

Kiva®

VCF Treatment System

Procedural Technique Guide



VCF Treatment System



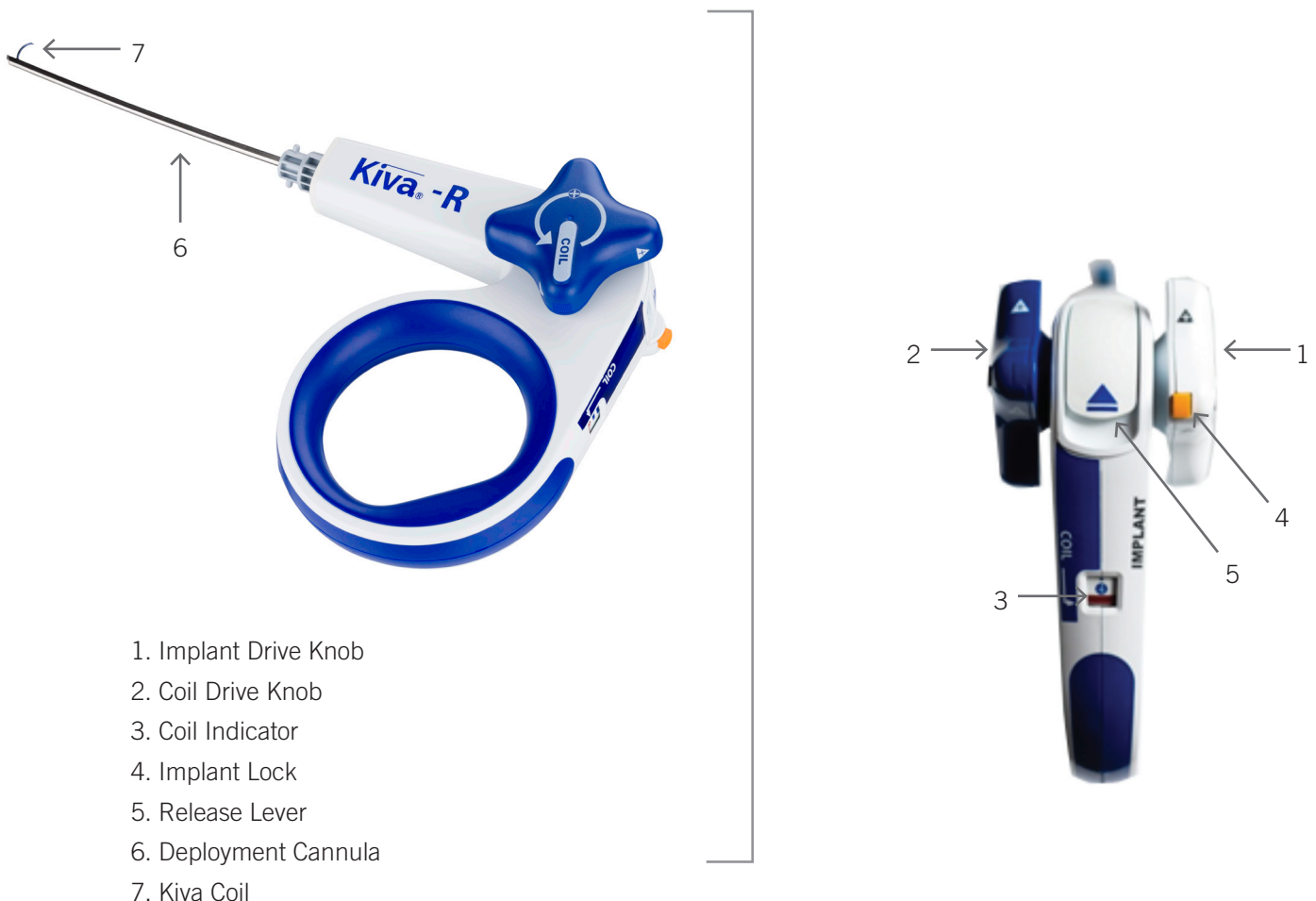
Kiva VCF Treatment System Procedural Technique Guide

The information presented in this guide is intended to supplement the Instructions for Use for the Kiva VCF Treatment System and is not intended as a spine surgery tutorial. For complete information regarding the indications for use, precautions, warnings, contraindications, adverse events, etc., please reference the Kiva VCF Treatment System's Instructions for Use.

SYSTEM DESCRIPTION

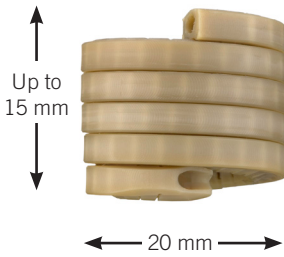
The Kiva VCF Treatment System consists of the single-use Deployment System, which contains the Kiva Coil and Kiva Implant, and a set of Access Tools intended for use in the treatment of vertebral compression fractures.

Kiva Deployment Handle

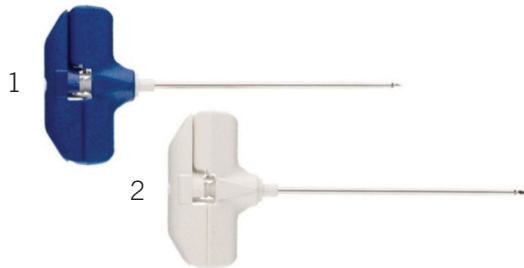


SYSTEM Description

Kiva Implant (*Housed within the Kiva Deployment Handle*)



Access Tools



1. Bone Access Needle – Diamond Trocar Tip (11G)
2. Bone Access Needle – Bevel Tip (11G)
3. Guide Pins
4. Working Cannula and Dilator (6G)
5. UltraFlex Cement Delivery Needle
6. Cement Needle Guide



Additional A la Carte Accessories – Sold Separately

See labeling for accessory products sold separately.

Bone Drill



Kiva Pilot – Right or Left



INDICATIONS

The Kiva VCF Treatment System is indicated for use in the reduction and treatment of spinal fractures of the thoracic and/or lumbar spine from T6-L5. It is intended to be used in combination with the IZI Vertebral Augmentation Cement Kit.

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 (if using a transpedicular approach).
- Evidence of fracture fragments retropulsed into the spinal canal.

See also WARNINGS, PRECAUTIONS, and ADVERSE EFFECTS sections of this guide.

SYSTEM SET-UP

Select either the Right or Left Access Kiva System based on the desired pedicle access.



Retract the Kiva Coil into the Deployment Cannula by rotating the (blue) Kiva Coil Drive Knob in the reverse (-) direction until it is completely inside the opening of the distal end and a hard stop has been detected.

The Coil Indicator will read "0". Be careful not to over-retract the Kiva Coil beyond this position, otherwise the handle will be unusable.

The Kiva VCF Treatment System is now ready to use.

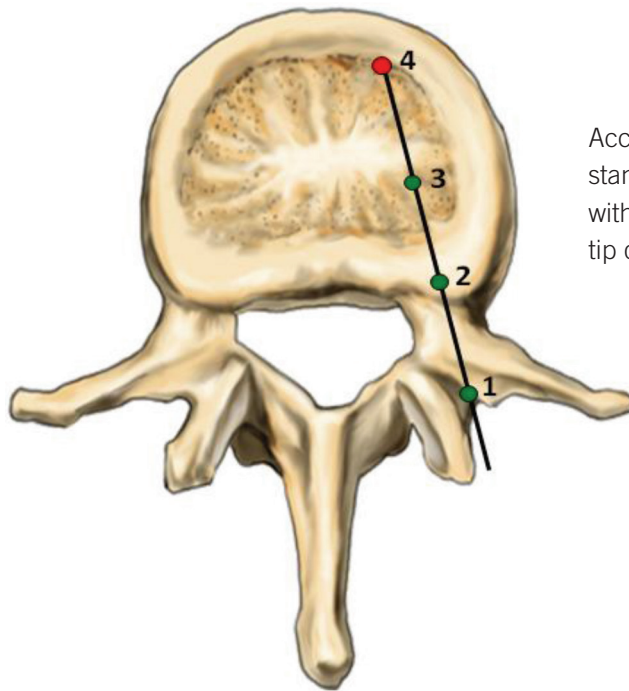


Tip of Deployment Cannula

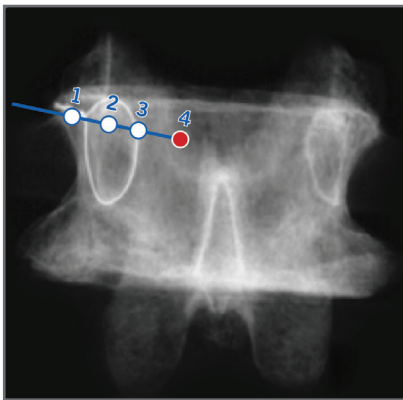


Coil Indicator on Handle

Transpedicular Vertebral Body Access

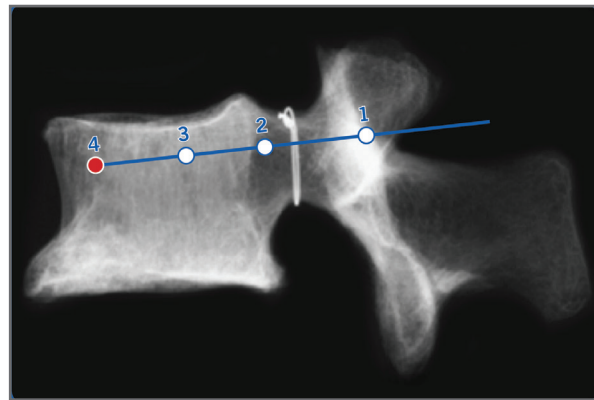


Access the vertebral body using a standard transpedicular approach with the Bone Access Needle with tip of choice.



AP view landmarks:

1. Lateral border of pedicle
2. Middle/center of pedicle
3. Medial border of pedicle
4. 4 - 5 mm lateral to midline



Lateral view landmarks:

1. Posterior aspect of pedicle
2. Entry into vertebral body
3. $\frac{1}{4}$ across vertebral body
4. 2 - 3 mm from anterior cortex

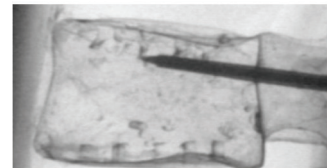
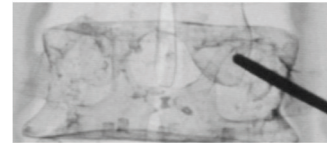
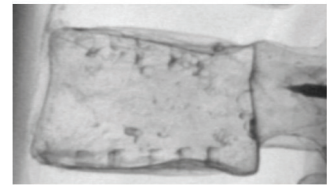
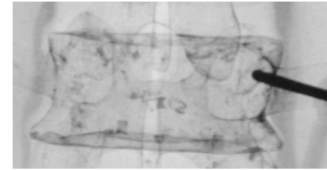
Transpedicular Vertebral Body Access



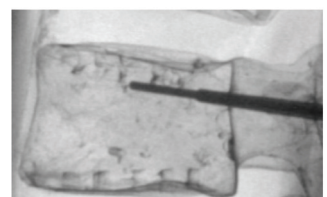
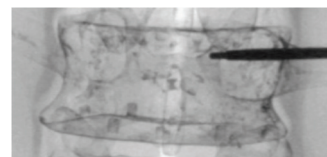
Target placement for the Bone Access Needle is half-way across the vertebral body, 1 - 2 mm below the superior endplate.



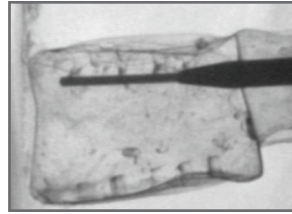
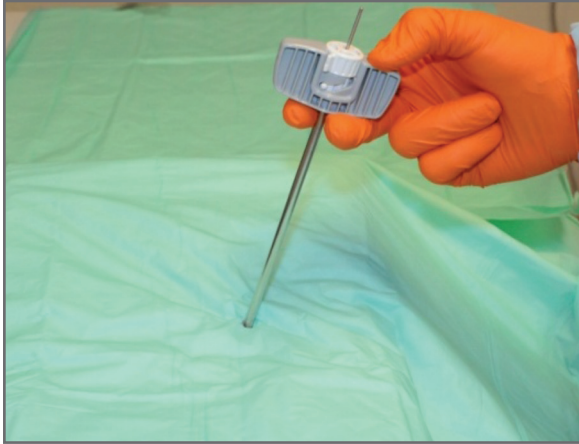
Remove the Bone Access Needle stylet and advance Guide Pin through the lumen to the desired depth within the bone. Remove the Bone Access Needle while leaving the Guide Pin in place.



If initial access is a struggle, this may be an indication you're working with hard bone. Using a Bone Drill instead of struggling with a mallet will facilitate subsequent access and removal of the Working Cannula.

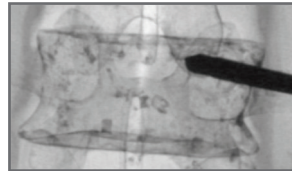


Placement of the Dilator and Working Cannula

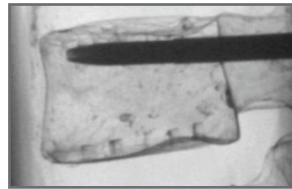


Insert the Working Cannula and Dilator over the Guide Pin and into the vertebral body until the tip of the Dilator is positioned*:

2 - 3 mm from the anterior cortex,
1 - 2 mm below the superior endplate,
and 4 - 5 mm lateral to midline



The Guide Pin may be removed while leaving the Dilator and Working Cannula in place once the Dilator has been advanced past the posterior 1/3 of the vertebral body.



The Bone Drill may also be used to gain access into the vertebral body. To use bone drill, remove Dilator from Working Cannula and insert bone drill over guide pin. Please refer to the individual IFU for each Bone Drill.

The final position of the Dilator is where the tip of the Deployment Cannula will be positioned.

**If a biopsy is necessary, place the Dilator and Working Cannula where desired within the vertebral body for optimal biopsy sample. Remove Dilator and obtain biopsy using preferred biopsy device. Once the biopsy is completed, re-insert Dilator and continue advancing until optimal Dilator and Working Cannula placement is achieved.*

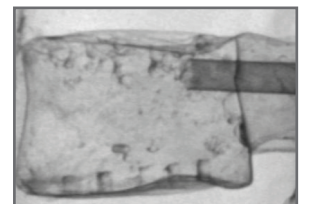


TIP

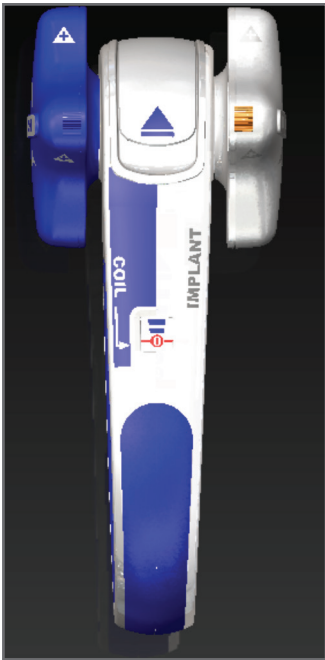
If bone is hard, rotate Working Cannula and Dilator 360° prior to next step.

Rotate the Dilator handle counter-clockwise to unlock position, remove the Dilator, and leave the Working Cannula in place.

Verify that the Working Cannula tip has cleared the posterior wall of the vertebral body.



Operation of Deployment Handle and Coil Indicator



Deployment of the Kiva Coil is controlled by the Kiva Coil Drive Knob (blue). The Knob is labeled “COIL” and features a “+” sign to indicate direction for the advancement of the Kiva Coil. The Coil is retracted by rotating the Knob in the opposite direction.

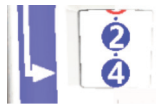
Deployment of the Kiva Implant is controlled by the Implant Drive Knob (white). The Knob is labeled “IMPLANT” and features a “+” sign to indicate direction for the advancement of the Implant.

The Kiva Implant can only be advanced and not retrieved. Reversal of the Implant Drive Knob will only retract Implant pusher but not the Implant.

The Coil Indicator will show the advancement and/or retraction of the Kiva Coil only:



Kiva Coil tip is inside Deployment Cannula



Amount of Kiva Coil Deployed



Red Bar - Kiva Coil has been fully deployed



Kiva Coil has been fully retracted

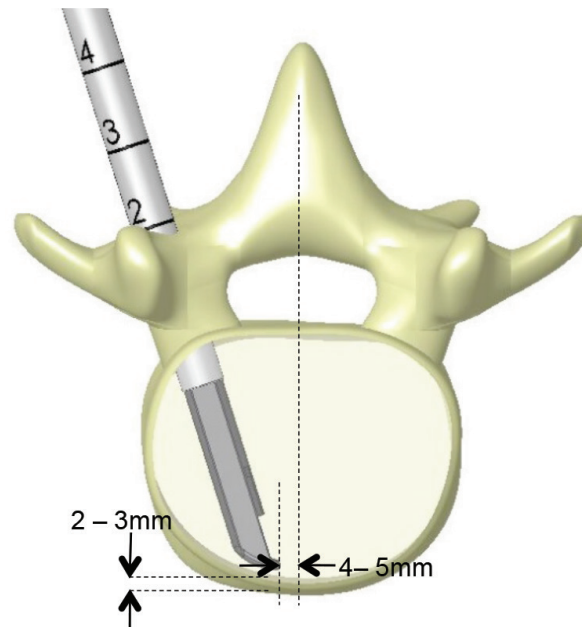
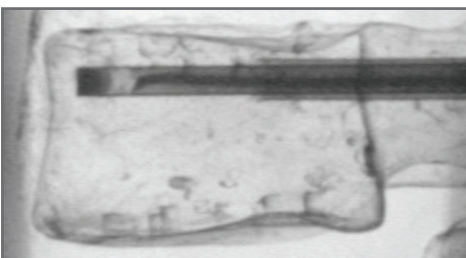
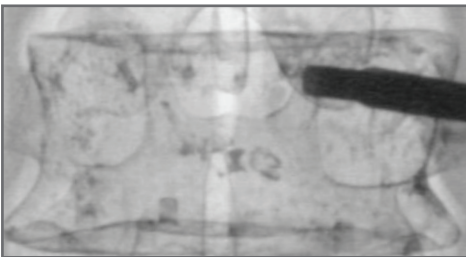
Locking of Deployment Handle



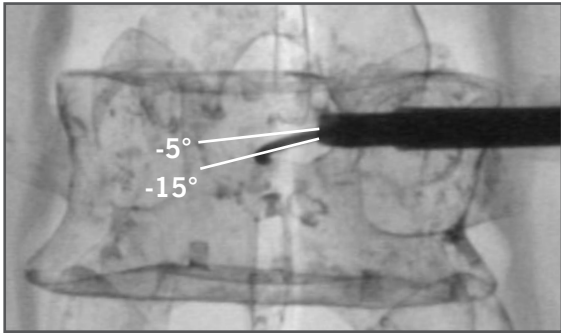
Insert the Deployment Cannula into the Working Cannula with the Deployment Handle aligned to midline.

Once the Deployment Cannula is docked to the Working Cannula, rotate the Deployment Handle 90 degrees clockwise to lock into Working Cannula.

The distal tip of the Deployment Cannula should be positioned 2 - 3 mm from the anterior cortex of the vertebra. Placement of Deployment Cannula to posterior may result in the Kiva Coil deploying into the posterior wall.

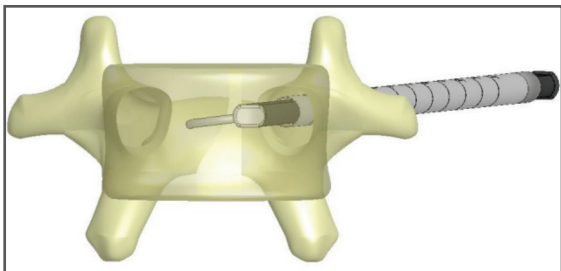


Deployment of Kiva Coil and Implant



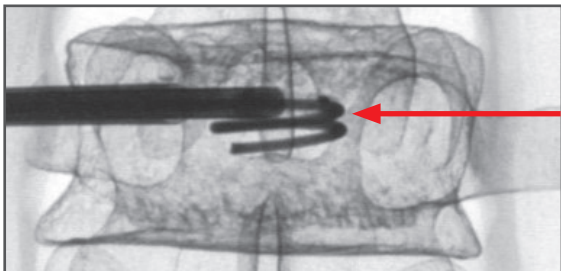
Rotate the Kiva Coil Drive Knob one quarter (¼) turn forward to begin deploying the Kiva Coil.

Verify under fluoro that the Kiva Coil is deploying toward the midline of the vertebral body with an inferior trajectory of -5 to -15 degrees relative to the transverse plane.



If re-orientation of the Kiva Coil tip is necessary, fully retract Kiva Coil tip into the Deployment Cannula prior to adjusting, until the hard stop is felt.

The deployment plane and orientation can be adjusted at this time by rotating the Deployment Handle caudal or cephalad to achieve the desired orientation. All adjustments to the orientation should be conducted under fluoroscopic visualization.



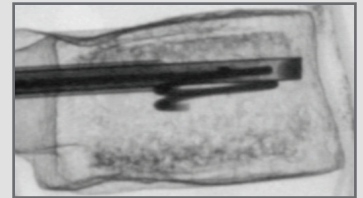
The Deployment Handle may occasionally require substantial reorientation to attain the desired Coil trajectory. In these cases, the Deployment Handle may be rotated more drastically than the resulting Coil trajectory. Prior to deploying the implant, position the Deployment Handle in line with the attained Coil trajectory. The Coil should be centered in the Deployment Cannula window when viewed on an AP image. Failure to complete this step may result in high friction during implant deployment.

Advance the Kiva Coil until 2 loops of Coil have been deployed or until resistance is encountered that prevents further advancement.



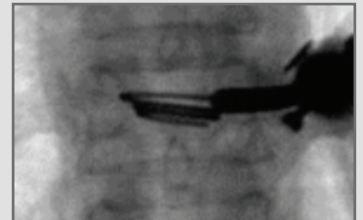
TIP

Try to establish the desired trajectory within the first 5 Coil deployment attempts. If more than 5 attempts are required to establish implant trajectory, it is important to monitor the Coil diameter upon deployment. In some cases, you may have to judge the trade off between establishing a perfect trajectory angle and the number of deployment attempts required to achieve this.



TIP

Take a radiographic image after each quarter turn of the Kiva Coil Drive Knob to verify proper Coil position during the deployment of the first loop.



TIP

If the top loop of the Kiva Coil begins to expand radially, retract Kiva Coil in ¼ turn increments until stack is corrected. Advance Implant to tip of Kiva Coil to reduce radial expansion.



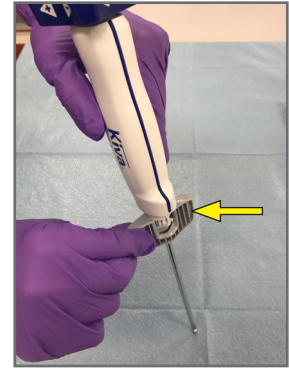
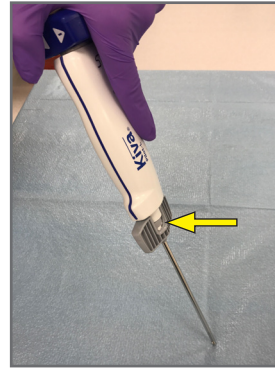
TIP

If significant resistance is met at ¼ to ½ loop of Kiva Coil deployment prior to Implant deployment, attempt a new trajectory at a different angle.

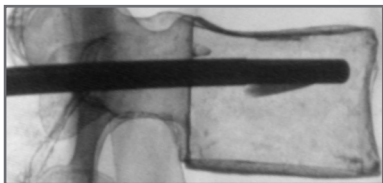
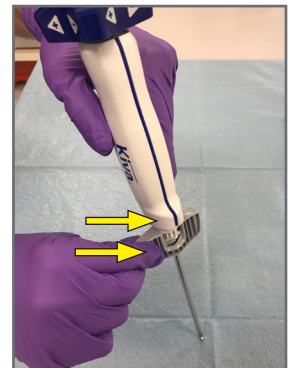
Deployment of Kiva Coil and Implant

If a new trajectory does not improve Coil advancement, retract Kiva Coil tip just into cannula then remove Delivery System, leaving Working Cannula in place.

Insert Kiva Pilot (Right or Left to match Kiva System) through Working Cannula, with the handle aligned to midline. Rotate Pilot Handle clockwise while holding device by wings, to lock into Working Cannula.



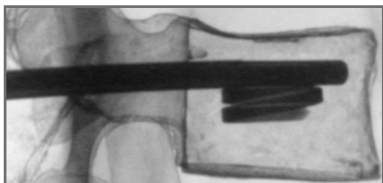
Ensure Kiva Pilot handle body is aligned with Working Cannula.



Kiva Pilot features a wire of larger diameter than the Kiva Coil which creates a channel that will facilitate deployment of a minimum of one loop of Kiva Coil and Implant.

Actuation of the Kiva Pilot is controlled by the knob on the proximal end of the device. The Knob features a "+" sign for the advancement and a "-" sign to indicate the retraction direction of the Kiva Pilot wire.

Eight (8) full turns of the Drive Knob are required to deploy the full loop of Pilot wire.



Once Kiva Pilot has created a channel, retract Kiva Pilot wire and remove from Working Cannula.

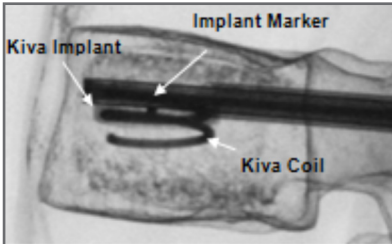
Reinsert Kiva Delivery System and proceed with Kiva Coil deployment.

If the Kiva Pilot encounters too much resistance to deploy fully, do not continue to advance. Retract wire and re-orient trajectory in a different angle.

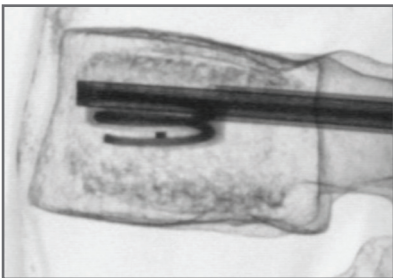
Deployment of Kiva Coil and Implant



Once 1½ to 2 loops of Kiva Coil have been delivered, depress Implant Lock (orange button) to unlock the Kiva Implant Knob.



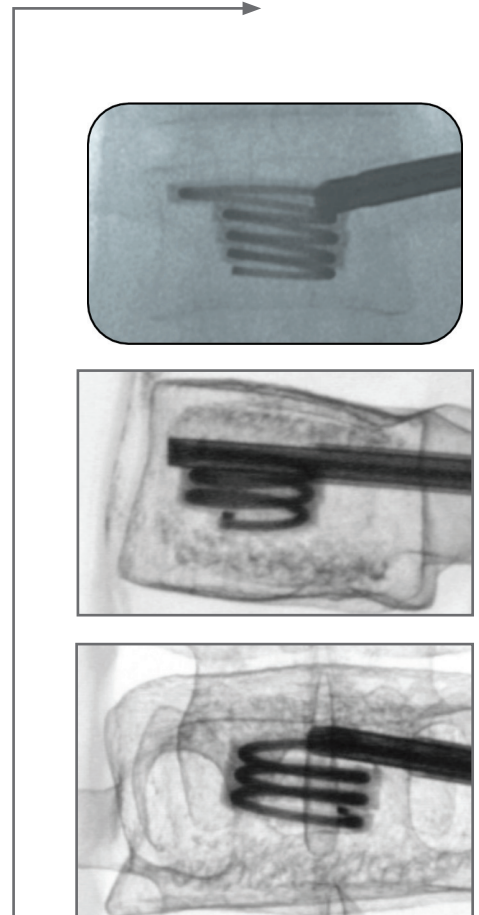
Deploy one loop of Implant to anchor the Implant into the vertebral body. The implant marker is located 2 mm from the distal tip of the Kiva Implant.



Continue advancing the Kiva Coil followed by Implant in ½ to 1 full turn increments until the desired amount of Implant has been deployed. **Do not advance the Implant beyond the distal tip of the Kiva Coil.**

Check A/P and lateral images frequently to verify proper Kiva Coil and Implant deployment.

A hard stop will indicate when the Kiva Coil is fully deployed.

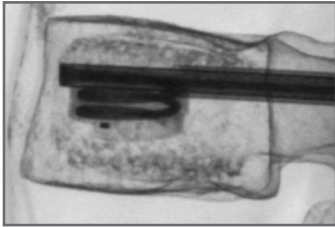


If radial expansion occurs during Implant deployment, retract the Implant Drive Knob ¼ turn, and then retract the Kiva Coil ¼ turn. This action may allow the Implant to partially recover its ideal coil orientation and provide better overall stacking.

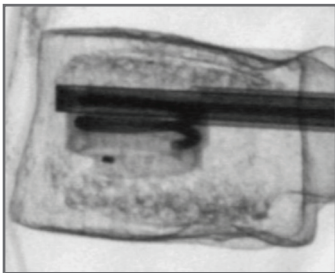
Procedure Endpoints:

- Treatment goals have been achieved.
- Entire Implant has been deployed (5 loops). A mild buzzing sound is heard and the Implant Drive Knob will spin freely at this point.
- Bone density does not allow further Kiva Coil or Implant deployment. A safety clutch will engage at this point within the Deployment Knobs and a distinct clicking will be heard when driving knobs forward.
- Excessive bowing of the Kiva Implant occurs such that it approaches the cortical wall.

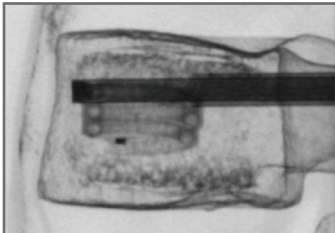
Kiva Coil Removal and Bone Cement Delivery



Once the desired amount of Implant has been deployed, retract the Implant Drive Knob until a hard stop is felt.



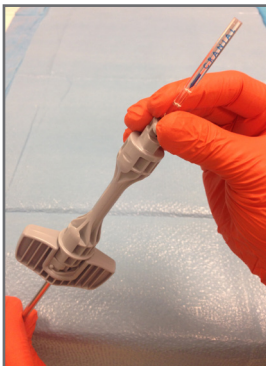
Retract the Kiva Coil beyond the first hard stop and continue retracting until the Coil Indicator begins to show red in the window, along with the blue eject arrow that matches the arrow on the release lever. A hard stop is felt at this point.



Use fluoroscopic imaging to ensure complete retraction of the Kiva Coil from the vertebral body prior to removing the System.



Once the Kiva Coil Indicator shows the blue eject arrow, deploy the Release Lever to separate handle from distal cartridge. Remove the handle by pulling it straight up - do not twist handle.

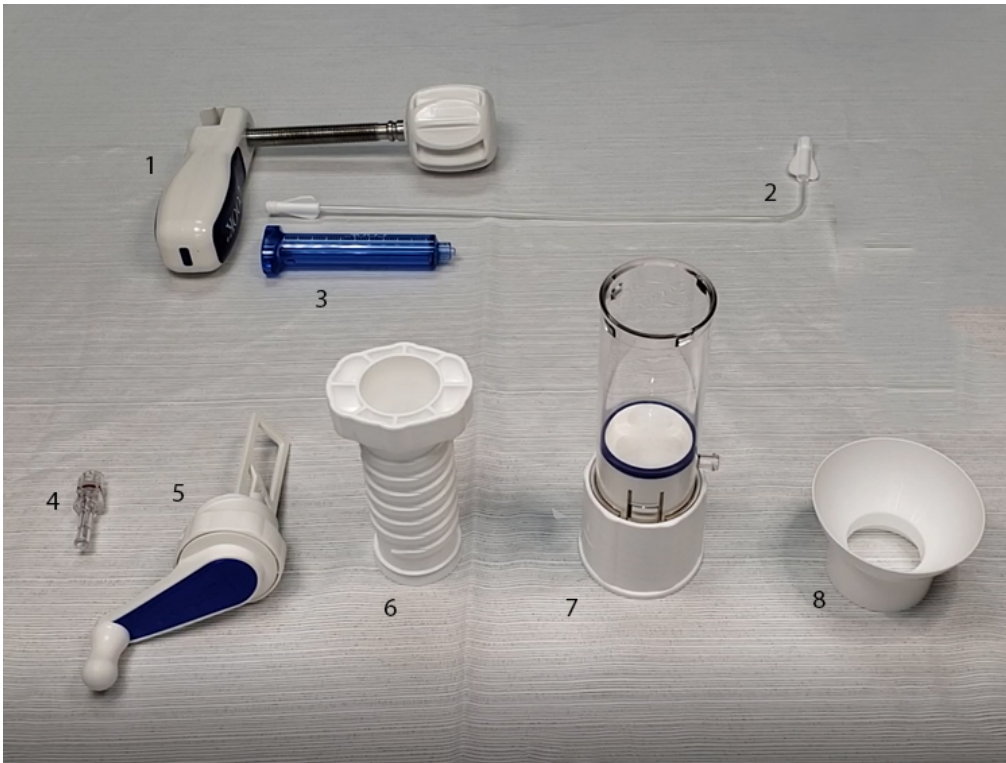


Insert Cement Needle Guide into Distal Cartridge with the word “Cranial” pointing cranially until it docks against the Kiva Implant within the Cartridge.

Break off proximal end of Cement Needle Guide at score mark closest to Distal Cartridge so that it is flush (or near flush) with the hub of the Deployment Cannula.

IZI Medical Vertebral Augmentation Cement Kit

The IZI Medical Vertebral Augmentation Kit is comprised of radiopaque polymethyl methacrylate (PMMA) bone cement and an injection system for use with the Kiva VCF Treatment System.



Mixing and Injection System

1. Cement Injector
2. Extension Tube
3. Syringe Barrel
4. Luer
5. Crank
6. Plunger
7. Mixer
8. Funnel



Bone Cement

1. Powder Pouch
2. Monomer Vial

Cement Working Time

Optimal Mixing Instruction for
Vertefix Plus:

OPTIMAL MIXING AND INJECTING TIMES FOR VERTEFIX® PLUS WITH KIVA®

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

Phase	Running Time
Using provided Funnel, pour all Powder into Mixing System	0'00"
Pour Liquid monomer into Mixing System and start mixing (time starts when liquid touches the powder)	0'00" - 0'40"
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"
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"
Prime the Duroject Extension Tube. Remove dry plug (purge at least 2 inches of cement)	4'00" - 4'30"
Connect UltraFlex Needle to Duroject Extension Tube and prime (purge at least 2 inches of cement)	4'30" - 5'00"
Insert UltraFlex Needle into Working Cannula and start injecting	5'00" - 10'00"

** times may vary with room and device temperature



SCAN FOR INSTRUCTIONAL VIDEO

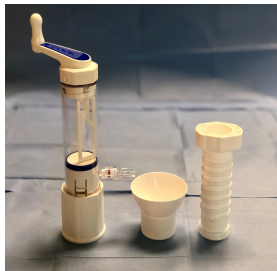
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Cement Mixing Procedure

The Injector



The Mixer



1



2



3

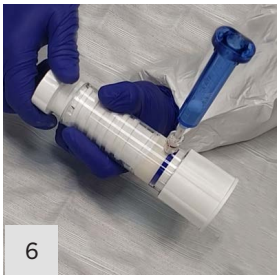


4



5

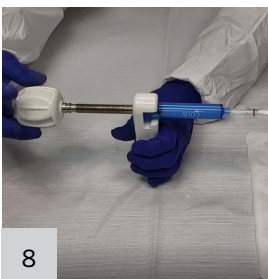
Floor



6



7



8

- 1 Remove the mixing paddle and place the funnel on top on the mixer. Then start to pour the cement powder into the mixer.
- 2 Break open monomer ampule at the top and pour ALL of the liquid into the mixer. Start the timer as soon as the liquid hits the powder.
- 3 Remove funnel and place the mixing paddle on. Start mixing vigorously until the timer hits 30 seconds.
- 4 Remove the existing paddle and replace with plunger. Ensure the plunger does not make contact with the cement yet. Push down a little and twist clockwise to engage the threads on the plunger.
- 5 Connect the luer adapter to the injector on the side of the mixer. Connect the syringe barrel to the adaptor. Lower the floor of the mixer by rotating the bottom part of the mixer counterclockwise.
- 6 Hold the mixer at an angle so cement does not flow back. Rotate the plunger slowly until the cement starts flowing into the syringe barrel. Make sure there are no leaks.
- 7 Disconnect the syringe barrel and luer from the mixer. Connect the extension tube to the luer.
- 8 Push the syringe barrel inside the injector and twist counter-clockwise. Rotate the injector knob clockwise to the prime the tube.

 **TIP**

All monomer must be transferred to mixer to ensure proper cement formulation. Once the monomer has been transferred into powder, do not hold powder container with palm of hand. Body heat will transfer to cement and may shorten its working time.

Cement Mixing Procedure



Attach Flexible Cement Delivery Needle to Extension Table.

Use of the Flexible Cement Needle will provide a more uniform cement flow throughout the Kiva Implant.

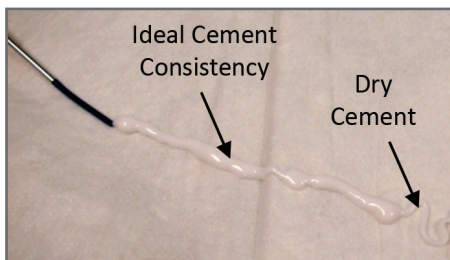


Connect Cement Needle to Extension Tube.



TIP

The tip of the Flexible Cement Needle is fragile and can kink during handling. If the tip kinks, replace with a new Cement Needle for the cement injection.



Rotating the large knob on the Injection Gun clockwise, slowly prime Cement Needle until bone cement is flowing uniformly and ALL dry cement has been expressed out. The cement should appear shiny not dull.

Delivering dry cement into the Kiva Implant may prematurely plug it. If no wet cement can be expressed, the cement has not been mixed properly and should be started over with a fresh kit.

The Cement Needle holds approximately 0.5 cc of bone cement.



TIP

Cement Needle **MUST** be primed prior to insertion into Implant/Deployment Cannula to prevent it from clogging. If the Cement Needle is clogged, it will not allow any or all of the intended cement to be delivered.

Cement Injection



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 snapped in place.

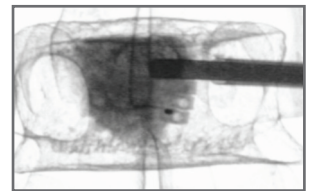
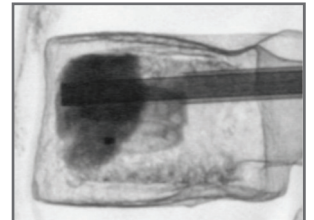
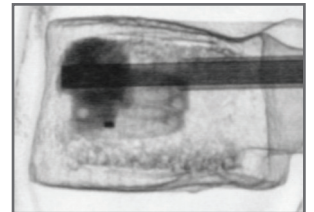
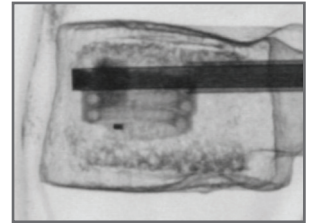


TIP

Verify that all connections to Injection Gun and needle are secure so that they will not separate under pressure during injection.



Deliver Bone Cement by slowly turning the large Cement Injector knob clockwise and monitoring via fluoroscopy. Each turn of the Knob delivers 0.2 cc of cement.

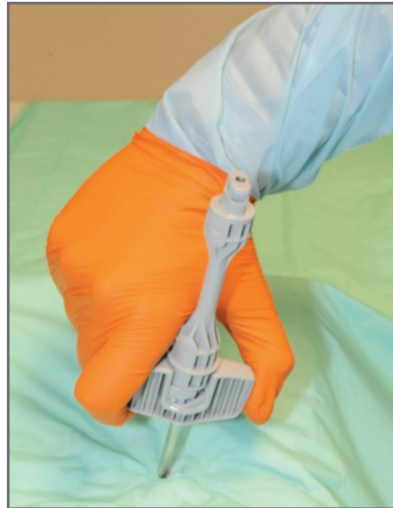


TIP

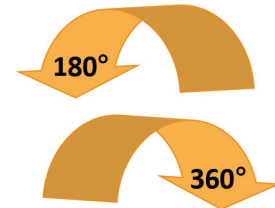
- If you do not see cement flowing into Implant shortly after starting injection, remove the Needle from the patient, and inject cement out of the needle on the back table. If cement is not flowing, switch to the other needle and prime with cement. If cement can be injected, re-insert the needle into the patient and continue injecting.
- If only a small amount of cement has been injected and the system is clogged AND the physician would like to inject more cement, use the Access Needle to deliver cement inside the Kiva Implant stack.



Once the desired amount of bone cement has been delivered, remove the Cement Needle from the Distal Cartridge immediately.



The Kiva Implant is terminated at the point where it exits the Deployment Cannula by rotating both the Working Cannula and Distal Cartridge simultaneously counter clockwise 180° then clockwise 360°.

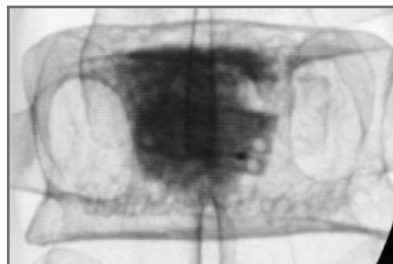
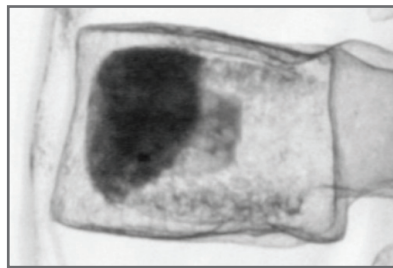


Working Cannula Removal

Remove the Access Cannula and Distal Cartridge from the vertebral body.

If removing the working cannula at the end of the procedure is challenging or difficult, remove the Deployment Cannula and then re-insert the Dilator (there may be some resistance in removing the Deployment Cannula, so use rotary motion). Re-inserting the Dilator will stiffen up the hollow tube, and should make it easier to remove. Tapping on the underside of the working cannula handle helps a great deal.

Follow standard procedures for wound closure.



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-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.
- 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.



VCF Treatment System

ADVERSE EVENTS

Adverse events potentially associated with use of the Kiva VCF Treatment System are the same as other vertebral augmentation procedures. These 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.
- Refer to IZI Medical Vertebral Augmentation Cement Kit “Instructions For Use” for adverse events related to the use of PMMA bone cement.

DISCLAIMER

This document is intended exclusively for physicians and is not intended for laypersons.

Information on the products and procedure contained in this technique guide is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutics statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part. Please refer to the Instructions for Use for each device for important product information, including but not limited to, contraindications, warnings, precautions, and adverse events.



VCF Treatment System



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INDICATIONS FOR USE AND IMPORTANT SAFETY INFORMATION 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 IZI Vertebral Augmentation Cement Kit. As with other vertebral augmentation devices and procedures, there are risks and considerations for use of the Kiva VCF Treatment System. The risks include serious complications up to and including death. Please see the product labeling for a more detailed discussion of risks, contraindications, warnings and precautions. © 2018 IZI Medical Products. All Rights Reserved.

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