

bonus[™]
demineralized**bone**matrix

*Would you like to
customize the DBM
Carrier according to
your Patient's need?*



Featuring

***Bone Morphogenetic Proteins with
the option of adding Patient's own
Stem Cells and Growth Factors***

BIOMET[®]
BIOLOGICS, INC.

bonusTM

demineralizedbonematrix

- **100% DBM**
- **Freeze dried**
- **Unique vacuum system takes in exact amount of fluid needed to hydrate graft**
- **Allows the surgeon to customize carrier to fit patient's specific needs by the following hydration options**
 - ◇ Platelet concentrate (GPS[®] and Vortech[™] Systems)
 - ◇ Plasma concentrate (Vortech[™] and Plasmax[™] Systems)
 - ◇ Bone marrow aspirate (Biomet Osteoprogenitor System)
 - ◇ Whole blood
 - ◇ Saline
 - ◇ Antibiotic solution
- **Allows surgeons to customize handling**
 - ◇ Product can be made into the consistency of a putty, gel or crunch-style graft (see handling characteristics)















bonusTM

demineralizedbonematrix

Introduction

DBM is the perfect balance between autograft and allograft. It promotes bone growth by providing osteoinductive growth factors and an osteoconductive scaffold, while avoiding pitfalls such as autograft donor site morbidity and lack of allograft induction capabilities.¹ Bonus™ DBM offers all the benefits of DBM while providing doctors ultimate flexibility. Bonus™ DBM can be customized for each patient by hydrating with platelet concentrate, plasma concentrate, bone marrow aspirate, whole blood, saline or antibiotic.

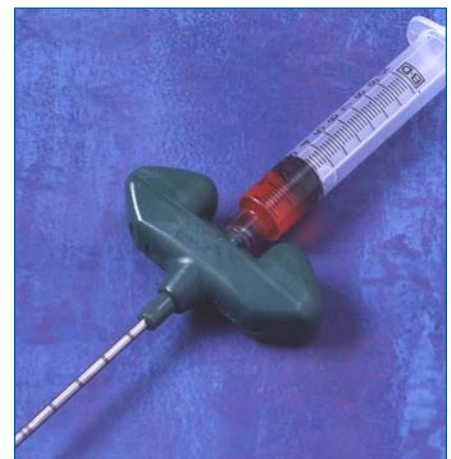
Bonus™ DBM (with PRP)	Bonus™ DBM (with Stem Cells)	Traditional DBM
		
	Matrix	
		
	Signals	
		
	Cells	
		
	Nutrition	

Patient-specific demands require options

Surgery is not an assembly line. Each patient has specific needs. Bonus™ DBM is the only DBM product capable of being customized for each patient via hydrating options for the surgeon.

Hydration Options

- **Platelet Concentrate (GPS® and Vortech™ Systems):**
Platelets recruit and enhance the environment for soft tissue healing and bone growth
- **Plasma Concentrate (Plasmax™ and Vortech™ Systems):**
Excellent hemostatic agent
- **Bone Marrow Aspirate (BOS™ needle):** Bone marrow contains progenitor cells, which can differentiate into muscle, fat, cartilage bone, etc.
- **Autologous Blood:** This safe autologous carrier improves handling
- **Saline:** Safe carrier improves handling
- **Antibiotic:** Prophylactic carrier for at-risk patients



BOS™ Biomet Osteoprogenitor System Needle for stem cell recovery.

Bonus™ DBM Advantages

Matrix	
Traditional DBM	Provides an osteoconductive scaffold to promote bone formation
Bonus™ DBM	Its porous scaffold allows full infiltration of stem cells and platelets
Signals	
Traditional DBM	Provides osteoinductive, proliferative and chemoattractive signals, including BMP-2, BMP-4, BMP-7 TGF, PDGF, IGF-I and FGF-I
Bonus™ DBM with GPS® Platelet Concentrate	Platelet concentrate further enhances these signals by the inclusion of PDGF, TGF, EGF and VEGF
Cells	
Traditional DBM	Encourages cell migration and differentiation from surrounding tissues
Bonus™ DBM with GPS® Platelet Concentrate	This cellular migration is greatly increased by the growth factors present in the platelet concentrate
Nutrition	
Traditional DBM	Depends on the local blood clot to provide growth factors
Bonus™ DBM with GPS® Platelet Concentrate	Platelet concentrate with its abundance of angiogenic factors, PDGF and VEGF, enhances the vascularization process, thereby providing nutritional support to new tissues

DBM: Handling Characteristics

Liquid to Bonus Ratio	Application	Delivery	Handling Consistency
10 ml: 10 ml 5 ml: 5 ml or 1 ml: 1 ml	Percutaneous injections, Contained defects	Fine bead nozzle, BOS™ needle	Flowable gel
6 ml: 10 ml 3 ml: 5 ml or .6 ml: 1 ml	Standard packing, Molding	Fine bead nozzle, Log	Putty
4 ml: 10 ml 2 ml: 5 ml or .4 ml: 1 ml	Very bloody environments with heavy irrigation	Log only	Crunchy

The unique vacuum system enables Bonus™ DBM to be handled as a putty, gel, or a very firm graft.

Ordering Information

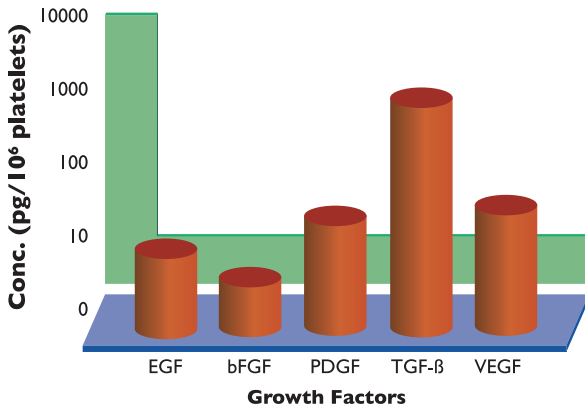
Part Number	Description
48-DBM1	5 ml Bonus™ DBM
48-DBM2	10 ml Bonus™ DBM
48-DBM4	1 ml Bonus™ DBM

Value of Growth Factors

Growth factors are critical in the bone healing process. Naturally, their release is initiated by the rush of platelets and white blood cells to the bone defect. Their functions include recruiting osteoprogenitor stem cells and osteoblasts, providing nutrition, and causing bone to mature more rapidly and increase its density.²⁻⁵

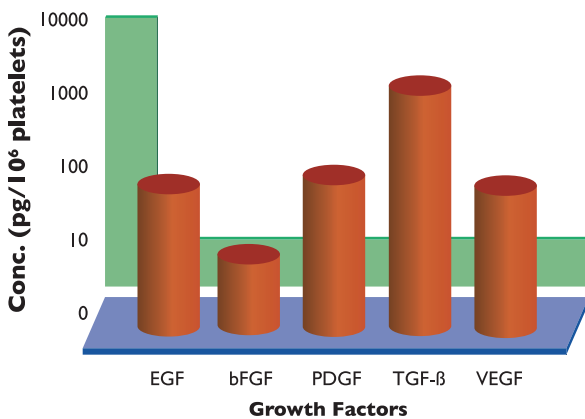
These valuable growth factors, present in platelet concentrate, are released at the time frames displayed below.

Initial Degranulation (t=0 hours)²



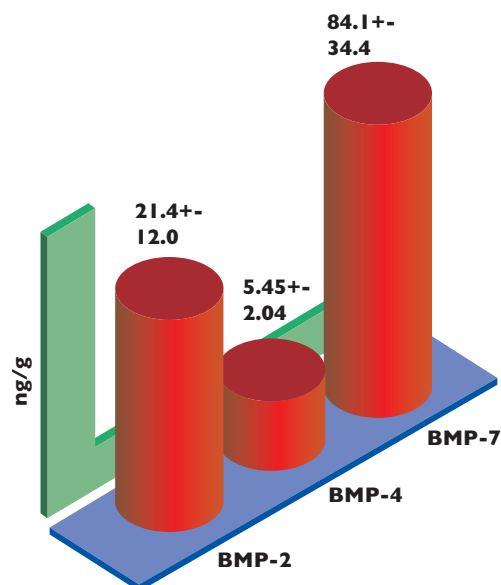
Growth Factor	Amount (pg/10 ⁶ platelets)	S.D.	% of Max	S.D.
EGF	7.59	2.83	13.21	4.92
bFGF	2.73	0.42	35.58	4.65
PDGF-BB	11.65	10.42	15.02	10.03
TGF-β ₁	633	300	49.17	26.29
VEGF	13.02	7.21	25.37	10.46

Maximum Concentration (t=20 hours)²



Growth Factor	Amount (pg/10 ⁶ platelets)	S.D.
EGF	60.69	16.19
bFGF	7.29	1.72
PDGF-BB	64.41	25.79
TGF-β ₁	1400	512
VEGF	54.22	25.70

DBM used in Bonus™ DBM is proven to contain measureable bone morphogenetic proteins.¹



Technique with 1 ml Bonus™ DBM



Figure 1

Twist the elbow to seat perpendicular to the tabs of the 1 ml graft preparation system containing Bonus™ DBM. Ensure that the elbow attachment is well seated in the 1 ml syringe with Bonus™ DBM. If not, push on elbow to seat.



Figure 2

Ensure that the yellow cap on the graft preparation system containing Bonus™ DBM is tightly seated. Attach the hydrating fluid of choice by twisting the syringe on the luer lock fitting. Note: In all subsequent steps, the syringe with hydrating fluid must be pointed down as illustrated in Figure 2.



Figure 3

Pull on the syringe plunger containing the hydrating fluid until fully extended. This will create a vacuum necessary for complete hydration (Figure 3). Release plunger to allow hydrating fluid to infiltrate the graft preparation system. Wait 2 to 3 minutes to proceed.



Figure 4

Use hydrating syringe to lever on the elbow. Attach plunger provided, remove yellow cap and expel hydrated Bonus™ DBM.

Technique with 5-10 ml Bonus™ DBM



Figure 1

Attach the 30 ml vacuum syringe to the valve fitting on the side of the graft preparation system containing Bonus™ DBM. With both hands on the vacuum syringe, pull on the vacuum syringe plunger until fully out — twist plunger to engage the locking mechanism. Remove vacuum syringe and repeat process a second time to ensure desired vacuum.



Figure 2

Holding the graft preparation system at the valve, twist off the 30 ml vacuum syringe. Attach a dispensing unit containing the liquid component onto the valve of the Graft Preparation System with Bonus™ DBM. Pushing in additional fluid will cause a more flowable material.



Figure 3

Detach the syringe. Piston the plunger for ten seconds. This assists with hydration. Prior to removing from chamber, gently pump the plunger two times.



Figure 4

Remove the cap from the end of the graft preparation system and push the graft out of the system using the plunger. The supplemental nozzle can be used to inject the DBM in a fine bead.

Application Possibilities for Bonus™ DBM

Orthopaedic surgery

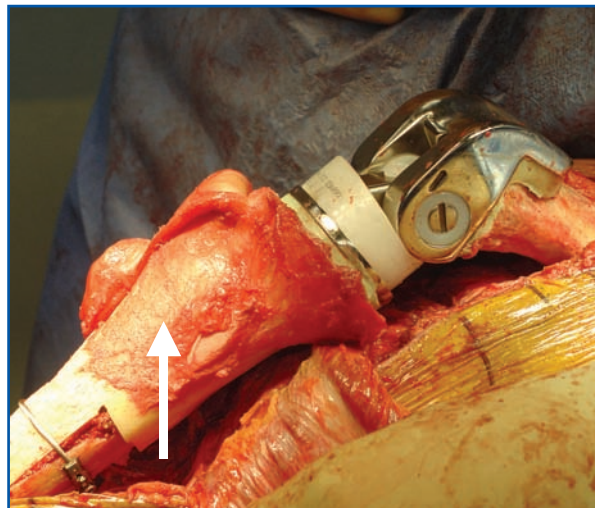
- Bone Nonunions^{6,7}
- Total Knee Arthroplasty⁸
- Knee Revisions⁹
- Bone defects/cysts¹⁰⁻¹²
- Spinal Fusion^{13,14}
- Ankle/Hindfoot Fusion¹⁵
- Revision Total Hip Arthroplasty¹⁶
- Tendon Fixation to Metal Implants¹⁷

Cranial/Maxillofacial Surgery

- Mandibular Reconstruction¹⁸
- Correction of Orbitocranial Defects¹⁹
- Reconstruction of Resorbed Maxilla²⁰
- Bone Regeneration^{21,22}

Otolaryngology

- Frontal Sinus Repair²³



Bonus™ DBM mixed with platelet-rich plasma applied to knee revision



Bonus™ DBM mixed with bone marrow aspirate for use in spine surgery



Bonus™ DBM mixed with bone marrow aspirate and platelet-rich plasma being applied to a fibular nonunion

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01-50-2507
Date: 05/06

1 / 2, Hepatitis B and C, Human T-Lymphotropic Virus I and II, Syphilis, bacteria, and fungi.

Bonus™ Demineralized Bone Matrix
Attention Operating Surgeon

DESCRIPTION

Bonus™ Demineralized Bone Matrix (Bonus™ DBM) is processed human bone that has been demineralized and combined with human collagen-derived carrier from the same donor. The final demineralized bone matrix is in a freeze-dried state. Bonus™ DBM is supplied in single use packages for single-patient use.

Bonus™ DBM contains donated human tissue procured from human cadaveric donors. The tissue has been determined eligible for transplantation by a Community Tissue Services (CTS) Medical Director after review of medical and social history, hospital records, infectious disease screening, autopsy report (if performed), and physical exam. Donors are tested and found negative (acceptable) for anti-HIV 1 / 2, HBsAg, anti-HBc, anti HCV, anti-HTLV 1 / II, syphilis, HCV RNA NAT, and HIV RNA NAT. Donors are also tested for CMV and can have a negative or positive result. Either result is acceptable. U.S. Food and Drug Administration (FDA) licensed test kits are used when available for a specific test. Communicable disease testing has been performed by a laboratory certified under CLIA or equivalent requirements.

Before demineralization, the tissue has been processed with Allowash®, a patented bone and soft tissue cleaning technology under license from LifeNet.

Bonus™ DBM is processed and prepared via a proprietary process at Community Tissue Services, Dayton, Ohio.

INDICATIONS FOR USE

Bonus™ DBM can be used to fill bony voids or gaps that have been surgically created or for filling osseous defects in non-weight bearing applications.

Bonus™ DBM may be used with orthopedic, spinal, reconstructive, craniofacial, maxillofacial and periodontal bone grafting procedures. It can be used alone or in combination with autologous bone, or other forms of allogenic bone in grafting procedures of non-weight bearing value. It can be used or hydrated with autologous blood, bone marrow aspirate or autologous blood derived products such as platelet rich plasma and platelet poor plasma. It may also be hydrated with saline or antibiotic solution.

Patient selection factors to be considered should include: 1. the ability and willingness of the patient to follow instructions; 2. control of weight and activity levels; 3. a good nutritional state.

CONTRAINDICATIONS

Infection at the surgical site and/or distant foci of infections that may spread to the surgical site is a contraindication for Bonus™ DBM.

RELATIVE CONTRAINDICATIONS

1. Uncooperative patient, or patient with neurologic disorders who is incapable of following directions, including weight control and activity levels.
2. Pregnancy.
3. Disorders or diseases, which may impair bone formation.

WARNINGS AND PRECAUTIONS

1. Bonus™ DBM contains donated human tissue.
2. This tissue has been processed with Bacitracin and/or Polymyxin B, HCl, alcohol, and sodium phosphate. Traces may remain.
3. Although this tissue has been tested and screened for selected human pathogens, processed under aseptic conditions, and gamma irradiated with a Cobalt 60 source at 15-25 kGy, human derived tissue may still transmit infectious agents.
4. Do not use Bonus™ DBM if package integrity has been compromised.
5. This tissue is intended for use in one patient on a single occasion only.
6. Once user breaks the container seal, the tissue must be transplanted or discarded.
7. This tissue may not be sterilized or re-sterilized.
8. Do not use for treatment of bone with compromised stability or load bearing value, or within articulating joints.
9. The surgeon is to be thoroughly familiar with Bonus™ DBM material and the surgical procedure prior to use of this tissue.
10. The patient is to be made aware of general risks associated with treatment and the possible adverse effects.

POSSIBLE ADVERSE EFFECTS

1. Complications associated with surgery such as hematoma, infection, migration, and other complications that may require additional surgery.
2. Incomplete or lack of bony ingrowth at the treatment site that may require additional surgery.
3. Immune rejection of the introduced tissue that may require additional surgery.
4. The transmission of known pathogens including Human Immunodeficiency Virus

STERILITY

This tissue has been processed under aseptic conditions. Bonus™ DBM has been irradiated in its final container with a Cobalt 60 source at 15-25 kGy.

INSTRUCTIONS FOR USE

1. Twist the elbow to seat perpendicular to the tabs of the 1 cc Graft Preparation System containing Bonus™ DBM. Ensure that the elbow attachment is well seated in the 1 cc syringe with Bonus™. If not, push on elbow to seat.
2. Ensure that the yellow cap on the Graft Preparation System containing Bonus™ DBM is tightly seated.
3. Attach the hydrating fluid of choice by twisting the syringe on to the Luer Lock fitting. NOTE – in all subsequent steps, the syringe with hydrating fluid must be pointing down.
4. Pull on the syringe plunger containing the hydrating fluid until fully extended. This will create a vacuum necessary for complete hydration.
5. Release plunger to allow the hydrating fluid to infiltrate the Graft Preparation System. Wait 2 to 3 minutes before proceeding.
6. Use hydrating syringe to lever out the elbow. Attach plunger provided, remove yellow cap and expel hydrated Bonus™ DBM.

STORAGE AND SHELF LIFE

Storage temperature ranges for Bonus™ DBM are between -25° C and 40° C. Ambient temperature is recommended. No refrigeration is necessary. See package label for expiration date. It is the responsibility of the Tissue Dispensing Service and/or end-user to maintain Bonus™ DBM in the appropriate storage conditions prior to transplant.

TRACKING AND TRACEABILITY

Please complete the enclosed Graft Tracking Record and return it to Biomet Biologics, Inc. Federal regulations (21 CFR.290(b)) require proper tracking of human tissue. It is the responsibility of the end-user to provide this tracking information, which enables Biomet Biologics, Inc. to maintain records for the purpose of human tissue post-transplant or any other final disposition (eg. tissue not used and discarded). Adverse outcomes potentially attributable to the tissue must be promptly reported to Biomet Biologics, Inc. Use the peel-off sticker from the label in the patient records.

Caution: Federal law (USA) restricts this tissue to sale by or on the order of a licensed physician. This tissue is intended for use by qualified health care specialists such as physicians, dentists, or podiatrists.

Community Tissue Services and Biomet Biologics, Inc. make no claims concerning the biological or biomechanical properties of the provided tissue. All tissue is recovered, processed, stored, and distributed for use in accordance with the standards of the American Association of Tissue Banks. Community Tissue Services and Biomet Biologics, Inc. disclaim all liability and responsibility for any misuse of tissue provided for clinical application.

Comments regarding this tissue can be directed to Attn: Regulatory Dept., Biomet, P.O. Box 587, Warsaw, IN 46581 USA Fax: 574-372-1683. Patent No. 6,576,249 and other pending patents.

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INSTRUCTIONS FOR USE

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2. By holding the Graft Preparation System at the valve, twist off the 30 cc vacuum syringe and attach a dispensing unit containing the liquid hydrating component of surgeon's choice onto the valve of the Graft Preparation System with Bonus™ DBM. Ensure a minimum of 6cc of fluid in syringe before attaching.
3. Appropriate amount of the liquid component will be dispensed into the Freeze Dried Putty automatically. Detach dispensing unit with the remaining liquid component. Let this mixture hydrate for at least 5 minutes before removing from chamber.
4. Remove the cap from the end of the Graft Preparation System and use the plunger to extract the graft.

STORAGE AND SHELF LIFE

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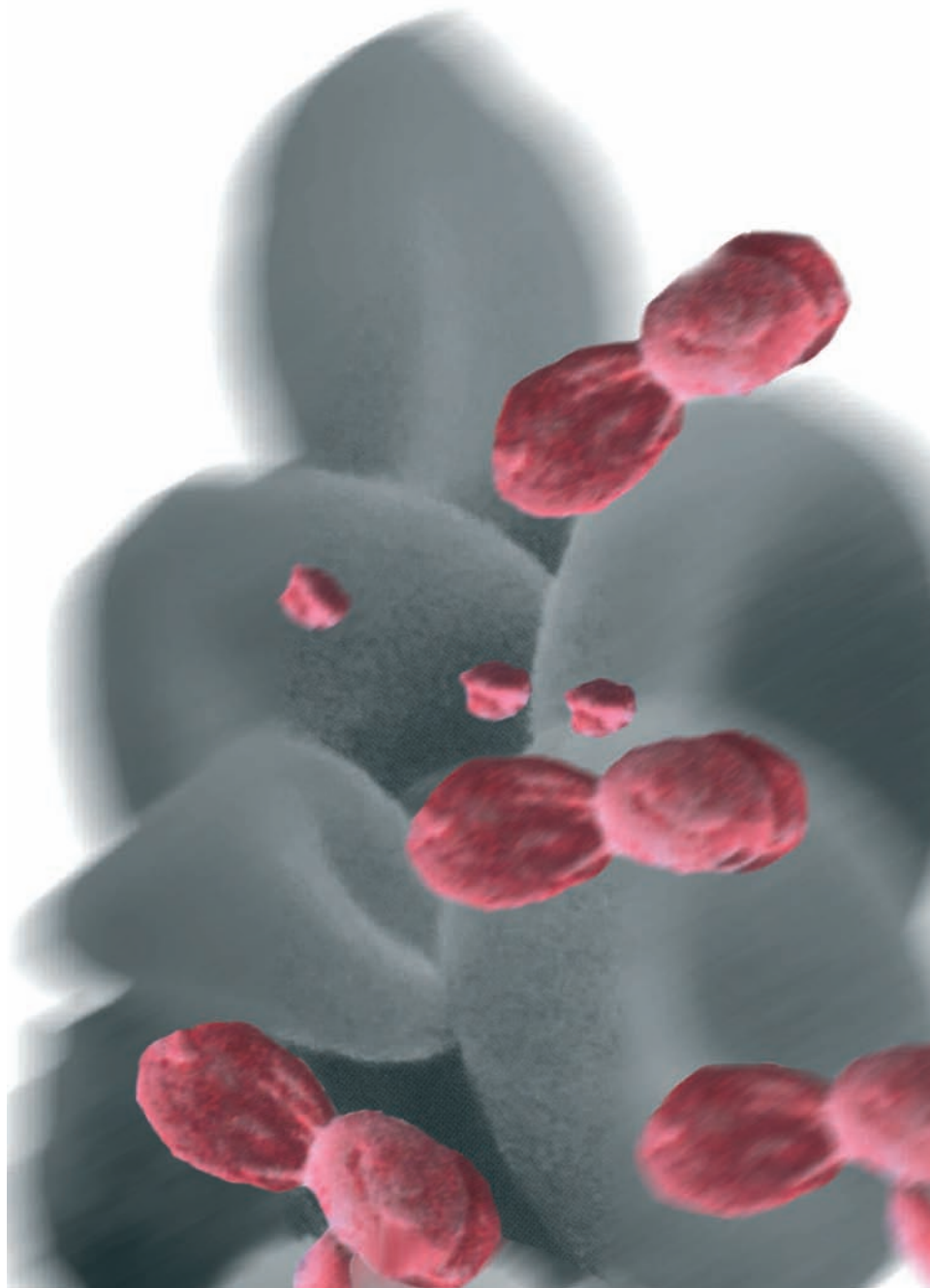
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