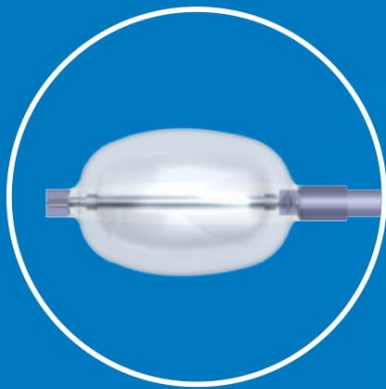


Carlton Kyphoplasty System

Surgical Technique



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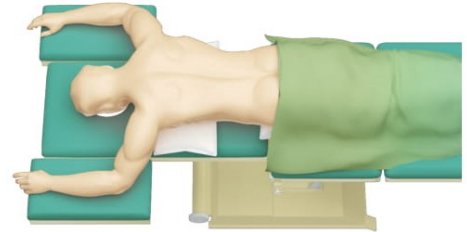
Product information

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Surgical Technique

Step 1 Patient Positioning

Position the patient to reduce any load on the fractured bone, if the fracture is located in the lumbar lordotic curvature, place the patient into hyper-lordosis. The operation table should be radiolucent, permitting AP and lateral view image under intensifier control.

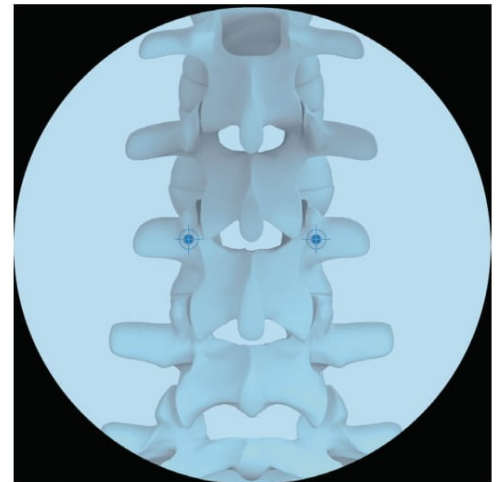


Step 2 Anaesthesia

The operation may either be performed under general or local anaesthesia.

Step 3 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.



Step 4 Bone Access

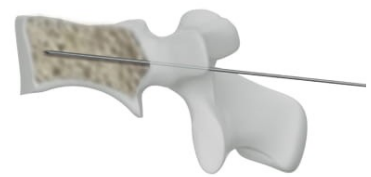
Before starting the procedure, determine the best inclination for bone access and placement for the balloon. Angle the guide pin inclination to the trajectory required for balloon placement. A wedge fracture will require a diagonal inclination while a central fracture will require a more horizontal inclination.



Superior wedge fracture

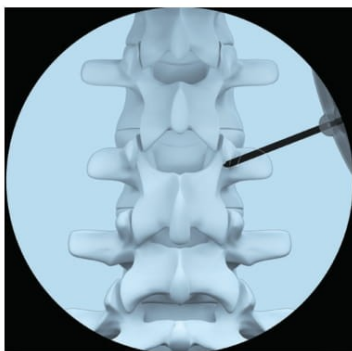


Central compression fracture



Inferior wedge fracture

Carlon Kyphoplasty System provides two optional procedure for creating the pathway. Uni-pedicular or bi-pedicular approach may be used depends on the surgeon's discretion. This surgical technique will illustrate with uni-pedicular approach.



4.1 Option 1

1. Insert trocar

Make a stab incision on the pedicle level of skin and manually insert the trocar in the desired position, verifying the angle of inclination and orientation in AP and lateral view. Continue the insertion through the pedicle in the AP view until reach the medial edge of the pedicle ring. Before entering the vertebral body, verify the position of the needle in the lateral view.



In the lateral view, advance the trocar to a point 2mm past the posterior wall of the vertebral body and remove the stylet.



2. Insert guide wire

Insert a guide wire to a desired depth through the trocar guide. Generally insert the guide wire into two-thirds of the vertebral body in order to prevent pulling-out the guide wire in the following procedure. Verify the final position of the guide wire in lateral and AP view is highly recommended.

3. Insert expander

Remove the trocur guide, position expander over the guide wire and advance it forward until it is at least 4mm past the posterior wall of the vertebral body. Remove the guide wire and the stylet of the expander, leave the expander guide as the final working passage.

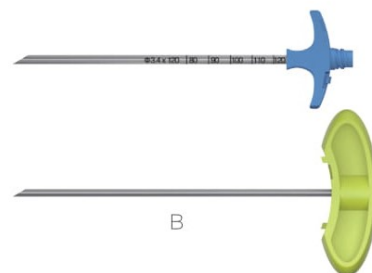


Option 2

Insert trocar expander

Make a stab incision on the pedicle level of skin and manually insert the trocar expander in the desired position, verifying the angle of inclination and orientation in AP and lateral view. Continue the insertion through the pedicle in the AP view until reach the medial edge of the pedicle ring. Before entering the vertebral body, verify the position of the trocar expander in the lateral view.

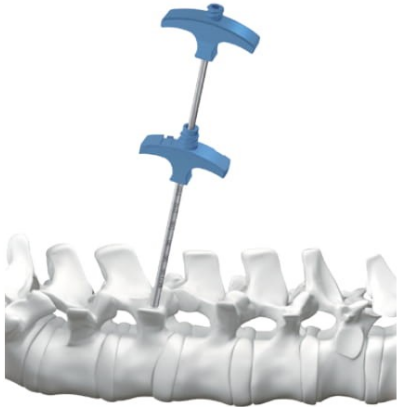
If the position and direction of the trocar expander is correct, continue advance it forward until it is at least 4mm past the posterior wall of the vertebral body. Remove the stylet of the trocar expander, leave the trocar expander guide as the final working passage.



Notes

The diameter of the trocar expander and expander is equal, so the trocur expander guide is the final working passage when use the trocar expander. It's highly recommended only surgeon who has rich experience could use trocar expander.

4.2 Biopsy(option)



Insert biopsy guide through the working passage, turn and collect desired biopsy sample. Insert biopsy stylet into biopsy guide to take out the biopsy sample.



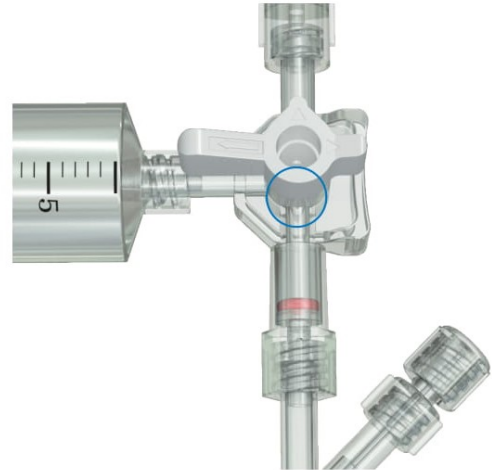
4.3 Drill

Use drill to create a space in the vertebral body to facilitate the insertion of balloon, stop at 2-3mm before the cortical wall under lateral image monitor.

a Prepare Kyphoplasty balloon

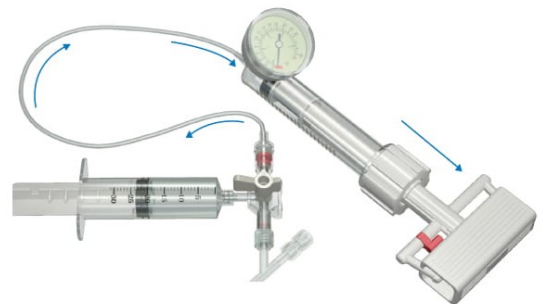
1. Assemble three-way stopcock device

Assemble the three-way stopcock, a syringe with enough contrast medium, pump and balloon together. Turn the stopcock and make the syringe connecting with the pump. Note, the portion with no arrow of the three-way stopcock always points to the channel which is closed, the lower side of the figure.



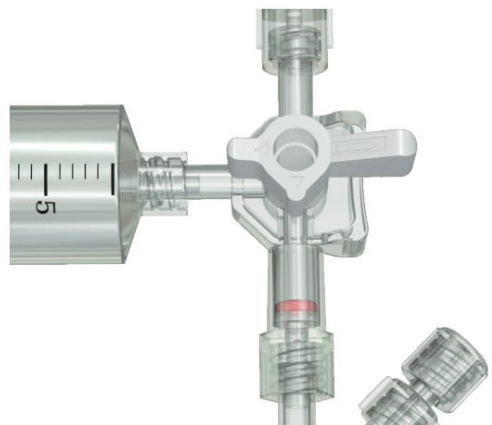
2. Fill the pump with contrast medium

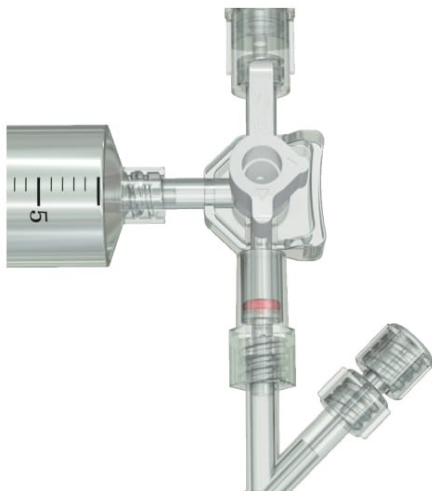
Pull the handle of the pump back, fill the pump with enough contrast medium which comes from the syringe, pull the air out and make sure the total pump is filled with fluid.



3. Connect balloon with syringe and create vacuum

Turn the stopcock to connect the syringe and balloon, pull back the handle of the syringe to pull the air out of the balloon, which creates vacuum in the balloon.





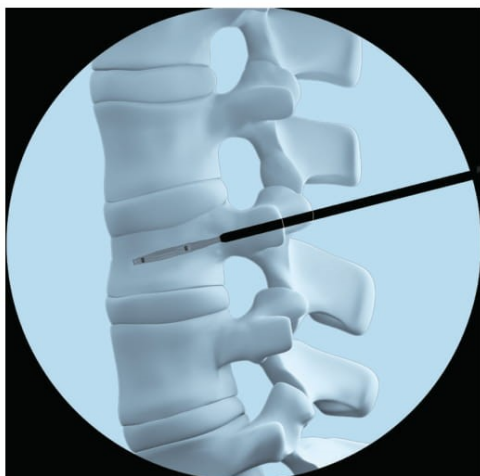
4. Connect the balloon with pump

Turn the stopcock to connect balloon with pump, and now the desired balloon is prepared.

b Restore Vertebral Body

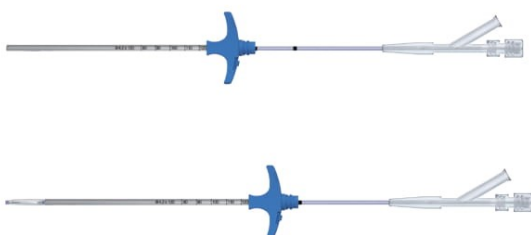
1. Insert the balloon

Insert the balloon through the expander guide or trocar expander guide, the two radiopaque markers of the balloon must be cleared manifested in the vertebral body and the proximal marker should be about 2-3mm outside the guide. The two black lines on the balloon catheter could also to show the position of the balloon, when the first line close to guide which means the balloon begin to come out of the guide, when the second line close to the guide which means the balloon comes out of the guide completely.



Notes

Note, before insert the 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 balloon. Insertion the balloon is highly recommended under image intensifier control.



2. Inflate balloon with fluid

Slowly rotate the handle of the pump clockwise while monitoring the pressure and volume, when the volume reaches 1-2ml, removes the stylet from the balloon. Continue to inflate the balloon slowly to restore the height of the collapsed vertebral body and create a cavity inside. The surgeon should record the amount of injected fluid (about 4ml for 10mm and 15mm balloon, 6ml for 20mm balloon) to predict the cement volume. The most suitable balloon pressure is around 220psi, and not yet beyond 300psi.

Stop increasing pressure when any of the following happen:

- The desired clinical outcome is reached;
- The balloon contacts with any of the cortical walls;
- The maximum volume is achieved, 4ml for 10mm and 15mm balloon, 6ml for 20mm balloon;
- The pressure reaches 220psi.



3. Balloon removal

Deflate the balloon by turning the handle of pump counter-clockwise until the indicator of the manometer points in the vac area. Or directly pull slowly the handle of the pump back to fully collapse the balloon and draw vacuum in the balloon. Remove the balloon from the working passage.

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Step 6 Cement Filling

6.1 Prepare bone cement

Please follow the manufacturer's recommendations to prepare the bone cement used in the vertebral.

6.2 Bone cement filling

1. Prepare bone cement filling system

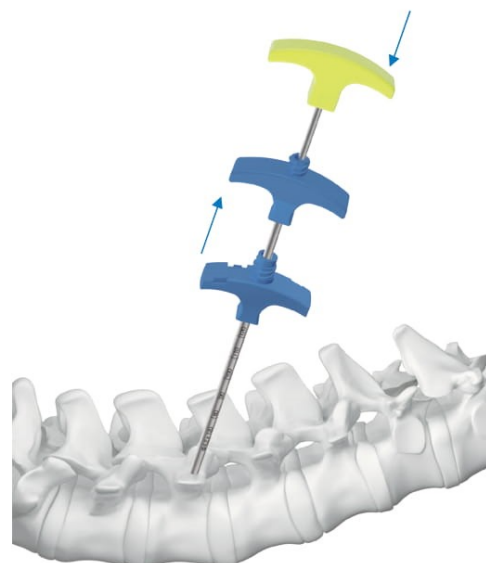
Prepare enough quantity of the bone cement filling system. The volume that the bone cement filling system could hold is 1.2ml for 3.4*120 specification.

The total volume of bone cement can be estimated from the amount of fluid that injected into the balloon. Attach the tip of bone cement injection which is already with enough bone cement to the end of bone cement filling guide and fill it.



2. Injection bone cement

Insert the bone cement filling system into the anterior edge of the created cavity through the working passage 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. In order to reduce the risk of cement leakage, this procedure is strongly recommended under a continuous lateral fluoroscopic image.



3. Remove bone cement filling system and guide



Before the cement is sufficiently hardened, turn the bone cement filling system and working passage in opposite direction every few seconds to cut the connection among the bone cement, filling system and working passage. This procedure could reduce the risk of pulling cement fibers into the muscle tissue. Once the cement is fully hardened according to the manufacturer's IFU, slowly remove the filling system and working passage. Close the incision.

Product information

Balloon



Specification		Product Code
L1	L	
15	120	S771711512

Expander



Specification	Product Code
D*L	
4.2*120	S771750503

Trocar



Specification		Product Code
Model	D*L	
B	3.0*120	S771750203

Trocar Expander



Specification		Product Code
Model	D*L	
B	4.2*120	S771750805

Bone Cement Filling System



Specification		Product Code
Model	D*L	
A	3.4*120	S771751405

Biopsy



Specification	Product Code
D*L	
3.4*120	S771750905

Surgical Technique

Guide Wire



Product Code	S771750300
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Pump



Product Code	S771751300
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Guide Pin



Product Code	S771750400
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Bone Cement Injection



Specification	Product Code
10ml	S771752510

Drill



Specification	Product Code
D*L	
3.5*120	S771750605

Bone Cement



Specification	Product Code
20g	S771700000

NOTE



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