

# *Graftys<sup>®</sup> Technologies*



*Smart Bone Substitute*

  
Graftys<sup>®</sup>

## Mechanism of Action

**Graftys® Cements** are macroporous injectable hardening resorbable bone substitute. The mineral part allows formation of a close bond with the native bone and provides advanced osteogenic properties. The material is gradually resorbed by cells participating in the natural bone remodeling cycle. Conduction and formation of mineralized healthy bone is thereby ensured. The organic part confers wettability and porosity to facilitate percolation of the body fluids throughout the implant and improves cohesion, elasticity, rheological properties, and injectability.

Surgeons have a choice among a variety of bone grafting options, including autograft, allograft or synthetic materials. The disadvantages of autografts have been identified in the literature (Bonnel F, Consolidation osseuse et médecine de rééducation, Masson (ed), 1986) such as the morbidity and cost of the harvesting procedure, and the lack of adequate quantity of quality material. Allograft comes with some risk of disease transmission and variable quality of material. Calcium Phosphate Cements (CPC), in forms such as granules, paste, and various geometric shapes, are increasingly used as an alternative for filling bone void defects. Most of these have been low porosity materials, however. Recently advances in CPC formulations, in moldable or injectable forms, offer improved osteoconductivity and enhanced ability of synthetic bone substitutes to restore natural bone.

**Graftys®** (Aix-en-Provence, France) has built on the success of calcium phosphate cements to date by developing a range of selfhardening, malleable, injectable, resorbable cement-type bone substitute that integrates a mineral phase similar to biological apatites and an organic phase, to create an injectable material with wettability and porosity to allow progressive percolation of body fluids throughout the implant. The combination of these two

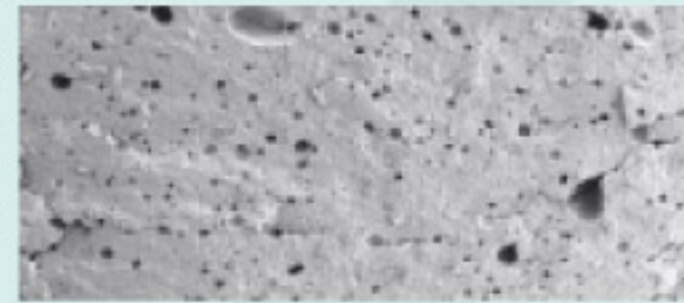
The development objectives for Graftys® Cement were to achieve the following characteristics:

- hardening, injectable, user-friendly cement system that has clinically reasonable setting time
- good mechanical strength
- suitable wettability
- porosity which allows the resorption rate to match the kinetics of natural bone formation.

components within the same medical device is innovative and further enhances the attractiveness of synthetic alternatives to auto or allografting. Besides replacing grafts, this type of device opens new clinical possibilities, such as:

- feasibility of use in MIS (minimally invasive surgical) techniques that require low viscosity, true injectability and the ability to access very small locations;
- improved cohesive properties in the wet environment of the surgical site;
- improved void filling as well as apposition against metal implants.

(Khairoun I, Patent WO2005077049)



**Macroporosity**



**Microporosity**

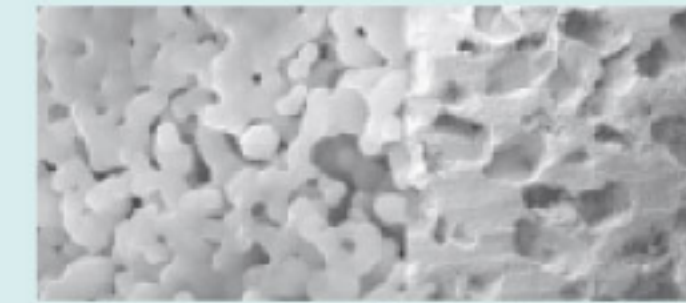


**Mesoporosity**

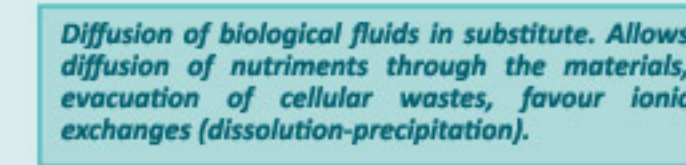
Calcium phosphate materials are biocompatible and capable of bonding chemically to bone. They are widely used as repair materials in human surgery because their chemical composition is similar to that of bone. Several compositions are used and each offers different properties. Among calcium phosphate biomaterials, they include :

- HA : Hydroxyapatite
- TCP : Tri Calcium Phosphate
- BCP : Biphasic Calcium Phosphates, mix of different ratio of HA & TCP

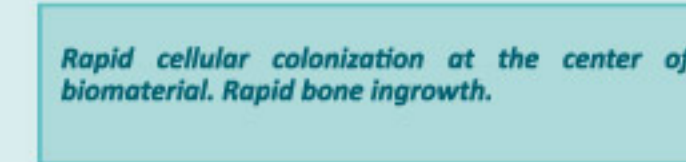
**Graftys® BCP** has been developed on a 60% HA & 40% TCP concept to



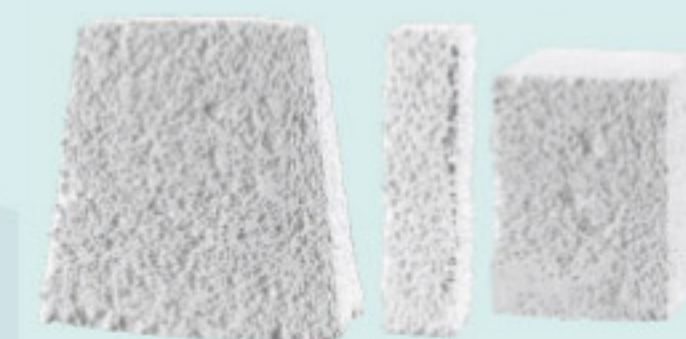
*Bone cells colonization at the center of biomaterials. Homogeneous bone ingrowth in the materials.*



*Diffusion of biological fluids in substitute. Allows diffusion of nutrients through the materials, evacuation of cellular wastes, favour ionic exchanges (dissolution-precipitation).*



*Rapid cellular colonization at the center of biomaterial. Rapid bone ingrowth.*



allow a balanced resorption/substitution process, rapid enough to be replaced with bone yet slow enough to participate in the natural remodeling process.

**Graftys®** porosity characteristics include:

- Macroporosity
- Mesoporosity (interconnection between pores)
- Microporosity

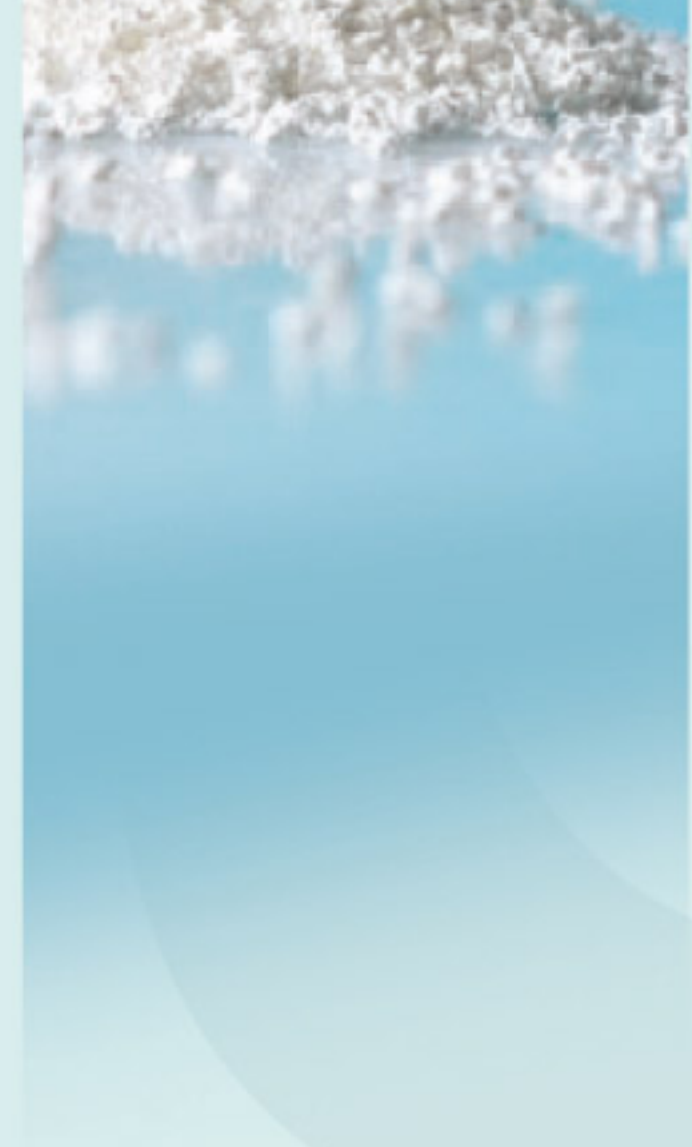
Detailed studies were performed on the synthetic bone substitute developed by **Graftys®** in order to optimize its bone architecture allowing obtaining an adequate porosity for a balanced bone resorption/substitution and a better permeability of the ceramic with fluids and bone cells without altering its mechanical properties. Thanks to a unique process, developed ceramics have numerous macro pores and interconnected canals between macroporous cavities, which allows that a rapid colonization of cells at the center of the biomaterial.

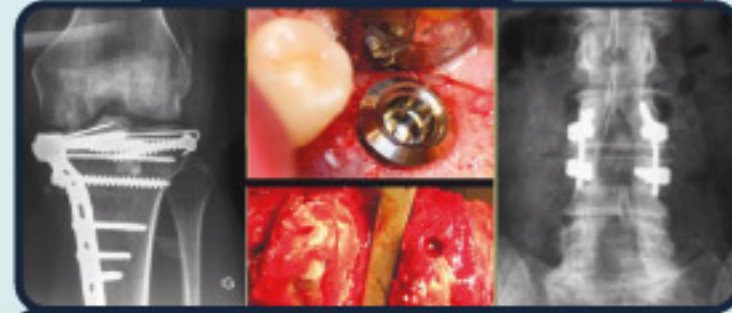


## Mechanism of Action

**Graftys® Ceramics** are macroporous biomaterials with a composition similar to the crystalline phase of the bone. The porosity structure of Graftys® BCP and Bioactys® Granules are fully penetrated by biological fluids, including cells.

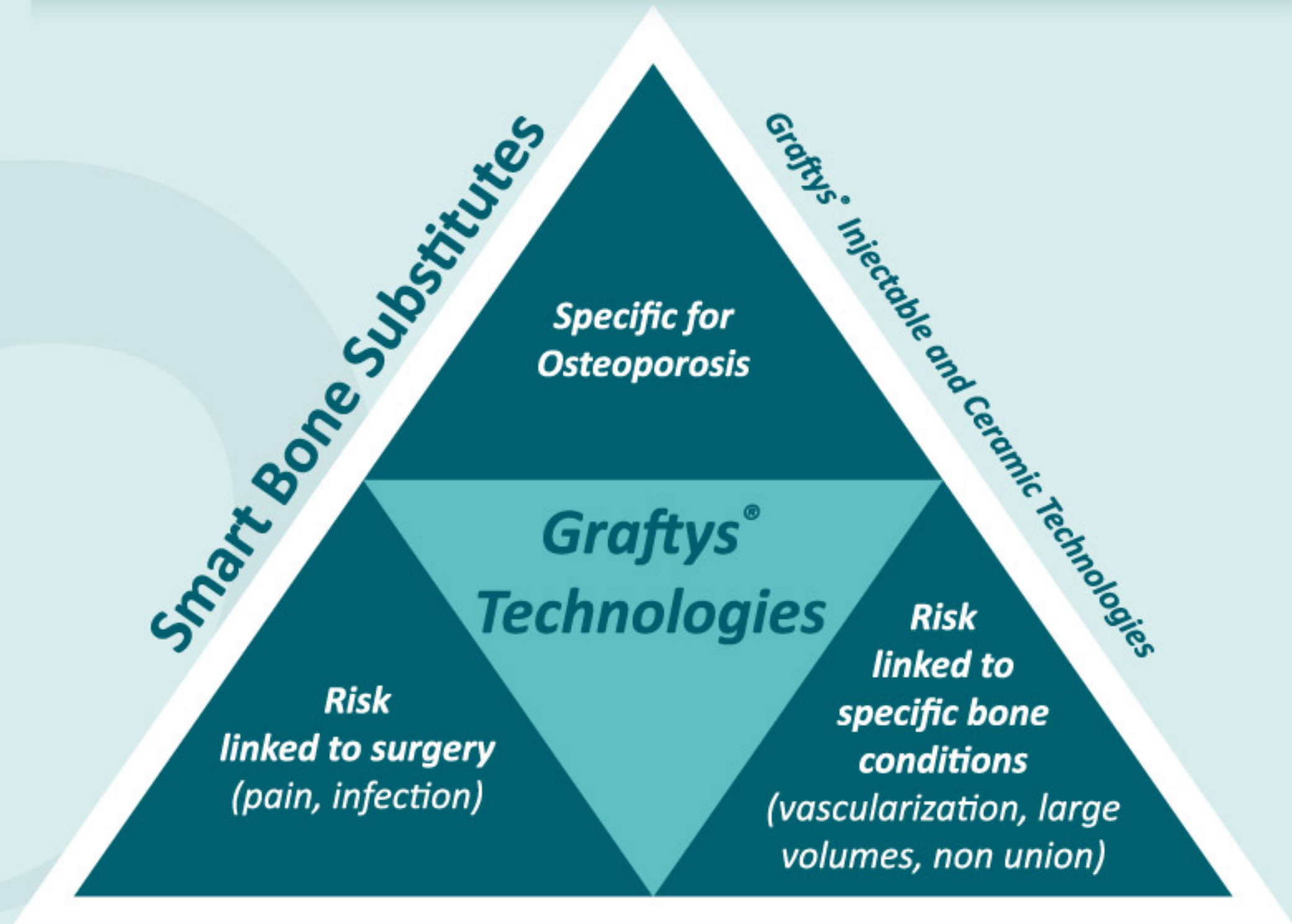
$\beta$ -TCP is partially dissolved before precipitating as apatite crystals on the HA structure. These apatite crystals, similar to native bone crystals, promote cellular adhesion to start the natural resorption cycle. The low dissolution rate of HA offers the stable scaffold needed for cells to form bone and material resorption (rapid dissolution can lead to fibrosis). Bone formation occurs throughout the material and occurs simultaneously with resorption of the implant.





- GRAFTYS® phosphocalcic cements have been developed with the future following objectives:
- Combination products to reconstruct bone architecture that is compromised by osteoporosis
  - Combination products to address risks linked to surgery infection, pain
  - As scaffold to receive biological, osteogenic activators to address complex bone reconstruction, large grafting volume or non union.

# Graftys®



# Graftys<sup>®</sup> Corporate

## Profile

**Graftys<sup>®</sup>** is a leader in synthetic bone graft substitutes with resorbable solid and injectable materials used in spine, trauma, reconstructive, oral/maxillofacial, dental, and sports medicine applications. Our development pipeline includes multiple drug/device technologies to address osteoporosis, infection and pain.

**Graftys<sup>®</sup>** products are sold in more than 20 countries, including Europe, USA, MEA, Latin America and Australasia. Our manufacturing facility is ISO 13485 certified and includes full inhouse biomaterials synthesis.

## History

**Graftys<sup>®</sup>** was founded in 2005 at Aix-en-Provence, France.

It has emerged from this partnership of Academic European/French research Institutions at the basis of the R&D team and behind all project developments.

Products & projects are developed and used under control of Clinician consultant in each specialty.

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