Fusiongraft®

TRABECULLAR SYNTHETIC BONE GRAFT

TECHNICAL INFORMATION ON FUSIONGRAFT PRODUCTS

Fusiongraft®

Trabecular micro-geometry Synthetic Bone Graft

MATERIAL QUALIFICATION

Fusiongraft® products are developed based on resorbable biomaterials based on calcium phosphate chemistry, and are manufactured under the strictest quality controls, meeting the highest scientific standards, and are available in various types of granular geometry. **Fusiongraft®** medical devices have properties similar to those of natural bone, contributing to improving people's quality of life.

The key to our products is the presence of an interconnected porous geometry, in the form of microchannels in the structure of the material. These channels have the appropriate dimension, (typically 0.0 5 mm in diameter), to facilitate the entry of blood and cellular components that enable biodegradation that allows replacement by the natural bone that replaces it.

OUR HISTORY

Our company, **Inmet Garnick S.A.**, was founded in 2004 with the purpose of collaborating with health professionals, offering them implantological products of the highest quality and thereby contributing to the health of their patients.

Under this commitment and in order to cover the gap in the market in the area of manufactured synthetic bone grafts, our company creates the **Fusiongraft®** brand, and establishes the bases for the distribution of our biomaterials.

At the same time, with the commitment to expand the range of applications, to respond to the great health needs and demands of professionals.

We are constantly evolving and with the firm commitment to delivering our customers products of the highest quality.

Welcome to **Fusiongraft®**.
Trabecular micro-geometry Synthetic Bone Graft.

OUR PURPOSE

The development and marketing of medical products of the highest quality exalts health professionals with innovative tools that contribute, in a decisive way, to improving the health and quality of life of their patients.

It is for this reason that our products are of synthetic origin, which is one of the greatest advantages compared to other solutions on the market:

Our products minimize the risks of infections.
Our products have no contraindications.
All of our products are 100% resorbable, blending in with natural bone.

Therefore, **Fusiongraft®** is a product that responds to an existing need in the market, contributing to the health of patients and the satisfaction of professionals.

GRANULES
0.1 - 0.5 mm

GRANULES
0.5 - 1.0 mm

ADVANTAGES

HIGH POROSITY
Three-dimensional bone regeneration at the defect site, through osteoconduction.

RADIOPAQUE
Allowing monitoring with radiodiagnosis graft osseointegration.

HIGH MECHANICAL RESISTANCE
Product designed to achieve the highest degree of porosity, maintaining maximum mechanical resistance.

REABSORBABLE
The graft is completely resorbed and replaced with new native bone.

WITHOUT MEMBRANE
The use of membrane is not required unless there is a a risk of graft exposure.

VASCULARIZATION
The trabecular design of interconnected porosity, forms an ideal environment for vascularization.

HYDROPHILIC
Particles with hydrophilic characteristics give excellent wettability to the particles.

EASY DRIVE
It is easy to mix with patient's blood, autologous bone marrow, saline or PRP and PRF.

FULLY SYNTHETIC
No risk of contagion or biological transmission, because it does not contain tissues from animals neither human nor derivative.

- Avoid the painful practice of autologous grafting technique.
- High availability of synthetic bone.
- Sure.
- Bio-compatible.
- Reduces surgical time.

FUSIONGRAFT TCP

99,9% TCP

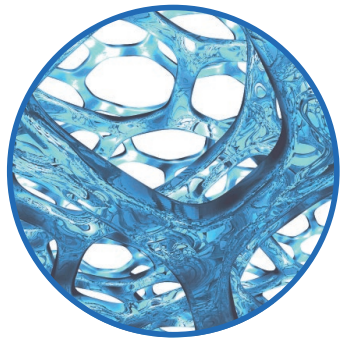
Fusiongraft TCP biomaterial is a trabecular synthetic bone graft material, based on pure beta-tricalcium phosphate (ß-TCP), designed for filling bone defects. The macro porosity of the **Fusiongraft® TCP** bone graft allows for excellent graft integration and its multidirectional interconnected porosity guides three-dimensional bone regeneration. These features provide total revascularization of the graft.

Fusiongraft TCP bone graft has excellent bioactivity and can be completely resorbed.

The **Fusiongraft TCP** bone graft is replaced by the new bone formed during the regeneration process.

Fusiongraft TCP bone graft is manufactured in the form of GRANULES of different sizes.

Fusiongraft®
TCP
Tricalcium Phosphate Bone Graft



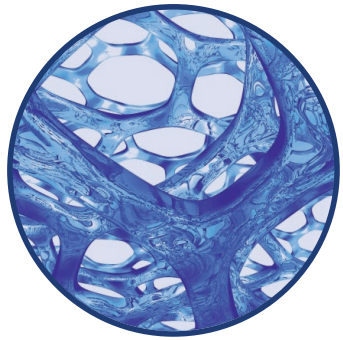
FUSIONGRAFT BCP

75% HAp / 25% TCP

Fusiongraft BCP biomaterial is a biphasic trabecular synthetic bone graft material, composed of 75% hydroxyapatite (HAp), and 25% beta-tricalcium phosphate (ß-TCP), designed for filling defects bone Calcium phosphate ceramic rapidly integrates into bone due to its chemical composition that is very similar to the mineral phase of human bone by presenting a multidirectional interconnected porosity that guides three-dimensional bone regeneration.
These features provide total revascularization of the graft.

The biphasic composition allows tricalcium phosphate to dissolve more quickly while maintaining a stable hydroxyapatite matrix, which together benefits much more effective bone development. **Fusiongraft BCP** bone graft comes in different granulometries.

Fusiongraft®
BCP
Biphasic Calcium Phosphate Bone Graft



INDICATION

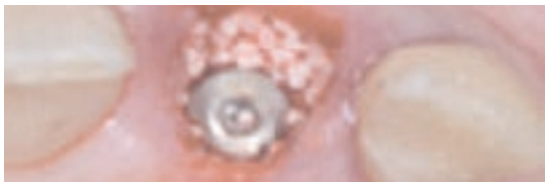
Fusiongraft® is designed to fill bone defects or bone alterations that are intrinsic to them and their stability. When placed in its implantation site, cell adhesion begins to occur on the surface of the pore and its proliferation continues, based on the interconnection of the pores, until the total mineralization of the extracellular matrix is favored.

It is presented in fine GRANULES 0.1 to 0.5 mm, medium GRANULES 0.5 mm to 1 mm, which cover practically all the applications of maxillofacial bone defects, including medium or small periodontal cystic defects, alveolar fillings, to increased filling of the maxillary sinuses including larger cysts.

The biggest difference between BCP and TCP lies in the resorption time. It can be said that BCP has a greater resemblance and similarity to a graft bone of natural origin, due to the greater difficulty of absorption. If an expert is used to working with products of animal origin, BCP
It is the material that best allows the "transition" between an animal product and a synthetic product, although we must also highlight the fast and effective regeneration obtained based on TCP.

THE ESSENTIAL FACTORS THAT INCREASE OSTEOINTEGRATION:

- Micro geometry of trabecular structure.
- Safety: 100 percent synthetic.
- There is no human or animal origin.
- GRANULE porosity: 90%.
- 300 to 500 micron pore size.
- Interconnected porosity creating open channels.
- Conductive osteo: interconnected porosity with high mechanical resistance.
- The material induces bone growth.
- 100% resorbed - replaced by new bone



Cell adhesion observed after 5 days.

INDICATIONS FOR GRAFTING

1. Fusiongraft® bone graft can be used in the form of GRANULES of different sizes.
2. Fusiongraft® graft with its granular shape helps to completely fill irregular empty spaces.
3. It is recommended to impregnate the Fusiongraft® biomaterial with the patient's blood or with physiological saline to handle it properly.
4. Fusiongraft® should make contact with the porous autologous bone which should bleed slightly.
5. Fusiongraft® should be applied generating gentle compression on its surface.
6. Adequate closure of the surgical wound must be performed; it is advisable to avoid exposure and maintain airtightness.
7. The combination of Fusiongraft® biomaterial with any other medical substance in the process of using this material is under the total responsibility of the acting surgeon.

REGARDING GRANULOMETRY

It is possible to use both **Fusiongraft BCP** and **Fusiongraft TCP** on all types of defects, as there are too many factors to take into account:

The size of the space to be grafted.
The age of the patient.
The type of surgery and the type of implant to be placed.
The waiting time.
The complexity of the different processes.

Clinical practice tends to use:

- GRANULES 0.1 - 0.5 mm, (fine),: used in implantology, lateral and vertical augmentation; small bone defects etc.
- GRANULES of 0.5 - 0.1 mm, (medium),: it is the most used in general, it can be applied for almost all processes, being widely used in:

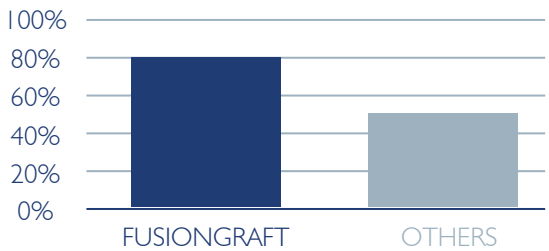
Implantology.

Maxillary sinus elevation.

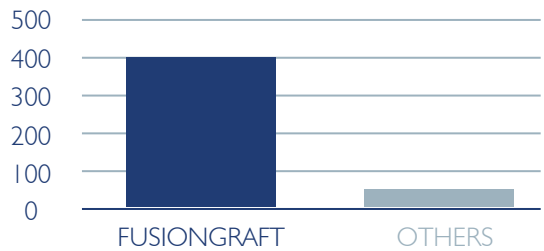
Alveolar preservation.

Obturation in general bone defects.

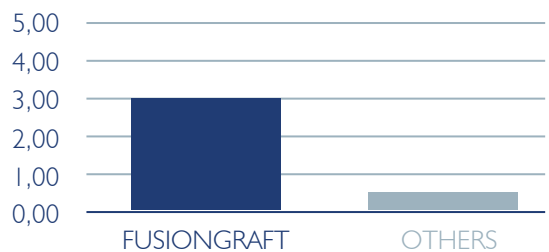
POROSITY



PORE SIZES



MECHANICAL RESISTANCE LIMIT



FUSIONGRAFT TCP

GEOMETRY	SIZE	ROAD CONTENT	QUANTITY UNITS	REFERENCE
GRANULES Fine	0,1-0,5 mm	0,5 g	Pack 5	FGT010505P
Medium GRANULES	0,5-1,0 mm	0,5 g	Pack 5	FGT050105P
Medium GRANULES	0,5-1,0 mm	1,0 g	Pack 5	FGT050110P
GRANULES Fine	0,1-0,5 mm	0,5 g	Pack 1	FGT010505P
Medium GRANULES	0,5-1,0 mm	0,5 g	Pack 1	FGT050105P
Medium GRANULES	0,5-1,0 mm	1,0 g	Pack 1	FGT050110P

FUSIONGRAFT BCP

GEOMETRY	SIZE	ROAD CONTENT	QUANTITY UNITS	REFERENCE
Medium GRANULES	0,5-1,0 mm	0,5 g	Pack 5	FGB050105P
Medium GRANULES	0,5-1,0 mm	1,0 g	Pack 5	FGB050110P
Medium GRANULES	0,5-1,0 mm	0,5 g	Pack 1	FGB050105P
Medium GRANULES	0,5-1,0 mm	1,0 g	Pack 1	FGB050110P

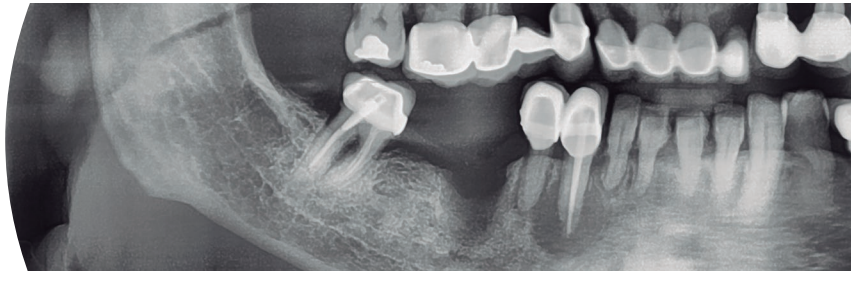
STUDY CASE

Below, we present a clinical case of a female patient aged 62 years in which it can be seen.
Materials used: mixture of **FusionGraft TCP** GRANULES 0.1-0.5 mm / **FusionGraft BCP** GRANULES 0.5-1.0 mm.

The case has been approached, through the extraction of the affected teeth, a careful and exhaustive curettage, eliminating the infected tissue and the reactional fibrous tissue, present in the bone defect cavities. Immediate post-extraction implants have been made to provide adequate support for the definitive restoration. A resorbable collagen membrane was used to cover the graft and the flap was subsequently completely repositioned and sutured to close the wound.

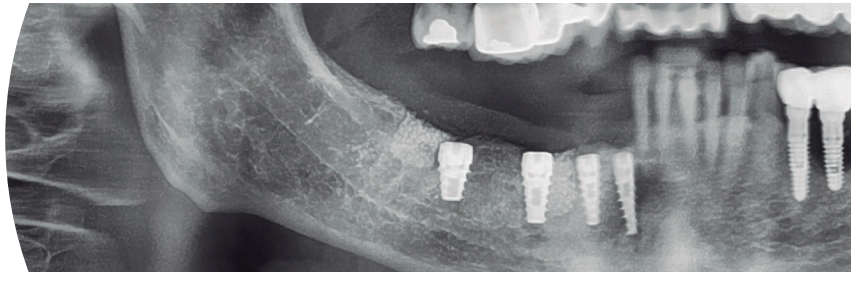
PRE-OPERATIVE

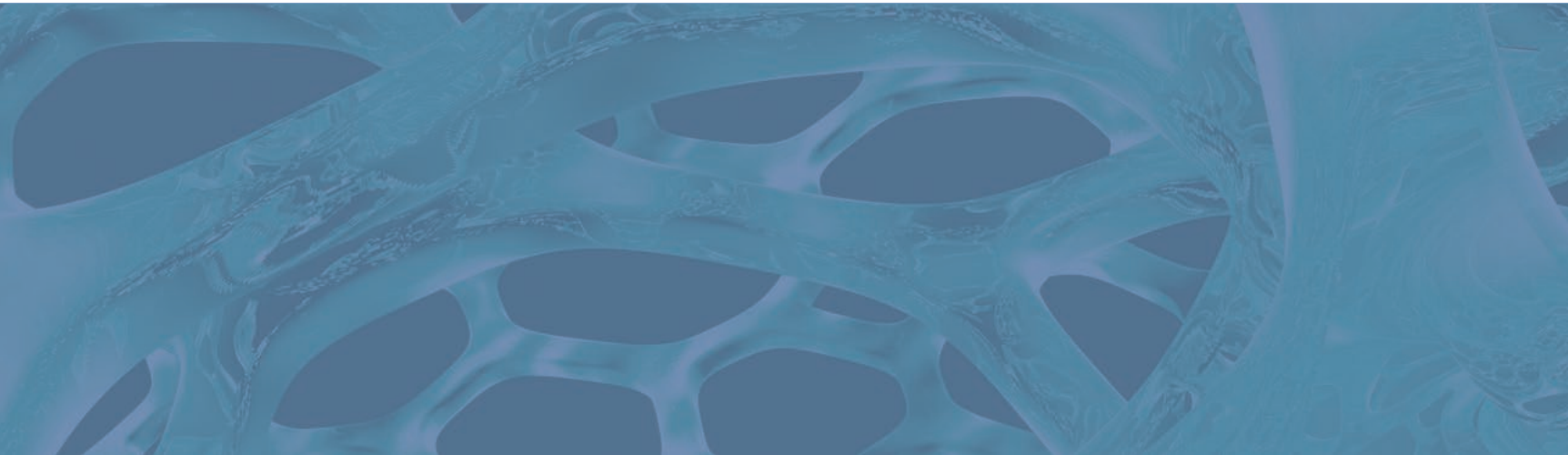
At the level of the fourth quadrant, the presence of teeth with compromised stability can be seen, along with several foci of infection that show severe degradation due to resorption of the mandibular bone tissue, evidenced by bone defects noticeable at a radiological level.



POST-OPERATIVE

Note the excellent radiological quality of the biomaterial in this image taken immediately after placing the implants. Presence of high homogeneity, completely covering the gaps generated by mandibular bone defects.



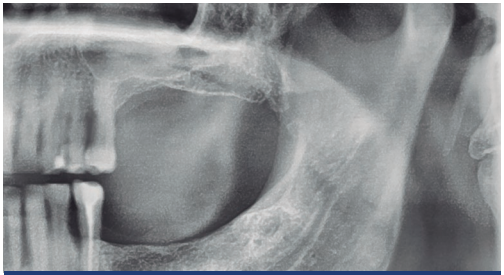


OPENING PHOTO AT FOUR MONTHS

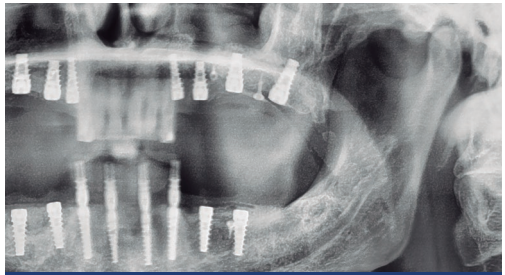
In this photograph you can see the excellent clinical-surgical quality of the biomaterial after the flap opening performed. In the image you can see the formation of a completely healthy bone, where even newly formed cortical bone, which covered the surgical caps of the implants, had to be removed to access their prosthetic function.

Some GRANULES of biomaterial can be perfectly seen in the cortex, even in the process of remodeling, due to the opening in a slightly shorter time than conventional.

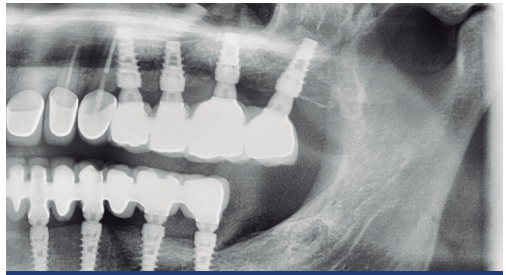
BONE REGENERATION CASES



Pre surgical

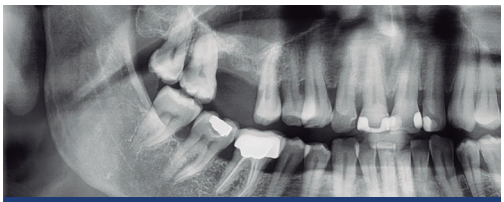


Post surgical

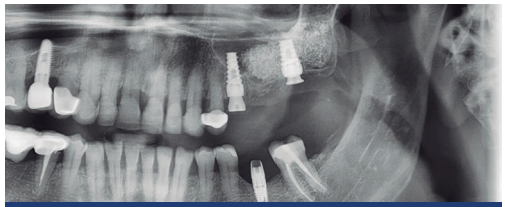


Result

Sinus floor regeneration in quadrant 2 of atrophic maxilla, (first image), using **FusionGraft BCP** 0.5-1.0 mm, with simultaneous insertion of 4 titanium implants, (second image), and definitive restoration placed after 6 months, with excellent result.

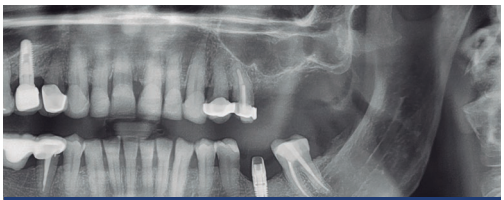


Pre regeneration

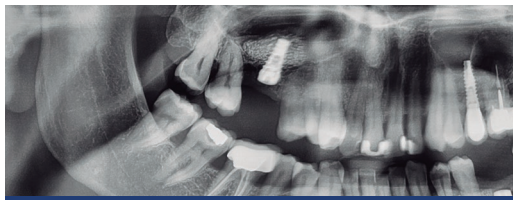


Post regeneration

Sinus floor regeneration in quadrant 2 of atrophic maxilla, (first image), using **FusionGraft BCP** 0.5-1.0 mm and **FusionGraft TCP** 0.1-0.5 mm, with simultaneous insertion of 2 titanium implants, (second image).



Pre regeneration



Post regeneration

Spot regeneration of the sinus floor for replacement of piece 16, (first image), using **FusionGraft BCP** 0.5-1.0 mm and **FusionGraft TCP** 0.5-1.0 mm, with contemporary insertion of a titanium implant, (second image).

IN CONCLUSION

SECURITY
100 percent synthetic. There is no human or animal origin.

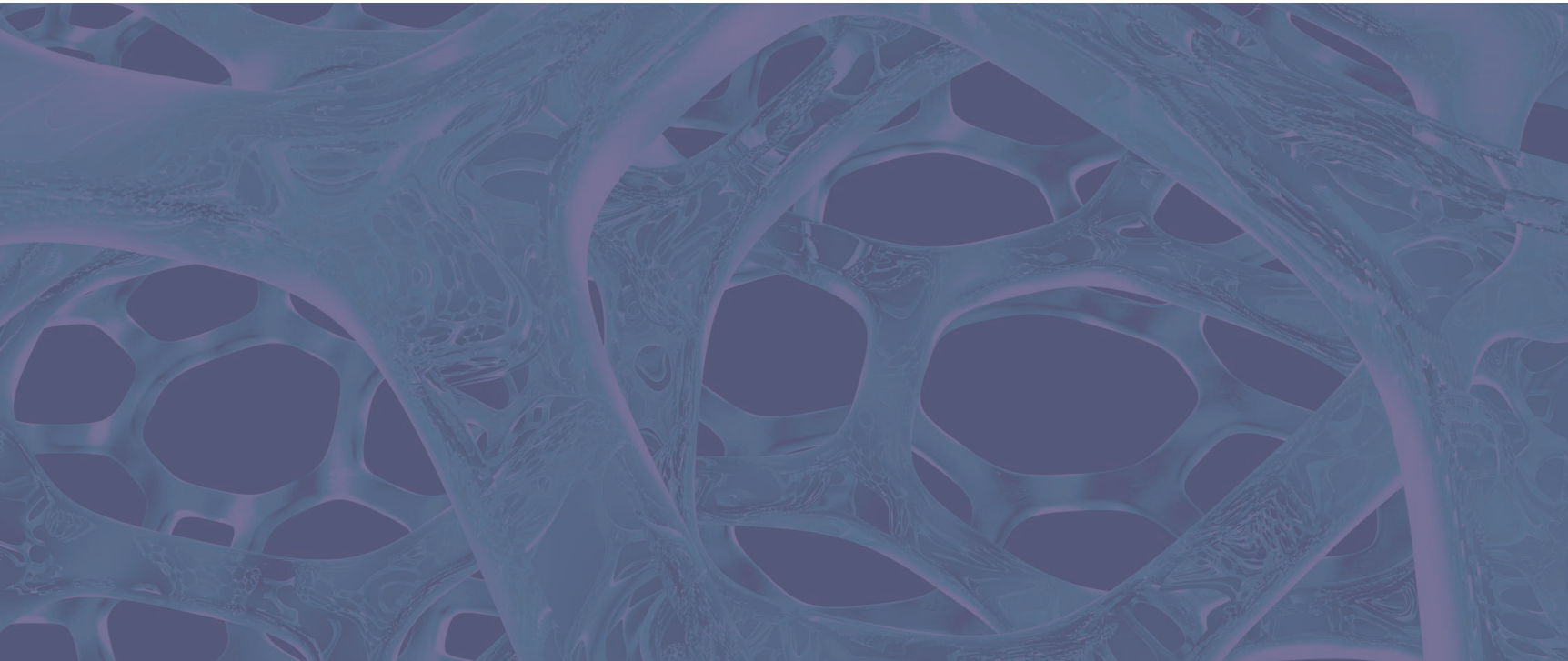
OSTEO-DRIVER
Trabecular structure of interconnected porosity with high mechanical resistance.

REABSORPTION
Fusiongraft® TCP is replaced by new bone in a regeneration process that takes between 1 to 6 months.
Fusiongraft® BCP is replaced by new bone in a regeneration process that takes between 6 to 24 months.
The resorption time may vary depending on the SIZE of the defect and the amount of synthetic biomaterial used.
There are no significant changes in bone density in the bone defect when it is replaced by the patient's own bone.

RADIOPAQUE
Allows correct monitoring of osseointegration.

EASY DRIVE
Its TRABECULAR structure is the only one with high interconnected porosity that increases the absorption of liquids and the agglomeration of particles, thus facilitating the application of the product at the graft site..

GEOMETRYS
Range of sizes and quantities.



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