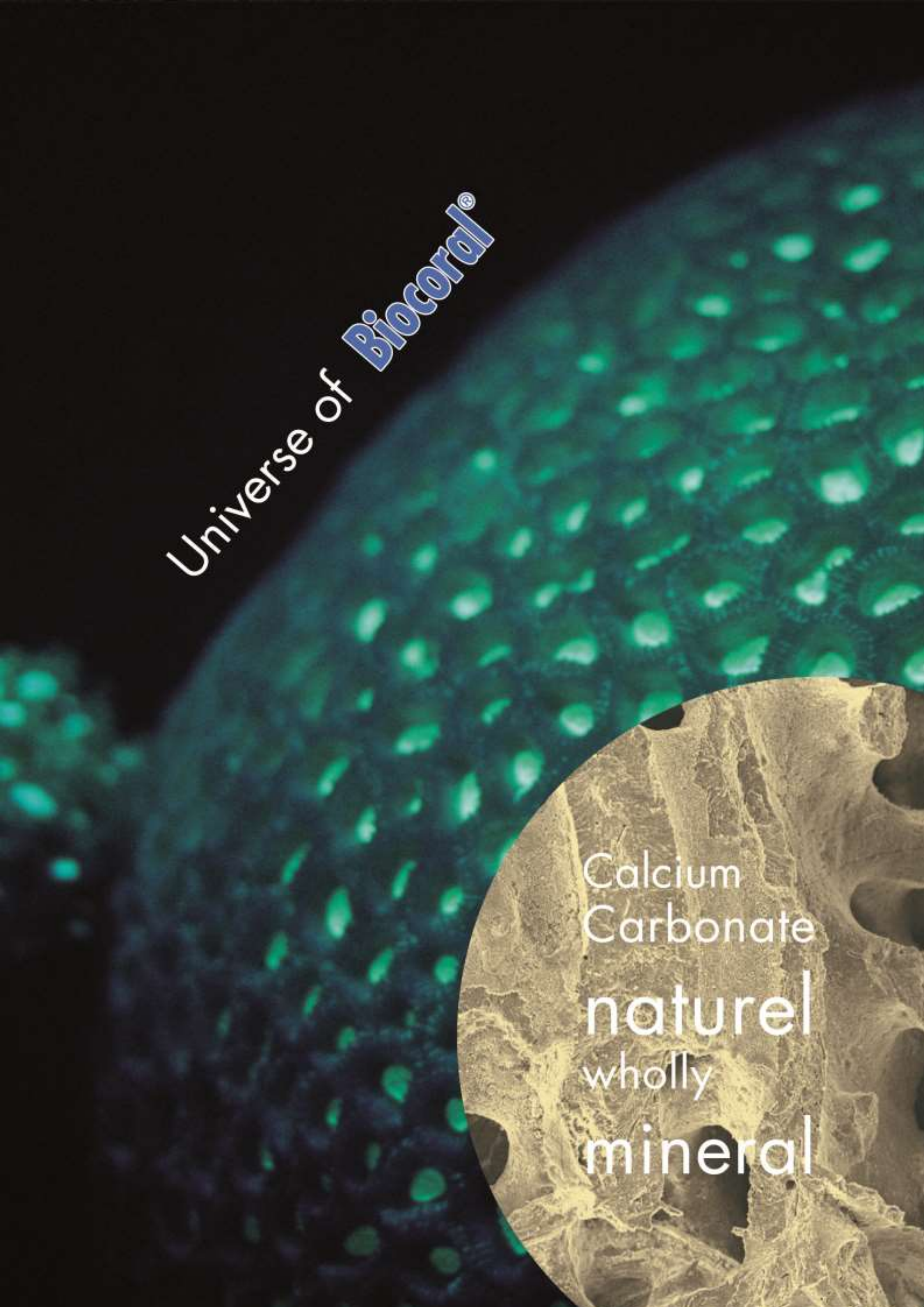

Universe of Biocoral®
Calcium Carbonate
naturel
wholly
mineral

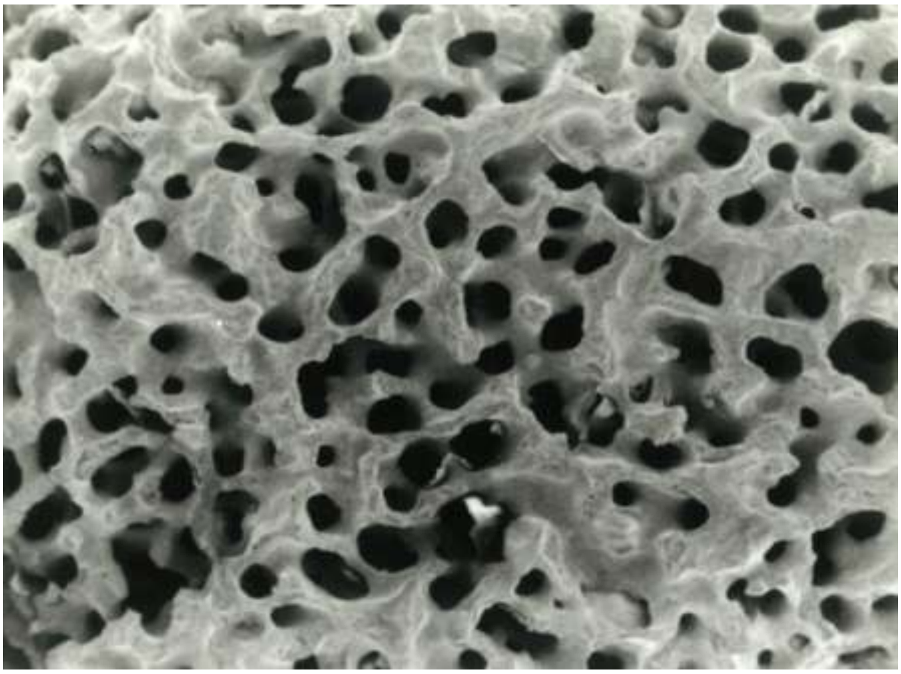
"Full fadom five thy father lies
of his bones are coral made
those are pearls that were his eyes
nothing of him that doth fade
but doth su er a sea-change
into something rich and strange."

William Shakespeare
THE TEMPEST (Act 1, SC II).

Biocoral®

Natural Calcium Carbonate bone substitute

Biocoral® is the only natural wholly mineral bone graft substitute having a highly porous architecture, which is formed from naturally occurring aragonite crystal with three-dimensional interconnectivity allowing for optimum formation of new bone.



Biocoral®:

- Natural Calcium Carbonate ($CaCO_3$),
- 3 dimensional randomly interconnected pore,
- Pore size: 150µm,
- Porosity: 50% allowing an ideal newly bone formation.

THE PHYSIOLOGY OF BONE GRAFTING

The biology of bone grafts and their substitutes is appreciated from an understanding of the bone formation processes of Osteogenesis, Osteoinduction and Osteoconduction.

***Osteogenesis**:* The cellular elements within a donor graft, which survive transplantation and synthesize new bone at the recipient site.

***Osteoinduction**:* New bone is formed through the active recruitment of host mesenchymal stem cells from the surrounding tissue, which differentiate into bone-forming osteoblasts. This process is facilitated by the presence of growth factors within the graft, principally Bone Morphogenetic Proteins (BMP).

Osteoconduction: The facilitation of blood-vessel incursion and new-bone formation into a defined passive trellis structure.

All bone graft and bone-graft-substitute materials can be described through these processes.

CHARACTERISTICS OF BIOCORAL®

Biocoral® is a natural bone substitute used since more than 30 years in all surgical, repair and bone regeneration procedures. Biocoral® is available in the form of granules, beads, blocks, and the shaped prostheses. The Biocoral® is the only natural wholly mineral resorbable bone substitute composed of Calcium Carbonate (>98%).

Biocoral® biocompatibility, together with its osteoconductive and osteophilic properties, induces specific biological activity in the recipient bone, similar to the physiological natural bone metabolism. This activity leads to graduate resorption of Biocoral® by osteoclasts and its replacement by osteoblasts in newly formed bone.

The porosity architecture of Biocoral® is in the form of aragonite crystalline. The regular structures of pores, their volume, their size and the thickness of their walls are the special characteristics of Biocoral®. The open porosity of Biocoral®, allows the blood cells and bone marrow cells (blood, anions, cations, etc...) to spread and infiltrate in its core which speed up the bone ingrowths. Biocoral® present the remarkable mechanical resistance qualities associated to its porosity (50% and 20%) similar to those of the cancellous and cortical bone respectively.

Section of a human femural cortex

Section of Biocoral®

GOOD REASONS TO USE BIOCORAL®

Biocompatible

Biocoral® is perfectly tolerated by the human body with no risk of contamination and is compatible with the structural requirements of bone growth.

Bioresorbable

Biocoral® has excellent bone integration with total resorption between 3 to 9 months.

Biocoral® because of its mineral and architectural characteristics (Aragonite Crystal and Porosity), once placed is bony sites is quickly impregnated with autogenous blood or bone marrow, with a proved calcification from the day 9^{th}.

Osteoconductor

Biocoral® has an ideal porosity which allows a quick invasion of bone marrow and integration of newly formed bone.

Re-Initiates Bone Mineralization Process

Biocoral® is used as an active ingredient for reinitiating the process of bone remineralization.

Replaced by Newly Formed Bone

Biocoral® is quickly vascularized and progressively resorbed by osteoclast cells, which is then replaced by osteoblast cells in order to conduct newly formed bone identical to the recipient bone.

No Risk of Viral Transfer & Contamination

Biocoral® follows strict quality control procedures which are performed at each stage of manufacturing process and guarantees its compliance with high quality standards and offers surgeons a truly trustworthy biomaterial.

Easy to Use

Biocoral® is available in a variety of shapes and sizes. It can easily be used and applied to the surgical site once infiltrated by autogenous blood or bone marrow.
Biocoral® is available in different forms: granules, beads, blocks and shaped prostheses.

Avoids taking autologous bone graft & Reduce Cost

Biocoral®'s uses avoids taking autologous bone graft (which can lead to risks such as postoperative infection, bleeding, pain) and prevent unwanted aesthetic disorders at donor site. The take of autologous bone graft increases the time of the surgical process and the costs related into. (the surgical act and miscellaneous costs).

Biocoral® is the best alternative to the autologous grafts and also contributes to decrease and minimize patient's hospitalization and its health care costs.

CHEMICAL COMPOSITION OF BIOCORAL®

Following the studies of Pr Le Petitcorps in 2006 at Hospital University Center of Bordeaux, L'ICMCB-ENSCPB (one of the CNRS laboratories (UPR 9048)), Biocoral®'s chemical composition is confirmed being wholly mineral as described below:

Chemical composition of Biocoral®

Calcium Carbonate (CaCo3)	> 98 %
(including calcium)	> 40 %
Trace elements (inlcuding Fluorine and Strontium)	0.7 à 1 %
Magnesium	0.05 à 0.2 %
Sodium	< 1 %
Potassium	< 0.03 %
Phosphore (phosphate form)	< 0.05 %
Water	< 0.5 %

Several components are present at levels equivalent to those found in mammalian bone, notably trace elements, which play a vital role in the process of mineralization and in the activation of enzymatic reactions in bone cells.

Two trace elements have specifics effects:

- Strontium is involved in the formation and growth of the crystalline component of bone, protects calcification mechanisms and increases mineralization. Furthermore, Strontium levels are higher in the most active bone structure the metaphysis and bone callus.

- Fluorine in proper quantity increases bone formation by direct effects on proliferation of cellular precursors of osteoblasts.

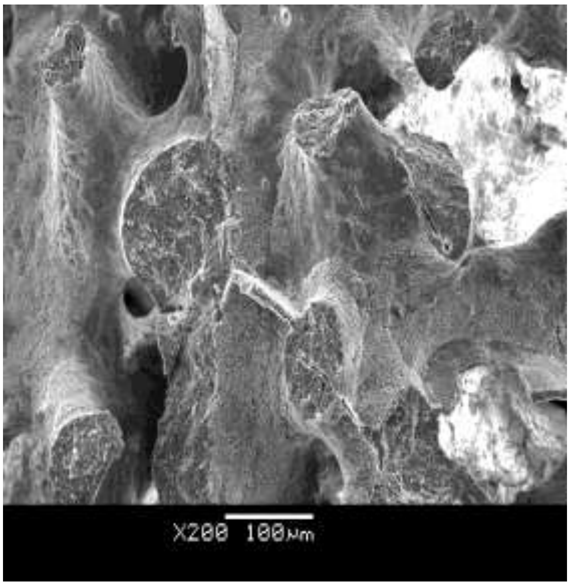
TECHNICAL PROOF ON BIOCORAL®

A. Determination of Pore Size

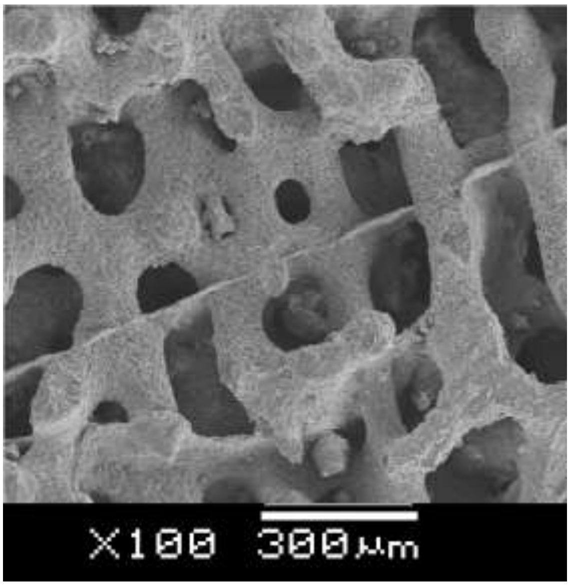
Biocoral® pore size is important as this offers the ideal environment for vascularization and migration of osteoclasts and osteoblasts. It ranges between 20% and 50% depending on the species selected. Acropora (20% of porosity) is very close to the cortical bone. The Porites (50% of porosity) is very close to the cancellous bone. That porosity allows the surgeon to choose Biocoral®, according to the clinical indication. However, those specifications do not constitute a rigid standard. Natural Calcium Carbonates with different porosities can be used according to the operating procedure.

Biocoral® pore size ranges between 150 to 500 microns, depending on the species, selected according to clinical indications. It has previously been shown that these sizes are optimal for occupation by fluids and bone marrow cells in order to complete mineralized newly formed bone. For indications where dense material is necessary, for example for strong mechanical compression strains, the natural microporous Calcium Carbonate (Acropora) can be used.

Bone cells (bone marrow and blood of the recipient bone) can freely invade the open porous structure of Biocoral® deep in its core. This cellular invasion determines the first phase of the bone restoration process characterized by the development of a neo-vascularization. Some corals (Porites in particular) have the architecture similar with the cancellous bone.



Section of Biocoral® 50% porosity



Section of Biocoral® 20% porosity

B. Overall porosity

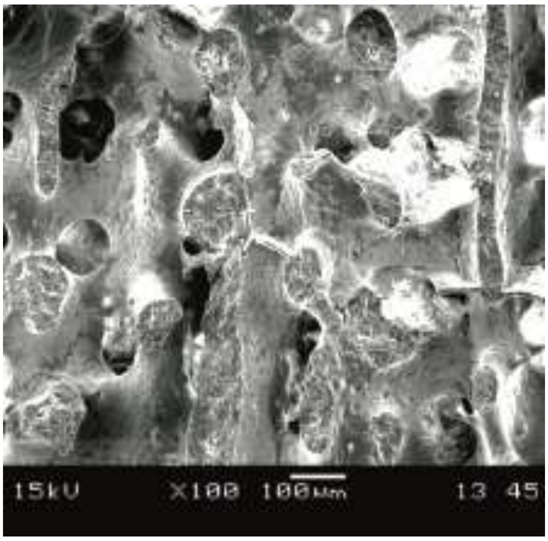
Biocoral® has a maximum porosity of 50% for allowing the ideal bone ingrowths. To induce the bone regeneration process overall porosity is one of the important key factors and its high porosity enhances the osteoconductivity.

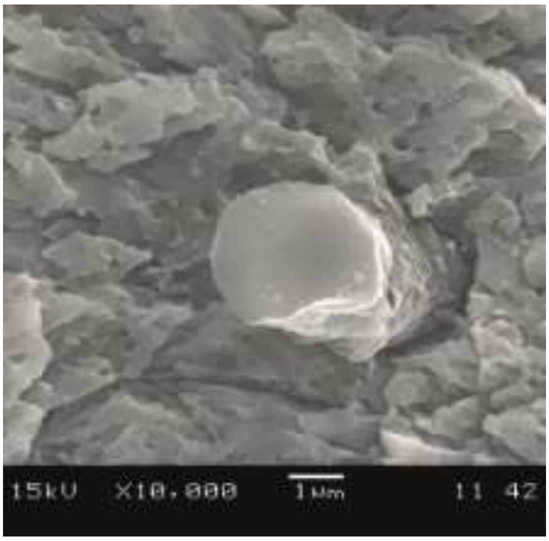
MECHANICAL CARACTERISTICS	BIOCORAL®		
	DENSE	**20% POROSITY**	**50% POROSITY**
Breaking deformation	0.47 ± 0.03 %	0.53 ± 0.12 %	0.26 ± 0.04 %
Breaking stress in compression in MPa	395 ± 29 *330 % that of fresh cortical bone* *50 % that of titanium alloy*	110 ± 32 *75 % that of fresh cortical bone*	25.2 ± 5.2 *25 % that of fresh cortical bone* *500 % that of cancellous bone*
Young's modulus (modulus of elasticity) in GPa	101.6 ± 3.7	24.6 ± 3.30	7.99 ± 0.37

(Orthopedics Researches Laboratory, U.A. C.N.R.S., 1161, Expert evaluation report, INOTEB, 1987)

C. Three-Dimensional interconnected pore for ideal Bony Growth

Biocoral®'s architecture is entirely porous and is defined by the total volume three-dimensional randomly interconnected to allow bone formation throughout the entire implant.(Photos below)





BIOCORAL®'S INDICATIONS

Biocoral® is a natural bone substitute used since more than 30 years in all surgical, repair and bone regeneration procedures.

Biocoral® is the only biocompatible and bioresorbable calcium salt used as an active ingredient for local treatment of diseases associated with demineralization or mineralization defects of bone, with the aim of reinitiating the bone remineralization process (Patented Application).

Orthopedic surgery:

- Substitution of cancellous bone graft,
- Insufficiency of autogenous bone graft,
- Filler of metaphyseal bone graft (osteoporotic disease),
- Femoral neck fracture associated with a cancellous bone demineralization,
- Demineralized bone cavity filling (bone-cyst, chondroma, acetabular cavity),
- Upper and lower limb fractures associated with bone demineralization,
- Non-union atrophic bone fractures,

Cranio-Maxillo-Facial surgery:

- Maxillo reconstructive and plastic surgery,
- Plastic and facial reconstructive surgery of Malar,
- Nasal sulcus filling,
- Plastic and reconstructive surgery of Orbit (post-traumatic, post-cancerous),

Oral surgery:

- Filling, reconstruction of bone defects and regeneration of bone for: Periodontal, implant and endodontic surgery,
- Filling, reconstruction of bone defects and regeneration of bone for: Pre prosthetic surgery and implant procedure: Filling after tooth extraction,
- Oral surgery: Filling of cystics cavities.

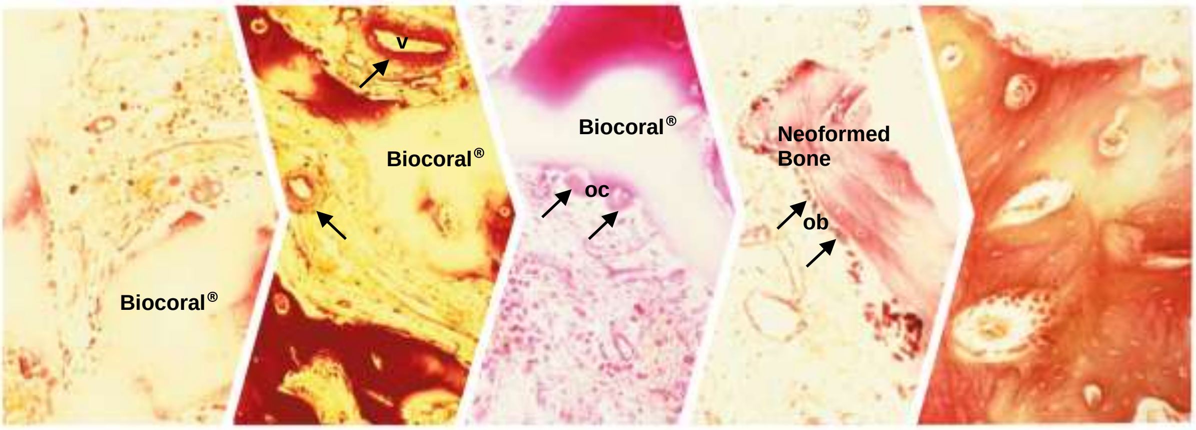
Particular Applications

- Sinus lift augmentation,
- Lateral sinus lift augmentation,
- Filling of voluminous cystics cavities,
- Filling and augmentation of lateral sinus.

Biocoral® is a bone graft substitute which provides an ostoeconductive matrix and it is a very useful for adding volume to autogenous graft to obtain osteoinduction. It is recommended to impregnate Biocoral® with bone marrow or blood, particularly when it is necessary to obtain immediate cohesion between Biocoral® granules or beads. Once blood is mixed with Biocoral®, the existence of fibrin in blood makes a composite easier to fill in the recipient bone.

HISTOLOGIC ANALYSIS OF FUSION MASS

A. From Biocoral® to Newly Formed Bone



Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Invasion	*Vascularization*	*Resorption*	*Bone Neoformation*	*Remodeling*

Phase 1: Invasion by blood cells and extravasated bone marrow.

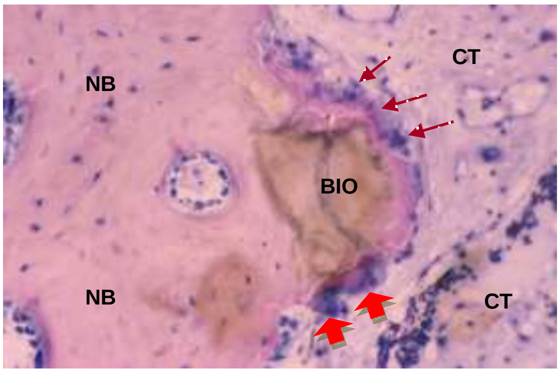
Phase 2: Vascularization (v: vessels).

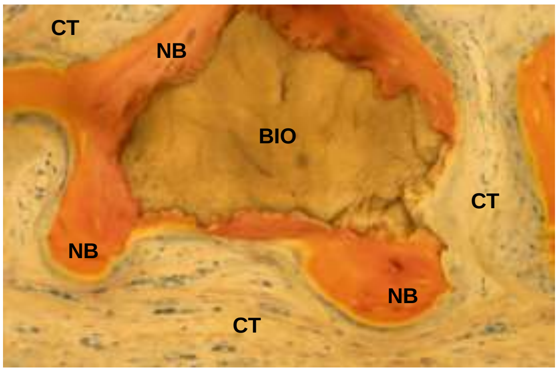
Phase 3: Resorption of Biocoral® by osteoclasts (oc: osteoclast).

Phase 4: Bone neoformation with osteoblastic (ob: osteoblast) apposition and concomitant resorption.

Phase 5: Remodeling of neoformed tissue to produce the architecture of the recipient bone.

B. New bone formation associated with the bone's physiological modification





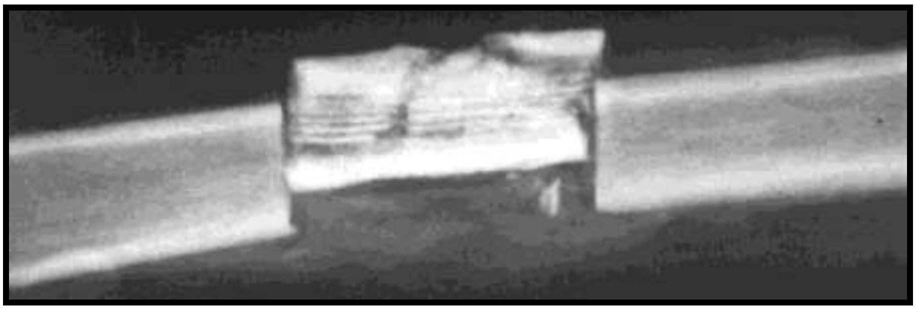
BIO : Biocoral® NB : Neformed Bone CT : Connective Tissue

→ : Osteoblast cells ➡ : Osteoclast cells

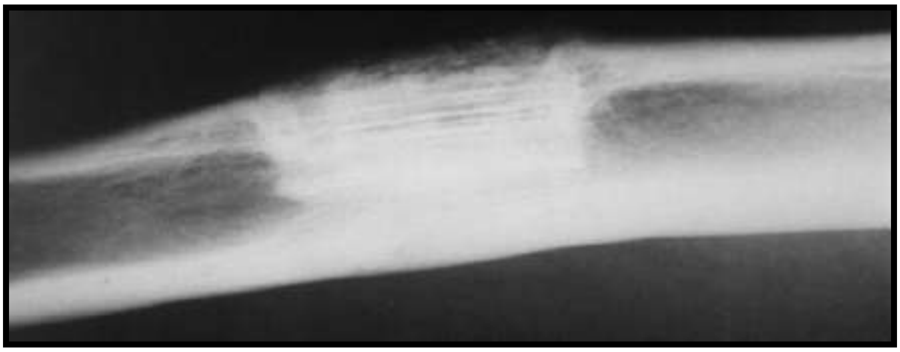
We can notice the physiological bony modification with an osteoblastic phase and an osteoclastic phase.

RADIOLOGICAL RESULTS OF FEMORAL LENGHTENING

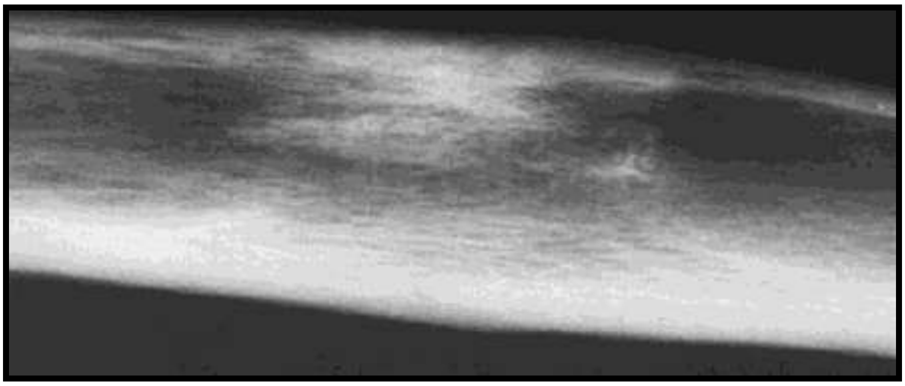
An eight year old child had a right leg that was more than five centimeters shorter than the left leg. Such a discrepancy normally calls for an elongation of the malformed leg. A Biocoral® graft was implanted. During the following years, Biocoral® was perfectly integrated into the site and there was a successful reconstruction of the femoral shaft.



Post Operative



One Year Later



Three Years Later

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Long- bone critical- size defects treated with Tissue- engineered Grafts: A study on sheep
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CLINICAL RESEARCH - ORTHOPAEDICS AND SPINE SURGERY

E. SOFFER[1]., J.P. OUHAYOUN.[2], A. MEUNIER[1], F. ANAGNOSTOU[2]
Effects of Autologous Platelet Lysates on Ceramic Particle Resorption and New Bone Formation in Critical Size Defects:
The Role of Anatomical Sites
[1] Laboratoire Biomatériaux et Biomécanique Ostéo-articulaires, UMR.-A-C.N.R.S. 7052, Paris, France
[2] Département de Parodontologie, Faculté de Chirurgie Dentaire Université Paris 7 et Laboratoire Biomatériaux et Biomécanique Ostéo-articulaire, U.M.R.-C.N.R.S. 7052, Paris, France
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W. BENSAID[a,b], J.T. TRIFFITT[b], C. BLANCHAT[a], K. OUDINA[a], L. SEDEL[a], H. PETITE[a,*]
A biodegradable fibrin scaffold for mesenchymal stem cell transplantation
[a] Laboratoire de Recherches Orthopédiques, UMR-CNRS 7052, Faculté de Médecine Lariboisière Saint-Louis, Université D. Diderot, 10 avenue de Verdun, Paris 75010, France
[b] Botnar Research Laboratory, Nuffield Department of Orthopaedic Surgery, University of Oxford, UK
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D. LOGEART-AVRAMOGLOU, F. ANAGNOSTOU, R. BIZIOQ, H. PETITE*
Engineering bone: challenges and obstacles
Laboratoire de Recherches Orthopédiques, Faculté de Médecine Lariboisière Saint-Louis, Université Denis Diderot, Paris, France
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[1] Ecole Nationale Vétérinaire d'Alfort, 7 avenue de Gaulle, 94700 Maisons Alfort, France
[2] Laboratoire de Recherches Orthopédiques, Centre Nationale de la Recherche Scientifique-Sciences pour l'Ingénieur,
Unité Mixte de Recherche 7052, Faculté de Médecine Lariboisière Saint-Louis, Université Denis Diderot, 10 avenue de Verdun, 75010 Paris, France
[3] Laboratoire de Radiologie Expérimentale, Centre Nationale de la Recherche Scientifique-Sciences pour l'Ingénieur,
Unité Mixte de Recherche 7052, Faculté de Médecine Lariboisière Saint-Louis, Université Denis Diderot, Paris, France
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E. ARNAUD[a], C. DE POLLAK[b], A. MEUNIER[b], L. SEDEL[b], C. Damien[c], H. PETITE[b,*]
Osteogenesis with coral is increased by BMP and BMC in a rat cranioplasty
[a] Unite& de chirurgie craniofaciale, Département de neurochirurgie, Hopital Necker, 75743 Paris cedex 15, France
[b] Laboratoire de Recherches Orthopédiques, Université D. Diderot, Paris VII, URA CNRS 1432, 10 ave. de Verdun 75010 Paris, France
[c] Sulzer Orthopedics, 4056 Youngxeld Street, Wheat Ridge, CO 80033, USA
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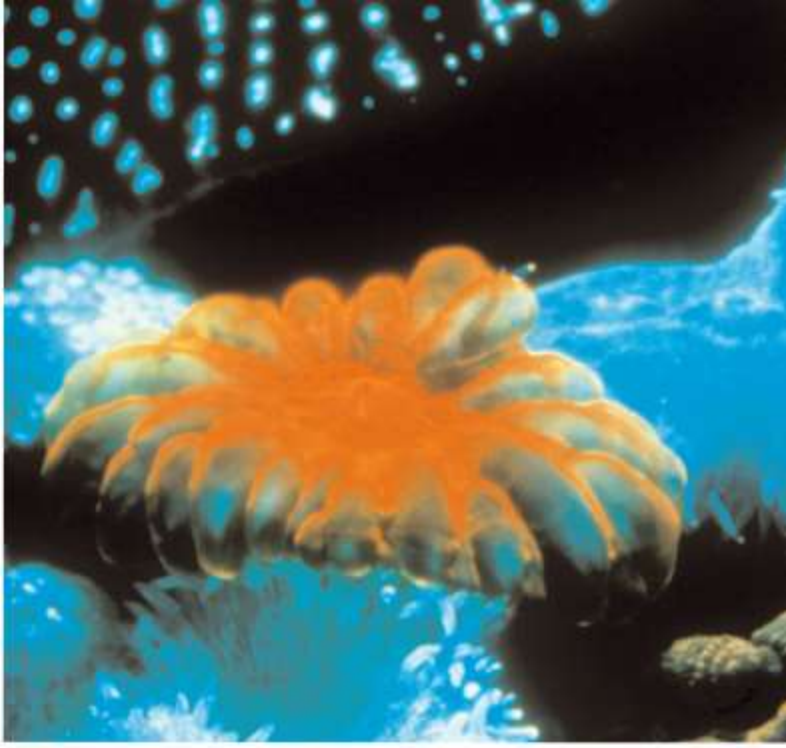



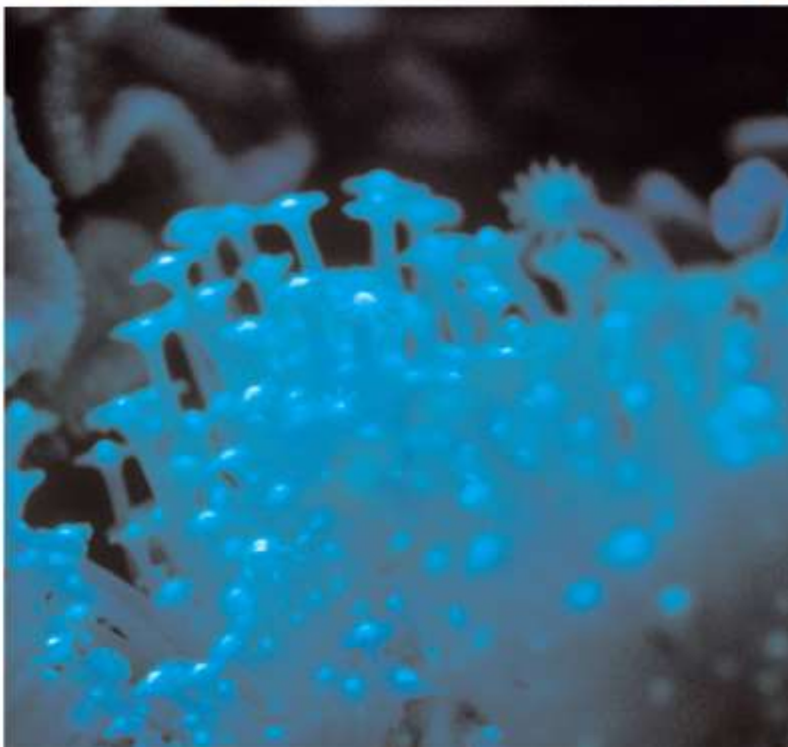

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Biocoral® obtained the authorization of marketing in the European countries market "EC lable" on December 30, 1996.

The manufacture of Biocoral® comply with the regulation inforc.

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BIO CORAL CALCIUM BONE
Biomaterials & Tissue Engineering Company
Le Guernol • 56920 Saint-Gonnéry - France
Tel: + 33 (0) 2 97 38 40 88 • Fax: + 33 (0) 2 97 38 41 13
e-mail: info@biocoral.com • www.biocoral.com