Stryker Biologics

Vitoss Storybook

Vitoss Bone Graft Substitute
#1 Selling Synthetic Bone Graft

Spine
Autologous iliac crest bone graft (ICBG) has a calcium phosphate (CaP) surface with an open, interconnected structure that serves as a scaffold.

ICBG contains bone marrow rich with mesenchymal stem cells and hematopoietic stem cells that facilitate bone regeneration and neovascularization. In addition, ICBG provides signals that help drive bone formation.

Vitoss + BMA resembles ICBG, the gold standard, in that it has the same three components: scaffold, cells, and signals.

The Gold Standard

What makes iliac crest bone graft (ICBG) the gold standard?

BMA Harvesting Sites

Bone marrow can be aspirated from several anatomical locations throughout the body, most commonly the iliac crest, vertebral body via the pedicle, and calcaneus.

Currently, there are over 300 510(k) clearances for orthopaedic bone graft products. Because of the vast number of products available, it is often difficult for surgeons to assess the best choices for bone grafting.

There are over 175 references supporting the use of bone marrow for grafting.

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<tbody>
<tr>
<td>Prospective; 100 patients with lumbar spinal stenosis; Multisegment laminectomies (avg. 3.6 segments) and one segment (78 patients) or two segment (22 patients) instrumented PLF</td>
<td>Dynamic X-rays; 2D-CT Scans; Post-operative outcomes using SF-36; Fusion assessed separately by 2 neuroradiologists blinded to the treatment; 3,4,5,6, and 12 month follow up with a minimum of 2.5 years and maximum of 5.0 years (avg. 3.1 years)</td>
<td>Successful fusion in 95% of patients (95/100) when judged by CT and Dynamic X-ray</td>
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Study Design

Prospective; 60 patients using Noninstrumented PLF; Average age = 70 years

Outcome Measures

CT scans - Fusion assessment; Dynamic X-rays; Fusion assessed separately by 2 neuro-radiologists blinded to the treatment; Post-operative outcomes using SF-36; 3, 6, 12, and 24 months follow up

Results

Successful fusion in 85% of patients (51/60) when judged by CT and P/E

Epstein, N.E., Iliac Crest Bone Graft (ICBG) has a calcium phosphate (CaP) surface with an open, interconnected structure that serves as a scaffold.

Vitoss + BMA resembles ICBG, the gold standard, in that it has the same three components: scaffold, cells, and signals.

The vast majority of products have no human clinical data to support their use. Ultimately, human clinical data should be used to select a bone graft.

Vitoss continues to be the #1 Selling Synthetic Bone Graft. It WORKS and has HUMAN CLINICAL DATA to support its efficacy.

Demonstrated Performance

Over 600,000 implantations worldwide

Design History

18 years of biomaterials development

Clinical Proof

10 years for product evaluation with numerous human clinical trials, including prospective and peer-reviewed studies, with 85 and 95% fusion rates when mixed with BMA and local bone.
The newest member of the #1 selling synthetic bone graft family.1 Enhance bioactivity through bimodal technology development.

**Vitoss BiModal features:**

- An ultraporous, open interconnected structure which guides the 3-dimensional regeneration of bone.2
- Bimodal bioactive glass particles which promote the deposition of calcium phosphate on the implant surface.3
- A broader range of particle distribution leading to an increased surface area of bioactive glass and both an immediate burst and sustained release of Ca²⁺, Na⁺, and Si⁺ ions.4

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**Structure and Porosity**²⁰

Only materials with interconnected porosity will allow for 3-D regeneration of bone as opposed to creeping substitution. Additionally, increased porosity has been shown to lead to higher fusion rates.1³ Vitoss is a highly porous calcium-phosphate (up to 90% porous).2³

Many synthetic bone grafts have similar chemistries, but very different structures and porosity. Implant pore structure and interconnectivity have been noted to play an important role in the resorption and integration of new bone into the material. The open-interconnected porous structure of Vitoss facilitates 3-D regeneration of bone as opposed to creeping substitution, by providing a scaffold for bone remodeling that allows cell penetration and attachment.³²

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**Chemistry**

Chemistry affects the rate of resorption. Bone grafts should resorb as new bone forms in a physiologic time frame. Vitoss is composed of β-TCP and is stable at physiologic pH. It resorbs during the natural remodeling process of bone. Evidence suggests that β-TCP resorbs in the most relevant time frame.¹⁷

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**Not All Scaffolds are Created Equal**

Comparison of Vitoss to ActiFuse, ProOsteon, and MasterGraft in a canine metaphyseal study in order to radiologically compare healing at 3, 6, 12, 24, and 52 weeks. A 10mm x 22mm drill defect was created in the proximal humerus and filled with 2cc of bone graft. Radiodense implant material was detectable in competitive groups, while Vitoss demonstrated implant resorption accompanied by new bone growth at the site of the defect.¹⁹

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**KEY**²⁰

- White = bone graft substitute material
- Black = A. space between pores within the material (i.e., Vitoss) or B. space between different particles of material
Bioactive glass has shown positive bonding-to-bone properties and facilitates bone formation in vitro and in animal studies.\textsuperscript{21-23} Bioactive glass has shown positive bonding-to-bone properties and has been shown to facilitate bone formation in vitro and in animal studies.\textsuperscript{21-23} Added bioactive glass particles promote the deposition of calcium phosphate on the implant surface, creating an environment favorable for osteoblast attachment and for bone regeneration. They immediately begin to react once implanted, releasing ionic constituents into the environment (Si\textsuperscript{+}, Na\textsuperscript{+}, and Ca\textsuperscript{2+}). Osteoblasts are stimulated by the released Si\textsuperscript{+}, Na\textsuperscript{+}, and Ca\textsuperscript{2+} ions.\textsuperscript{24} Bioactive glass stimulates the local bone formation environment and has been shown in animal studies to facilitate bone regeneration.\textsuperscript{18} The Vitoss Bioactive family of products have unique porosity, structure, bioactivity and chemistry to drive the 3D regeneration of bone and potentially increase the rate of healing as shown in an animal model.\textsuperscript{18}

A broader range of particle size distribution (32 to 90 and 90 to 150µm) leads to an increased surface area of bioactive glass and both an immediate burst and sustained release of Si\textsuperscript{+}, Na\textsuperscript{+}, and Ca\textsuperscript{2+} ions.\textsuperscript{25}

Only products containing bioactive glass. Bioactivity assessed in vitro may not correlate to clinical performance.
Vitoss Family of Products

**Foam Strip**
Vitoss Foam Strip is a compression resistant pre-formed strip that is flexible when wet, can soak and hold bone marrow, and is easily customized for various grafting applications.
*Also available in Vitoss BA*

<table>
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<tr>
<th>Foam Strip</th>
<th>Size</th>
<th>Code</th>
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<tr>
<td>25x50x6mm</td>
<td>5cc</td>
<td>2101-1106</td>
</tr>
<tr>
<td>25x60x6mm (BA)</td>
<td>5cc</td>
<td>2101-1505</td>
</tr>
<tr>
<td>25x100x4mm (BA)</td>
<td>10cc</td>
<td>2101-1910</td>
</tr>
<tr>
<td>25x100x6mm (BiModal)</td>
<td>10cc</td>
<td>2101-1915</td>
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<tr>
<td>3x100x4mm</td>
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<td>2101-1100</td>
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<td>25x100x4mm (BA)</td>
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<tr>
<td>25x100x8mm (BiModal)</td>
<td>20cc</td>
<td>2101-1215</td>
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<tr>
<td>25x240x4mm</td>
<td>25cc</td>
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**Foam Pack**
Vitoss Foam Pack is a versatile material that is stable in a fluid environment, can soak and hold bone marrow to form a composite.
*Also available in Vitoss BA, BA2X, and BiModal*

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<tr>
<td>25x240x4mm</td>
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**Canisters**
Vitoss Canisters offer the handling and delivery of Vitoss Morsels with the use of bone marrow aspirate or blood. It is a closed system designed to minimize handling and exposure to potential contaminants.

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**Imbibe Needle**
The Imbibe Needle is a manually operated needle that may be used to assist in the aspiration of autologous blood or bone marrow and/or the placement of guidewires (e.g. K-wires) for orthopedic surgery. These guidewires may be used to place other hardware utilized in orthopedic procedures including pedicle screws.

**Foam Flow**
Vitoss Foam Flow can be percutaneously injected into contained bone defects, allowing for an even fill of graft material.

**Vitoss Foam Flow**

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**Morsels**
Vitoss Morsels and Blocks are an economical way to provide a quality synthetic product to your patients for large volume grafting applications. Vitoss Morsels offer a cost comparative option to allograft chips.

<table>
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<td>2.0cc Blocks</td>
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<td>30cc Macro [10]</td>
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Reconstructive

Hips
Knees
Trauma & Extremities
Joint Preservation
Orthobiologics

Medical & Surgical

Power Tools & Surgical Accessories
Image Guided Navigation
Endoscopy & Arthroscopy
Integrated Communications
Beds, Stretchers & EMS
Sustainability Solutions

Neurotechnology & Spine

Craniomaxillofacial
Interventionspine
Neurosurgical, Spine & ENT
Neurovascular
Spinal Implants

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 postero-medial 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.

The 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.

For Foam Products only (containing bovine collagen): Vitoss Foam 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 does not recommend any product for use in the use of any particular product before using it in surgery. The information presented in this brochure is intended to demonstrate a Stryker product. Products may not be available in all markets. Product availability is subject to the regulatory and medical environments that govern individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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

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11. K994337 - Vitoss SCAFFOLD SYNTHETIC CANCELLOUS BONE VOID FILLER K032689 - VITOSS SCAFFOLD FOAM BONE GRAFT MATERIAL K072184 - VITOSS BIOACTIVE FOAM BONE GRAFT SUBSTITUTE K102545 - Vitoss BAX K103173 - VITOSS BA BMODAL BIOACTIVE BONE GRAFT SUBSTITUTE
15. Stryker Test Report P/N 1070-0068R.
16. Stryker Test Report P/N 1050-0089R.
20. Stryker Test Report P/N 1015-0039F.02
26. Stryker Test Report P/N 1010-0117R.