



i≡FACTOR™
Peptide Enhanced Bone Graft

BIOLOGIC BONE GRAFT

i-FACTOR bone graft is the only biologic bone graft that utilizes a synthetic small peptide (P-15) bound to anorganic bone mineral (ABM) to act as an attachment factor for specific integrins on osteogenic precursor cells. This novel mechanism of action enhances the body's natural bone healing process resulting in safe, predictable bone formation.

Anorganic Bone Mineral (ABM)

One component of i-FACTOR Biologic Bone Graft is anorganic bone mineral. ABM particles are a natural form of hydroxyapatite $[Ca_{10}(PO_4)_6(OH)_2]$ that contains crystal lattice defect sites. ABM provides an ideal scaffold for bone growth because of its:

Composition

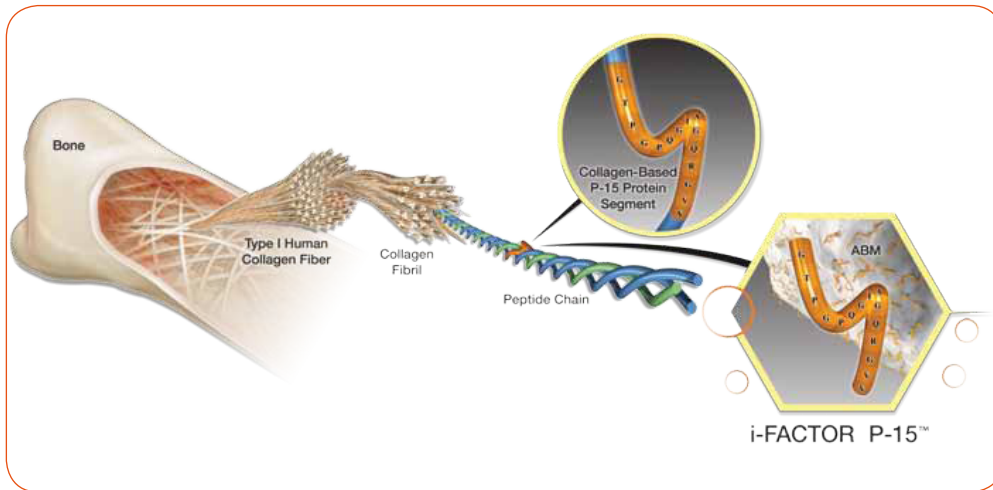
It is composed of natural calcium phosphate bone mineral.

Resorption

It is capable of effective cellular mediated resorption properties.

Manufacturability

After processing, ABM shows a high affinity and capacity for binding the P-15 protein segment.



Synthetic Replicate of P-15

i-FACTOR technology is based on the biological activity of a 15-amino acid peptide found in Type I human collagen. Type I collagen is the primary organic component making up autograft bone. This protein segment (P-15) is responsible for the attachment and proliferation of osteogenic cells. These cells bind to the synthetic P-15 found in i-FACTOR the same way they would bind to Type I collagen.

MECHANISM OF ACTION - HOW i-FACTOR WORKS



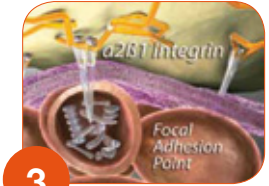
1

i-FACTOR Biologic Bone Graft is placed in a bony defect in the presence of bleeding bone, an environment rich with osteogenic cells.



2

Once implanted, i-FACTOR increases the opportunity for cell binding in the fusion site by making an abundance of P-15 available to osteogenic precursor cells.



3

Osteogenic cells contain $\alpha 2\beta 1$ -integrins that act as signaling receptors, allowing the cell to attach to P-15



4

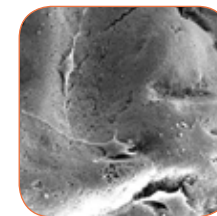
Cell binding between P-15 and $\alpha 2\beta 1$ -integrins initiates natural signaling of mechanical and chemical information within the cell and the extracellular matrix, contributing to the production of specific growth factors, cytokines and bone morphogenic proteins (BMPs).



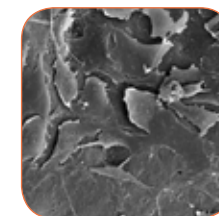
5

The cascade of events leading to new bone proliferation and natural bone healing occurs, leading to fusion.

Scanning Electron Microscopy shows enhanced cell attachment and proliferation on ABM/P-15 compared to ABM alone.



ABM alone



ABM/P-15



CELL ATTACHMENT

Osteoprogenitor cells attach to the protein segment P-15 via $\alpha 2\beta 1$ integrins as the first step in the osteogenic process.



NATURAL SIGNALING

$\alpha 2\beta 1$ integrins signal osteogenic cells to release natural BMPs and growth factors that stimulate proliferation.



PROLIFERATION

The natural osteogenic cascade results in bone cell activation and accelerated proliferation.



Activating the Body's Production of BMPs and Growth Factors

P-15™, the active ingredient in i-FACTOR Biologic Bone Graft, is a protein segment that actively triggers cellular attachment of osteogenic cells, resulting in the natural production of bone morphogenic proteins.¹⁾

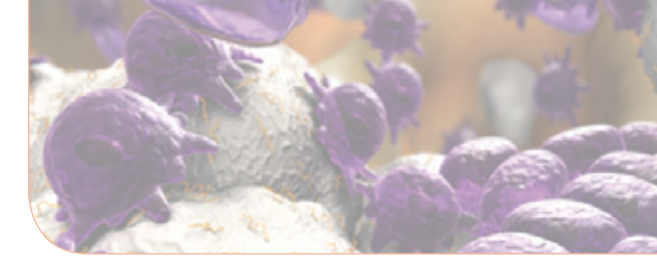
The effect is accelerated bone growth the safe, natural way.²⁾



10 weeks post-op / L5-S1 ALIF
Image courtesy of Dr. RJ Mobbs MD



16 weeks post-op / L5-S1 ALIF
Image courtesy of Dr. RJ Mobbs MD



i-FACTOR Biologic Bone Graft Initiates Natural Bone Morphogenic Proteins (BMPs) and Growth Factor Production

The ideal bone graft product is osteoinductive³⁾, osteoconductive, and clinically reliable. i-FACTOR Bone Graft (P-15™ on Anorganic Bone Mineral) is proven to enhance cellular migration, attachment and differentiation of osteogenic cells. i-FACTOR products offer surgeons the optimal choice in biologic bone grafts.

Bone Formation at 16 weeks Post-Op
CT (1 mm) of 58 year-old female patient with DDD, L5-S1 ALIF



Image courtesy of Dr. RJ Mobbs MD
Prince of Wales Hospital, Randwick, Australia
University of New South Wales, Sydney, Australia

i-FACTOR biological bone graft is available in two forms:



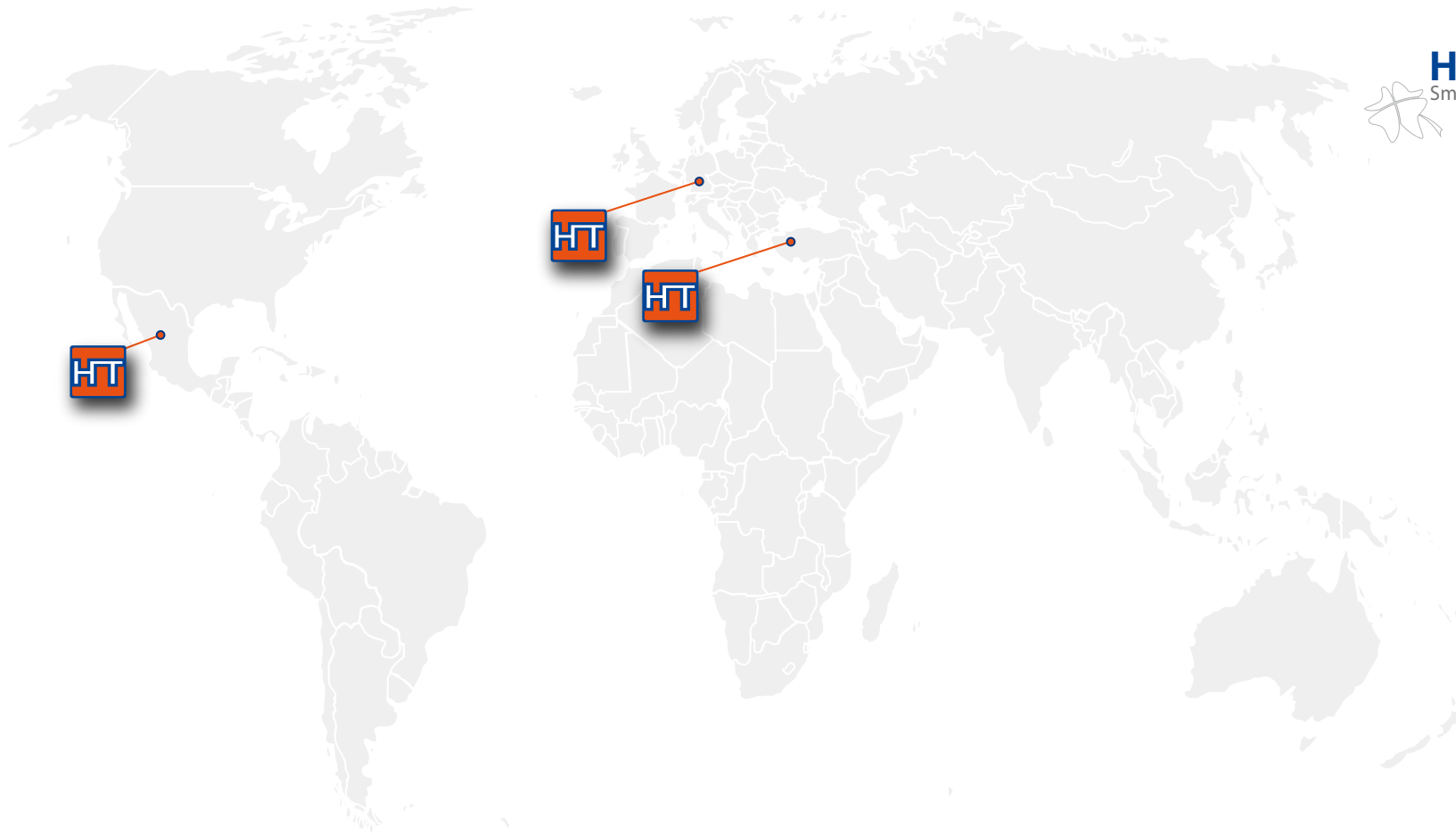
Description	Art.No.	Description	Art.No.
i-FACTOR Putty 0,5 cc	3001000005	i-FACTOR Flex 25x25x4 mm	3002000025
i-FACTOR Putty 1,0 cc	3001000010	i-FACTOR Flex 50x25x4 mm	3002000050
i-FACTOR Putty 2,5 cc	3001000025	i-FACTOR Flex 100x25x4 mm	3002000100
i-FACTOR Putty 5,0 cc	3001000050		
i-FACTOR Putty 10,0 cc	3001000100		

To learn about i-FACTOR Biologic Bone Graft as a new option for your orthobiologic needs, contact the HumanTech-Team

1) Biomimetic collagen scaffolds for human bone cell growth and differentiation. Yang XB, Bhatnager RS, Li S, Oreffo ROC. Tissue Engineering, 2004 Vol 10, 7/8:1148-59.

2) Bioactivation of an organic bone matrix by P-15 peptide for the promotion of early bone formation. Thorwarth M, et al. Biomaterials. 2005 Oct; 26(28): 5648-57.

3) Urist MR. Bone transplants and implants. In: Urist MR, editor. Fundamental and Clinical Bone Physiology. Lippincott Williams and Wilkins; P 331-368, (1980).



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