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, hepatitis 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
Surgical Technique

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

2. 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.

3. Create a pathway
Truson 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.
Percutaneous Kyphoplasty System

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.

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 (2-3 mm 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 2-3 mm 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.

Step 4. 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)

Step 5. Restore the vertebral body

1) Insert the balloon
Insertion of 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 clearly manifested in the vertebral body and the proximal mark should be about 2-3mm outside the expander guide.

Notes:
- Before insertion of 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 of the kyphoplasty balloon is strongly recommended under image intensifier control.

2) Inflated 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).

Step 6. Cement delivery

1) Prepare the bone cement

Note:
- This procedure is strongly recommended to follow the manufacturers' 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 manufacturer’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

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<th>Quantity</th>
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<td>Needle Guide</td>
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