

Biomet Biologics
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LD49-1000

Revision B

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READ BEFORE USING

The tissue was recovered from deceased donor whose legal next-of-kin 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 CC Matrix

ATTENTION OPERATING SURGEON

DESCRIPTION

Bonus CC Matrix is processed human cortical bone that has been ground and demineralized (DBM, demineralized bone matrix) and combined with mineralized ground cancellous bone from the same donor. Bonus CC Matrix is supplied in single-use packages for single-patient use.

MATERIALS

Bonus CC Matrix 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 patented bone and soft tissue cleaning technology.

Single-use Package:

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

INDICATIONS

Bonus CC Matrix 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 CC Matrix 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 CC Matrix.

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 CC Matrix 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 and processed under aseptic conditions, human-derived tissue may still transmit infectious agents.
4. Do not use Bonus CC Matrix 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 CC Matrix 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.

STORAGE AND SHELF LIFE

Bonus CC Matrix 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 CC Matrix in the appropriate storage conditions prior to transplant.

PRODUCTION

Tissue Processing Procedures:

Bonus CC Matrix products are produced by a validated production process. Tissue processing is completed in a facility accredited by the American Association of Tissue Banks (AATB).

Summary of Donor 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 hemodilution calculation that was conducted by or contract tested by and for the tissue provider) has been approved for transplantation by the tissue provider's Medical Director.

Donor 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. 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 taken at the time of recovery 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 (RPR or FTA)
 - g. Nucleic Acid Testing (NAT) for HIV-1
 - h. NAT for HCV
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. The above tests were performed by laboratories certified under the Clinical Laboratories Improvement Amendments of 1988 (CLIA) or equivalent requirements.

INSTRUCTIONS FOR USE

1. Attach the 30cc vacuum syringe to the valve fitting on the side of the graft syringe containing Bonus CC Matrix and pull on the vacuum syringe plunger until fully out – twist plunger to engage the locking mechanism.
2. Holding the graft syringe 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 syringe with Bonus CC Matrix. Ensure a minimum ratio of 0.6ml fluid to 1cc Bonus CC Matrix prior to attaching syringe to graft syringe..
3. The appropriate amount of the liquid component will be dispensed into the Bonus CC Matrix automatically. Detach dispensing syringe. Piston the plunger of the graft syringe with Bonus CC Matrix for 10 seconds. This assists with hydration.
4. Remove the cap from the end of the graft syringe and push in the plunger to extract the hydrated graft.

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 (1-3 are required and 4-10 are suggested):

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

As a convenience, a Graft Tracing Record has been included to be completed at the time of the surgical procedure. Please complete the enclosed Graft Tracing Record and return it to Biomet Interpore Cross, following the directions provided on the Graft Tracing Record. Use the peel-off sticker from the label in the patient records. A completed original is to be retained in the patient record and the copy sent back to Biomet Interpore Cross, as indicated on the enclosed Graft Tracing Record. If the entire tissue product was discarded, return the Graft Tracing Record and explain the reason for discard. Once completed, return the bottom copy of the form using the self-mailer to Biomet Interpore Cross for our permanent records. File the top copy in the patient chart.

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/EU (2006/86/EU, annex I.I.E.) to

the Tissue Establishment indicated on the package label. Bonus CC distributed in the EU complies with the European Directive 2004/23/EC.

STERILITY

This tissue has been processed under aseptic conditions. Do not sterilize. Single Use Only. Do Not Reuse. Do not use any component from an opened or damaged package.

Biomet Biologics and Biomet Interpore Cross 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 Biomet Interpore Cross disclaim all liability and responsibility for any misuse of tissue provided for clinical application.

Caution: Federal law (USA) restricts this device to sale, distribution, or use by or on the order of a licensed physician.

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., 56 East Bell Drive, P.O. Box 587, Warsaw, Indiana 46581-0587 USA, Fax: 574-372-3968.

Bonus CC Matrix and all other trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

Allowash® is a registered trademark of LifeNet.

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
	Caution, Consult accompanying Documents
	Sterilized using Ethylene Oxide
	Sterilized using Irradiation
	Sterile
	Sterilized using Aseptic Processing Techniques
	Sterilized using Steam or Dry Heat
	Use By
	WEEE Device
	Catalogue Number
	Batch Code
Rx Only	CAUTION: Federal (USA) restricts this device to sale by or on the order of a licensed physician.
	Flammable
	Authorized Representative in the European Community