

THE CDO™ SYSTEM

CURVED DELIVERY OPTION



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The delivery of bone graft to hard-to-reach sites can pose a challenge to surgeons. Accessing those sites can result in undesired damage to adjacent hard and soft tissue. The CDO™ System is designed to deliver viscous bone grafting materials in a minimally invasive fashion.



THE CDO™ SYSTEM

A sterile, single-use system designed to access and address challenging bone grafting sites

- A curved, malleable delivery cannula that allows for easy access to hard-to-reach anatomy
- Facilitates graft material delivery through small diameter spaces
- Ensures an effective delivery of a viscous bone grafting material to a precise orthopedic surgical site
- Can be used for revision hip and total knee arthroplasty, ACL repair, core decompression and spinal procedures
- Ideal delivery system for Bonus® Demineralized Bone Matrix (DBM), autograft, allograft and synthetic bone graft material



BONUS® DBM

- Is 100 percent freeze dried DBM, no artificial carrier is added to the product
- Surgeons can hydrate Bonus® DBM with a media of their choice. Hydration options include whole blood, platelet-rich plasma, bone marrow aspirate, and antibiotics
- Adapter tip in CDO™ System can be used with 5 and 10cc sizes of Bonus® DBM

THE CDO™ SYSTEM WITH BONUS® DBM IN A REVISION HIP ARTHROPLASTY



1. Attach the 30ml 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 the vacuum syringe plunger until it is fully extended, and then twist plunger to engage the locking mechanism.



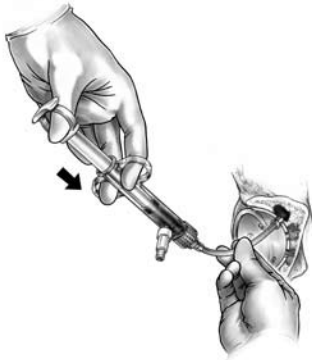
2. Holding the Graft Preparation System at the valve, twist off the 30ml vacuum syringe. Attach a syringe containing the surgeon's choice of hydration fluid onto the valve of the Graft Preparation System with Bonus® DBM. Bonus® DBM should be hydrated at a 0.6ml liquid to 1ml graft ratio for optimal handling in the CDO™ System.



3. Detach the hydration syringe and gently piston the plunger for 10 seconds. This assists with hydration. Allow to hydrate for approximately 5 minutes prior to use.

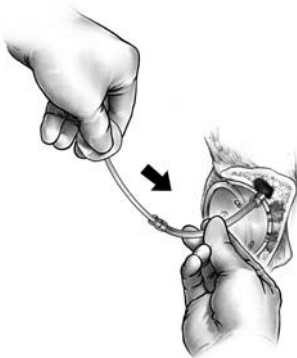


4. Attach the optional luer lock connector to Graft Preparation System and attach to the proximal end of the curved cannula.



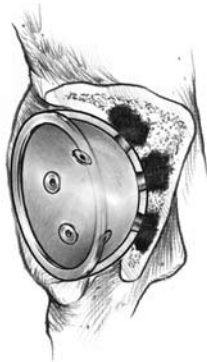
5. After preparation of defect with appropriate debridement, position curved cannula into the orthopedic surgical site.

6. Using thumb pressure, push hydrated Bonus® DBM through the curved cannula.



7. Remove optional luer lock connector and Graft Preparation System, leaving curved cannula in place.

8. Use the flexible plunger to advance any remaining material through the cannula, into the orthopedic surgical site.



9. Remove curved cannula.

ORDERING INFORMATION

DESCRIPTION	CATALOGUE NUMBER
CDO™ (Curved Delivery Option) System	800-0526
5cc Bonus® DBM	48-DBM1
10cc Bonus® DBM	48-DBM2

Figure 1

Curved Delivery Option (CDO™) System

ATTENTION OPERATING SURGEON

NOTE: FOR SINGLE USE ONLY. Discard the entire disposable system after use by an acceptable method for devices potentially contaminated with blood products.

DESCRIPTION

The CDO™ System consists of:

- A modified syringe used to pre-mix/hydrate bone graft material,
- A curved delivery cannula used for delivery of the hydrated bone graft material to an orthopedic surgical site,
- A flexible plunger to advance any hydrated bone graft material remaining in the cannula into the surgical site, and
- A syringe adapter tip used to connect an optional graft preparation syringe (P/N 800-0350, packaged separately) to the curved delivery cannula.

See Figure 1 for labeled diagram of the CDO™ System

MATERIALS

Cannula	Stainless steel and anodized aluminum
Plunger	Ultra high molecular weight polyethylene
Syringe	Polycarbonate, ABS, and silicone (non-latex)
Adapter Tip	Acrylic co-polymer

All components in this system are latex-free.

INDICATIONS

The CDO™ system is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft material with I.V. fluids, blood, plasma concentrate, platelet-rich plasma, bone marrow or other specified blood components deemed necessary by the clinical use requirements.

WARNINGS AND PRECAUTIONS

1. Single-use device. Do not reuse.
2. Do not use sterile components of this system if package is opened or damaged.
3. The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
4. The patient is to be made aware of the general risks associated with the treatment and possible adverse effects.

POSSIBLE ADVERSE EFFECTS

1. Delayed wound healing and/or infection.
2. Temporary or permanent nerve damage that may result in pain or numbness.
3. Early or late postoperative infection.

STERILITY

The CDO™ System is sterilized by exposure to a minimum dose of 25 kGy gamma radiation. Do not re-sterilize. Do not use past expiration date.

INSTRUCTIONS FOR USE

NOTE 1: Use standard aseptic technique throughout the following procedures.

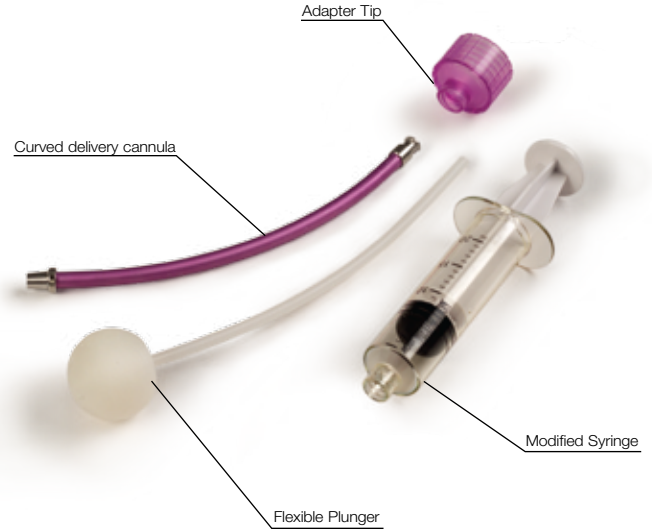
NOTE 2: Steps 1-3 are for use with the modified, large-bore syringe included in this system. When using P/N 800-0350 (packaged separately), follow the package insert included with that product for hydration instructions.

1. **HYDRATE:** Place bone graft material in a sterile bowl. Apply doctor's choice of hydrating liquid at a minimum ratio of 0.6ml liquid to 1ml bone graft material, and mix thoroughly.
2. **FILL:** Remove plunger from modified syringe, and fill syringe with hydrated bone graft material.
3. **PISTON** the syringe 10 times to assist in hydrating the bone graft material.
4. **CONNECT** the proximal end of the curved delivery cannula to either the luer lock on the modified syringe used in steps 1-3, OR to the luer lock on the syringe adapter tip, attached to the optional graft preparation syringe (P/N 800-0350, packaged separately), filled with hydrated bone graft material.
5. **POSITION** the curved delivery cannula tip to the appropriate orthopedic surgical site.
6. **DELIVER** the hydrated bone graft material to the surgical site by depressing the plunger on the modified syringe OR graft preparation syringe.
7. **REMOVE** the modified syringe OR graft preparation syringe with adapter tip, leaving the curved delivery cannula in place.
8. **ADVANCE:** Use the flexible plunger to advance any remaining hydrated bone graft material through the curved delivery cannula into the orthopedic surgical site.
9. **REMOVE** the flexible plunger and curved delivery cannula from the surgical site.

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

Comments regarding this device can be directed to Attn: Regulatory Dept, Biomat, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

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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 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™ DBM is processed and prepared via a proprietary process at Interpore Cross International, Irvine CA.

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 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™ 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 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™ 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.
11. The product must not be used if the expiration date shown on the package label has passed.

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



Figure 1

1. Attach the 30cc vacuum syringe to the valve fitting on the side of the Graft Preparation System containing Bonus™ DBM and pull on the vacuum syringe plunger until fully out-twist plunger to engage the locking mechanism (Figure 1).



Figure 2

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™ DBM (Figure 2). Ensure a minimum ratio of 0.6ml fluid to 1cc DBM prior to attaching syringe to Graft Preparation System.



Figure 3

3. The appropriate amount of the liquid component will be dispensed into the Bonus™ DBM automatically. Detach dispensing syringe. Piston the plunger of the Bonus™ DBM unit for 10 seconds. This assists with hydration. Let the mixture hydrate for 5 minutes before removing from the chamber (Figure 3).



Figure 4

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™ 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 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, Inc. 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, Inc. 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, Inc. 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, Inc. 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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For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert herein and Biomet's website.



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