Biomet Biologics
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01-50-2514
Revision C
Date: 2016-02

READ BEFORE USING

DONATED HUMAN TISSUE: The tissue was recovered from deceased donor in which the authorized person has given permission for the bone to be donated. Recovery was performed using aseptic procedures. Processing and packaging were performed using aseptic techniques in controlled clean room environments.

Bonus® II Demineralized Bone Matrix

ATTENTION OPERATING SURGEON

Not For Sale In The U.S.A.

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.

Before demineralization, the tissue has been processed with Allowash®, a proprietary bone and soft tissue cleaning technology.

Bonus II DBM is processed and prepared via a proprietary process at Interpore Cross International, LLC, Irvine, CA USA, a Zimmer Biomet company.

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 17.5-25 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.

Extensive medical screening procedures have been used in the selection of all tissue donors for LifeLink Tissue Bank (please see Donor Selection, Screening and Testing). Despite the extensive tissue donor selection and qualification process used in providing this tissue graft, transmission of infectious diseases through use of this tissue graft may still be possible.

POSSIBLE ADVERSE EFFECTS

Potential adverse effects that may result from placement of Bonus II DBM include, but are not limited to the following:

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.

SUMMARY OF RECORDS

The completed donor chart for the enclosed tissue (including but not limited to, serology results, recovery culture results, medical and social history evaluation and plasmadilution calculation that was conducted by or contract tested by and for the tissue provider) has been approved for transplantation by the Medical Director of the tissue provider (LifeLink Tissue Bank, Tampa, FL).

Donor Selection, Screening and Testing:

1. Prior to donation, the donor's medical/social history was screened for medical conditions or disease processes that would contraindicate the donation of tissues. The tissue provider's policies and procedures for donor screening, serologic and microbiologic testing meet current standards established by the AATB and regulations by the FDA. Contraindications for tissue donation include, but are not limited to, the following: presence of infectious disease, malignant disease, neurological degenerative diseases, disease of unknown etiology, and exposure to toxic substances. The donor's medical/social history was

also screened for HIV high risk factors in accordance with current United States Public Health Services Recommendations for the Prevention of HIV Transmission through Tissue and Organ Donation.

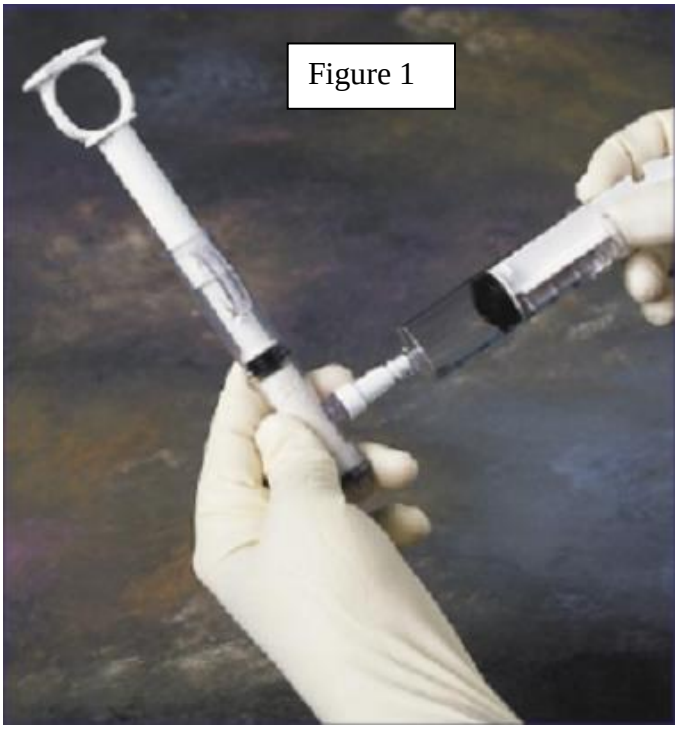
2. Testing of donor blood and tissue samples began at the site of recovery and continued throughout processing. Donor blood samples were tested using U.S. Food and Drug Administration (FDA) licensed test kits when available for a specific test and found negative (acceptable) for the following:
   a. Hepatitis B surface antigen (HBsAg)
   b. Hepatitis B core antibody (anti-HBc)
   c. Hepatitis C antibody (anti-HCV)
   d. Human immunodeficiency virus Type 1 and Type 2 antibodies (anti-HIV-1 and anti-HIV-2)
   e. Human T-lymphotropic virus Type 1 and Type 2 antibodies (anti-HTLV-1 and anti-HTLV-2)
   f. Syphilis
   g. Nucleic Acid Testing (NAT) for HIV-1
   h. NAT for HCV
   i. NAT for HBV
3. The individual tissues collected at recovery were subject to microbiological testing and determined to be free of specific aerobic/ anaerobic microorganisms and fungal contaminants whose presence would preclude the tissue from transplantation.
4. Communicable disease testing was performed on a qualified blood sample by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

STERILITY

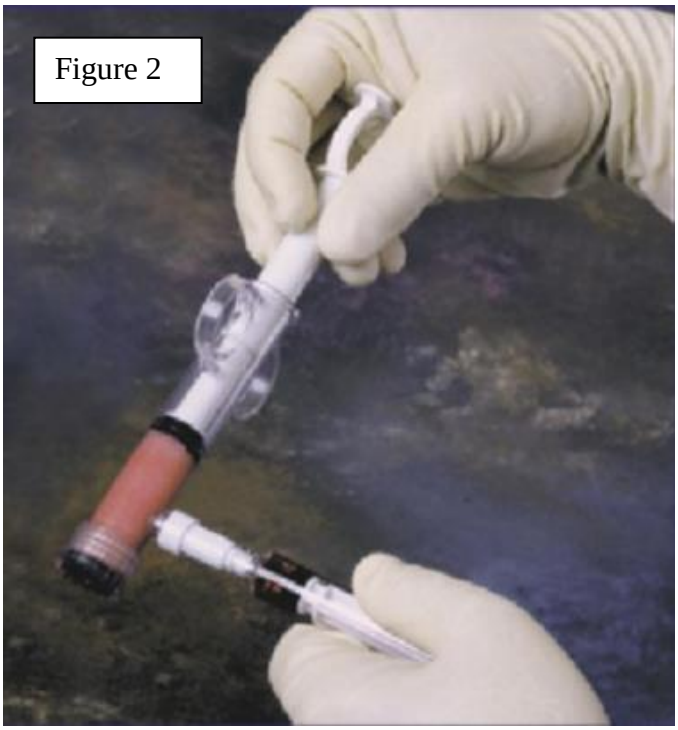
This tissue has been processed under aseptic conditions. Bonus II DBM has been irradiated in its final container with a Cobalt 60 source at 17.5-25 kGy. Single Use Only. Do Not Reuse. Do not use any component from an opened or damaged package.

INSTRUCTIONS FOR USE

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).

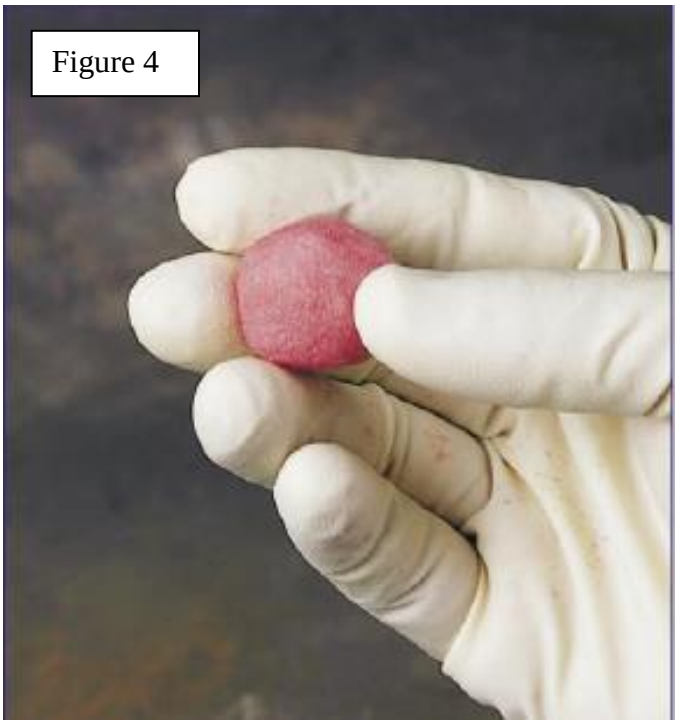


2. Holding the Graft Preparation System at the valve, twist off the 30cc vacuum syringe. Attach a dispensing unit containing the liquid hydrating component of surgeon's choice onto the valve of the Graft Preparation System with Bonus II DBM (Figure 2). Ensure a minimum ratio of 0.6ml fluid to 1cc DBM 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
Bonus II DBM products are to be stored in a clean, dry place at ambient temperature. 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.

PRODUCTION
Tissue Processing Procedures:
Bonus II DBM products are produced by a validated production process at Interpore Cross International, LLC, a Zimmer Biomet Company (Irvine, CA), a facility accredited by the American Association of Tissue Banks (AATB).

TRACKING AND TRACEABILITY
Patient Records
The clinic or hospital is responsible for maintaining recipient records for the purpose of tracing allograft tissue post-implantation. Ensure that the following information is recorded in the patient's medical record and the hospital implant records (1-5 are required and 6-10 are suggested):

1. Description of Tissue
2. Donor Identification Number
3. Product Code
4. Date and Time of Procedure
5. Surgeon Name
6. Expiration Date
7. Quantity Implanted
8. Antibiotics Used
9. Description of Procedure
10. Any Other Pertinent Information

As a convenience, a Graft Tracking Record has been included to be completed at the time of the surgical procedure.

Please complete the enclosed Graft Tracking Record and return it to Interpore Cross International, following the directions provided on the Graft Tracking Record. Use the peel-off sticker from the label in the patient records. Federal regulations (21 CFR 1271.290 (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. In the European Union (EU), reporting of serious adverse reactions and/or events shall be in accordance with articles 5 and 6 of 2006/86/EC (2006/86/EC, annex II.E.) to the Tissue Establishment indicated on the package label. Bonus II DBM distributed in the EU complies with the European Directive 2004/23/EC. Use the peel-off sticker from the label in the patient records.

CAUTION: These devices are only approved for distribution outside the United States. 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, Inc. P.O. Box 587, Warsaw, IN 46581 USA Fax: 574-372-3968

Provided By
Tissue provided by LifeLink Tissue Bank, a non-profit, non-governmental network of eye and tissue banks. LifeLink Tissue Bank is accredited by the American Association of Tissue Banks (AATB).

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

Symbol Legend

	Manufacturer
	Date of manufacture
	Do not reuse
	Do not resterilize
	Caution, see instructions for use
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterile
	Sterilized using aseptic processing techniques
	Sterilized using steam or dry heat
	Use by date
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician

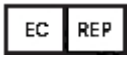
Do not use if package is damaged (Pack Damaged)

WEEE device

Catalogue number

Batch code

Flammable



Authorized representative in the European Community