



Precautionary Statement (01-50-2507)

Biomet Biologics, Inc. 01-50-2507

P.O. Box 587 Date: 05/06

56 East Bell Drive

Warsaw, IN 46581 USA

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 I / 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 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™ 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 (Figure 1).
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 onto the Luer Lock fitting. **NOTE** – in all subsequent steps, the syringe with hydrating fluid must be pointing down as illustrated in Figure 2.
4. Pull on the syringe plunger containing the hydrating fluid until fully extended. This will create a vacuum necessary for complete hydration (Figure 3).

5. Release plunger to allow the hydrating fluid to infiltrate the Graft Preparation System. Wait 2 to 3 minutes before proceeding (Figure 4).
6. Use hydrating syringe to lever out the elbow. Attach plunger provided, remove yellow cap and expel hydrated Bonus™ DBM (Figure 5).

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.



Figure 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 within the 1 cc syringe. If not, push on elbow to seat.



Figure 2. 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 as illustrated.



Figure 3. Pull on the syringe plunger containing the hydrating fluid until fully extended. This will create a vacuum necessary for complete hydration.



Figure 4. Release plunger to allow the hydrating fluid to infiltrate the Graft Preparation System. Wait 2 to 3 minutes before proceeding.



Figure 5. Use hydrating syringe to lever out the elbow. Attach plunger provided, remove yellow cap and expel hydrated Bonus™ DBM.