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. It is intended to be used in combination with the Benvenue Vertebro Augmentation Cement Kit.

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 Benvenue 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

1. Implant Drive Knob
2. Coil Drive Knob
3. Coil Indicator
4. Implant Lock
5. Release Lever
6. Deployment Cannula
7. Kiva Coil

Figure 1b: Kiva Implant
Up to 15 mm
20 mm

Figure 1c: Access Tools

1. Bone Access Needle, Trocar Tip, 11GA
2. Bone Access Needle, Bevel Tip, 11GA
3. Guide Pins
4. Working Cannula with Dilator, 6GA
5. Flexible Cement Needle with Guide

1 Not included with KIV2150 and KIV2250
2 KIV2150 and KIV2250 includes quantity of one
3 KIV2150 and KIV2250 does not include Dilator
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 above 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 (PMMA) through the Kiva Implant and into the vertebral body. The Kiva VCF Treatment System is indicated for use with the Benvenue Medical Vertebral Augmentation Cement Kit, which includes the cement monomer, powder, mixing vial and delivery gun. This cement is fully compatible with the Kiva VCF Treatment System and has a working time of up to 9.5 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
- Infusion, 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/uncontrollable coagulopathy.
- Neurologic signs/symptoms related to the compression fracture.
- Previous surgical treatment for a compression fracture on the same vertebra.
- Neurologic signs/symptoms related to the compression fracture.
- Pedicle(s) not large enough to accept a 5mm cannula.
- Evidence of fracture fragments retrospused 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 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 retrospused bone fragments potentially resulting in radiculopathy, paresis or paralysis.
- Hemotorax or pneumotorax.
- 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 vertebral/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 Procedural Technique Guide ML3325 EN 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. Follow the Instructions for use of the Benvenue Medical Vertebral Augmentation Cement Kit for preparation of the bone cement.

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.
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 BENVENUE 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 Benvenue Medical if explantation 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:

Benvenue Medical, Inc.
5403 Betsy Ross Drive
Santa Clara, CA, 95054 – USA
Phone: 800-99-SPINE (800-997-7463)
Fax: 855-SPINE-05 (855-774-6305)
www.benvenuemedical.com

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

PRODUCT RETURNS
To return product, contact Benvenue Medical Inc. at 800-99-SPINE (800-997-7463).

The Benvenue Medical Kiva VCF System device and methods of use are covered by a number of US and foreign patents; a full listing can be found at www.benvenuemedical.com/legal

SYMBOL DEFINITIONS
Caution

Manufacturer
Do not reuse

Catalog Number
Sterile by irradiation

Batch Code
Use by

Latex Free
Keep Dry

Do Not Re-sterilize
Consult instructions for use

MR Conditional

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.