Instruction for Use

Bone Drill
Size: 10GA

Sterile
For Single Use Only

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

Device Description
The Bone Drill 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 penetrating bone tissue for vertebral body access during Vertebral Augmentation procedures. The device consists of one primary component:

1. Bone Drill (Compatible with IZI Medical's 10GA Access Needle)

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

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Bone Drill 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.
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. Insert the 10GA access needle into the vertebral body using the Instruction for Use (IFU) for the access needle.
6. Insert the bone drill coaxially into the 10GA access needle.
7. Hold the Bone Drill with the proximal end in palm and the index finger against the shaft near the tip. This position stabilizes the needle and allows better control.
8. Using gentle, but firm pressure, advance the Bone Drill into the bone. Rotate the needle in an alternating clockwise and counterclockwise motion while applying forward pressure. If the bone is very hard, lightly striking the handle with a mallet may advance the needle more easily.
9. Once inside the vertebral body, remove the Drill, leaving the Working Cannula in place within the pedicle.
10. 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

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Product Returns

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