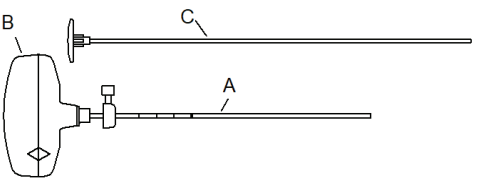
# PRESTON™

Bone Filler

## INSTRUCTIONS FOR USE




**PRODUCT DESCRIPTION**

The Preston™ Bone Filler is designed for vertebroplasty cement delivery when used with the Preston™ Transpedicular Introducer (supplied separately, see Table #2). Each unit has the following contents. For specific sizes, see Table #1.

| | |
|---|---|
| **A** | 2 x Filler |
| **B** | 2 x Handle (with Stiffener) |
| **C** | 2 x Pusher |

**INDICATIONS**

Cement delivery for vertebroplasty.

**PRECAUTIONS**

The device must only be used by a physician trained to carry out biopsies or radiology interventions, or under his/her supervision. The device is supplied in a sterile state and should be considered as such unless the packaging has been opened or is damaged. Do not use if the packaging is damaged. When using equipment from other suppliers, check that their length and diameter are compatible with the components of the device. When in use, only apply pressure with your fingers and ensure that you do not apply excessive axial pressure or bend the elements. After use, this product may pose a potential biological risk. All products of this type must be handled and destroyed in accordance with accepted medical practices, legislation and applicable provisions.

**STORAGE**

Store in a cool, dry place (below 26° C), away from humidity and direct heat. Do not use after the expiry date.

**REUSE PRECAUTION STATEMENT**

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

**CONTRAINDICATIONS**

Contraindicated for use on patients who are receiving heavy anticoagulant therapy or who have a severe bleeding problem. Prior to procedure, patient's medical records should be carefully checked for any history of hemorrhagic activity.

**DIRECTIONS FOR USE**

The following is a suggested method for using the device. The procedure should be accurately planned and executed using diagnostic imaging and clinically approved techniques. The Preston Bone Filler should be used in conjunction with the corresponding size Preston Transpedicular Introducer (supplied separately, see Table #2). Follow the instructions for use for to achieve access with the Cutting Cannula of the Transpedicular Introducer, ready for vertebroplasty cement delivery.

**FIG. 1** Adjust the depth gauge on the Filler (A) to the appropriate centimeter marker and tighten to provide a visual guide.
**Note**: The selected centimeter marker (see Fig. 1) will represent the Filler (A) protrusion beyond the corresponding Cutting Cannula (Preston Transpedicular Introducer).

Fill a syringe with cement of choice (not supplied, using manufacturer's directions to achieve desired viscosity), attach to the luer end of Filler (A), and fill with cement.

**FIG. 2** Insert the Filler (A) into the positioned Cutting Cannula (Preston Transpedicular Introducer) until the depth gauge on the Filler (A) comes into contact with the luer end of the Cutting Cannula.
**Note**: The syringe may be kept on the Filler (A) to avoid cement leaking prematurely.

**FIG. 3** With the syringe removed, insert the Handle (B) into the Filler (A) and carefully push until it meets the luer end of the Filler (A), whilst monitoring cement flow under imaging.
**Note**: At this point, approximately half of the Filler (A) volume of cement has been delivered (see Table #1).

**FIG. 4** Withdraw the Handle (B) and insert the Pusher (C). Carefully push the Pusher (C) whilst monitoring cement flow under imaging, until it meets the luer end of the Filler (A) to deliver the complete Filler (A) volume of cement (see Table #1).
**Note**: If it is necessary to deliver more cement, the Filler and Pusher (A+C) can be withdrawn and the process can be repeated from Fig. 1 using a new Preston Bone Filler.

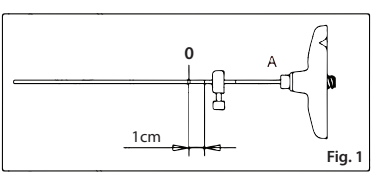


Fig. 1

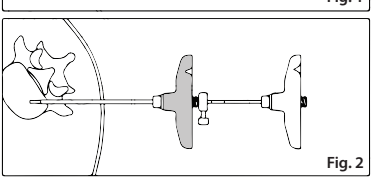


Fig. 2

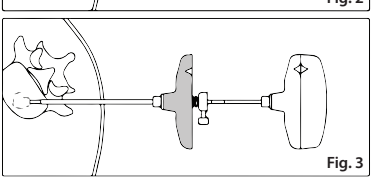


Fig. 3

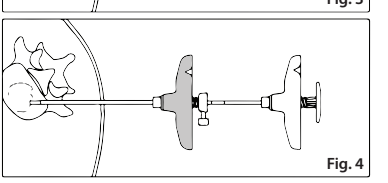


Fig. 4

| #1 | CR1320 | CR1020 |
|---|---|---|
| **A** | 13G x 20cm (Volume 0.57ml) | 10G x 20cm (Volume 1.49ml) |
| **C** | Ø1.8mm x 23.3cm | Ø2.8mm x 23.3cm |

| # 2 | CR1320 | CR1020 |
|---|---|---|
| | TV1110 | TV813 |

| | |
|---|---|
|  | Single use |
|  | Do not resterilize |
|  | Caution: consult accompanying documents |
| STERILE EO | Sterilized using ethylene oxide |
|  | Do not use if package is damaged |
|  | For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID number. For printed copy, call U.S.A or E.U. Customer Service |
|  | Temperature limitation |
| Rx ONLY | Federal (USA) law restricts this device to sale by or on the order of a physician. |

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