

Inion BioRestore™

INION

Bone Graft Substitute
Product Overview



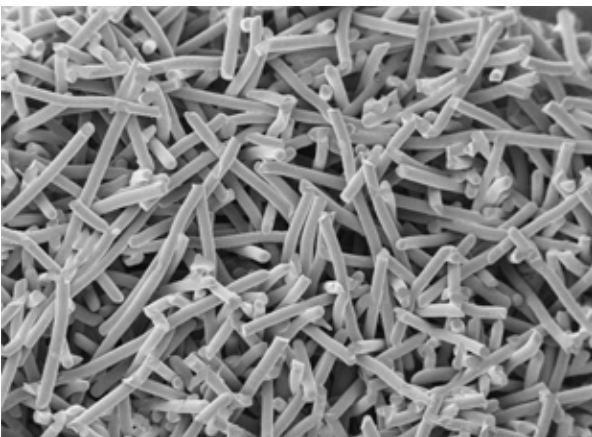
Introduction

Inion BioRestore™ is a synthetic bone graft substitute, which remodels into bone and is easy to use. Inion BioRestore™ is made from degradable bioactive glass which once in contact with the natural body fluids forms a silica gel and calcium phosphate layer which provides scaffolding for new bone tissue to be formed.

Its synthetic origin and biocompatibility makes it safe to use within the body. The degradable bioactive glass properties used in Inion BioRestore™ have an excellent in vivo behaviour. The Inion BioRestore™ scaffold provides ideal osteoconductivity and osteostimulativity. Inion BioRestore™ undergoes a time-dependent, kinetic modification of the surface that occurs when implanted in living tissue. Specifically, the surface reaction results in the formation of a calcium phosphate layer that is substantially equivalent in composition and structure to the hydroxyapatite found in bone mineral.

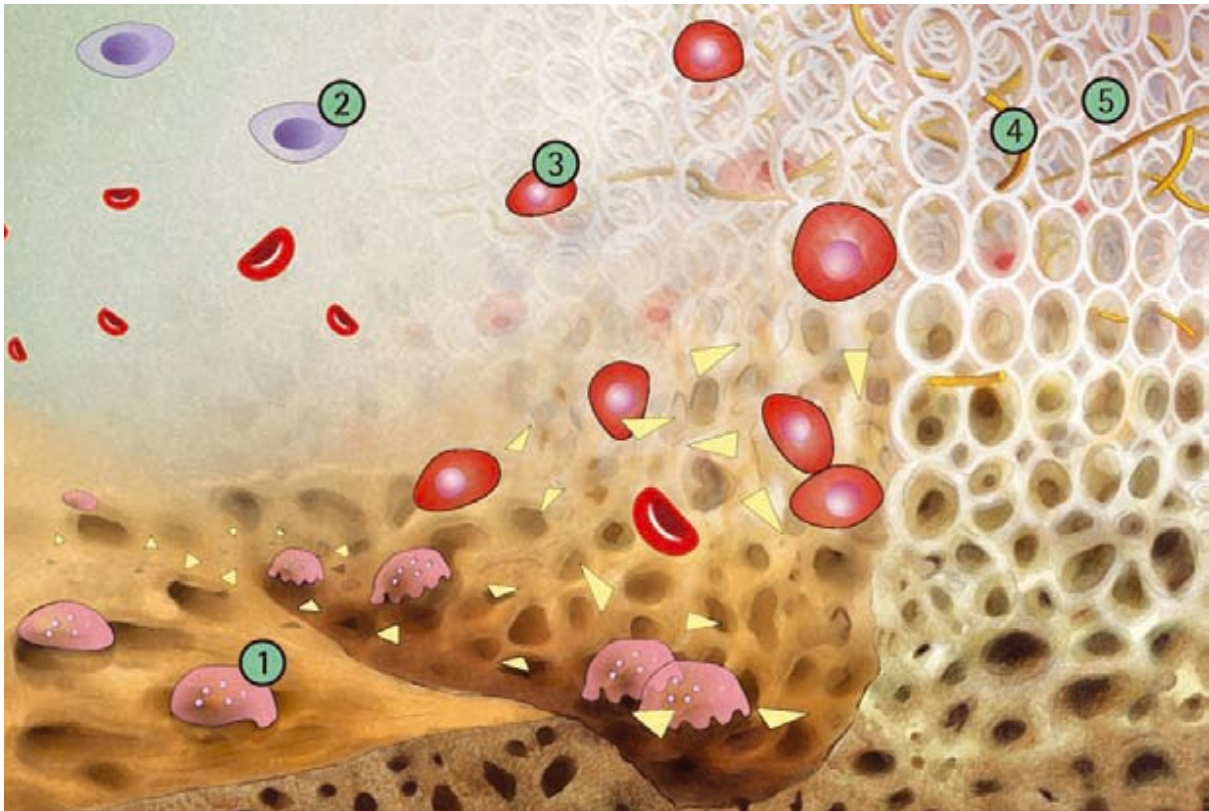
This apatite layer provides scaffolding onto which the patient's new bone will grow allowing repair of the defect. Inion BioRestore™ is gradually resorbed and replaced by new bone during the healing process, this process is estimated to take 6 months in vivo (based on preclinical testing). An important point to note is that the Inion BioRestore™ degrades significantly faster than products made of hydroxyapatite. Inion BioRestore™ can be used for orthopaedic trauma, as well as for spine, CMF and dental surgeries for bony voids or gaps that are not intrinsic to the stability of the bony structure, including defects associated with spinal stabilisation and fusion. The defects may be surgically created osseous defects or those caused by a traumatic injury to the bone.

The use of Inion BioRestore™ is an advantageous alternative to harvesting of autograft bone and use of allograft bone. It shortens operative time, overcomes the limitations in quantity and quality of available bone graft, avoids donor site morbidity and risk of disease transmission.



Inion BioRestore™ provides a scaffold or temporary framework used to support new bone formation and remodelling where a bone defect has occurred, for example traumatic injury.

How Inion BioRestore™ works?



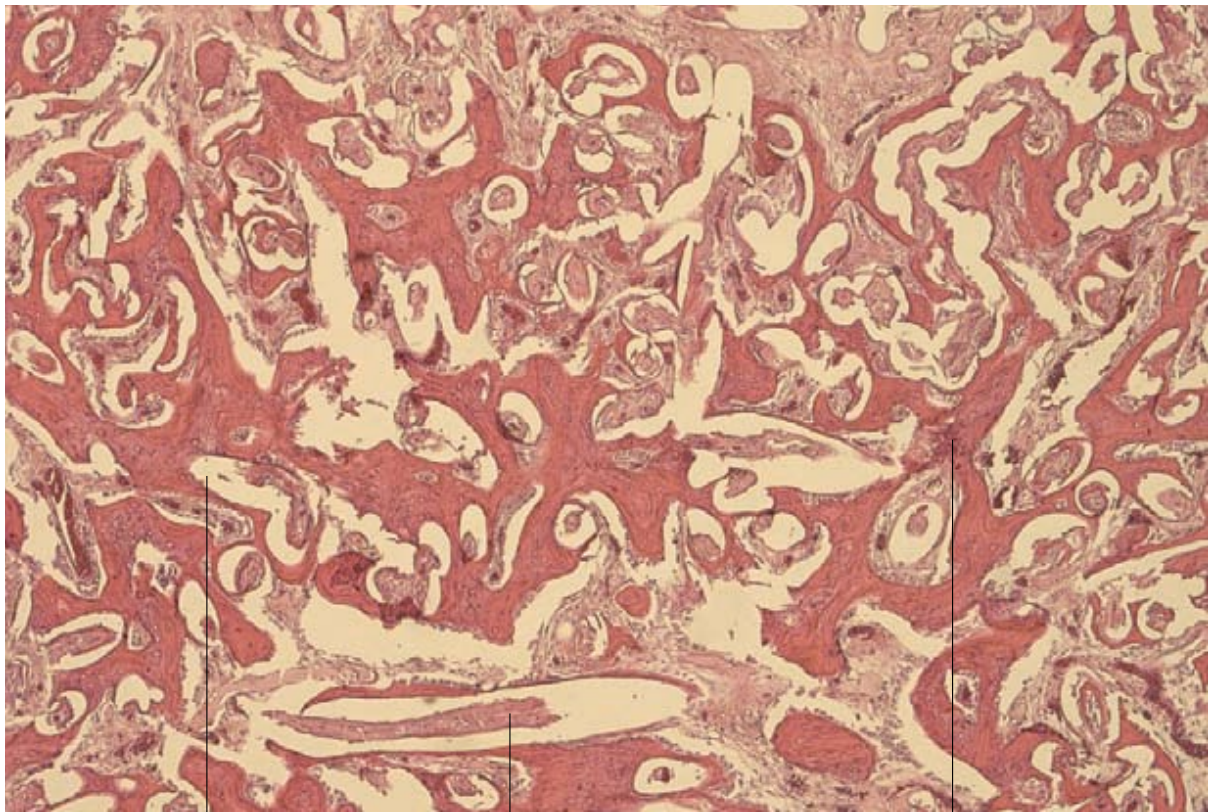
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1. Osteoclast Scaffold material
2. Mesenchymal stem cell
3. Osteoblast
4. Protein
5. Inion BioRestore™ scaffold

- Increased level of osteoblast activity and differentiation have been shown by increased levels of alkaline phosphatase
- Bone grows not only from the outside of the defect towards its insides (osteoconductivity), but also throughout the defect (osteostimulativity)

Inion BioRestore™ works by osteostimulation which is defined as the active stimulation of osteoblast proliferation and differentiation. As shown during in vitro studies by increased levels of alkaline phosphatase, Inion BioRestore™ supports raised osteoblast activity and expression and acts as a scaffold around and through which new bone forms.

Scaffolds are composed of fibres which are welded together to form an interconnected, fully open three dimensional structure that allows for the bone cells to weave between the scaffold and lay down a solid matrix of new bone tissue.



Scaffold material

Bony tissue formation
inside a degraded fibre

Bony tissue formation
inside the 3D structure

The modified surface of the Inion BioRestore™ immediately begins to interact with the body's own proteins, cells and growth factors for tissue regeneration.

In a continuing chemical reaction occurring over the next few days, a temporary scaffold of hydroxyapatite crystals forms on the surface of the Inion BioRestore™ particles which traps and bonds these building blocks to create a bed for new tissue growth.

Advantages of Inion BioRestore™

Comparison of synthetic HA, TCP and Inion BioRestore™ as bone graft substitutes

	HA	TCP	Bioactive Glass
Physical Form	Porous/bulk blocks and granules.	Porous blocks, morsels and granules.	Bulk blocks and granules
Basic Mechanism	Serves as osteoconductive surface.	Serves as osteoconductive surface.	Forms chemical bonding with ongrowing new bone. Osteostimulative in addition to osteoconductive.
Molecular Mechanism of Action In Vivo	Not defined.	Not defined.	Induce high local bone turnover.
Regulation of Bioactivity	Material dependent.	Material dependent.	Tailored by varying composition.
Resorption Rate	Slowly / very slowly resorbed (years / decades).	Fast degraded (months).	Fast degraded (months).
Mechanism of Resorption	Chemical dissolution and osteoclastic degradation.	Chemical dissolution and osteoclastic resorption.	Chemical dissolution.

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- Inion BioRestore™ is osteostimulative as it actively stimulates bone cells whilst providing a temporary scaffold to support the new bone formation process.
- The highly porous and fully open structure of the Inion BioRestore™ scaffold enables better flow of fluid, cells and nutrients.
- The ability of Inion BioRestore™ to develop a calcium phosphate layer during degradation provides an extremely high surface area and enhances osteointegration and bone tissue incorporation.
- Inion BioRestore™ scaffolds resorb significantly faster than the commercially available products made from HA and are resorbed in a controlled manner.
- The use of Inion BioRestore™ is an advantageous alternative to harvesting autograft bone and use of allograft bone in a variety of surgical procedures. Its synthetic origin excludes risks of disease transmission and overcomes the limitations in quantity and quality of available bone graft. Donor site morbidity is avoided as no autograft needs to be taken or in case autograft is used through filling the donor site defect with Inion BioRestore™.

Choose appropriate Inion BioRestore™ product. Preoperative radiographic evaluation of the defect site is essential to accurately assess the extent of the defect and to aid in the selection and placement of the graft material.

- 1 The Inion BioRestore™ should be wet with patient's blood or marrow, or sterile saline or water before application.
- 2 While the Inion BioRestore™ can be moistened with either sterile saline or water, osseous regeneration may occur more rapidly by using the patient's osteogenic blood or marrow obtained by scoring the surface or drilling into the cortical bone at the surgical site. Place the material in contact with the desired fluid to soak up the fluid in a sterile basin or other suitable container.
- 3 The porous structure of the material will allow the fluid to immediately permeate into the implant.

Care should be taken not to over-compress morsels into defect. Inion BioRestore™ should be gently packed into the bone void so to guarantee that the Inion BioRestore™ morsels retain their three-dimensional structure and optimal pore size.



Ordering information

Inion BioRestore™

Art. No.	Description
BRS-5430	Morsels 1.5 cc
BRS-5431	Morsels 4.5 cc



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