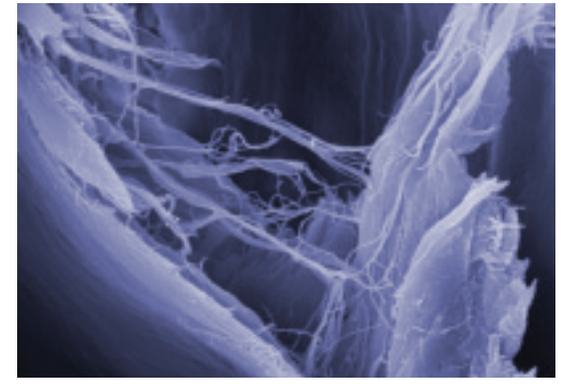
Product Specifications



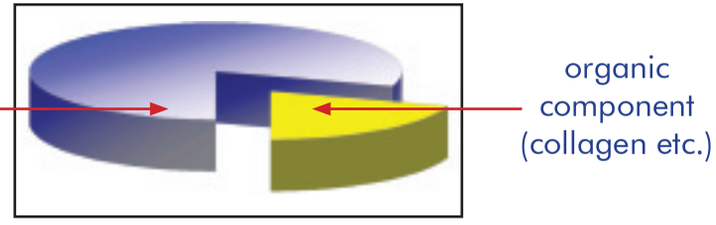
OsteoBiol®

Collagenated fillers composition





heterologous bone composition



cancellous bone | cortical bone

Collagenated mix | Collagen gel

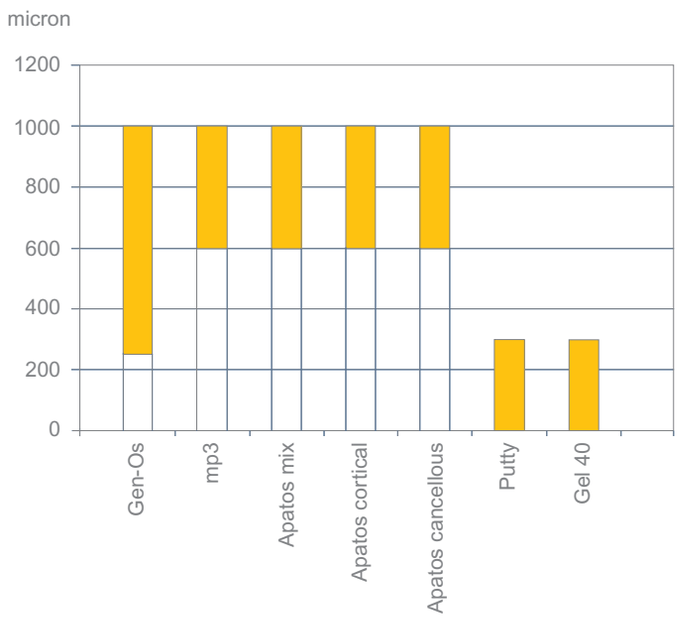
Gen-Os granules	mp3 granules	Putty paste	Gel 40 gel	Gel 0 gel
100% Mix 250-1000 µm	90% Mix 600-1000 µm in Gel type 0	80% Mix ≤ 300 µm in Gel type 0	60% Mix ≤ 300 µm in Gel type 0	

* Approximate percentages in volume subjet to a variability range depending on the heterologous origin of the bony tissue

PHYSICAL/CLINICAL CHARACTERISTICS OF OSTEOBIOL BONE SUBSTITUTES

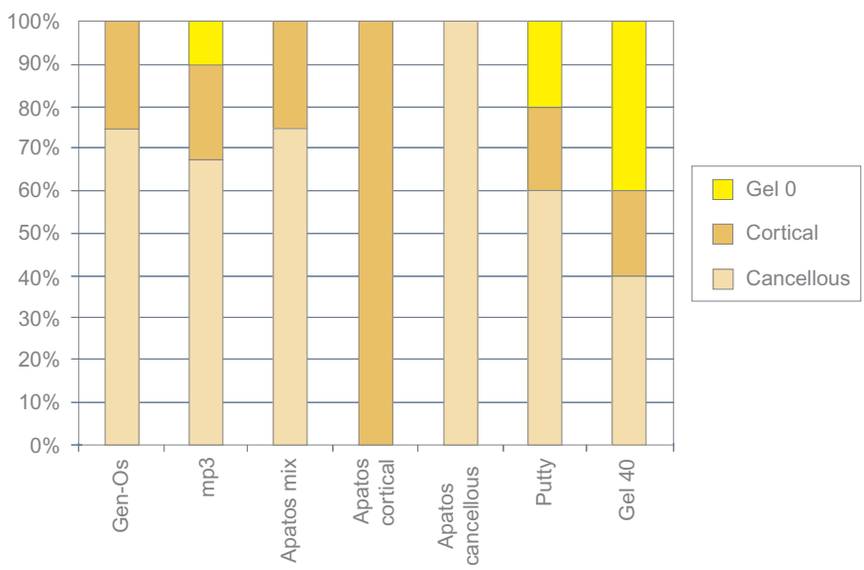
GRANULOMETRY

The average reported values are indicative and subject to a variability range depending on the heterologous origin of the products.



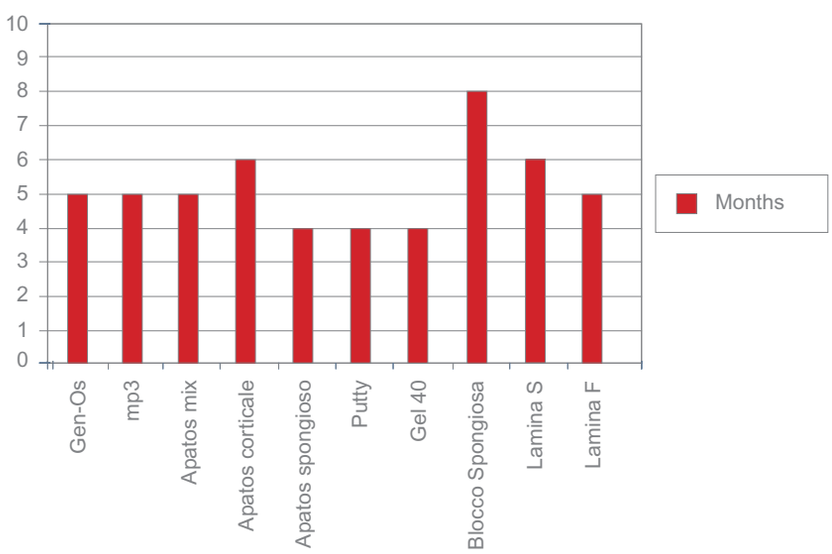
COMPOSITION

The average reported values are indicative and subject to a variability range depending on the composition of the tissues of origin.



RE-ENTRY TIME

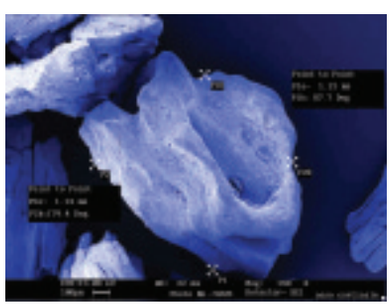
The reported values are estimates and purely indicative: these values can therefore vary depending on the patient and grafting site.

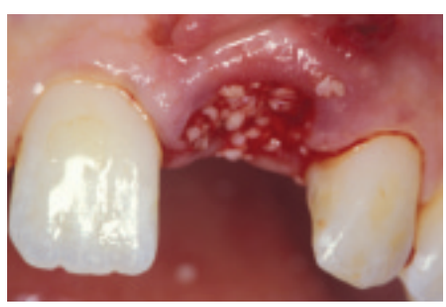


Gen-Os

CE 0373

TISSUE OF ORIGIN	MIX OF CANCELLOUS AND CORTICAL HETEROLOGOUS BONE
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	GRANULES SLIGHTLY RADIOPAQUE
GRANULOMETRY	STANDARD 250-1000 μm
RE-ENTRY TIME	4/5 MONTHS DEPENDING FROM GRAFTING SITE CHARACTERISTICS
CATALOG LINKS	CASE REPORTS PAG. 34 - 36 - 37 - 41 - 42 - 45 BIOCOMPATIBILITY TESTS PAG. 52 - 53
PACKAGING AND CODES	VIAL 0,25 gr. - VIAL 0,5 gr. - VIAL 1,0 gr. - VIAL 2,0 gr.





Characteristics: a natural replicate of autologous bone, Gen-Os conserves the same intimate structures (matrix and porous form) and presents a high osteoconductive activity. 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 (osteoconductive property). Moreover, thanks to its collagen content, the product facilitates blood clotting and the subsequent invasion of repairing and regenerative cells, favoring restitutio ad integrum of missing bone. Because of its marked "hydrophilia", it can function as a carrier for selected medication and drugs.

Handling: Gen-Os must always be hydrated and thoroughly mixed with a few drops of sterile saline to activate its collagen matrix and to enhance its adhesivity; it can also be mixed either with OsteoBiol Gel 0 or with patient's blood. If necessary it can as well be mixed with the drug selected for surgery.

Bibliography

Barone A, Crespi R, Nicoli Aldini N, Fini M, Giardino R, Covani U. Maxillary sinus augmentation: histologic and histomorphometric analysis.
The International Journal of Oral and Maxillofacial Implants, 2005, 20: 519-525

Barone A, Santini S, Sbordone L, Crespi R, Covani U. A clinical study of the outcomes and complications associated with maxillary sinus augmentation.
The International Journal of Oral and Maxillofacial Implants, 2006, 26: 81-85

Cardaropoli D, Cardaropoli G. Preservation of the postextraction alveolar ridge: a clinical and histologic study.
The International Journal of Periodontics and Restorative Dentistry, 2008, 28: 469-477

Covani U, Barone A, Cornelini R, Crespi R. Clinical outcome of implants placed immediately after implant removal.
Journal of Periodontology, 2006, 77: 722-727

Nannmark U, Sennerby L. The bone tissue responses to prehydrated and collagenated cortico-cancellous porcine bone grafts.
A study in rabbit maxillary defects. Clinical Implant Dentistry and Related Research, 2008, 10: 264-270

Vozza I, Scarano A, Quaranta M. Clinical and histological study on maxillary sinus lift and filling with collagenized pig bone.
Italian Journal of Osteointegration, 2004, 4: 19-23

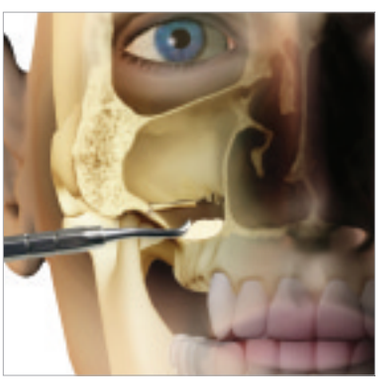
Clinical applications

Oral surgery: granulomas, dentigenous cysts and split crests.

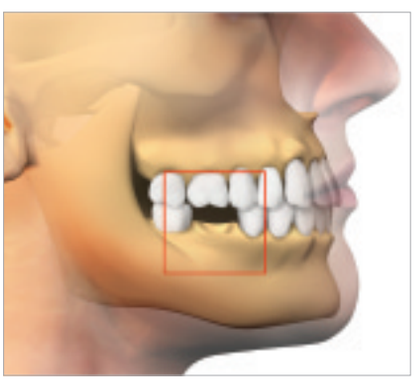
Periodontology: filler of deep intrabony defects and furcations.

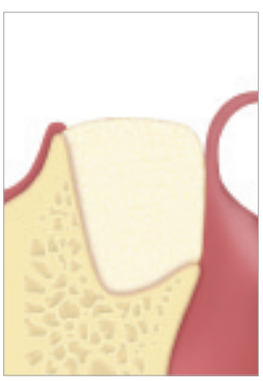
Implantology: universal filler used in treatment of dehiscences and periimplantitis, two wall defects, lateral and crestal access sinus lift. When needed Gen-Os graft can be stabilized mixing with OsteoBiol Gel 0 and protected with OsteoBiol membranes or Cortical Laminae.

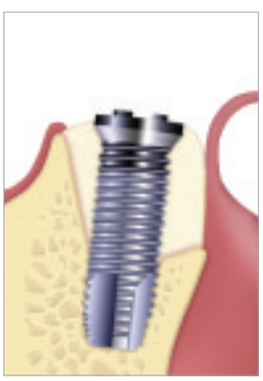
Lateral access sinus lift



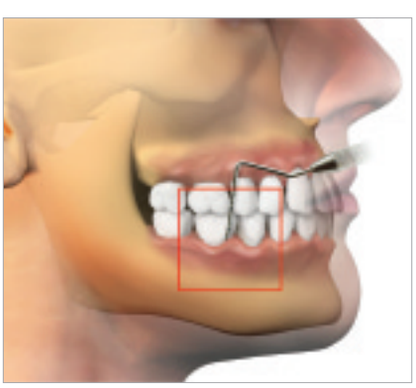
Two wall defects graft with delayed or immediate implant

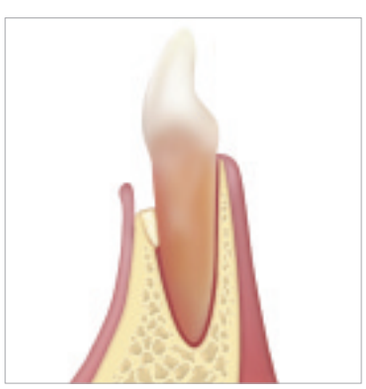




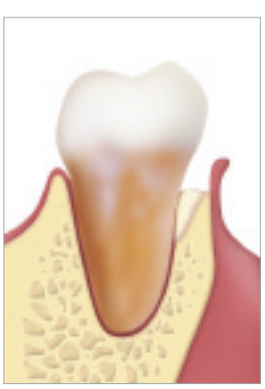


Gingival recessions



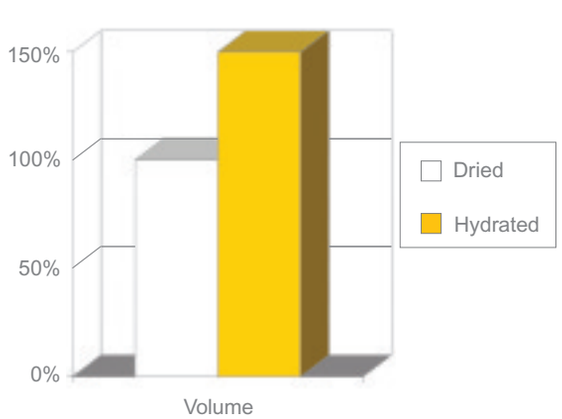


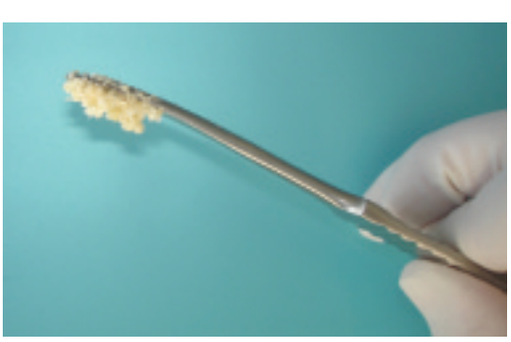
Intrabony defects



Advantages

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

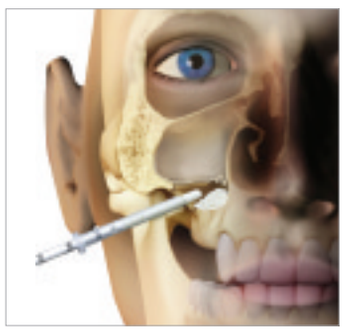


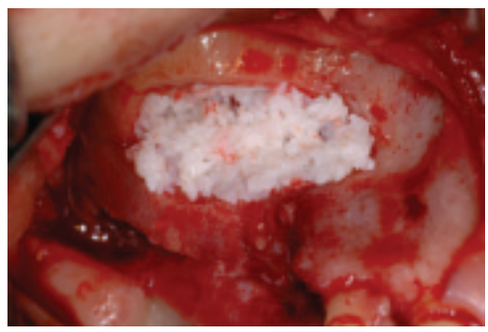


mp3

CE 0373

TISSUE OF ORIGIN	HETEROLOGOUS CORTICO-CANCELLOUS COLLAGENATED BONE MIX
TISSUE COLLAGEN	ABOUT 10% (GEL 0)
PHYSICAL FORM	PRE-HYDRATED GRANULES AND COLLAGEN GEL
GRANULOMETRY	600-1000 μm
RE-ENTRY TIME	ABOUT 5 MONTHS
CATALOG LINKS	CASE REPORTS PAG. 40 – 46 – 47
PACKAGING	STERILE SYRINGE 1 CC (EXTERNAL Ø 7 mm - INTERNAL Ø 6 mm) 3 STERILE SYRINGES 0,5 CC (EXTERNAL Ø 7 mm - INTERNAL Ø 6 mm)





Characteristics: heterologous origin biomaterial made of 600-1000 μm pre-hydrated collagenated cortico-cancellous granules, properly mixed with OsteoBiol Gel 0. Its particular consistency and the availability in sterile syringe allow **mp3** grafting without any preventive manipulation. 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, 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, it preserves the original graft shape and volume (osteoconductive 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.

Clinical applications

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. OsteoBiol Evolution or Special membranes are recommended to cover the antrostomy.

Bibliography

Barone A, Aldini NN, Fini M, Giardino R, Calvo Guirado JL, Covani U. Xenograft versus extraction alone for ridge preservation after tooth removal: a clinical and histomorphometric study. Journal of Periodontology, 2008, 79: 1370-1377.

Barone A, and Covani U. Maxillary alveolar ridge reconstruction with nonvascularized autogenous block bone: clinical results. Journal of Oral and Maxillofacial Surgery, 2007, 65: 2039-2046.

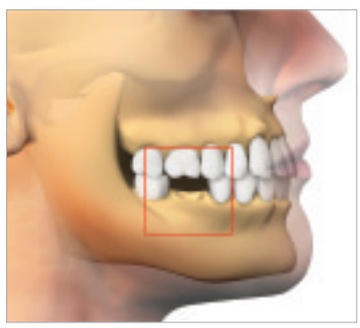
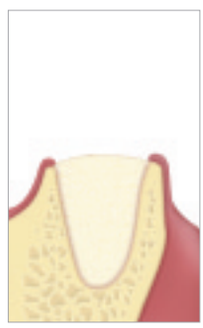
Barone A, Marconcini S, Santini S and Covani U. Osteotomy and membrane elevation during the maxillary sinus augmentation procedure. A comparative study: piezoelectric device vs. conventional rotative instruments. Clinical Oral Implants Research, 2008, 19: 511-515

Nannmark U, Sennerby L. The bone tissue responses to prehydrated and collagenated cortico-cancellous porcine bone grafts.
A study in rabbit maxillary defects. Clinical Implant Dentistry and Related Research, 2008, 10: 264-270

Putty

CE 0373

TISSUE OF ORIGIN	MIX OF CANCELLOUS AND CORTICAL HETEROLOGOUS BONE
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	BONE PUTTY WITH PLASTIC CONSISTENCY COMPOSED OF COLLAGEN GEL LOADED WITH 80% MICRONIZED BONE MIX
GRANULOMETRY	FINE ≤ 300 μm
RE-ENTRY TIME	ABOUT 4 MONTHS
CATALOG LINKS	CASE REPORTS PAG. 34
PACKAGING AND CODES	SYRINGE 0,5 cc (1 gr.) - VIAL 1,0 cc (2 gr.) - 3 SYRINGES 0,5 cc (3 gr.)


Characteristics: Putty is a bone paste with at least 80% micronized heterologous bone (granulometry ≤ 300 μm) and collagen gel (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: apply the product and adapt it to defect morphology without compression; any non stable residue must be removed before soft tissue suture.

Clinical applications

Implantology: versatile alveolar filler to preserve crestal volume and in immediate post-extractive implants where it facilitates primary stableness; ideal for the treatment of periimplantitis and in split crests. In crestal access sinus lift, Putty can be used in association with Gen-Os (ratio 1 part Putty, 3 parts Gen-Os) to facilitate insertion.

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

Bibliography

Arcuri C, Cecchetti F, Germano F, Motta A, Santacroce C. Clinical and histological study of a xenogenic substitute used as a filler in postextractive alveolus. Minerva Stomatologica, 2005, 54: 351-362.

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.

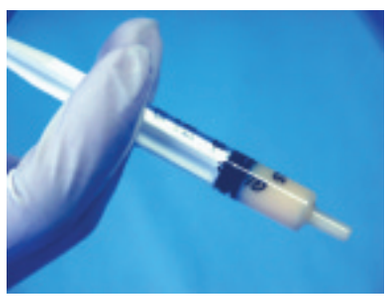
Calvo Guirado JL, Pardo Zamora G, Saez Yuguero MR. Ridge splitting technique in atrophic anterior maxilla with immediate implants, bone regeneration and immediate temporisation: a case report. Journal of the Irish Dental Association, 2007, 53: 187-190.

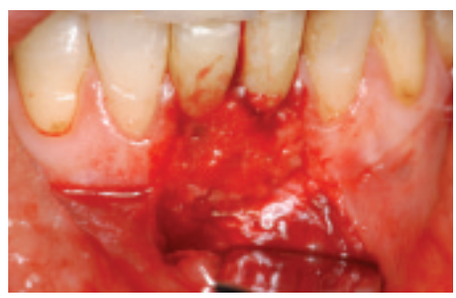
Covani U, Ameri S, Crespi R, Barone A. Preservazione del processo alveolare con osso eterologo. Considerazioni istologiche. Italian Oral Surgery, 2004, 3: 17-23.

Gel 40 - Gel 0

CE 0373

TISSUE OF ORIGIN	MIX OF CANCELLOUS AND CORTICAL HETEROLOGOUS BONE (GEL 40)
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	COLLAGEN GEL LOADED WITH 60% BONE MIX (GEL 40) COLLAGEN GEL TYPE I AND III (GEL 0)
GRANULOMETRY	FINE ≤ 300 μm (GEL 40)
RE-ENTRY TIME	ABOUT 4 MONTHS
CATALOG LINKS	CASE REPORTS PAG. 38 - 39 - 41
PACKAGING GEL 40	1 SYRINGE 0,5 cc - 3 SYRINGES 0,5 cc
PACKAGING GEL 0	1 SYRINGE 0,5 cc - 3 SYRINGES 0,5 cc





Characteristics: collagen matrix (type I and III) obtained using exclusive Tecnoss process, available in a pure preparation as Gel 0 or loaded for 60% of its volume with micronized heterologous bone (granulometry ≤ 300 μm) as Gel 40.
Both products are in a gel state at temperatures below 30° C; at higher temperatures the viscosity is reduced and Gel 0 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.
Gel 0 is rapidly and totally resorbed; it is also endowed with exceptional anti-inflammatory, eutrophic and cicatrizing properties. Gel 0 is ideal to use with bone substitutes in granules (OsteoBiol Gen-Os or Apatos) to obtain a more adhesive mix, easier to stabilize.
This lipophilia is due mainly to a percentage of polyunsaturated fatty acids of the oleic-linoleic series (to which Omega 3 also belongs) directly derived from the raw material. Such components possess a valuable antioxidant action on the free radicals and therefore aid tissue regeneration.

Handling: the distinctive characteristics of viscosity and density of both Gels facilitate handling of the product by the operator, providing a glue-like support. If viscosity is excessive, add a few drops of sterile lukewarm sterile saline and then re-mix thoroughly to obtain the desired density. Placed on site, Gel 0 and Gel 40 combine with blood, contributing to the fast and compact formation of primary blood clot.

Bibliography

Barone A, Cornelini R, Ciaglia R, Covani U. Implant placement in fresh extraction sockets and simultaneous osteotome sinus floor elevation: a case series. International Journal of Periodontics and Restorative Dentistry, 2008, 28: 283-289.

Covani U, Cornelini R, Barone A. Buccal bone augmentation around immediate implants with and without flap elevation: a modified approach. The International Journal of Oral and Maxillofacial Implants, 2008, 23: 841-846.

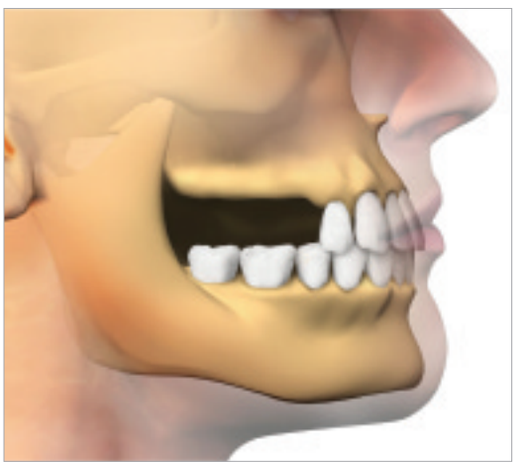
Cardaropoli D, Cardaropoli G. Healing of gingival recessions using a collagen membrane with a demineralized xenograft: a randomized controlled clinical trial. Int J Periodontics Restorative Dent. 2009 Feb; 29(1): 59-67.

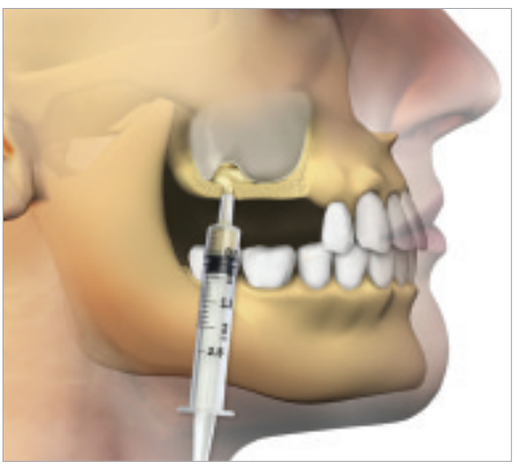
Clinical applications

Gel 40: maxillary sinus lift with crestal access; treatment of periodontal pockets and gingival recessions; it can also be used mixed with OsteoBiol Gen-Os as graft stabilizer.

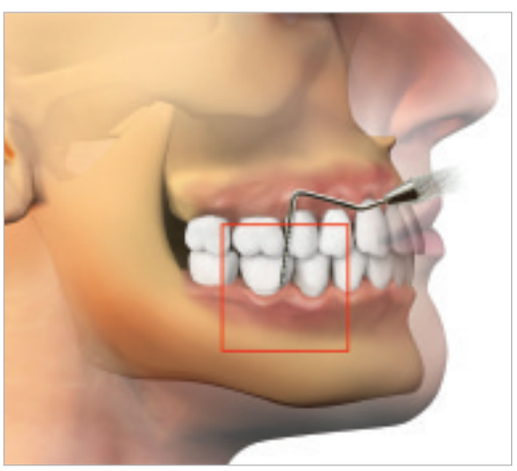
Gel 0: can be used mixed with OsteoBiol Gen-Os or Apatos as graft stabilizer or alone as cicatrizing agent.

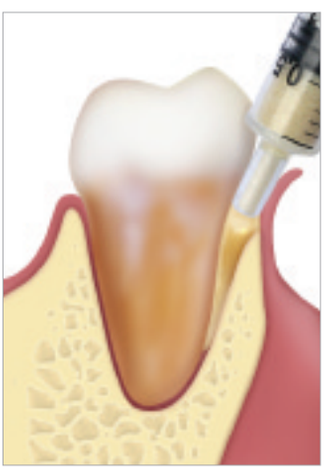
Crestal access sinus lift

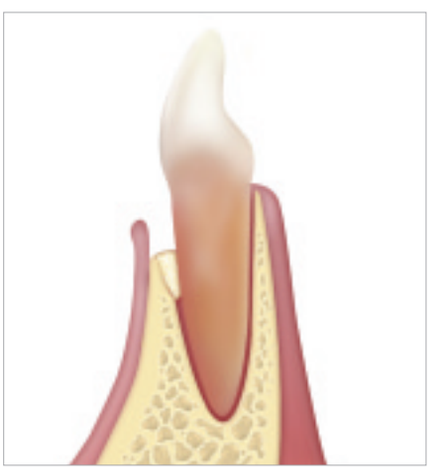




Periodontal pockets and gingival recessions



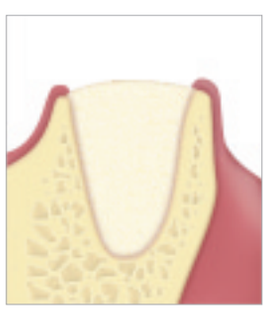
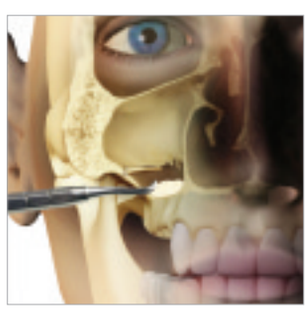
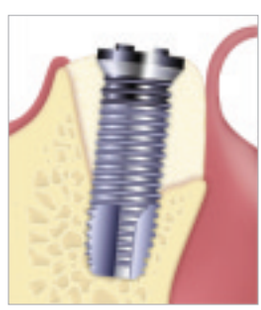




Apatos

CE 0373

TISSUE OF ORIGIN	HETEROLOGOUS CORTICAL AND CANCELLOUS BONE
TISSUE COLLAGEN	DEGRADED
PHYSICAL FORM	RADIOPAQUE GRANULES OF MINERAL HYDROXYAPATITE
GRANULOMETRY	600-1000 μm
RE-ENTRY TIME	ABOUT 4 MONTHS APATOS CANCELLOUS - 5 MONTHS APATOS MIX 6 MONTHS APATOS CORTICAL
CATALOG LINKS	CASE REPORTS PAG. 44
PACKAGING AND CODES	CANCELLOUS: VIAL 0,5 gr. - VIAL 1,0 gr. MIX: VIAL 0,5 gr. - VIAL 1,0 gr. - VIAL 2,0 gr. CORTICAL: VIAL 0,5 gr. - VIAL 1,0 gr.

Characteristics: Apatos is a biomaterial of heterologous origin with characteristics similar to mineralized human bone; it can therefore be used as alternative to autologous bone.

The natural micro-porous 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 applications

Oral surgery: granulomas, dentigenous cysts and split crests.

Implantology: universal filler used in treatment of dehiscences and periimplantitis, 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 graft volume.
When needed, Apatos graft can be protected with OsteoBiol Evolution membrane or Soft Cortical Lamina.

Bibliography

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, Caputi S, Piattelli A. Histological and Ultrastructural Analysis of Regenerated Bone in Maxillary Sinus Augmentation Using a Porcine Bone-Derived Biomaterial. Journal of Periodontology, 2006, 77: 1984-1990.

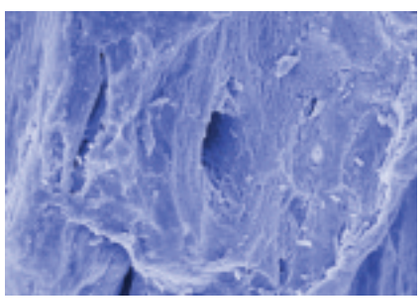
Scarano A, Iezzi G, Quaranta A, Fiera E, Piattelli A. I biomateriali in chirurgia odontostomatologica. Italian Oral Surgery, 2006, 1: 1-13.

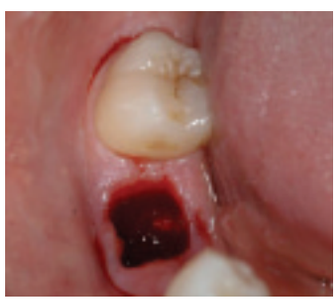
Trubiani O, Scarano A, Orsini G, Di Iorio D, D'Arcangelo C, Piccirilli M, Sigismondo M, Caputi S. The performance of human periodontal ligament mesenchymal stem cells on xenogenic biomaterials. Journal of Immunopathology and Pharmacology, 2007, 20: 89-93

Tablet

CE 0373

TISSUE OF ORIGIN	CORTICO-CANCELLOUS HETEROLOGOUS BONE MIX
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	FRIABLE DRIED BLOCK
GRANULOMETRY	FINE ≤ 300 μm
RE-ENTRY TIME	ABOUT 4 MONTHS
PACKAGING	BLISTER 6 PCS. mm 10x10x10





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. If necessary, proceed with suture of the alveolar margins.

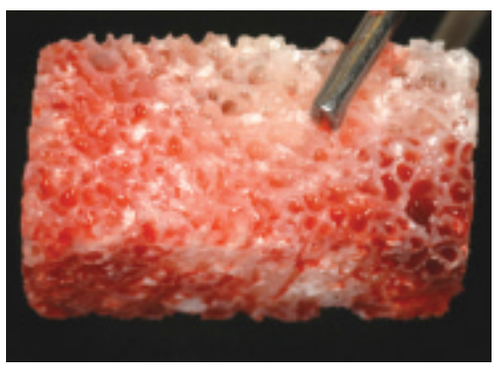
Clinical applications

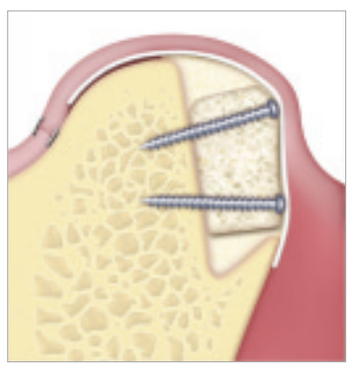
Traumatology, Dentistry and wherever fast and prolonged antihaemorrhagic action is needed; Tablet provides also a scaffold function in order to avoid the collapse of the alveolar walls after dental extractions, with consequent both vertical and horizontal bone loss.

Sp-Block

CE 0373

TISSUE OF ORIGIN	EQUINE CANCELLOUS BONE
TISSUE COLLAGEN	PRESERVED (CODES BN1E / BN2E) - DEGRADED (CODE ABL10E)
PHYSICAL FORM	RIGID DRIED BLOCK
RE-ENTRY TIME	VARIABLE DEPENDING ON CHARACTERISTIC AND IRRORATION GRADE OF GRAFTING SITE AND ON CLINICAL CONDITIONS OF PATIENT - ABOUT 8 MONTHS
PACKAGING	COLLAGENATED BLOCKS mm 10x10x20 / mm 20x20x10 APATOS BLOCK mm 12x12x22





Characteristics

Collagenated block: cancellous block of equine 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.

Apatos block: made of natural mineral hydroxyapatite which is endowed with similar properties of human mineralized bone. It can be shaped according to clinical needs and must only be grafted as a filler without exposure to loading.

The blocks complete biocompatibility and bioavailability have been demonstrated by tests conducted at the Università degli Studi di Torino, according to the ISO 10993 method.
Because of their marked "hygroscopicity", they can function as carriers of selected medication and drugs.

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 (OsteoBiol Lamina or Evolution membrane).

Clinical applications

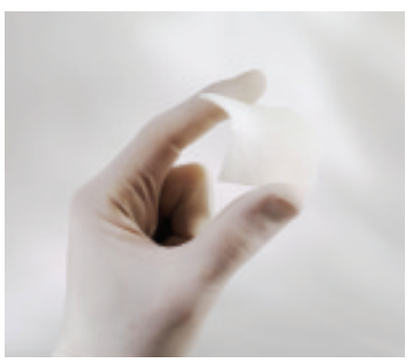
Dental and Oral Surgery: vertical and horizontal bone augmentation of wide volume requiring grafts with good scaffold properties.

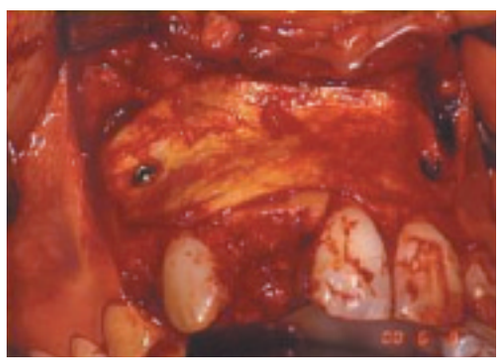
Maxillofacial Surgery: partial or total reconstruction of destroyed anatomical parts due to traumas and tumors.

Lamina

CE 0373

TISSUE OF ORIGIN	HETEROLOGOUS CORTICAL BONE
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	DRIED LAMINA, FLEXIBLE AFTER RE-HYDRATION
THICKNESS	STANDARD (2-4 mm) - FINE (0,4-0,6 mm)
RE-ENTRY TIME	STANDARD ABOUT 8 MONTHS - FINE ABOUT 6 MONTHS
CATALOG LINKS	CASE REPORT PAG. 44 - 45
PACKAGING AND CODES	STANDARD mm 30x30 FINE mm 25x25 - mm 20x40 - oval mm 35x25





Characteristics: Soft Cortical Laminae are 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 consistency of the bone tissue from which it originates; the margins are soft in order not to cause micro traumas to the surrounding tissues.

Handling: Soft Cortical 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; normally it should be immobilized with titanium microscrews or it can be sutured directly to the surrounding tissues with a triangular section non-traumatic needle.
In case of exposure, it should only be removed if there is a clear suprainfection, because its plasticity and consistency is such as to allow it to achieve a complete second intention healing of the wound.

Clinical applications

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.

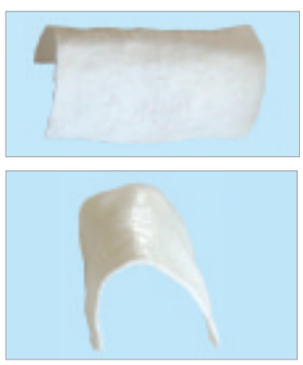
Bibliography

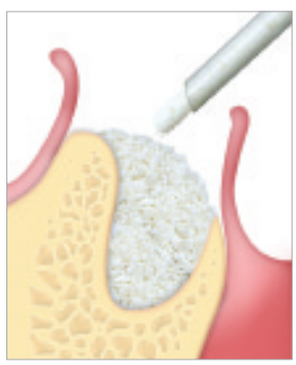
Rinna C, Ungari C, Saltarel A, Cassoni A, Reale G. Clinical notes. Orbital Floor Restoration. The Journal of Craniofacial Surgery, 2005, 16: 968-972.

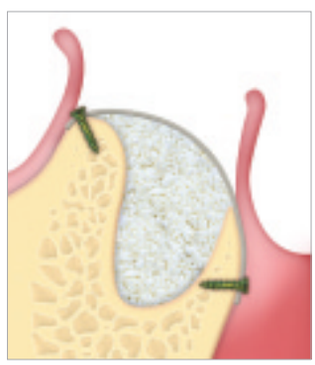
Curved Cortical Lamina

CE 0373

TISSUE OF ORIGIN	HETEROLOGOUS CORTICAL BONE
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	RIGID DRIED LAMINA
THICKNESS AND WIDTH	MEDIUM (0,8-1,0 mm)
RE-ENTRY TIME	ABOUT 6 MONTHS
PACKAGING	1 BLISTER mm 30x30







Characteristics: cortical bone of heterologous origin produced with an exclusive Tecnoss process that avoids ceramization of hydroxyapatite crystals, thus allowing progressive phisiological resorption.
After a process of superficial decalcification, mantains the typical compact consistency of the bone tissue from which it originates.

Handling: Curved Cortical Lamina should not be hydrated and can be shaped with sterile scissors until the desired size is reached.
Once shaped to cover properly the bone defect, it should be immobilized with titanium microscrews: it is recommended to fill the defect with OsteoBiol mp3 or OsteoBiol Gen-Os.
In case of exposure, it should only be removed if there is a clear suprainfection, because its consistency is such as to allow a complete second intention healing of the wound.

Clinical applications

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

Implantology: ideal for protection and stabilization of two-wall defect grafts.

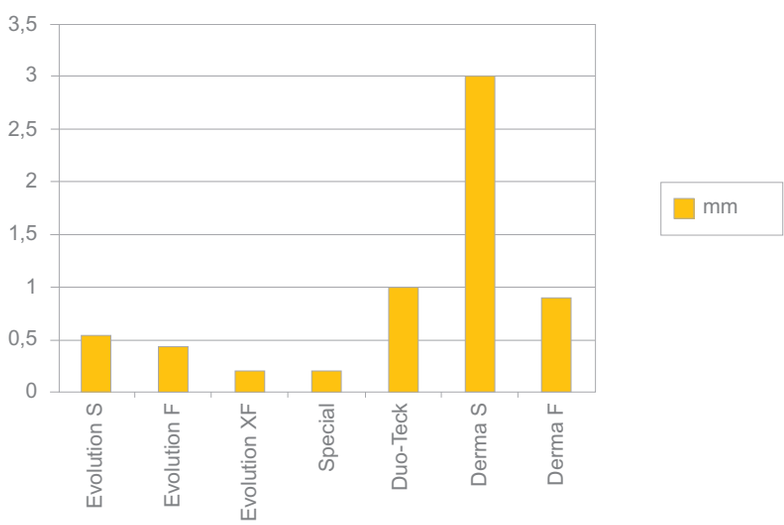
PHYSICAL/CLINICAL CHARACTERISTICS OF OSTEOBIOL MEMBRANES

SIZE

20X20	25X25	30X30	25X35
Evolution S Evolution F Evolution XF Special Derma S Duo-Teck	Derma F	Evolution S Evolution F Evolution XF Special Derma S	Evolution S Evolution F

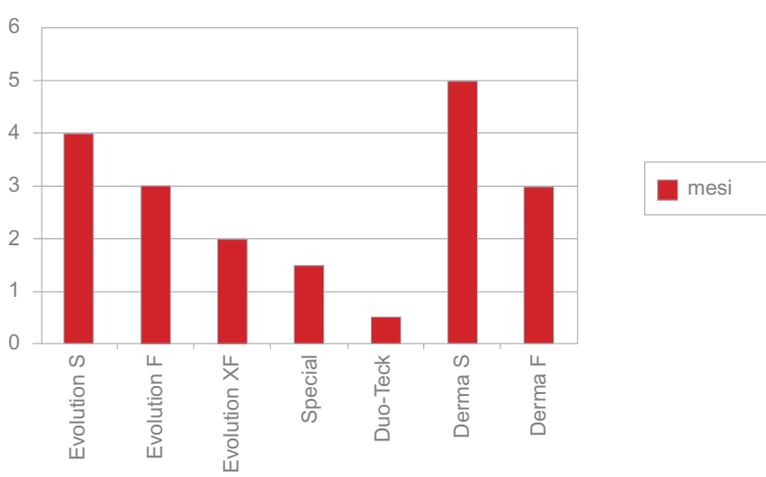
THICKNESS

The average reported values are indicative and subject to a variability range depending on the composition of the tissues of origin.



ESTIMATED RESORPTION TIME

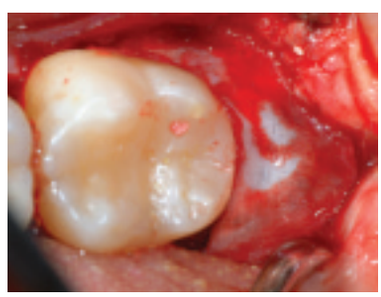
The reported values are estimates and purely indicative: these values can therefore variate depending on the patient and grafting site.



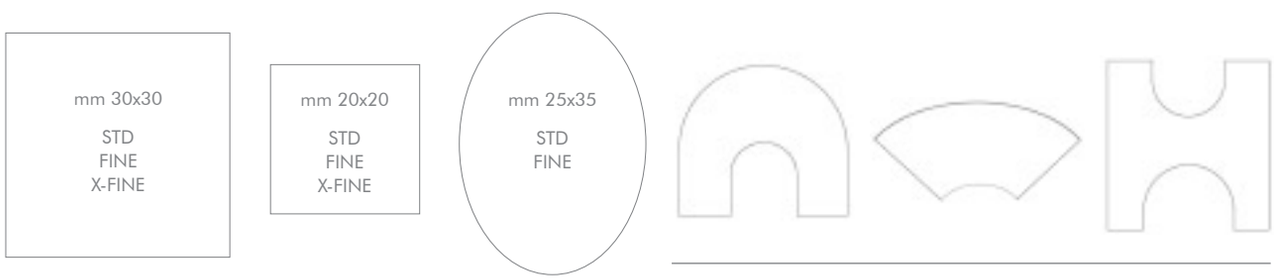
Evolution

CE 0373

TISSUE OF ORIGIN	HETEROLOGOUS PERICARDIUM
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	DRIED MEMBRANE WITH ONE SMOOTH SIDE AND ONE MICRO-ROUGH SIDE
THICKNESS	STANDARD - FINE - EXTRA FINE
ESTIMATED RESORPTION TIME	ABOUT 4 MONTHS (STANDARD) - 3 MONTHS (FINE) - 2 MONTHS (EXTRA FINE)
CATALOG LINKS	CASE REPORTS PAG. 34 - 37 - 38 - 41- 42 BIOCOMPATIBILITY TESTS PAG. 54 - 55
PACKAGING	STD mm 20x20 - STD mm 30x30 FINE mm 20x20 - FINE mm 30x30 X-FINE mm 20x20 - X-FINE mm 30x30 STD OVAL mm 25x35 - FINE OVAL mm 25x35 PERIO-KIT 6 SHAPED X-FINE MEMBRANES (2 FOR EACH SHAPE)



Types:



PERIO-KIT

Characteristics: 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:

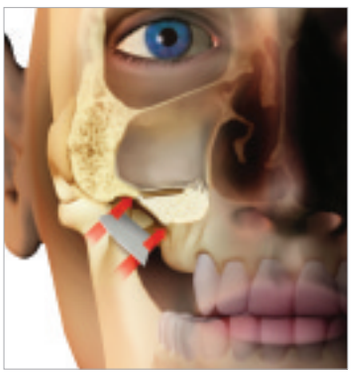
- the maximum adaptability to bone tissue and soft tissues
- an easy and secure suturability to nearby tissues
- the best membrane/bone and membrane/periosteum interface
- stability and prolonged protection of the underlying graft

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.

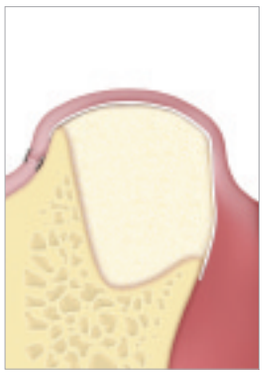
Clinical applications

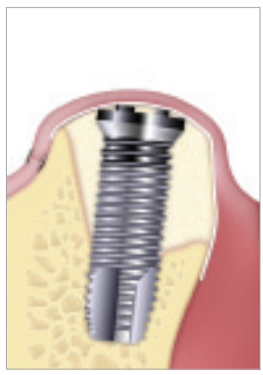
Oral surgery and Traumatology: the standard model is always recommended in case of large regenerations with risks of exposure.
Implantology: ideal for covering antrostomy and for protection of two wall defects graft.
Periodontology: protection of grafted intrabony defects when flaps suture presents risks of exposure (fine model); space making in gingival recessions (x-fine model).
Besides an eutrophic effect, Evolution membranes provide grafting site stabilization as well as long lasting protection against external agents.

Covering of antrostomy

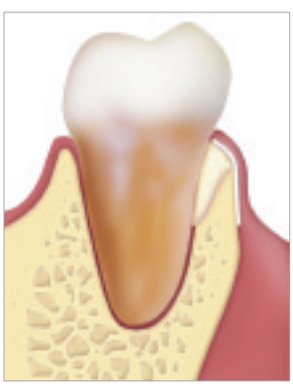


Two wall defects graft protection with immediate or delayed implant

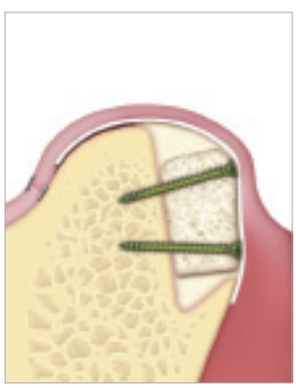




Intrabony defects graft protection



Cancellous block grafts protection



Bibliography

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.

Barone A, Crespi R, Nicoli Aldini N, Fini M, Giardino R, Covani U. Maxillary sinus augmentation: histologic and histomorphometric analysis. The International Journal of Oral and Maxillofacial Implants, 2005, 20: 519-525.

Barone A, Marconcini S, Santini S and Covani U. Osteotomy and membrane elevation during the maxillary sinus augmentation procedure. A comparative study: piezoelectric device vs. conventional rotative instruments. Clinical Oral Implants Research, 2008, 19: 511-515.

Barone A, Santini S, Sbordone L, Crespi R, Covani U. A clinical study of the outcomes and complications associated with maxillary sinus augmentation. The International Journal of Oral and Maxillofacial Implants, 2006, 26: 81-85.

Cardaropoli D, Cardaropoli G. Preservation of the postextraction alveolar ridge: a clinical and histologic study. The International Journal of Periodontics and Restorative Dentistry, 2008, 28: 469-477.

Cardaropoli D, Cardaropoli G. Healing of gingival recessions using a collagen membrane with a demineralized xenograft: a randomized controlled clinical trial. Int J Periodontics Restorative Dent. 2009 Feb;29(1): 59-67.

Covani U, Barone A, Cornelini R, Crespi R. Clinical outcome of implants placed immediately after implant removal. Journal of Periodontology, 2006, 77: 722-727.

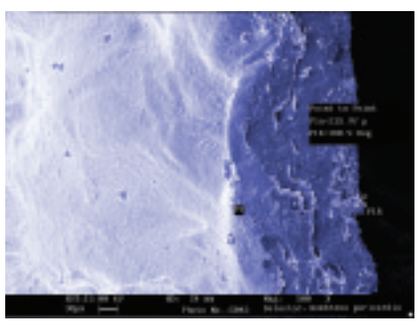
Covani U, Cornelini R, Barone A. Buccal bone augmentation around immediate implants with and without flap elevation: a modified approach. The International Journal of Oral and Maxillofacial Implants, 2008, 23: 841-846.

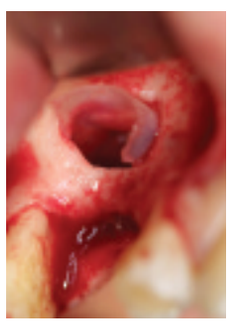
Nannmark U, Sennerby L. The bone tissue responses to prehydrated and collagenated cortico-cancellous porcine bone grafts. A study in rabbit maxillary defects. Clinical Implant Dentistry and Related Research, 2008, 10: 264-270.

Special

CE 0373

TISSUE OF ORIGIN	HETEROLOGOUS PERICARDIUM
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	TRANSLUCENT DRIED MEMBRANE
THICKNESS	EXTRA FINE
ESTIMATED RESORPTION TIME	ABOUT 40 DAYS
CATALOG LINKS	CASE REPORTS PAG. 35 - 40 - 41
PACKAGING	X-FINE mm 20x20 / X-FINE mm 30x30





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.

N.B.: if Special 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 applications

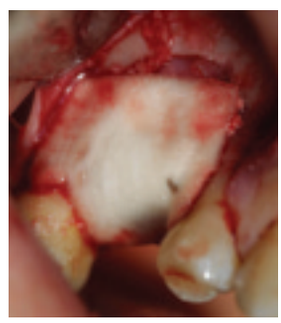
Periodontology: the Special membrane can be used as a separator of bone and soft tissues in treatment of gingival recessions.

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

Duo-Teck

CE 0373

TISSUE OF ORIGIN	EQUINE LYOPHILIZED COLLAGEN FELT AND EQUINE BONE
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	DRIED MEMBRANE COVERED WITH MICRONIZED BONE
THICKNESS	ABOUT 1 MM
ESTIMATED RESORPTION TIME	ABOUT 15 DAYS
PACKAGING	mm 20x20 IN BLISTER



Characteristics: Duo-Teck is a membrane 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 reposition of soft tissues.

Handling: Duo-Teck must be rehydrated with lukewarm physiological solution. Once it acquires the desired plasticity, it can be easily placed it 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 applications

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 be also used for closure of antrostomy, before replacement of the muco-gingival flap.

Derma

CE 0373

TISSUE OF ORIGIN	PORCINE DERMA
TISSUE COLLAGEN	PRESERVED
PHYSICAL FORM	DRIED MEMBRANE
THICKNESS	STANDARD (2-4 mm) - FINE (0,8-1 mm)
ESTIMATED RESORPTION TIME	STANDARD ABOUT 5 MONTHS - FINE ABOUT 3 MONTHS
PACKAGING AND CODES	STANDARD mm 20x20 - STANDARD mm 30x30 - FINE mm 25x25

Characteristics: obtained from derma of porcine origin, using an exclusive Tecnoss process, Derma membranes are completely resorbable.
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 applications

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

Implantology: protection of two wall defects graft.

Periodontology: space making in gingival recessions (x-fine model).

Publications and Case Reports

Publications

Arcuri C, Cecchetti F, Germano F, Motta A, Santacroce C. Clinical and histological study of a xenogenic substitute used as a filler in postextractive alveolus. Minerva Stomatologica, 2005, 54: 351-362.

Barone A, Aldini NN, Fini M, Giardino R, Calvo Guirado JL, Covani U. Xenograft versus extraction alone for ridge preservation after tooth removal: a clinical and histomorphometric study. Journal of Periodontology, 2008, 79: 1370-1377.

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.

Barone A, Cornelini R, Ciaglia R, Covani U. Implant placement in fresh extraction sockets and simultaneous osteotome sinus floor elevation: a case series. International Journal of Periodontics and Restorative Dentistry, 2008, 28:283-289.

Barone A, and Covani U. Maxillary alveolar ridge reconstruction with nonvascularized autogenous block bone: clinical results. Journal of Oral and Maxillofacial Surgery, 2007, 65: 2039-2046.

Barone A, Crespi R, Nicoli Aldini N, Fini M, Giardino R, Covani U. Maxillary sinus augmentation: histologic and histomorphometric analysis. The International Journal of Oral and Maxillofacial Implants, 2005, 20: 519-525.

Barone A, Marconcini S, Santini S and Covani U. Osteotomy and membrane elevation during the maxillary sinus augmentation procedure. A comparative study: piezoelectric device vs. conventional rotative instruments. Clinical Oral Implants Research, 2008, 19: 511-515.

Barone A, Santini S, Sbordone L, Crespi R, Covani U. A clinical study of the outcomes and complications associated with maxillary sinus augmentation. The International Journal of Oral and Maxillofacial Implants, 2006, 26: 81-85.

Calvo Guirado JL, Pardo Zamora G, Saez Yuguero MR. Ridge splitting technique in atrophic anterior maxilla with immediate implants, bone regeneration and immediate temporisation: a case report. Journal of the Irish Dental Association, 2007, 53: 187-190.

Cardaropoli D, Cardaropoli G. Preservation of the postextraction alveolar ridge: a clinical and histologic study. The International Journal of Periodontics and Restorative Dentistry, 2008, 28: 469-477.

Cardaropoli D, Cardaropoli G. Healing of gingival recessions using a collagen membrane with a demineralized xenograft: a randomized controlled clinical trial. International Journal of Periodontics and Restorative Dentistry, 2009, 29: 59-67.

Covani U, Barone A, Cornelini R, Crespi R. Clinical outcome of implants placed immediately after implant removal. Journal of Periodontology, 2006, 77: 722-727.

Covani U, Cornelini R, Barone A. Buccal bone augmentation around immediate implants with and without flap elevation: a modified approach. The International Journal of Oral and Maxillofacial Implants, 2008, 23: 841-846.

Nannmark U, Sennerby L. The bone tissue responses to prehydrated and collagenated cortico-cancellous porcine bone grafts. A study in rabbit maxillary defects. Clinical Implant Dentistry and Related Research, 2008, 10: 264-270.

Orsini G, Scarano A, Piattelli M, Piccirilli M, Caputi S, Piattelli A. Histological and Ultrastructural Analysis of Regenerated Bone in Maxillary Sinus Augmentation Using a Porcine Bone-Derived Biomaterial. Journal of Periodontology, 2006, 77: 1984-1990.

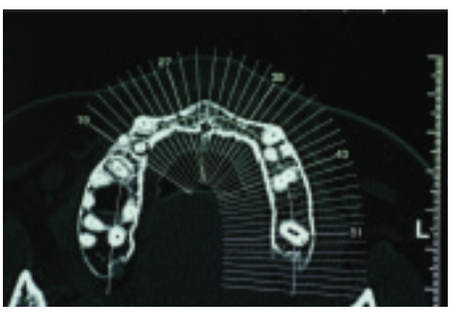
Rinna C, Ungari C, Saltarel A, Cassoni A, Reale G. Clinical notes. Orbital Floor Restoration. The Journal of Craniofacial Surgery, 2005, 16: 968-972.

Trubiani O, Scarano A, Orsini G, Di Iorio D, D'Arcangelo C, Piccirilli M, Sigismondo M, Caputi S. The performance of human periodontal ligament mesenchymal stem cells on xenogenic biomaterials. Journal of Immunopathology and Pharmacology, 2007, 20: 89-93.

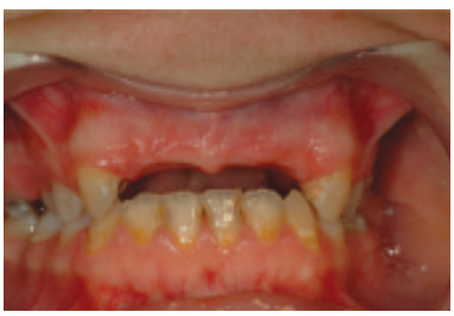
Vozza I, Scarano A, Quaranta M. Clinical and histological study on maxillary sinus lift and filling with collagenized pig bone. Italian Journal of Osteointegration, 2004, 4: 19-23.

Bone regeneration after ridge splitting and immediate implant-prosthetic placement

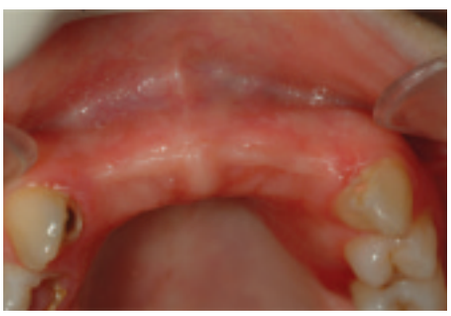
information about patient
> sex: female
> age: 23



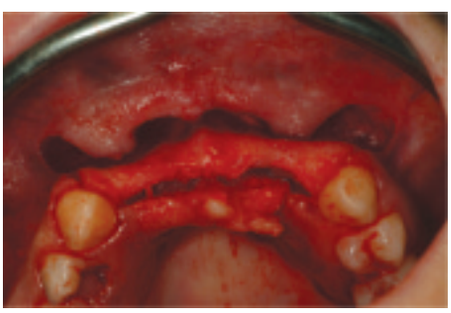
Initial TC that shows anterior bone resorption.



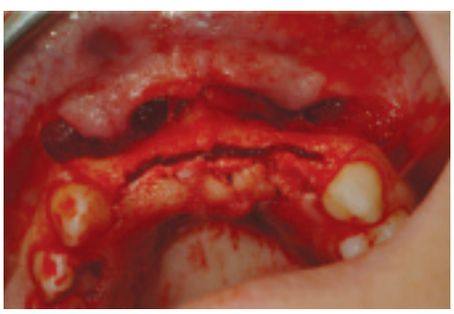
Initial intraoral image showing the tissue deficit in the crown-apical sense.



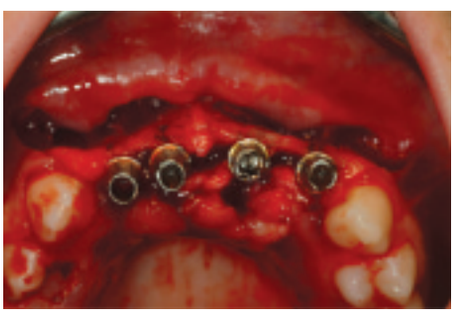
Initial occlusal image showing the tissue deficit in the buccal-lingual sense.



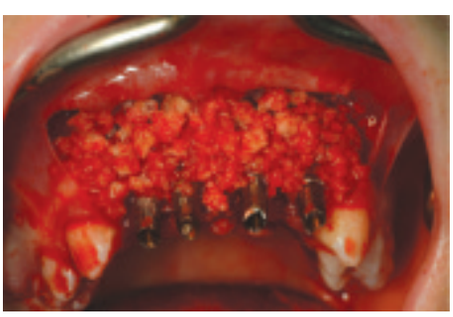
Intraoperative image showing bone resorption.



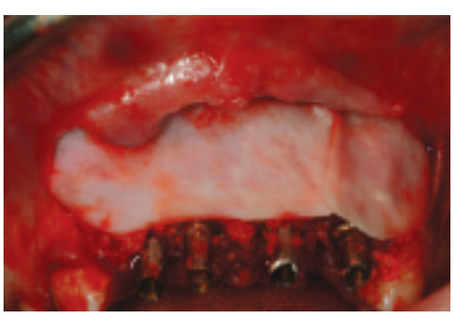
Intraoperative image of anterior bone ridge splitting.



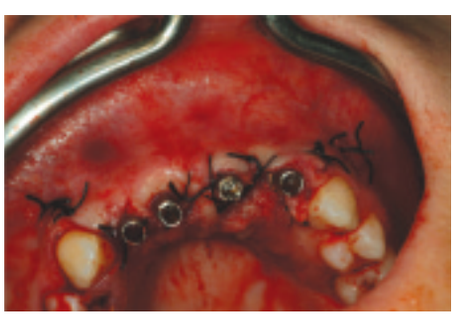
Intraoperative image after placement of the fixtures in zones 1.2, 1.1, 2.1 and 2.2.



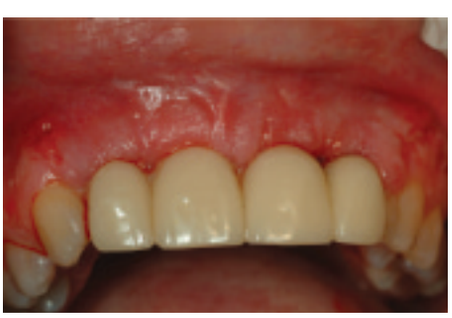
Intraoperative image showing buccal bone defects grafted with OsteoBiol Gen-Os and Putty mix.



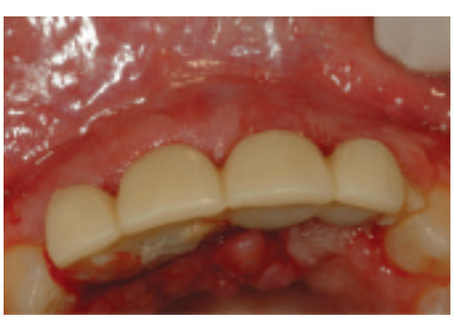
OsteoBiol Evolution membrane properly shaped in place for bone regeneration covering and protection.



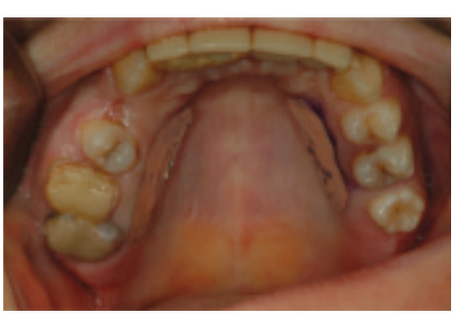
Implant abutments immediate placement and flap suture.



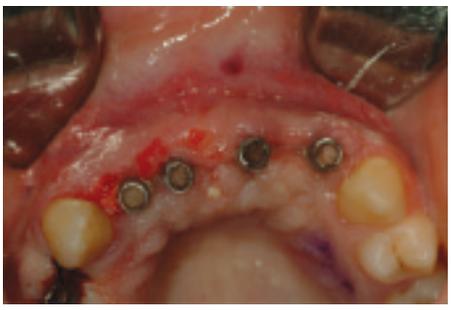
Provisional crowns in place after 15 days from bone regeneration surgery.



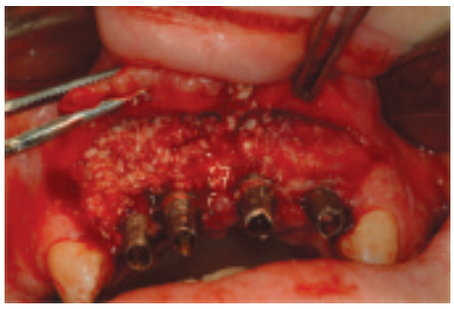
Intraoperative occlusal image with provisional crowns in place: it is possible to appreciate the buccal bone augmentation.



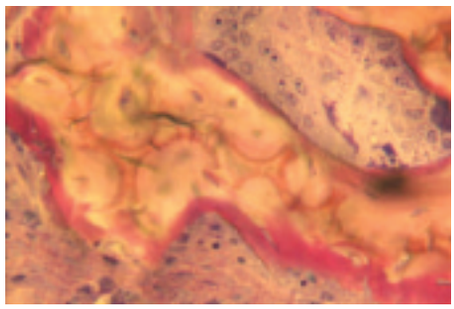
After 6 months, a connective tissue graft is needed.



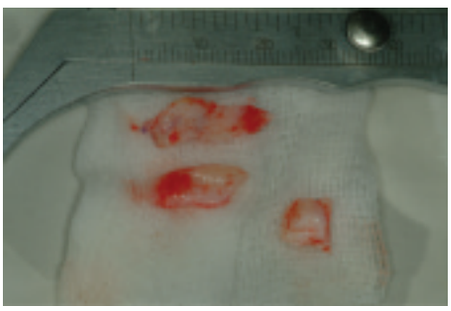
Intraoperative image showing the new bone regenerated ridge with abutments in place (re-entry after 6 months).



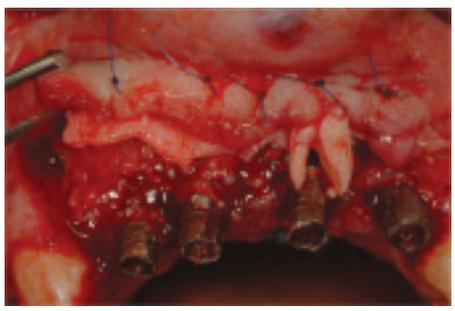
Intraoperative image showing the integration of OsteoBiol Gen-Os and Putty mix with regenerated bone.



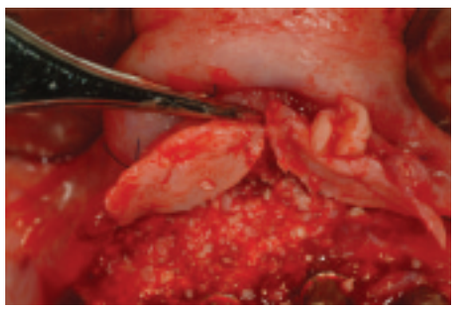
Histology EE 200x on biopsy in the site of bone regeneration surgery: diagnosis of trabecular bone fragment, which is 80 % woven bone type and 20 % lamellar bone.



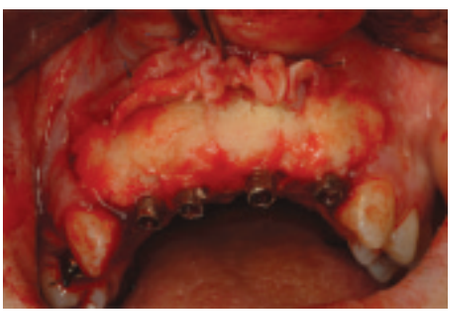
Connective tissue grafts after harvesting.



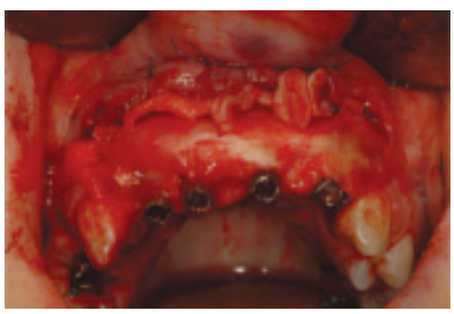
Intraoperative image of second surgery showing connective tissue graft in place.



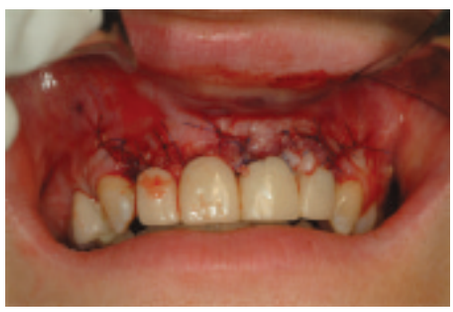
Connective tissue was placed under buccal flap.



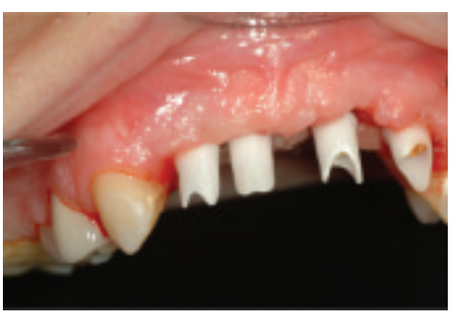
The alveolar crest was further augmented in buccal sense by grafting OsteoBiol Putty.



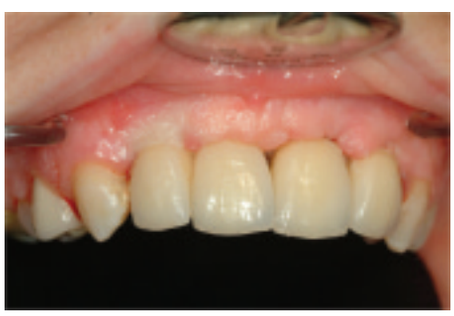
OsteoBiol Special membrane properly shaped was placed as a protection for the grafting material.



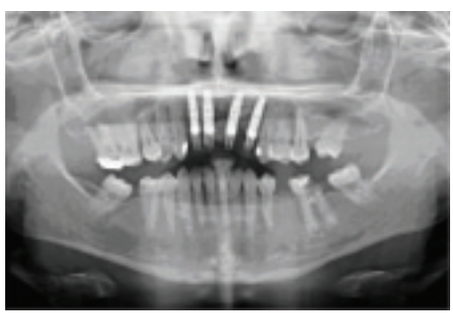
Flap suture and immediate placement of provisional crowns.



Zirconium abutments screwed into internal connection implants.



Definitive ceramic crowns: prosthetic loading



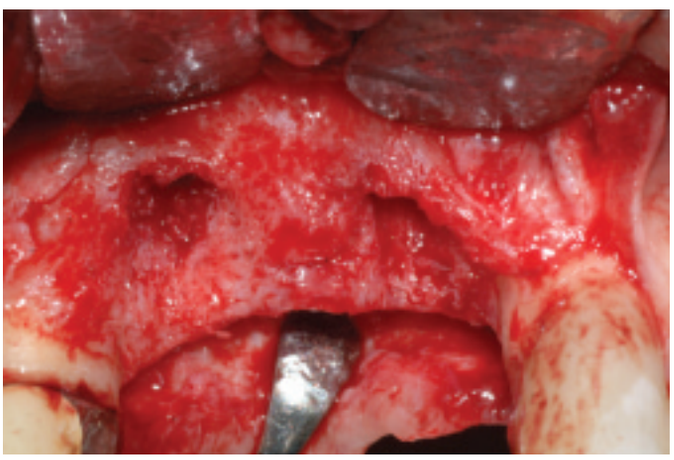
Control Rx OPT image.

Documentation provided by Prof. Dr. Jose Luis Calvo Guirado

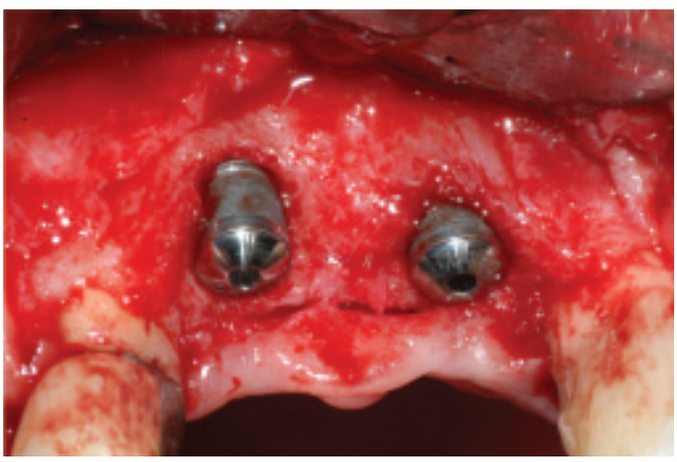
Professor at University of Murcia (Spain) - email: josecalvog@ono.com

Peri-implant bone regeneration on 1.1 e 2.1

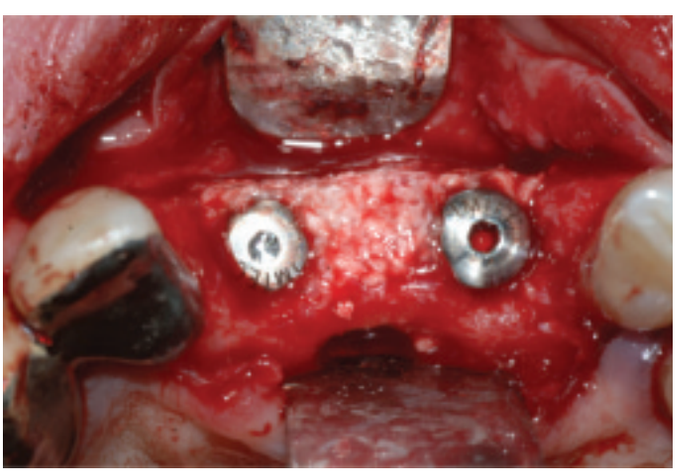
information about patient
> sex: male
> age: 60



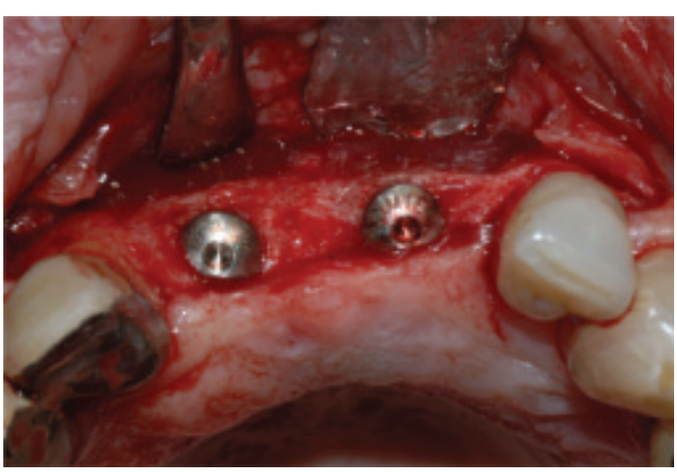
Alveolar bone crest with defects derived from extraction of 1.1 and 2.1 teeth executed two months before.



Placement of two implants: it is possible to appreciate residual buccal dehiscence on both implants.



Reconstruction of bone defects by grafting OsteoBiol Gen-Os and fibrin glue mixture

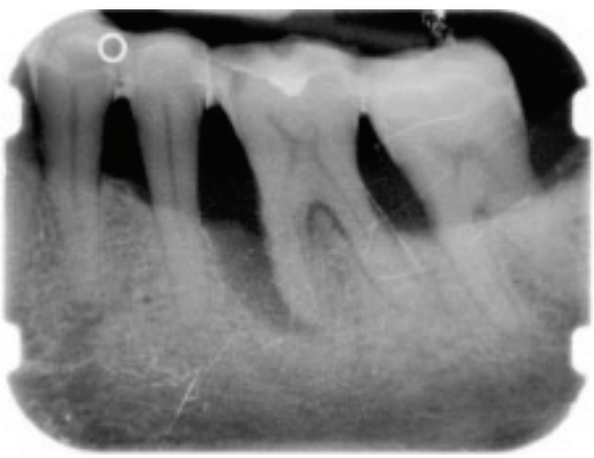


Surgical re-entry after six months shows the complete regeneration of bone defects.

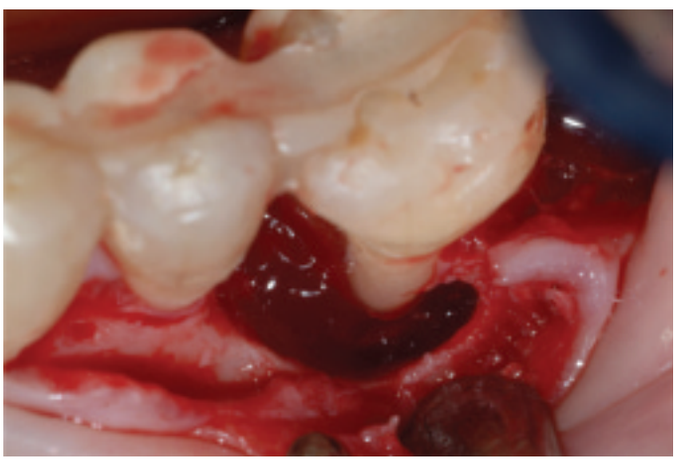
Documentation provided by Dr. Roberto Abundo and Dr. Giuseppe Corrente
Adjunct Clinical Professors in Periodontics – University of Pennsylvania and Private Practitioners in Turin (Italy)
e-mail: info@sicor-corsi.com

Periodontal regeneration on 3.6

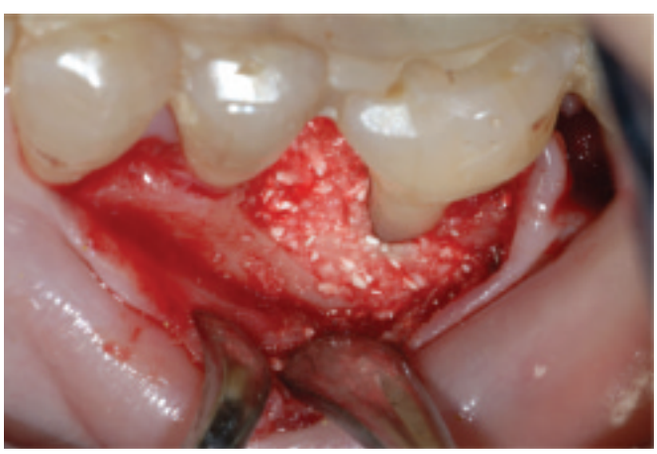
information about patient > sex: female
> age: 59



Pre-operative peri-apical x-ray: it is possible to appreciate the deep intrabony defect on the mesial root of 3.6 tooth.

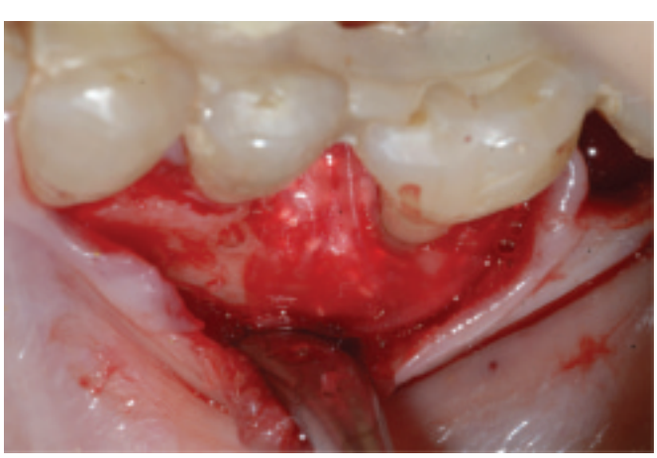


Intra-operative image of intrabony defect.

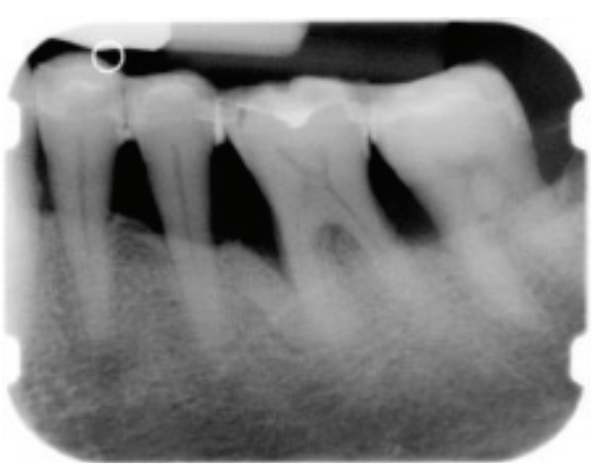


Filling of defect with OsteoBiol Gen-Os.

X-Fine Evolution membrane properly shaped.



Placement of shaped membrane to protect the defect and to cover the grafted material.



Control peri-apical x-ray after 12 months from surgery: the defect is completely filled.

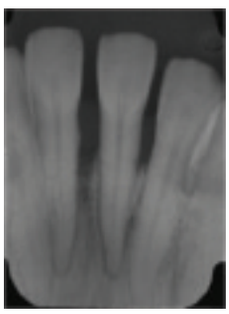
Documentation provided by Dr Roberto Abundo and Dr. Giuseppe Corrente

Adjunct Clinical Professors in Periodontics – University of Pennsylvania and Private Practitioners in Turin (Italy)

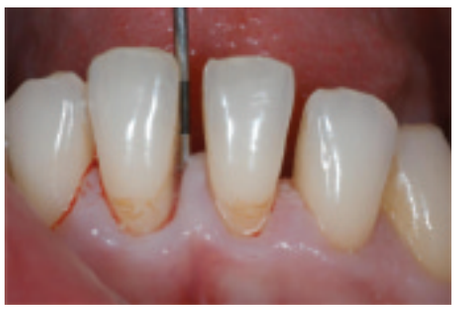
e-mail: info@sicor-corsi.com

Treatment of a deep intra-bony defect mesial on 4.1

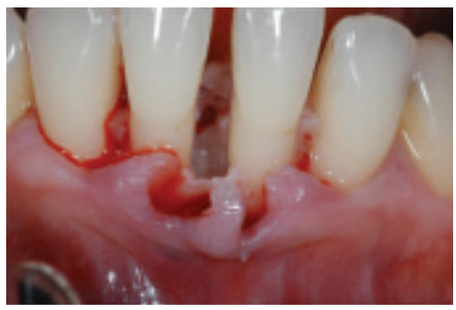
information about patient
> sex: female
> age: 39



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

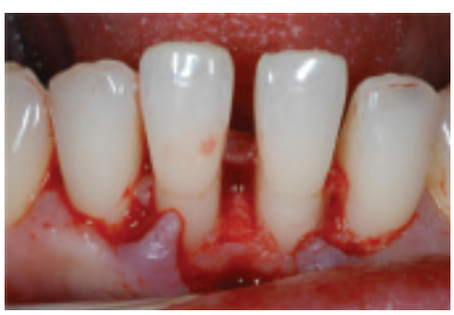


The bone defect is 7 mm deep.

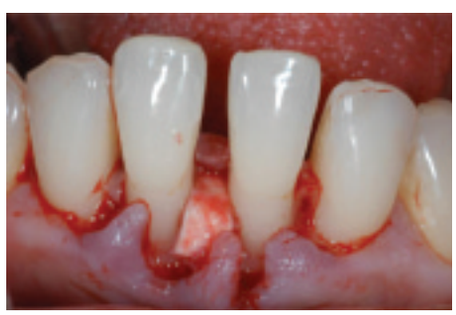


Intraoperative image showing the two-wall defect after cleansing of radicular surfaces.

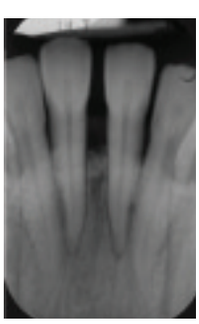
OsteoBiol Gel 40.



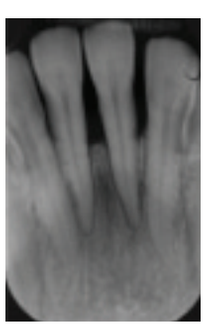
The defect was grafted with OsteoBiol Gel 40.



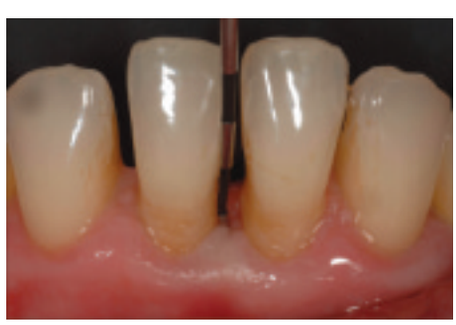
A properly shaped OsteoBiol Evolution membrane was placed to contain and protect the particulate grafting material.



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



Control endoral x-ray after 1 year from treatment: radiographically the biomaterial is bio-integrated and identical to natural bone.



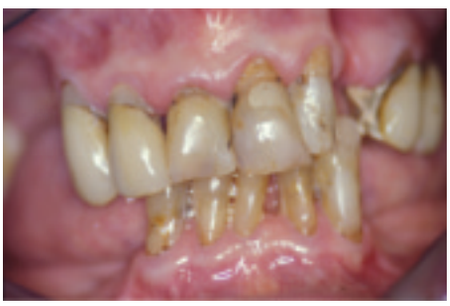
The probing depth was reduced to 2 mm.

Documentation provided by Dr. Walter Rao

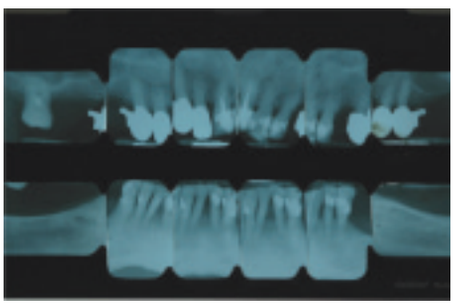
Private practitioner in Pavia (Italy) - tel. +39 0382 530730 - email: rao@venus.it

Maxillary sinus lift with crestal access grafting OsteoBiol Gel 40: 18 months follow-up

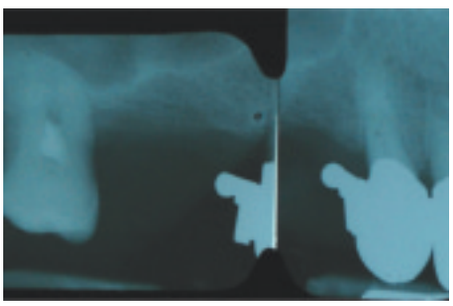
information about patient
> sex: female
> age: 64



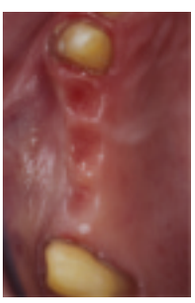
Initial intraoral image.



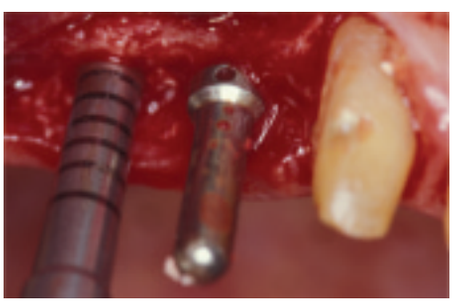
Initial endoral x-rays showing severe bone deficits both at maxillary and mandibular levels.



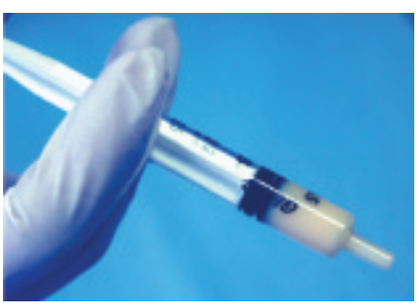
Detail of endoral x-ray (ERSE) showing the severe maxillary deficit.



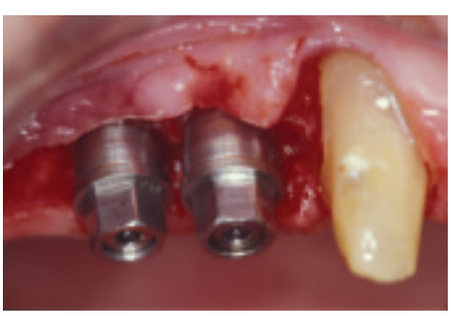
Pre-treatment clinical image after prosthesis removal.



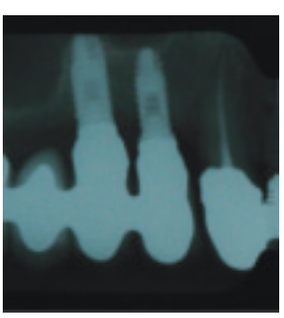
Maxillary sinus lift with crestal access: osteotomy before grafting with OsteoBiol Gel 40.



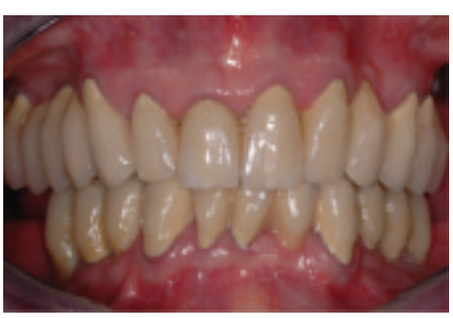
OsteoBiol Gel 40.



Implant placement.



Final endoral x-ray (re-entry 1 year after surgery and 8 months after implant loading).



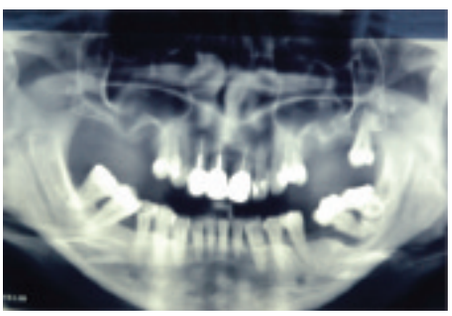
Intraoral image after 1 year from surgery (8 months after implant loading).

Documentation provided by Dr. Roberto Rossi

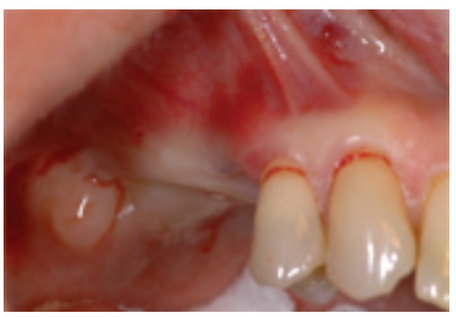
Private practitioner in Genova (Italy) - tel. +39 010 5958853 - email: drrossi@mac.com

Bilateral sinus lift with lateral access

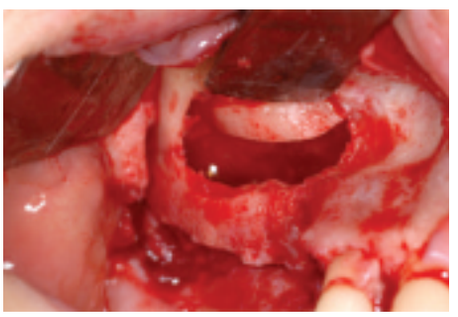
information about patient
> sex: female
> age: 48



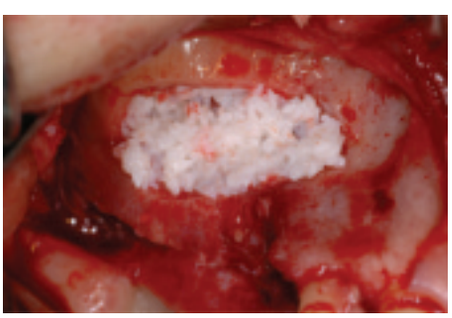
Initial x-ray OPT image showing a severe maxillary atrophy in posterior region.



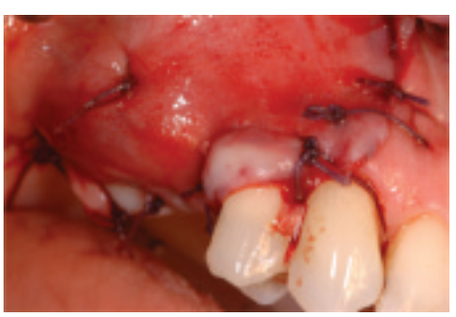
Pre-operative intraoral image, right sector.



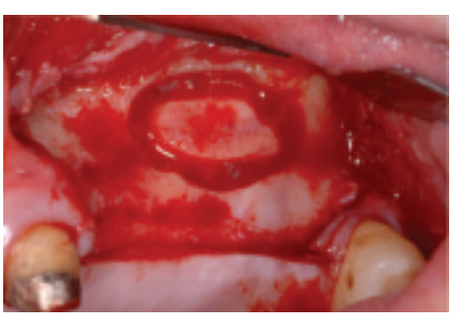
Osteotomy to access the right maxillary sinus.



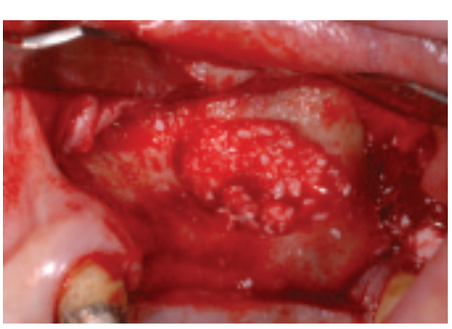
Intraoral image showing the right maxillary sinus filled with OsteoBiol mp3.



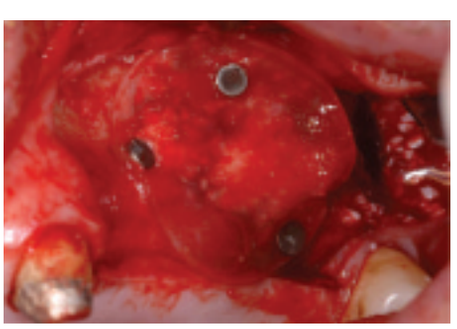
Suture of mucoperiosteal flap.



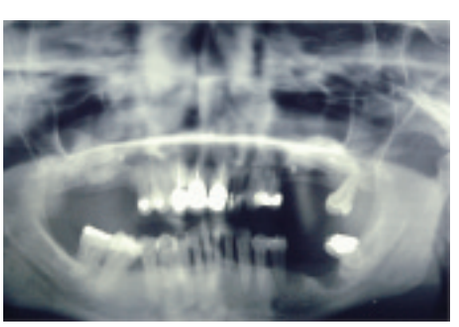
Osteotomy to access the left maxillary sinus.



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



A properly shaped OsteoBiol Special membrane was placed as left maxillary sinus antrostomy covering.

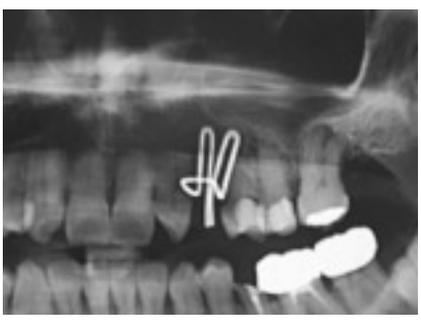


X-ray image after 8 months from sinus lift surgery.

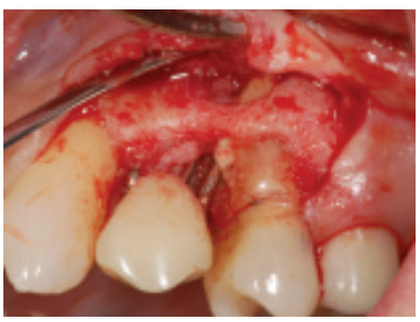
Documentation provided by Dr. Antonio Barone and Prof. Ugo Covani
Odontostomatology Department, "Ospedale della Versilia", Lido di Camaiore, Lucca (Italy)
e-mail: barosurg@libero.it

Lateral augmentation: self containing area

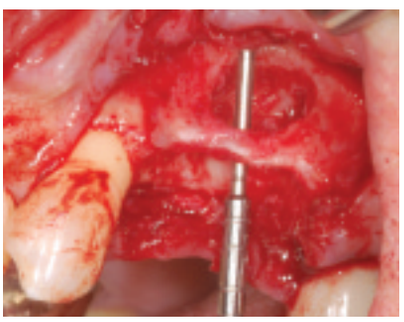
information about patient > sex: female
> age: 53



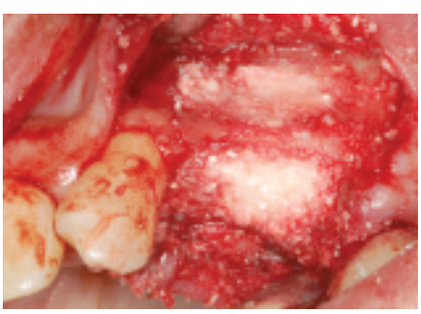
53 year old female patient presenting with failing "paper clip" implant



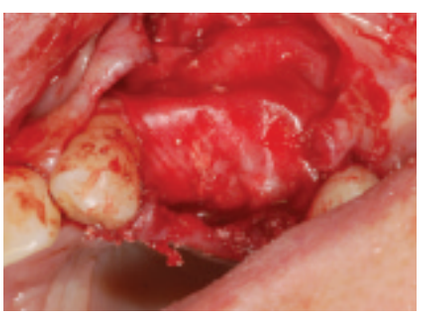
Exposure of the area showing resorption around implant and 2° premolar.



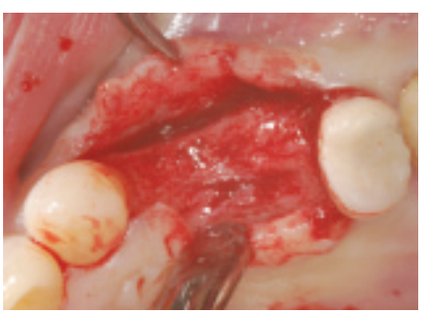
Showing defect after removal of implant and premolar



Defect filled with Gen-Os graft mixed with Gel 0.

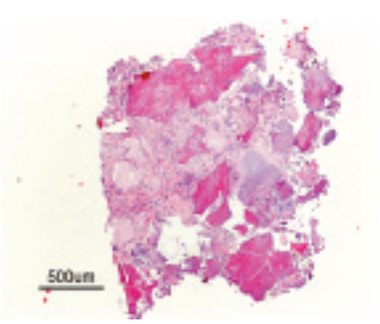


Area covered by an Evolution membrane.

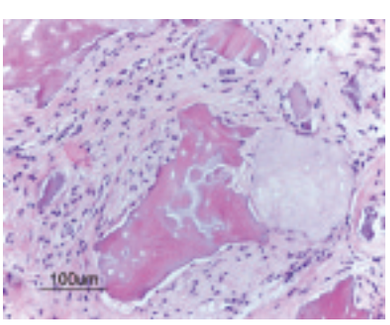


Re-entery after 6 months showing good regereration of the defect

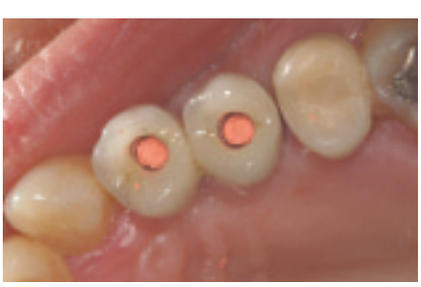
Biopsy taken from one implant site showing viable bone tissue.



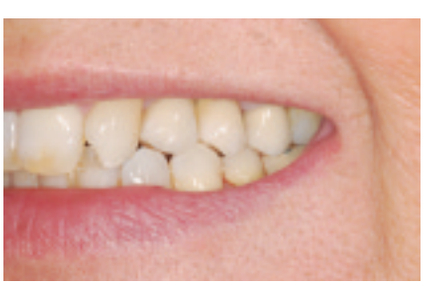
Histological section of decalcified specimen showing a mixture of new bone, loose connective tissue and Gen-Os particles.



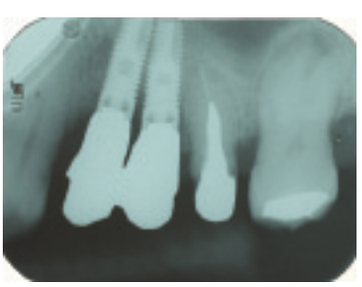
Close up showing new bone formation and subsequent resorption of a Gen-Os particle.



Occlusal view of final construction before filling of screw holes.



Buccal view of final construction.

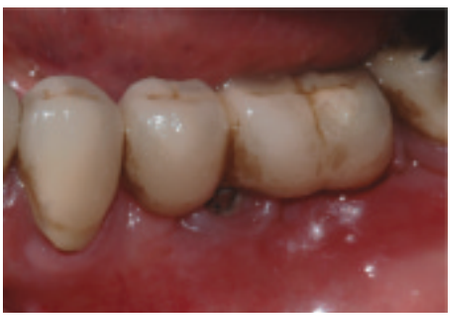


Radiograph of final construction.

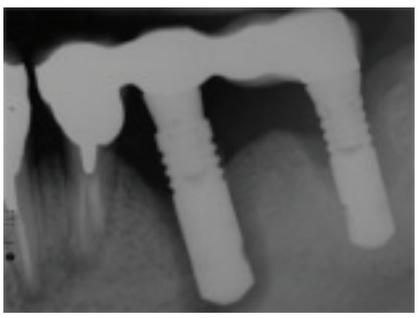
Documentation provided by Drs P. Andersson, D. Verrocchi, R. Viinamäki and L. Sennerby
Private practitioners in Fiera di Primiero, Italy – E-mail: andersson_verrocchi@virgilio.it
Histology provided by Prof. Ulf Nannmark, Dept Anatomy and Cell Biology, Göteborg University, Sweden

Treatment of bone defects due to peri-implantitis in 3.5-3.6 zone and implant rehabilitation

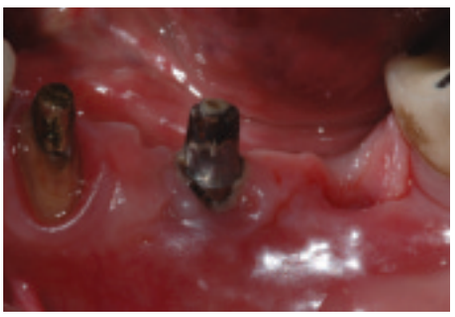
information about patient
> sex: male
> age: 54



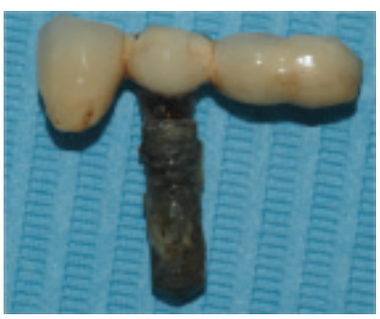
Initial intraoral image: it is possible to appreciate severe inflammation of the soft tissues. The prosthesis is subjected to considerable mobility.



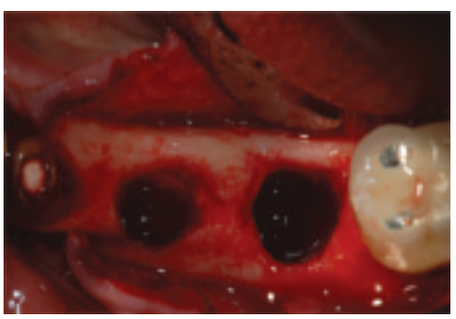
Endoral x-ray image: the diagnosis of peri-implantitis in 3.5-3.6 zone was confirmed.



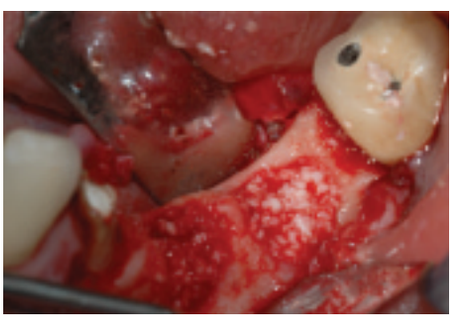
Intraoral image after prosthesis removal.



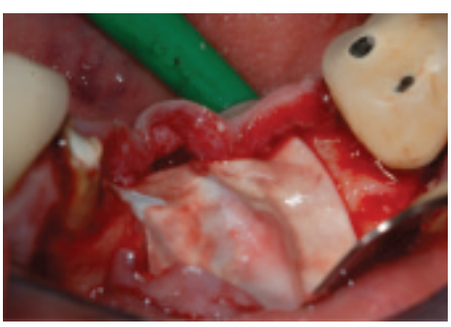
Removed prosthesis and implant with infected surface.



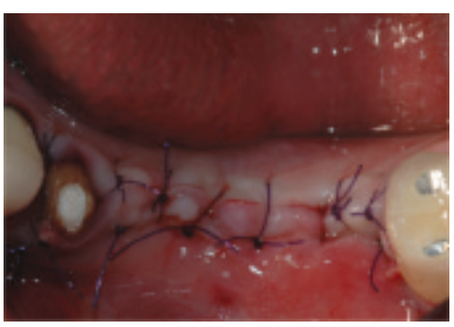
Intraoral image showing the residual bone defects: in particular 3.5 site was defective of all buccal coronal half.



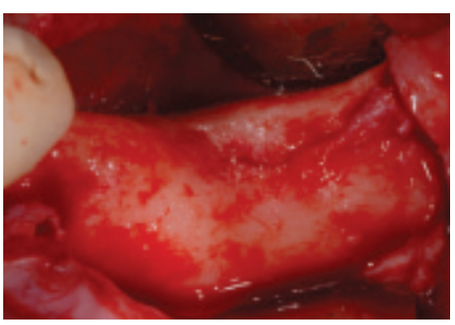
Defects were grafted with OsteoBiol Gen-Os.



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

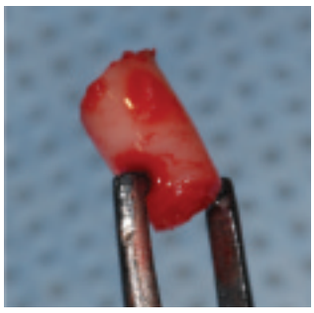


Soft tissues were repositioned and sutured.

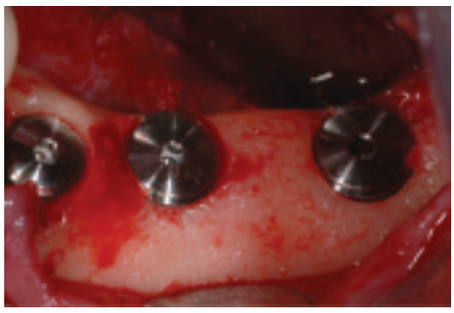


Intraoral image of second surgical phase (re-entry after 8 months). It is possible to appreciate a complete regeneration of pre-existent bone defects.

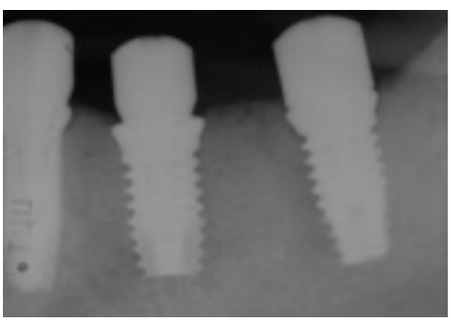
The endoral x-ray image confirms a volume of bone tissue adequate to implant rehabilitation.



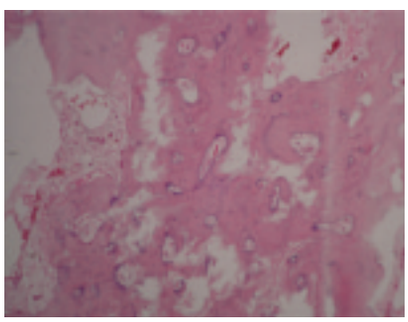
Detail of biopsy sample of regenerated bone drawn by a trephine bur.

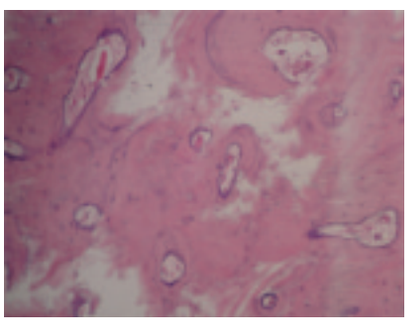


Placement of 3 implants on the base of a monophasic protocol.

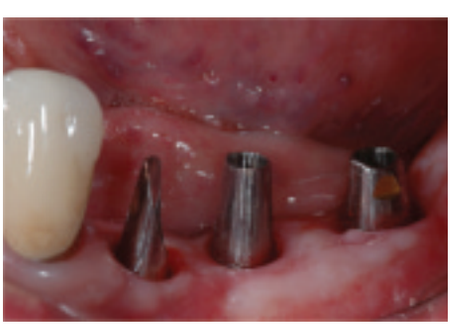


Endoral x-ray image confirming the correct implant positioning. The technique of "Platform Switching" was applied in order to preserve the crestal bone.

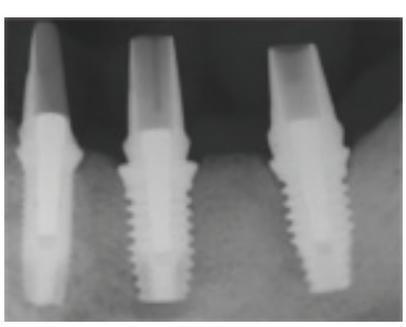




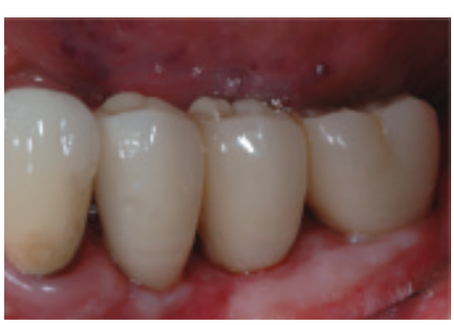
EE histology (40X and 400X magnification) on biopsy performed during implant placement surgery (Prof. Navone, Department of Pathological Anatomy, University of Torino): diagnosis of mature lamellar bone and neo-formed bone, with no trace of necrosis or inflammation (residual biomaterial in grafting site: 10%).



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



Endoral x-ray image. It is possible to proceed with "Platform Switching".



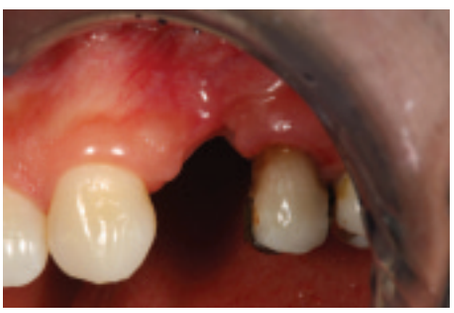
Placement of 3 provisional acrylic crowns connected together. The final restoration with definitive prosthesis was scheduled after 3 months.

Documentation provided by Dr. Roberto Cocchetto

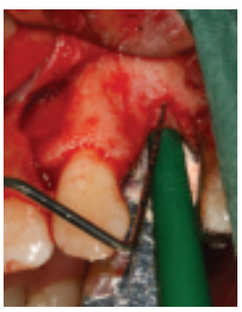
Private practitioner in Zevio (VR) (Italy) Tel. +39 045 7850948 - email: rcocchetto@yahoo.it

Augmentation beyond the skeletal envelope

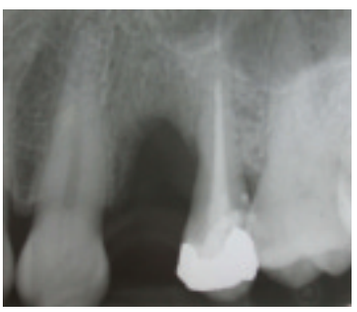
information about patient > sex: female
> age: 33



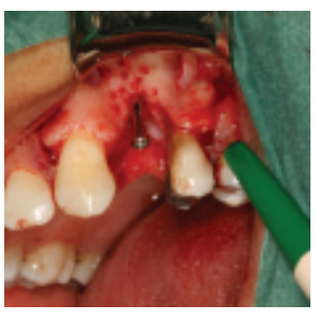
Front vision of bone and soft tissue defect



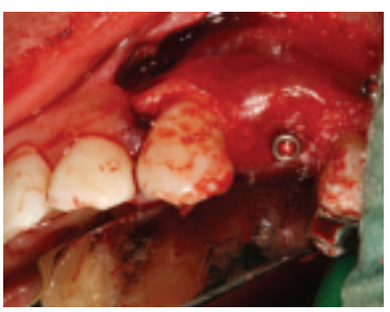
Initial intraoral image of crestal defect



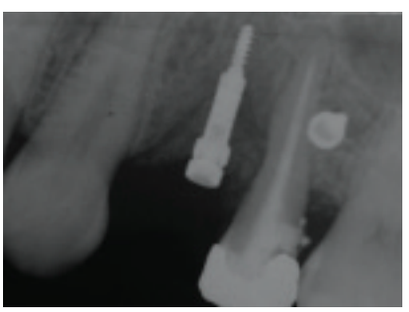
Initial x-ray image showing the extension of crestal defect



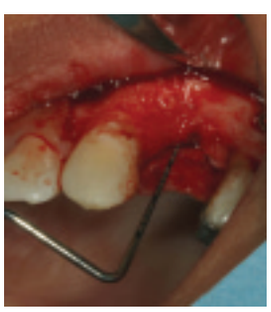
Positioning of a space maintaining pin.



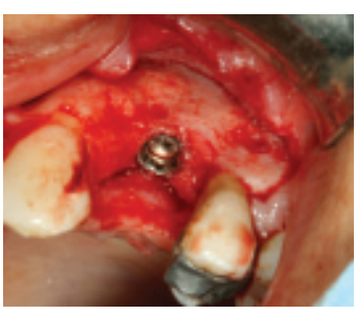
Protection of Gen-Os graft with OsteoBiol Cortical Lamina fixed with osteosynthesis screws.



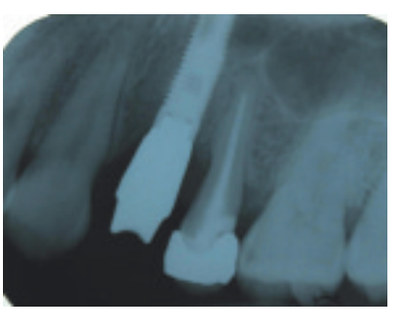
Post operative x-ray.



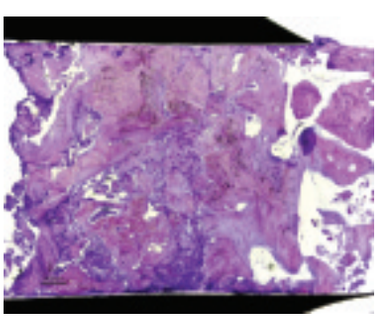
Surgical re-entry after 6 months shows a good regeneration of the pre-existing bone deficit.

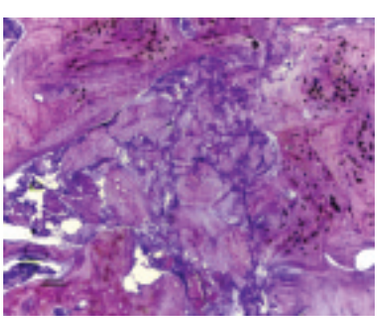


Implant placement.

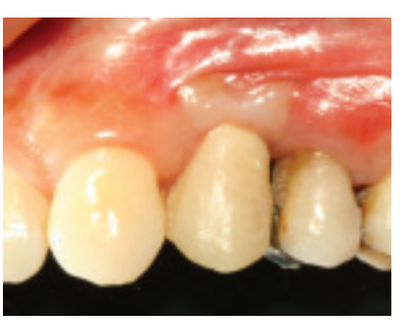


Final x-ray: prosthetic rehabilitation 10 months after surgery.





Histology after 6 months of healing shows an admixture of new bone and incorporated Gen-Os particles. (Prof.Lars Sennerby, Department of Biomaterials, Institute for Clinical Sciences, Göteborg University.)

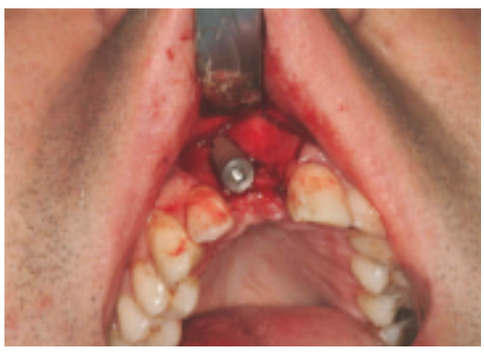


Temporary crown at 10 months.

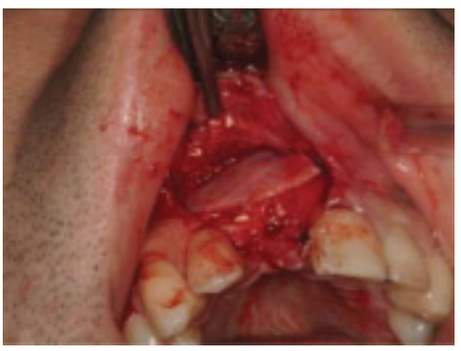
Documentation provided by Dr.Luca Giovanni Maria Pagliani
Private practitioner in Milano - tel. +39 02 58309761 - email: luca.pagliani@yahoo.it

Peri-implant regeneration on 1.1

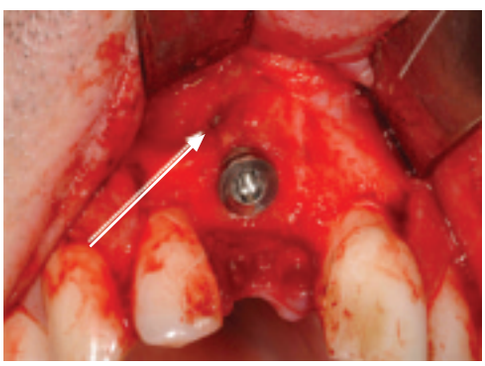
information about patient
> sex: male
> age: 41



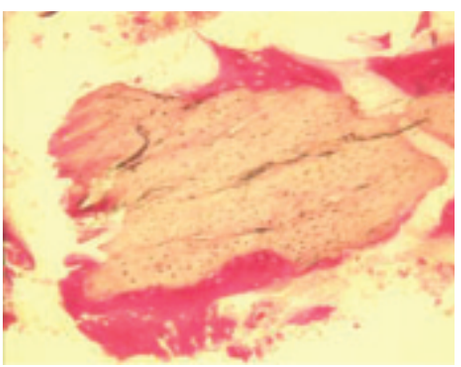
Bone defect consequent to traumatic avulsion of 1.1.



Peri-implant defect grafted with OsteoBiol Gen-Os and protected with OsteoBiol Soft Cortical Lamina.



After 4 months, it is possible to appreciate the presence of regenerated bone. During this surgical procedure, a biopsy sample was collected in the zone indicated by arrow.

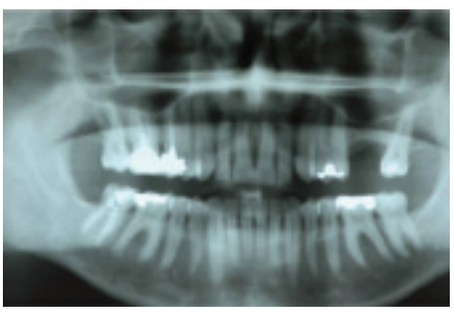


The histology analysis demonstrated the presence of neo-formed bone surrounding OsteoBiol Gen-Os granule (courtesy of Prof. Adriano Piattelli).

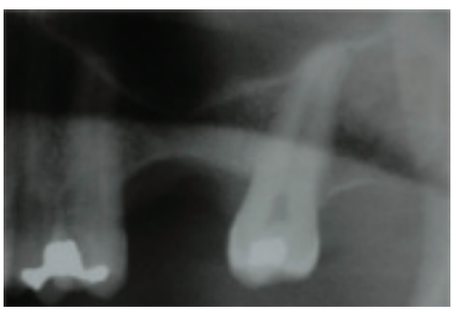
Documentation provided by Prof. Antonio Scarano
Researcher at "G. D'Annunzio" University, Chieti (Italy) Tel. +39 0871 3554084 - email: ascarano@unich.it

Maxillary sinus lift and simultaneous implant placement

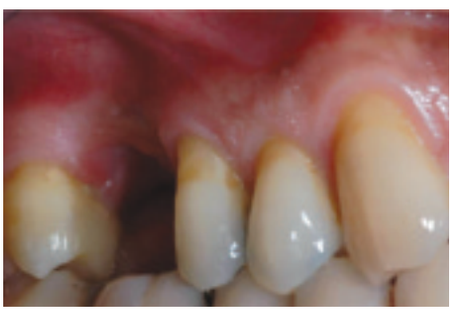
information about patient
> sex: male
> age: 40



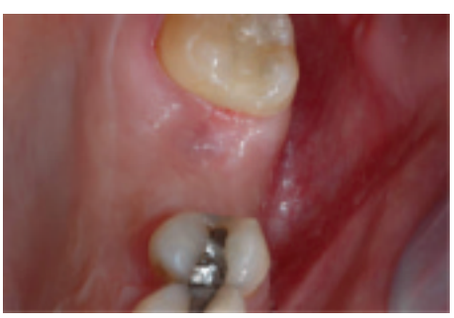
Initial x-ray OPT image showing a severe maxillary atrophy in right posterior region.



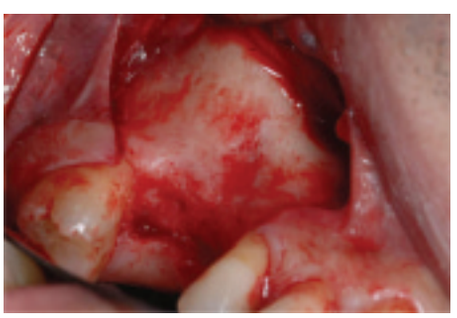
Radiographic detail of bone defect.



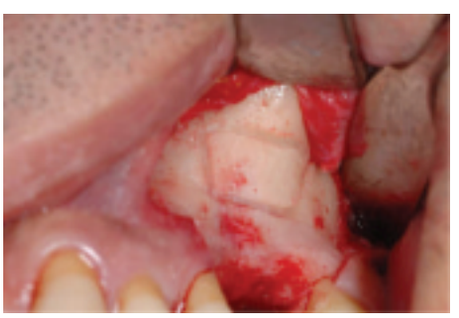
Pre-operative intraoral image showing the tissue deficit in crown-apical sense.



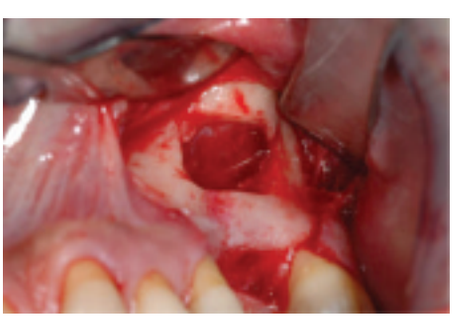
Intra-operative occlusal image evidencing the buccal-lingual sense.



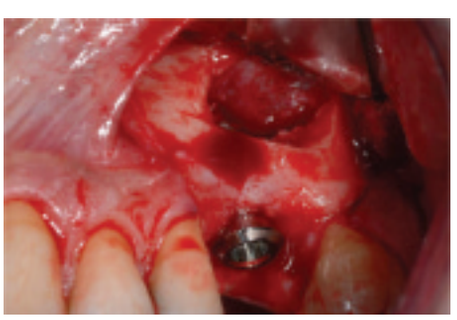
Surgical preparation of sinus access osteotomy: elevation of a full-thickness flap.



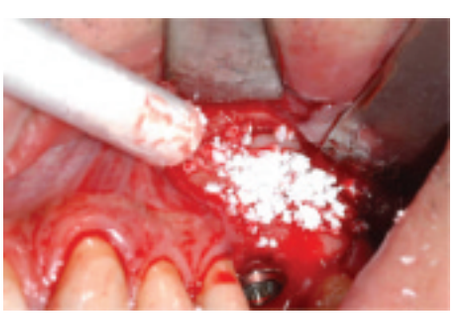
Osteotomy to access the right maxillary sinus.



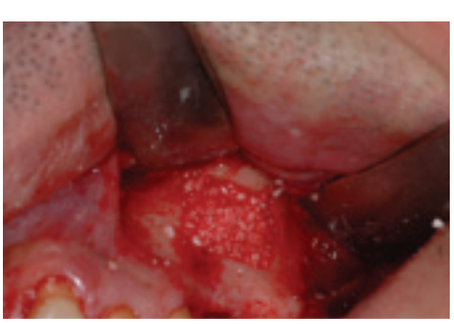
Intra-operative image showing the perfect integrity of Schneider membrane.



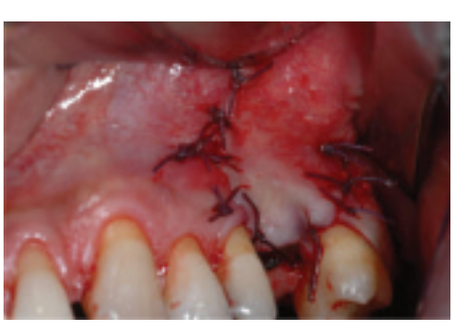
Simultaneous placement of an implant.



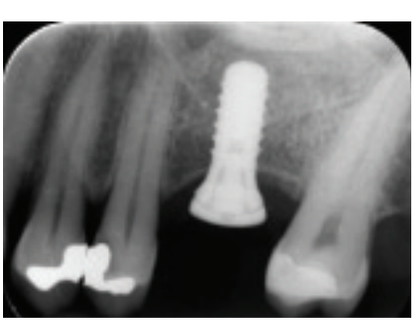
Intra-oral image showing the right maxillary sinus filled with OsteoBiol mp3.



The grafted material was perfectly stabilized with blood clot.



Flap suture.

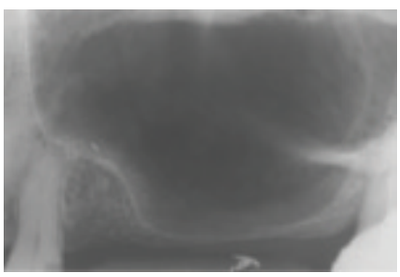


Control x-ray after 8 weeks from surgery, evidencing the good tissue response.

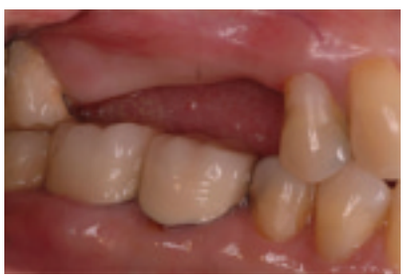
Documentation provided by Prof. Claudio Arcuri
Professor at Tor Vergata University, Rome and private practitioner in Rome (Italy)
tel. +39 06 5412415 - email: arcuri@med.uniroma2.it

Severe crestal atrophy rehabilitated with maxillary sinus lift

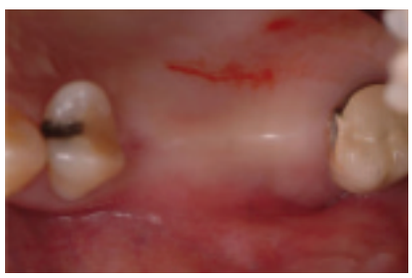
information about patient
> sex: female
> age: 70



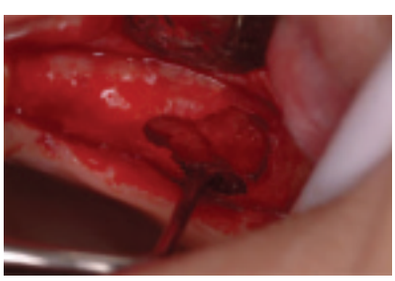
Pre-operative endoral x-ray showing a severe crestal atrophy and a wide pneumatization of maxillary sinus.



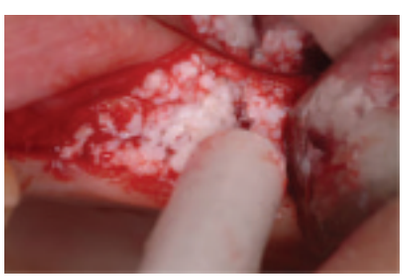
Initial intraoral image: view of bone defect in coronal-apical sense.



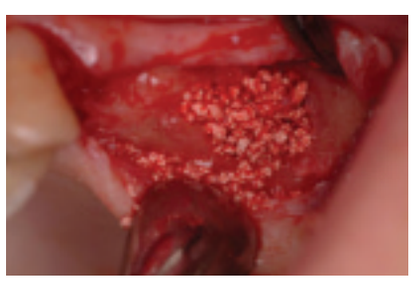
View of bone defect in buccal-lingual sense.



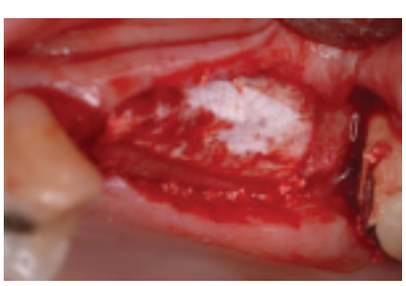
The residual crest thickness of 2 mm only prevented lateral access sinus lift procedure. A window crestal approach was chosen. Image showing the sinus membrane dissection.



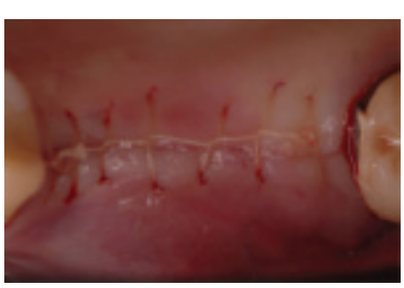
Intra-operative image showing the defect filled with OsteoBiol mp3.



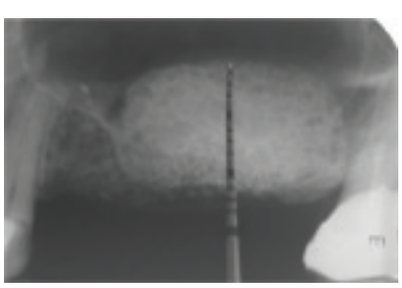
The grafted biomaterial was perfectly stabilized with blood clot.



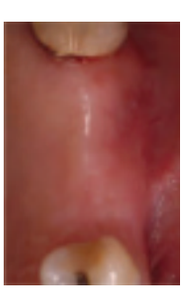
The graft was covered and protected with a properly shaped OsteoBiol Evolution membrane.



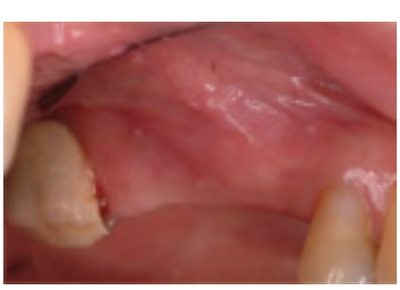
Flap suture.



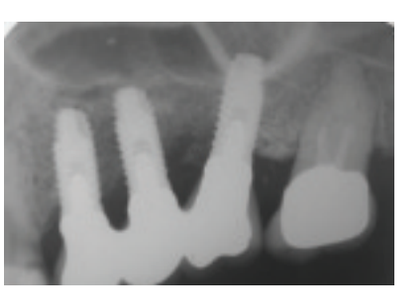
Control endoral x-ray immediately after surgery: it is possible to appreciate a bone defect filling of 11 mm.



Intraoral image after 6 months from grafting.



Coronal-apical view showing the good rehabilitation of crestal bone defect.



Final endoral x-ray.

Documentation provided by Dr. Roberto Rossi
Private practitioner in Genova (Italy) - tel. +39 010 5958853 - email: drrossi@mac.com
and Dr. Regina Isabel Santos-Morales
Practitioner in Makati City (Philippines) – tel. +6328932813

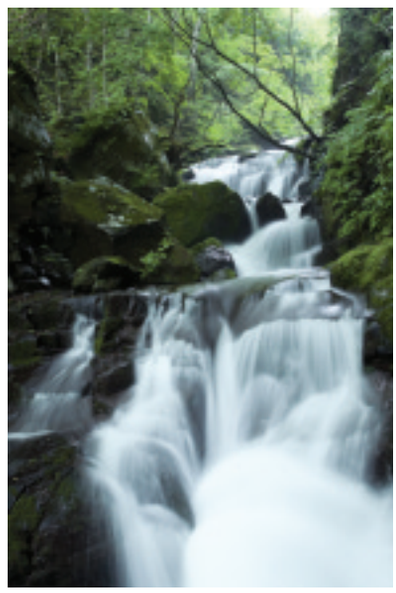
Certifications and laboratory analyses

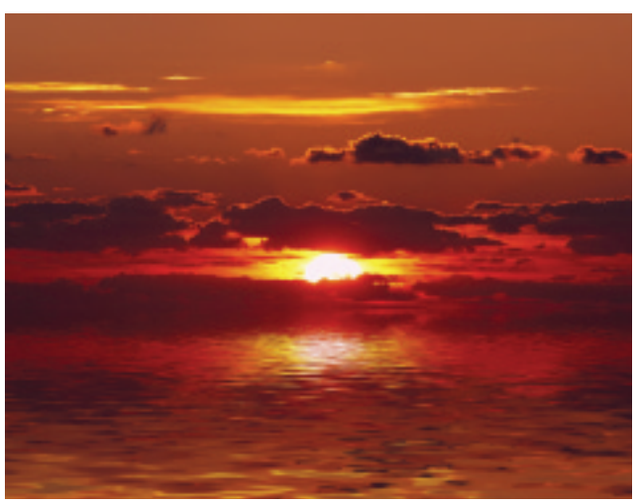
OsteoBiol®: from nature to man

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 under a new technology that conditions animal tissues in order to neutralize the antigenic components present in animal bony tissue (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.





The raw material from which Tecnoss obtains its products comes from Italian animal farms, selected and certified under the strict control of the **Italian National Veterinary Health Service**.

OsteoBiol biomaterials are manufactured in conformity with 93/42/CEE (D.Lgs 47/97 and next modifications), 2003/32/CE (D.Lgs 67/2005) European rules. Italian Istituto Superiore di Sanità (ISS) is the Notified Body (0373) for CE mark of Tecnoss Medical Devices.

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.

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 production.

Important notice: all OsteoBiol products contain collagen; use is thus advised against for subjects with allergic reaction to this substance.

CERTIFICATE

The Certification Body TÜV Rheinland Group

certifies, in accordance with the "TÜV Rheinland Group procedures, that the Company

TECNOSS S.r.l.

P.zza Papa Giovanni XXIII, 2, I - 10094 Giaveno (TO)

Production site: Via Monte Nero 13, I – 10050 Cozzo (TO)

has established and applies a quality management system for the following scope:

Manufacturing and sale of bone substitutes, membranes and collagen felts for bone and tissue regeneration. EA 19

Through an Audit, Report No. 11 50810, proof has been furnished that the requirements according to the standard

UNI EN ISO 13485:2004 and of the Document SINCERT RT-28

are fulfilled.

Please refer to the Quality Manual for the details about the exclusions with respect to the requirements of the standard.

Certificate Registration No. 39 05 1150010.

The validity of this Certificate is subject to periodical annual / semiannual surveillance and to a complete review of the management system of the Company every three years.

Milan, 2007-11-15.

SINCERT

www.tuv.com

TÜV Rheinland Group

Istituto Superiore di Sanità

Organismo Notificato N° 0373

ATTESTATO DI CERTIFICAZIONE CE

secondo l'Allegato III della Direttiva Europea 93/42/CEE
(recepita con il Decreto Legislativo n. 46 del 24/2/1997)

CE CERTIFICATION DOCUMENT
according to Annex III of EC Directive 93/42/EEC
enforced by the Decreto Legislativo n. 46 issued on 24/2/1997)

L'Istituto Superiore di Sanità, Organismo Notificato n° 0373, attesta che il dispositivo medico
The Istituto Superiore di Sanità, Notified Body n° 0373, certifies that the medical device

Linea OsteoBiol
Matrice ossea e collagenica (vedi allegato)

fabbricato da
manufactured by

TECNOSS S.r.l.

soddisfa ai requisiti applicabili della Direttiva Europea 93/42/CEE.
satisfies the requirements set out in EC Directive 93/42/EEC.

Certificato n° / Certificate no.	867 CTP 230	Addendum n° / addendum no.	//	Rilasciato il / issued on	26.08.2005

Il presente certificato ha la validità massima di cinque anni dalla data del rilascio.
This certificate expires five years after the date of issue.

Il Direttore del Dipartimento
di Ambiente e Connessa Prevenzione primaria

Istituto Superiore di Sanità

Organismo Notificato N° 0373

ATTESTATO DI CERTIFICAZIONE CE

secondo l'Allegato III della Direttiva Europea 93/42/CEE
(recepita con il Decreto Legislativo n. 46 del 24/2/1997)

CE CERTIFICATION DOCUMENT
according to Annex III of EC Directive 93/42/EEC
enforced by the Decreto Legislativo n. 46 issued on 24/2/1997)

L'Istituto Superiore di Sanità, Organismo Notificato n° 0373, attesta che il dispositivo medico
The Istituto Superiore di Sanità, Notified Body n° 0373, certifies that the medical device

Membrane alcoliche e Membrane essiccate (vedi allegato)

fabbricato da
manufactured by

TECNOSS S.r.l.

soddisfa ai requisiti applicabili della Direttiva Europea 93/42/CEE.
satisfies the requirements set out in EC Directive 93/42/EEC.

Certificato n° / Certificate no.	867 CTP 232	Addendum n° / addendum no.	//	Rilasciato il / issued on	26.08.2005

Il presente certificato ha la validità massima di cinque anni dalla data del rilascio.
This certificate expires five years after the date of issue.

Il Direttore del Dipartimento
di Ambiente e Connessa Prevenzione primaria

Istituto Superiore di Sanità

Organismo Notificato N° 0373

ATTESTATO DI CERTIFICAZIONE CE

secondo l'Allegato III della Direttiva Europea 93/42/CEE
(recepita con il Decreto Legislativo n. 46 del 24/2/1997)

CE CERTIFICATION DOCUMENT
according to Annex III of EC Directive 93/42/EEC
enforced by the Decreto Legislativo n. 46 issued on 24/2/1997)

L'Istituto Superiore di Sanità, Organismo Notificato n° 0373, attesta che il dispositivo medico
The Istituto Superiore di Sanità, Notified Body n° 0373, certifies that the medical device

Linea OsteoBiol
Feltri e Membrane di collagene biOSSizzato equino (vedi allegato)

fabbricato da
manufactured by

TECNOSS S.r.l.

soddisfa ai requisiti applicabili della Direttiva Europea 93/42/CEE.
satisfies the requirements set out in EC Directive 93/42/EEC.

Certificato n° / Certificate no.	867 CTP 231	Addendum n° / addendum no.	//	Rilasciato il / issued on	26.08.2005

Il presente certificato ha la validità massima di cinque anni dalla data del rilascio.
This certificate expires five years after the date of issue.

Il Direttore del Dipartimento
di Ambiente e Connessa Prevenzione primaria

OsteoBiol Gen-Os: biocompatibility test

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

DIRECT CONTACT CYTOTOXICITY TEST

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

MATERIALS AND METHODS

The direct contact cytotoxicity test was performed on a culture at confluence of murine fibroblasts belonging to NCTC L929 clone (Lgc Promochem, Teddington, Middlesex, UK) in exponential growth phase. An eluate with culture Medium was prepared, by dipping the study material in culture Medium to obtain a 0,2 g/ml weight/volume ratio.
The assay sample was incubated for 72 hours at 37°C ±1°C temperature.
Then, 2 ml extract was incubated with cultured NCTC L929 cells for a period of 48 hours in incubator at 37°C ±1°C temperature, with CO_2 atmosphere in air.

RESULTS

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

CONCLUSIONS

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

INTRACUTANEOUS REACTIVITY TEST

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

MATERIALS AND METHODS

A intracutaneous reactivity assay on rabbit was performed. 2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 0.2 g/ml weight/volume ratio.
Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 0,2 ml of each extract was subcutaneously injected in 3 rabbits to evaluate macroscopic signs of cutaneous irritation such as erythema, oedema and eschars.

RESULTS

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

CONCLUSIONS

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

SYSTEMIC TOXICITY TEST

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

MATERIALS AND METHODS

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

RESULTS

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

CONCLUSIONS

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

DELAYED HYPERSENSITIVITY TEST

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

MATERIALS AND METHODS

2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 0.2 g/ml weight/volume ratio.
Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 15 guinea-pigs were used for each eluate analysis, whom 10 were treated with each study material extract and 5 as controls.
Cutaneous sensitization assay is characterized by an induction phase and by a challenge phase.
Induction phase
During induction phase the group of 10 treated guinea-pigs was inoculated with 3 couples (0,1 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 extraction liquid was inoculated (vegetable oil and saline) and in the 3rd injection extraction liquid + FCA (1:1 ratio).
After 6 days from intradermal injection in both treated and control animals, a topical application through massage of 0,5 ml Sodium Lauryl Sulfate at 10% was performed.
After 7 days from intradermal injection, on the skin of 10 treated animals the study material extract was applied in a volume of 0,5 ml/animal for a incubation period of 48 hours. The same treatment was performed in the control group, using the respective extraction liquid.
Challenge phase
After 21 days from the beginning of treatment, on all treated and control animals the challenge phase was induced, by applying on the right side of their back 0,5 ml 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 10993-10:2004 rule, OsteoBiol Gen-0s study material must be defined as NON SENSITIZING.

Salmonella typhimurium REVERSION TEST (AMES TEST)

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

MATERIALS AND METHODS

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

RESULTS

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

CONCLUSIONS

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

OsteoBiol Evolution: biocompatibility test

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

DIRECT CONTACT CYTOTOXICITY TEST

AIM: cytotoxic potential evaluation of OsteoBiol Evolution resorbable membrane

MATERIALS AND METHODS

The direct contact cytotoxicity test was performed on a culture at confluence of murine fibroblasts belonging to NCTC L929 clone (Lgc Promochem) in exponential growth phase.
The study material was incubated with cultured NCTC L929 cells in monolayer for a period of 24 hours in incubator at 37°C ±1°C temperature, with CO_2 atmosphere in air. After 24 hours incubation, the cell culture was observed to evaluate biological reactivity.

RESULTS

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

CONCLUSIONS

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

INTRACUTANEOUS REACTIVITY TEST

AIM: local toxic effects evaluation of OsteoBiol Evolution resorbable membrane

MATERIALS AND METHODS

A intracutaneous reactivity assay on rabbit was performed. 2 eluates of study material were prepared using as extraction liquids vegetable oil or saline. The extracts were obtained under static conditions by dipping the study material in saline or vegetable oil to reach a 6 cm^2/ml surface/volume ratio.
Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 0,2 ml of each extract were subcutaneously injected in 3 rabbits to evaluate macroscopic signs of cutaneous irritation such as erythema, oedema and eschars.

RESULTS

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

CONCLUSIONS

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

SYSTEMIC TOXICITY TEST

AIM: systemic toxicity effects evaluation of OsteoBiol Evolution resorbable membrane

MATERIALS AND METHODS

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

RESULTS

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

CONCLUSIONS

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

DELAYED HYPERSENSITIVITY TEST

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 6 cm^2/ml surface/volume ratio.
Each assay sample was incubated for 72 hours at 37°C ±1°C temperature. 15 guinea-pigs were used for each eluate analysis, whom 10 were treated with each study material extract and 5 as controls.
Cutaneous sensitization assay is characterized by an induction phase and by a challenge phase.
Induction phase
During induction phase the group of 10 treated guinea-pigs was inoculated with 3 couples (0,1 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 extraction liquid was inoculated (vegetable oil and saline) and in the 3rd injection extraction liquid + FCA (1:1 ratio).
After 6 days from intradermal injection in both treated and control animals, a topical application through massage of 0,5 ml Sodium Lauryl Sulfate at 10% was performed.
After 7 days from intradermal injection, on the skin of 10 treated animals the study material extract was applied in a volume of 0,5 ml/animal for a incubation period of 48 hours. The same treatment was performed in the control group, using the respective extraction liquid.
Challenge phase
After 21 days from the beginning of treatment, on all treated and control animals the challenge phase was induced, by applying on the right side of their back 0,5 ml 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 10993-10:2004 rule, OsteoBiol Evolution resorbable membrane must be defined as NON SENSITIZING.

Salmonella typhimurium REVERSION TEST (AMES TEST)

AIM: mutagenesis effects analysis of OsteoBiol Evolution resorbable membrane

MATERIALS AND METHODS

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

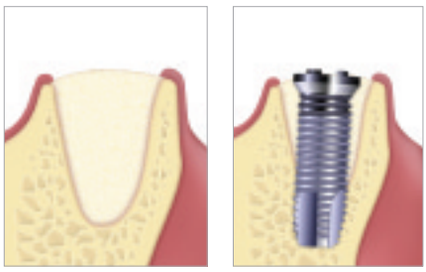
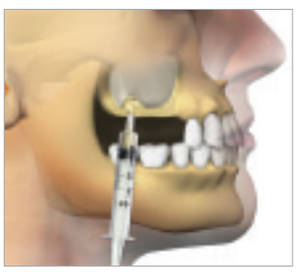
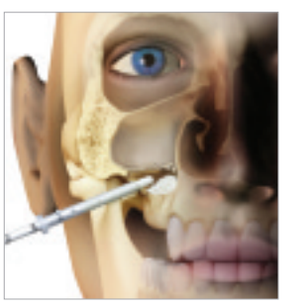
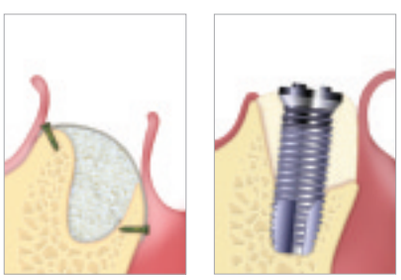
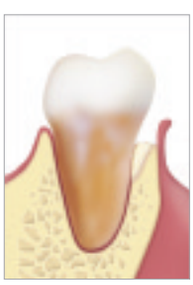
RESULTS

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

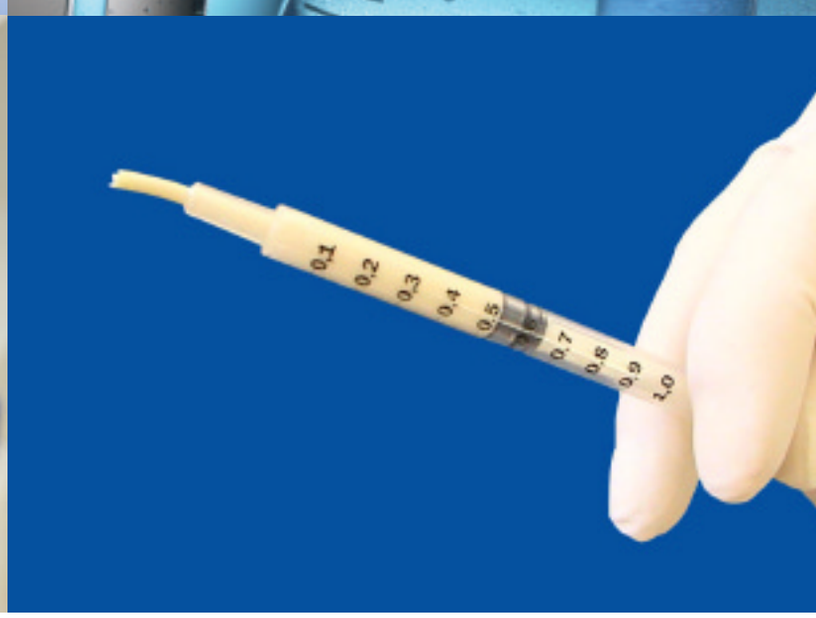
CONCLUSIONS

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

MAIN CLINICAL INDICATIONS

REGENERATION TYPE	PRODUCT 1	PRODUCT 2	POSSIBLE ALTERNATIVES
 POST-EXTRACTIVE SOCKETS	 ONLY IF DEFECT WALLS ARE PRESERVED	 ONLY IF THERE IS GRAFT EXPOSURE RISK	 IN CASE OF COAGULATION PROBLEMS
 CRESTAL ACCESS SINUS LIFT	 GEL WITH GRANULES ≤ 300 MICRON		 GRANULOMETRY 250-1000
 LATERAL ACCESS SINUS LIFT	 GRANULOMETRY 600 - 1000	 ANTROSTOMY COVERING	 GRANULOMETRY 250 - 1000
 TWO WALL DEFECTS	 GRANULOMETRY 250 - 1000	 STANDARD MODEL	 MUST BE FIXED WITH OSTEOSYNTHESIS SCREWS
 INTRABONY DEFECTS	 3 WALL DEFECTS WITH < 30° ANGLE	 WIDE DEFECTS AND FURCATIONS	

Product	Packaging	Content or type	Size mm	Code porcine	Code equine
BONE SUBSTITUTES AND AUXILIARY PRODUCTS					
GEN-OS	1 Vial	Gr. 0,25		M1052FS	
GEN-OS	1 Vial	Gr. 0,5		M1005FS	M1005FE
GEN-OS	1 Vial	Gr. 1,0		M1010FS	
GEN-OS	1 Vial	Gr. 2,0		M1020FS	M1020FE
MP3	1 syringe	cc 1,0		A3005FS	A3005FE
MP3	3 syringes	cc 0,5 x 3		A3015FS	A3015FE
APATOS MIX	1 Vial	Gr. 0,5		A1005FS	
APATOS MIX	1 Vial	Gr. 1,0		A1010FS	
APATOS MIX	1 Vial	Gr. 2,0		A1020FS	
APATOS SPONGIOSA	1 Vial	Gr. 0,5		AS1005FS	
APATOS SPONGIOSA	1 Vial	Gr. 1,0		AS1010FS	
APATOS CORTICAL	1 Vial	Gr. 0,5		AC1005FS	
APATOS CORTICAL	1 Vial	Gr. 1,0		AC1010FS	
PUTTY	1 Vial	cc 1,0 (2 Gr.)		HPT01S	
PUTTY	1 Syringe	cc 0,5 (1 Gr.)		HPT09S	
PUTTY	3 Syr. (Vials*)	cc 0,5 x 3 (3 Gr.)		HPT35S	HPT15E*
GEL 40	3 Syringes	cc 0,5 x 3		15GEL40S	15GEL40E
GEL 40	1 Syringe	cc 0,5		05GEL40S	
GEL 0	3 Syringes	cc 0,5 x 3		15GEL00S	
GEL 0	1 Syringe	cc 0,5		05GEL00S	
TABLET	6 Blister		10 x 10 x 10	BLE10S	
SP-BLOCK	1Blister	COLLAGENATED	10 x 10 x 20		BN1E
SP-BLOCK	1Blister	COLLAGENATED	10 x 20 x 20		BN2E
SP-BLOCK	1Blister	NON COLLAGENATED	12 x 12 x 22		ABL10E
SOFT CORTICAL LAMINA	1 Blister	STD	30 x 30 x (2-4)	LS03SS	LS03SE
SOFT CORTICAL LAMINA	1 Blister	FINE	25 x 25 x (0,4-0,6)	LS25FS	LS25FE
SOFT CORTICAL LAMINA	1 Blister	FINE OVAL	25 x 35 x (0,4-0,6)	LS23FS	LS23FE
SOFT CORTICAL LAMINA	1 Blister	FINE	20 x 40 x (0,4-0,6)	LS24FS	
CURVED LAMINA	1 Blister	MEDIUM	35 x 35 x (0,8-1)	LS10HS	
MEMBRANES					
EVOLUTION	1 Blister	STD	20 x 20		EV02HHE
EVOLUTION	1 Blister	STD	30 x 30		EV03HHE
EVOLUTION	1 Blister	STD	Oval 25 x 35		EV0HHE
EVOLUTION	1 Blister	FINE	20 x 20		EV02LLE
EVOLUTION	1 Blister	FINE	30 x 30		EV03LLE
EVOLUTION	1 Blister	FINE	Oval 25 x 35		EV0LLE
EVOLUTION PERIO-KIT	6 Blister	X-FINE		EM96XS	
EVOLUTION	1 Blister	X-FINE	20 x 20	EM02XS	
EVOLUTION	1 Blister	X-FINE	30 x 30	EM03XS	
SPECIAL	1 Blister	X-FINE	20 x 20	EM02LS	
SPECIAL	1 Blister	X-FINE	30 x 30	EM03LS	
DUO-TECK	1 Blister	COATED	20 X 20		DT020
DERMA	1 Blister	STD	30 x 30 x (2-4)	ED03SS	
DERMA	1 Vial	FINE	25 x 25 x (0,8-1)	ED25FS	



OsteoBiol® Authorized Distributor:

Tecnoss®

P.za Papa Giovanni XXIII, 2
10094 Giaveno (TO)
☎ +39 011 9377347
info@tecnoss.com
www.tecnoss.com

Tecnoss® Dental

Via Torino 23
10044 Pianezza (TO)
☎ +39 011 9682823
info@tecnoss-dental.com
www.tecnoss-dental.com

Biomaterials Engineering

International Sales & Marketing