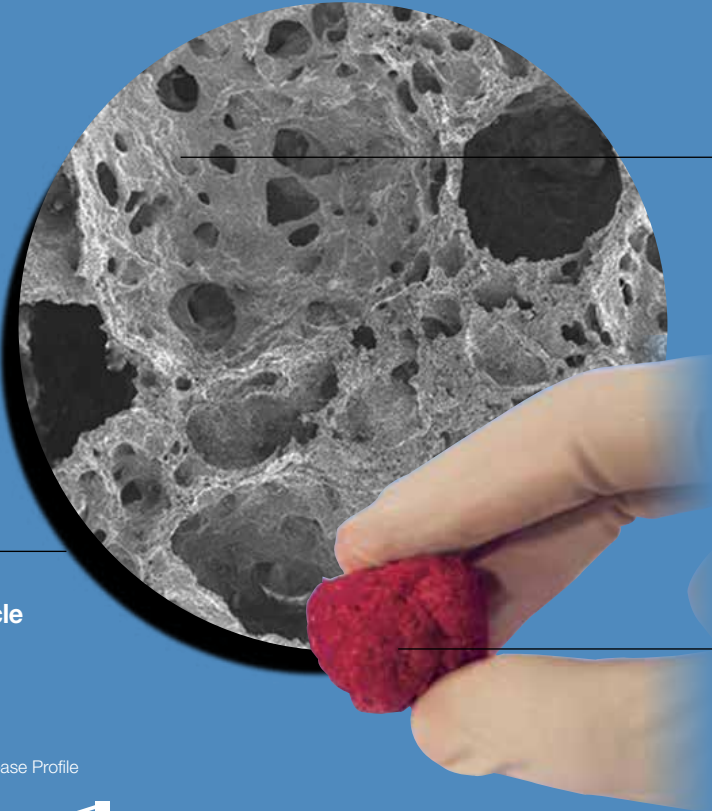


# Vitoss® BiModal

Bioactive Bone Graft Substitute

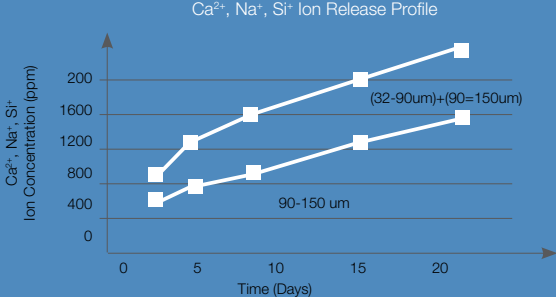
Vitoss BiModal is the latest formulation of Vitoss, the #1 selling synthetic bone graft<sup>1</sup>



Vitoss BiModal has demonstrated **increased calcium phosphate deposition** as shown in in-vitro models compared to other forms of Vitoss with bioactive glass<sup>2</sup>

Vitoss BiModal offers a **broader range of bioactive glass particle distribution**, resulting in both an immediate burst and sustained release of  $Ca^{2+}$ ,  $Na^+$  and  $Si^+$  ions<sup>3</sup>

**Ultraporous, open interconnected structure** which guides the 3-dimensional regeneration of bone<sup>4</sup>

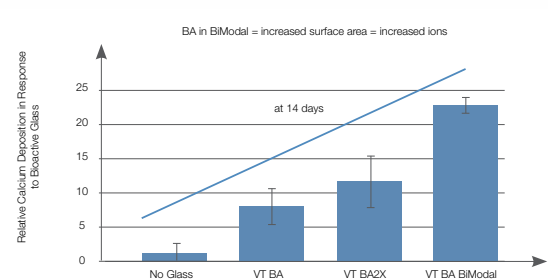


# Vitoss<sup>®</sup> Family of Bone Graft Substitutes

## Proven Clinical Results

- Vitoss has been studied in multiple clinical evaluations including two prospective and peer-reviewed studies in spine with **85% and 95% fusion rates<sup>5,6</sup> when mixed with autograft and BMA**
- Vitoss' **patented structure<sup>7</sup>** features a highly porous beta-tricalcium phosphate (up to 90% porous).<sup>8</sup> Increased porosity has been shown to lead to **higher rates of bony ingrowth** (in an animal model)<sup>9</sup>
- Vitoss with bioactive glass promotes the deposition of calcium phosphate on the implant surface. This creates a favorable environment for bone regeneration<sup>10</sup> and for osteoblast attachment<sup>\*10</sup>

Relative Cellular Calcium Deposition Between Vitoss Products



## User Experience

- **#1 selling synthetic bone graft substitute<sup>1</sup>** with its unique chemistry, porosity, and structure
- Vitoss has **Level 1 Clinical Evidence<sup>11</sup>**
- **10 years of product evaluation<sup>12</sup>**
- Vitoss Foam Pack is stable in a fluid environment, can soak and hold bone marrow, is compression-resistant<sup>13</sup> and can be mixed with local bone<sup>5,6</sup>
- National and local **surgeon-led education courses** offer HCP the opportunities to gain practical experience and product knowledge in **both didactic and simulated OR settings**

## Economic Solutions

- Vitoss is available in a **variety of forms** to meet your clinical and cost-control needs
- Like all synthetics, Vitoss BiModal is **priced less than commercially available growth factors** and cellular allograft tissue forms

## Cross Divisional Capabilities

- Vitoss is just one option in the **comprehensive Stryker Biologics portfolio** for Spine, Trauma, Foot and Ankle and Joint Preservation

\* The bioactive response of Vitoss BiModal has not been assessed in any animal study or clinical investigation and the results from laboratory testing may not be predictive of human clinical experience.

<sup>1</sup> US Markets for Orthopedic Biomaterials 2013 Source: Millennium Research Group. <sup>2</sup> Orthovita Test Report P/N 1010-0117R. <sup>3</sup> Orthovita Test Report P/N 1015-0083. <sup>4</sup> Orthovita Test Report P/N 1050-0003R <sup>5</sup> Epstein, N.E. (2008). An analysis of non instrumented posterolateral lumbar fusions performed in predominantly geriatric patients using lamina autograft and beta tricalcium phosphate. The Spine Journal, 1-6. <sup>6</sup> Epstein, N.E. (2009). Betatricalcium phosphate: observation of use in 100 posterolateral lumbar instrumented fusions. The Spine Journal, 9, 630-638. <sup>7</sup> U.S. Patents: 5,939,039, 6,325,987, 6,383,519, 6,521,246, 6,969,501, 6,991,803. <sup>8</sup> Orthovita Test Report P/N 1070-0008R. <sup>9</sup> Motomiya, M., et al., Effect of Hydroxyapatite Porous Characteristics on Healing Outcomes in Rabbit Posterolateral Spinal Fusion Model. European Spine Journal, 2007; 16: 2215-2224. <sup>10</sup> Hench, L.L., Polak, J.M., Xynos, I.D., Butterly, L.D.K., Bioactive Materials to Control Cell Cycle. Materials Research Innovations, 3: 313-23, (2000). <sup>11</sup> Resnick DK. Reconstruction of anterior iliac crest after bone graft harvest decreases pain: a randomized controlled clinical trial. Neurosurgery, 2005;57(3):526-529. <sup>12</sup> Stryker Orthobiologics Internal Sales Data, April 2012. <sup>13</sup> Orthovita Test Report P/N 1010-0063R.

Vitoss Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bone Graft Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone. Vitoss Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and posterolateral spine) and may be combined with autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

Contraindications: Use of Vitoss Bone Graft Substitute is contraindicated in the presence of one or more of the following clinical situations: growth plate fractures; segmental defects; conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware; significant vascular impairment proximal to the graft site; metabolic or systemic bone disorders that affect bone or wound healing; infected sites; osteomyelitis at the operative site; defect site stabilization is not possible; intraoperative soft tissue coverage is not planned or possible; in direct contact with the articular space; conditions in which general bone grafting is not advisable.

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Vitoss Foam, Vitoss BA Foam, and Vitoss BiModal Bone Graft Substitutes must not be used in patients with a history of anaphylaxis, history of multiple allergies, known allergies to bovine collagen, or who are being treated for desensitization to meat products because this product contains bovine collagen.

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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DDM/GS

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