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01-50-1473
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Authorized Representative: Biomet U.K., Ltd.
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CE 0086

Graft Delivery Instrument

ATTENTION OPERATING SURGEON

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

DESCRIPTION
The Graft Delivery Instrument, consisting of an open bore exchange barrel with piston plunger, delivery cannula, and cannula plunger, is used to facilitate delivery of bone graft material (packaged separately) to an orthopedic site-.

MATERIALS
The graft delivery instrument component materials consist of polycarbonate, ABS, silicone and acrylic co-polymer.

All components of this instrument are latex-free.

INDICATIONS
The Graft Delivery Instrument is intended to be used for the delivery of bone graft material to an orthopedic surgical site.

WARNINGS AND PRECAUTIONS
1. Instrument is single use only. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.
2. Do not use components of this instrument 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.

STERILITY
The Graft Delivery Instrument is sterilized by exposure to a minimum dose of 25 kGy gamma radiation. Single use only. Do not re-sterilize. Do not use past expiration date.

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

1. **TRANSFER** the open bore exchange barrel, delivery cannula, and cannula plunger to the sterile field.
2. **ACTUATE** exchange barrel plunger and provide space for graft material in barrel.
3. **FILL** the open bore exchange barrel with bone graft material.
4. **ATTACH** the delivery cannula onto the open bore exchange barrel and hand tighten.
5. **DELIVER** the hydrated bone graft material to the orthopedic surgical site per the surgeon's preference.
6. **REMOVE** the open bore exchange barrel from the delivery cannula
7. **INSERT** the cannula plunger into the delivery cannula to expel remaining graft material in cannula.

Caution: Federal law (USA) limits this device to sale, distribution, or use 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
- STERILE EO — Sterilized using Ethylene Oxide
- STERILE R — Sterilized using Irradiation
- STERILE — Sterile
- STERILE A — Sterilized using Aseptic Processing Techniques
- STERILE — Sterilized using Steam or Dry Heat
- Use By
- WEEE Device
- REF — Catalogue Number
- LOT — Batch Code
- FLAMMABLE — Flammable
- EC REP — Authorized Representative in the European Community