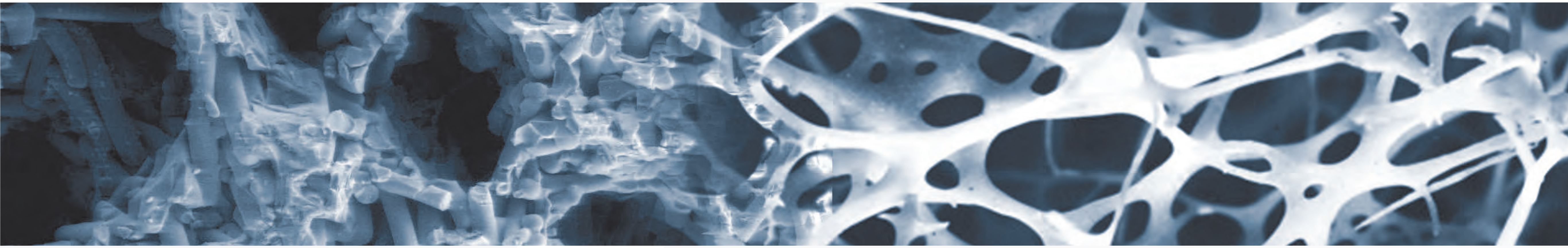

Vitrium® Wedge System Monograph

INTRODUCTION

Vitrium is a resorbable, bioactive material constructed exclusively from bioactive glass. A proprietary process is used to generate an optimized, three dimensional structure that facilitates the remodeling of healthy, vascularized bone while having the compressive strength of cortico-cancellous allograft.

BIOACTIVE GLASS TECHNOLOGY

Bioactive glass has a long history of scientific investigation and clinical use and consists of elements existing naturally in the body. Specifically, most traditional bioactive glass formulations contain varying ratios of SiO_2, Na_2O, CaO, P_2O_5.

Next

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When in contact with body fluids, bioactive glass undergoes a series of chemical reactions in solution forming a silica-gel layer on the glass surface. This surface acts as a template for calcium phosphate (CaP) precipitation which crystalizes to form a hydro- xyapatite (HA) layer to bond with the surrounding tissue.

The table below more fully describes the mechanism of action of bioactive glass.

ENGINEERED POROSITY

Bioactive glasses exhibit unique properties supporting bone regeneration. The brittleness of the material, however, has limited its use to enhancing the bioactivity of other materials (most notably beta-tricalcium phosphate) or in particle form suspended in a carrier. Vitrium is the first bioactive glass material available for use in structural applications such as osteotomy wedges and fusion.

Vitrium is produced by sintering bioactive glass fiber into a three dimensional structure resembling that of cancellous bone. Pore formers are utilized to create macro pores ranging from 100 to 600 microns. The process also provides micro pores. The interconnected micro and macro pores allow for both vascularization and bone ingrowth. The pore formers are vaporized during the patented sintering process, rendering the final composition of Vitrium to be exclusively bioactive glass.

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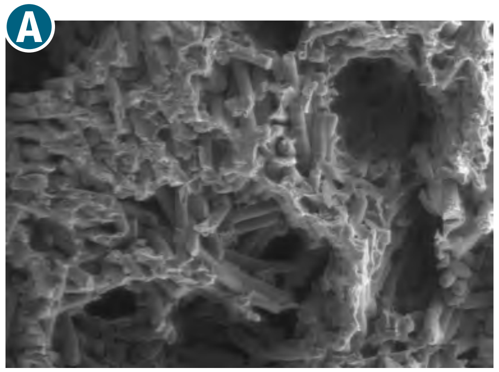
Mechanism Stage

A


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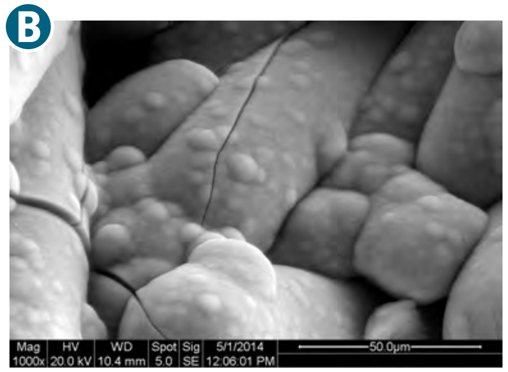

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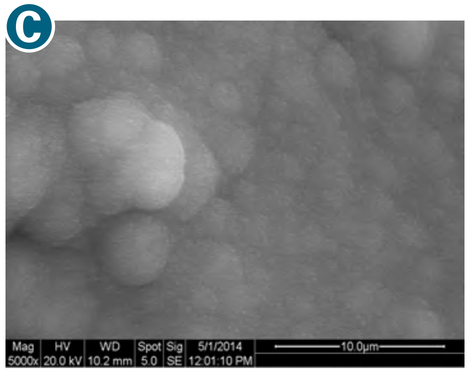


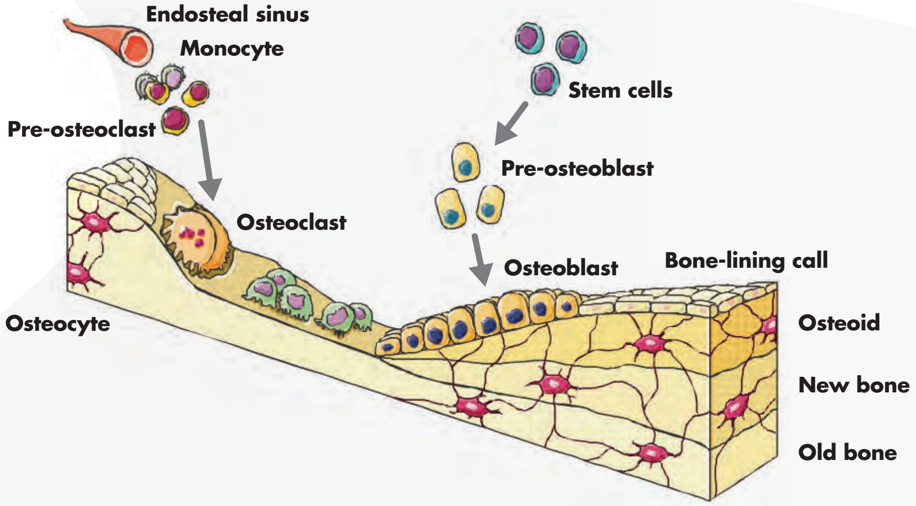
D


A Vitrium features an interconnected porosity with both micro and interconnected macropores providing a large surface area of material to interact with the body. The ensuing hydrolytic process results in the release of Na, P, Ca and other ions and the elevation of pH to create a beneficial chemical environment for the formation of new bone.

B The surface is modified into a silica gel-like layer followed by precipitation of amorphous calcium phosphate on the gel. (1000x magnification).

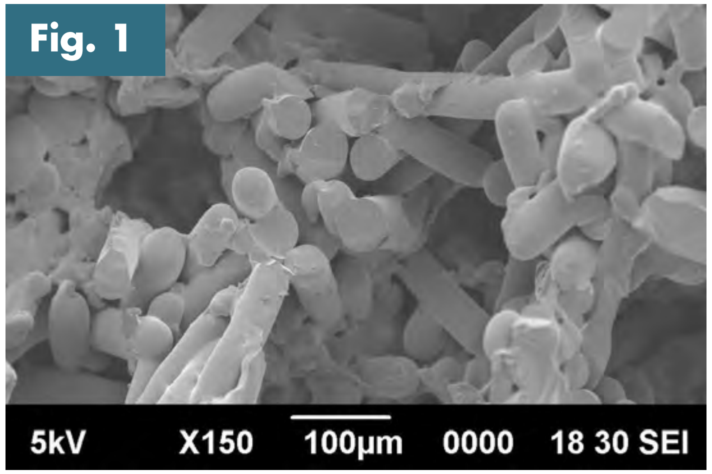
C Mineralization results in the transformation of the calcium phosphate layer into hydroxyapatite, the primary constituent of bone.

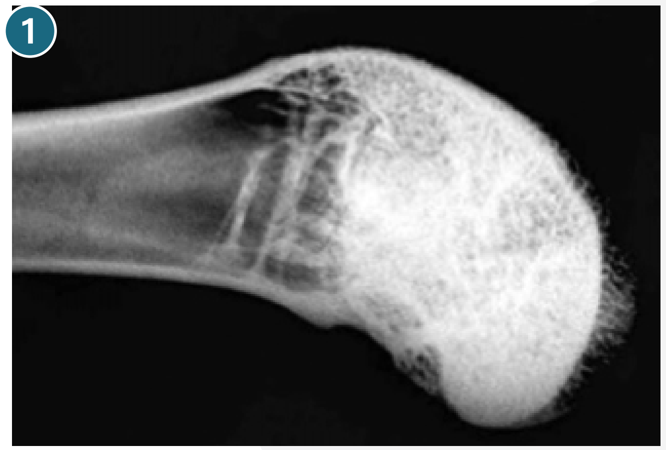
Stem cells attach to HA and differentiate into osteoblasts leading to generation of extracellular matrix and formation of vascularized bone.

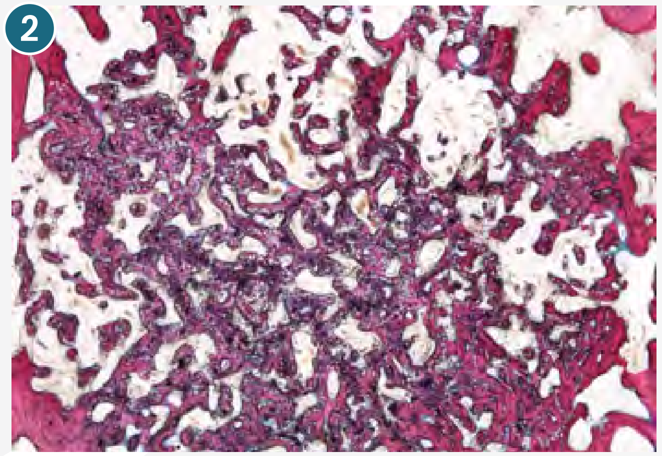


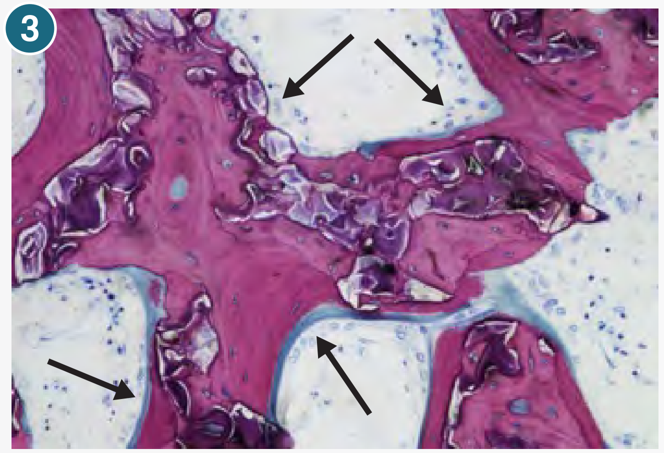
D A balanced gradual, dissolution of the bioactive glass matrix and biosynthesis of new bone on its surface occurs over time, as shown here in this 8 week post-operative histopathology image from a rabbit femur study.

Another important feature of Vitrium's structure is the result of using a fiber based system. As illustrated in Fig. 1, the fibers overlay in a manner producing micropores throughout the material. These micropores increase the internal surface area available for surface modification and resorption to enhance performance.









1 **8 weeks post op** - no evidence of voids

2 **16 weeks post op** - a substantial amount of new bone and bone marrow are present

3 **24 weeks post op** - incorporation of the residual implant material within calcified bone is apparent. Healthy bone formation [arrows] is ongoing

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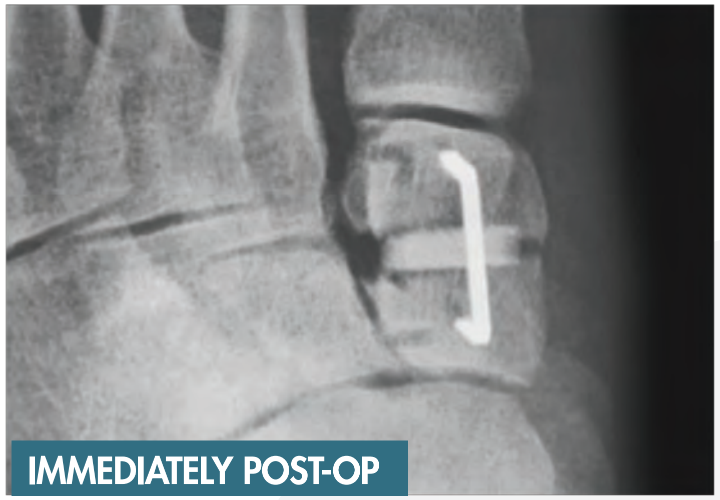
MECHANICAL PROPERTIES

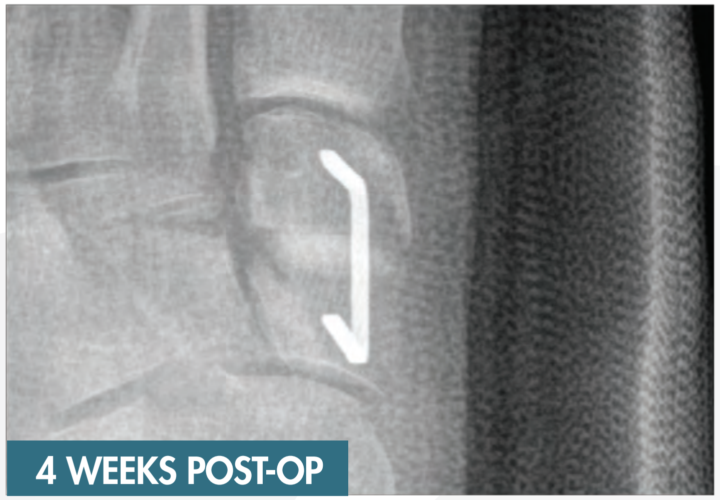
An important advantage of a fiber based materials system is the ability to produce a high ratio of porosity to compressive strength, a critical attribute for orthopedic applications. Fibers overlap such that the bounds created by sintering are stronger than those created in particle based systems, where the points of contact are tangential in nature. The table below describes key mechanical properties of Vitrium and compares them to materials currently in clinical use.

PROPERTY	BIO2 VITRIUM	BIO2 VITRIUM LP`	TRABECULAR BONE	CORTICAL BONE-TCP	VITOSS β-TCP	HA
POROSITY	50-60	30-40	30 - 90	8 - 28	88 - 02	54 - 63
PORE SIZE [µm]	100-600 + micropores	100-600 + micropores	1- 900	5 - 200	1-1000	0.2 - 0.5
COMPRESSIVE STRENGTH	>15	>35	1.5 - 10	50 - 250	0.1- 0.6	142 - 265
COMPRESSIVE MODULUS	1-3	2.5-5	0.05 - 0.9	5 - 35	0.001 - 0.01	3.2 - 4.4

VITRIUM RESORBABLE IMPLANTS

Implants constructed with Vitrium offer the surgeon performance advantages over the bone graft substitutes currently in use such as allograft, TCP and porous metals.





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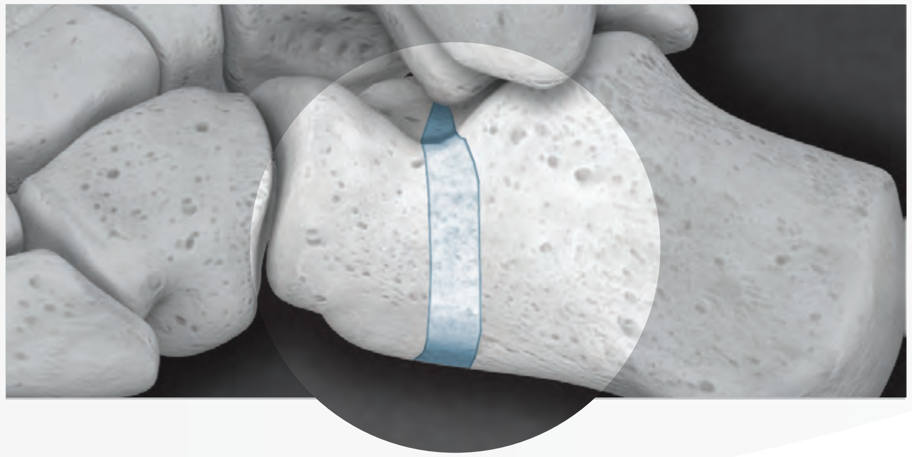
The synergies of the mechanism of action of bioactive glass and the unique porous structure of Vitrium yield the following beneficial properties:

- Bioactivity - silica gel layer formation promoting CaP precipitation and formation of hydroxyapatite.
- Osteoconduction – bone growth supported by the presence of a three dimensional porous scaffold, with a compressive strength superior to cancellous bone.
- Vascularization – ionic stimulation of angiogenic growth factors eliciting endothelial tube formation.
- Fluid wicking – interconnected macropores and micropores allow for rapid absorption of biologic fluids.
- Safe resorption – little or no cellular response was evident in in vivo studies, consistent with the published record of bioactive glass.
- Intraoperative flexibility - Vitrium may be trimmed, drilled and tapped using common manual and power surgical instruments and fixed with bone screws.



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