Kiva®
VCF Treatment System

IZI Medical Products

Instructions for Use - English

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

INDICATIONS FOR USE

The Kiva VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-L5.

IMPORTANT: These instructions provide guidance to experienced physicians using the Kiva VCF Treatment System to treat vertebral compression fractures. This is not a reference to spine surgery technique. **Failure to properly follow the instructions or to heed any warnings or precautions could result in patient injury. Do not attempt to use the Kiva VCF Treatment System prior to receiving comprehensive training from IZI Medical personnel.**

SYSTEM DESCRIPTION

The Kiva VCF Treatment System consists of the single-use Deployment System, in which the Kiva Coil and Kiva Implant are preloaded, as well as a set of Access Instruments. They are packaged within a single product box and sterilized via irradiation. Each of these is pictured below and a narrative description follows.

Figure 1a: Deployment System and Implant

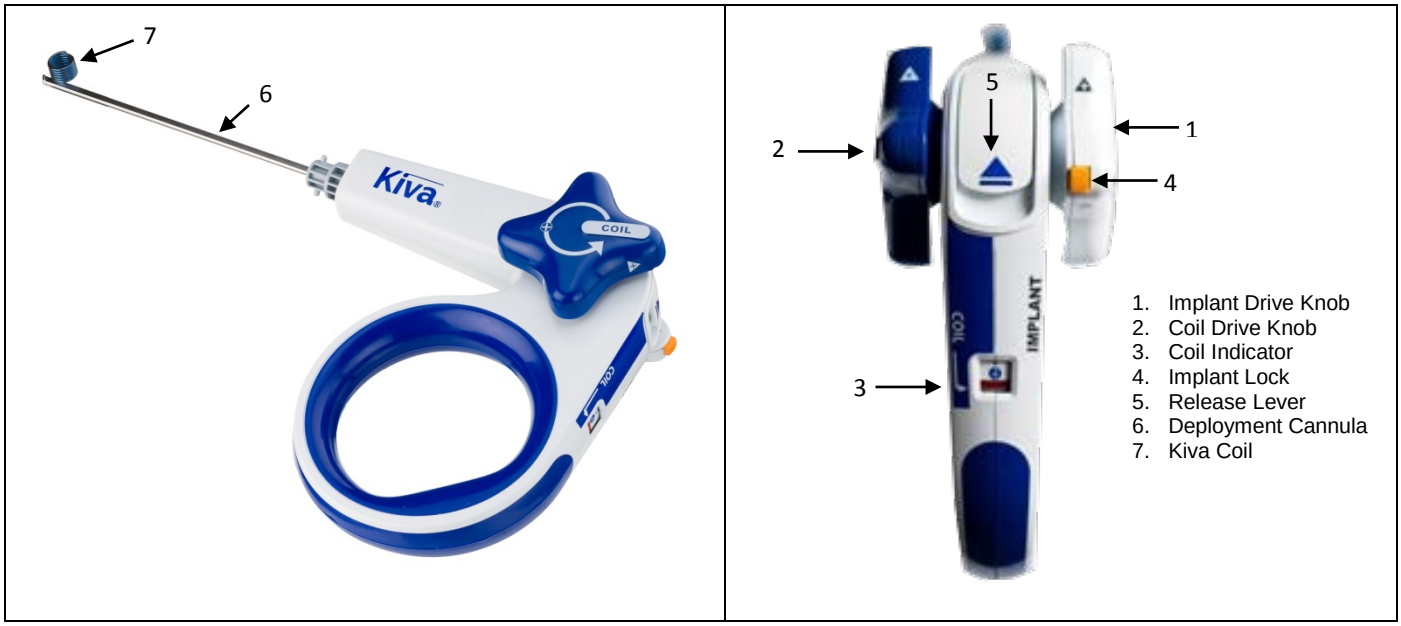


Figure 1b: Kiva Implant

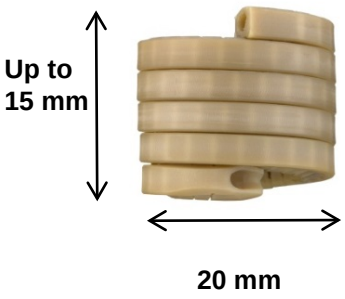
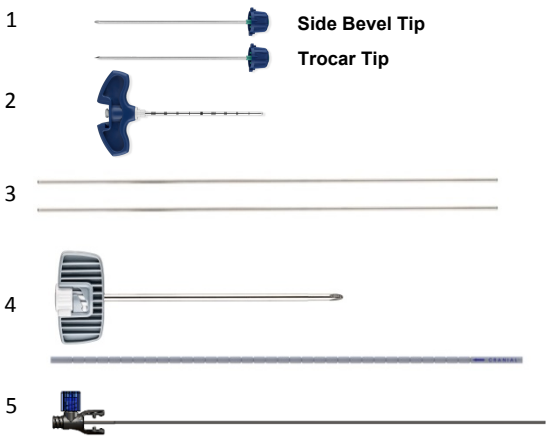


Figure 1c: Access Tools



FOR OPTIMAL PERFORMANCE OF THE VERTEFIX® PLUS CEMENT WITH KIVA VCF TREATMENT SYSTEM, USE THE FOLLOWING PHASES:

At operating room and device temperature of 68°F (20°C):

1) Using provided Funnel, pour all Powder into Mixing System
2) Pour Liquid monomer into Mixing System and shake vigorously (time starts when liquid touches the powder): 0'00" - 0'40"
3) Insert Plunger into Mixing System and connect Blue Syringe to Mixing System. WAIT TILL 3 MINUTES BEFORE FILLING THE BLUE SYRINGE: 0'40" - 3'00"
4) Lower the floor of the Mixing System and transfer cement to Blue Syringe. Disconnect the Blue Syringe from Mixing System and connect it to the DuroJect Handle and Extension Tube: 3'00" - 4'00"
5) Prime the DuroJect Extension Tube. Remove dry plug (purge at least 2 inches of cement): 4'00" -4'30"
6) Connect UltraFlex Needle to DuroJect Extension Tube and prime (purge at least 2 inches of cement): 4'30" - 5'00"
7) Insert UltraFlex Needle into Working Cannula and start injecting: 5'00" -10'00"

**times may vary with room and device temperature

Kiva Deployment System: The Deployment System is a single-use device that is used to position and deliver the Kiva Coil and Kiva Implant. Both the Kiva Coil and Kiva Implant are contained within the Deployment System and are deployed into the vertebra via a handle mechanism. The Deployment System is removed after the Kiva Implant is deployed and the Kiva Coil fully retracted. A Right and Left Pedicle version is available to provide the option to access the vertebral body from either pedicle.

Kiva Coil: The Kiva Coil is a non-implantable nitinol wire with a beveled tip. The Coil is preloaded within the Deployment System, which is used to insert the Kiva Coil into the vertebral body. Upon insertion, the Kiva Coil attains a stacked coil configuration with an *in situ* outer diameter of 15mm. Up to 5 loops of the Kiva Coil may be inserted into the vertebral body for a maximum coil stack height of 7.5mm. The Kiva Coil creates a channel within the cancellous bone and provides a delivery track for the deployment of the Kiva Implant. Once the implant is deployed, the Kiva Coil is fully retracted back into the Deployment System.

Kiva Implant: The Kiva Implant is made from PEEK loaded with 15% barium sulfate to render the implant visible with fluoroscopy and includes a distal marker made of tantalum as well as a silicone based lubricant (PDMS). It is preloaded within the Deployment System and is delivered over the Kiva Coil into the vertebral body. It is inserted incrementally to form a stacked, cylindrical column with an *in situ* outer diameter of 20mm that consists of up to 5 loops that reduces the compression fracture via height distraction of the vertebral body. Since each loop of Implant is 3mm tall, the full stack may attain a height of up to 15mm. Once the Kiva Coil is retracted from within the Kiva Implant, PMMA bone cement is then injected into the lumen of the Kiva Implant. The slot features of the Implant preferentially direct the cement to flow toward the inner diameter of the stacked Implant coil. Once cured, the cement interlocks the Implant to the cancellous bone. With proper symmetric placement about the midline of the vertebrae, the Kiva Implant and PMMA construct provide bilateral fracture support via a unilateral access.

Bone Cement: The procedure is completed with the injection of bone cement through the Kiva Implant and into the vertebral body. The IZI Medical Vertefix® Plus cement and injection system includes the cement monomer, powder, mixing vial and delivery gun. This cement is compatible with the Kiva VCF Treatment System and has a working time of up to 6 minutes. Once injected through the Kiva Implant, the cement interdigitates between the Implant and cancellous bone in the vertebral body.

Access Instruments: A collection of general surgical orthopedic instruments (needles, stylets, and cannulas) is used to gain transpedicular access to the vertebrae at the start of the procedure and to facilitate cement delivery. The set of tools includes the following: Rigid and Flexible Cement Delivery Needles, Needle Guide, Working Cannula with Dilator, Guide Pin and Access Stylet with Needle. A cannulated drill and biopsy needle are available and sold separately.

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.
- Previous surgical treatment for a compression fracture on the same vertebral body.
- Index level(s) vertebral body collapse to the degree that access to the vertebral body is not feasible.
- Sclerotic cancellous bone.
- Paget's disease.
- Pedicle(s) not large enough to accept a 5mm 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 5mm 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. Ideal placement of Deployment Cannula is approximately 2 to 3 mm from the anterior wall.
- If high resistance is experienced during deployment of Kiva Coil or Implant, extreme caution should be used for further advancement.

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.
- Prior to use, the Kiva VCF Treatment System should be examined to verify functionality and ensure that its size is suitable for the specific procedure for which it is to be used.
- It is important to read the Instructions for Use and these precautions prior to device operation.
- Use the Kiva VCF Treatment System prior to the Use By date noted on the package.
- The physician shall be trained in the use of the Kiva VCF Treatment System prior to surgery.
- The physician should be familiar with the anatomy and pathology being treated with this device.
- 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.
- Use of the Kiva Access Tools is required to achieve compatibility with the Deployment Cannula.
- The amount of Kiva Coil and Implant deployment is determined by the physician based on quality of bone, fracture morphology, degree of compression or collapse, and desired fracture reduction results.
- The user should avoid contact with the distal tip of the Kiva Coil as it may puncture the user's glove.
- The physician should be experienced in the standard approach for access to the vertebral body.
- Never attempt to deploy the Kiva Coil or the Implant without the use of the Handle and Deployment Cannula provided with the system.
- Never attempt to remove the Kiva VCF Treatment System from a patient without first verifying complete Kiva Coil retraction from the vertebral body and into Deployment Cannula. Use fluoroscopic imaging to ensure complete retraction of the Kiva Coil from the vertebral body prior to removing the System.

ADVERSE EVENTS: Adverse events potentially associated with the use of the Kiva VCF Treatment System 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, such as fracture of vertebrae/pedicle.
- Osteomyelitis.
- Allergic reaction to medications/implanted materials used during the procedure and/or need for open surgery.

KIVA VCF TREATMENT SYSTEM INSTRUCTIONS FOR USE:

Refer to KIVA Procedural Guide L135 for illustrated and detailed procedural technique.

System Set-up

1. Retract the Kiva Coil completely back into the Deployment Cannula by rotating the Kiva Coil Drive Knob slowly in the reverse (-) direction until completely inside the opening of the distal end and a hard stop has been detected.
2. The Coil Indicator will read "0". The Kiva VCF Treatment System is now ready to use.

Accessing the Vertebral Body

1. Verify pedicle identified for access to the index fracture has a diameter that can accept a 5mm cannula.
2. Access the vertebral body using standard vertebral access technique (Figure 2). Use of the Kiva Access Tools is required to achieve compatibility with the Deployment Cannula.

Positioning and Deployment of the Kiva Coil

The Kiva Coil is advanced using the Kiva Coil Drive Knob. The Knob should be rotated forward in ¼ turn increments to advance the Kiva Coil.

1. Using imaging guidance, insert the Deployment Cannula into the Working Cannula with the Deployment Handle aligned to midline. Once the Deployment Cannula is docked to the Working Cannula, rotate the Deployment Handle 90 degrees clockwise to lock into Working Cannula.
2. Rotate the Kiva Coil Drive Knob on the handle forward slowly to incrementally control the deployment of the Kiva Coil in the cancellous bone. After each quarter turn, check fluoroscopic image for proper orientation of the Kiva Coil exiting the Deployment Cannula (Figure 3).
3. If the Kiva Coil is not oriented in the proper plane or at the proper position, retract the Kiva Coil back into the Deployment Cannula and reposition the Deployment Cannula to achieve an optimal orientation.
4. Using imaging guidance to ensure proper Kiva Coil path and orientation, continue to deploy the Kiva Coil until the desired amount of loops have been deployed in order to support Implant deployment, which is a minimum of 1 loop, or until resistance is encountered that prevents further advancement (Figure 4).

The amount of Kiva Coil and Implant deployment is determined by the physician based on quality of bone, fracture morphology, degree of compression or collapse, and desired fracture reduction results. Overall height of Implant will be determined by the number of loops deployed inside the vertebral body.

Deployment of the Implant and Kiva Coil Removal

The Implant is advanced using the Implant Drive Knob. The Implant can only be advanced forward and may not be retracted once advanced.

1. Once the Kiva Coil has been adequately deployed into the cancellous bone, depress the Implant Drive Knob Lock (orange button) to unlock Kiva Implant Knob. Using imaging guidance, advance the Implant over the Kiva Coil (Figure 5).
2. Rotate the Implant Drive Knob forward in ¼ turn increments. Regularly monitor advancement of the Implant using fluoroscopy at least every 1 full turn increment to ensure proper advancement of the Implant.
3. Using imaging guidance, continue advancing the Implant until the Implant reaches the end of the Kiva Coil, resistance is encountered and the Drive Knob clutches, or the desired fracture reduction results are achieved.
4. At this point, Implant deployment is complete (Figure 6). Retract the Implant Drive Knob completely until a hard stop is detected.
5. Retract the Kiva Coil until the Kiva Coil Indicator shows a blue arrow and a hard stop is felt. Deploy the Release Lever to separate the handle from the distal cartridge. Remove the handle.

Bone Cement Delivery and Procedure Completion

1. Insert the Cement Needle Guide into the Distal Cartridge with the word "CRANIAL" pointing cranially until it docks against the Kiva Implant within the Cartridge. Snap the Guide to length such that is is flush to the proximal end.
2. For optimal performance of the Vertefix® Plus cement, use the instructions on page 1 of this document.
3. Attach the delivery nozzle of the cement delivery system to the hub of Cement Delivery Needle and inject bone cement through the Needle to prime it.
4. Insert Cement Needle through Needle Guide in Deployment Cannula and into the proximal end of the Implant. Verify that the hub of the Cement Needle has locked in place.
5. Inject cement slowly into the Kiva Implant and vertebral body while monitoring with fluoroscopy. Once the desired amount of bone cement has been delivered, immediately remove Bone Cement Delivery Needle from Distal Cartridge.
6. Detach the Implant from the Deployment Cannula by rotating both the Working Cannula and and Distal Cartridge simultaneously counter clockwise 180° then clockwise 360°.Both the Working Cannula and Distal Cartridge can now be removed from the vertebral body. (Figure 7).
7. Follow standard operating procedures for procedure completion.

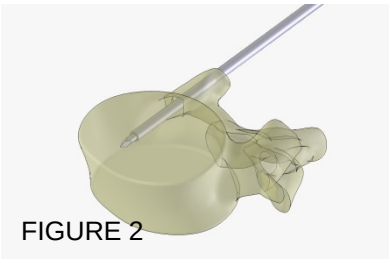


FIGURE 2

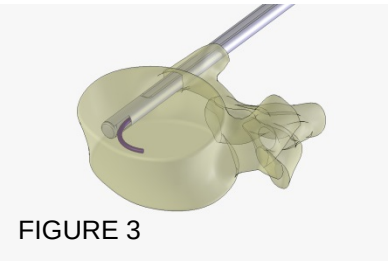


FIGURE 3

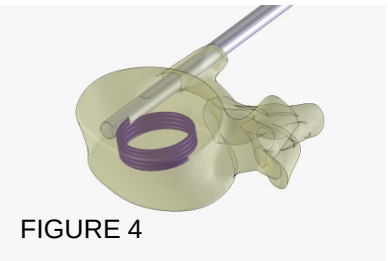


FIGURE 4

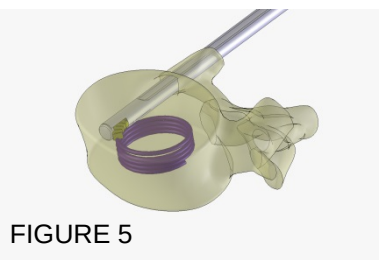


FIGURE 5

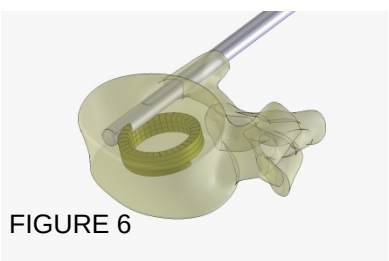


FIGURE 6

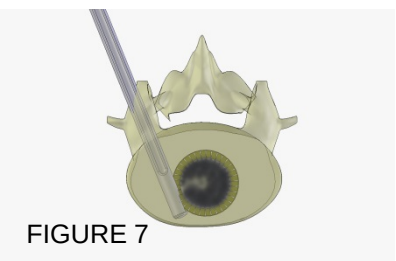


FIGURE 7

HOW SUPPLIED
The Kiva VCF Treatment System is supplied sterile in peel open packages 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 Kiva VCF Treatment System will not be damaged.

DISPOSAL
The Kiva VCF Treatment System does not require any special handling or unique requirements for disposal. Disposal of the device should be according to standard hospital waste disposal requirements.

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 KIVA VCF TREATMENT SYSTEM, BASED UPON BREACH OF CONTRACT (INCLUDING BREACH OF WARRANTY).

RETRIEVAL INFORMATION
Notify IZI Medical if explanation of the device is required.

SERVICE REPRESENTATIVES AND REQUESTS FOR INFORMATION
For service, technical support, requests for information or reorder information, contact, in the United States:

IZI Medical Products
5 Easter Court, Suite J
Owings Mills, MD 21117 USA
(410) 594-9403 (T)
(410) 594 0540 (F)
www.izimed.com

Any device-related-incident or problem which is believed to represent a safety issue should be immediately reported to IZI Medical, Inc. or Authorized European Representative.

PRODUCT RETURNS

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

The IZI Medical Kiva VCF System device and methods of use are covered by a number of US and foreign patents.

SYMBOL DEFINITIONS

Caution		Manufacturer	
Do not reuse		Catalog Number	REF
Do not use if package damaged		Sterile by Ethylene Oxide	STERILE EO
Batch Code	LOT	Use by	
Not made with natural rubber latex	LATEX	Keep Dry	
Do Not Re-sterilize	STERILIZE	Consult instructions for use	
MR Conditional	MR		

MRI Safety Information

Non-clinical testing has demonstrated that the Kiva Implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3 Tesla only
- Maximum spatial gradient magnetic field of 4,000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body average specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)

Under the scan conditions defined above, the Kiva Implant is expected to produce a maximum temperature rise of 3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 10mm or less from the Kiva Implant when imaged with gradient echo pulse sequence and a 1.5 or 3.0 Tesla MRI system.

IZI Medical Products