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 SiO₂, Na₂O, CaO, P₂O₅.

INTRODUCTION
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 hydroxyapatite (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.

**Mechanism Stage**

**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.

**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 below, 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.

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.

PRE-CLINICAL TESTING
More than 2,000 experiments and iterative animal testing were completed during the development of Vitrium. In pre-clinical studies Vitrium successfully demonstrated:
- Bone in-growth throughout implant at eight weeks and continuing bone mineralization through 24 weeks
- Equivalent performance compared to other bone graft substitutes
- Implant resorption ongoing at 24 weeks post-op

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

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.