Biomet Biologics
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Revision B
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PerFuse Hip and PerFuse Shoulder Percutaneous Decompression Instrument Disposables

ATTENTION OPERATING SURGEON

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

DESCRIPTION

PerFuse Hip

The PerFuse Hip Decompression Instrument Disposables consists of a sterile cannula, trocar rod, and plunger and are to be assembled with the PerFuse Decompression Instrument Handle. The Instrument is designed to access the femoral head for decompression in patients with necrotic lesions to deliver blood components and/or bone graft material to the site of decompression.

PerFuse Shoulder

The PerFuse Decompression Instrument Disposables consists of a sterile cannula, trocar rod, and plunger and are to be assembled with the PerFuse Decompression Instrument Handle. The Instrument is designed to access the humeral head for decompression in patients with necrotic lesions to deliver blood components and/or bone graft material to the site of decompression.

MATERIALS

The materials used for the PerFuse Hip and Shoulder Decompression Instrument Disposables consist of medical grade stainless steel that are suitable for medical use. All components in this instrument are medical grade and are latex-free.

INDICATIONS

The PerFuse Percutaneous Decompression System is intended to be used for the delivery of allograft, autograft, or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate mixing and 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.

CONTRAINDICATIONS

The PerFuse Percutaneous Decompression System should not be used for vertebroplasty or kyphoplasty procedures.

WARNINGS

- This instrument is single use only. After use, the instrument may be a potential biohazard. After use or any breach of sterile barrier, the instrument should be disposed of appropriately. Reuse of instruments labeled for single-use may result in product contamination, patient infection and/or failure of the instrument to perform as intended. Do not attempt to re-clean or re-sterilize these products.
- Do not use instruments that have been, even momentarily, placed in a different patient.
- Discard and DO NOT USE opened or damaged instruments, and use only instruments that are packaged in unopened or undamaged containers as sterility will not be maintained, otherwise.
- Correct handling of instruments is extremely important. Do not modify instruments. Do not notch or bend instruments. Notches, scratches or other damage and/or wear in the instrument occurring during surgery may contribute to breakage.
- Do not reshape or bend instruments in any way. If an instrument should become bent from its original shape, do not use, as this will affect the performance of the instrument. Bent instruments should be returned to Biomet, Inc.
- The Surgeon is to be familiar with the equipment, instruments and surgical procedure prior to performing surgery.
- Users should exercise caution when handling surgical needles to minimize the risk of inadvertent needle sticks. Discard used needles in "sharps" containers.

PRECAUTIONS

- Intraoperative fracture or breaking of instruments has been reported for general instruments.
- Instruments that have experienced extensive use or excessive force are susceptible to fracture.
- Surgical instruments should only be used for their intended purpose.
- All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.
- The patient is to be warned by his physician of all surgical risks in advance.

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 PerFuse Hip and PerFuse Shoulder Decompression Disposables are sterilized by exposure to a minimum dose of 25kGy gamma irradiation. Single Use Only. Do not resterilize or reuse. 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. Using aseptic technique, peel open packaging and remove the sterile cannula, trocar, and plunger from its sterilized package and place on the sterile field.

Instrument Assembly

2. Assemble the cannula to the handle via the quick-release connection.
3. Slide the trocar rod through the instrument handle and cannula. Ensure the trocar point protrudes from the cannula tip. If not, verify the cannula is fully seated on the handle.
4. Thread on the strike cap to lock the trocar in place. The instrument is now fully assembled.

Femoral Head Decompression

1. Under radiographic guidance, lay the instrument over the hip to determine proper entry location and trajectory.
2. Advance the trocar point through the lateral aspect of the femur by gentle mallet taps until the lateral cortical wall is penetrated.
3. Confirm proper trajectory via biplanar fluoroscopy. Continue advancement of Instrument with gentle mallet taps until the trocar tip is within the necrotic tissue region.
4. Release Instrument Handle from Cannula and remove trocar from cannula.
5. The cannula may be used to deliver blood components and/or graft material to the decompression site and core track.

Humeral Head Decompression

1. Under radiographic guidance, lay the instrument over the shoulder to determine proper entry location and trajectory.
2. Advance the trocar point through the lateral aspect of the humerus by gentle mallet taps until the lateral cortical wall is penetrated.
3. Confirm proper trajectory via biplanar fluoroscopy. Continue advancement of Instrument with gentle mallet taps until the trocar tip is within the necrotic tissue region.
4. Release Instrument Handle from Cannula and remove trocar from cannula.
5. The cannula may be used to deliver blood components and/or graft material to the decompression site and core track.

Bone Graft Delivery

1. 1. Place graft material in a sterile mixing bowl on the sterile field. Apply doctor's choice of hydrating liquid at minimum ratio of 3ml liquid to 1ml bone graft material. **Note**: The cannula bore diameter is 3.9mm.
2. Thoroughly mix the liquid and graft material until a uniform mixture is obtained.
3. Draw the hydrated bone graft into a luer-lock syringe.
4. Attach the syringe to the PerFuse cannula and deliver the graft material to the decompression site and core track.
5. Use the plunger to advance any remaining liquid and/or graft material from the cannula bore to the decompression site.
6. Remove cannula from the surgical site by attaching the Slide Hammer Adapter and Slide Hammer to the cannula to carefully retract the cannula from the surgical site. **Note:** When the Slide Hammer is attached to the Slide Hammer Adapter, ensure the bell end of the Hammer faces away from the Slide Hammer Adapter to prevent interference with the adapter.

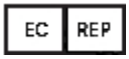
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

EC REP Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend
CF31 3XA UK

CE 0086

Symbol Legend
 Manufacturer
 Date of manufacture
 Do not reuse
 Do not resterilize
 Caution, see instructions for use
 Sterilized using ethylene oxide
 Sterilized using irradiation
 Sterile
 Sterilized using aseptic processing techniques
 Sterilized using steam or dry heat
 Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
 Do not use if package is damaged (Pack Damaged)
 Use by date
 WEEE device
 Catalogue number
 Batch code
 Flammable
 Authorized representative in the European Community