Bioactive Glass
Biphasic β-TCP & HA Granules
Alkylene Oxide Polymer Carrier
## Principles of Bone Healing

<table>
<thead>
<tr>
<th>Healing Cascade</th>
<th>Bone Graft Mode of Action</th>
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</thead>
<tbody>
<tr>
<td><strong>Reparative Phase</strong></td>
<td></td>
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<tr>
<td>1. Cellular infiltration and migration to site (fibroblasts, macrophages, mesenchymal stem cells)</td>
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<tr>
<td>2. Granular tissue formation and vascularization</td>
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<td>3. Cell differentiation into osteoclasts and osteoblasts</td>
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<td>4. Collagen matrix deposition and mineralization</td>
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<td>5. Woven bone formation</td>
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<tr>
<td><strong>Remodeling Phase</strong></td>
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<tr>
<td>1. Replacement of woven bone with lamellar bone</td>
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<td>2. Structural orientation of maturing fusion bed</td>
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<tr>
<td>3. Marrow space formation</td>
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<tr>
<td>4. Restoration of normal bony architecture and strength</td>
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<tr>
<td>1. Resorption of carrier</td>
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<tr>
<td>2. Biological fluid adsorption and infiltration</td>
<td></td>
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<tr>
<td>3. Dissolution of graft materials</td>
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<tr>
<td>4. Biostimulative effects (bioactive, osteostimulatory)</td>
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<tr>
<td>5. Cellular attachment, proliferation and differentiation</td>
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<tr>
<td>6. Osteoclast resorption and osteoblast deposition of new bone on graft materials</td>
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<tr>
<td>7. Osteoconduction of new host bone</td>
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<tr>
<td>8. Woven bone matrix bridging between granules</td>
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</tr>
<tr>
<td>1. Continued dissolution and resorption of graft material</td>
<td></td>
</tr>
<tr>
<td>2. Gradual replacement with new host bone</td>
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</tbody>
</table>

Rapid resorption impact: Formation of non-mineralized fibrous tissue at the implant site.
Slow resorption impact: Limited remodeling, leaving defect site susceptible to focused mechanical stress.
Rapid resorption impact: Formation of non-mineralized fibrous tissue at the implant site.
Slow resorption impact: Limited remodeling, leaving defect site susceptible to focused mechanical stress.
Design Rationale

• **Patented Formulation of Proven Biomaterials**
  • Synthetic osteostimulative graft
  • Engineered to support bone healing at all stages
  • 20% Bioactive Glass, 32% β-TCP Granules, 48% HA Granules

• **Unparalleled Handling**
  • Rapid 24 hour resorption of biocompatible carrier
  • Waxy, desirable viscosity with exceptional moldability
  • Excellent graft adherence and containment

• **Surgery-Ready Convenience**
  • Stored at room temperature (no thawing)
  • No mixing, re-hydration, or special preparation required
  • Can be mixed with autograft

INDICATIONS: MEDLINEUNITE Bioactive Bone Graft is a bone void filler device intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. MEDLINEUNITE Bioactive Bone Graft is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities, pelvis and posterolateral spine fusion procedures). MEDLINEUNITE Bioactive Bone Graft can also be used with autograft as a bone graft extender in posterolateral spine. The device provides a bone void filler that is resorbed and replaced with host bone during the healing process.
45S5 Bioactive Glass (Bioglass)

- Silicon Dioxide (SiO₂)
- Calcium Oxide (CaO)
- Sodium Oxide (Na₂O)
- Phosphorous Pentoxide (P₂O₅)
- Irregularly shaped granules
- Patented particle size range (200 – 420μm)
Bioactive Properties

• Bioactive glass ions released following carrier resorption
• Ions reacts with body fluids and stimulate formation of osteoconductive apatite layer
• Ionic dissolution products of bioactive glass have been shown to:
  • Increase osteoblast differentiation and proliferation (e.g. osteostimulative effect)
  • Upregulate osteogenic gene expression
  • Stimulate angiogenesis
  • Minimize persistence of inflammatory responses
  • Have antimicrobial effectiveness

Scanning electron microscopy (SEM) images of the apatite layer formation on the implant surface following immersion in simulated body fluid (SBF). In vitro performance may not be predictive of performance in humans.

Biphasic $\beta$-TCP/HA

- Combines the long-term stability of HA with the rapid solubility of $\beta$-TCP.
- Provides a more gradual and optimized resorption profile.
- More amenable to the body’s natural bone healing process.

**Patented Granules**

- Particle size range:
  - 0.5 – 1.0mm (50%)
  - 1.0 – 2.0mm (50%)
- Irregularly shaped to fully pack void space
- Multidirectional, interconnected porous structure
- Mimics human cancellous bone
Granule Macro- and Microporosity

SEM images of β-TCP/HA Granules

- 50 – 55% macroporous (300 – 600μm)
- Macropores correspond to the size of trabecular bone to support osteoconduction.
- 20 – 30% microporous (<10μm)
- Micropores allows for diffusion of biological fluids and increased surface area for exchange of calcium and phosphate ions (important to healing process).

Alkylene Oxide Polymer (AOP) Carrier

- Provides excellent handling, resorbs quickly to expose $\beta$-TCP/HA and bioactive glass
Optimized Resorption Profile

Bioactive Glass
- Vitoss

β-TCP
- ChronOS
- Mastergraft

NanOss
- Actifuse

HA

RESORPTION RATE (TIME)

MATERIAL COMPOSITION

LOW ← SOLUBILITY → HIGH
## Market Comparison

Only MEDLINE UNITE contains all three ideal synthetic bone graft components

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Bioglass</th>
<th>β-Tricalcium Phosphate</th>
<th>Hydroxyapatite</th>
<th>Carrier</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEDLINE UNITE</td>
<td>20%</td>
<td>32%</td>
<td>48%</td>
<td>Alkylene Oxide Polymer</td>
</tr>
<tr>
<td>Stryker Vitoss</td>
<td>10%</td>
<td>70%</td>
<td>None</td>
<td>20% Bovine Collagen</td>
</tr>
<tr>
<td>DePuy Synthes</td>
<td>None</td>
<td>100%</td>
<td>None</td>
<td>Sodium Hyaluronate</td>
</tr>
<tr>
<td>ChronOS</td>
<td>None</td>
<td>85%</td>
<td>15%</td>
<td>Bovine Collagen</td>
</tr>
<tr>
<td>Medtronic Mastergraft</td>
<td>None</td>
<td>None</td>
<td>0.8% Silicate Substituted Calcium Phosphate</td>
<td>Alkylene Oxide Copolymer</td>
</tr>
<tr>
<td>Baxter Actifuse</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Alkylene Oxide Copolymer</td>
</tr>
<tr>
<td>RTI Surgical NanOss</td>
<td>None</td>
<td>None</td>
<td>Nanostructured</td>
<td>Porcine Collagen</td>
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MEDLINEUNITE® Bioactive Bone Graft

- Patented Formulation of Proven Biomaterials
- Unparalleled Handling
- Surgery-Ready Convenience

For more information or to schedule a case, contact your MEDLINEUNITE Foot & Ankle Representative.