Instructions for Use

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. Rigid Cement Needle
6. Flexible Tip 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
ADVERSE EVENTS.

INDICATIONS
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 Vertebral Augmentation Cement Kit.

Important: 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 training from Benvenue Medical.

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 above and a narrative description follows.

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 OPTIMA® loaded with 15% barium sulfate to render the implant visible with fluoroscopy. 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 (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.

MATERIALS NOT SUPPLIED
The Benvenue Medical Vertebral Augmentation Cement Kit, Kiva Pilot, bone drill, and biopsy needles are provided separately from the Kiva VCF Treatment System. Refer to each product’s Instructions For Use for proper use, indications, contraindications, adverse events, warnings and precautions.

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

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 retroplanted 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
- 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-stereileze 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 it’s 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.
- Do not use the Right Access System in the left pedicle. Do not use the Left Access System in the right pedicle.
- 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.
- Failure to observe recommendations may contribute to 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 retroplanted bone fragments potentially resulting in radiculopathy, paresis or paralysis.
- Hemorrhax or pneumorrhax.
- Untintended 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:

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).

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 it 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.
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www.benvenuemedical.com

PRODUCT RETURNS

To return Kiva product, contact Benvenue Medical Inc. at (888) 717-9333.

The Benvenue Medical Kiva VCF Treatment System device and methods use are covered by U.S. Patent Numbers 7,666,226; 7,666,227; 7,670,374 and 7,670,375.

Benvenue Medical, Advancing Spine Repair and Kiva are registered trademarks of Benvenue Medical Inc.

SYMBOL DEFINITIONS

Caution

Manufacturer

Do not reuse

Catalog Number

Do not use if package damaged

Sterile by irradiation

Batch Code

Use by

Latex Free

Keep Dry

Do Not Re-sterilize

Consult instructions for use