

# Blazer-C Vertebral Augmentation System IZI Medical Products

## Instructions for Use - ENGLISH

**Caution:** Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.

**INDICATION FOR USE:** Blazer-C is indicated for the treatment of pathological compression fractures of the vertebral body that may result from osteoporosis, benign lesions, and/or malignant lesions, by creating channels in the existing spinal bone structure for the flow of Polymethylmethacrylate bone cement (PMMA).

**IMPORTANT:** These instructions provide guidance to experienced physicians using the Blazer-C Vertebral Augmentation System to create channels in cancellous bone. This is not a reference to spine surgery technique. **Failure to properly follow the instructions may result in serious patient injury. Do not attempt to use the Blazer-C Vertebral Augmentation System prior to receiving comprehensive training from IZI Medical personnel.**

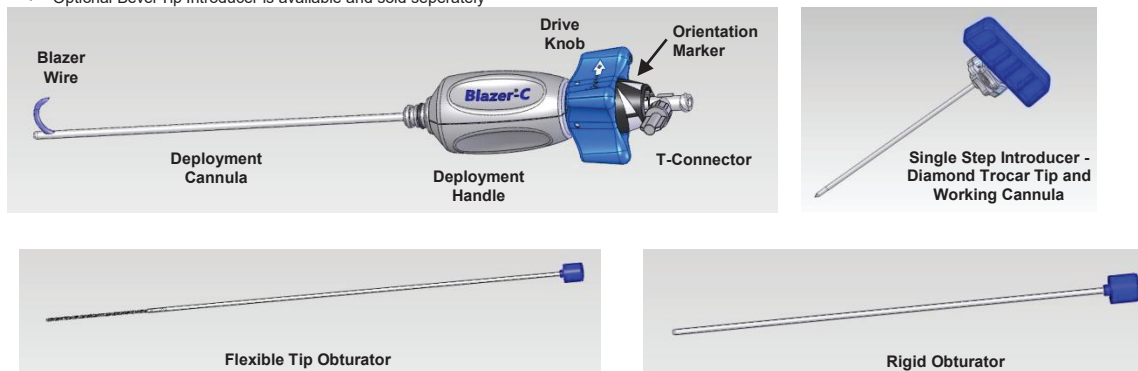
**Device Description:** Blazer-C Vertebral Augmentations System is packaged as a single-use, sterile, non-implantable device.

The Blazer-C device consists of four primary components: Blazer- C Wire, a Deployment Cannula, a Deployment Handle with Drive Knob, and a T-Connector to allow for insertion of obturators and cement injection.

The Blazer-C Wire is cannulated, pre-shaped into a 180° arc and can be temporarily straightened into Deployment Cannula for delivery into cancellous bone. Once positioned in cancellous bone, the Blazer-C Wire is advanced forward and out of Deployment Cannula. The physician controls the amount of Blazer-C Wire deployment with the use of Drive Knob, which allows for incremental deployment. Repositioning of Deployment Handle provides directional control. Upon exiting Deployment Cannula, the Blazer-C Wire regains its arc shape as it channels through cancellous bone.

The system includes a set of Accessory Tools and consists of the following:

- Single Step Introducer with Diamond Trocar Tip and Working Cannula
- Flexible Obturator (packaged in place through vertical port of T-Connector and into Blazer-C Wire)
- Rigid Obturator
- Optional Bevel Tip Introducer is available and sold separately



### Device Preparation

1. The Blazer-C is packaged with Flexible Obturator in place. Retract Blazer-C Wire into Deployment Cannula by rotating Drive Knob slowly in the counter-clockwise direction until a hard stop is detected.
2. Ensure that the distal tip of Blazer-C Wire is completely inside the Deployment Cannula and not protruding.
3. Blazer-C is ready to use.

### Accessing the Vertebral Body

1. Using fluoroscopy, access vertebral body using a Single Step Introducer and Working Cannula via standard transpedicular or extrapedicular technique. If necessary, the Diamond Trocar Tip Introducer may be exchanged for either the Bevel or Drill Tip Introducer. To exchange Introducer, unlock Working Cannula, replace Introducer, and re-lock Working Cannula.
2. Once desired position is attained with Introducer, unlock and remove Introducer, leaving Working Cannula in place.

### Deploying Blazer-C Wire

1. Under fluoroscopic visualization, insert Blazer-C through Working Cannula and into access site. Position Deployment Cannula to deploy Blazer-C Wire in the anterior column (See Fig. 2A) and in the orientation desired to create channel. Lock Working Cannula hub.
2. With Flexible Obturator in place, rotate Drive Knob slowly to incrementally deploy Blazer – C Wire into cancellous bone. After each full turn of Drive Knob, verify orientation and path of Blazer-C Wire under image guidance (See Fig. 2B). Continue to deploy Blazer-C Wire, until desired amount of wire has been deployed and channels have been created.
3. Prepare bone cement product in accordance with the manufacturer's Instructions for Use (IFU).
4. Unlock the Working Cannula hub and remove Blazer-C from Working Cannula. Remove Flexible Obturator and attach cap. Connect cement injector to Blazer – C to the horizontal port of T-Connector and prime Blazer-C Wire outside the patient until cement viscosity is smooth and consistent.
5. Reinsert Blazer-C into Working Cannula and lock in place. Redeploy Blazer – C Wire into the first channel created and inject desired amount of bone cement. The orientation marker may be used to determine channel location.
6. If additional channels are desired, retract Blazer-C Wire into Deployment Cannula. Reorient Deployment Cannula to achieve desired path and orientation. Using image guidance, create additional channels and inject desired amount of bone cement.
7. If necessary, the Rigid Obturator may be used to assist in delivering cement or expelling clogs in Blazer-C Wire. To use Rigid Obturator, remove cap on vertical port of T-Connector and insert Obturator.
8. Once the desired numbers of channels are created and bone cement has been injected, retract Blazer-C Wire completely back into Deployment Cannula until a hard stop is detected. Remove Blazer-C and Working Cannula from patient. Optionally, the Introducer may be inserted to help remove the Working Cannula. **The Working Cannula should never be removed by itself without internal support.**

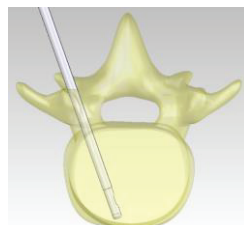


Figure 2A: Lateral Access

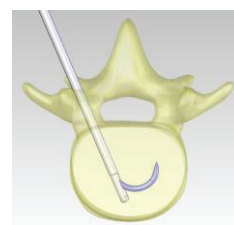


Figure 2B: Lateral Access with Blazer-C Wire Deployment

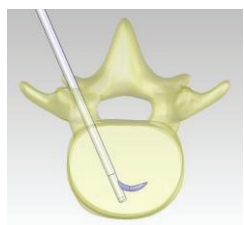


Figure 3A: Midline Access with Partial Contralateral Deployment of Blazer - C wire

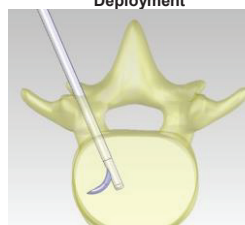


Figure 3B: Midline Access with Ipsilateral Deployment of Blazer - C wire

## CONTRAINDICATIONS

- Infection, systemic or local, such as osteomyelitis or discitis, to the surgical site is a contraindication for any spinal surgical procedure.
- Any medical condition that would preclude the patient from having surgery or would impede the benefit of surgery such as spinal cord compression or abnormal anticoagulation status/uncorrectable coagulopathy.
- Neurologic signs/symptoms related to the compression fracture.
- Index level(s) vertebral body collapse to the degree that access to the vertebral body is not feasible.
- Pedicle(s) whose diameters are too small to accept the Working Cannula.
- Evidence of fracture fragments retropulsed into the spinal canal.

## WARNINGS: Failure to follow any instructions or failure to heed any warnings or cautions could result in serious patient injury.

- The pedicle identified for access to the index fracture has a diameter that can accept a 3.75mm cannula as determined by treating physician.
- Placing the Deployment Cannula either too anterior or too posterior in the vertebral body may result in patient injury.
- If high resistance is experienced during deployment of Blazer-C wire, extreme caution should be used for further advancement.
- Do not remove the Working Cannula from the patient without internal support. Only remove it with internal support, such as with the Introducer or Blazer-C.

## PRECAUTIONS

- Failure to observe recommendations may contribute to serious patient injury.
- Do not use if the packaging appears to be damaged or if there is evidence of tampering.
- This device is intended for single-use only. Do not re-sterilize or reuse. Reuse of the device could result in infection, cross-contamination, and a failure to perform in a safe manner as intended.
- The user should inspect the device for damage prior to use. If the device appears damaged, do not use. Discard or return to the manufacturer.
- It is important to read the Instructions for Use and these precautions prior to device operation.
- Use the Blazer-C System prior to the Use By date noted on the package.
- The physician should be familiar with the anatomy and pathology being treated with this device.
- The physician should be experienced in the standard transpedicular approach for access to the vertebral body.
- The physician should be trained in the use of Blazer-C prior to clinical use.
- The Insertion of the device and injection of the cement needs to be accomplished under High Quality Imaging (such as bi-plane fluoroscopy). Failure to use fluoroscopic guidance could result in serious patient injury.
- The user should avoid contact with the sharp distal tip of the Blazer-C Wire as it may puncture the user's glove.
- Never attempt to deploy the Blazer-C Wire without the use of the deployment handle and Working Cannula provided with the system.
- Never attempt to remove Blazer-C from patient without first verifying complete Blazer-C Wire retraction into the Deployment Cannula. Use fluoroscopic imaging to ensure complete retraction of Blazer-C Wire from the vertebral body prior to removing the Deployment Cannula.
- To reduce risk of excessive wear to device and potential failure, do not deploy the Blazer-C wire more than 16 times.
- Do not rotate handle to "sweep" Blazer-C wire while the wire is deployed if wire does not also rotate. Doing so may damage the device.
- Placing the Deployment Cannula too anterior or too posterior in the vertebral body may result in patient injury.
- Stop Blazer-C deployment if significant resistance is observed, it does not regain its shape, or goes in an undesired location.
- Caution should be taken when deploying Blazer-C from regions of very soft bone such as a cleft into very dense bone, as this may lead to significant deflection of the cannula tip and damage the instrument.
- Use of Blazer-C in dense bone (osteosclerotic vertebrae) or in diseases causing abnormal bone formation (Paget's disease), may limit the penetration of the Wire.

## ADVERSE EVENTS Adverse events potentially associated with the use of the Blazer-C are the same as most other percutaneous spinal procedures. Those may include:

- Nerve injury including puncture of the spinal cord or nerve roots, or retropulsed bone fragments potentially resulting in radiculopathy, paresis or paralysis.
- Hemothorax or pneumothorax, unintended puncture wounds including vascular puncture and dural tear.
- Deep or superficial wound infection.
- Bleeding, hematoma and/or venous embolism.
- Pain or lack of pain relief.
- Damage to vertebral posterior elements due to access, fracture of vertebrae/pedicle, or breach of cortical wall.
- Osteomyelitis.
- Allergic reaction to medications/implanted materials used during the procedure and/or need for open surgery.
- Potential subsequent fractures at index or other vertebral levels.
- Cardiovascular impairment due to fat emboli.

## CONTENTS

Each Box will contain one Blazer-C device, one Single Step Introducer – Diamond Trocar Tip with Working Cannula, one Flexible Obturator, and one Rigid Obturator

## HOW SUPPLIED

The Blazer-C Vertebral Augmentation System is supplied sterile in peel open package and should not be re-sterilized. Do not use device if package is damaged or opened, if product is accidentally contaminated before use, or if beyond expiration date.

## STORAGE

Store in a cool, dry place. Proper care should be taken to ensure that the Blazer-C Vertebral Augmentation System will not be damaged.

## 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 BLAZER-C VERTEBRAL AUGMENTATION SYSTEM, 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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Any device-related-incident or problem which is believed to represent a safety issue should be immediately reported to IZI Medical.

## PRODUCT RETURNS

To return product, contact IZI Medical Products at 800-231-1499.

The IZI Medical Blazer-C device and methods of use are covered by a number of US and foreign patents.

## SYMBOL DEFINITIONS

|                                    |   |                              |   |
|------------------------------------|---|------------------------------|---|
| Caution                            |  | Manufacturer                 |  |
| Do not reuse                       |  | Catalog Number               |  |
| Do not use if package damaged      |  | Sterile by Ethylene Oxide    |  |
| Batch Code                         |  | Use by                       |  |
| Not made with natural rubber latex |  | Keep Dry                     |  |
| Do Not Re-Sterilize                |  | Consult instructions for use |  |