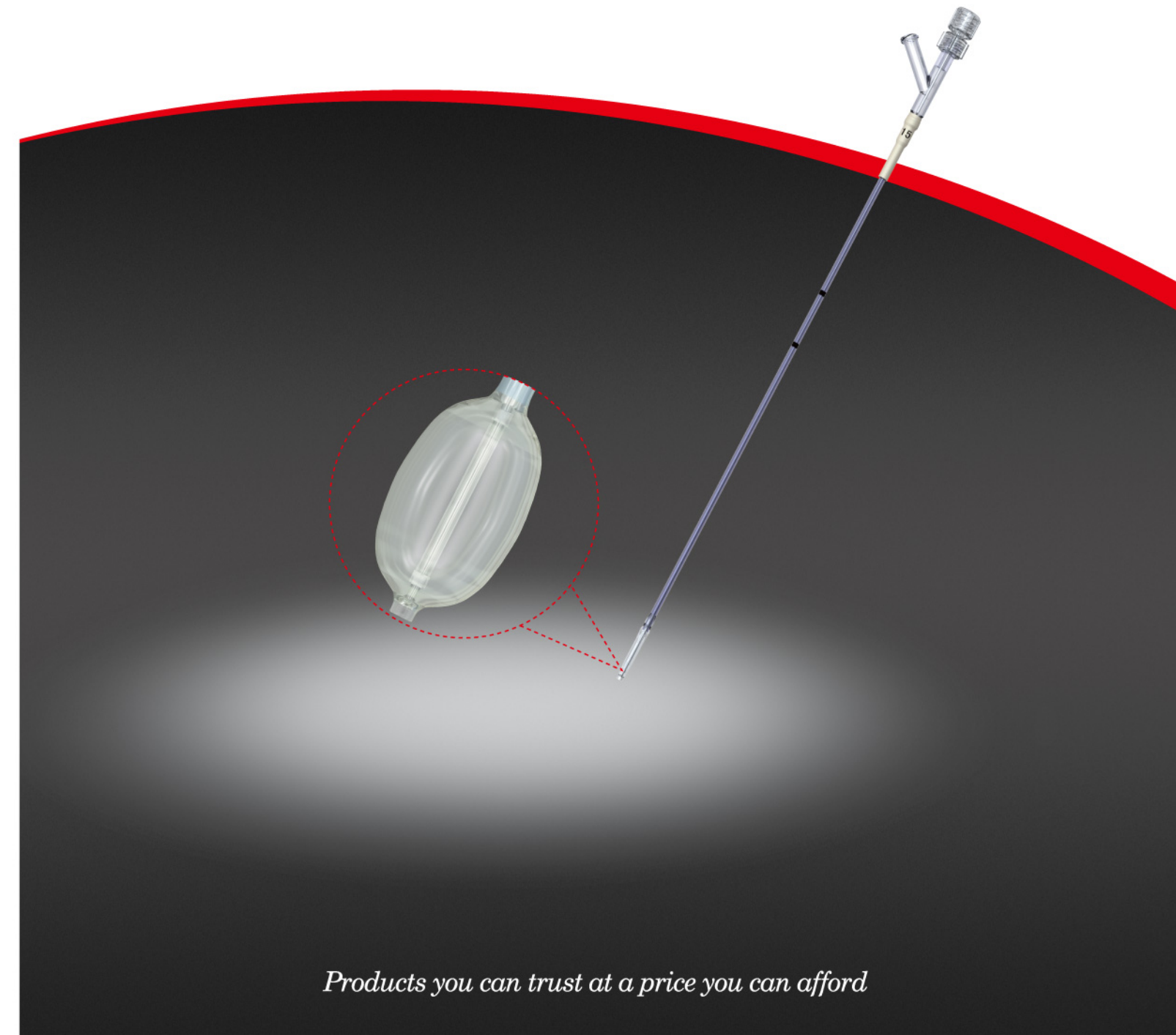


Percutaneous Kyphoplasty System

Surgical Technique



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Warning

This instruction is for reference only.
Operation must be performed under the guides of professional doctors.

Introduction

Trauson percutaneous kyphoplasty balloon system is designed for reducing the VCFs which may result from osteoporosis, osteotraumatic injuries, myelomas or other degenerative bone disease and creating a cavity in cancellous bone in the affected vertebral body by inflating the balloon. This procedure helps to ensure a controlled and contained cement delivery into the fractured vertebral body. The kyphoplasty balloon not only has the advantage of improving or restoring vertebral height and kyphotic deformities, but also decreases the risk of cement leakage and reduces the occurrence of new fracture. It is confirmed in clinical research that it can stabilize the vertebral body fracture, rapidly reduces pain, improve function and patient's health-related quality of life.

Indications

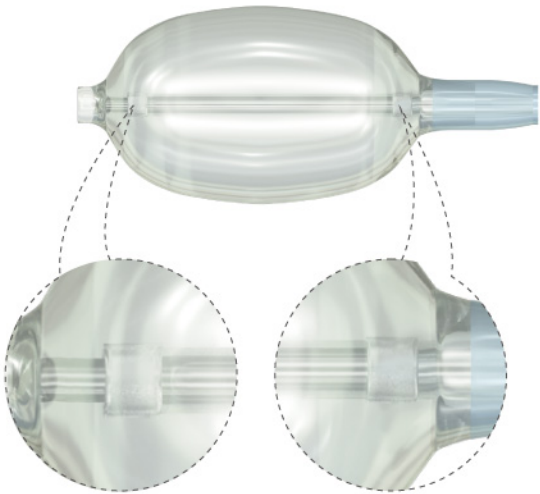
- Fresh VCFs without nerve injury
- Old VCFs (more than 6 months) with severe kyphosis and correlative back pain
- Multi-VCFs secondly to single VCF for osteoporosis
- Pathologic VCFs, such as innocence or malignancy tumor

Contraindications

- Vertebral burst fracture with nerve injury
- Can't tolerance operation for severe heart failure, hepatosis or kidney failure
- VCF with facet joint dislocation
- Osteomyelitis or systemic infection
- Hyperlipemia with vascular embolization record
- Pregnant women
- Bone cement or instrument allergy

Features & Benefits

- Two sizes (15mm, 20mm) to fit more indications
- Simple, ease-of-use balloon pump device
- Two radiopaque markers on the balloon indicates accurate positioning
- Percutaneous surgical approach
- Decrease the risk of cement leakage
- Rapidly restore the collapsed vertebral body



Instruments



Puncture Needle



Needle Guide



Puncture System



Expander Guide



Expander Core



Expander System



Bone Cement Filling Guide



Bone Cement Filling Pusher



Bone Cement Filling System



Puncture System (three-in-one)

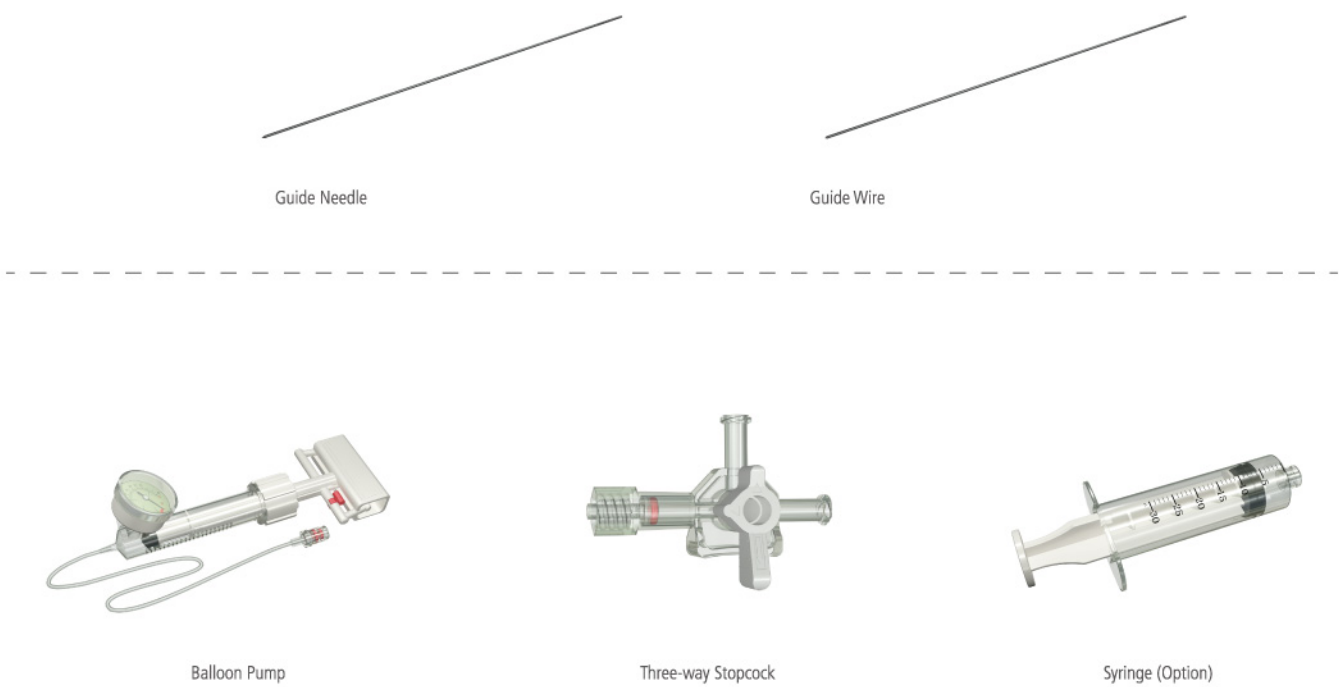


Biopsy System



Drill

Instruments



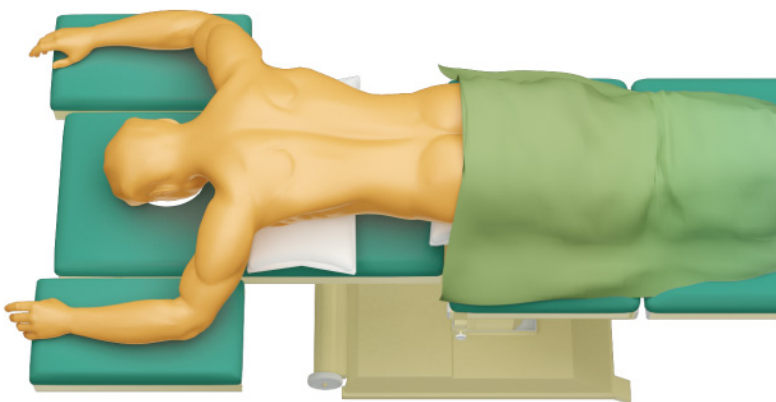
Implants



Surgical Technique

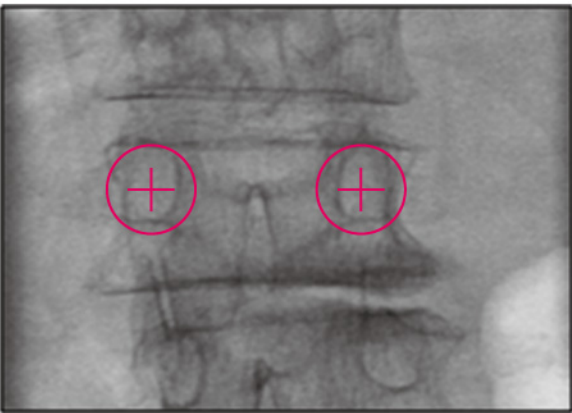
Step1. Patient positioning

The patient should be in a prone position on a radiolucent table, permitting AP and lateral view under image intensifier control.



Step2. Determine entry point

Identify the anatomical landmarks of the affected segments under image intensifier control in AP view and draw some marks of the pedicle on the body surface.



Note:

-The desired incision should facilitate insertion directly through the pedicle.

Step3. Create a pathway

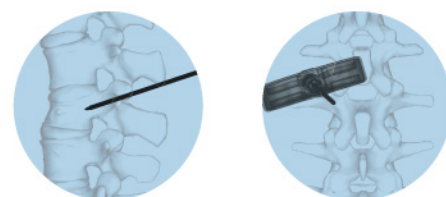
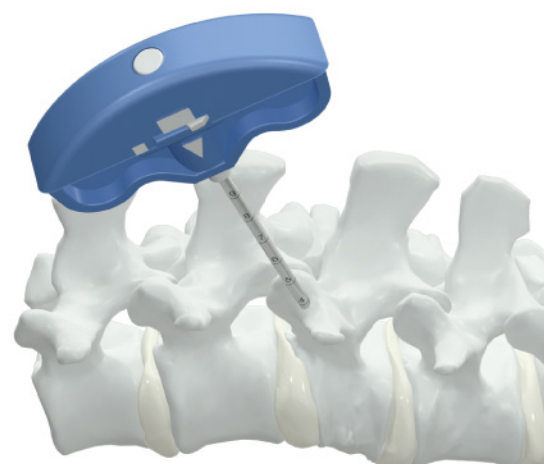
Trauson kyphoplasty balloon system provides two optional procedures for creating the pathway. Uni-pedicular or bi-pedicular approach may be used depends on the surgeon's discretion. Illustrate with uni-pedicular approach.

Surgical Technique (Continue)

Option 1

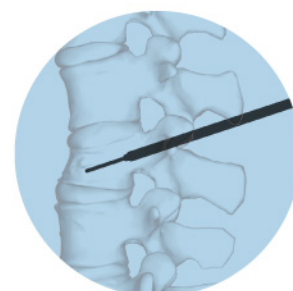
1). Insert puncture system

Make a stab incision on the pedicle level of skin and manually insert the puncture system (puncture needle and needle guide) in the desired position. Penetrate the lateral cortex of the affected vertebral body, the puncture position should be confirmed under image intensifier in AP and Lateral view.



2). Insert guide wire

Remove the puncture needle, insert a guide wire to a desired depth through the puncture needle guide and make sure the tip of the guide wire parallel is to the superior endplate in the lateral view.



Notes:

- The guide wire should be inserted deeper (generally insert the guide wire into two-thirds of the vertebral body) which prevents pulling-out the guide wire in the following procedure.
- The final position of the guide wire in AP and Lateral view is strongly recommended under image intensifier

3). Insert expander system

Remove the puncture needle guide, manually insert the expander system (expander core and expander guide) over the guide wire to a desired length (2-3mm anterior to the posterior cortical edge of the vertebral body). Remove the expander core and guide wire, leave the expander guide as the final working passage for insertion kyphoplasty balloon.



Note:

- Insert the expander system by applying gentle blows with the hammer is also available.

4) Insert biopsy system (option)

Insert the biopsy system through the working passage, collect desired biopsy sample using the serration tip of the biopsy system.

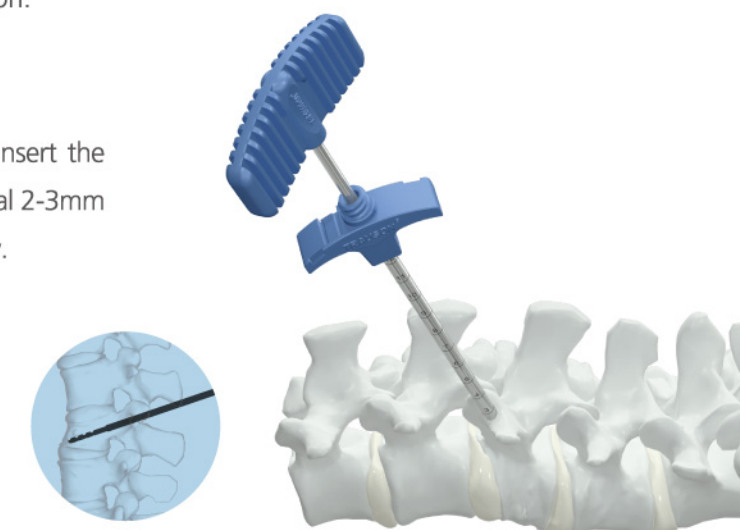


Note:

- Generally speaking, this system is used to collect the biopsy specimen which needs to be clinically determined, such as tumors or tuberculosis, and so on.

5) Drill

Under image intensifier control in lateral view, insert the drill through the expander guide and drill proximal 2-3mm to the anterior cortical edge of the vertebral body.



Surgical Technique (Continue)

Option 2

Make a stab incision and direct manually insert the three-in-one puncture system (puncture needle and needle guide) in the desired position. Penetrate the lateral cortex of the affected vertebral body, the three-in-one puncture system position should be confirmed under image intensifier in AP and Lateral view.

If the position and direction of the three-in-one puncture system is correct, continue manually inserting it into the vertebral body to a desired depth. Remove the puncture needle and leave the three-in-one puncture needle guide as the final working passage for insertion kyphoplasty balloon. Then insert the drill through the three-in-one puncture needle guide and drill proximal 2-3mm to the anterior cortical edge of the vertebral body.



Notes:

- The difference between puncture system and three-in-one puncture system as follows: the needle guide of three-in-one puncture system has the same diameter as expander guide (in option 1, it's the final working passage for insertion balloon)
- It is recommended that the three-in-one puncture system should be used by the surgeon who has rich experience.

Step4. Prepare the kyphoplasty balloon

1) Assemble stopcock device

Attach the three-way stopcock, a syringe filled enough contrast medium and the balloon pump together, turn the stopcock and make the syringe connecting with the balloon pump (image).

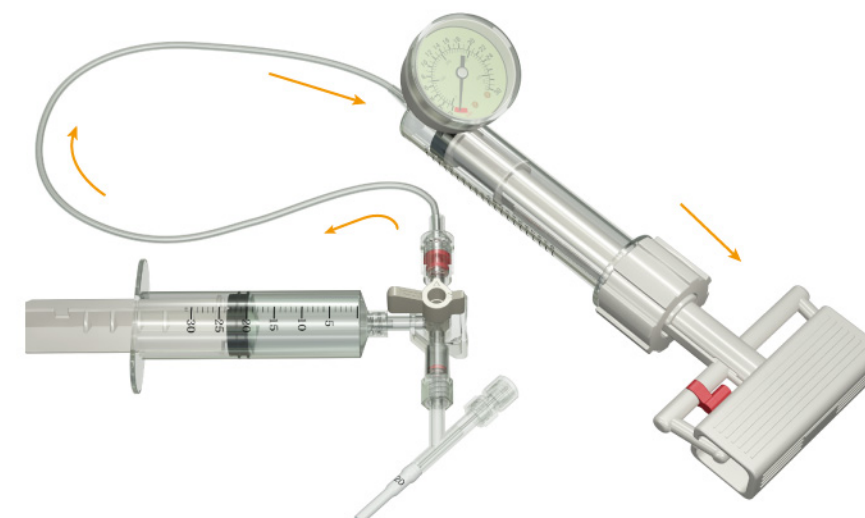


Note:

- The semi-circle portion (red line) of the three-way stopcock always points to the channel which is closed.

2) Fill the balloon pump

Pull the handle of the balloon pump back, fill the balloon pump with enough contrast medium which comes from the syringe, pull the air out and make sure the total balloon pump is filled with fluid.



3) Connect balloon with syringe and create vacuum

Turn the stopcock to connect the syringe with the kyphoplasty balloon (image), pull back the handle of the syringe to pull the air out of the kyphoplasty balloon, which creates a vacuum in the kyphoplasty balloon.



4) Connect the balloon with the balloon pump

Turn the stopcock to connect the balloon with its pump (image), now the desired kyphoplasty balloon is prepared.

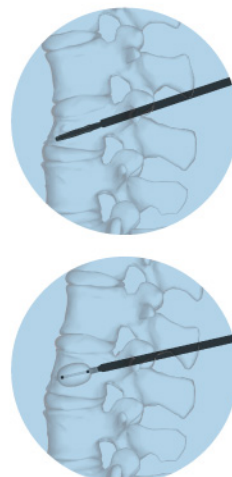


Surgical Technique (Continue)

Step5. Restore the vertebral body

1) Insert the balloon

Insertion the kyphoplasty balloon through the expander guide (or puncture needle guide of the three-in-one puncture system), the two radiopaque markers of the balloon must be cleared manifested in the vertebral body and the proximal mark should be about 2-3mm outside the expander guide.

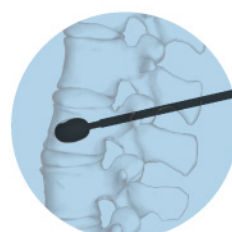


Notes:

- Before insertion the kyphoplasty balloon, use the bone cement filling system to smooth the bone debris of the balloon working passage, this procedure reduce the risk of the bone debris damaging the kyphoplasty balloon.
- Insertion the kyphoplasty balloon is strongly recommended under image intensifier control.

2) Inflate balloon with fluid

Slowly rotate the handle of the balloon pump clockwise while monitoring the pressure and volume. Inflate the balloon slowly to restore the height of collapsed vertebral body and create a cavity inside, the surgeon should record the amount of injected fluid (about 4ml for 15mm balloon, 6ml for 20mm balloon) to predict the cement volume. The most suitable balloon pressure is around 15bar (220psi) and not yet beyond 300psi.



Notes:

Stop increasing pressure when any of the following happen:

- The desired clinical outcome is reached
- Can't restore the collapsed vertebral body anymore, but the balloon already reaches the endplate of the vertebral body
- The maximum volume is achieved, 4.0mm for 15mm balloon, 6mm for 20mm balloon
- The pressure reaches 220psi

3) Kyphoplasty balloon removal

Deflate the balloon by turning the handle of balloon pump counterclockwise, until the indicator of the manometer points in the VAC area (image). Or directly pull slowly the handle of the balloon pump back to fully collapse the balloon and draw a vacuum in the balloon. Remove the kyphoplasty balloon from the working passage (expander guide or three-in-one puncture guide)



Step6. Cement delivery

1) Prepare the bone cement

Note:

-This procedure is strongly recommended to follow the manufactures' recommendations for bone cement use in the vertebral body.

2) Prepare the bone cement filling system

Attach the tip of the syringe which is already with enough bone cement to the end of the bone cement filling guide and fully fill it. Prepare enough quantity of the bone cement filling system.

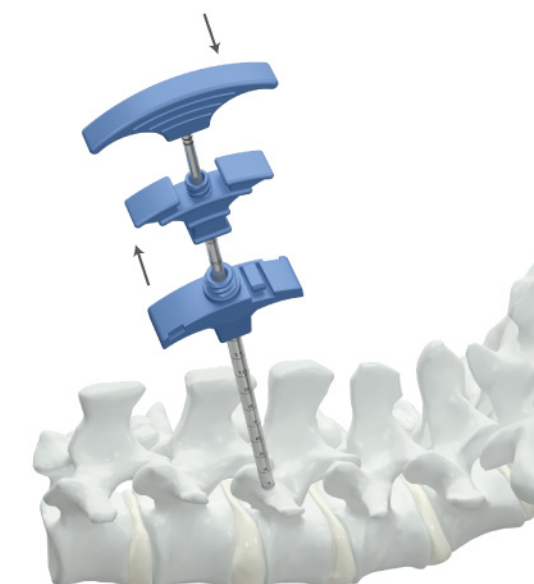
Note:

-Illustrate with 15mm kyphoplasty balloon, prepare at least four bone cement filling system is recommended.



3) Injection the bone cement

Insert the bone cement filling system (bone cement filling guide and bone cement filling pusher) to the anterior edge of the created cavity through the working passage (expander guide or three-in-one puncture guide) and inject the bone cement by slowly pushing the bone cement filling pusher, meanwhile pull the bone cement filling guide back slowly. Fill the remained cavity with the same procedure.



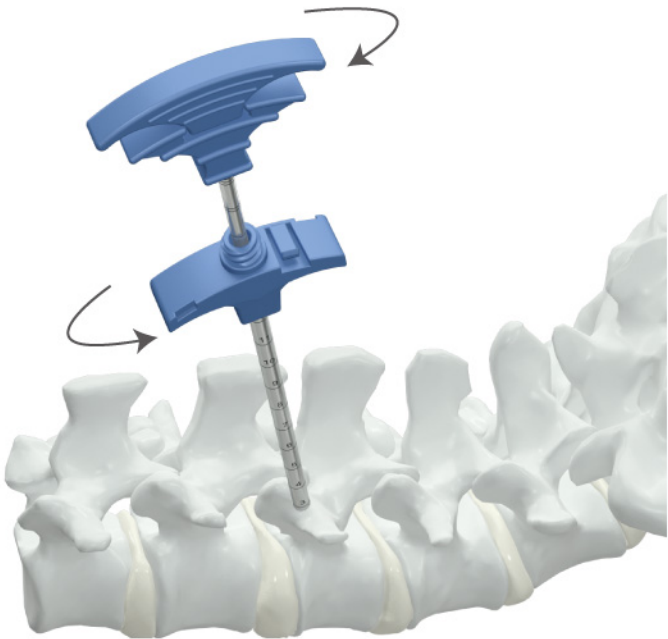
Surgical Technique (Continue)

Note:
-In order to reduce the risk of cement leakage, this procedure is strongly recommended under image intensifier control in lateral view.



4. Remove the bone cement filling system and working passage
Once the cement has fully hardened according to the manufacture’s IFU, slowly remove the filling system and working passage. Close the incision.

Note:
-Before the bone cement is sufficiently hardened, turn the bone cement filling system and working massage clockwise every few seconds to “cut” the connection among the bone cement, the filling system and working passage. This procedure may reduce the risk of pulling cement fibres into the muscle tissue.



Instruments Ordering Information

P/N	Description	Quantity
13803100E	Puncture Needle	2
13803200E	Needle Guide	2
13800300E	Expander Core	1
13800400E	Expander Guide	2
13800500E	Drill	1
13800601E	Guide Wire	2
13800602E	Guide Needle	2

P/N	Description	Quantity
13800700E	Bone Cement Filling Guide	4
13800800E	Bone Cement Filling Pusher	4
13800915E	Ballon,15mm	1
13800920E	Ballon,20mm	1
13801000E	Ballon Pump	1
13803500E	Biopsy Guide	1
13803600E	Biopsy Pusher	1