



Biomaterials Engineering

Tecnoss[®]

REGENERATION SCIENCE

INSPIRED BY NATURE

Nature provides all the necessary elements for bone regeneration

TECNOSS® BONE MATRIX: A DUAL PHASE REVOLUTION

TecnoSS® Bone Matrix granules are endowed with characteristics very similar to human mineral bone¹, 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)².

1 | FIGUEIREDO M ET AL | JOURNAL OF BIOMEDICAL MATERIALS RESEARCH PART B: APPLIED BIOMATERIALS (2009)

University of Coimbra, Portugal

2 | NANNMARK U ET AL | CLINICAL IMPLANT DENTISTRY AND RELATED RESEARCH (2008)

University of Göteborg, Sweden



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.

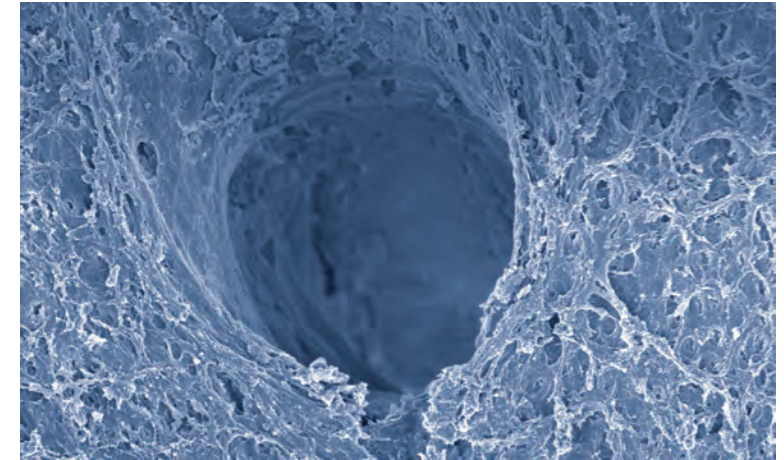
The examination of clinical results and the commercial diffusion of various kinds of products developed by the biomedical industry show a clear superiority of products of natural origin over those of synthetic derivation.

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

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 TecnoSS® 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.

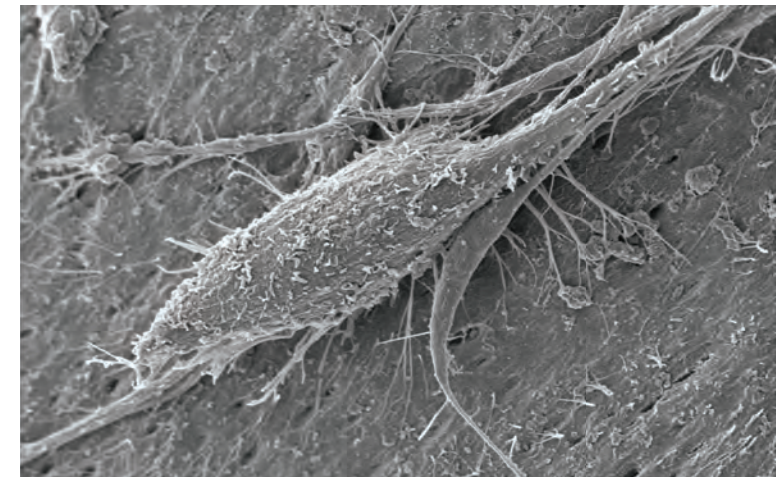


SEM image of a TecnoSS® Gen-Os granule: vascular canal entrance with evident centralized osteonic structure

Courtesy of Dr Ulf Nannmark, Göteborg University, Sweden

OUR AIM IS TO ACCELERATE AND GUIDE THE NATURAL BONE REGENERATION PROCESS

TecnoSS® developed and patented a unique biotechnology that prevents the ceramization phase of natural bone and preserves the tissue collagen, allowing an osteoclastic-type remodelling of the biomaterial, similar to physiological bone turnover



SEM image of a TecnoSS® Gen-Os granule colonized by osteoblasts from a cell-line (MG63)

Courtesy of Dr Ulf Nannmark, Göteborg University, Sweden

Collagen, a key factor for clinical success

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

Moreover, the molecular structure of natural hydroxyapatite is not significantly altered thanks to the limited maximum process temperature¹.

These characteristics of Tecnoss® 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 marrow²
- c) it increases the proliferation rate of the osteoblasts up to 2/3 times³
- d) it stimulates the activation of the platelets, osteoblasts and osteoclasts in the tissue healing process

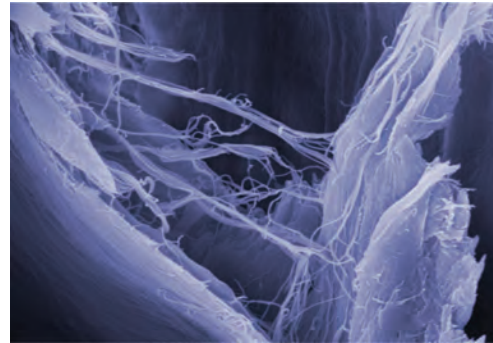
The presence of collagen inside each granule makes Tecnoss® Bone Matrix hydrophilic and facilitates further mixing with collagen gel (Tecnoss® Gel 0). This technology has permitted the development of two new versatile and innovative products: Tecnoss® mp3 and Tecnoss® Putty. Their consistency allows an ideal filling of bone defects and spinal cages and guarantees simple handling and fast application.

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

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

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

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



SEM image of a Tecness® Evolution collagenic matrix
Nobil Bio Ricerche, Villafranca d'Asti, Italy

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- β (Bone Morphogenetic Proteins belong to this superfamily) which starts bony callus formation.

>> the **osteoblastic precursors** deriving from bone marrow mesenchymal stem cells are responsible, after cell differentiation in osteoblasts, for the second phase of the healing process (enchondral and/or 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)^{4,5,6}.

In vitro studies demonstrated that heterologous collagen is able to induce differentiation of mesenchymal osteoprogenitor stem cells into osteoblasts², and that association of collagen type I with a scaffold of hydroxyapatite significantly enhances osteoblasts proliferation rate³.

This important scientific evidence provides the rationale behind **Tecnoss® 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 repair 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 Tecnoss® 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 osteoblasts².

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 rate³, while as a resorbable membrane it is able to guide connective tissue regeneration.

Therefore all collagenated biomaterials of Tecnoss® 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.

INTRODUCTION

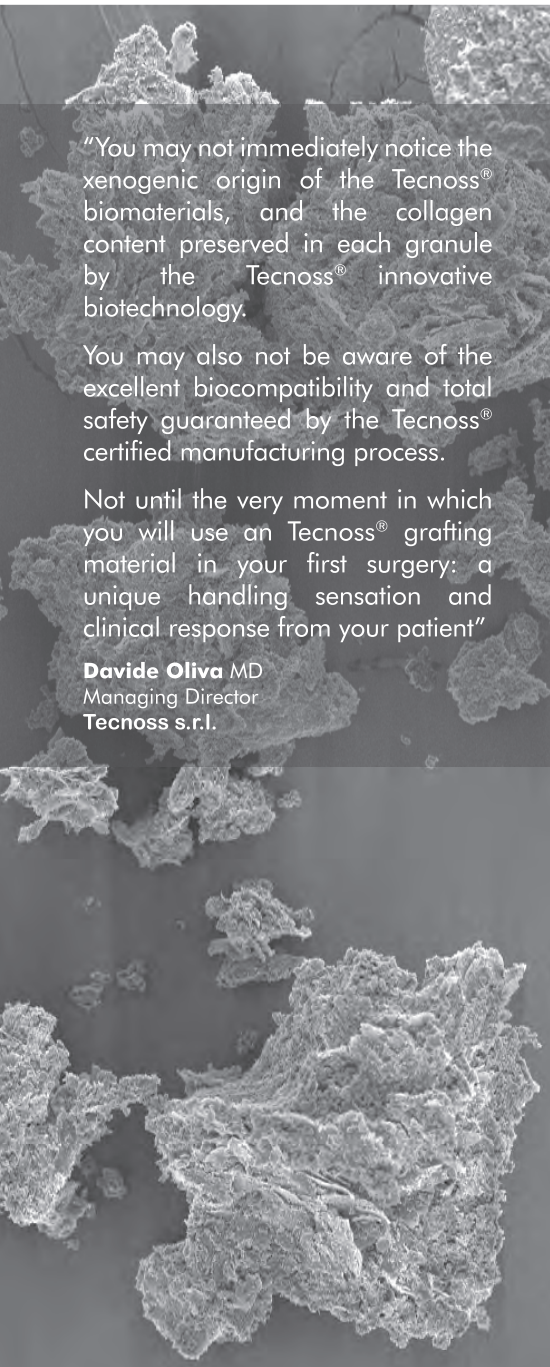
A REVOLUTIONARY INNOVATION

BIBLIOGRAPHY

- 1 | FIGUEIREDO M ET AL | JOURNAL OF BIOMEDICAL MATERIALS RESEARCH PART B: APPLIED BIOMATERIALS (2009)
- 2 | SALASZNYK RM ET AL | JOURNAL OF BIOMEDICINE AND BIOTECHNOLOGY (2004)
- 3 | HSU FY ET AL | BIOMATERIALS (1999)
- 4 | GRIFFITH LG ET AL | SCIENCE (2002)
- 5 | REDDI AH | TISSUE ENGINEERING (2000)
- 6 | NAKASHIMA N ET AL | NATURE BIOTECHNOLOGY (2003)



Pre-hydrated and ready-to-use bone mix and paste



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

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

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

Davide Oliva MD
Managing Director
Tecross s.r.l.

Tecross® mp3

Heterologous cortico-cancellous collagenated pre-hydrated bone mix



Characteristics

Bone crunch made of 2-4mm pre-hydrated collagenated cortico-cancellous granules, mixed with additional collagen gel (Tecross® Gel 0).

Handling

Available in ready-to-use syringes, can be easily grafted avoiding the hydration and manipulation phases decreasing the risk of accidental exposure to pathogens.

Features

Remodelled and replaced by host bone gradually within time.

Clinical indication

Filler of bone defects after trauma, reconstruction or corrections in non-load-bearing indications. May be used as a drug-carrier.

**CRANIOTOMY
BONE FILLER**



**LEG
SURGERY**



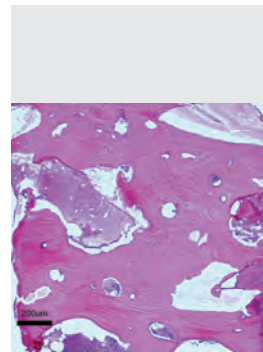
**TIBIAL
OSTEOTOMY**



**SHOULDER
SURGERY**



**KNEE
SURGERY**



Bone origin

Equine

Tissue collagen

Preserved

Physical form

Pre-hydrated granules in ready-to-use sterile syringe

Composition

90% bone mix and 10% collagen gel (Tecross® Gel 0)

Granulometry

2-4mm

Re-entry time

6 months

Packaging

Sterile syringe
A3410FE (2cc)
A3450FE (5cc)
A3415FE (15cc)

Tecross® Putty

Heterologous cortico-cancellous collagenated pre-hydrated bone paste



Characteristics

Bone paste made of micronized pre-hydrated collagenated cortico-cancellous bone (granulometry less than 0.3mm) and additional collagen gel (Tecross® Gel 0).

Handling

Its exceptional malleability and plasticity make it easy to apply as cage filler (spinal surgery) and as bone substitute in smaller self-contained defects.

Features

Remodelled and replaced by host bone gradually within time.

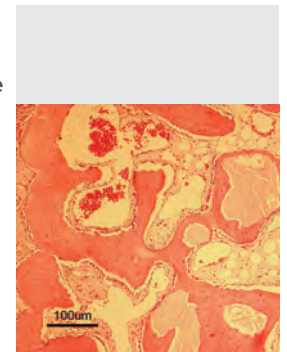
Clinical indication

In Spinal Surgery as cage filler and in Orthopaedic as bone filler of self-contained bone defects after trauma, reconstruction. May be used as a drug-carrier.

**SPINAL
SURGERY**



**HAND
SURGERY**



Bone origin

Equine

Tissue collagen

Preserved

Physical form

Bone paste of malleable consistency in ready-to-use sterile syringe

Composition

80% bone mix and 20% collagen gel (Tecross® Gel 0)

Granulometry

Up to 0.3mm

Re-entry time

4 months

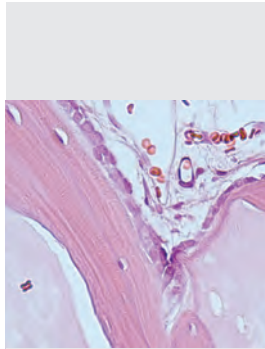
Packaging

Sterile syringe
HPT62E (2cc)
HPT65E (5cc)

Collagenated dried bone mix

Tecnos[®] Gen-Os

Heterologous cortico-cancellous collagenated bone mix (dried granules)



Characteristics

Gradually resorbable, Tecnos[®] Gen-Os provides support in bone neof ormation helping to preserve the original graft shape and volume.

Handling

Must always be hydrated and thoroughly mixed with sterile physiological solution to activate its collagen matrix and enhance adhesivity.

Features

Remodelled and replaced by host bone gradually within time.

Clinical indication

Filler of bone defects after trauma, reconstruction or corrections in non-load-bearing indications. Can function as a carrier for selected medication and drugs.

Bone origin

Equine

Tissue collagen

Preserved

Physical form

Dried granules slightly radiopaque

Composition

100% cortico-cancellous bone mix

Granulometry

2-4mm

Re-entry time

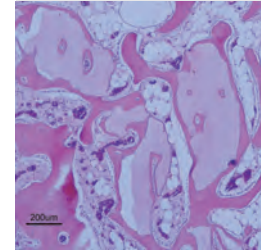
6 months

Packaging

Sterile vial
G4E05 (5cc)
G4E10 (10cc)

Tecnos[®] Chips

Heterologous cancellous collagenated bone mix (large dried chips)



Characteristics

Similar characteristics as Tecnos[®] Gen-Os, Tecnos[®] Chips present a larger granulometry.

Handling

Must always be hydrated and thoroughly mixed with sterile physiological solution to activate its collagen matrix and enhance adhesivity.

Features

Remodelled and replaced by host bone gradually within time.

Clinical indication

Filler of bone defects after trauma, reconstruction or corrections in non-load-bearing indications. Can function as a carrier for selected medication and drugs.

Bone origin

Equine

Tissue collagen

Preserved

Physical form

Dried chips slightly radiopaque

Composition

100% cancellous bone mix

Granulometry

4-10mm

Re-entry time

6 months

Packaging

Sterile vial
BMS95E (5cc)
BMS01E (10cc)
BMS02E (20cc)

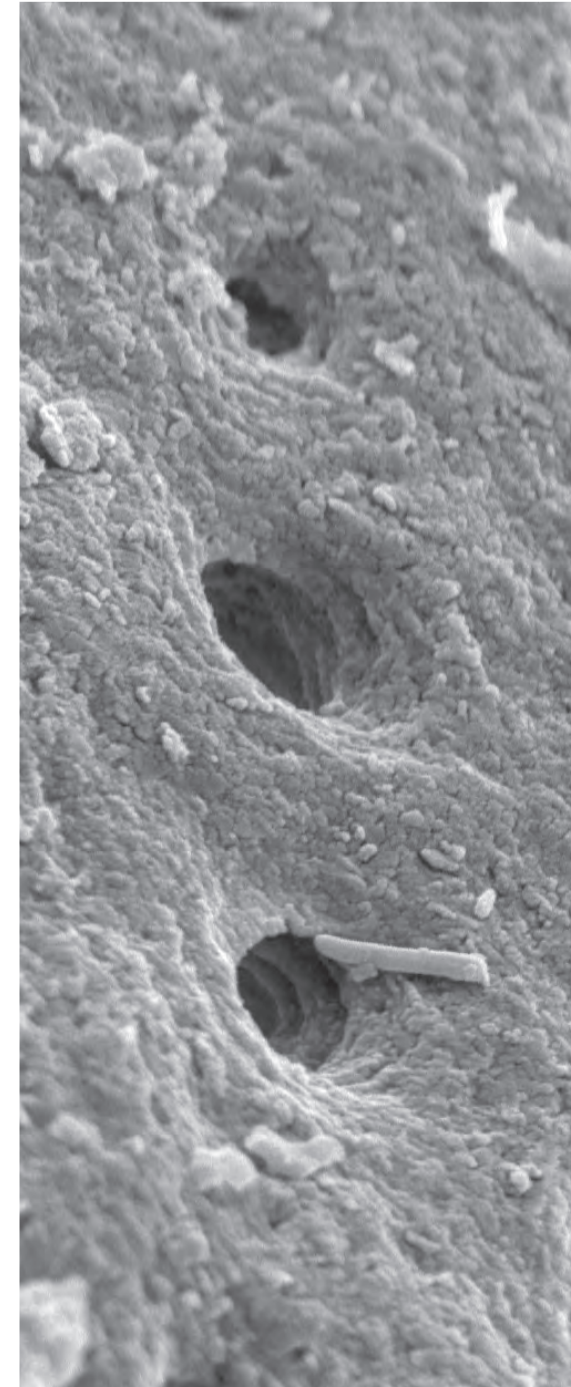
HAND SURGERY



CRANIOTOMY BONE FILLER



KNEE SURGERY



MEDICAL LINE

COLLAGEN MEMBRANES AND
CORTICAL BONE BARRIERS

"All Tecnos[®] collagenated biomaterials 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"

Giuseppe Oliva MD
R&D Director
Tecnos s.r.l.

Collagen membranes and bone barriers

Tecnos[®] Evolution

Heterologous collagen membrane



Characteristics

Made of high consistency dense collagen fibers of extraordinary resistance. Completely resorbable.

Handling

Can be shaped with sterile scissors until the desired size; it must be rehydrated with lukewarm physiological solution.

Features

Maximum adaptability to hard and soft tissues, easy and secure suturability to nearby tissues. Ample stability and sufficient protection of underlying graft.

Clinical indication

In Neurosurgery as Dura Mater Patch. In Orthopaedics where protection of graft and/or neoformation of soft/hard tissues is required. Can be used as a drug-carrier.

DURA MATER RESTORATION



LEG SURGERY



TIBIAL OSTEOTOMY



FOOT/HAND SURGERY



KNEE SURGERY



SHOULDER SURGERY



Tissue origin

Equine mesenchymal tissue

Tissue collagen

Preserved

Physical form

Dried membrane with a smooth and a micro-rough side

Composition

100% heterologous serous

Resorption time

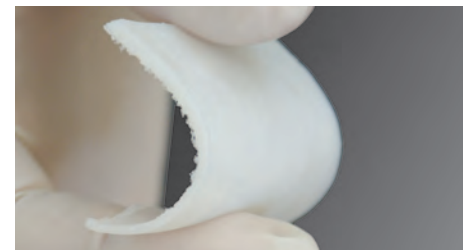
3 months

Packaging

Sterile blister
EV05LLE (50x50mm)
EV06LLE (80x60mm)
EV07LLE (80x140mm)
EV10LLE (100x100mm)

Tecnos[®] Lamina

Heterologous cortical bone



Characteristics

Made of cortical bone of heterologous origin. After a process of superficial decalcification, it acquires an elastic consistency.

Handling

Can be shaped with sterile scissors until the desired size, then it must be hydrated for 5/10 minutes in sterile physiological solution.

Features

Provides structural support to bony defects where synthetic substitutes scaffold may be limited. Remodelled and replaced by host bone gradually within time.

Clinical indication

Reconstruction or corrections in non-load-bearing indications and hip revisions. Can be used as a drug-carrier.

CRANIAL RESTORATION



HIP REVISION



TIBIAL OSTEOTOMY



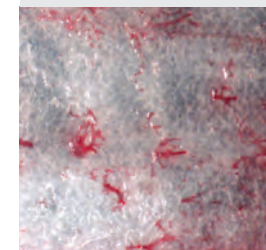
FOOT/HAND SURGERY



KNEE SURGERY



SHOULDER SURGERY



Bone origin

Equine

Tissue collagen

Preserved

Physical form

Pre-shaped cortical block, slightly radiopaque

Composition

100% cortical bone

Resorption time

6 months

Packaging

Sterile blister
LS35LE (35x35x1-2mm)
LS57HE (d70xh4-5mm)
(Acetabulum Mat)

Pre-shaped collagenated blocks and wedges

Tecnos[®] Sp-Block

Heterologous cancellous collagenated bone block



Characteristics

Cancellous block, 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.

Handling

Must be hydrated before use for 5/10 minutes with sterile lukewarm physiological solution.

Features

Provide structural support to bony defects where synthetic substitutes may be limited.

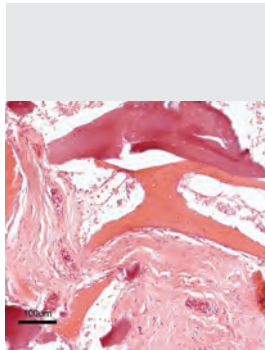
Clinical indication

Filler of larger size bone defects. Trauma, tumor resections, hip and knee revisions. Posterior spinal fusions.

SHOULDER SURGERY



FOOT SURGERY



Bone origin

Equine

Tissue collagen

Preserved

Physical form

Rigid pre-shaped cancellous bone block, slightly radiopaque

NORM medium mineralization

SOFT decreased mineralization (flexible)

HARD mineralization similar to natural bone (rigid)

Composition

100% cancellous bone

Re-entry time

6 months

Packaging

Sterile blister

NORM

BN3E (40x30x10mm)

BN4E (50x40x10mm)

BN5E (50x40x5mm)

BN7E (40x30x15mm)

SOFT

BS7E (25x50x3mm)

BS8E (25x50x5mm)

BS9E (50x50x3mm)

HARD

BH001E (10x10x20mm)

BH002E (20x20x10mm)

BH622E (60x20x20mm)

Tecnos[®] V-Block

Heterologous cancellous collagenated bone wedge



Characteristics

Cancellous wedge, 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.

Handling

Must be hydrated before use for 5/10 minutes with sterile lukewarm physiological solution.

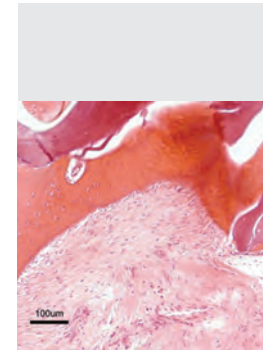
Features

Provide structural support to bony defects where synthetic substitutes may be limited.

Clinical indication

Tibial osteotomy. Trauma, tumor resections, knee revisions.

TIBIAL OSTEOTOMY



Bone origin

Equine

Tissue collagen

Preserved

Physical form

Pre-shaped cancellous bone wedge, slightly radiopaque

Composition

100% cancellous bone

Re-entry time

6 months

Packaging

Sterile blister

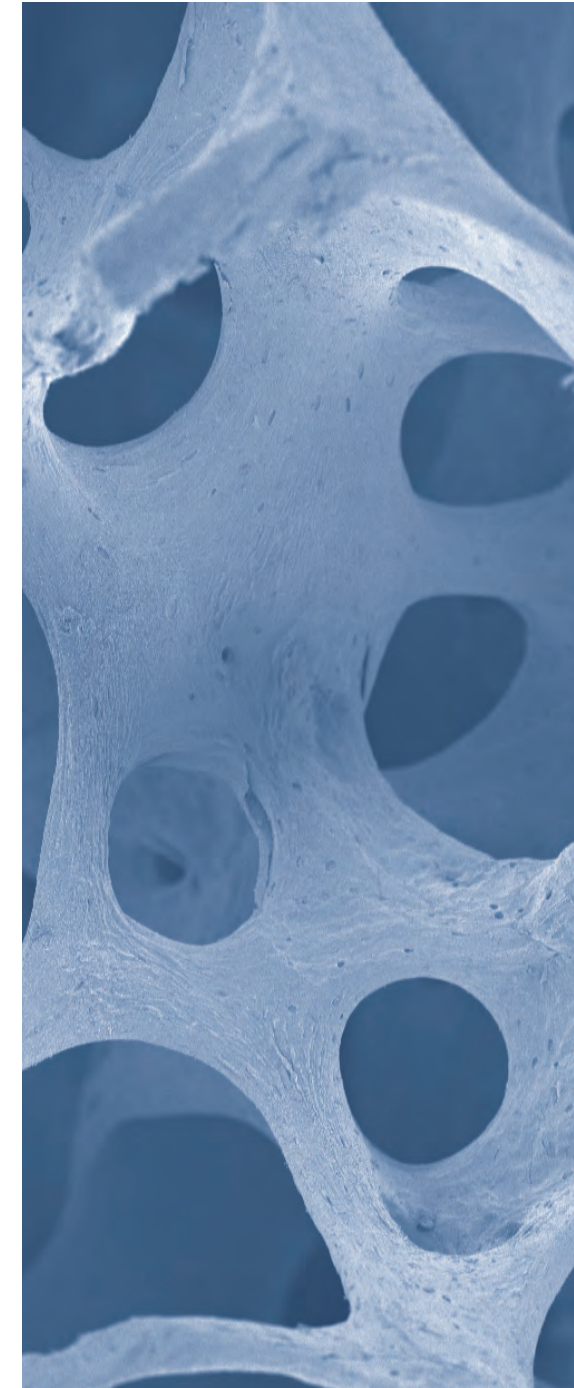
CN1E (40x30x10mm)

CN2E (40x30x15mm)

CN3E (50x40x10mm)

CN4E (50x40x15mm)

CN5E (50x20x20mm)



MEDICAL LINE

CORTICO-CANCELLOUS BLOCKS AND HEMI-HEAD

"At Tecnos[®] we dedicate all our energy and resources to improve hard and soft tissue regeneration: this is our only activity and focus.

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

And every Tecnos[®] product contains a biological added value that will create confidence in your regenerative surgery and clinical success with your patients"

Giuseppe Oliva MD
R&D Director
Tecnos s.r.l.

Specific collagenated blocks

Tecnos[®] Dual-Block

Heterologous cortico-cancellous collagenated bone block



Characteristics

Cortico-cancellous block. The cortical layer, naturally anchored to the cancellous bone, provides stability and long term protection to the graft functioning as a barrier in case of exposure.

Handling

Must be hydrated before use for 10 minutes with sterile lukewarm physiological solution. Remaining gaps can be filled with bone substitutes (Tecnos[®] Gen-Os or Tecnos[®] Chips).

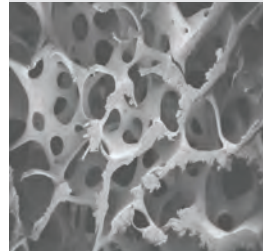
Features

Provide structural support to bony defects where synthetic substitutes may be limited.

Clinical indication

Filler of bone defects after trauma, reconstruction or corrections in non-load-bearing indications. Can be used as a drug-carrier.

LEG SURGERY



Bone origin

Equine

Tissue collagen

Preserved

Physical form

Pre-shaped cortico-cancellous block, slightly radiopaque

NORM stiffness similar to natural bone

SOFT decreased mineralization grade: flexible product

Composition

Cancellous bone with a layer of cortical bone

Re-entry time

6 months

Packaging

Sterile blister

NORM

STN1E (50x10x3mm)

STN2E (50x10x5mm)

SOFT

STS1E (50x10x3mm)

STS2E (50x10x5mm)

Tecnos[®] Hemi-Head

Heterologous decorticated cancellous collagenated femoral hemi-head



Characteristics

Decorticated cancellous femoral hemi-head.

Handling

Must be hydrated before use for 5/10 minutes with sterile lukewarm physiological solution.

Features

Provide structural support to bony defects where synthetic substitutes may be limited. Not indicated for use in load bearing situations, unless used in combination with appropriate osteosynthesis fixation.

Clinical indication

Hip revisions.

HIP REVISION



Bone origin

Equine

Tissue collagen

Preserved

Physical form

Femur hemi-head of decorticated cancellous bone with spherical bowl shape, slightly radiopaque

Composition

Cancellous bone

Re-entry time

8 months

Packaging

Sterile blister
ETE (60x20mm)

Highest quality standards

MEDICAL LINE

CE CERTIFICATES AND ISO 13485



Tecnoss® products comply with the highest quality standards such as ISO 10993, ISO 13485, 93/42/EEC and 03/32/EEC

CE 0373 NOTIFIED BODY



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 tissues (achievement of biocompatibility) and allows development of products unique in their kind, capable of satisfying every surgical need.

Tecnoss® 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 Tecnos® obtains its products comes from Italian animal farms, selected and certified under the strict control of the Italian National Veterinary Health Service.

The biological matrix from which the Tecnos® 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.

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

All Tecnos® 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.

All Tecnos® products contain collagen; use is thus advised against for subjects with allergic reaction to this substance.



Products engineered for specific clinical indications ...

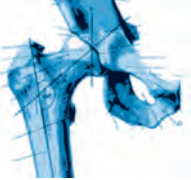

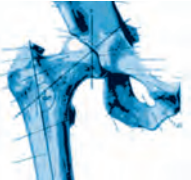
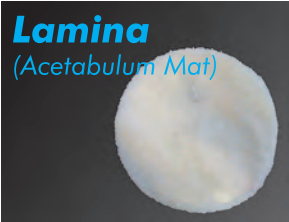

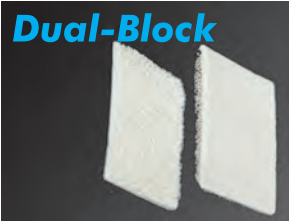


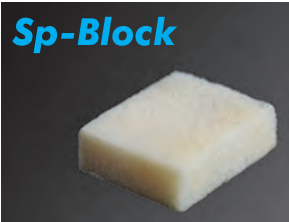







		Bone substitute		Protection membrane / barrier	
Surgery		Dried product	Ready-to-use product	Collagen membrane	Bone barrier
HAND		Gen-Os 	Putty 	Evolution 	Lamina
SHOULDER		Sp-Block 	mp3 	Evolution 	Lamina
KNEE		Chips 	mp3 	Evolution 	Lamina
TIBIAL OSTEOTOMY		V-Block 	mp3 	Evolution 	Lamina
DURA MATER		Gen-Os 	mp3 	Evolution 	Lamina

... to deliver excellence in every clinical case, every time

CLINICAL INDICATIONS

TECNOSS® BIOMATERIALS

		Bone substitute		Protection membrane / barrier	
Surgery		Dried product	Ready-to-use product	Collagen membrane	Bone barrier
HIP REVISION		Hemi-Head 			
		Lamina (Acetabulum Mat) 			
LEG		Dual-Block 		Evolution 	
FOOT		Sp-Block 	mp3 	Evolution 	Lamina 
			Putty 		
SPINAL					

"TecnoSS® is the **most complete range of biomaterials available** on the market today.

Our products are **specifically engineered** to fulfill your needs in every single clinical indication. We believe that your valuable regenerative work should not be limited to one single product adapted to all clinical indications but it should be given instead a solution **thought and designed specifically for your different needs.**

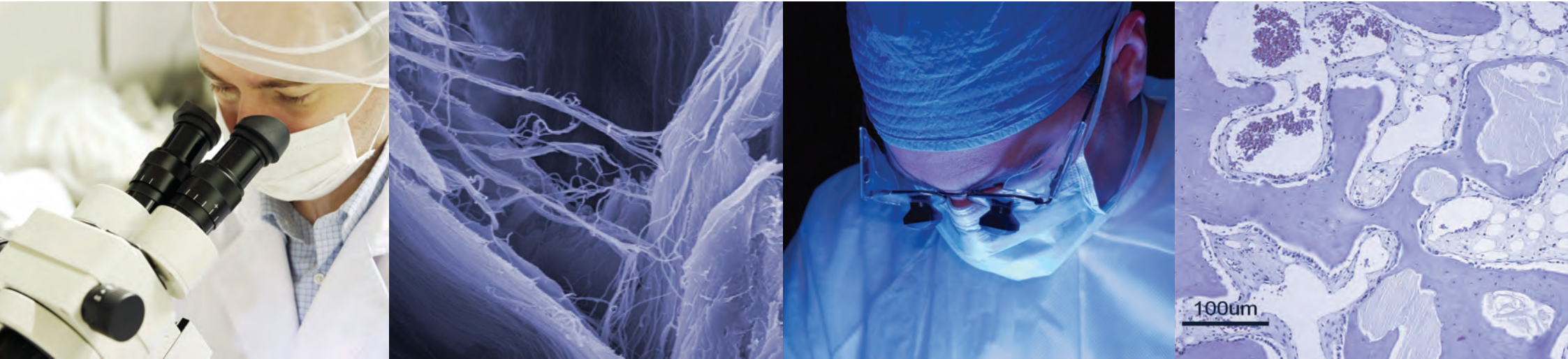
Each regeneration protocol is different, this is why we work hard to deliver you the best solutions to help you improve your surgical procedures everyday.

Your clinical success is our only mission."

Katia Gaetano BPharm
Production Manager
TecnoSS s.r.l.



Tecnoss®



Tecnoss s.r.l. is an innovative, globally active company that develops, produces and documents premium-quality xenogenic biomaterials by the brands Tecnoss® and OsteoBiol®.

Its 15 years of research led to its patent-protected production process that ensures neutralization of antigenic components in order to achieve biocompatibility while preserving the natural collagen matrix inside the biomaterial.

Tecnoss® products comply with highest quality standards such as ISO 10993, ISO 13485 (notified body TÜV Rheinland), 93/42/EEC and 03/32/EEC (notified body CE 0373).

Tecnoss® s.r.l.

Piazza Papa Giovanni XXIII, 2
10094 Giaveno (TO), Italy
Tel. +39 011 937 7347
Fax. +39 011 936 3262
info@tecnoss.com
www.tecnoss.com



DISTRIBUTED BY

