

Blazer[®]
Vertebral Augmentation System

Procedural Technique Guide

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Vertebral Augmentation System



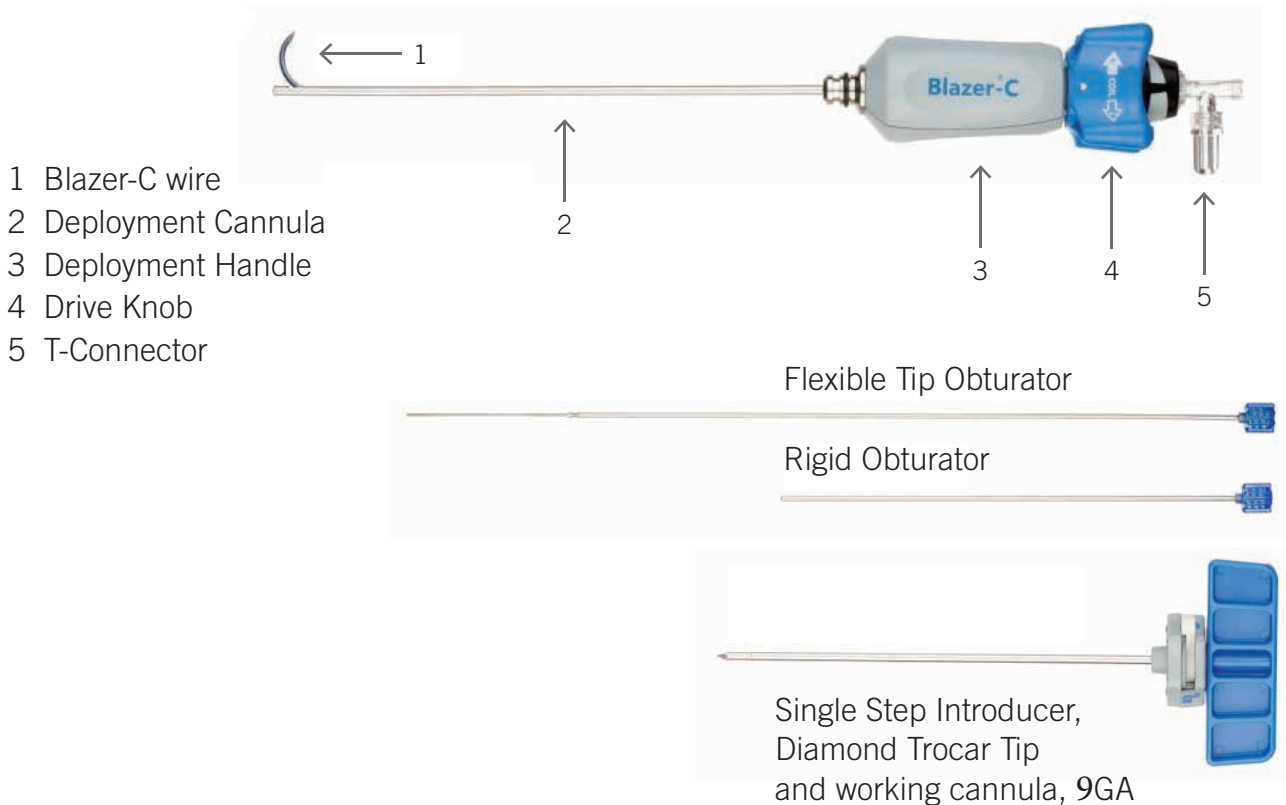
Blazer-C Vertebral Augmentation System Procedural Technique Guide

The information presented in this guide is intended to supplement the instructions for use for the Blazer-C Vertebral Augmentation System and is not intended as a spine surgery tutorial. For complete information regarding the instructions for use, precautions, warnings, contraindications, adverse events, etc., please reference the Blazer-C Vertebral Augmentation Systems Instructions for use.

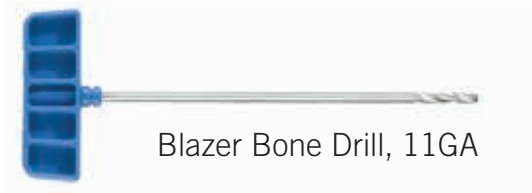
SYSTEM DESCRIPTION

The Blazer-C device consists of the Blazer-C wire, a deployment cannula, a deployment handle with drive knob, a T-Connector to allow for insertion of obturators & cement injection, and a set of access and accessory tools.

Blazer-C

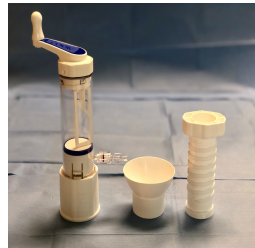


Additional Accessories – Sold Separately



Blazer Bone Drill, 11GA

Cement System



Injector and Mixer Set



Medium
Viscosity
Bone Cement

Blazer-C Vertebral Augmentation System

INDICATIONS

Blazer-C is indicated for the treatment of pathological compression fractures of the vertebral body that may result from osteoporosis, benign lesions, and/or malignant lesions, by creating channels in the existing spinal bone structure for the flow of polymethylmethacrylate bone cement (PMMA).

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.
- Index level(s) vertebral body collapse to the degree that access to the vertebral body is not feasible.
- Pedicle(s) whose diameters are too small to accept the working cannula.
- Evidence of fracture fragments retropulsed into the spinal canal.

PRECAUTIONS

- Failure to observe recommendations may contribute to serious patient injury.
- Do not use if the packaging appears to be damaged or if there is evidence of tampering.
- This device is intended for single-use only. Do not re-sterilize or reuse. Reuse of the device could result in infection, cross-contamination, and a failure to perform in a safe manner as intended.
- The user should inspect the device for damage prior to use. If the device appears damaged, do not use. Discard or return to the manufacturer.
- It is important to read the Instructions for Use and these precautions prior to device operation.
- Use the Blazer-C system prior to the use by date noted on the package.
- The physician should be familiar with the anatomy and pathology being treated with this device.
- The physician should be experienced in the standard transpedicular approach for access to the vertebral body.
- The physician should be trained in the use of Blazer-C prior to clinical use.
- 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.
- The user should avoid contact with the sharp distal tip of the Blazer-C wire as it may puncture the user's glove.
- Never attempt to deploy the Blazer-C wire without the use of the deployment handle and working cannula provided with the system.
- Never attempt to remove Blazer-C from patient without first verifying complete Blazer-C wire retraction into the deployment cannula. Use fluoroscopic imaging to ensure complete retraction of Blazer-C wire from the vertebral body prior to removing the deployment cannula.
- To reduce risk of excessive wear to device and potential failure, do not deploy the Blazer-C wire more than 16 times.
- Do not rotate handle to "sweep" Blazer-C wire while the wire is deployed if wire does not also rotate. Doing so may damage the device.
- Placing the deployment cannula too anterior or too posterior in the vertebral body may result in patient injury.
- Stop Blazer-C deployment if significant resistance is observed, it does not regain its shape, or goes in an undesired location.
- Caution should be taken when deploying Blazer-C from regions of very soft bone such as a cleft into very dense bone, as this may lead to significant deflection of the cannula tip and damage the instrument
- Use of Blazer-C in dense bone (osteosclerotic vertebrae) or in diseases causing abnormal bone formation (Paget's disease), may limit the penetration of the wire.

ADVERSE EVENTS

Adverse events potentially associated with the use of the Blazer-C are the same as most other percutaneous spinal procedures.

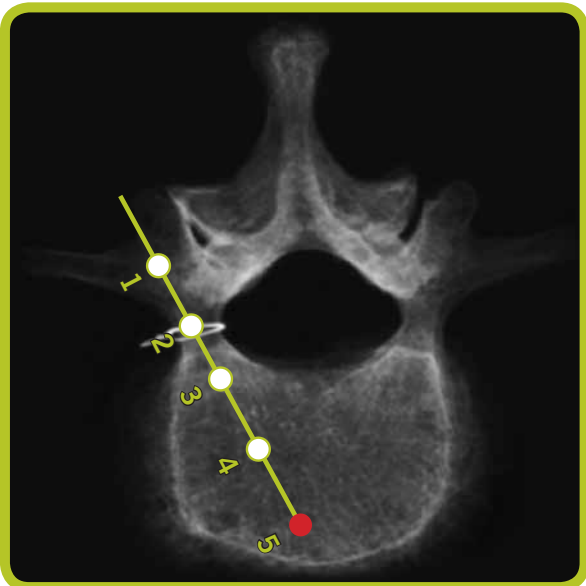
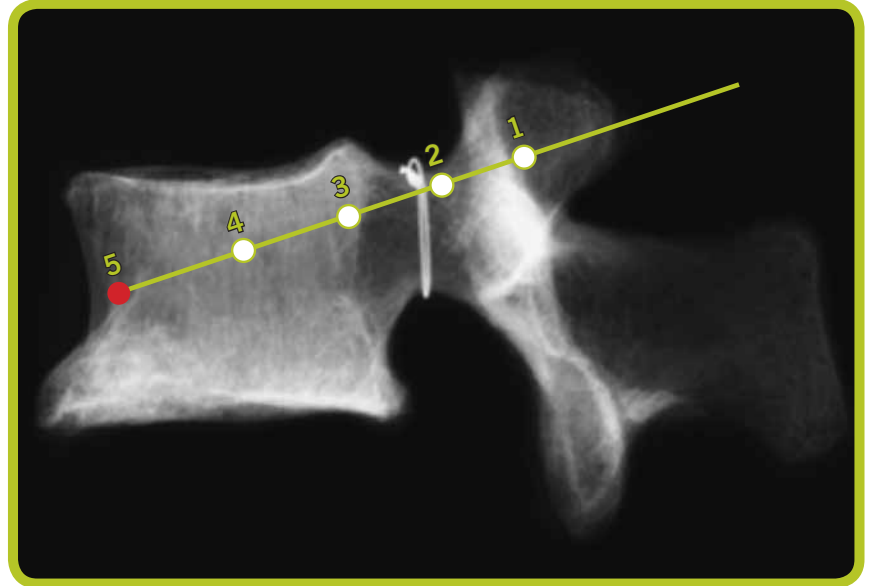
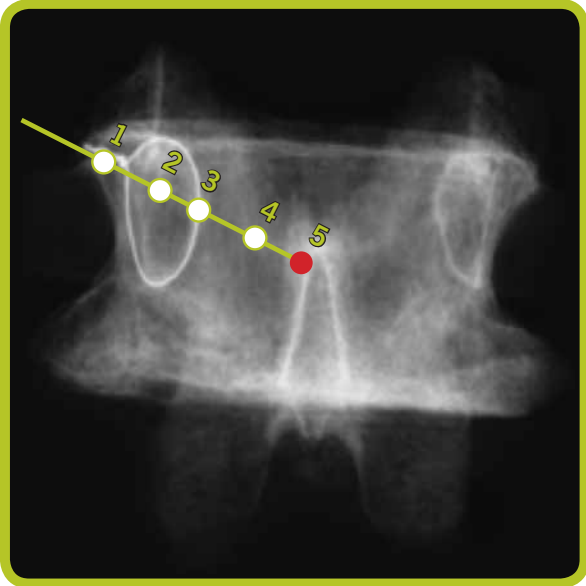
Those may include:

- Nerve injury including puncture of the spinal cord or nerve roots, or retropulsed bone fragments potentially resulting in radiculopathy, paresis or paralysis.
- Hemothorax or pneumothorax.
- Unintended puncture wounds including vascular puncture and dural tear.
- Deep or superficial wound infection.
- Bleeding, hematoma and/or venous embolism.
- Pain or lack of pain relief.
- Damage to vertebral posterior elements due to access, fracture of vertebrae/pedicle, or breach of cortical wall.
- Osteomyelitis.
- Allergic reaction to medications/implanted materials used during the procedure and/or need for open surgery.
- Potential subsequent fractures at index or other vertebral levels.
- Cardiovascular impairment due to fat emboli.

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.

Blazer-C Approach Card



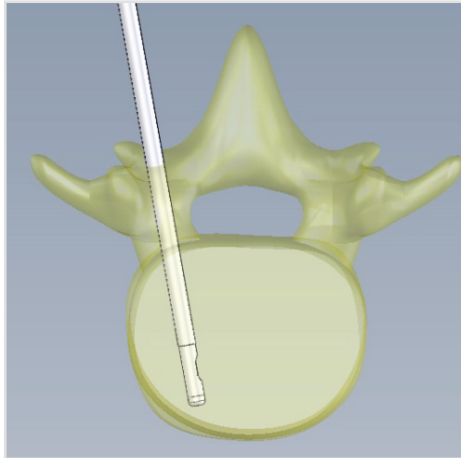
IZI Medical

BLAZER-C APPROACH CARD

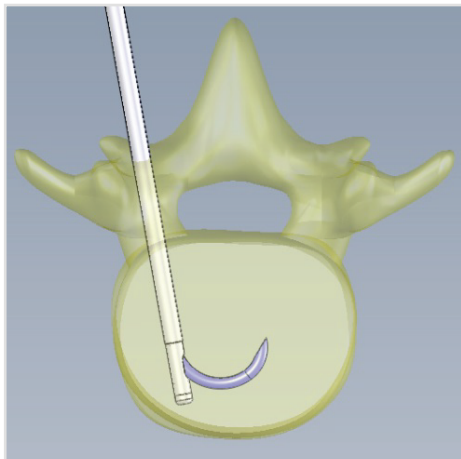
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Blazer-C Deployment Trajectories

LATERAL ACCESS

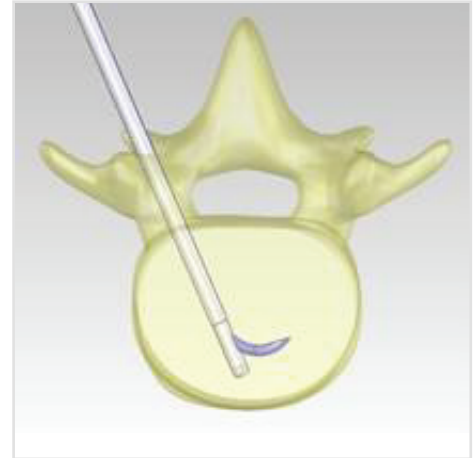


Initial cannula placement

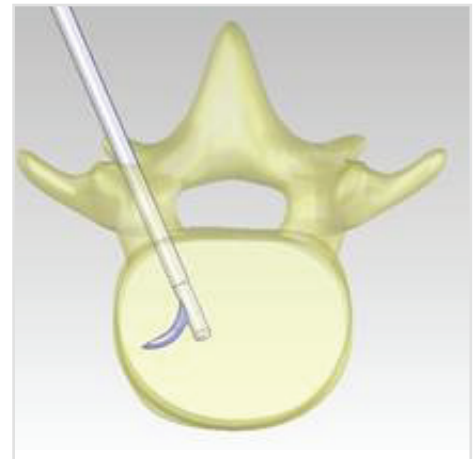


Blazer-C wire deployment

MIDLINE ACCESS



Partial contralateral deployment of Blazer-C wire

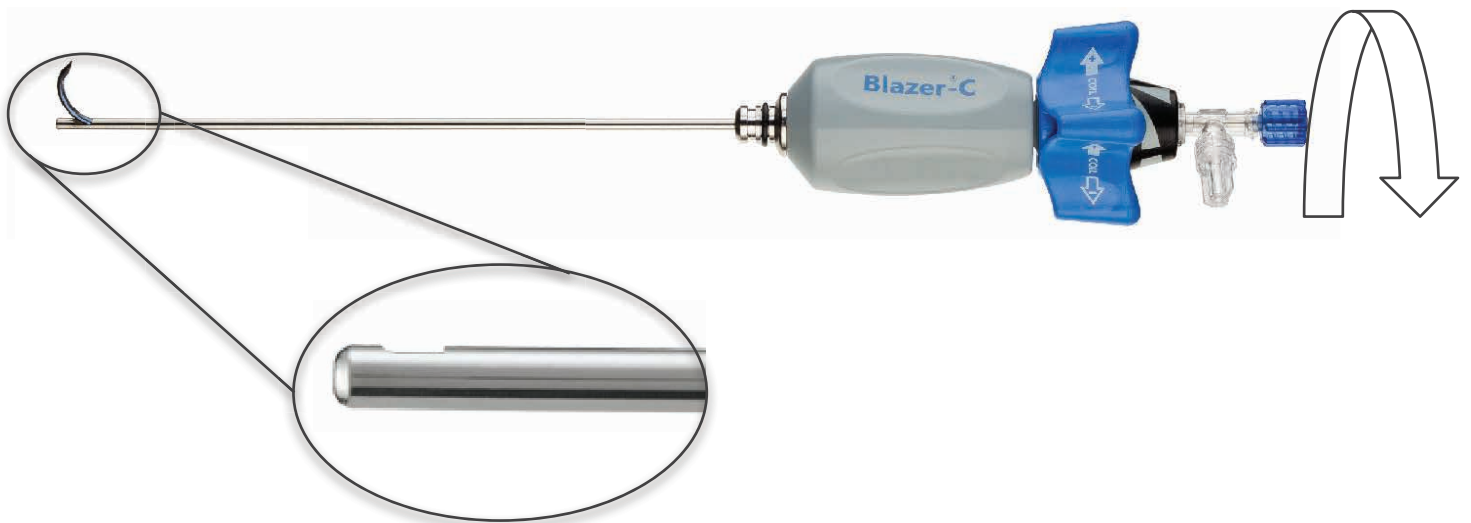


Partial ipsilateral deployment of Blazer-C wire

Placement of working cannula and vertebral body size will determine the ability to reach contralateral aspect of vertebral body.

System Set-up

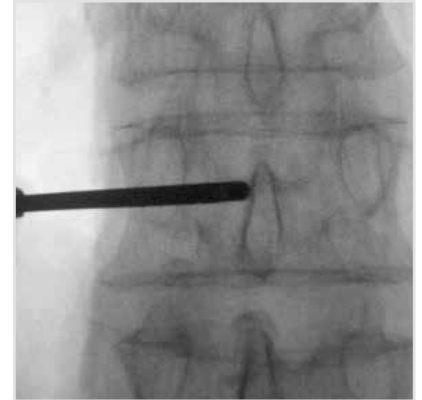
- Retract the Blazer wire into the deployment cannula by rotating the drive knob slowly in the counter-clockwise direction.
- 4 full turns will fully retract/deploy the wire.
- Ensure that the distal tip of the Blazer wire is fully retracted inside the cannula – a hard stop will be felt.



Vertebral Body Access



- 1 Stylet must be locked while advancing introducer into position.
- 2-3 Introducer may be advanced manually (*with a twisting motion*) or with a mallet
- 4 Once final position is reached, unlock working cannula.
- 5 Remove Single Step stylet from working cannula. Working length of stylet is identical to that of the Blazer cannula.



Final midline placement

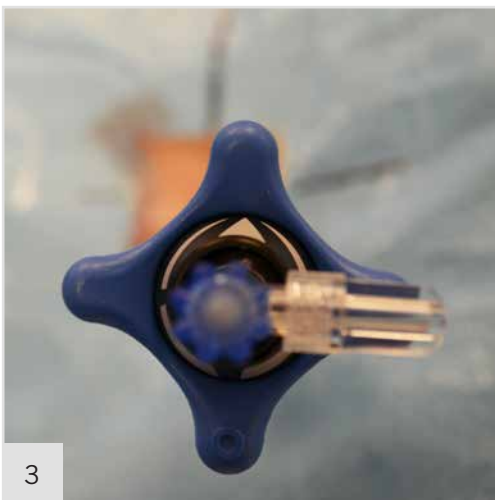


Final anterior position



Final working cannula placement

Blazer Deployment



- 1 Insert Blazer-C into working cannula.
- 2 Lock in place.
- 3 The white arrow on the black surface indicates the direction of the wire deployment.
- 4 Rotate the drive knob clockwise (“+” sign) to deploy Blazer wire.

-
- 4 full turns will fully deploy the wire.
 - Check Blazer wire trajectory using fluoro after every full turn of drive knob.
-

CAUTION

The Blazer wire has the power to penetrate cortical bone and end plates with relative ease. Verify all deployments with multi plane imaging.

The Blazer wire is not intended to be “swept” through bone. Do not rotate the handle while the wire is deployed! An internal clutch mechanism will prevent the cannula from rotating under this condition.

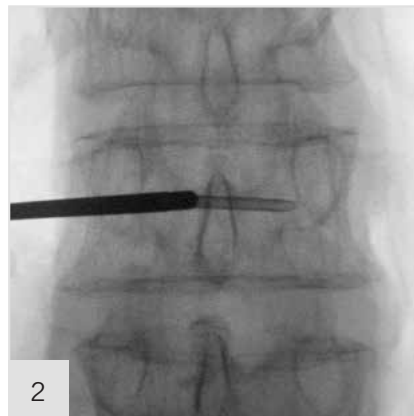
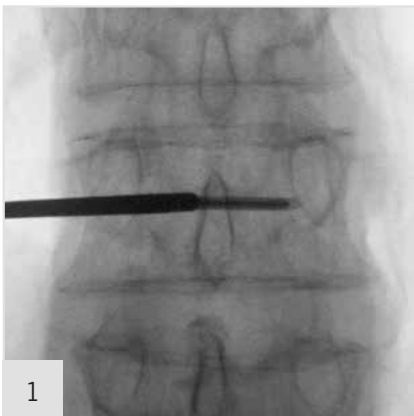
Standard Technique

Create at least one channel in the vertebral body before preparing the cement. The flexible obturator must be engaged for this deployment. The user can then gauge the toughness of the cancellous bone and decide whether to create ALL channels first (to then fill with cement as a separate step) or to immediately proceed with cement preparation and injection.

If proceeding directly to cement injection:

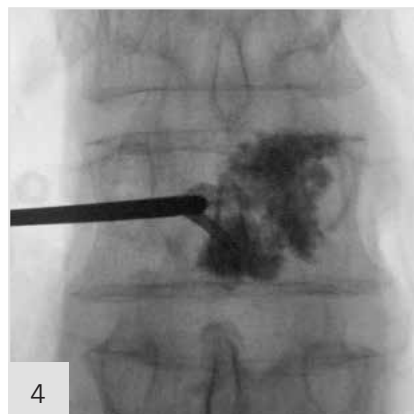
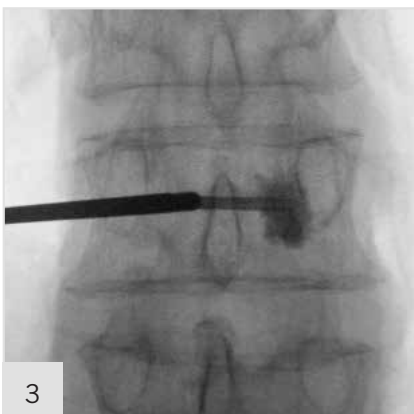
- Fully retract wire and undock device, remove flexible obturator, and prime with cement per standard procedure on the back table.
- Dock device and re-deploy wire into primary channel. Inject cement as desired.
- Retract wire, reorient, and re-deploy to create additional channel(s) at desired injection location(s). The high viscosity cement will prevent wire lumen from occluding with bone.

ALL CEMENT PRIMING MUST BE DONE AT BACK TABLE



1 Initial wire deployment with flexible obturator in place (required to prevent bone from occluding wire lumen).

2 Blazer-C has been retracted, removed, and primed on the back table. Initial wire deployment finds initial channel already created.



3 Cement is injected at initial site.

4 Blazer wire is retracted, device re-oriented, and wire redeployed for subsequent cement injection. In soft bone, presence of cement in wire lumen prevents bone occlusion.

REPEAT AS NEEDED

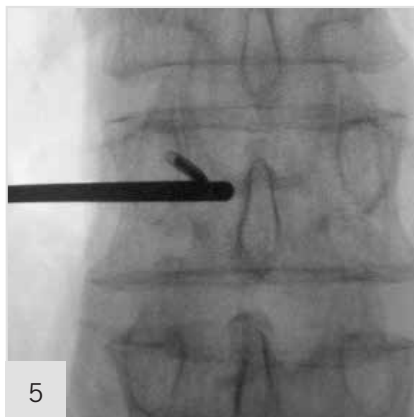
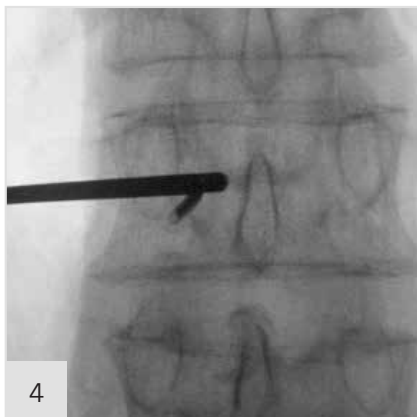
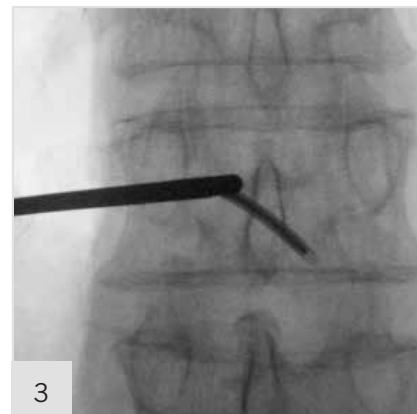
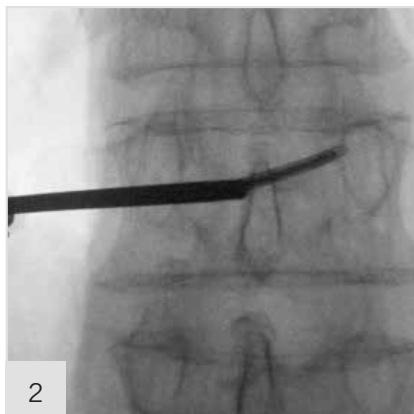
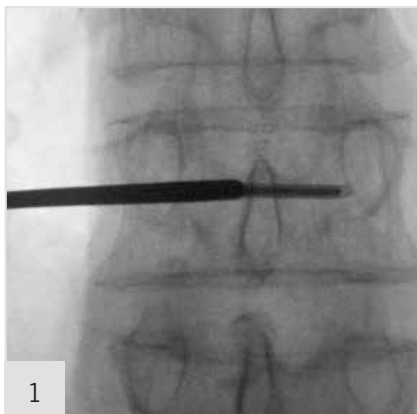
Hard Bone Technique

If treating hard, dense bone, create all desired channels prior to mixing and priming cement system. Keep the flexible obturator in place during all channel creation activities, as this will prevent lumen occlusion from the highly dense bone.

Once all desired channels are created, retract wire and undock device. Mix and prime cement system per standard procedure. **ALL CEMENT PRIMING MUST BE DONE AT BACK TABLE.**

Re-access each channel and inject with the desired amount of cement. For each injection site, wire should be retracted $\frac{1}{2}$ to 1 turn from fully deployed position in order to flow cement properly into the channel.

All wire deployment is performed with flexible obturator in place. This prevents the hard, dense bone from occluding the wire lumen.



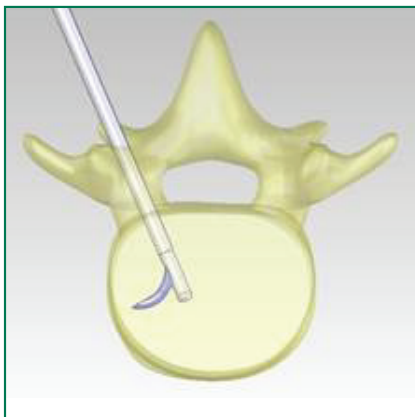
1-3 Perform contralateral channel creation as needed.

4-5 Perform ipsilateral channel creation, if desired. See next page for more details.

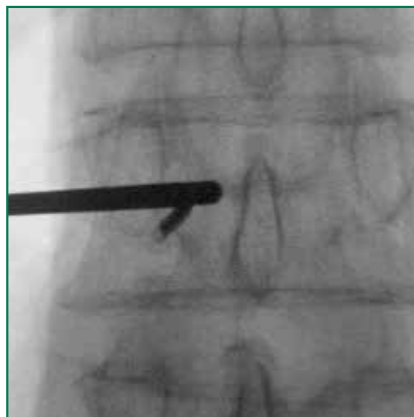
**INJECT CEMENT AFTER PRIMING
BLAZER-C SYSTEM AND RE-ACCESSING
EACH CHANNEL CREATED ABOVE**

Ipsilateral Channel Creation

If ipsilateral channels are desired, unlock working cannula and retract the Blazer device back (posteriorly) to ensure sufficient space for wire deployment. Advance Blazer wire slowly and do not deploy completely on the ipsilateral side.



Axial view



AP view



Lateral view

Cement System

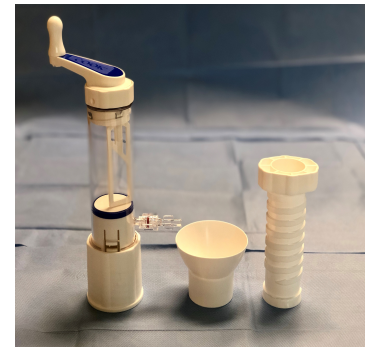


Monomer Ampule

PMMA Powder Pouch



Injector and Mixer Set

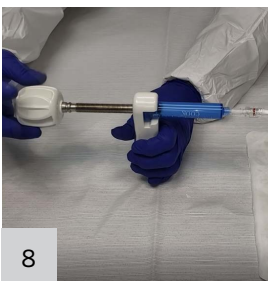
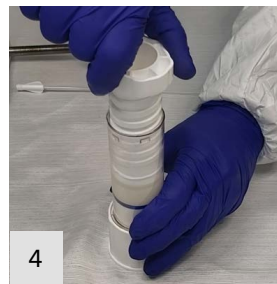
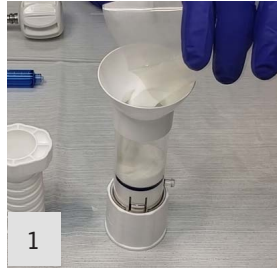
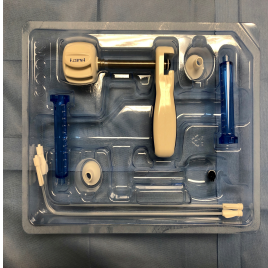


Filling Mixer and Mixing	Transfer to Injection Gun	Delivery into Vertebral Body	Hardening Time (post-injection)
30 seconds	30 seconds to 6 minutes 10 seconds	6 minutes 10 seconds to 21 minutes 40 seconds	21 minutes 40 seconds to 33 minutes 20 seconds

Cement Mixing Procedure

The Injector

The Mixer



- 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 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.

Total mixing Time: 30 seconds (20 seconds in warmer environments)

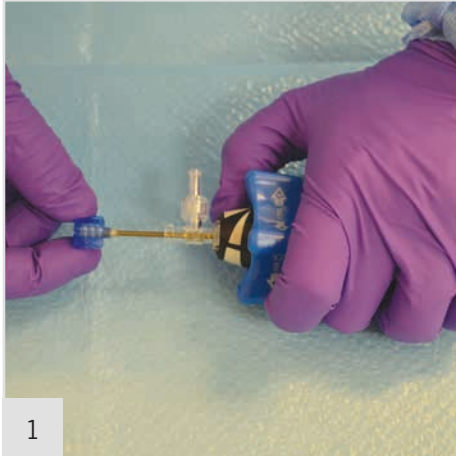
Ideal Cement Consistency



Dry Cement

The cement should appear shiny
not dull.

Blazer-C Priming



- 1 Remove the flexible obturator.
- 2 Attach extension tube to Blazer-C top luer.

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Note: Ensure that
Blazer wire is in the
deployed state.
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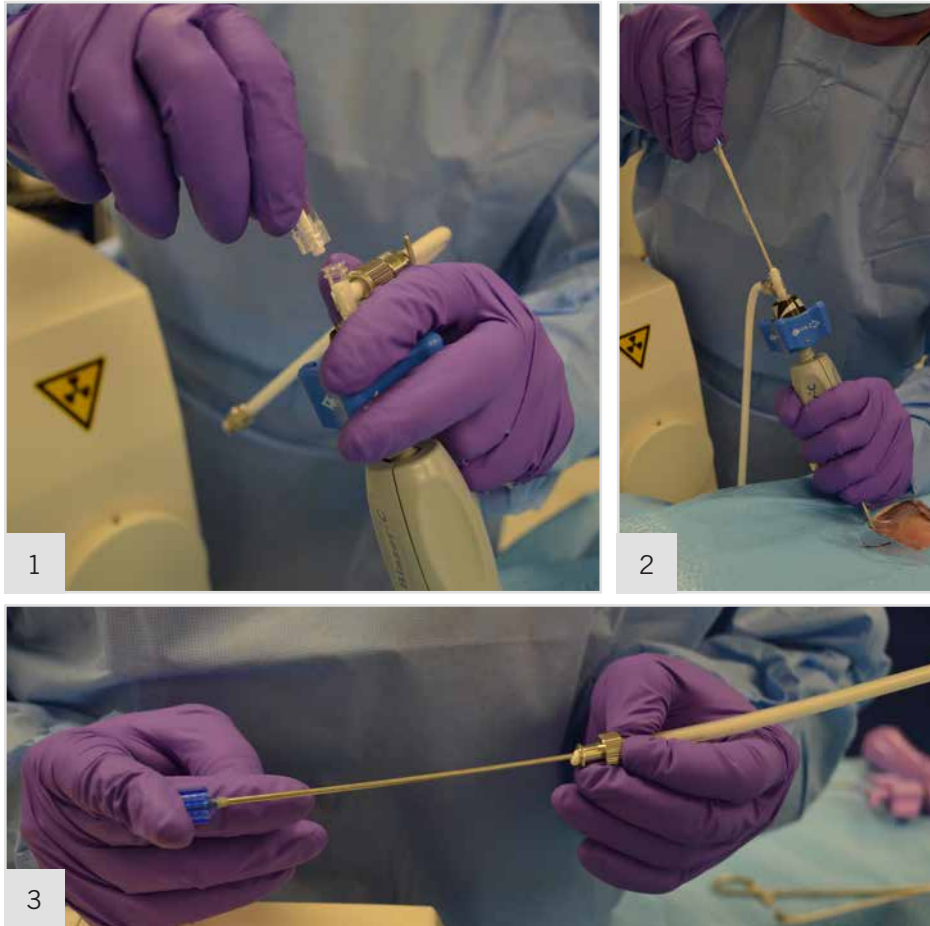
- 3 Prime the device until bone cement is flowing uniformly and all dry cement has been expressed out.



Cement Delivery

- 1 Fully retract Blazer wire and re-insert into working cannula.
Deploy wire under fluoro guidance.
- 2 Begin cement delivery when distal tip of wire is at desired location within the vertebral body.

Cement Delivery Tips

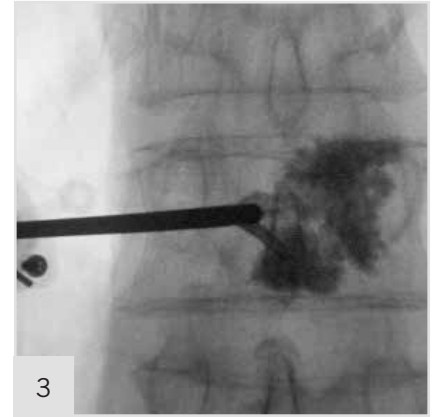
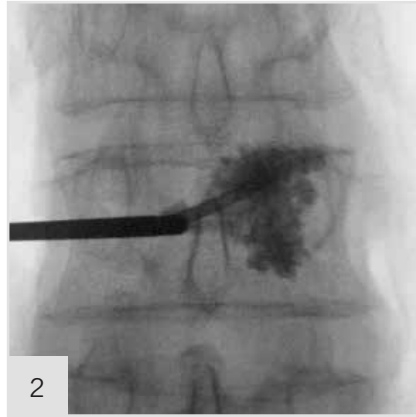


How to address blockage:

If cement is not flowing out of the tip of Blazer wire, retract wire slightly to allow for cement to flow. Be sure wire is deployed at least $\frac{1}{4}$ turn.

- 1-2 If the tip of the wire appears to be plugged, remove proximal Luer cap and insert rigid obturator to clear plug. Remove obturator and replace Luer cap. Continue cement injection.
- 3 Rigid obturator can be used to express cement from the flexible extension tube to utilize cement contained within.

Blazer – C Cement Delivery



Under live lateral fluoro, begin injecting bone cement into the vertebral body.

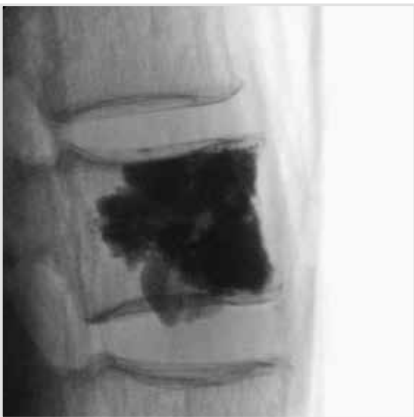
NOTE: AP images are shown as reference only to demonstrate capability of the device. Only inject cement under lateral fluoro to monitor posterior cement flow.

Procedure Completion



- Once the desired amount of bone cement has been injected, fully retract the wire and remove working cannula and Blazer simultaneously.
- If treating multiple levels, re-dock stylet into working cannula and remove together
- Do not remove working cannula by itself!

NOTE: Blazer Osteo-fix cement has a working time of approximately 6 minutes 10 seconds from time of initial mixing. Please keep this in mind at procedural completion. Keep patient immobile for at least 22 minutes beyond working time to allow cement to fully harden.





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