btk the smile system®

oxofix

Reabsorbable bone regenerator

www.bioteconline.com

FEATURES

OXOFIX is a product range of synthetic bone regenerators carefully designed to fill bone in the oral cavity and to favor bone growth and especially to do act as a stimulator for all those biological elements (collagen, osteoblasts, etc.) involved in bone formation processes.

OXOFIX is made of β-tricalcium-phosphate under international standard ASTIM F1088-04, which means a phase-purity of 95%, nevertheless OXOFIX products present a purity of over 99% and are therefore above the demands of the international standard.

BENEFITS

- It delivers mechanic stability, avoiding micro-movements.
- It preserve the shape and volume of the defect to avoid bone resorption.
- It favor rapid colonization of proteins and cells.
- It acts as ideal support, as it is recongnised by the body and the blood capillaries and cells adhere to it to form the bone (fig. 1).

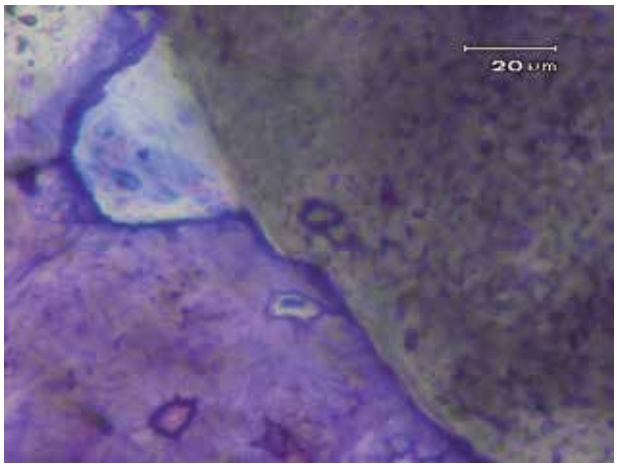

Fig. 1 - Blood capillaries and cells that adhere to OXOFIX to form new bone

PROPERTIES

The composition of **OXOFIX** implies that once it is implanted in the area to be regenerated and through the features of the physiological medium, a surface reaction with that medium happens, slowly dissolving and releasing Ca^{2+} and PO_4^{3-} ions.

This leads to the precipitation of hydroxyapatite on the implant surface. This precipitation produces an interphase of some microns of thickness in which collagen, osteoblasts and immature bone fiber appear. They look rather amorphous and will later develop and become structured, while the implant dissolution moves towards the inside, with the final result of implant replacement by bone, i.e., the total absorption of the **OXOFIX** implant (fig. 2).

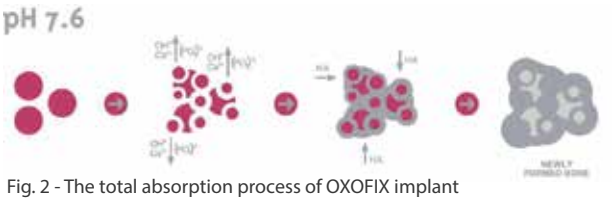

Fig. 2 - The total absorption process of OXOFIX implant

The most important feature of OXOFIX is its three-dimensional structure (fig. 3), **identical to the trabecular structure of spongy bone, with open average porosity of 60and average pore size of 250 microns.**
This porosity, of interconnected nature, allows for and favours the process of cell and vascular colonisation.

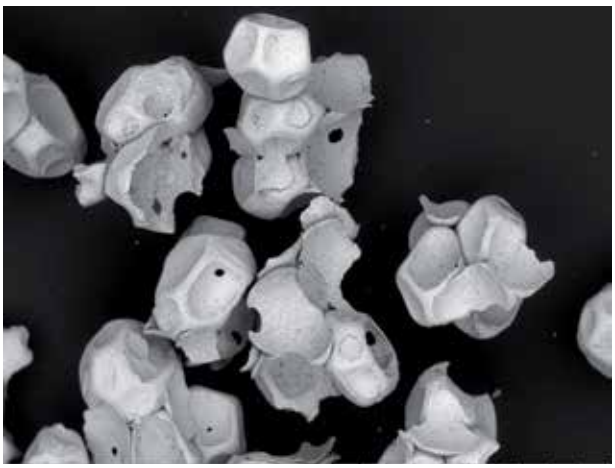

Fig. 3 - OXOFIX three-dimensional structure

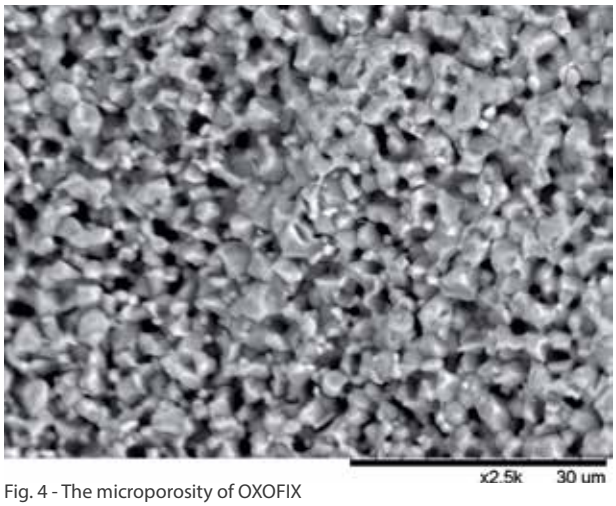

Fig. 4 - The microporosity of OXOFIX

Both the macroporosity of **OXOFIX** due to its structure (interconnected diameter porosity of over 250 microns) and the microporosity (fig. 4) developed in progress, favour the colonisation process of the biomaterial by the bone, the generation of osteoblasts and newly formed bone on all the biomaterial and not only on the surface, as is the case with other biomaterials.

The interconnected mesh structure favours, on the one hand, that cells can completely penetrate the implant and be more efficiently fed, and on the other hand, that due to microporosity adherence to the implant surface both of bone cells as well as the growth factors we may add (PRP, PGDF,...) is improved and thus the osteoinductive capacity of the implant is enhanced (fig. 5).

These features imply that bone regeneration time goes down in a remarkable way in comparison to other products in the market.

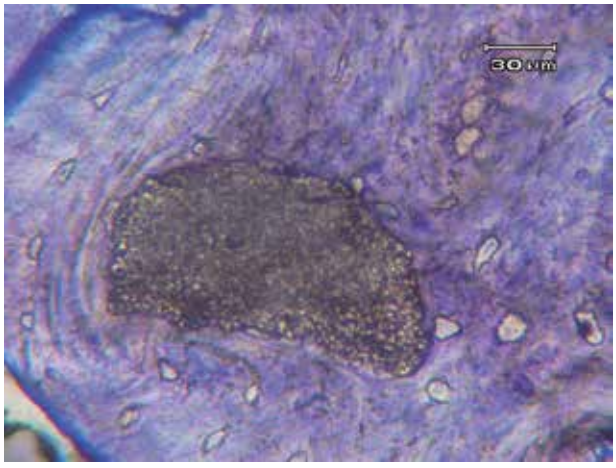

Fig. 5 - Enhanced osteoinductive capacity of the implant

INDICATIONS

- Filling material for maxillary and mandibular bone cavities after dental extraction, avoiding reabsorption of the alveolar process linked to later instability of removable prosthesis for the rehabilitation of edentulous spaces.
- Filling material in surgical cavities originated by teeth extraction of totally included teeth.
- Filling material of surgical cavities after apicectomy and periapical cystectomy.
- Coating material for bone fenestration in those cases in which the vestibular-lingual dimension of the alveolar crest is reduced.
- Filling material for defects of margin adjustment between the onlay of autologous bone and surgical bed.
- Filling material of bone cavities after definitive loss of a tooth at an age when implant replacement is not feasible.
- Adjuvant material for optimum aesthetic results as in the case of anterior front teeth extraction, thus preventing the collapse of bone and gum.
- Elevations of the maxillary sinus.
- Filling of post-extraction bone cavities.
- Covering of fenestrations.
- Expanding bone regeneration.
- Crest reconstruction.
- Intrabone defects in periodontics.
- Furcal lesions.
- Radicular exposures.

CLINICAL USE

In no case must **OXOFIX** be used in cases of chronic or acute infection not adequately treated with antibiotics. It must not be used either in areas that do not ensure primary stability of the implant or in areas that exclude the possibility of bone growth around the implant.

Due to the granulate and porous morphology of **OXOFIX** products, it is advisable that, at the time of use, they are mixed with the patient's blood or blood serum, or otherwise with artificial physiological serum, in order to avoid that the material may be dispersed during implant due to the features of the oral cavity (high concentration of fluids).

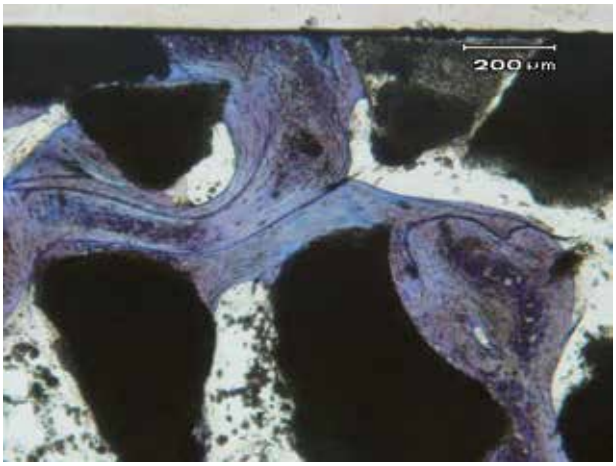

Fig. 6 - Complete osteonal restructuring

CLINICAL ADVANTAGES

INCREASE IN OSTEOCONDUCTION

From the point of view of osteoconduction (delivery of a platform for the capillary that will vascularise the area of the defect anew and for hone forming cells in the recipient site), porous OXOFIX materials, due to their open and interconnected porous structure, work exactly as autografts or allografts of spongy hone. They deliver the same three-dimensional network both in composition and structure, which supports blood capillaries and osteogenic cells in the affected area.

EXCELLENT VOLUME MAINTENANCE AND PRIMARY STABILITY OF THE IMPLANT

OXOFIX protects the adjacent bone against reabsorption. The anchorage effect of OXOFIX due to its porous structure allows for the preservation of shape and stability in the volume of the implant area. This leads to excellent mechanic stability avoiding undesired micromovements of the implant.

TOTAL ABSENCE OF IMMUNOLOGICAL ACTIVITY

OXOFIX, as it is a completely synthetic material, it is immunologically inactive and free of antigenic elements. Therefore its use is completely safe.

EFFECTIVE BONE REGENERATION

It has been proven that filling of bone defects with OXOFIX has remarkably accelerated the bone scaring process of the defect. Studies have proven that apart from accelerating the consolidation process, these materials are fully osteointegrated in bone tissue with total osteocompatibility, and then participate in the process of bone remodelling of the defect and thus complete osteonal restructuring (fig. 6).

NO INFECTIONS

OXOFIX has been developed in strictly aseptic conditions and is delivered in a sterile state so there is no risk of infection due to the nature of the material.

NO ANTIBIOTICS

The use of antibiotics is usually unnecessary in the case of OXOFIX. We cannot recommend mixing it with any antibiotic as we cannot make studies that analyse the combined used of these compounds.

NO AUTOLOGOUS BONE

OXOFIX has been designed to be used without having to mix it with the bone of the patient. There is no problem whatsoever if the user wants to mix it with autologous bone.

WHY PREFERE OXOFIX?

The graphic below shows the differences between OXOFIX and biomaterials of animal origin.

	BIOMATERIALS	VS	OXOFIX
ORIGIN	Donor Animals		Synthetic
COMPOSITION	Carbohydroxyapatite		B-Tricalcium Phosphate
MANUFACTURING	Elimination of organic matter present in the donor's bone structure		Chemical process based on industrial reagents
MORPHOLOGY	Depends on the donor animal and the part from which the biomaterial was obtained		Specifically designed according to the requirements for cells involved in bone regeneration
μ - POROSITY (Approximate Average Value)	40%		25%
SPECIFIC SURFACE (Approximate Average Value)	60 m^2/g		0.25 m^2/g
CONTROL	Partially controlled end product		Fully controlled end product
FINAL RESULT	Bone Repair		Bone Regeneration

Bone Repair means formation of scar tissue with different characteristics from the original.

BONE REGENERATION means formation of **new bone** which after remodelling is **identical to the pre-existing bone**.

QUALITY

OXOFIX is the result of 15 years of research in the field of ceramic biomaterials.
The research and development studies for these materials were started in the 90s at the Instituto de Ceramica de Galicia (Galicia's Ceramic Institute) of the University of Santiago de Compostela (Spain). At the end of the 90s, these studies led to the creation of KERAMAT, a Spanish partner of **Biotec-BTK** working in the design, manufacturing and marketing of ceramic biomaterials for clinical use.

OXOFIX materials comply with all the required quality standards for health products at international level and has on-site Quality Insurance Systems based on the demanding ISO 9001:2000/ISO 13485:2000. It also has an EC Label to be sold in the whole European Union.
In order to ensure quality of all the **OXOFIX** products, the producer undertakes strict quality controls in several production stages. KERAMAT uses 12%; of its production for quality control. In this way, OXOFIX has become a reference in terms of quality and safety.

The products are produced and packed in conditions of total asepsis and are subjected as a last step to sterilisation through gamma radiation.

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btk the smile system®

btk in the World!

We strive to become the reference benchmark for implant dentist technicians
in every country in the world, developing partnerships based on trust,
guided by respect and aimed at achieving common goals.

Visit our website at www.bioteconline.com to watch how we expand day after day.

Products with the EC mark.

Quality system certified UNI EN ISO 9001 and UNI EN ISO 13485,
in accordance with Directive 93/42/EEC - Annex II(3).

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