Bone graft substitute portfolio

Vitoss
Bone Graft Substitute

HydroSet XT
Injectable Bone Substitute

Stryker DBM
Demineralized Bone Matrix

BIO⁴
Viable Bone Matrix
**Synthetic**

**Vitoss**
Bone Graft Substitute

*Vitoss* is a highly porous beta-tricalcium phosphate bone graft with clinical research demonstrating efficacy in a variety of anatomical locations.¹ Vitoss can be hydrated with bone marrow aspirate, whole blood, or saline. It is available in a variety of forms including moldable pack, malleable strip, and morsels.

![Open, interconnected structure designed to allow for 3-D bone regeneration.²](image)

*Vitoss* is up to 90% porous, which mimics the chemistry and structure of cancellous bone.³

**Scaffold resorbs at a relevant time frame during bone repair.⁴**
Research has shown, in a bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

![Forms of Vitoss containing bioactive glass are available.⁵](image)

In vitro testing showed cells exposed to Stryker’s proprietary formulation of bioactive glass demonstrated increased cell proliferation, increased collagen elaboration, and increased mineralization compared to cells cultured without exposure to bioactive glass.⁶

**HydroSet & HydroSet XT**
Injectable Bone Substitute

*HydroSet & HydroSet XT* are injectable, self-setting calcium phosphate bone substitutes. Following implantation, the formulation converts to hydroxyapatite, the principle mineral component of bone.

**Effectively sets in a wet field environment.⁷**
Under wet field conditions, HydroSet has been shown to set significantly faster compared to competitive products. It is designed to offer rigidity, structure, and to encourage new bone formation.⁸,⁹

**Augment provisional hardware.¹⁰**
HydroSet may be used to augment provisional hardware (e.g. K-wires, plates, screws, etc.) to help support bone fragments during the surgical procedure.

**Fast setting**
Able to set within eight minutes after implantation under normal physiological circumstances.¹⁰

**HydroSet XT**
Features a pre-filled, self-contained mixing and delivery system designed to enhance ease of use, simplify product preparation, and increase working time.¹⁰,¹¹,¹²
**Allograft**

**BIO⁴**

Viable Bone Matrix

BIO⁴ is a unique allogenic viable bone matrix which contains a natural cancellous scaffold, endogenous viable cells, cortical bone and growth factors to support osteoconduction, osteoinduction, osteogenesis, and angiogenesis.

**Alternative to Autograft.** BIO⁴, like Autograft, includes all components of bone: cancellous bone, cortical bone and periosteum. The periosteum contains angiogenic growth factors such as VEGF, which have been documented to be important for bone repair.¹³,¹⁵,¹⁶

**Viable Cells**

Prior to release, each final lot is tested to ensure a minimum of 600,000 viable cells per cc, a minimum of 70% cell viability, and the presence of VEGF.¹³,¹⁴

**No decanting required**

BIO⁴ requires no decanting of the cryoprotectant after a 15 minute thaw and can be implanted directly into the patient.

**BIO⁴** is human tissue and is subjected to strict processing and release criteria.¹³,¹⁴ Please see the tissue testing and release criteria summarized in the table below. The product is available in multiple sizes and is delivered cryopreserved.

<table>
<thead>
<tr>
<th>Assay</th>
<th>Source</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral serology panel</td>
<td>Donor serum</td>
<td>Pass</td>
</tr>
<tr>
<td>Total bioburden</td>
<td>Pre-antibiotic treatment sample</td>
<td>Pass</td>
</tr>
<tr>
<td>Sterility per USP &lt;71&gt;</td>
<td>Final tissue</td>
<td>Pass</td>
</tr>
<tr>
<td>Cell viability</td>
<td>Final tissue</td>
<td>≥ 70%</td>
</tr>
<tr>
<td>Cell count</td>
<td>Final tissue</td>
<td>≥ 600,000 cell/cc</td>
</tr>
<tr>
<td>VEGF</td>
<td>Final tissue</td>
<td>Present</td>
</tr>
</tbody>
</table>

Lot release criteria for BIO⁴.¹³,¹⁴

**Stryker DBM**

Demineralized Bone Matrix

Demineralized bone matrix (DBM) is allograft bone combined with a polymer carrier to offer enhanced handling properties. It is available in multiple forms including gel, putty, and putty plus cancellous chips, to allow graft selection to be tailored to the needs of a given patient.

**Offers excellent handling characteristics.** Utilizes a novel reverse phase media carrier to allow for malleability at room temperature and increased viscosity after implantation.¹⁷

**Osteoinductive potential**

Each final lot of DBM is tested using the Urist Mouse Model to confirm osteoinductive potential.¹⁸
Ordering info

Vitoss bone graft substitute
2102-2201 .......... VITOSS BBTrauma foam pack .......... 1.2cc
2102-2202 .......... VITOSS BBTrauma foam pack .......... 2.5cc
2102-2205 .......... VITOSS BBTrauma foam pack .......... 5cc
2102-2210 .......... VITOSS BBTrauma foam pack .......... 10cc
2102-2101 .......... VITOSS BA2X foam pack .......... 1.2cc
2102-2102 .......... VITOSS BA2X foam pack .......... 2.5cc
2102-2105 .......... VITOSS BA2X foam pack .......... 5cc
2102-2110 .......... VITOSS BA2X foam pack .......... 10cc
2102-1601 .......... VITOSS bioactive foam pack .......... 1.2cc
2102-1602 .......... VITOSS bioactive foam pack .......... 2.5cc
2102-1605 .......... VITOSS bioactive foam pack .......... 5cc
2102-1610 .......... VITOSS bioactive foam pack .......... 10cc
2102-1401 .......... VITOSS foam pack .......... 1.2cc
2102-1402 .......... VITOSS foam pack .......... 2.5cc
2102-1405 .......... VITOSS foam pack .......... 5cc
2102-1410 .......... VITOSS foam pack .......... 10cc
2102-1500 .......... VITOSS bioactive foam strips 25x100x4mm
2102-1505 .......... VITOSS bioactive foam strips 25x50x4mm
2102-1510 .......... VITOSS bioactive foam strips 25x50x8mm
2102-1520 .......... VITOSS bioactive foam strips 25x100x8mm
2102-1100 .......... VITOSS foam strips 25x100x4mm
2102-1101 .......... VITOSS foam strips 25x240x4mm
2102-1105 .......... VITOSS foam strips 25x50x4mm
2102-1110 .......... VITOSS foam strips 25x50x8mm
2102-1120 .......... VITOSS foam strips 25x100x8mm
2102-1056 .......... VITOSS foam cups 56mm (DIA)
2102-0026 .......... VITOSS micro canisters .......... 5cc
2102-0027 .......... VITOSS micro canisters .......... 10cc
2102-0028 .......... VITOSS micro canisters .......... 15cc
2102-0029 .......... VITOSS micro canisters .......... 30cc
2102-0030 .......... VITOSS standard canisters .......... 5cc
2102-0031 .......... VITOSS standard canisters .......... 10cc
2102-0032 .......... VITOSS standard canisters .......... 15cc
2102-0033 .......... VITOSS standard canisters .......... 30cc
2102-0020 .......... VITOSS morsels .......... 15cc
2102-0021 .......... VITOSS morsels .......... 30cc
2102-0131 .......... VITOSS morsels 300cc (10 pk of 30cc)
2102-0006 .......... VITOSS blocks .......... 10cc
2102-1305 .......... VITOSS foam flow .......... 5cc
2102-1310 .......... VITOSS foam flow .......... 10cc

References:
1. 5701-0002 Vitoss bibliography
2. TR.1050-0003R.
3. TR.1070-0006R.
7. TR.1808.E703
8. TR.1808.E706
9. TR.1808.A701
11. K161447
12. TR.1000.2034R
13. AGFT-BR-1 BIO4 technical monograph
14. Osiris Therapeutics – Data on File
17. K103036
18. IFU MIS1144.02

HydroSet injectable HA bone substitute
397003 .......... HydroSet ........................................ 3cc
397005 .......... HydroSet ........................................ 5cc
397010 .......... HydroSet ........................................ 10cc
397015 .......... HydroSet ........................................ 15cc
897003 .......... HydroSet XT .................................... 3cc
897005 .......... HydroSet XT .................................... 5cc
897010 .......... HydroSet XT .................................... 10cc
897015 .......... HydroSet XT .................................... 15cc

BIO⁴ viable bone matrix
3102-2101 .......... BIO⁴ viable bone matrix-ortho .......... 1cc
3102-2102 .......... BIO⁴ viable bone matrix-ortho .......... 2.5cc
3102-2105 .......... BIO⁴ viable bone matrix-ortho .......... 5cc
3102-2110 .......... BIO⁴ viable bone matrix-ortho .......... 10cc

Demineralized bone matrix
3102-1002 .......... DBM putty ..................................... 2.5cc
3102-1005 .......... DBM putty ..................................... 5cc
3102-1010 .......... DBM putty ..................................... 10cc
3102-1101 .......... DBM gel ........................................ 1cc
3102-1105 .......... DBM gel ........................................ 5cc
3102-1110 .......... DBM gel ........................................ 10cc
3102-1205 .......... DBM plus putty .............................. 5cc
3102-1210 .......... DBM plus putty .............................. 10cc

Imbibe bone marrow aspirate system
2105-0010 .......... Imbibe syringe ................................ 10cc
2105-0020 .......... Imbibe syringe ................................ 20cc
2105-0030 .......... Imbibe syringe ................................ 30cc
2090-9027 .......... Imbibe needles 11 gauge x 10cm
2090-9028 .......... Imbibe needles 11 gauge x 15cm
2090-9029 .......... Imbibe needles 8 gauge x 15cm
2090-9030 .......... Imbibe needles, Fenestrated 8 gauge x 15cm

Grind size

<table>
<thead>
<tr>
<th></th>
<th>Micro</th>
<th>1mm - 2mm</th>
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<tbody>
<tr>
<td>Standard</td>
<td>1mm - 4mm</td>
<td></td>
</tr>
<tr>
<td>Macro</td>
<td>4mm - 7mm</td>
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</table>

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Content ID: B4ALL-BR-6_14190
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