BioReady™ Demineralized Bone Matrix (DBM) is a ready-to-use, osteoinductive* bone graft that provides convenience, robust handling and unsurpassed safety. Processed from 100 percent donated human tissue, this graft is available in a variety of options to meet your surgical needs. This graft does not require any preparation, such as thawing or mixing, and is available in various sizes for use as a bone void filler in surgical applications.

**Proven Osteoinductive Potential**

BioReady™ DBM has demonstrated potential for inducing new bone growth throughout its entire shelf life.

To verify the osteoinductive potential of BioReady DBM throughout its shelf-life, samples of the finished implant were implanted using the Urist assay. Implants were removed and histology was reviewed to assess the osteoinductive potential as well as the inflammatory response.

The data presented indicates that BioReady DBM maintains its osteoinductive potential for at least one year.

**Bone Void Filler Applications**

- **SPINE**
  - Cervical fusion procedures
  - Lumbar fusion procedures
  - Deformity

- **EXTREMITY**
  - Fusion procedures
  - Primary joint surgery
  - Revision joint surgery

- **TRAUMA & ONCOLOGY**
  - Fresh fractures
  - Non-union fractures

- **LARGE JOINT RECONSTRUCTION**
  - Primary joint surgery
  - Revision joint surgery

**Osteoinductivity of BioReady™ DBM Putty in Athymic Rat Model**

Pictures below represent $T_0 + 11$ days and $T_0 + 365$ days.

**LEGEND**
- Demineralized Bone Matrix (DBM), Bone Marrow (BM), Osteocytes in lacunate (OC), New Bone Matrix (NBM), Calcification (mineralization) line (CL), Fibrous Tissue (FT).
- Single histology sections across study time points.

*DBM or representative finished implant is either assayed in vivo in the modified athymic nude rat for bone formation or in vitro for endogenous BMP-2 as a surrogate test marker for osteoinductive potential. Because the combination of various proteins is responsible for osteoinductive potential, when assayed in vitro, DBM is also screened for the presence of BMP-7. Findings from an in vitro assay or animal model are not necessarily predictive of human clinical results.
GRaFT FEATURES

• 100 percent DBM
• Ready-to-use; no warming, thawing or mixing necessary
• Pre-mixed in a syringe or jar for easy extrusion and removal
• Pliable without becoming hard or setting
• Putty-like consistency that easily molds and shapes to fit various bony defects

• Maintains a very robust consistency minimizing the risk of graft migration during irrigation
• Handles well in a wet environment
• Putty: 56 percent DBM by weight
  Putty With Chips: 42 percent DBM by weight

Safety
The highest level of safety is provided through redundant safeguards, including stringent donor screening, laboratory testing and validated tissue processing (including viral inactivation and terminal sterilization).

BioReady DBM Putty and Putty With Chips is sterilized through the Cancelle® SP DBM Sterilization Process, which is designed to preserve protein activity and maintain osteoinductive potential. Through a combination of oxidative treatments and acid or alcohol washes, debris is removed and pathogens are inactivated. Cleansing rinses remove residual chemicals, maintaining biocompatibility, and terminal low temperature, low dose gamma irradiation achieves device-level sterility (SAL 10⁻⁶), preserving the utility of the graft.

Quality
In order to consistently provide the highest quality DBM implants, RTI performs a series of in-process and post-process quality checks. Osteoinductive potential is verified by 100 percent lot testing after sterilization.

QUALITY CONTROL RELEASE CRITERIA
The following tests are performed on every lot before release:
• Osteoinductivity
• Residual calcium
• Residual moisture
• Extrusion of finished graft
• Handling of finished graft
• Dissolution of finished graft
BioReady™ DBM Putty

<table>
<thead>
<tr>
<th>Composition: DBM + Carrier DBM + Water</th>
<th>Ordering Code</th>
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<tbody>
<tr>
<td>0.5cc Threaded Syringe/Cap</td>
<td>D00100</td>
</tr>
<tr>
<td>1.0cc Threaded Syringe/Cap</td>
<td>D00101</td>
</tr>
<tr>
<td>2.0cc Open Bore Dispenser</td>
<td>D00102</td>
</tr>
<tr>
<td>5.0cc Open Bore Dispenser</td>
<td>D00105</td>
</tr>
<tr>
<td>10.0cc Open Bore Dispenser (2x5cc Open Bore Dispensers)</td>
<td>D00110</td>
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BioReady™ DBM Putty with Chips

<table>
<thead>
<tr>
<th>Composition: DBM + Carrier DBM + Water + Mineralized Cortical Cancellous Chips</th>
<th>Ordering Code</th>
</tr>
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<tbody>
<tr>
<td>Small Chips (chip size range: 0.25mm-1.0mm)</td>
<td></td>
</tr>
<tr>
<td>1.0cc Twist Cap</td>
<td>D00301</td>
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<tr>
<td>2.0cc Open Bore Dispenser</td>
<td>D00302</td>
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<tr>
<td>Large Chips (chip size range: 1.0mm-3.0mm)</td>
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<tr>
<td>5.0cc Jar Dispenser</td>
<td>D00305</td>
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<tr>
<td>10.0cc Jar Dispenser</td>
<td>D00310</td>
</tr>
</tbody>
</table>


For Extremities, Trauma, General Orthopedic orders, call RTI directly: 800.624.7238

For Spine orders, call RTI directly: 800.557.9909

- Accredited by American Association of Tissue Banks
- ISO 13485 Certified
- AdvaMed Member

Reimbursement Info: Call 877.839.7152
rtireimbursementsupport@rtix.com

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