



Instruction for Use

Coaxial Cement Injection Cannula
Size: 11GA

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 Coaxial Cement Injection Cannula 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. Coaxial Cement Injection Cannula (Compatible with IZI Medical's 11GA 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 Coaxial Cement Injection Cannula 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 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.



Biopsy Procedure:

1. Follow the Instructions for Use (IFU), for the chosen Bone Access Tools to create access channel in the bone.
2. Follow the Instructions for Use for the chosen procedure to create a void or cavity in the vertebral body.
3. Follow the Instructions for Use for mixing the bone cement and transferring to injector.
4. After mixing with mixer, transfer cement from mixer to injector following the Instruction for Use (IFU) for the cement mixing system.
5. Fill Coaxial Cement Injection Cannula by connecting the Coaxial Cement Injection Cannula to the extension tube of the cement injection system. Ensure the extension tube is primed prior to connecting the Coaxial Cement Injection Cannula.
6. Prime the Coaxial Cement Injection Cannula. This will ensure the cement flows properly and safely. This also tests the connections of the system's components.
7. 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.
8. Using direct visualization or imaging guidance, advance the Coaxial Cement Injection Cannula into the working cannula to the bone void. Slide depth adjustor to the distal most marking below the bottom of the Coaxial Cement Injection Cannula handle. Tighten the depth adjustor. Insert Coaxial Cement Injection Cannula into the access needle. Luer lock the depth adjustor onto the access cannula. Verify placement of the cannula tip at the intended location using direct visualization or X-Ray imaging prior to delivery of bone cement.
9. The distal tip of the cannula has reached the end of the distal end of the cannula when the proximal end of depth adjustor on the cannula is at the distal marking on the cannula.
10. Dispense slowly and consistently until the desired cement fill is achieved.
11. 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 Coaxial Cement Injection Cannula. If cement does not flow freely from the extension tube after disconnecting from the Coaxial Cement Injection Cannula, the blockage is likely due to improper mixing or air entrapment within the cement mix. Re-mix and use a new cement, mixer, injector and Coaxial Cement Injection Cannula.
12. When finished with cement fill, remove the system from the working cannula of the bone access tool. Tamp down with the Coaxial Cement Injection Cannula, as needed, to verify the cement has set. Spin and rotate both the bone access tool and Coaxial Cement Injection Cannula as required to prevent adhesion to the cement.
13. 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).



IZI Medical

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Product Returns

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