rti surgical®

BioReady®

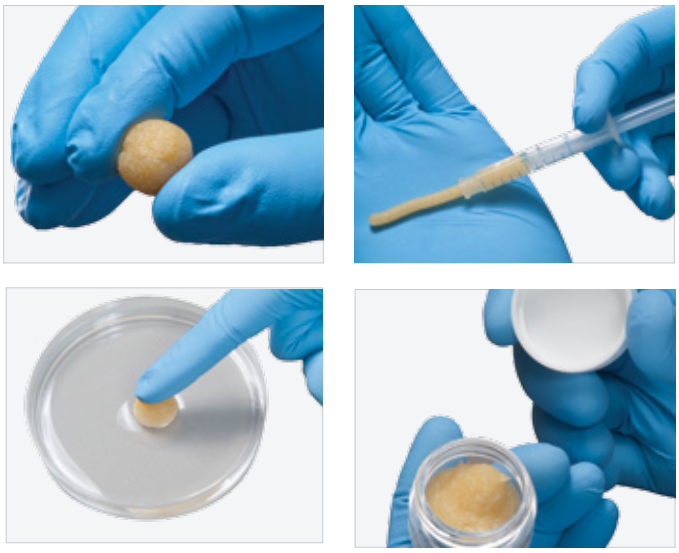
DEMINERALIZED BONE MATRIX

A **HIGHER** STANDARD®

BioReady®
DEMINERALIZED BONE MATRIX

A READY-TO-USE, 100% ALLOGRAFT

BioReady® Demineralized Bone Matrix (DBM) is a ready-to-use, bone graft with osteoinductive potential* 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.



Bone Void Filler Applications

SPINE
- Cervical fusion procedures
- Lumbar fusion procedures
- Deformity

TRAUMA & ONCOLOGY
- Fresh fractures
- Non-union fractures

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

LARGE JOINT RECONSTRUCTION
- Primary joint surgery
- Revision joint surgery

Proven Osteoinductive Potential

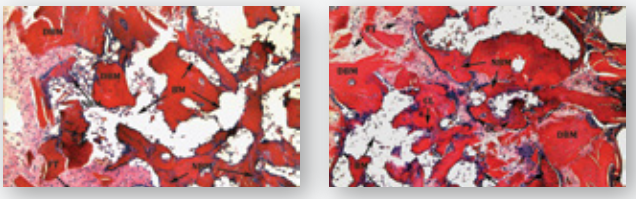
BioReady® DBM has demonstrated potential for inducing new bone growth throughout its entire shelf life.[1]

To verify the osteoinductive potential of BioReady DBM throughout its shelf-life, samples of the finished implant were implanted and removed after 28 days. Histology was reviewed to assess the osteoinductive potential as well as the inflammatory response using the Urist assay.[2]

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

Osteoinductivity of BioReady® DBM Putty in Athymic Rat Model[1]

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



T_0+11 DAYS **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

- 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.

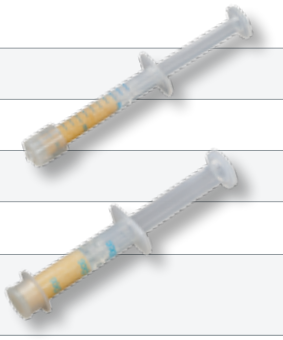
QUALITY CONTROL RELEASE CRITERIA

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

Composition: DBM + Carrier DBM + Water	Ordering Code
0.5cc Threaded Syringe/Cap	D00100
1.0cc Threaded Syringe/Cap	D00101
2.0cc Open Bore Dispenser	D00102
5.0cc Open Bore Dispenser	D00105
10.0cc Open Bore Dispenser (2x5cc Open Bore Dispensers)	D00110



BioReady® DBM Putty with Chips

Composition: DBM + Carrier DBM + Water + Mineralized Cortical Cancellous Chips

Small Chips (chip size range: 0.25mm-1.0mm)	Ordering Code
1.0cc Twist Cap	D00301
2.0cc Open Bore Dispenser	D00302
Large Chips (chip size range: 1.0mm-3.0mm)	
5.0cc Jar Dispenser	D00305
10.0cc Jar Dispenser	D00310

Reference:

1. Moore, S., Zhukauskas, R., Cobb, R. *Osteoinductivity of BioReady™ DBM Putty in Athymic Rat Model.* 2012. RTI Surgical, Inc., Alachua, FL.
2. Urist, MR. *Bone: Formation by Autoinduction.* Science. 1965; 150(689): 893.

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 13485:2003 Certification
- AdvaMed Member

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