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BONE TISSUES
Technical information

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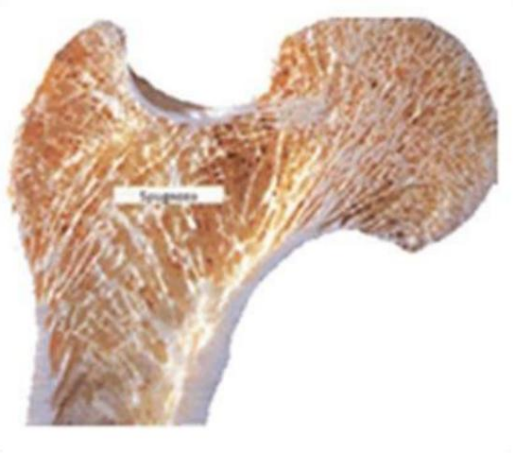
DIFFERENCES BETWEEN BONE TISSUES AND BIOMATERIALS



ELEMENT	BONE TISSUE	BIOMATERIAL
Mineral scaffold	Yes	Yes
Collagen	Yes	No
Growth factors	Yes	No
Load resistance	Yes	No
Total physiological reabsorption	Yes	No
Allotropic form of apatite crystal	No	Yes
Possibility to modify the mechanical characteristics	Yes	No

Scaffold

The scaffold is made up of the bone mineral component.

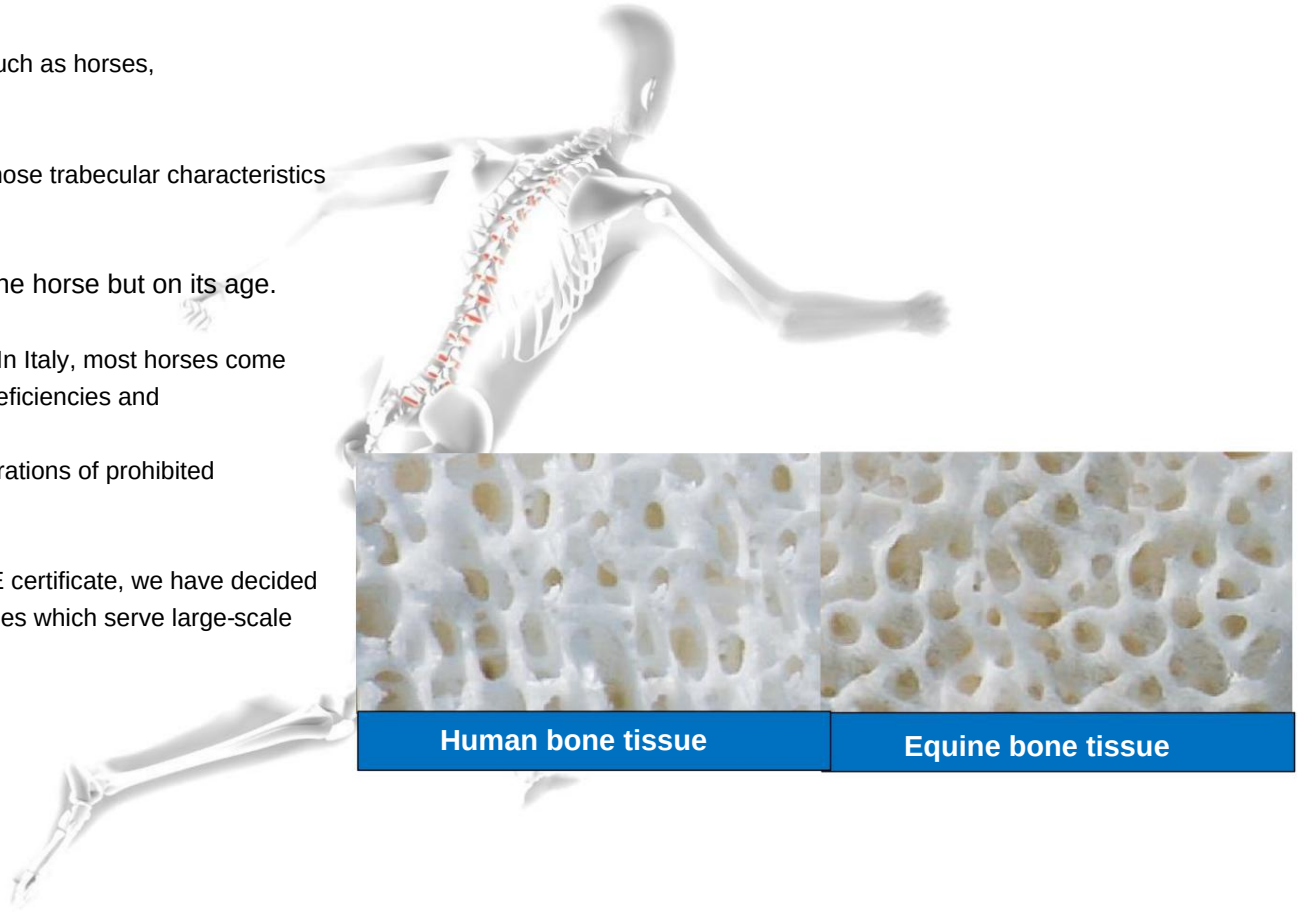
With experience, it is possible to obtain a scaffold from animal breeds such as horses, cattle and pigs that is completely similar to the human one.

Inside the femur there are bone sections at certain anatomical points whose trabecular characteristics are superimposable on those of humans.

The quality of the bone does not depend on the genetic breed of the horse but on its age.

The horses used come from animals intended for human consumption. In Italy, most horses come from Eastern European countries. These animals have serious health deficiencies and often end up in
slaughter of riding or racing animals that may contain very high concentrations of prohibited drugs, such as phenylbutazone, etc.

In collaboration with the Istituto Superiore di Sanità which issues our CE certificate, we have decided to use only horses coming from Spain and slaughtered in slaughterhouses which serve large-scale distribution which carries out
constantly analyzing the meat



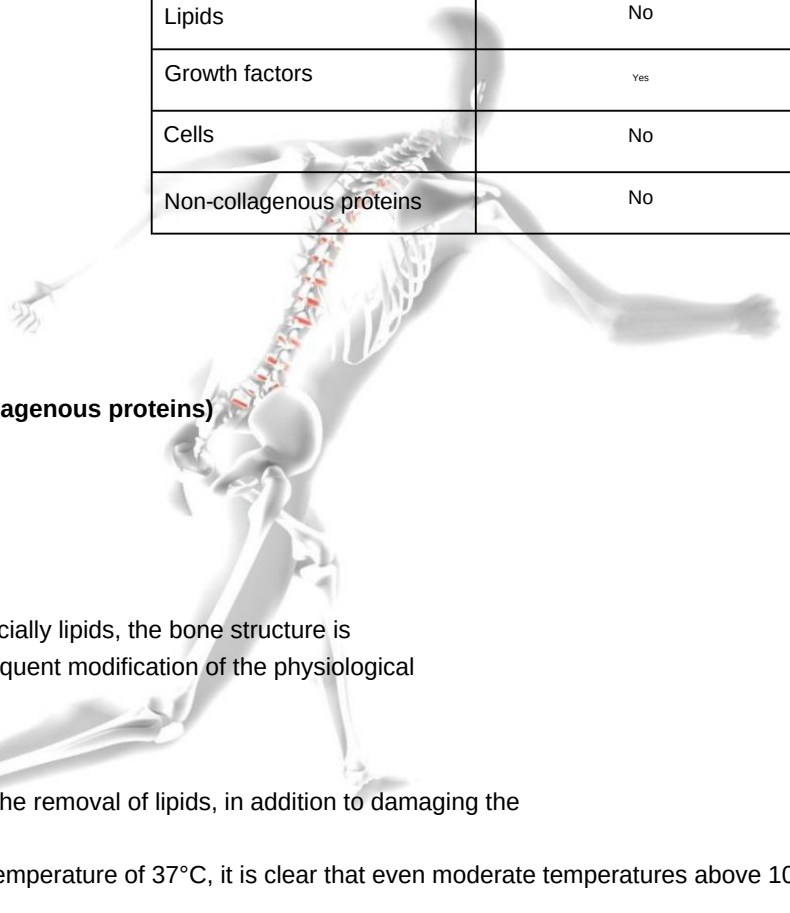
THE DEANTIGENIZATION SYSTEM

Humans and horses belong to two different genetic species.
It is not possible to completely transfer tissue from one species to another without the immune system intervening to prevent antigens from entering the body and causing rejection.

ELEMENT	COMPATIBILITY	PERCENTAGE
Bone mineral	Yes	100%
Collagen	Yes	98%
Lipids	No	0%
Growth factors	Yes	100%
Cells	No	0%
Non-collagenous proteins	No	0%

Deantigenization systems have the function of eliminating unnecessary and harmful components present in bone tissue.

The system developed by Dr. Sergio Maggi for Maggi srl was launched in 1995 and has proven highly reliable over time. In its non-original form, it is used by several companies. The system takes into account the following criteria:



· Complete elimination of antigenic components (lipids - cells and non-collagenous proteins)

· Maintenance of collagen and growth factors

· Intact mineral structure in non-allotropic form

It often happens that in the attempt to eliminate unnecessary components, especially lipids, the bone structure is damaged, creating irreparable alterations to the apatite crystal lattice with consequent modification of the physiological bone remodeling systems (turnover).

The high temperatures that are often used to eliminate the solvents needed for the removal of lipids, in addition to damaging the collagen and growth factors, promote an allotropic form of the apatite crystal.
Considering that mammalian bone is formed at atmospheric pressure and at a temperature of 37°C, it is clear that even moderate temperatures above 100°C can cause irreparable damage.

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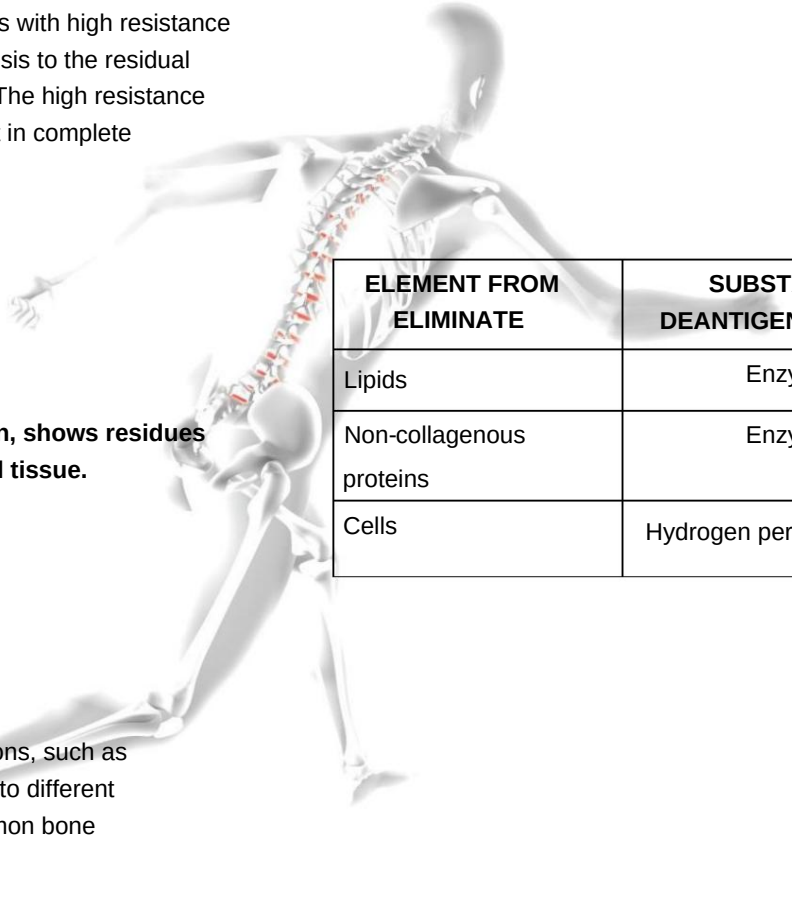
THE DEANTIGENIZATION SYSTEM

Operating at a maximum temperature of 37°C, the system does not induce any substantial changes in the crystalline lattice, preserving both growth factors and natural collagen. Maintaining collagen allows the tissue to be sectioned into blocks of various sizes and types with high resistance to load and fracture. This material can and should be stabilized by osteosynthesis to the residual skeletal structures to be regenerated without suffering any structural damage. The high resistance to load allows for immediate functional rehabilitation, which over time will result in complete regeneration of bone tissue without the presence of osteoid tissue.



ELEMENT FROM ELIMINATE	SUBSTANCE DEANTIGENATING	TEMPERATURE
Lipids	Enzyme	37°C
Non-collagenous proteins	Enzyme	37°C
Cells	Hydrogen peroxide	18°C

Osteoid tissue is a regenerate tissue that, upon histological examination, shows residues of integrated “biomaterial” without the presence of fibrous but non-vital tissue.

The bone material obtained with these systems allows for further manipulations, such as transformation into ELASTA or OSTEOGEN tissue, which adapt the product to different types of reconstructive surgery with characteristics superior to those of common bone tissue found in nature, changing both its mechanics and resorption times.

OSTEOINTEGRATION AND REGENERATION

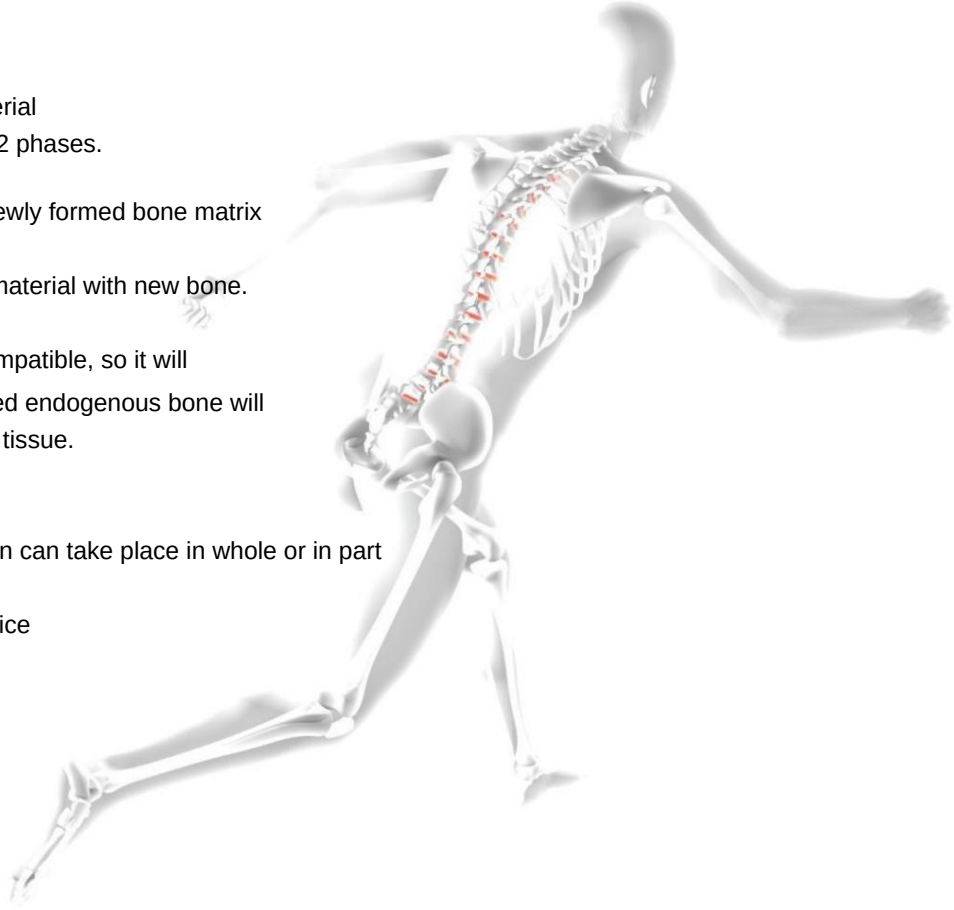
The process of repairing a bone injury using material outside the organism goes through 2 phases.

PHASE 1: inclusion of the material into the newly formed bone matrix

PHASE 2: total replacement of the included material with new bone.

In PHASE 1, the material is only required to be biocompatible, so it will behave like a titanium dental implant; the newly formed endogenous bone will incorporate it without the formation of reactive fibrous tissue.

PHASE 2 in the case of using a material of bone origin can take place in whole or in part depending on the deantigenization method used and any allotropic modifications made to the lattice crystalline of bone apatite.



OSTEOINTEGRATION AND REGENERATION

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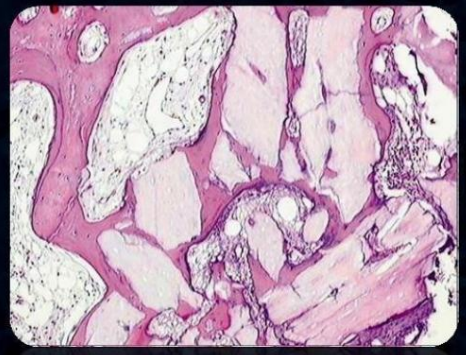
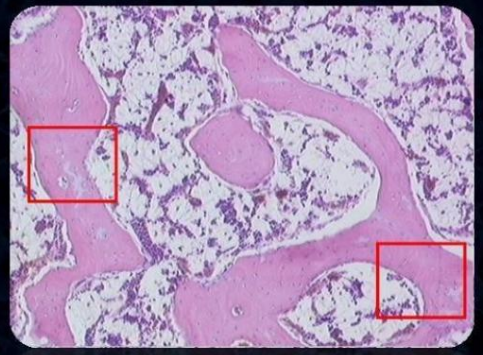
Denaturazione Enzimatica



Cortical and spongy bone, t = 1 month



Cortical and spongy bone, t = 1 year

Rimodellamento del tessuto osteoide

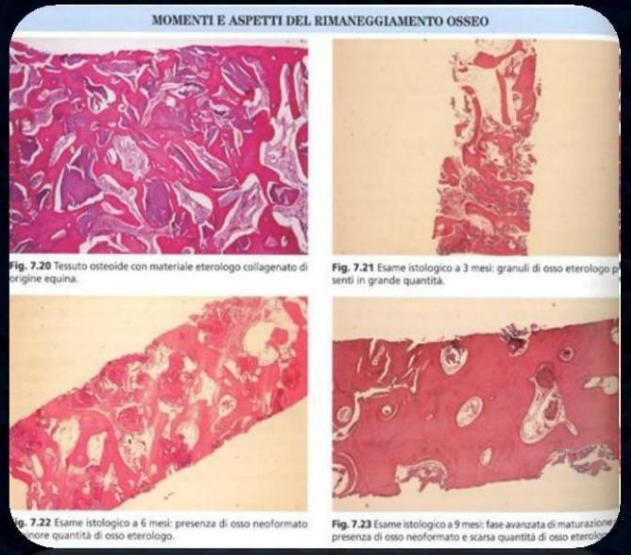


Fig. 7.20 Tessuto osteoide con materiale eterologo collagenato di origine equina.

Fig. 7.21 Esame istologico a 3 mesi: granuli di osso eterologo p… senti in grande quantità.

Fig. 7.22 Esame istologico a 6 mesi: presenza di osso neoformato …nore quantità di osso eterologo.

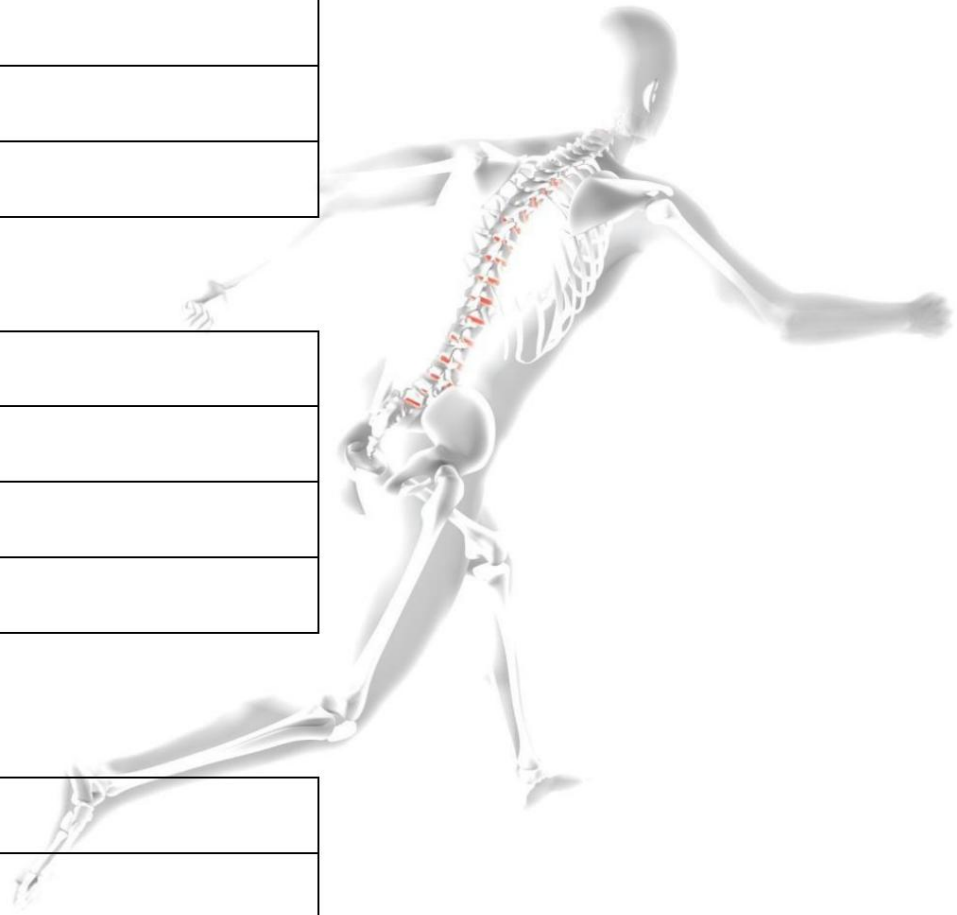
Fig. 7.23 Esame istologico a 9 mesi: fase avanzata di maturazione… presenza di osso neoformato e scarsa quantità di osso eterolo…

BONE PRODUCTS

BIOPLANT
High load-bearing strength bone mineral scaffold
Natural bone collagen
Angiogenic and osteogenic growth factors

BIOPLANT ELASTA
Demineralized bone mineral scaffold
Natural trabecular bone collagen
Angiogenic and osteogenic growth factors

OSTEOGEN
Weakened bone mineral scaffold



BIOPLANT

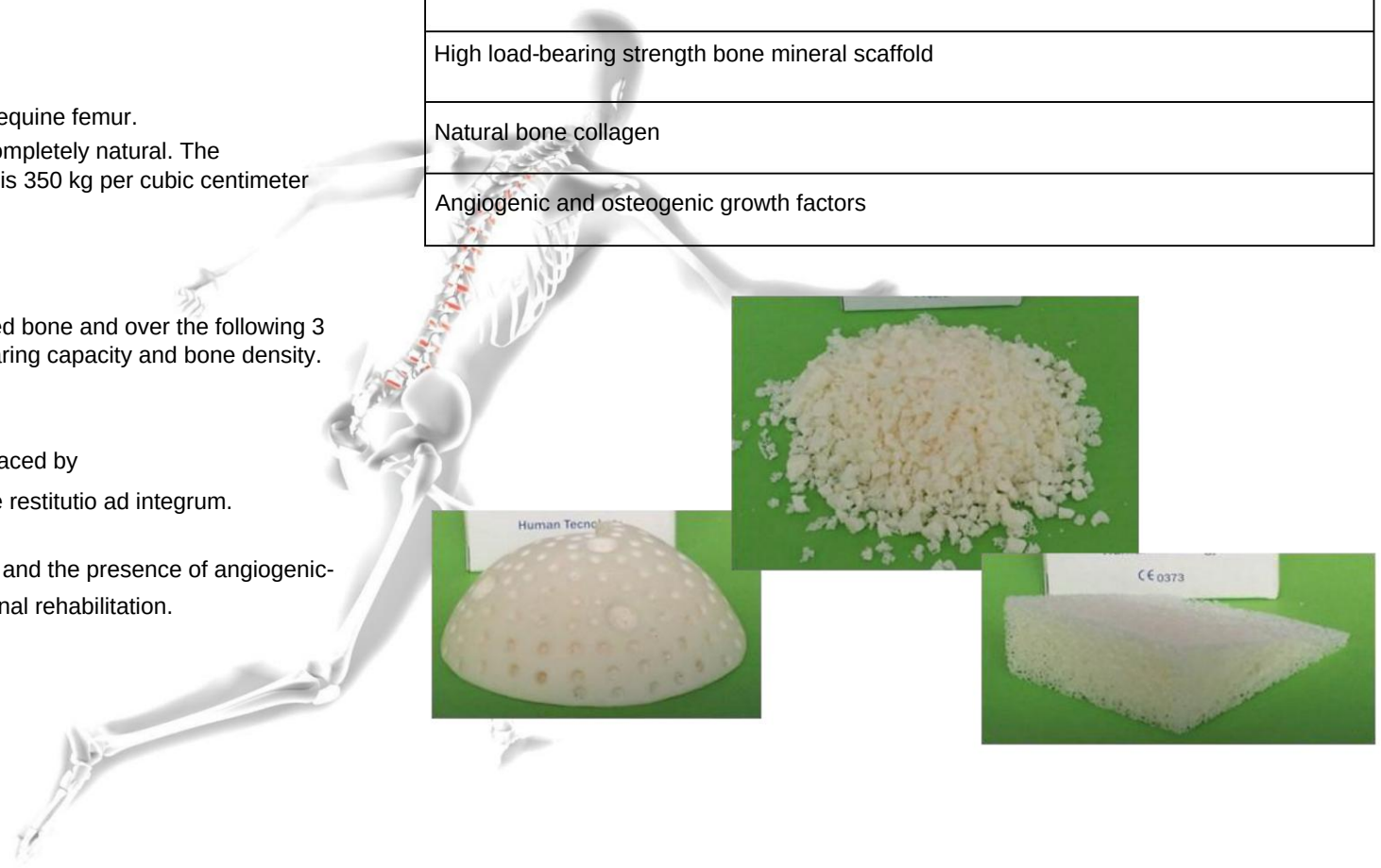
BIOPLANT
High load-bearing strength bone mineral scaffold
Natural bone collagen
Angiogenic and osteogenic growth factors

The tissue is obtained from whole sections of equine femur.
It is therefore not a reconstructed tissue but completely natural. The load-bearing capacity of the rehydrated tissue is 350 kg per cubic centimeter with a 2% loss over the following 8 hours.

The material is integrated into the newly formed bone and over the following 3 months the grafted area increases its load-bearing capacity and bone density.

Within 12 months the tissue is completely replaced by newly formed endogenous bone with complete restitutio ad integrum.

Thanks to its high load-bearing characteristics and the presence of angiogenic-osteogenic factors, it allows immediate functional rehabilitation.



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BIOPLANT ELASTA

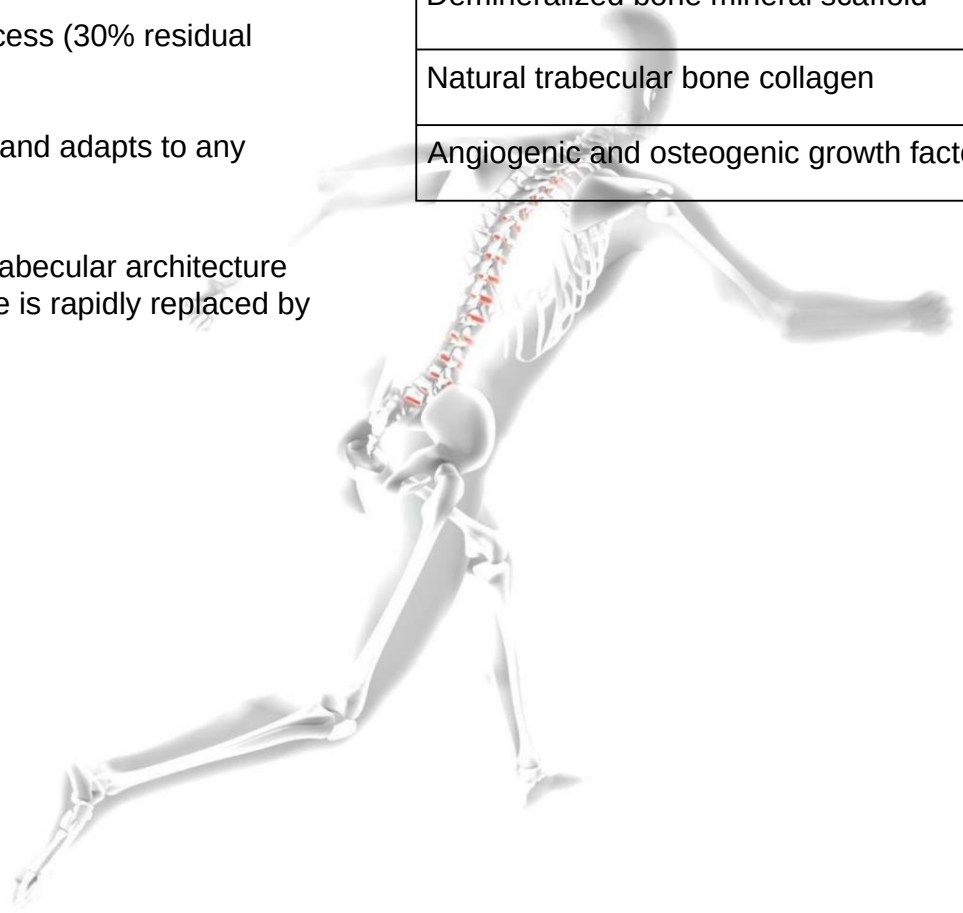
This type of fabric does not exist in nature and falls into the category of fabrics “engineered”.

BIOPLANT bone tissue is subjected to a partial demineralization process (30% residual mineral) with exposure of the collagen fiber and growth factors.

After rehydration, BIOPLANT ELASTA bone tissue becomes flexible and adapts to any skeletal conformation.

Thanks to the presence of the angiogenic factors WGF, the correct trabecular architecture and the reduced quantity of bone apatite present, the preformed bone is rapidly replaced by endogenous bone in a single phase of bone turnover.

BIOPLANT ELASTA
Demineralized bone mineral scaffold
Natural trabecular bone collagen
Angiogenic and osteogenic growth factors



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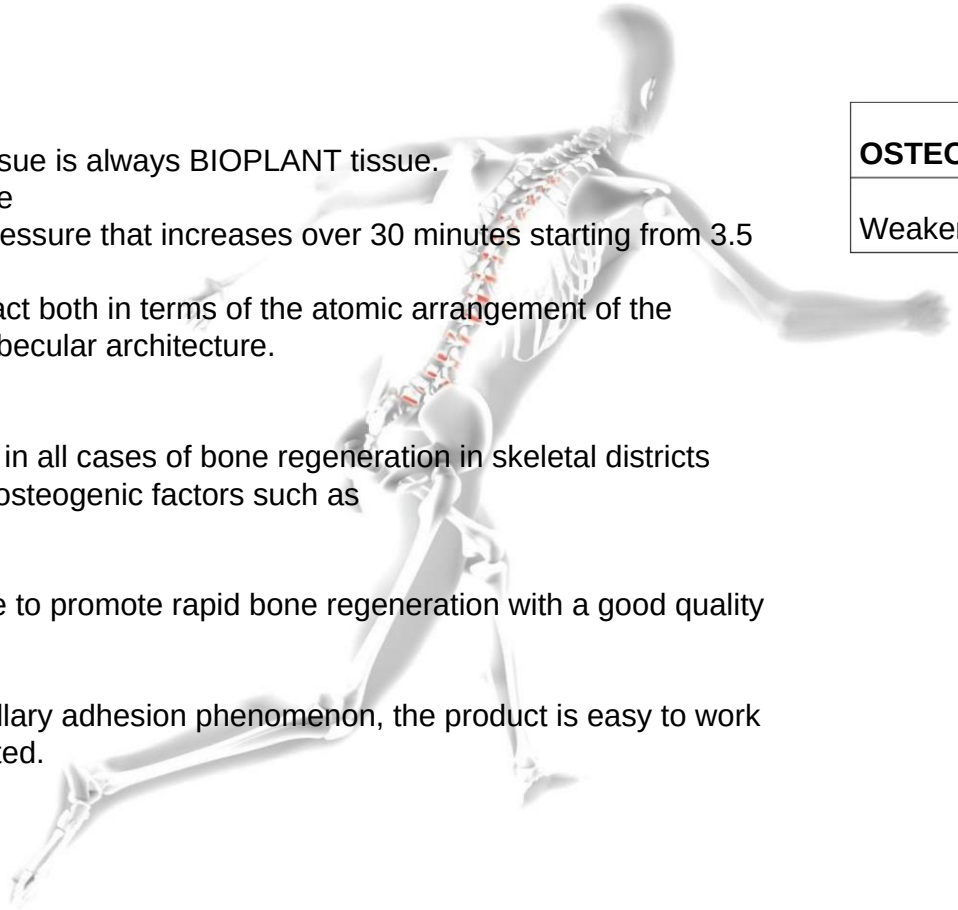
OSTEOGEN



OSTEOGEN
Weakened bone mineral scaffold

The starting point for this modified bone tissue is always BIOPLANT tissue.
The fibre is extracted using a special device
collagen, subjecting the bone tissue to a pressure that increases over 30 minutes starting from 3.5 atm and reaching 5 atm.
The end result is a bone mineral that is intact both in terms of the atomic arrangement of the bone apatite crystal, both in terms of its trabecular architecture.

This type of material is particularly suitable in all cases of bone regeneration in skeletal districts with poor cellular activity and low levels of osteogenic factors such as
for example dental use.

Thanks to its weakened structure, it is able to promote rapid bone regeneration with a good quality regenerate with early mineralization.

Thanks to its high hygroscopicity and capillary adhesion phenomenon, the product is easy to work with and position in the site to be regenerated.

RAW MATERIAL SELECTION AND GROWTH FACTORS

The major problem in using preparations containing growth factors is the uncertainty in the percentage of these factors in the product.

As we can see from the table on the side, different batches of the same product have very different percentage levels of morphogenic components.

In preparations of human origin this is due to the age of the multi-organ cadaver donors which can range from children to the elderly.

For the production of bone tissue, Maggi srl uses only safe Spanish horses, all slaughtered at the same age, thus providing consistent and guaranteed levels of growth factors, and a single genetic breed selected for consistent levels of osteogenic and angiogenic components.

Table 4. Concentrations of BMP-2 and BMP-7 Assayed From Extracts From Various DBM Formulations

	Lot No. 1 ng/g DBM	Lot No. 2 ng/g DBM	Lot No. 3 ng/g DBM	CV
ELISA analysis of BMP-2 ng/g DBM				
Allomatrix® C bone graft putty[7]	97.5	30.1	28.2	76.01%
DBX® DBM putty[8]	51.4	40.9	36.6	17.72%
DynaGraft® II osteoinductive gel[9]	49.2	38.8	25.4	31.56%
DynaGraft® II osteoinductive putty[11]	39.5	30.8	29.5	16.34%
Grafton® gel[12]	85.6	33.6	20.2	74.35%
Grafton® putty[13]	61.3	51.9	29.0	35.05%
Grafton® crunch (written communication, February 2004)	40.8	30.5	29.0	19.21%
InterGro® DBM putty (written communication, November 2003)[14]	89.7	50.5	33.0	50.29%
Osteofil® allograft paste[15]	120.6	48.4	28.4	73.71%
BMP-2, lots: $F = 15.12$, $P < 0.0002$; products: $F = 1.29$, NS	70.6	39.5	28.8	
ELISA analysis of BMP-7 ng/g DBM				
Allomatrix® C bone graft putty[7]	118.8	67.8	66.3	35.45%
DBX® DBM putty[8]	179.7	94.1	90.9	41.43%
DynaGraft® II osteoinductive gel[9]	188.9	95.6	54.2	61.11%
DynaGraft® II osteoinductive putty[11]	226.8	67.9	55.0	82.08%
Grafton® gel[12]	70.5	69.9	60.3	8.56%
Grafton® putty[13]	84.7	80.0	78.6	3.95%
Grafton® crunch (written communication, February 2004)	73.5	68.1	66.9	5.06%
InterGro® DBM putty (written communication, November 2003)[14]	77.5	72.7	72.7	3.71%
Osteofil® allograft paste[15]	81.6	68.1	66.5	11.51%
BMP-7, lots: $F = 6.43$, $P < 0.01$; products: $F = 1.19$ NS	122.4	76.0	67.9	

NS indicates not significant, CV, coefficient of variation.

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