Instruction for Use

Curette
Size: 10GA & 11GA

Sterile
For Single Use Only

Indication for Use
The Curette is intended for percutaneous access to bone with the Vertebral Augmentation System.

Device Description
The Curette 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 Working Cannula, for the purpose of displacing bone tissue for vertebral body access during Vertebral Augmentation procedures. The device consists of one primary component:

1. Curette (Compatible with IZI Medical's 10GA & 11GA Access Needles)

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 Drill 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.

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, repackage, or reprocess this device.
- DO NOT modify any system component or accessory unless otherwise specified. Use only IZI-approved system components and accessories, unless otherwise specified.

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Biopsy Procedure:

1. This instrument must be used in conjunction with an appropriately sized Working Cannula (not supplied) to provide a working channel to the vertebra. ALWAYS use fluoroscopic guidance when manipulating the curette and components of the system. DO NOT use the curette while a balloon is inflated within the vertebral body. Failure to comply may cause the balloon to rupture.
2. Using sterile technique, prepare the skin with antiseptic and drape.
3. Infiltrate the marked area with local anesthetic, especially the periosteum.
4. Make a skin incision with a scalpel blade over the marked area.
5. Use an access cannula/stylet assembly to create an access channel in the bone.
6. Remove any instrumentation, such as a stylet or balloon catheter, from the cannula.
7. Introduce the curette through the cannula. If severe resistance is met during insertion, DO NOT continue to push curette through cannula. DO NOT hit curette with mallet or another device. Failure to comply may cause curette and/or cannula to move and result in damage of the pedicle or the curette. If so occurs, remove curette, and make sure an appropriately sized IZI Medical access cannula is in place.
8. The tip will remain in place at the distal end of the cannula, and the handle withdrawn to expose the depth marks. The depth marks indicate the distance the tip will extend past the distal end of the cannula after full insertion.
9. ALWAYS consider the orientation of the curette before advancing the curette into the bone. Use the arrow mark on the curette handle which indicates the orientation of the curette. Under fluoroscopic guidance, advance the curette through the cannula into the bone, and verify the placement of the tip at its intended location.
10. Upon insertion, hard or sclerotic bone may prevent the tip from flexing. The tip will flex to its fully articulated position during gradual displacement of the bone. DO NOT allow the proximal end of the curette to contact the fluoroscopic C-arm while inserted in the cannula. Failure to comply may result in damage to the pedicle or the curette.
11. While physically maintaining the position of the cannula, and under fluoroscopic guidance, us a rotational and/or push-and pull motion on the curette to carefully displace the bone.
12. ALWAYS consider the orientation of the curette before retracting the tip and removing the cannula. When displacement is complete, rotate the thumbwheel clockwise to fully retract the tip into the cannula.
13. While physically maintaining the position of the cannula, remove the curette from the cannula. If severe resistance is met while removing the curette, simultaneously remove the curette and cannula from the surgical site.
14. Continue with the 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:

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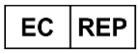

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Product Returns

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