

Instructions for Use

Blazer Single Step Introducer

IZI Medical Products

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ENGLISH

IMPORTANT: These instructions provide guidance to the experienced physician using the Blazer Single Step Introducer 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.**

INDICATION FOR USE: Intended for percutaneous access to bone with the Blazer Vertebral Augmentation System.

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: For single patient use only. Product may present a biohazard and sharps hazard. Dispose of in accordance with applicable laws and regulations.

DEVICE DESCRIPTION: The Blazer Single Step Introducer 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 Blazer Working Cannula, for the purpose of penetrating bone tissue for vertebral body access during Blazer Vertebral Augmentation procedures. The device consists of one primary component:

1. Introducer with Handle (Diamond Trocar or Bevel Tip)

BIOPSY PROCEDURE:

1. This instrument must be used in conjunction with an appropriately sized Blazer 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. Hold the Single Step Introducer 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.
6. Introduce the needle through the incision and bring it into contact with the bone.
7. Using gentle, but firm pressure, advance the Introducer 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.
8. Once inside the vertebral body, remove the Introducer, leaving the Working Cannula in place within the pedicle.
9. Continue with the Blazer 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).

SERVICE REPRESENTATIVES AND REQUESTS FOR INFORMATION

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

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PRODUCT RETURNS

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