Algea therapies

Interventions for Life

AFFIRM®

Vertebral Compression Fracture System

VERTEBRAL AUGMENTATION SURGICAL TECHNIQUE

Algea therapies

A Division of Globus Medical

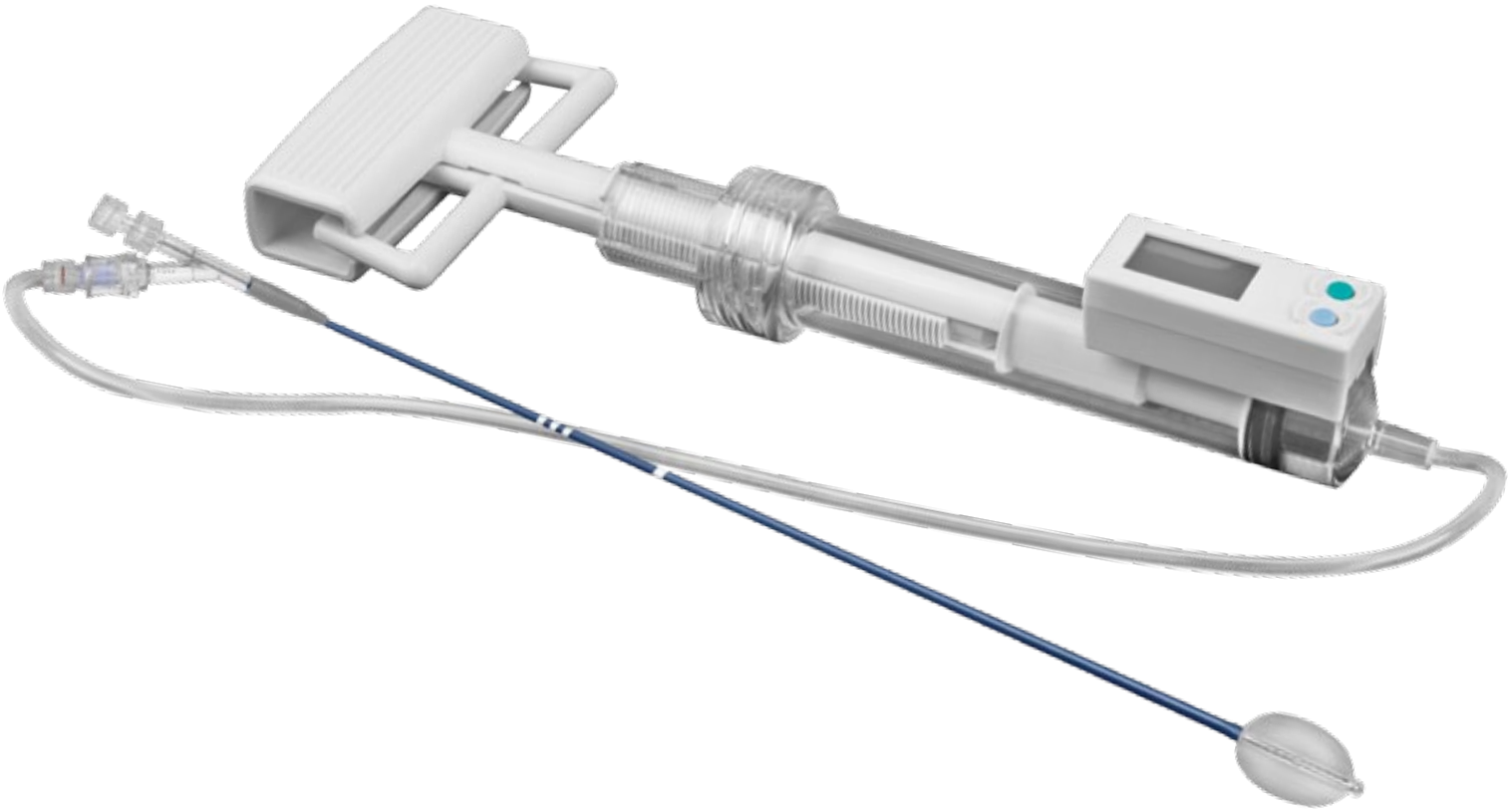
At Algea Therapies, we are committed to finding innovative, minimally invasive solutions to treat back pain and restore quality of life. We realize that swiftly returning patients to active living is one of the most important goals of treatment. Through world-class engineering, exceptional response to physician needs, and collaboration with thought leaders in the field of interventional spine treatment, Algea is advancing patient care by developing therapies that are effective, easy to use, and designed with the patient's quality of life in mind.

Interventions for Life

AFFIRM®

Vertebral Compression Fracture System

Every one of your VCF patients is unique. The AFFIRM® VCF System from Algea Therapies allows you to customize your VCF treatment based on your patients' specific needs, from bone access through cement delivery. AFFIRM® cannulas are designed to insert more easily, dock more securely, and prevent adjacent level interference. AFFIRM® also features a fully adjustable cavity creation tool that can create specialized cavities based on vertebral body size and fracture type. Designed for both vertebroplasty and vertebral augmentation, AFFIRM® is the only system you need to effectively treat your VCF patients.



AFFIRM®

Customized VCF treatment for every patient, every time.

- ### Custom Cavity Creation

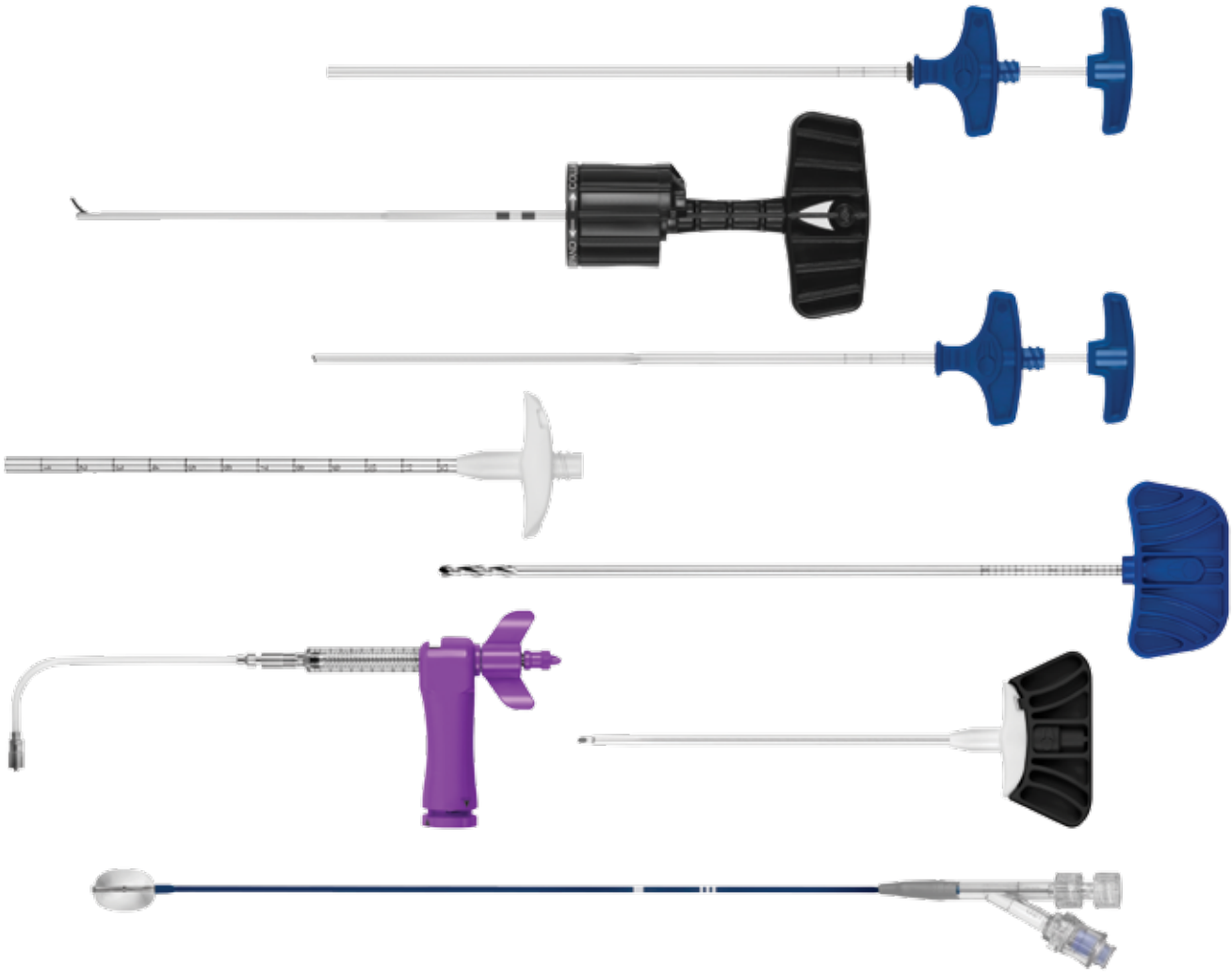
  The fully adjustable AFFIRM® Expanding Scraper easily cuts through high-density cancellous bone to create specialized cavities based on vertebral body size and fracture type.

- ### Intelligent Cannula Design

  AFFIRM® cannulas feature winged pull handles and a threaded cam for ease of removal and a streamlined approach.

- ### An Array of Treatment Options

  Choose from numerous options for access, cavity creation, and cement delivery to create a unique treatment plan for every patient.



Contents

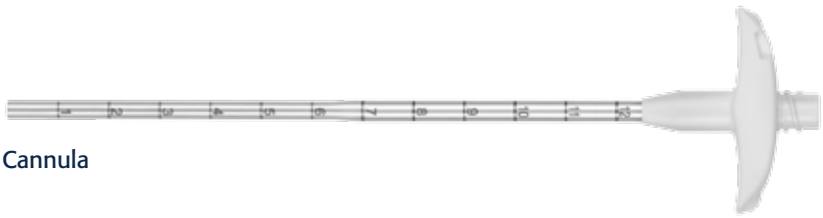
The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Algea directly for more information.

Product Specifications

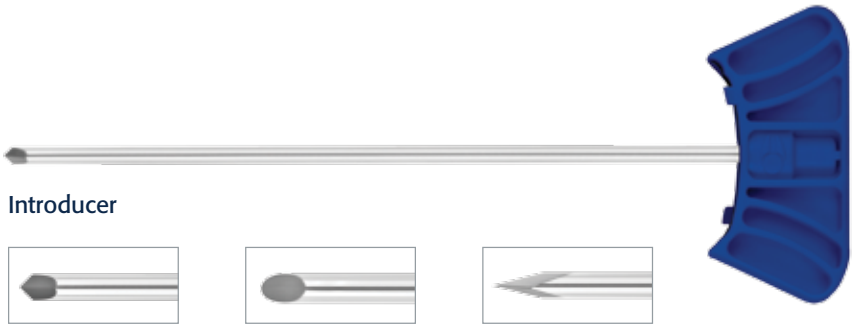
ACCESS

Access Instruments

- Includes Cannulas, Introducers, and Drills
- Ultra (10Ga.)
- Premier (8Ga.)
- Available in packs and singles



Cannula



Introducer

Quad Tip
(blue handle)

Bevel Tip
(black handle)

Trocar Tip
(white handle)

Biopsy Needle

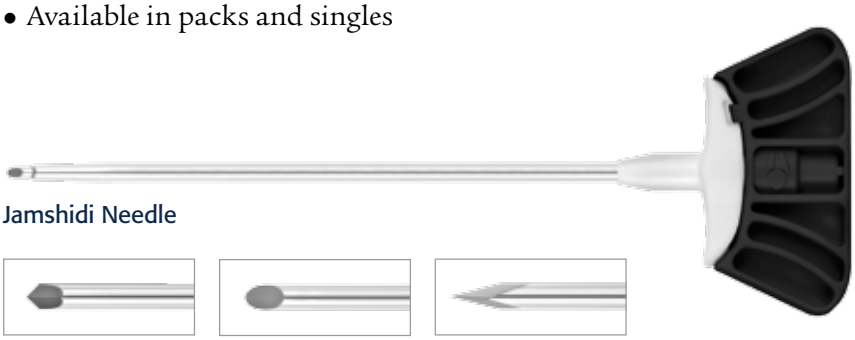
Drill

Product Specifications

ACCESS (cont'd)

Cannulated Access Instruments

- Includes K-Wires, Jamshidi Needles, Cannulas, Introducers, and Drills
- Premier (8Ga.)
- Available in packs and singles



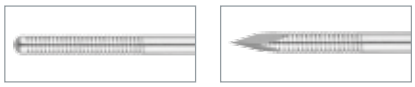
Jamshidi Needle

Quad Tip
(blue handle)

Bevel Tip
(black handle)

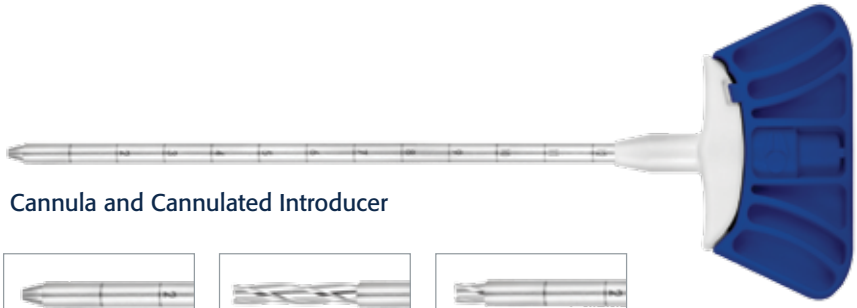
Trocar Tip
(white handle)

K-Wire



Round Tip

Trocar Tip



Cannula and Cannulated Introducer

Blunt Tip
(blue handle)

Drill Tip
(blue handle)

Short Drill Tip
(blue handle)

Drill

Product Specifications

BONE CEMENT

Bone Cement, 20g

- PMMA cement with 30% barium sulfate infusion
- 20g dose
- 5 minute dough time and 10 minute working time at 23°C (73°F)*
- 5 minute set time at normal body temperature

CONCORD™ Bone Cement, 40g

- PMMA cement with 28% barium sulfate
- 40g dose
- 5 minute dough time and 10 minute working time at 23°C (73°F)*
- 5 minute set time at normal body temperature

CONCORD™ HP Bone Cement, 26g

- PMMA cement with 45% zirconium sulfate
- 26g dose
- 4 minute dough time and 15 minute working time at 23°C (73°F)*
- 7 minute set time at normal body temperature

* Dependent on O.R. temperature

Product Specifications

CEMENT MIXING AND DELIVERY

Filler Delivery Needles

- Ultra (10Ga.) includes 8 Filler Delivery Needles with Plungers
- Premier (8Ga.) includes 6 Filler Delivery Needles with Plungers
- Available in packs or singles

Disposable Injection Pack

- Includes Disposable Cement Gun with Disposable Syringe and 12” Extension Tube with rotating luer attachment

Cement Mixing/Injection Packs

Cement Mixer Pack

CONCORD™ Injection Pack with Mixer

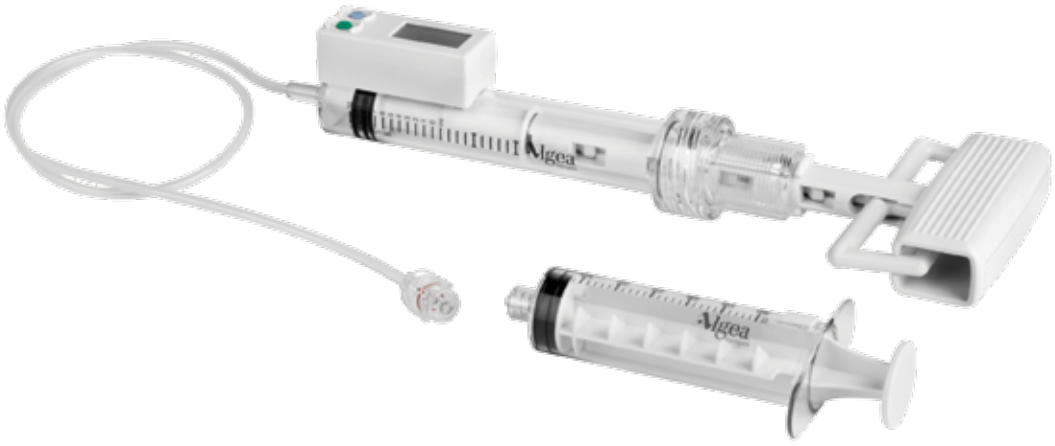
Product Specifications

CAVITY CREATION

Expanding Scraper

- 3.4mm diameter
- Works with both Ultra and Premier instruments
- 8mm maximum cutting radius
- Stainless steel sheath
- Nitinol tip

AFFIRM® Expanding Scraper



AFFIRM® Inflation Device with VacLok® Syringe

Product Specifications

CAVITY CREATION (cont'd)

Inflatable Bone Tamps

Ultra, 10U

Ultra, 15U

Premier, 10P

Premier, 15P

Premier, 20P

Inflatable Bone Tamps, Ultra – For 3.4mm Diameter Working Channel

	10U	15U
Maximum Inflation Volume	4cc ± 0.4cc	5cc ± 0.4cc
Maximum Inflation Pressure	400psi (27ATM)	400psi (27ATM)
Nominal Inflated Diameter	16mm	16mm
Nominal Inflated Length	20mm	28mm

Inflatable Bone Tamps, Premier – For 4.22mm Diameter Working Channel

	10P	15P	20P
Maximum Inflation Volume	4cc ± 0.4cc	4cc ± 0.4cc	6cc ± 0.4cc
Maximum Inflation Pressure	400psi (27ATM)	400psi (27ATM)	400psi (27ATM)
Nominal Inflated Diameter	17mm	16mm	17mm
Nominal Inflated Length	20mm	22mm	30mm

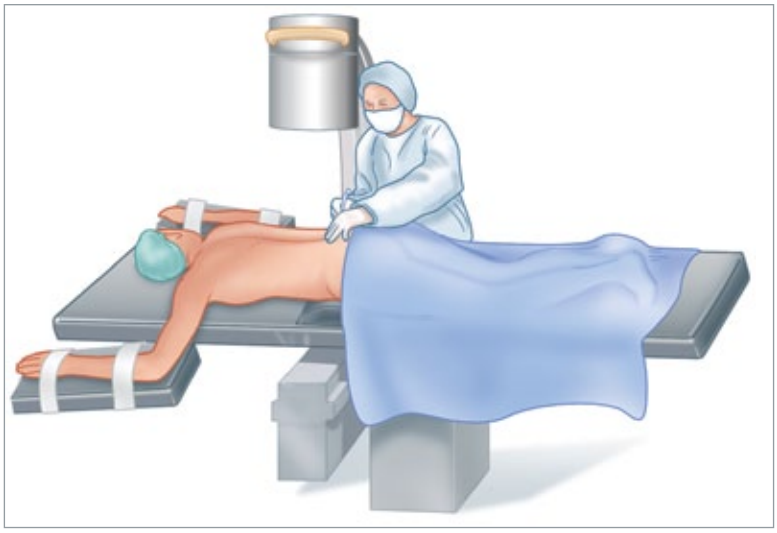
AFFIRM® VCF System
Surgical Technique

Step 1. Approach and Instrument Selection

Place the patient under local or general anesthesia in a prone position. Carefully clean the operative area and use a scalpel to make an incision at the appropriate vertebral level(s). If planning height restoration, find the closest normal vertebral bodies above and below the treatment area and note their heights for reference.

Using the patient's anatomy as a guide, select the appropriate AFFIRM® instruments to be used — Premier (8Ga.) or Ultra (10Ga.).

Note: Height restoration may not be achieved in chronic fractures.[1]



Patient Positioning

Step 2. Bone Access

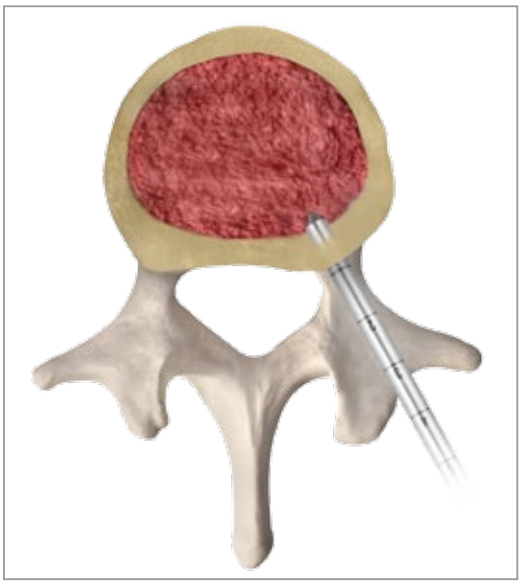
There are two possible approaches for bone access: transpedicular and extrapedicular. This surgical technique guide describes a transpedicular approach.

1. Crandall D, Slaughter D, Hankins PJ, Moore C, Jerman J. *Acute versus chronic vertebral compression fractures treated with kyphoplasty: early results.* Spine Journal. 2004 Jul-Aug; 4(4):418-24.

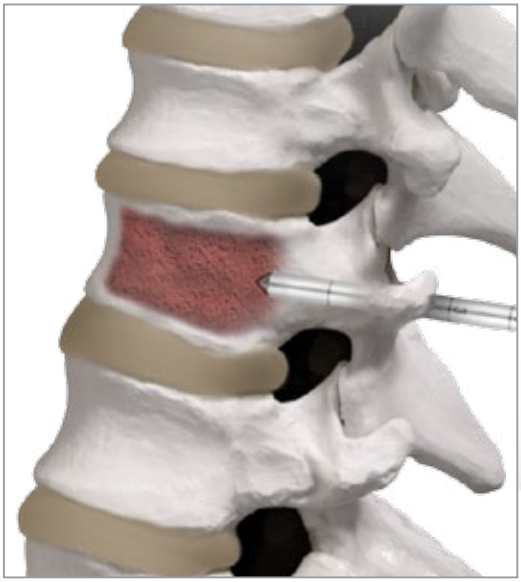
Option A: Non-Cannulated Access — Premier or Ultra

Insert an **Introducer** through its corresponding **Cannula** and advance both instruments through the soft tissue into the pedicle of the selected vertebra. Use fluoroscopic guidance to confirm that the tips of the Cannula and Introducer are positioned just past the pedicle and inside the vertebral body.

Repeat these steps and use additional cannulae as needed for multiple levels.



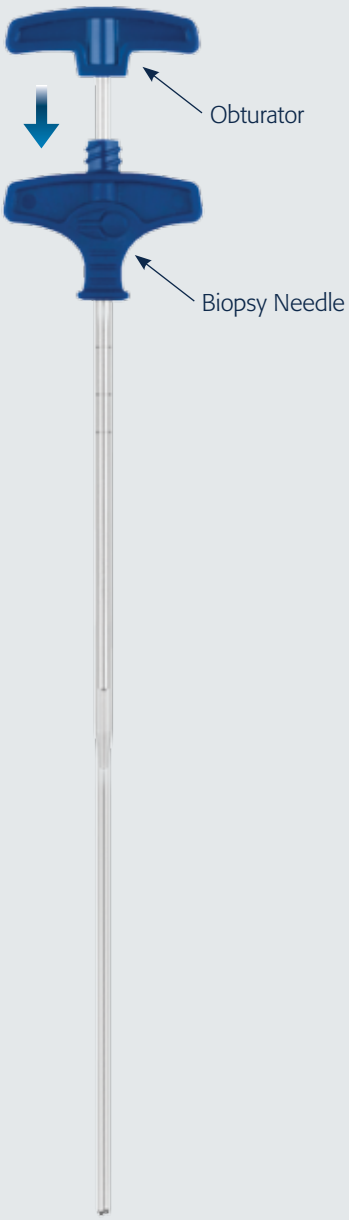
Inserting the Introducer — Axial View



Inserting the Introducer — Sagittal View

Biopsy Collection

Separate the **Obturator** from the **Biopsy Needle**. Insert the needle through the Cannula into the vertebra under fluoroscopic guidance and rotate the handle clockwise for tissue collection. Remove the needle once tissue collection is complete. Push the Obturator through the needle to expel the tissue sample from the needle.

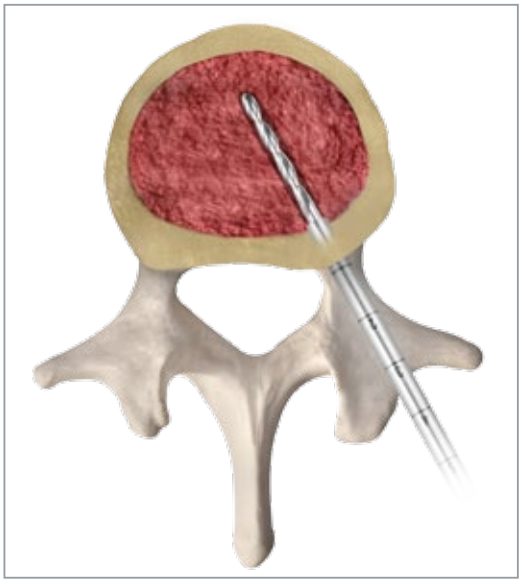


Remove the Introducer from the Cannula by rotating it counterclockwise and pulling upward, leaving the Cannula in the vertebra.

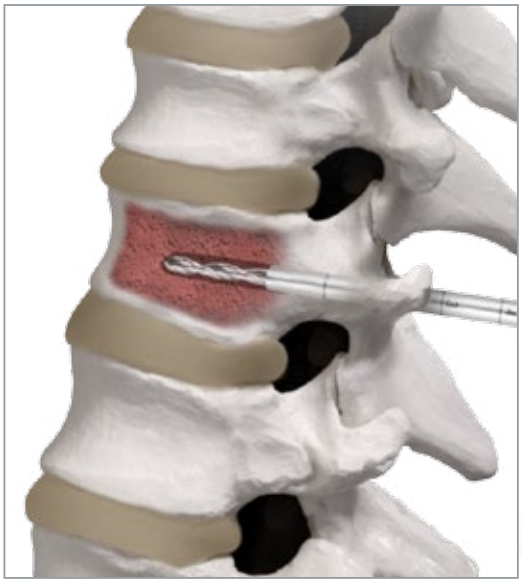
Removing the Introducer

If desired, perform biopsy collection (as shown at left) at this point in the procedure.

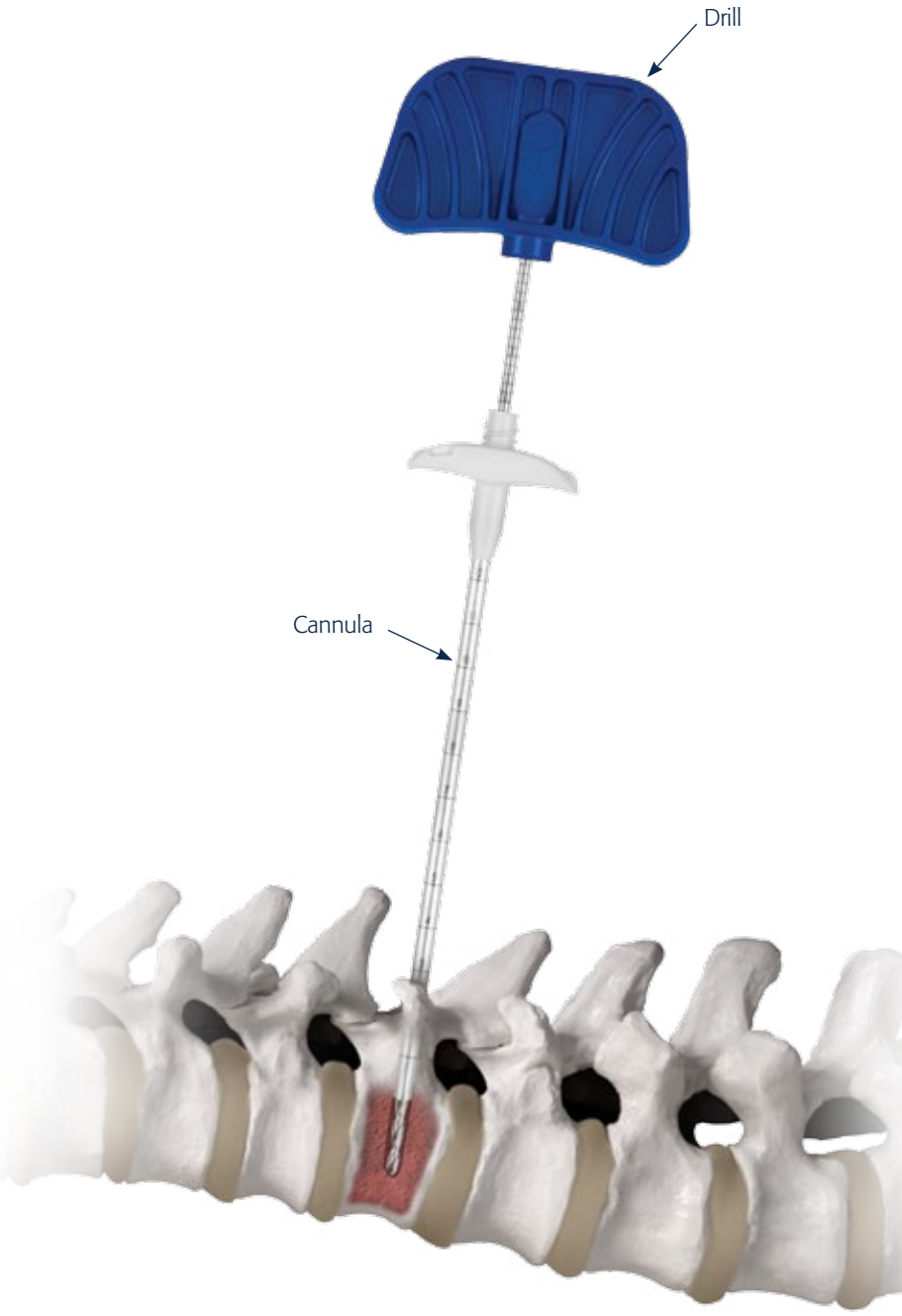
Insert the **Drill** through the Cannula and twist continuously in a clockwise direction under fluoroscopic guidance to advance the access channel. If necessary, the Drill can be repositioned by backing out and reinserting at a different angle. Once the length and trajectory of the channel are acceptable, remove the Drill from the Cannula.



Drilling the channel — Axial View



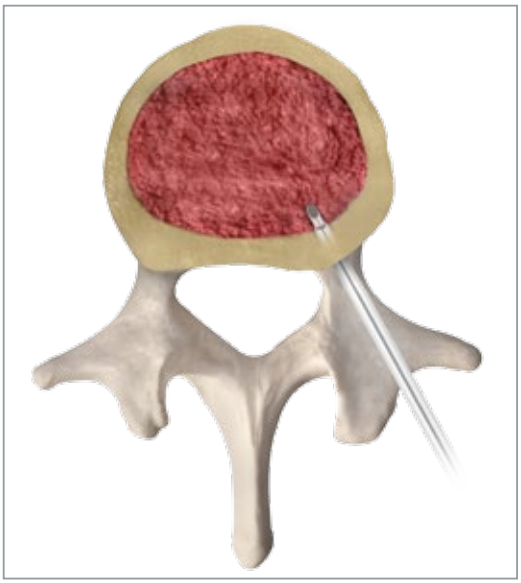
Drilling the channel — Sagittal View



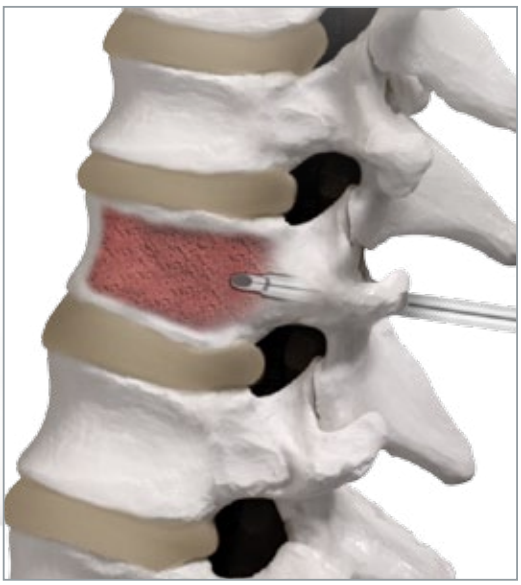
Option B: Cannulated Access — Premier Only

Insert a **Jamshidi Needle, Bevel Tip, Premier** through the soft tissue into the pedicle of the selected vertebra. Use fluoroscopic guidance to confirm that the tip of the needle has moved just past the pedicle into the vertebral body. Upon reaching the desired depth, remove the needle from the Jamshidi Cannula by rotating the black handle and pulling upwards.

Place a **K-Wire** through the Jamshidi Cannula into the vertebra using fluoroscopic guidance.



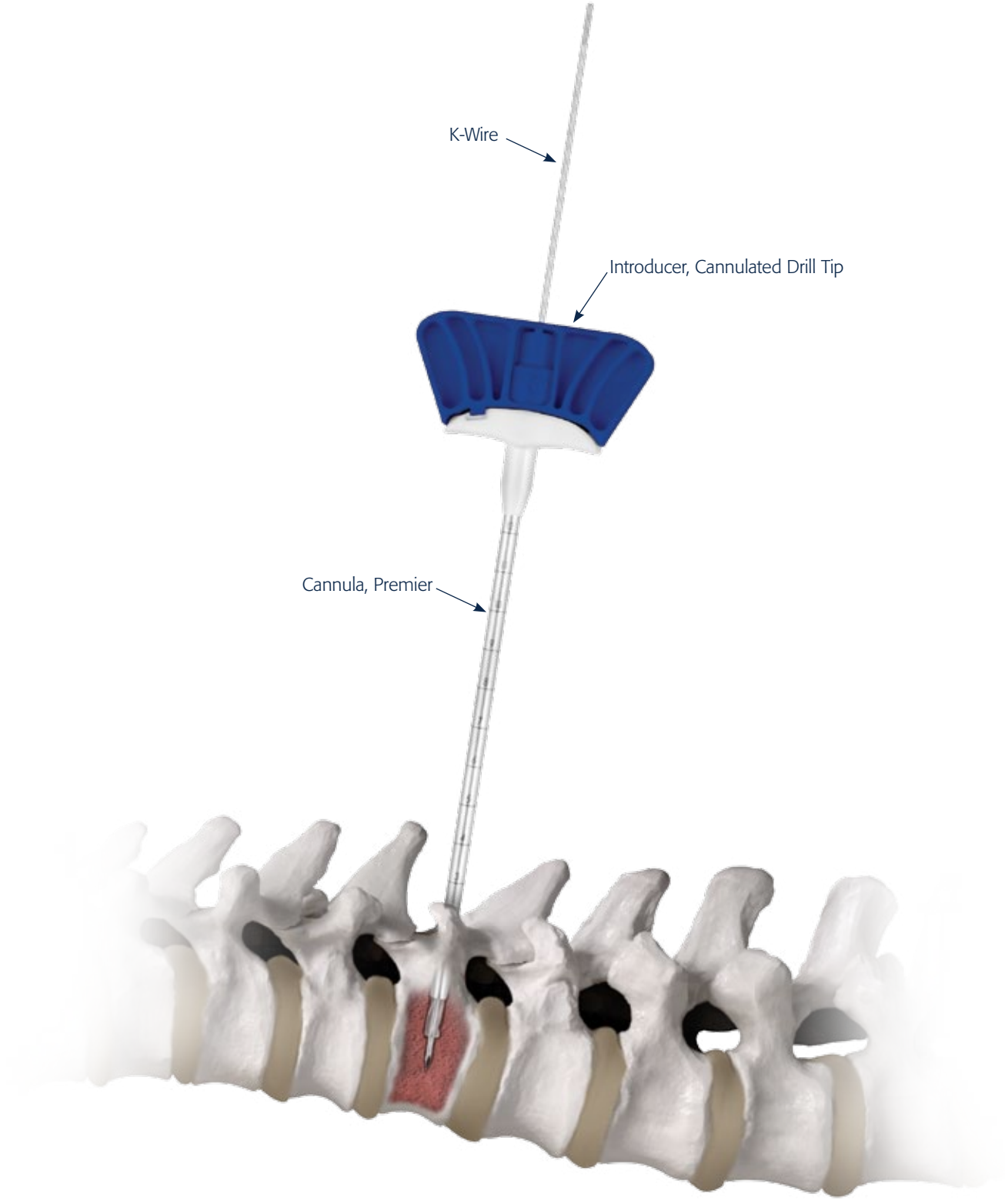
Inserting the Jamshidi Needle — Axial View



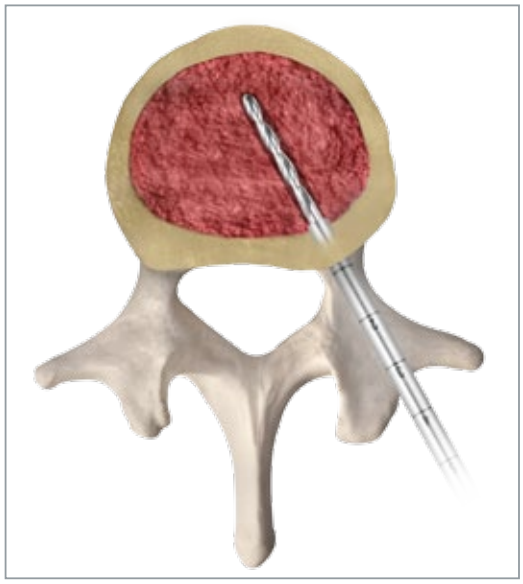
Inserting the Jamshidi Needle — Sagittal View

Remove the Jamshidi Cannula and place the assembled **Introducer, Cannulated Drill Tip, Premier** and **Cannula, Premier** over the K-Wire. Rotate the introducer handle clockwise to advance further into the vertebra using fluoroscopic guidance. Upon reaching the desired depth, remove the introducer and the K-Wire.

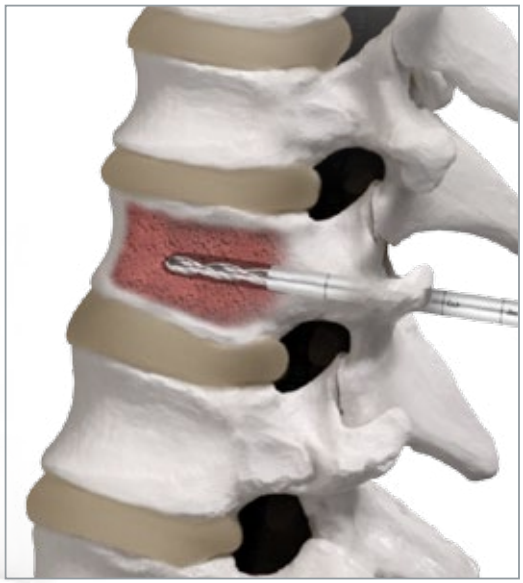
Repeat these steps and use additional cannulae as needed for multiple levels.



Insert the **Drill, Premier** through the cannula and rotate continuously in a clockwise direction under fluoroscopic guidance to advance the access channel. If necessary, the drill can be repositioned by backing out and reinserting at a different angle. Once the length and trajectory of the channel are acceptable, remove the drill from the cannula.



Drilling the channel — Axial View



Drilling the channel — Sagittal View

Step 3. Cavity Creation

Option A: Expanding Scraper

Insert the **Expanding Scraper** through the Cannula and advance it to the desired depth under fluoroscopic guidance. Holding the T-handle stationary, slowly rotate the black knob to control the expansion and retraction of the scraper tip inside the vertebral body, expanding the cutting tip incrementally.

Using fluoroscopic guidance, create a suitable cavity for cement injection. Create the cavity as the cutting tip is incrementally advanced. Do not advance if there is substantial resistance within the bone. If resistance is felt, reduce the radius of the cutting tip by adjusting the black knob and create the cavity.

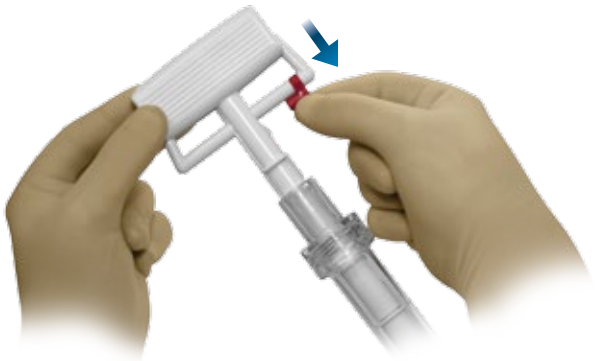
After creating the desired cavity, slowly rotate the black knob on the T-handle clockwise until it stops to retract the scraper tip. Carefully pull the scraper out of the cannula under fluoroscopic guidance.

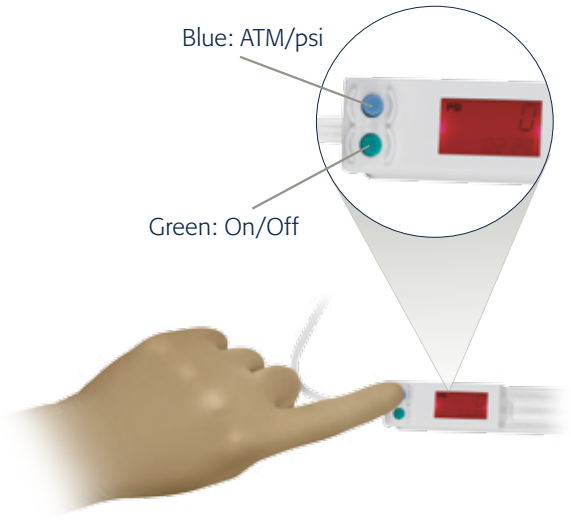
Rotating the black knob to control the Expanding Scraper tip

Option B: Inflatable Bone Tamp

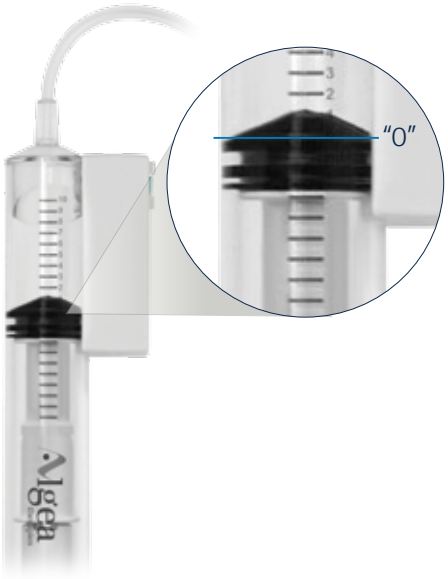
Select an appropriately sized **Inflatable Bone Tamp**. Use the **Inflation Device with VacLok® Syringe** to prepare the Inflatable Bone Tamp as follows:

Remove the red tab from the inflation device, turn on the pressure gauge, and change the display from ATM to psi units.

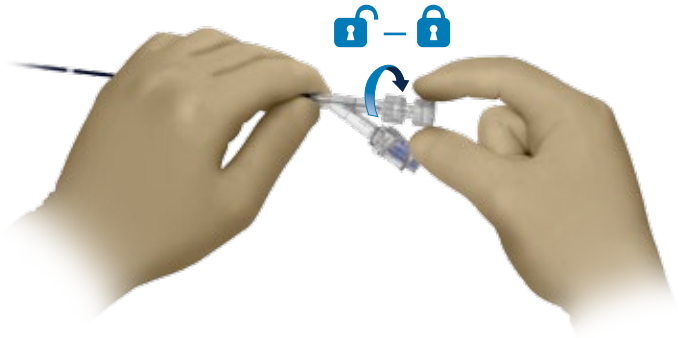




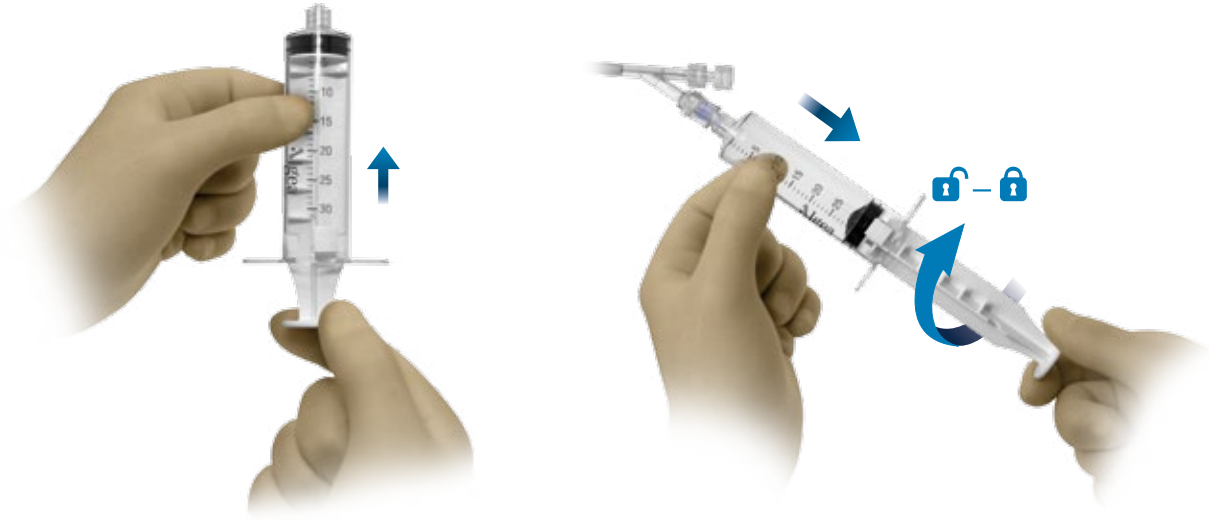
Fill the inflation device with contrast medium. Align the inflation device plunger with the zero on the barrel and remove all air bubbles from inside the barrel and the tubing.



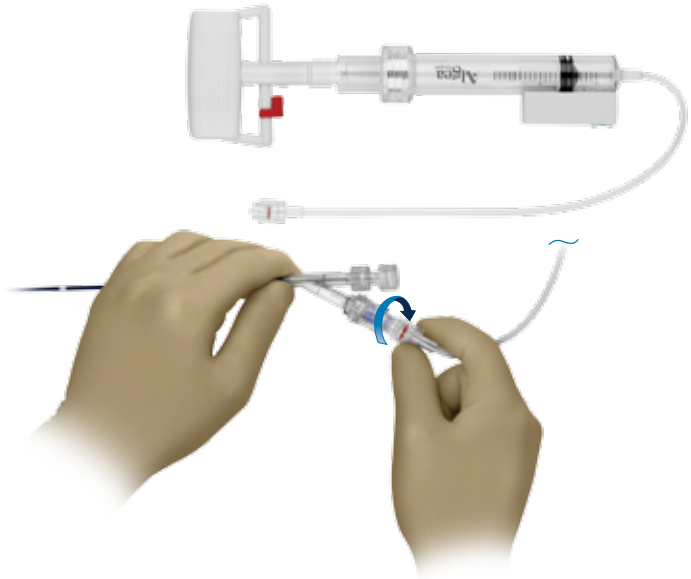
Tighten the stylet into the bone tamp and confirm that it is locked in place.



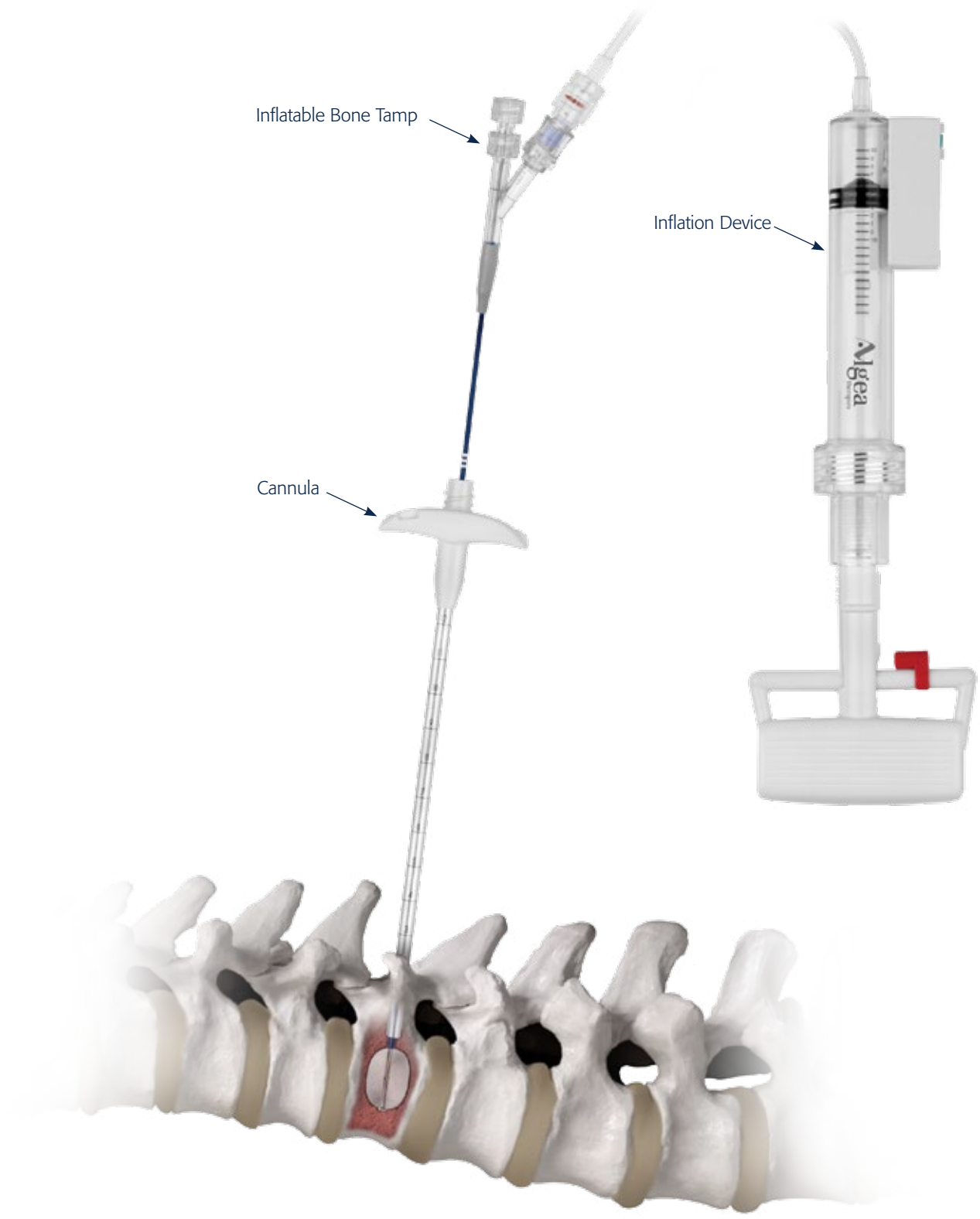
Push the VacLok® Syringe plunger fully into the barrel. Attach the VacLok® Syringe to the open port on the bone tamp, then pull the VacLok® Syringe plunger back and rotate it clockwise to lock the vacuum. Repeat this step as needed to remove all air from the bone tamp.



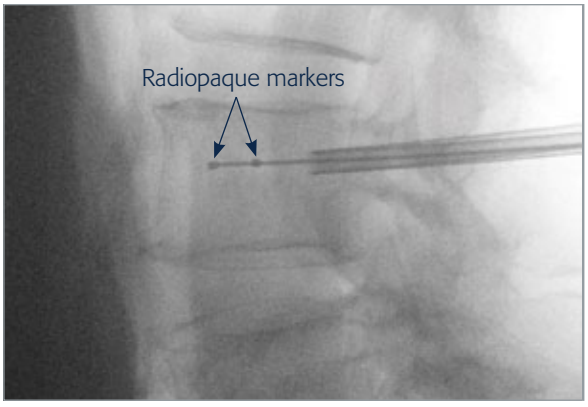
Once all air is removed from the bone tamp, remove the VacLok® Syringe and attach the inflation device to the vacated port.



Place the bone tamp through the Cannula into the vertebra and advance it to the desired depth under fluoroscopic guidance.



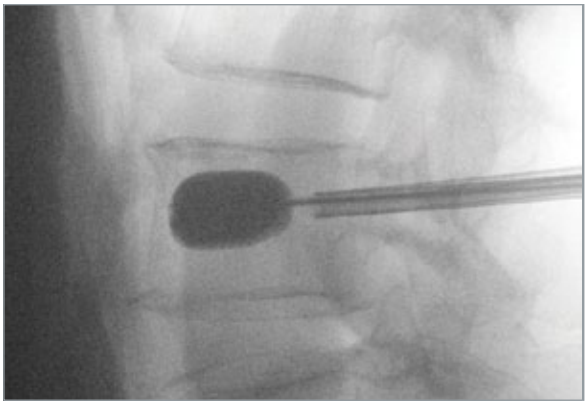
Verify the location of the bone tamp by identifying the radiopaque markers at both ends of the balloon under fluoroscopy, as shown below.



Appearance under fluoroscopy — uninflated

Slowly inflate the bone tamp (as described at right). Take A/P and lateral fluoroscopy images every 0.5cc to confirm progress until achieving the desired inflation volume. Inflate no more than the maximum volume of the selected balloon.

Note: Be careful not to perforate any cortical bone surfaces.



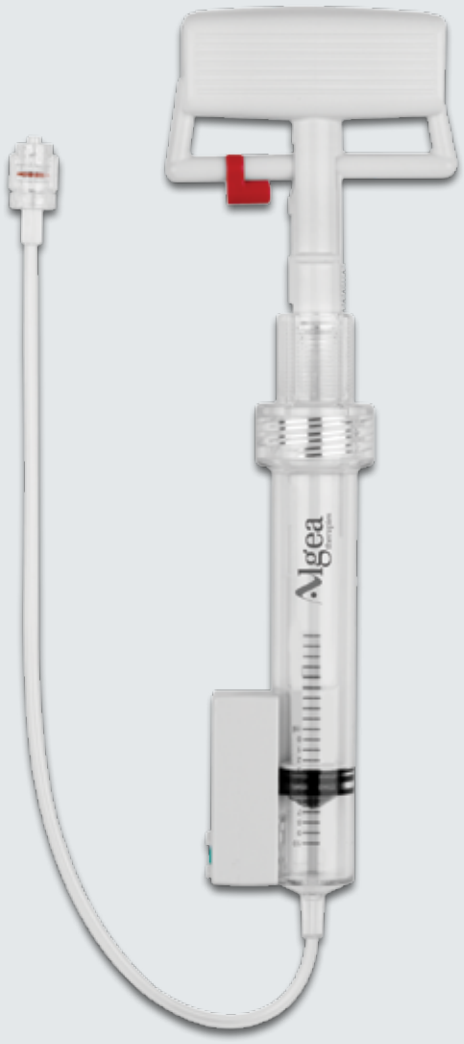
Appearance under fluoroscopy — inflated

After safely achieving the desired balloon inflation, leave the bone tamp inflated for 3-5 minutes to help slow any intracancellous bleeding.

When ready, deflate the bone tamp by compressing the handle of the inflation device and pulling it all the way back. Remove the bone tamp from the vertebra by slowly pulling it back through the Cannula under fluoroscopic guidance.

Inflating the Inflatable Bone Tamp

When using the inflation device to inflate the bone tamp, each 360° clockwise rotation of the inflation device handle will deliver approximately 0.5cc of fluid to the balloon.



Step 4. Cement Delivery

Prepare the **Bone Cement** by mixing together the liquid and powder components according to the Bone Cement Instructions for Use. If desired, cement may be mixed using the **Cement Mixer** as per the Cement Mixer Instructions for Use.

CAUTION: Injection of polymethylmethacrylate bone cement into the vertebral body is associated with a low but documented risk of certain severe or life-threatening complications. Please see the Bone Cement Instructions for Use for further information.

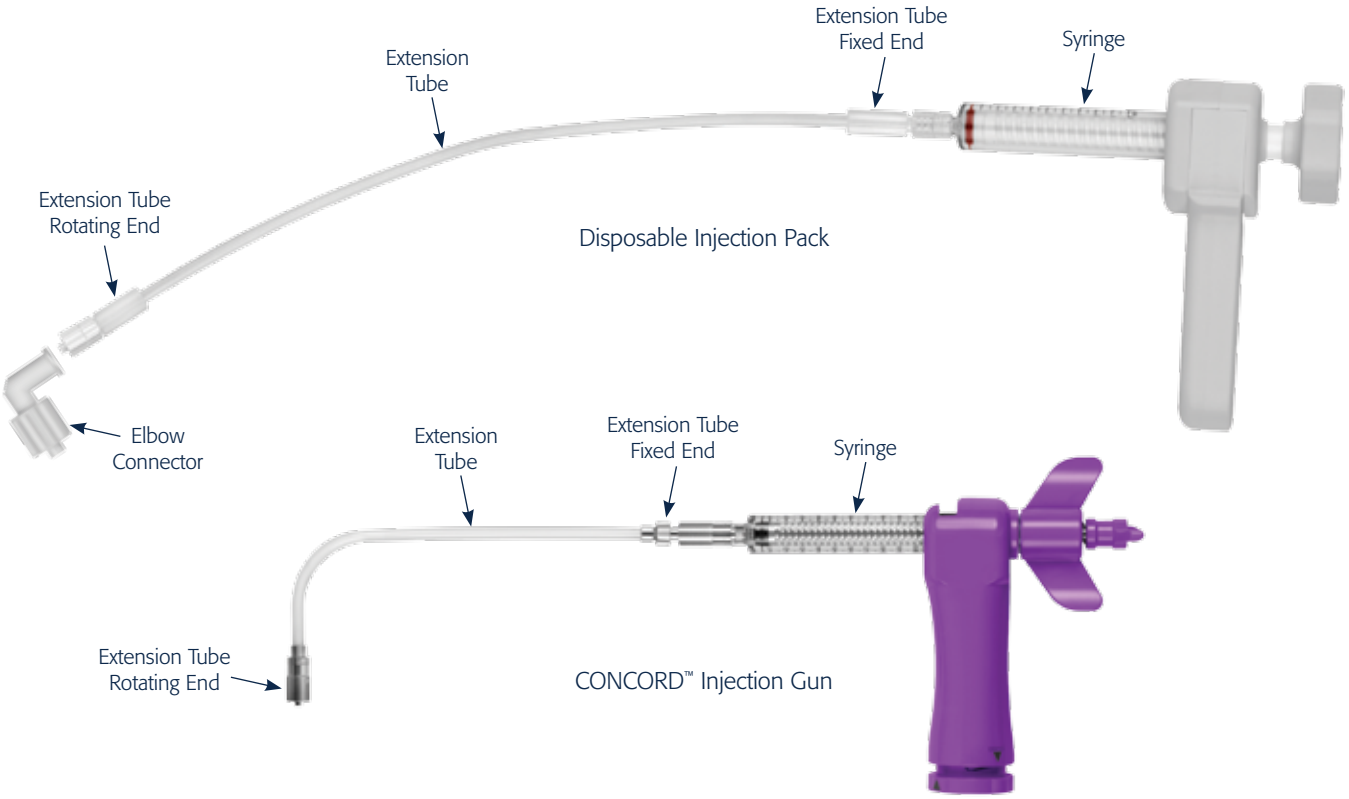
Option A: Cement Gun

Select the **AFFIRM® Cement Injection Pack** or the **CONCORD™ Cement Injection Pack**. Attach the injection gun to the cement mixer and load cement into the syringe. Proceed according to the respective instruction for use.

Loading cement into the Disposable Cement Gun

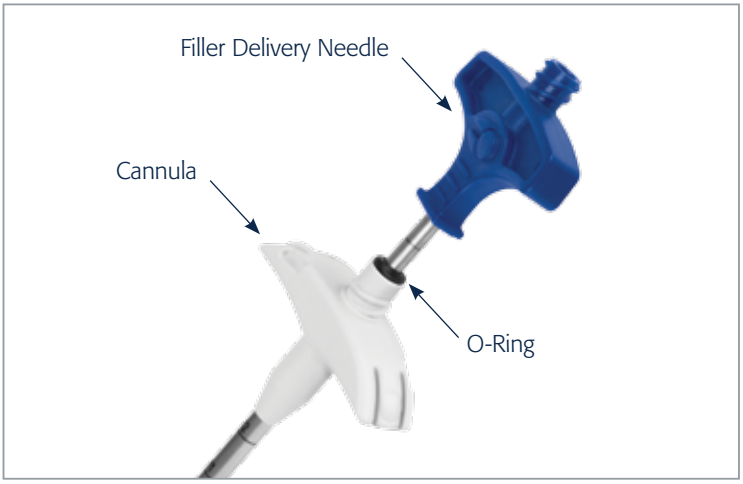
Loading cement into the CONCORD™ Injection Gun

Connect the fixed end of the Extension Tube to the Syringe. Attach the rotating end of the tube to the luer connection on the **Filler Delivery Needle** to deliver cement. If desired, use the Elbow Connector to attach the tube to the luer connection on the needle.



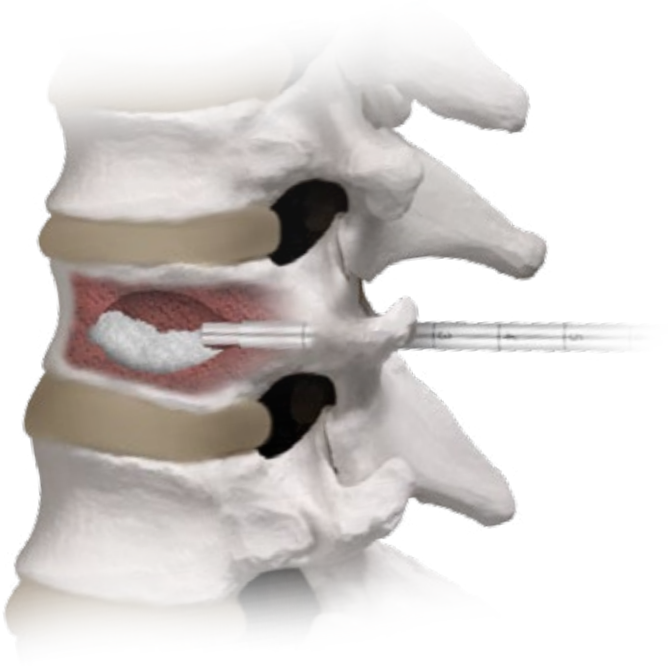
Rotate the Syringe plunger clockwise to expel air from, and inject cement into, the tube and the needle. Ensure that all air is expelled by allowing a few drops of cement to drip from the tip of the needle.

Advance the needle through the Cannula to the desired depth using fluoroscopic guidance. Use the O-Ring to keep the needle in place.



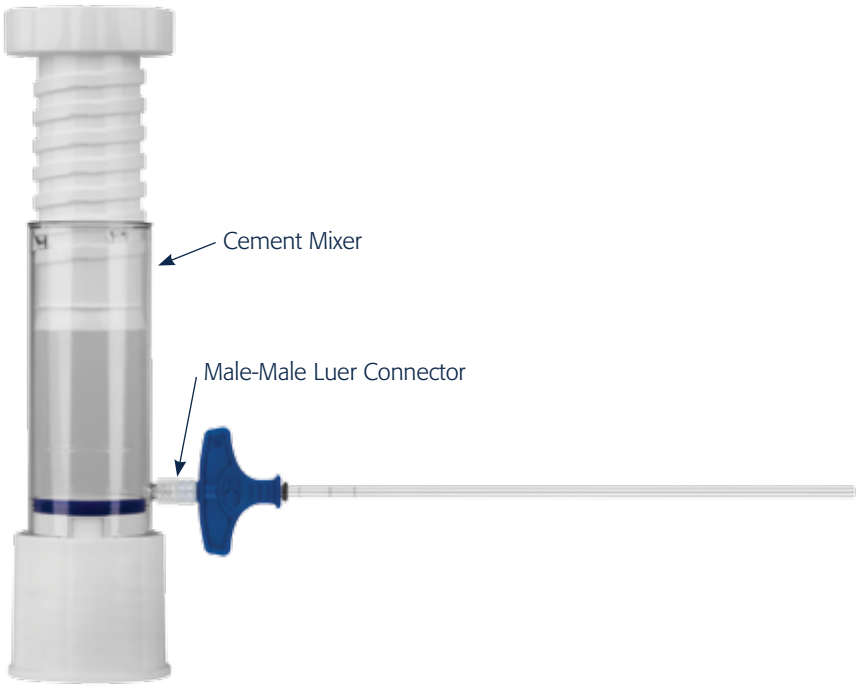
Deliver cement into the vertebra by rotating the Syringe plunger clockwise under fluoroscopic guidance. Once the desired amount of cement has been injected, detach the cement gun from the tube and allow the cement to fully cure. The Bone Cement Instructions for Use provide guidance on adequate curing time.

While the cement is curing, periodically rotate the instruments and the Cannula in order to keep them from adhering to the cement. After confirming that the cement is fully cured, remove the instruments and the Cannula under fluoroscopic guidance.



Option B: Cement Needle

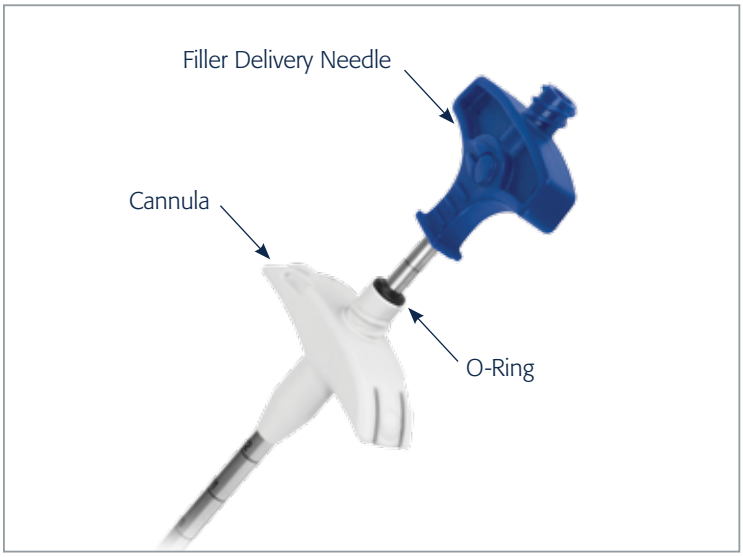
Load the Filler Delivery Needle or syringe with Bone Cement. If desired, repeat this step to load multiple needles or syringes with cement. After the syringe has been filled, connect the Filler Delivery Needle to the syringe.



Loading Filler Delivery Needle with Bone Cement

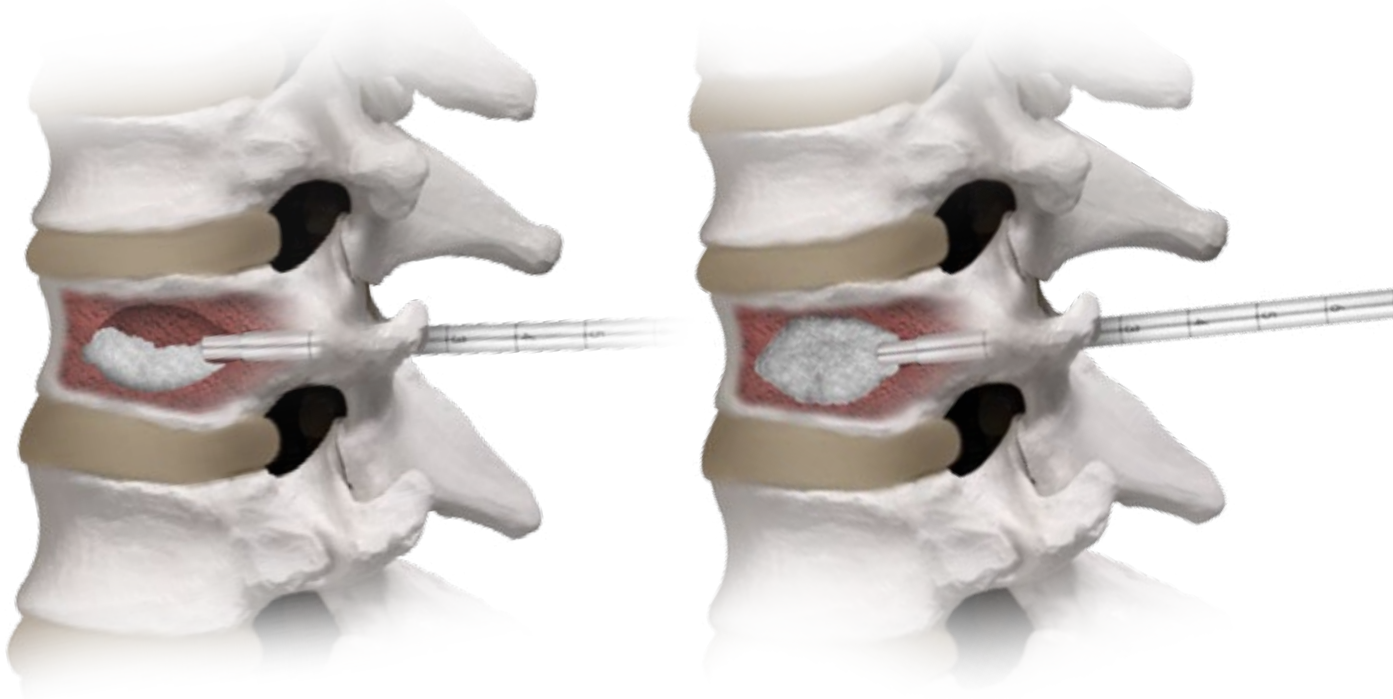
Loading syringe with Bone Cement

Advance the needle through the Cannula to the desired depth under fluoroscopic guidance. Use the O-Ring to keep the needle in place.



Deliver Bone Cement into the vertebra under fluoroscopic guidance. Once the desired amount of cement has been injected, allow it to fully cure. The Bone Cement Instructions for Use provide guidance on adequate curing time.

While the cement is curing, periodically rotate the needle and the Cannula in order to keep it from adhering to the cement. After confirming that the cement is fully cured, remove the needle and the Cannula under fluoroscopic guidance.



AFFIRM®

VERTEBRAL COMPRESSION FRACTURE SYSTEM

The AFFIRM® VCF system from Algea Therapies creates a unique treatment plan for every patient, every time.

Ideal for both vertebroplasty and vertebral augmentation, AFFIRM® offers numerous options for access, cavity creation and cement delivery.

AFFIRM®'s modular packaging can help control costs by minimizing wasted instruments.

Items are available in procedural kits and individual component packs. Simply choose the kit and/or components needed for each unique case to customize treatment and minimize costs.

To order, contact Algea Therapies customer service at 855.639.6612
www.AlgeaTherapies.com

ORDERING GUIDE

Bone Cement & Mixing

458.691S **Bone Cement, 20g**

4129.4000S **CONCORD™ Bone Cement, 40g**

458.693S **CONCORD™ HP Bone Cement, 26g**

658.919S **Cement Mixer Pack**
Includes: Mixer, 40g (1)
Funnel (1)
Ventilation Tube (1)
Spatula (1)
Mixer Plunger (1)

658.913S **CONCORD™ Cement Mixer Pack**
Includes: Syringe (5)
Mixing Tube (1)
Mixing Ball (1)

658.5001S **PLEXIS™ Cement Injector**
Includes: Mixer (1)
Extension Tube (1)

VCF Kits

658.920S **Premier, 10P**
658.921S **Premier, 15P**
658.922S **Premier, 20P**
Includes: Cannula (2)
Cannula Introducer, Trocar Tip (1)
Cannula Introducer, Quad Tip (1)
Drill (1)
Filler Delivery Needle (6)
Inflation Device (2)
Inflatable Bone Tamp (2)

658.923S **Ultra, 10U**
658.924S **Ultra, 15U**
Includes: Cannula (2)
Cannula Introducer, Bevel Tip (1)
Cannula Introducer, Quad Tip (1)
Drill (1)
Filler Delivery Needle (8)
Inflation Device (2)
Inflatable Bone Tamp (2)

Cannulated Access Kits

658.932S **Premier, 10P**
658.933S **Premier, 15P**
658.934S **Premier, 20P**
Includes: Cannula (2)
Inflatable Bone Tamp (2)
Filler Delivery Needle (6)
K-Wire, Trocar Tip (2)
K-Wire, Round Tip (2)
Jamshidi Needle, Quad Tip (1)
Jamshidi Needle, Bevel Tip (1)
Cannulated Introducer, Short Drill Tip (1)
Cannulated Introducer, Blunt Tip (1)
Drill (1)
Inflation Device (1)

Additional Level Fracture Kits

Premier, 10P (658.926S)
Premier, 15P (658.927S)
Premier, 20P (658.928S)
Includes: Cannula (2)
Inflatable Bone Tamp (2)
Filler Delivery Needle (6)

Ultra, 10U (658.929S)
Ultra, 15U (658.930S)
Includes: Cannula (2)
Inflatable Bone Tamp (2)
Filler Delivery Needle (8)

To order, contact Algea Therapies customer service at 855.639.6612
www.AlgeaTherapies.com

ORDERING GUIDE

Cannula Packs

958.015S **Premier**
958.111S **Ultra**
Includes: Cannula (2)

Inflatable Bone Tamp Packs

958.301S **Premier, 10P**
958.302S **Premier, 15P**
958.303S **Premier, 20P**
958.351S **Ultra, 10U**
958.352S **Ultra, 15U**
Includes: Inflatable Bone Tamp (2)

Extension Delivery Pack

658.912S **Extension Delivery Pack**
Includes: Extension Tube (1)
Syringe (1)
Elbow (1)

Filler Delivery & Injection Packs

658.601S **Premier**
Includes: Filler Delivery Needle (6)

658.914S **Ultra**
Includes: Filler Delivery Needle (8)

658.917S **Cement Injection Pack**
Includes: Gun with Syringe (1)
Extension Tube (1)
Elbow (1)

658.916S **CONCORD™ Cement Injection Pack**
Includes: Mixing Tube (1)
Mixing Ball (1)
Gun with Syringe (1)
Extension Tube (1)

Access Packs

658.901S **Premier**
Includes: Cannula (2)
Cannula Introducer, Quad Tip (1)
Cannula Introducer, Trocar Tip (1)
Drill (1)

658.902S **Ultra**
Includes: Cannula (2)
Cannula Introducer, Quad Tip (1)
Cannula Introducer, Bevel Tip (1)
Drill (1)

658.903S **Cannulated**
Includes: K-Wire, Trocar Tip (2)
K-Wire, Round Tip (2)
Jamshidi Needle, Quad and Bevel Tip (2)
Cannula (2)
Cannulated Introducer, Short Drill Tip (1)
Cannulated Introducer, Blunt Tip (1)
Drill (1)

To order, contact Algea Therapies customer service at 855.639.6612
www.AlgeaTherapies.com

ORDERING GUIDE

Premier Components

658.501S	AFFIRM® Cannula, Premier (1)
658.502S	AFFIRM® Cannula & Introducer, Trocar Tip, Premier (1)
658.503S	AFFIRM® Cannula & Introducer, Bevel Tip, Premier (1)
658.507S	AFFIRM® Drill, Premier (1)
658.509S	AFFIRM® Filler Delivery Device, Premier (1)
658.511S	AFFIRM® Cannula & Introducer, Quad Tip, Premier (1)
658.514S	AFFIRM® Cannula & Cannulated Introducer, Blunt Tip, Premier (1)
658.515S	AFFIRM® Cannula & Cannulated Introducer, Drill Tip, Premier (1)
658.521S	AFFIRM® Inflatable Bone Tamp, Premier, 10P (1)
658.522S	AFFIRM® Inflatable Bone Tamp, Premier, 15P (1)
658.523S	AFFIRM® Inflatable Bone Tamp, Premier, 20P (1)

Ultra Components

658.504S	AFFIRM® Cannula, Ultra (1)
658.505S	AFFIRM® Cannula & Introducer, Trocar Tip, Ultra (1)
658.506S	AFFIRM® Cannula & Introducer, Bevel Tip, Ultra (1)
658.508S	AFFIRM® Drill, Ultra (1)
658.510S	AFFIRM® Filler Delivery Device, Ultra (1)
658.512S	AFFIRM® Cannula & Introducer, Quad Tip, Ultra (1)
658.524S	AFFIRM® Inflatable Bone Tamp, Ultra, 10U (1)
658.525S	AFFIRM® Inflatable Bone Tamp, Ultra, 15U (1)
658.610	AFFIRM® Inflatable Bone Tamp, 10U, Steerable (1)
658.615	AFFIRM® Inflatable Bone Tamp, 15U, Steerable (1)

Miscellaneous Components

658.114S	Biopsy Needle, 11Ga. (1)
658.116S	Biopsy Needle, 9Ga. (1)
658.216S	AFFIRM® Expanding Scraper (1)
658.513S	AFFIRM® Jamshidi Needle, Quad Tip (1)
658.517S	AFFIRM® Jamshidi Needle, Bevel Tip (1)
658.518S	AFFIRM® Jamshidi Needle, Trocar Tip (1)
658.519S	AFFIRM® K-Wires (Trocar tip and Round Tip) (2)
658.909S	AFFIRM® Inflation Device (1)

To order, contact Algea Therapies customer service at 855.639.6612
www.AlgeaTherapies.com

Important Information on the AFFIRM® VCF SYSTEM – Inflatable Bone Tamp

DESCRIPTION

The AFFIRM® Inflatable Bone Tamp is a bone tamp with an inflatable balloon attached to the distal end, designed to create a void in cancellous bone. The Inflatable Bone Tamp is a sterile, single-use device manufactured from polyurethane.

INDICATIONS

The AFFIRM® VCF System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. Vertebral compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery include:

- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae;
- Rupture with fragmentation of the inflatable portion of the IBT resulting in retention of a fragment within the vertebral body;
- Rupture of the IBT causing contrast medium exposure, possibility resulting in an allergic reaction or anaphylaxis;
- For a transpedicular approach, if the pedicle is not large enough or stable enough to withstand the procedure, pedicle fracture may occur;
- Complications that may occur during a parapedicular approach include pneumothorax and bleeding;
- Avoid contact between the balloon and the bone cement;
- The balloon component of the Inflatable Bone Tamp may fail due to bone splinters and/or surgical tool contact;
- Do not inflate the balloon until it has been fully deployed in the vertebral body, hand, tibia, radius, or calcaneus. Inflating the balloon prior to full deployment may result in balloon failure due to contact between the balloon and the access cannula;
- Do not use this product after the expiration date printed on the package. The device may not be safe or effective beyond its expiration date;
- Deep or superficial wound infection;
- Retropathy, paresis or paralysis; and
- Bleeding or hematoma

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of spinal fracture.

Inflating the AFFIRM® Inflatable Bone Tamp balloon beyond the maximum inflation volume may cause the balloon to rupture before reaching the maximum inflation pressure.

Inflating the AFFIRM® Inflatable Bone Tamp balloon beyond the maximum inflation pressure may cause the balloon to rupture before reaching the maximum volume.

PRECAUTIONS

Use of the AFFIRM® VCF System should be performed only by experienced surgeons with specific training in the use of this system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered prior to performing kyphoplasty.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

- Never use any gaseous medium to inflate the Inflatable Bone Tamp when it is inside the patient.
- Follow manufacturer's instructions for contrast medium indications and usage. Unintended contrast medium exposure to the patient may occur in the use of the Inflatable Bone Tamp.
- The Inflatable Bone Tamp should only be used when an inflation syringe is attached.
- Inflatable Bone Tamps are intended for single use only. Do not re-sterilize and/or reuse it.
- The inflation characteristics of the Inflatable Bone Tamp are altered by inflation inside the bone.

CONTRAINDICATIONS

Use of the AFFIRM® VCF System is contraindicated in patients with the following conditions:

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials;
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the Kyphoplasty procedure during healing and may be at a higher risk of failure;
- Bleeding disorder or treatment that increases the chance of excessive bleeding;
- Any known severe allergy to contrast material or bone cement;
- Instability of posterior wall and/or pedicles;
- Pedicle fracture,
- Epidural abscess;
- Sepsis;
- Osteomyelitis;
- Active infection;
- Discitis;
- Uncorrectable coagulopathy;
- Symptomatic cord compression at the level of fracture;
- Severe cardiopulmonary disease; and
- Pregnancy

The bone tamp should not be used if the vertebral body, hand, tibia, radius or calcaneus dimensions or fracture pattern do not allow safe placement and inflation of balloon.

CONTACT INFORMATION

Algea Therapies may be contacted at 1-855-639-6612. A surgical technique manual may be obtained by contacting Algea Therapies.

Important Information on the AFFIRM® VCF SYSTEM – Inflatable Bone Tamp

DIRECTIONS FOR USE – INFLATABLE BONE TAMP

1. Use the existing access channel through cancellous bone for cavity creation.
2. Select the appropriate Inflatable Bone Tamp. Fill the Inflation Device with 60% contrast medium according to manufacturer's instructions.
3. Turn the cap of the Stylet to tighten the Stylet into the Inflatable Bone Tamp.
4. Attach the VacLok® Syringe from the Inflation Device Pack to the inflation port of the Inflatable Bone Tamp.
5. Pull the plunger of the VacLok® Syringe back and rotate to lock the plunger in the position of the last slot to remove any air from the Inflatable Bone Tamp prior to use.
6. Detach the VacLok® Syringe from the Inflatable Bone Tamp. Attach the connection port of the Inflation Device to the inflation port of the Inflatable Bone Tamp according to the Inflation Device manufacturer's instructions.
7. Place the Inflatable Bone Tamp through the access cannula into the vertebra and advance to the intended location under fluoroscopic guidance.
8. Use AP and lateral fluoroscopy to ensure desired placement of the Inflatable Bone Tamp. Check the radiopaque band at the distal tip of the Inflatable Bone Tamp on fluoroscopy to verify location.
9. Inflate the Inflatable Bone Tamp to 45psi to secure its position.
10. Inflate the Inflatable Bone Tamp under continuous fluoroscopy until the vertebral body wall or the endplate is touched, or the maximum pressure or maximum volume is achieved, according to the inflation chart parameters listed below. No cortical bone should be perforated.
11. Once inflation is completed, deflate and remove the Inflatable Bone Tamp under fluoroscopy.
12. Proceed to cement delivery.

Bone Tamp (1)

INFLATION CHARTS

Premier (10P, 15P, 20P) for ø4.2mm working channel

Description	Inflatable Bone Tamp 10P	Inflatable Bone Tamp 15P	Inflatable Bone Tamp 20P
Max. Inflation Volume	4cc ±0.4	4cc ±0.4	6cc ±0.4
Max. Inflation Pressure	400psi (27ATM)	400psi (27ATM)	400psi (27ATM)
Nominal Inflated Diameter	17mm	16mm	17mm
Nominal Inflated Length	20mm	22mm	30mm

Ultra (10U, 15U) for ø3.4mm working channel

Description	Inflatable Bone Tamp 10U	Inflatable Bone Tamp 15U
Max. Inflation Volume	4cc ±0.4	5cc ±0.4
Max. Inflation Pressure	400psi (27ATM)	400psi (27ATM)
Nominal Inflated Diameter	16mm	16mm
Nominal Inflated Length	20mm	28mm

UNCONSTRAINED INFLATION CHART

Ultra 10U (worst case unconstrained test condition)

Description	Inflatable Bone Tamp 10U
Inflation Volume	7cc ±0.7
Inflation Pressure	118psi (8ATM)

STERILIZATION

The AFFIRM® Inflatable Bone Tamp and Sleeve components are sterilized by gamma radiation to ensure a Sterility Assurance Level (SAL) of 10^{-6}. The expiration date is provided on the package label. Do not use if expired. These components are considered sterile unless the packaging has been opened or damaged.

STORAGE

The AFFIRM® Inflatable Bone Tamp should be stored in its original shipping materials. Proper care should be taken to ensure that the Inflatable Bone Tamp will be not damaged. Store the Inflatable Bone Tamp in a cool, dry place; 10°C - 40°C (50°F - 104°F).

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

REV A

Important Information on the AFFIRM® VCF SYSTEM – Instruments

DESCRIPTION

The AFFIRM® VCF System instruments are instrument kits or packs which consist of: access instruments (including drills, cannulas. jamshidi needles, and K-wires), biopsy needle, cavity preparation instruments (expanding scraper), sleeve, an inflation device, and cement delivery instruments (cement mixer, cement guns, and filler delivery needles).

The AFFIRM® VCF System instruments are fabricated from stainless steel and nitinol as specified in ASTM F899 and ASTM 2063, and from polyurethane.

INDICATIONS

The AFFIRM® VCF System is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. Vertebral compression fractures may result from osteoporosis, benign lesions and/or malignant lesions such as metastatic cancer and myeloma. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

WARNINGS

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery include:

- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae;
- Rupture with fragmentation of the inflatable portion of the IBT resulting in retention of a fragment within the vertebral body;
- Rupture of the IBT causing contrast medium exposure, possibility resulting in an allergic reaction or anaphylaxis;
- For a transpedicular approach, if the pedicle is not large enough or stable enough to withstand the procedure, pedicle fracture may occur;
- Complications that may occur during a parapedicular approach include pneumothorax and bleeding;
- Do not use this product after the expiration date printed on the package. The device may not be safe or effective beyond its expiration date;
- Deep or superficial wound infection;
- Retropathy, paresis or paralysis; and
- Bleeding or hematoma

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of spinal fracture.

PRECAUTIONS

The implantation of the AFFIRM® VCF System should be performed only by experienced spinal surgeons with specific training in the use of this system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered prior to performing kyphoplasty.

Adequately instruct the patient. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

CONTRAINDICATIONS

Use of the AFFIRM® VCF System is contraindicated in patients with the following conditions:

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials;
- Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the Kyphoplasty procedure during healing and may be at a higher risk of failure;
- Bleeding disorder or treatment that increases the chance of excessive bleeding;
- Any known severe allergy to contrast material;
- Instability of posterior wall and/or pedicles;
- Pedicle fracture;
- Epidural abscess;
- Sepsis;
- Osteomyelitis;
- Active infection;
- Discitis;
- Uncorrectable coagulopathy;
- Symptomatic cord compression at the level of fracture;
- Severe cardiopulmonary disease; and
- Pregnancy

These instruments should not be used if the vertebral body, hand, tibia, radius or calcaneus dimensions or fracture pattern do not allow safe placement.

CONTACT INFORMATION

Algea Therapies may be contacted at 1-855-639-6612. A surgical technique manual may be obtained by contacting Algea Therapies.

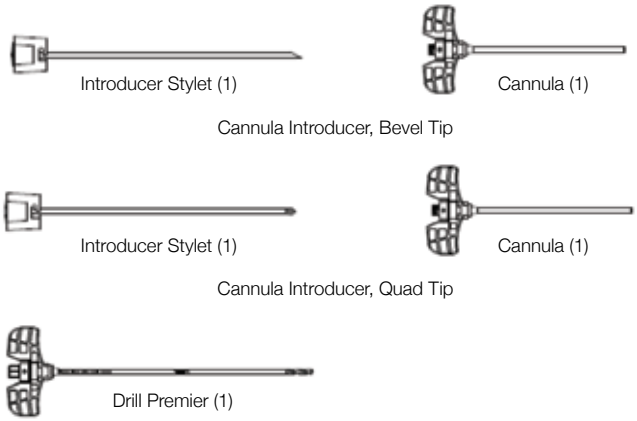
DIRECTIONS FOR USE – ACCESS TRAY or PACK (PREMIER and ULTRA)

1. Select appropriate access instrument(s).
2. Make an incision on the skin over the selected vertebra using a scalpel.
3. Advance a Cannula Introducer through the soft tissue into the selected vertebra using alternating AP and lateral fluoroscopy as guidance.
4. Remove the Introducer Stylet from the Cannula Introducer.
5. Remove the handle from the Cannula and leave the Cannula in bone.
6. Insert the Drill through the Cannula into the bone to advance the access channel.
7. Drill cautiously with image guidance to the required depth.
8. Remove the Drill once the required depth is reached.

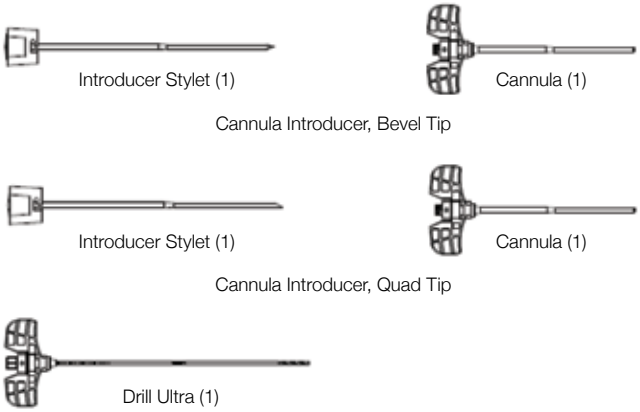
For additional level(s), use Cannulae from the AFFIRM® Cannula Pack.

Important Information on the AFFIRM® VCF SYSTEM – Instruments (cont'd)

AFFIRM® ACCESS TRAY or PACK, PREMIER (4.2mm diameter)



AFFIRM® ACCESS TRAY or PACK, ULTRA (3.4mm diameter)

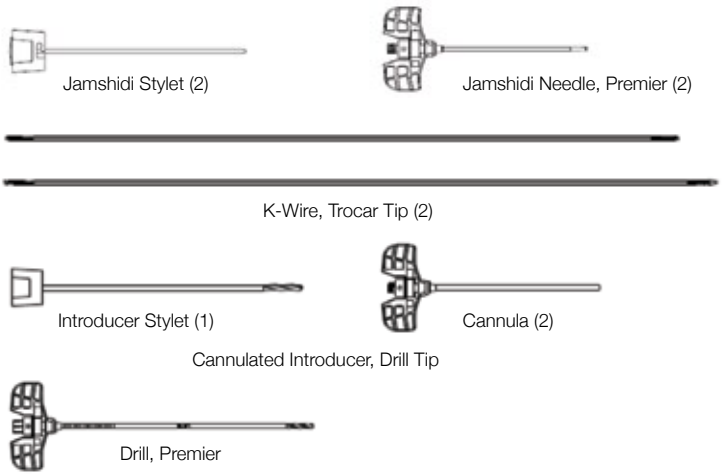


DIRECTIONS FOR USE – CANNULATED ACCESS TRAY or PACK (PREMIER ONLY)

1. Make an incision on the skin over the selected vertebra using a scalpel.
2. Place the Jamshidi Needle though the soft tissue into the selected vertebra, using alternating AP and lateral fluoroscopy as guidance.
3. Remove the Jamshidi Stylet from the Jamshidi Needle.
4. Place a K-Wire through the Jamshidi Needle into the bone with image guidance. Remove the Jamshidi Needle and leave the K-Wire in the bone.
5. Place the Cannulated Introducer over the K-Wire and advance the Cannulated Introducer into the vertebra under fluoroscopy, then remove the K-Wire.
6. Remove the Introducer Stylet from the cannulated Introducer.
7. Remove the handle from the Cannula and the leave the Cannula in the bone.
8. Insert the Drill through the Cannula into the bone to advance the access channel.
9. Drill cautiously with image guidance to required depth.
10. Remove the Drill once the required depth is reached.

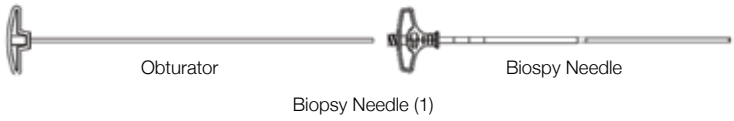
For additional level(s), use Cannulae from the AFFIRM® Cannula Pack.

CANNULATED ACCESS TRAY or PACK (4.2mm diameter)



DIRECTIONS FOR USE – BIOPSY NEEDLE

1. Use the existing access channel for biopsy collection.
2. Remove the Obturator from the Biopsy Needle.
3. Insert the Biopsy Needle through the access cannula into the vertebra using fluoroscopic guidance.
4. Rotate the handle of the Biopsy Needle for biopsy collection.
5. Remove the Biopsy Needle once biopsy collection is completed.
6. Place the Obturator through the Biopsy Needle for biopsy collection.



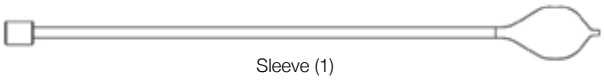
DIRECTIONS FOR USE – EXPANDING SCRAPER

1. Use the existing access channel through for cavity preparation.
2. Attach the Handle to the Expanding Scraper. Insert the Expanding Scraper through the access cannula into the vertebra.
3. Advance the Expanding Scraper into the bone using fluoroscopy to ensure correct placement of the Expanding Scraper.
4. Rotate the knob on the Expanding Scraper counterclockwise to extend the scraper tip into contact with bone under fluoroscopic guidance.
5. Actuate the scraper to prepare the cavity using fluoroscopic guidance. Adjust the angle as necessary.
6. Rotate the knob on the Expanding Scraper clockwise to retract the scraper tip under fluoroscopy. When the scraper tip is completely retracted, remove the Expanding Scraper.

Important Information on the AFFIRM® VCF SYSTEM – Instruments (cont'd)

DIRECTIONS FOR USE – SLEEVE

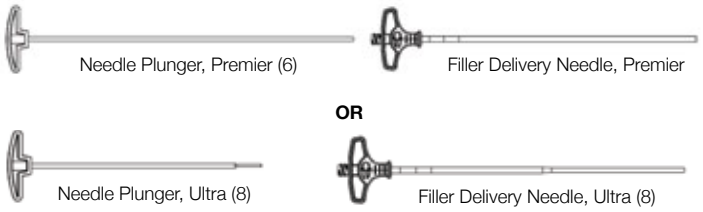
1. If additional reinforcement is desired for the Inflatable Bone Tamp, the Sleeve may be placed over the Inflatable Bone Tamp, prior to inserting into the access channel.
2. Continue to follow instructions for insertion and inflation of the Inflatable Bone Tamp.
3. Remove the Inflatable Bone Tamp and Sleeve prior to injecting cement into the cavity.



Sleeve (1)

DIRECTIONS FOR USE – FILLER DELIVERY TRAY or PACK

1. Use existing access channels for delivery of bone cement to the prepared cavity.
2. Prepare bone cement in the Cement Mixer according to the mixer manufacturer's instructions and the bone cement manufacturer's instructions.
3. Separate the Needle Plunger from the Filler Delivery Needle.
4. Attach the Filler Delivery Needle to the Mixer and fill with bone cement.
5. Detach the Filler Delivery Needle from the Mixer.
6. To fill multiple Filler Delivery Needles, repeat steps 1 through 5.
7. Place the Filler Delivery Needle through the Cannula into the vertebra and advance the Filler Delivery Needle to the intended location under image guidance.
8. Deliver cement to the intended location of the vertebra by placing the Needle Plunger through the Filler Delivery Needle under continuous fluoroscopic guidance.



Needle Plunger, Premier (6)

Filler Delivery Needle, Premier

OR

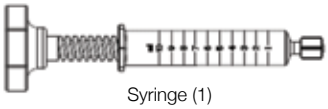
Needle Plunger, Ultra (8)

Filler Delivery Needle, Ultra (8)

DIRECTIONS FOR USE – EXTENSION DELIVERY PACK

1. Use the existing access channel for delivery of bone cement into the prepared cavity.
2. Prepare bone cement in the Cement Mixer according to the mixer manufacturer's instructions and the bone cement manufacturer's instructions.
3. Attach the Syringe to the Cement Mixer.
4. Transfer bone cement to the Syringe.
5. Detach the Syringe from the Cement Mixer. Point the Syringe upward; rotate the plunger to inject cement into the distal end of the Disposable Syringe to remove air.
6. Load the Syringe in the Cement Gun.
7. Connect the fixed end of the Extension Tube to the Syringe.
8. Separate the Needle Plunger from the Filler Delivery Needle.
9. Connect the rotating end of the Extension Tube to the luer port of the Filler Delivery Needle.
10. Purge air from the Syringe and the Filler Delivery Needle by rotating the plunger of the Syringe to inject cement to the distal end of the Filler Delivery Needle.
11. Place the Filler Delivery Needle through the access cannula into the vertebra and advance the Filler Delivery Needle to the intended location under fluoroscopic guidance.
12. Deliver cement to the intended location of the vertebra by rotating the plunger of the Syringe under continuous fluoroscopic guidance.
13. Once cement delivery is completed, remove the Extension Tube and Filler Delivery Needle under fluoroscopy.

Extension Tube (1)

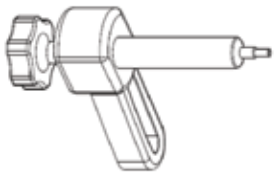


Syringe (1)

DIRECTIONS FOR USE – CEMENT INJECTION PACK

1. Use the existing access channel for delivery of bone cement into the prepared cavity.
2. Prepare bone cement in the Cement Mixer according to the mixer manufacturer's instructions and the bone cement manufacturer's instructions.
3. Attach the Cement Gun with Syringe to the Cement Mixer.
4. Transfer bone cement to the Cement Gun.
5. Detach the Cement Gun from the Cement Mixer. Point the gun upward; rotate plunger to inject cement into the distal end of the syringe to remove air.
6. Connect the fixed end of the Extension Tube to the Cement Gun.
7. Separate the Needle Plunger from the Filler Delivery Needle.
8. Connect the rotating end of the Extension Tube to the luer port of the Filler Delivery Needle.
9. Purge air from the Cement Gun and the Filler Delivery Needle by rotating the plunger of the Syringe to inject cement to the distal end of the Filler Delivery Needle.
10. Place the Filler Delivery Needle through the access cannula into the vertebra and advance the Filler Delivery Needle to the intended location under fluoroscopic guidance.
11. Deliver bone cement to the intended location of the vertebra by rotating the plunger of the Syringe under continuous fluoroscopic guidance.
12. Once cement delivery is completed, remove the Extension Tube and Filler Delivery Needle under fluoroscopy.

Extension Tube (1)



Cement Gun with Syringe (1)

Important Information on the AFFIRM® VCF SYSTEM – Instruments (cont'd)

STERILIZATION

The AFFIRM® instruments and Cement Mixer are sterilized by gamma radiation using a standard medical device sterilization dose of 25-40kGy. This dose was validated using the VD_{Max} method according to ANSI/AAMI/ISO 11137-2:2006 Sterilization of Healthcare Products. Sterilization validation was performed to ensure a sterility assurance level (SAL) of 10^{-6}.

The Inflation Device is sterilized using Ethylene Oxide (EtO) and meets the requirements of ANSI/AAMI/ISO 11135:1994 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization. Sterilization validation was performed to ensure a sterility assurance level (SAL) of 10^{-6}.

Some AFFIRM® instruments are provided NONSTERILE. Sterilization is recommended as follows:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132° C (270° F)	25 Minutes	45 Minutes
Steam	Pre-vacuum (Wrapped) Preconditioning Pulses: 3	132° C (270° F)	15 Minutes	30 Minutes

STORAGE

The AFFIRM® instruments should be stored in their original shipping materials. Proper care should be taken to ensure that the instruments are not damaged. Store the instruments in a cool, dry place.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

REV A

Important Information on CONCORD™ Radiopaque Bone Cement

(Polymethyl Methacrylate, Methyl Methacrylate-styrene copolymer and Barium sulfate)

IMPORTANT INFORMATION

Please Read Before Use

STERILE R — Sterilized by gamma irradiation (Powder Component)

STERILE A — Sterilized by filtration (Liquid Component)

STERILE EO — Sterilized by ethylene oxide (Contents of Blister Pack)

Single Use Only

Attention, See Instructions For Use

Rx ONLY — CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Manufacturer

25°C 77°F — Upper temperature limit

DESCRIPTION

CONCORD™ Radiopaque Bone Cement is packaged in two sterile components.

One component is a vial containing 16.4g (full dose) of monomer. The monomer is a colorless, flammable liquid material with a very distinctive odor of the following composition:

Methyl Methacrylate	99.0% w/w
N:N Dimethyl-p-toluidine	1.0% w/w
Hydroquinone	100 ppm

Hydroquinone is added to prevent premature polymerization. N:N Dimethyl-p-toluidine is added to initiate polymerization at operating room temperatures.

The liquid component is sterilized by filtration methods.

The other component is a bottle containing 40.0g (full dose) of powder polymer with the following composition:

Polymethyl Methacrylate / Methyl Methacrylate-styrene copolymer	71.3% w/w
Benzoyl peroxide	0.7% w/w
Barium sulfate	28.0% w/w

Barium sulfate is added to make the material radiopaque.

The powder component is sterilized by gamma irradiation.

All components are single use and not re-sterilizable. Do not use if packaging is opened or damaged.

INDICATIONS FOR USAGE

CONCORD™ Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

INFORMATION FOR USE

A dose is prepared by adding the entire contents of the liquid monomer to the entire contents of the powder. Do not add the powder to the liquid monomer.

MIXING INSTRUCTIONS

1. Using sterile technique and under sterile conditions, empty the entire contents of the powder component into a sterile, inert mixing device.
2. Add the entire contents of the liquid monomer to the powder. Mix the material by following the device manufacturer's instructions or until the powder is completely saturated with the liquid monomer and the material reaches the desired consistency. The handling characteristics and setting time of the material may vary with temperature, mixing technique and humidity.
3. Determine the preferred method or procedure for bone cement delivery into the patient and, if applicable, follow the device manufacturer's instructions.

CONTRAINDICATIONS

The use of **CONCORD**™ Radiopaque Bone Cement is contraindicated in patients with:

- The presence of active or incompletely treated infection
- Allergies or sensitivity to Methyl Methacrylate or any of the chemical compositions of the product
- Traumatic fractures of the vertebra that are non-pathological in nature
- Cardiopulmonary disease
- Coagulation disorders
- Severe vertebral body collapse (vertebra plana)
- Prophylaxis with no evidence of acute fracture
- Clinically effective medical therapy

Important Information on CONCORD™ Radiopaque Bone Cement

WARNINGS

Read and understand these instructions. Familiarization with the bone cement prior to use is important.

- **CONCORD**™ Radiopaque Bone Cement is intended for single patient use. DO NOT re-use or re-sterilize. Sterility is assured only if the package is unopened and undamaged.
- For safe and effective use of **CONCORD**™ Radiopaque Bone Cement, the surgeon should be familiar with the material properties, handling characteristics and the application of the material and devices used for mixing and dispensing the material.
- **CONCORD**™ Radiopaque Bone Cement should only be used by physicians familiar with percutaneous cement delivery, vertebroplasty and kyphoplasty.
- **CONCORD**™ Radiopaque Bone Cement is not recommended for patients that do not exhibit a pathologic condition, such as osteoporosis or a tumor that would impair the ability of the patient to heal using conservative treatment methods.
- Give proper consideration to other conventional therapies prior to performing percutaneous vertebroplasty or kyphoplasty.
- It is the responsibility of the physician to determine the appropriate procedure, technique and device for each individual patient.
- Inadequate fixation or unanticipated postoperative events may affect the cement-bone interface and lead to micromotion of cement against bone surface. Loosening of the bone cement may occur due to the development of fibrous tissue between the bone cement and the bone. Long-term follow-up is advised for all patients on a regularly scheduled basis
- Monomer is highly flammable. The operating room should be provided with adequate ventilation to eliminate concentrated monomer vapor. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the vapors which may produce respiratory irritation, irritation to the eyes and possibly the liver.
- Personnel wearing contact lenses should NOT be near or involved in mixing this material.
- The liquid component is a powerful lipid solvent. It is recommended that all operating room staff who come in contact with the material double glove to lessen the risk of contact dermatitis which may occur in susceptible individuals after long term exposure to the monomer. Wearing double gloves and adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The liquid component should not be allowed to come in contact with rubber or latex gloves.
- Monomer can cause hypersensitivity in susceptible persons which may produce an anaphylactic response.
- **Use in Pregnancy:** Although the results of animal studies with similar materials have been negative, the safety of PMMA materials in pregnancy, children, or by women of childbearing potential has not been established and requires that the potential benefits must be weighed against the possible hazards to the mother, child, or fetus.
- Adverse reactions in patients due to bone cements have affected the cardiovascular system and in some cases hypotensive reactions have resulted in cardiac arrest. Patients should be monitored for any change in blood pressure and pulse rate during and immediately following treatment with bone cement.
- Precautions should be taken to detect and rectify the transitory fall in blood pressure that may occur when bone cement is introduced into a patient.
- Clinical data indicates the need for good surgical principles and techniques in delivery of bone cement. Postoperative infection is a serious condition and may require removal of the implanted bone cement. Postoperative infection may occur immediately or not manifest for several years.
- Use high quality motorized C-arm fluoroscopy, high quality biplanar fluoroscopy or real-time CT to guide needle insertion.
- Place the needle tip in the anterior third of the vertebral body.
- Polymerization of bone cement is an exothermic reaction, which occurs while it is hardening in situ. The released heat may damage bone or other surrounding tissues. The long term effect to surrounding tissues exposed to the exothermic temperatures produced by the polymerization process is not known.
- Patient positioning should be maintained until the completion of the polymerization process of the bone cement to achieve proper fixation. The polymerization process may vary due to room temperature and delivery system.
- Be aware that treating multiple levels may increase the risk of sudden drop in blood pressure, particularly if more than three vertebral levels are treated in a single operation.
- Delivery of excessive bone cement may lead to extrusion of the bone cement beyond the intended application area and cause damage to surrounding tissues and the circulatory system.
- DO NOT deliver bone cement into a vertebral body without appropriate imaging techniques such as high quality lateral fluoroscopic guidance.
- Long-term effects of bone cement in pathological fractures of the vertebral body have not been established.
- Leaks can also occur when injecting if the needle is in a vein or if unseen microfractures are prevalent.
- If bone cement is seen outside of the vertebral body or in the circulatory system during percutaneous vertebroplasty or kyphoplasty, immediately stop the injection.
- Consider carefully the risk/benefit analysis for patients with malignant conditions who also have epidural extension or malignant collapse, in view of risk of precipitating cord compression. Ensure that immediate surgical support is available.
- Consider carefully the risk/benefit analysis for patients with traumatic burst fractures with disruption of the posterior vertebral body.

Important Information on CONCORD™ Radiopaque Bone Cement

PRECAUTIONS

- This product should not be used after the expiration date printed on the package label.
- Do not introduce other substances or foreign materials into this product. Do not modify the mixing ratios in any form. Modification of the composition can cause unpredictable handling characteristics, increased exposure to the monomer component, increased risk of venous embolization and unpredictable final mechanical properties.

ADVERSE REACTIONS

The most serious adverse reactions, some resulting in death, reported with the use of similar acrylic bone cements are:

Cardiac arrest
Myocardial infarction
Pulmonary embolism
Cerebrovascular accident
Hypertension
Hypotension
Anaphylaxis
Nerve entrapment

The most frequent adverse reactions reported are:

Transitory fall in blood pressure
Thrombophlebitis
Trochanteric bursitis
Trochanteric separation
Hemorrhage and hematoma
Surgical wound infection
Deep wound infection

Other adverse reactions reported are:

Heterotopic new bone
Pyrexia
Hematuria
Bladder fistula
Short-term irregularities in cardiac conduction

The physician must be aware of these possible reactions and be prepared to treat them if they are encountered.

IMPORTANT PHYSICIAN INFORMATION

ADVERSE REACTIONS AFFECTING THE CARDIOVASCULAR SYSTEM HAVE BEEN ATTRIBUTED TO LEAKAGE OF UNPOLYMERIZED MONOMER INTO THE CIRCULATORY SYSTEM. DATA INDICATES THAT THE MONOMER UNDERGOES RAPID HYDROLYSIS TO METHACRYLIC ACID, AND THAT A SIGNIFICANT FRACTION OF THE CIRCULATING METHACRYLATE IS IN THE FORM OF FREE ACID RATHER THAN THE METHYL ESTER. CORRELATION BETWEEN CHANGES IN CIRCULATING CONCENTRATIONS OF METHYL METHACRYLATE/METHACRYLIC ACID AND CHANGES IN BLOOD PRESSURE HAS NOT BEEN ESTABLISHED. USE PROPER TECHNIQUE TO AVOID LAMINATIONS IN THE MATERIAL AS WELL AS ENTRAPPING AIR.

HYPOTENSIVE REACTIONS WERE REPORTED TO OCCUR AFTER INTRODUCTION OF BONE CEMENT BETWEEN 10 TO 165 SECONDS WITH DURATION OF 30 SECONDS TO 5-6 MINUTES. THE PATIENT SHOULD BE MONITORED DURING AND AFTER THE INTRODUCTION OF BONE CEMENT FOR ANY CHANGE IN BLOOD PRESSURE, ESPECIALLY IF THE PATIENT IS PRONE TO HIGH BLOOD PRESSURE AND/OR CARDIOVASCULAR ABNORMALITIES.

HOW SUPPLIED

Individual Unit

Full Dose:
One sterile package containing one bottle with 40.0g of powder polymer and one vial with 16.4g of liquid monomer.

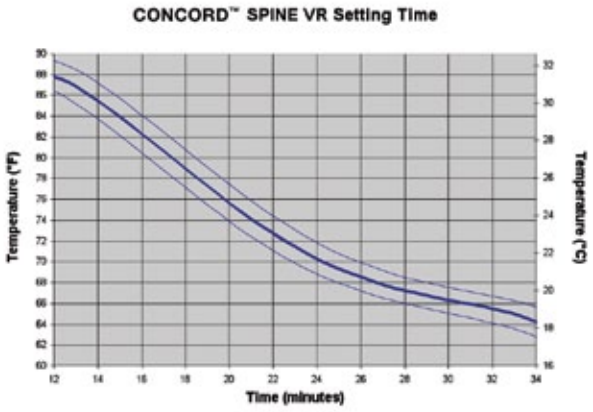
SAFE DISPOSAL

The polymer component may be disposed in an authorized waste facility. The liquid component can be evaporated under a vented hood or absorbed by an inert material for disposal.

STORAGE

Warning: Flammable

Store below 25°C (77°F) and protect from light.



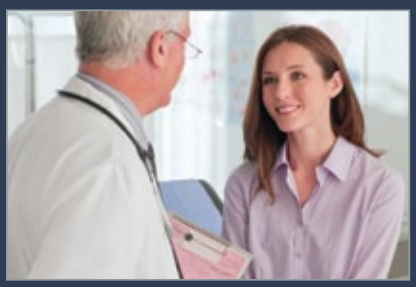
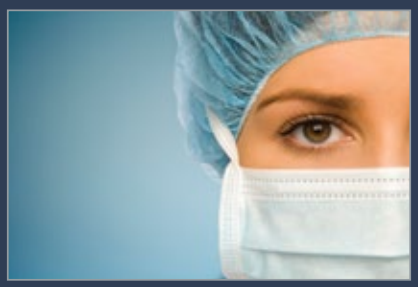
Setting time may vary and the surgeon should be aware of the behavior of the material and the operating room conditions

REV B

Notes

Notes

Notes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