



Bonus® II

Demineralized Bone Matrix

Customized to the patient's specific needs

BIOMET®
BIOLOGICS

Bonus® II Demineralized Bone Matrix

Introduction

Bone grafting during surgery is not an assembly line. Bonus® II DBM was designed to maximize surgeon flexibility by allowing them to choose from a variety of hydration and handling options.

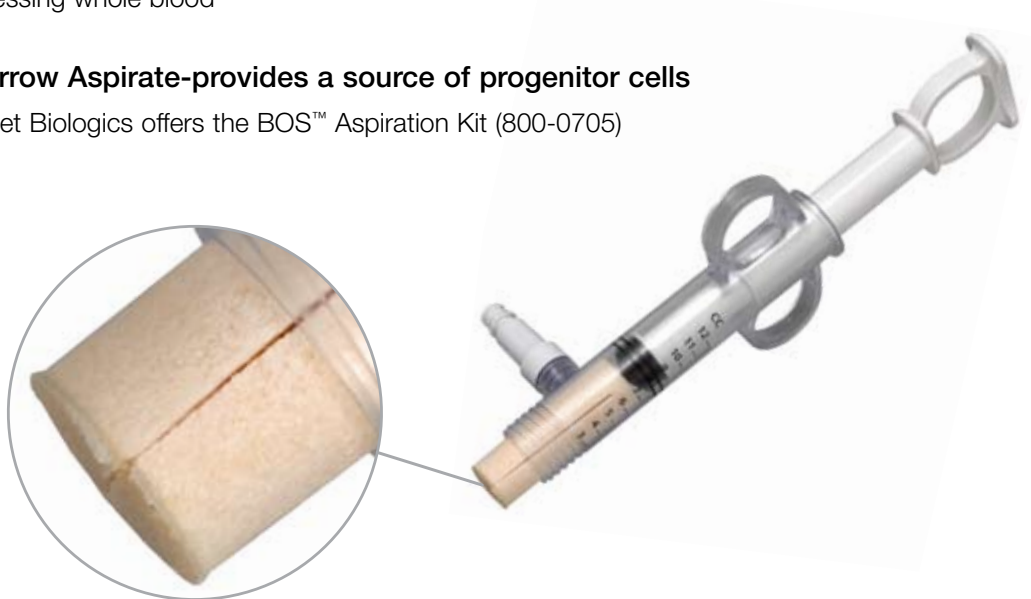
Hydration Options Offered by Biomet Biologics

Platelet Rich Plasma-provides a concentration of autologous platelets and white blood cells

- Biomet Biologics offers the GPS® III Platelet Concentration System (standard-800-1003A, mini-800-0505A) for processing whole blood

Bone Marrow Aspirate-provides a source of progenitor cells

- Biomet Biologics offers the BOS™ Aspiration Kit (800-0705)



Handling Characteristics

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

Bonus® II Demineralized Bone Matrix

Step One

Attach the 30cc vacuum syringe to the valve fitting on the side of the Graft Preparation System containing Bonus® II DBM. Pull on the vacuum syringe plunger until fully out — twist plunger to engage the locking mechanism.



Step Two

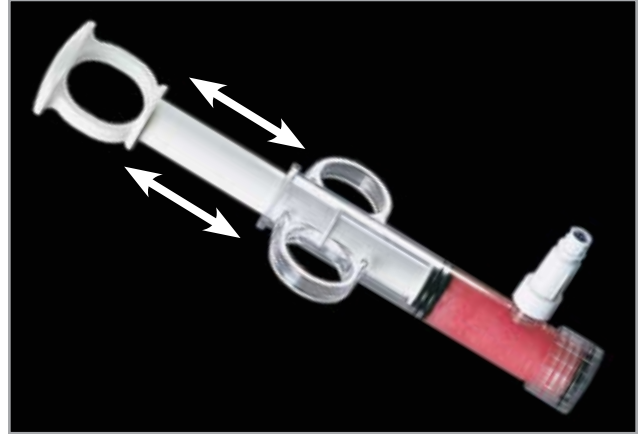
Twist off the 30cc vacuum syringe. Attach a dispensing unit containing the liquid component onto the valve of the Graft Preparation System with Bonus® II DBM. Pushing in additional fluid will cause a more flowable material.



Bonus® II Demineralized Bone Matrix

Step Three

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



Step Four

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.



Bonus® II Demineralized Bone Matrix

Bonus® II DBM vs. Traditional DBM—Innovation of Choice

Bonus® II DBM has all the advantages of a traditional DBM product. In addition, Bonus® II DBM provides an array of graft options by allowing the surgeon to customize the hydration liquid and graft handling properties.

Cells

- Traditional DBM-Encourages cell migration and differentiation from surrounding tissues and blood
- Bonus® II DBM-When hydrated with bone marrow aspirate, the graft will be infused with progenitor cells

Matrix




- Traditional DBM-Provides an osteoconductive scaffold to promote bone formation
- Bonus® II DBM-Porous scaffold allows for infiltration of cells and platelets

Delivery Options

- Traditional DBM-delivery options are limited by the pre-packaged handling properties of the DBM
- Bonus® II DBM-various delivery options are available because the handling properties can be customized by the amount of hydration fluid used



Ordering Information

	Description	Catalog Number
	5cc Bonus® II DBM	48-DBM5
	10cc Bonus® II DBM	48-DBM10
	CDO™ System	800-0526

References

1. Huston Davis Adkisson, Jena Straus-Schoenberger, Mary Gillis, Ross Wilkins, Marc Jackson, and Keith A. Hruska, "Rapid Quantitative Bioassay of Osteoinduction," *Journal of Orthopaedic Research Society*.
2. Barry L. Eppley, M.D., D.M.D., Jennifer E. Woodell, Ph.D., and Joel Higgins, "B.S. Platelet Quantification and Growth Factor Analysis From Platelet-Rich Plasma (PRP)," Implications for Wound Healing.

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01-50-2514
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Bonus™ II Demineralized Bone Matrix
ATTENTION OPERATING SURGEON

DESCRIPTION

Bonus™ II Demineralized Bone Matrix (Bonus™ II 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™ II DBM is supplied in single-use packages for single-patient use.

MATERIALS

Bonus II DBM: Donated human tissue procured from human cadaveric donors.

Bonus™ II DBM contains donated human tissue procured from human cadaveric donors. The tissue has been determined eligible for transplantation by a qualified tissue bank 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 I / II, syphilis, HCV NAT, and HIV NAT. 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™ II DBM is processed and prepared via a proprietary process at Interpore Cross International, Irvine CA.

Single-use Package:

Body	Acrylic copolymer
Cap	Acrylic copolymer
Plunger	Polycarbonate
Plunger Tip	Synthetic Isoprene
Gasket	Platinum cured silicone
Check Valve	Polycarbonate/Silicone

INDICATIONS FOR USE

Bonus™ II 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™ II 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 allogeneic 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.

CONTRAINDICATIONS

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

RELATIVE CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

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; and /or 3) a good nutritional state.

1. Bonus™ II 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™ II 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™ II 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.
11. The product must not be used if the expiration date shown on the package label has passed.
12. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

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

STERILITY

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

INSTRUCTIONS FOR USE



Figure 1



Figure 2



Figure 3



Figure 4

1. Attach the 30cc vacuum syringe to the valve fitting on the side of the Graft Preparation System containing Bonus™ II DBM and pull on the vacuum syringe plunger until fully out – twist plunger to engage the locking mechanism (Figure 1).
2. Holding the Graft Preparation System at the valve, twist off the 30cc vacuum syringe. Attach a dispensing unit containing the liquid hydrating component of surgeon's choice onto the valve of the Graft Preparation System with Bonus™ II DBM (Figure 2). Ensure a minimum ratio of 0.6ml fluid to 1cc DBM prior to attaching syringe to Graft Preparation System.
3. The appropriate amount of the liquid component will be dispensed into the Bonus™ II DBM automatically. Detach dispensing syringe. Piston the plunger of the Bonus™ II DBM unit for 10 seconds. This assists with hydration. Let the mixture hydrate for 5 minutes before removing from the chamber (Figure 3).
4. Remove the cap from the end of the Graft Preparation System and use the plunger to extract the hydrated DBM (Figure 4). The supplemental nozzle can be used to extract the DBM in a fine bead.

STORAGE AND SHELF LIFE

Storage temperature ranges for Bonus™ II 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™ II DBM in the appropriate storage conditions prior to transplant.

TRACKING AND TRACEABILITY

Please complete the enclosed Graft Tracking Record and return it to Interpore Cross International, following the directions provided on the Graft Tracking Record. 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 to maintain records for the purpose of human tissue post-transplant or any other final disposition (e.g., tissue not used and discarded). Adverse outcomes potentially attributable to the tissue must be promptly reported to Biomet Biologics. Use the peel-off sticker from the label in the patient records.

Caution: Federal law (USA) restricts this tissue to sale, distribution, or use 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.

Biomet Biologics and Interpore Cross International 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. Biomet Biologics and Interpore Cross International 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: 574-372-3968. Patent No. 6,576,249 and other pending patents.

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