Bone Graft Selection Guide
One Surgeon. One Patient.

Over 1 million times per year, Biomet helps one surgeon provide personalized care to one patient.

The science and art of medical care is to provide the right solution for each individual patient. This requires clinical mastery, a human connection between the surgeon and the patient, and the right tools for each situation.

At Biomet, we strive to view our work through the eyes of one surgeon and one patient. We treat every solution we provide as if it’s meant for a family member.

Our approach to innovation creates real solutions that assist each surgeon in the delivery of durable personalized care to each patient, whether that solution requires a minimally invasive surgical technique, advanced biomaterials or a patient-matched implant.

When one surgeon connects with one patient to provide personalized care, the promise of medicine is fulfilled.
Bone Graft Selection Guide

Purpose

Sales Representative Education Tool Provides

• Guidance on positioning Biomet Biologics bone-grafting products for various orthopaedic applications.
• Examples of clinical applications for various bone-grafting products.
• Definition of Mechanism of Action (MOA) and Handling Characteristics/Delivery Mechanism for the various bone-grafting options.
• Guidance on product combinations (i.e., PRP+DBM, etc.).
• Information on FDA-cleared clinical indications.
Bone Graft Selection Guide

Published Scientific Literature References to MOA Terms

- **Osteoconductive** materials provide the framework or scaffolding within a bone environment for cells to infiltrate and attach. It also offers the porosity for vascular pathways and cell migration. Materials that are generally referred to as osteoconductive include certain calciumphosphate/sulphate based synthetics and allograft cortical or cancellous chips, sponges, and strips.\(^1,2\)

- **Osteopromotive** materials enhance the natural bone-healing process.\(^3,4,5\) Osteopromotive materials, such as PRP, are mixed with autograft or allograft materials to impart better graft-handling characteristics.\(^3,4,5\)

- **Osteoinductive** materials induce bone-formation in a bony or non-bony environment via the action of growth factors or signaling proteins, such as Bone Morphogenetic Proteins (BMPs). These proteins stimulate the conversion of progenitor cells into bone forming osteoblasts.\(^2,4\)

- **Osteogenic** materials, such as autograft and/or bone marrow aspirate, contain viable cells, such as mesenchymal stem cells, osteoprogenitor cells, or osteoblasts, which are capable of synthesizing new bone.\(^2\)

*Products that produce a PRP output do not currently have FDA clearance to be characterized with a specific mechanism of action. PRP, in and of itself (i.e., without the autograft or allograft), is not FDA cleared as “osteopromotive”.

Bone Graft Selection Guide

Essentials of Bone Healing

Scaffold / Matrix:
Osteoconductive

Proteins / Growth Factors:
Osteoinductive
Osteopromotive

Osteoprogenitor Cells:
Osteogenic

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Bone Graft Selection Guide

Product Portfolio

- **StaGraft** DBM Putty & PLUS
- **StaGraft** Canc. DBM Sponge/Strips
- **Bonus CC** Matrix
- **CERAMENT™|BONE VOID FILLER**
  - Bonus Synthetic Bone Graft Substitute
- **BMA Kit**
- **StaGraft** DBM Putty & PLUS
- **StaGraft** Canc. DBM Sponge/Strips
- **CERAMENT™|BONE VOID FILLER**
  - Bonus Synthetic Bone Graft Substitute
- **BMA Kit**

These products also exhibit Osteoconductive properties.

- **BioCUE**
- **GPS III**
- **Plasmax**

**Osteoconductive**

**Osteogenic**

**Osteopromotive**

**Osteoinductive**

Mixed with autograft and/or allograft bone
# Bone Graft Selection Guide

<table>
<thead>
<tr>
<th>Step</th>
<th>Material: Synthetic granules</th>
</tr>
</thead>
</table>
| 1    | **Bonus Synthetic Bone Graft Substitute**  
MOA: Osteoconductive  
Clinical Demand: Low  
Handling: Medium |

<table>
<thead>
<tr>
<th>Step</th>
<th>Material: Synthetic self-setting paste</th>
</tr>
</thead>
</table>
| 2    | **CERAMENT™|BONE VOID FILLER**  
MOA: Osteoconductive  
Clinical Demand: Medium  
Handling: Very High |

<table>
<thead>
<tr>
<th>Step</th>
<th>Material: DBM putty or DBM putty+Synthetic granules</th>
</tr>
</thead>
</table>
| 3    | **StaGraft Putty/Plus**  
MOA: Osteoconductive, Osteoinductive  
Clinical Demand: Medium  
Handling: Very High |

| Step | Autologous Input Materials: Whole blood  
Graft Material: PPPc + allograft materials  
(DBM or DBM + Cancellous Chips)  
**PPPc: Plasmax**  
**Allograft Materials: StaGraft Canc. DBM (or) Bonus CC Matrix** |
|------|-------------------------------------------------|
| 4    | MOA: Osteoconductive, Osteoinductive, Osteopromotive  
Clinical Demand: Medium  
Handling: Very High |

| Step | Autologous Input Materials: Whole blood  
Graft Material: PRP from BMA + allograft materials  
(DBM or DBM + Cancellous Chips)  
**PRP: BioCUE**  
**Allograft Materials: StaGraft Cancellous DBM (or) Bonus CC Matrix** |
|------|-------------------------------------------------|
| 5    | MOA: Osteoconductive, Osteoinductive, Osteopromotive  
Clinical Demand: High  
Handling: High |

| Step | Autologous Input Materials: Whole blood  
Graft Material: PRP from BMA + allograft materials  
(DBM or DBM + Cancellous Chips)  
**PRP: BioCUE**  
**Allograft Materials: StaGraft Cancellous DBM (or) Bonus CC Matrix** |
|------|-------------------------------------------------|
| 6    | MOA: Osteoconductive, Osteoinductive, Osteopromotive  
Clinical Demand: High  
Handling: High |

**Handling Properties**:  
- **Low**: Extremely low cohesion, sand-like particles.  
- **Medium**: Not cohesive, i.e., loose granules.  
- **High**: Good cohesion and/or molding properties.  
- **Very High**: Excellent cohesion and/or molding properties.

*Data on file at Biomet.

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**Bone Graft Selection Guide**

**Examples of Non-load Bearing Potential Clinical Applications & Graft Delivery**

1. **Material:** Synthetic granules
   - *Fractures and bone cysts.*
   - Delivery via finger-packing and push/tamp with curette

2. **Material:** Synthetic self-setting paste**
   - *Proximal and distal tibial, femoral and humeral fractures, forefoot and midfoot fusions, osteotomies, bone voids, osteolytic lesions, distal radial fractures.*
   - Delivery - inject via 16g or larger needle, or finger-pack and push/tamp with curette

3. **Material:** DBM putty or DBM putty + Synthetic granules
   - *Proximal and distal tibial, femoral and humeral fractures, forefoot and midfoot fusions, osteotomies, bone cysts, osteolytic lesions, posterolateral spine fusions.*
   - Delivery via open bore syringe or finger-packing and push/tamp with curette

4. **Autologous Input Materials:** Whole blood
   - **Graft Material:** PPPc + allograft materials (DBM or DBM + Canc. Chips)
   - *Proximal and distal tibial, femoral and humeral fractures, forefoot and midfoot fusions, osteotomies, bone cysts, osteolytic lesions, spine fusions as an autograft extender.*
   - Create hydrated “log” or hydrated strip/cube. Delivery via finger-packing and push/tamp with curette

5. **Autologous Input Materials:** Whole blood
   - **Graft Material:** PRP + allograft materials (DBM or DBM + Canc. Chips)
   - *Proximal and distal tibial, femoral and humeral fractures, forefoot and midfoot fusions, osteotomies, bone cysts, osteolytic lesions, spine fusions as an autograft extender, non-unions.*
   - Create hydrated “log” or hydrated strip/cube. Delivery via finger-packing and push/tamp with curette

6. **Autologous Input Materials:** aBMA (blood and bone marrow aspirate)
   - **Graft Material:** PRP from aBMA + allograft materials (DBM or DBM + Canc. Chips)
   - *Proximal and distal tibial, femoral and humeral fractures, forefoot and midfoot fusions, osteotomies, bone cysts, osteolytic lesions, spine fusions, non-unions, Charcot foot reconstruction.*
   - Create hydrated “log” or hydrated strip/cube. Delivery via finger-packing and push/tamp with curette

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*The procedures listed above are not specified in Biomet Biologics’ individual product clearances. The above procedures are listed solely for sales force education as examples of applications wherein surgeons might select and utilize various biologics products. Unless specifically identified in the product’s FDA clearance, sales representative must not target or promote the use of Biomet Biologics products for specific clinical applications.

**Contraindicated for vertebroplasty and kyphoplasty. Data on file at Biomet.**

**Handling Properties***: Low: Extremely low cohesion, sand-like particles. Medium: Not cohesive, i.e., loose granules. High: Good cohesion and/or molding properties. Very High: Excellent cohesion and/or molding properties.
## Bone Graft Selection Guide

### User Preference-Based Graft Choices

<table>
<thead>
<tr>
<th></th>
<th>Synthetic User</th>
<th>Canc. Chip / DBM User</th>
<th>Autograft User</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Material: Synthetic granules</td>
<td>Graft Material: DBM putty &amp; DBM putty + Synthetic granules</td>
<td>Graft Material: PRP from sBMA + allograft materials (DBM or DBM + Canc. Chips)</td>
</tr>
<tr>
<td></td>
<td><em>Bonus Synthetic Bone Graft Substitute</em></td>
<td><strong>StaGraft Putty/Plus</strong></td>
<td>PRP: <em>BioCUE</em></td>
</tr>
<tr>
<td></td>
<td>Material: Synthetic self-setting paste</td>
<td>Graft Material: PPPc + allograft materials (DBM or DBM + Canc. Chips)</td>
<td>Allograft Materials: <em>StaGraft</em> Cancellous DBM (or) <em>Bonus CC Matrix</em></td>
</tr>
<tr>
<td></td>
<td>CERAMENT™</td>
<td>BONE VOID FILLER</td>
<td><strong>Plasmax</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Allograft Materials: <em>StaGraft</em> Cancellous DBM (or) <em>Bonus CC Matrix</em></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>Graft Material: PRP + allograft materials (DBM or DBM + Canc. Chips)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>GPS III</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Allograft Materials: <em>StaGraft</em> Cancellous DBM (or) <em>Bonus CC Matrix</em></td>
<td></td>
</tr>
</tbody>
</table>
## Indications for Use - Please see package inserts for additional device information/labeling.

<table>
<thead>
<tr>
<th>Device</th>
<th>Clinical Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GPS III Platelet Concentrate Separation Kit with ACD-A</strong></td>
<td>The GPS III Platelet Concentrate Separation Kit with ACD-A is designed to be used for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of the patient’s blood at the point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.</td>
</tr>
<tr>
<td><strong>Plasmax Plasma Concentrator</strong></td>
<td>The Plasmax Plasma Concentrator with GPS III Platelet Concentrate Separation Kit with ACD-A is designed to be used for the safe and rapid preparation of concentrated platelet-poor-plasma (PPPc) and autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient’s point of care. The PPPc and PRP can be mixed with autograft and allograft bone prior to application to an orthopedic surgical site as deemed necessary by the clinical use requirements.</td>
</tr>
<tr>
<td><strong>BioCUE Platelet Concentration System</strong></td>
<td>The BioCUE Platelet Concentration System is designed to be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet poor plasma (PPP) and platelet rich plasma (PRP) from a small sample of blood and bone marrow mixture. The plasma and concentrated platelets produced can be used for diagnostic tests. Additionally, the platelet rich plasma (PRP) can be mixed with autograft and/or allograft bone prior to application to an orthopedic site.</td>
</tr>
<tr>
<td><strong>CERAMENT™ BONE VOID FILLER</strong></td>
<td>CERAMENT™ BONE VOID FILLER is a ceramic bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. CERAMENT™ BONE VOID FILLER is indicated to be injected into bony voids or gaps in the skeletal system, i.e., extremities, pelvis, and spine (only during open surgery in the spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. CERAMENT™ BONE VOID FILLER provides a bone void filler that resorbs and is replaced by bone during the healing process. CERAMENT™ BONE VOID FILLER is not intended for use in load bearing applications such as vertebroplasty and kyphoplasty.</td>
</tr>
<tr>
<td><strong>Bonus Synthetic Bone Graft Substitute Resorbable Bone Graft Substitute</strong></td>
<td><em>Bonus</em> Synthetic Bone Graft Substitute Resorbable Bone Graft Substitute is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. <em>Bonus</em> Synthetic Bone Graft Substitute is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. <em>Bonus</em> Synthetic Bone Graft Substitute can be combined with autogenous bone marrow aspirate, autogenous blood, and/or sterile fluids (saline or Ringer’s solution). The product provides a bone void filler that resorbs and is replaced with bone during the healing process.</td>
</tr>
<tr>
<td><strong>StaGraft Cancellous Graft</strong></td>
<td>These allografts meet the definition of a tissue-based product as defined in 21 CFR Part 1271, Human Cells, Tissues and Cellular and Tissue-based products (HCT/Ps) and are solely regulated under Section 361 of the Public Health Services Act. Tissue-based products regulated as 361 HCT/Ps are exempt from premarket requirements.</td>
</tr>
<tr>
<td><strong>StaGraft DBM (Putty, Plus) also known as InterGro DBM (Putty, Paste, Plus)</strong></td>
<td>StaGraft DBM products (Putty, Plus) are to be used for filling bony voids or gaps in the extremities and pelvis that are not intrinsic to the bony stability of the structure, and as an autograft extender in spine. StaGraft Plus may also be used as a bone void filler in the spine (posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to bone. StaGraft DBM may also be used for filling craniofacial defects and craniotomies that are no larger than 25 cm². The amount of StaGraft DBM products to be used should be based on the type of procedure and size of graft site.</td>
</tr>
<tr>
<td><strong>BMA Kit</strong></td>
<td>The Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow.</td>
</tr>
</tbody>
</table>
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Questions/Comments

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