Biomet Biologics
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01-50-1251
Rev. B
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Graft Preparation 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 Graft Preparation System, consisting of a modified, 12ml syringe with a check valve, plunger and end cap, is used to facilitate pre-mixing of bone graft material (packaged separately) with a hydrating liquid (see Indications section for appropriate hydrating liquid specifications).

MATERIALS
The graft preparation syringe components consist of polycarbonate, ABS, silicone and acrylic co-polymer.

All components in this system are latex-free.

INDICATIONS
The Graft Preparation 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.
6. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.
7. Patient smoking may result in delayed healing, non-healing and/or compromised sterility in or around the placement site.
8. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.
9. All system components must be removed prior to closing the surgical site. Do not implant.
10. Intraoperative fracture or breaking of product components may occur if excessive force is applied. Components of this system should only be used for their intended purpose.

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 Graft Preparation System is sterilized by exposure to a minimum dose of 25 kGy gamma radiation. Do not re-sterilize. Do not use past expiration date. Do not use any component from an opened or damaged package.

INSTRUCTIONS FOR USE
NOTE: Use standard aseptic technique throughout the following procedures.

1. **TRANSFER** the graft preparation syringe to the sterile field.
2. **REMOVE** the plunger from the graft preparation syringe.
3. **FILL** the graft preparation syringe with bone graft material.
4. **PLACE** the plunger back into the syringe and compact the bone graft material.
5. **ATTACH** a syringe containing the liquid hydrating component of the surgeon's choice onto the valve of the graft preparation syringe. Ensure the hydrating syringe contains a minimum ratio of 0.6ml liquid to 1ml bone graft material.
6. **HYDRATE** the bone graft material by expressing the liquid contained in the hydrating syringe into the graft preparation syringe.
7. **DETACH** the hydrating syringe from the graft preparation syringe.
8. **PISTON** the plunger unit for 10 seconds to assist with hydration of the bone graft material.
9. **REMOVE** the cap from the end of the graft preparation syringe. An optional syringe adaptor tip which connects to the CDO System curved delivery cannula (both of which are included in P/N 800-0526, sold separately) may be attached to the graft preparation syringe.
10. **DELIVER** the hydrated bone graft material to the orthopedic surgical site per the surgeon's preference.

Caution: Federal law (USA) limits this device to sale by or on the order of a 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.

Symbol Legend

 Manufacturer

 Date of manufacture

 Do not reuse

 Caution, see instructions for use

Sterilized using ethylene oxide

Sterilized using irradiation

Sterile

Sterilized using aseptic processing techniques

Sterilized using steam or dry heat

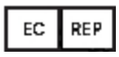
 Use by date

 WEEE device

Catalogue number

Batch code

Flammable



Authorized representative in the European Community