Biomet Biologics

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01-50-1458
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CDO™ (Curved Delivery Option) 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.
5. Device is single use only. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.

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 0.6 ml 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 t**he 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, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-3968.

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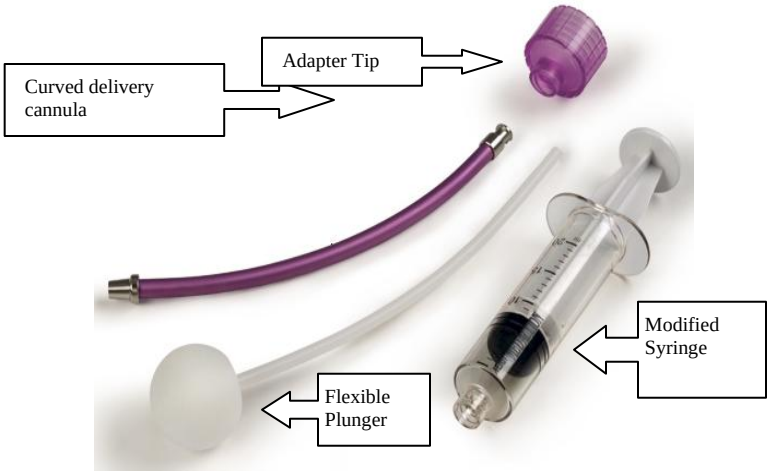

Figure 1