Instruction for Use

Bone Filler
Size: 10GA

Sterile
For Single Use Only

Indication for Use
Intended for the delivery of bone cement to bone with the Osteo-site Vertebral Balloon.

Device Description
The Bone Filler is packaged as single-use, sterile, non-implantable device. It is a percutaneous surgical instrument designed to be used in conjunction with an appropriately sized Kyphoplasty Working Cannula, for the purpose of penetrating bone tissue for vertebral body access during Kyphoplasty Vertebral Augmentation procedures. The device consists of one primary component:

1. Bone Filler (Compatible with IZI Medical's 10GA Access Cannula)

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

IMPORTANT:
These instructions provide guidance to the experienced physician using the Bone Filler for accessing the vertebral body during a Vertebral Augmentation Procedure. This is not a reference to general surgery technique. **Failure to properly follow the instructions may result in serious patient injury. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.**

Contraindications
For the use of vertebral body access as determined by a licensed physician only. This product should be used by a physician familiar with the potential side effects of this procedure. Patients with bleeding disorders, or those receiving anti-coagulant therapies, should be evaluated for this procedure under physician judgment. If the flow of cement stops at any time during dispensing to determine and correct the cause the cause of blockage. Remove cement delivery system and bone filler device from the patient when to prevent them from becoming fixated within the vertebral body.

Precautions
- Read the Instruction for Use prior to device operation.
- For single patient use only.
- Product may present a biohazard and sharps hazard. Dispose of in accordance with applicable laws and regulations
- DO NOT use if package or component is damaged.
- DO NOT reuse, reprocess, or repackage this device.
- DO NOT modify any system component or accessory unless otherwise specified. Use only IZI-approved system components and accessories, unless otherwise specified.
- Only use with Polymethyl-Methacrylate (PMMA) based bone cement.
- DO NOT use with bone substitutes or bone void fillers.
- DO NOT overfill bone void.

5 Easter Court, Suite J
Owings Mills, MD 21117 USA
P / + 1 410 594 9403
www.izimed.com

Bone Filler Procedure:

1. Follow the Instructions for Use (IFU), for the chosen Bone Access Tools to create access channel in the bone.
2. Follow the IFU for the chosen procedure to create a void or cavity in the vertebral body.
3. Follow the IFU for mixing the bone cement and transferring to injector.
4. After mixing with mixer, transfer cement from mixer or injector to the bone filler following the IFU for the cement mixing system.
5. Fill bone filler either directly from the mixer using a coupler (if required) or use syringes to fill the bone filler.
6. Fill until completely full. Fill one at a time.
7. Purge a small amount of cement to ensure no blockage. This will ensure the cement flows properly and safely. This also tests the connections of the system's components.
8. Allow time for the cement to reach a working state (doughy). Crank out a small amount of cement again to test the cement's viscosity to confirm the cement has reached a doughy state.
9. Using direct visualization or imaging guidance, advance the Bone Filler into the working cannula to the bone void. Verify placement of the cannula tip at the intended location using direct visualization or X-Ray imaging prior to delivery of bone cement.
10. The distal tip of the Bone Filler cannula has reached the distal end of the access cannula when the most distal marking on the Bone Filler cannula is inside the working cannula. Advance further if necessary.
11. Dispense slowly and consistently until the desired cement fill is achieved.
12. If the flow of cement stops at any time during dispensing, stop dispensing to determine and correct the cause of blockage. Correct blockage or replace the Bone Filler.
13. When finished with cement fill, remove the system from the working cannula of the bone access tool. Tamp down with the Bone Filler, as needed, to verify the cement has set. Spin and rotate both the bone access tool and Bone Filler as required to prevent adhesion to the cement.
14. Continue with the Kyphoplasty Vertebral Augmentation procedure per associated Instructions for Use.

Storage

Store in a cool, dry place. Proper care should be taken to ensure that the product will not be damaged or rendered non-sterile.

Limitation of Liability

IN NO EVENT SHALL IZI MEDICAL BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES ARISING OUT OF OR IN CONNECTION WITH THE PRODUCT, BASED UPON BREACH OF CONTRACT (INCLUDING BREACH OF WARRANTY).

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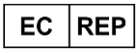
Service Representatives and Requests For Information

For service, technical support, requests for information or reorder information, contact:

IZI Medical Products
5 Easter Court, Suite J
Owings Mills, MD 21117 USA
+1 410 594-9403 (T)
+1 410 594 0540 (F)
www.izimed.com



ILUMARK GmbH
Hohenlindner Str. 11c
85622 Feldkirchen
GERMANY

Product Returns

To return product, contact IZI Medical Inc. at (410) 594-9403