VESSEL-X® BONE FILLING CONTAINER SYSTEM

"VESSELPLASTY" - KYPHOPLASTY REINVENTED

Spirit Spine

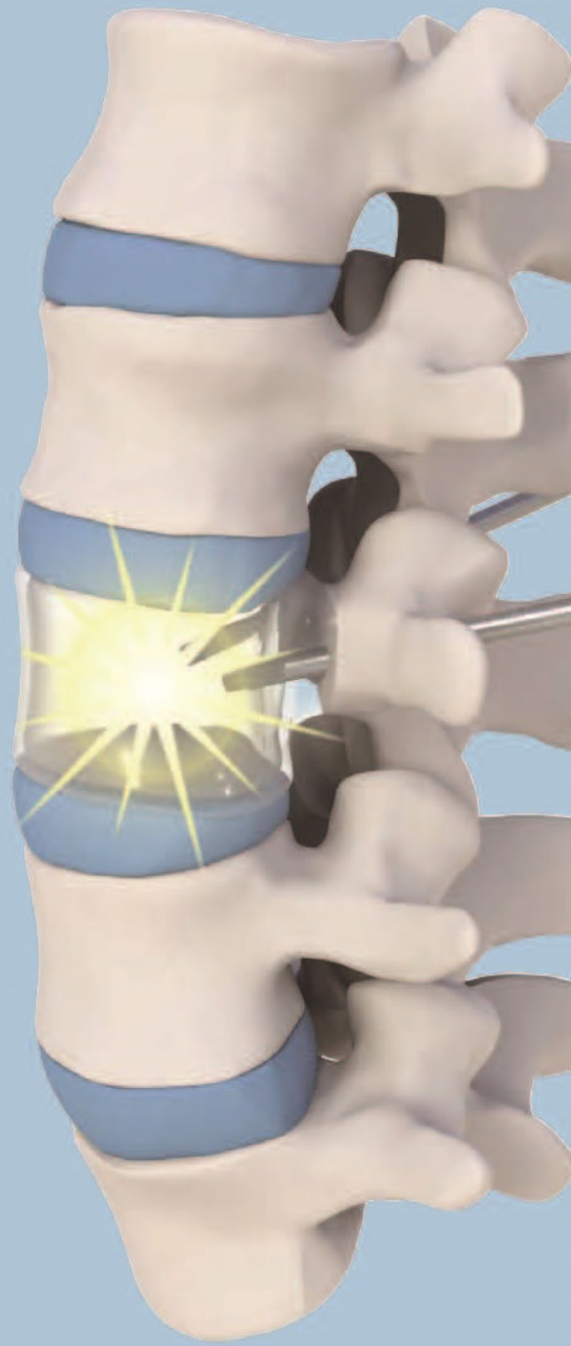
"Simplicity, Stability, and Safety" for Interventional Spine Surgeo

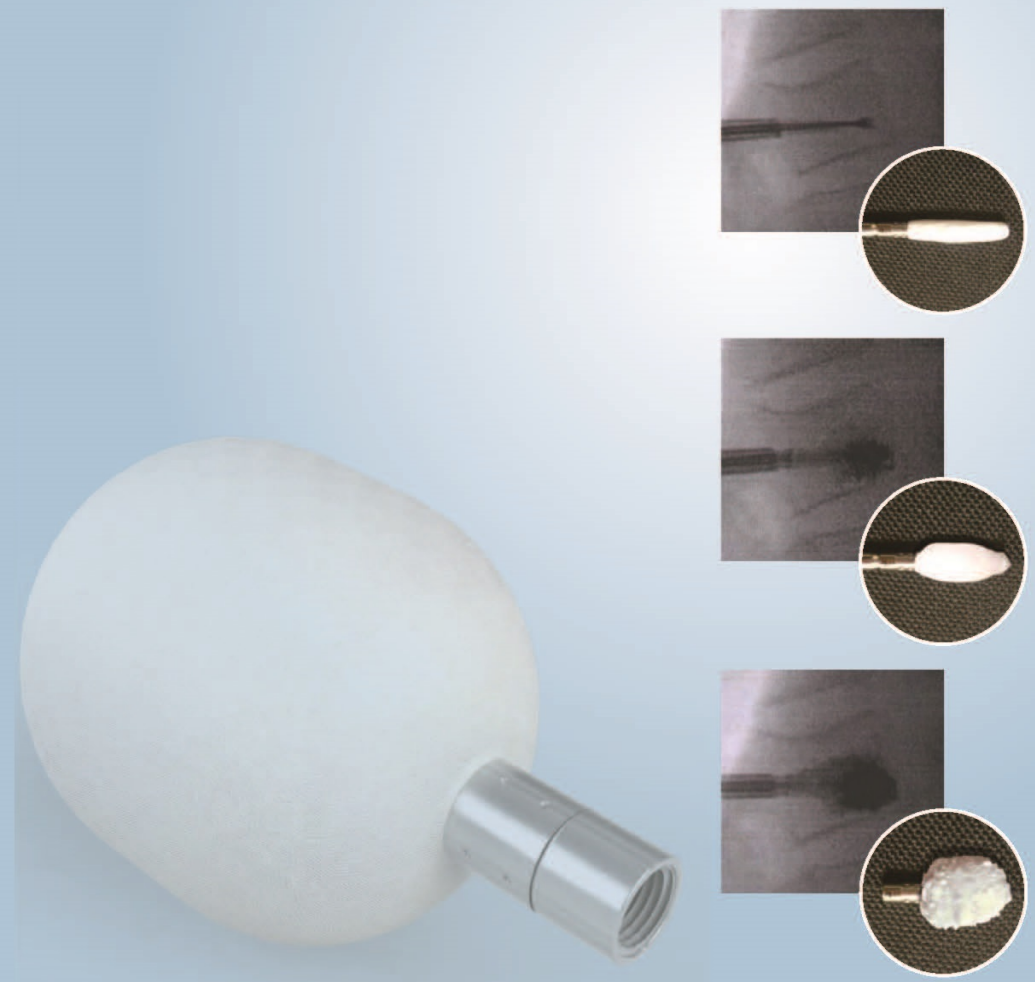
Content

Spine

Cautions

- The Vessel-X® Bone Filling Container System is intended for permanent implant and is for single use only. Do not reuse, reprocess, or resterilize. Reusing the device carries the risk of contamination and may cause patient infection on cross-infection, regardless of the cleaning and resterilizaton methods. There is also an increased risk of the deterioration of the device performance sue to the reprocess steps, which may lead to patient injury or death
- It is important to read the Instruction for Use and these precautions carefully prior to device operation
- Do not use this device if any portion of the packages has been opened or damaged
- The use of this device is by prescription only
- Size of the Vessel-X® Bone Filling Container shall be confirmed before surgery by lateral view of CT scan
- The Vessel-X® Bone Filling Container System should be performed only by experienced spinal surgeons with specific training in the use of this device
- The scale marked of device is for reference only. Physician must confirm patient status at any time by C-arm
- Physicians should inform of all the potential risks and adverse events to the patient
- Twisting power of the Controllable Cement Delivery Device (CCD) E-Plus handle must be added gradually when injecting the bone filler material to restore the proximal height of the jeopardized vertebral body
- To maintain the integrity of the instruments, do not use the working cannula without the stylet





Intended Use

Vessel-X® Bone Filling Containment System is a sterile,single use, implantable device indicated for use in percutaneous procedures in adult patients for the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6 – L5. It is intended to be used in combination with PMMA bone cement that had been cleared for commercial use

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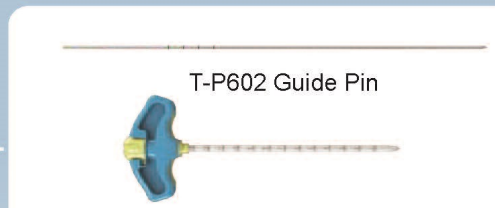
Instruction for Use



T-N201T Bone Access Needle

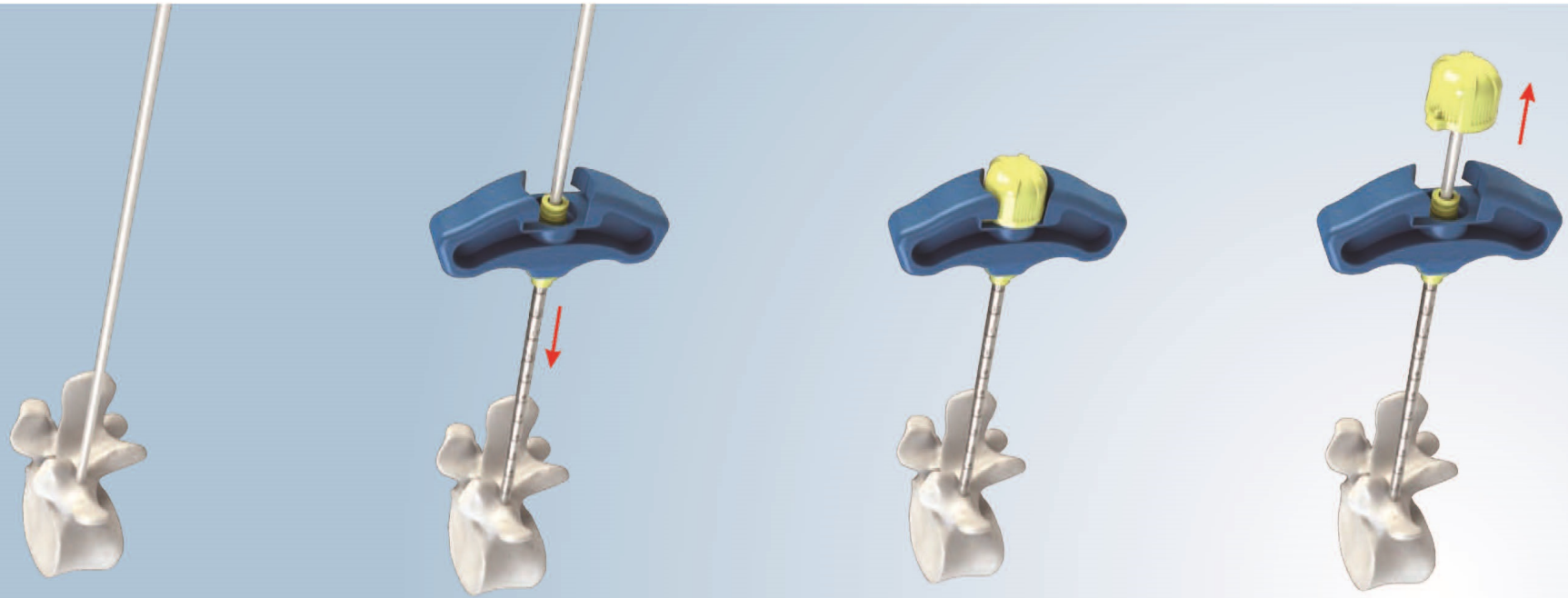
VESSEL-X®

1. Use Guide Pin to confirm the ideal pedicle position under C-Arm fluoroscopy.

2. Separate cannula and stylet of the Bone Access Needle. Insert the cannula along Guide Pin down to the pedicle. Then remove the Guide Pin.

3. Insert the stylet into cannula and pass through the pedicle to the vertebral body.

4. Remove the stylet and leave the cannula in the vertebral body.



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Instruction for Use

T-D401 Precision Drill

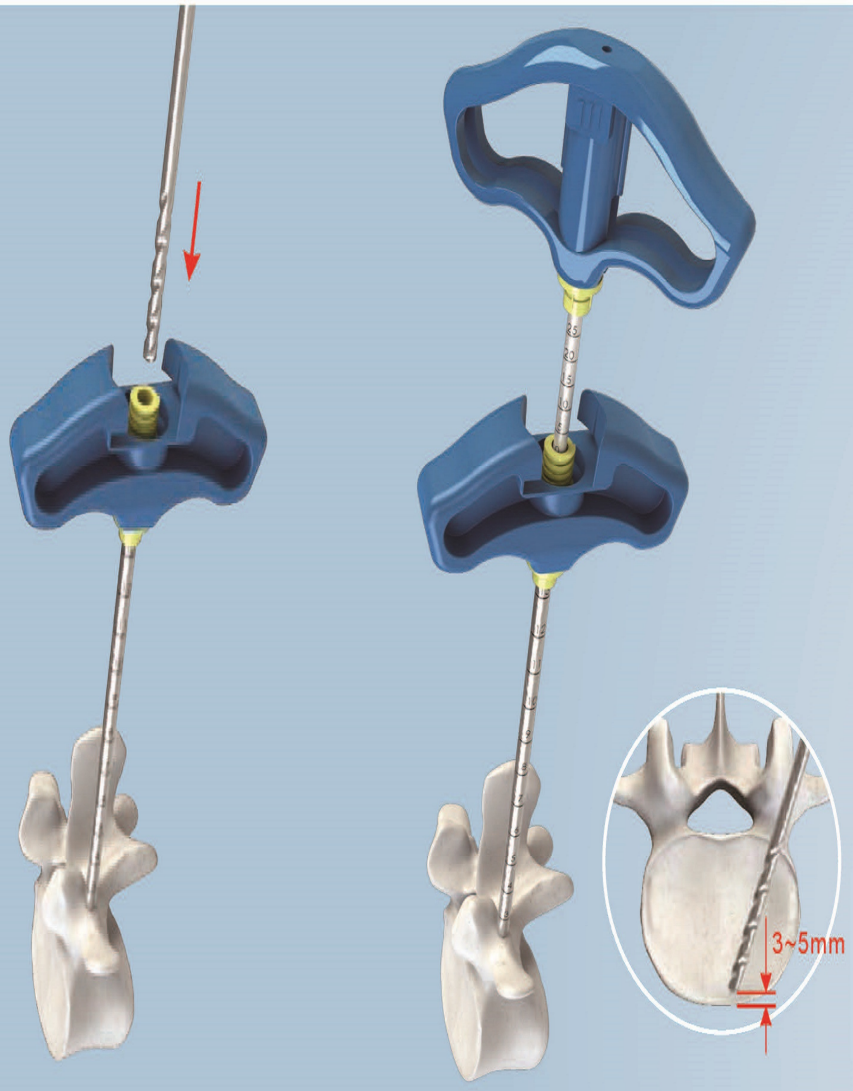
VESSEL-X®

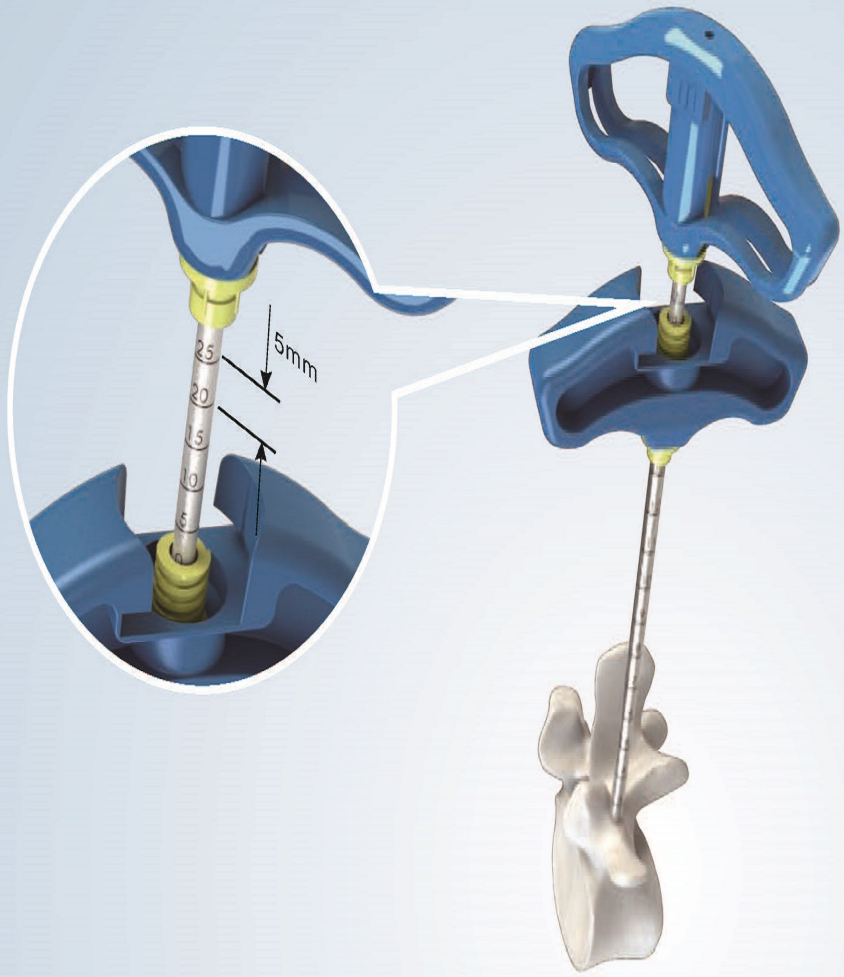
5. Under fluoroscopy guidance, insert the Precision Drill through the cannula.

6. Rotate the Precision Drill close to the center of the vertebral body. Under fluoroscopy guidance, confirm that the depth of the Precision Drill is at about 3-5 mm posterior to the anterior wall of the vertebra.

7. Each hatch mark on the Precision Drill represents an increment of 5mm. When the Precision Drill is fully inserted through the cannula, the depth reached by the Precision Drill is 3 cm. Pay attentions not to breach the anterior wall of the vertebra body while advancing the Precision Drill.

8. If it is needed, repeat the above steps for bi-lateral approach. If bone pathology is necessary, insert Biopsy Needle (optional) through the cannula for biopsy collection.





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Instruction for Use

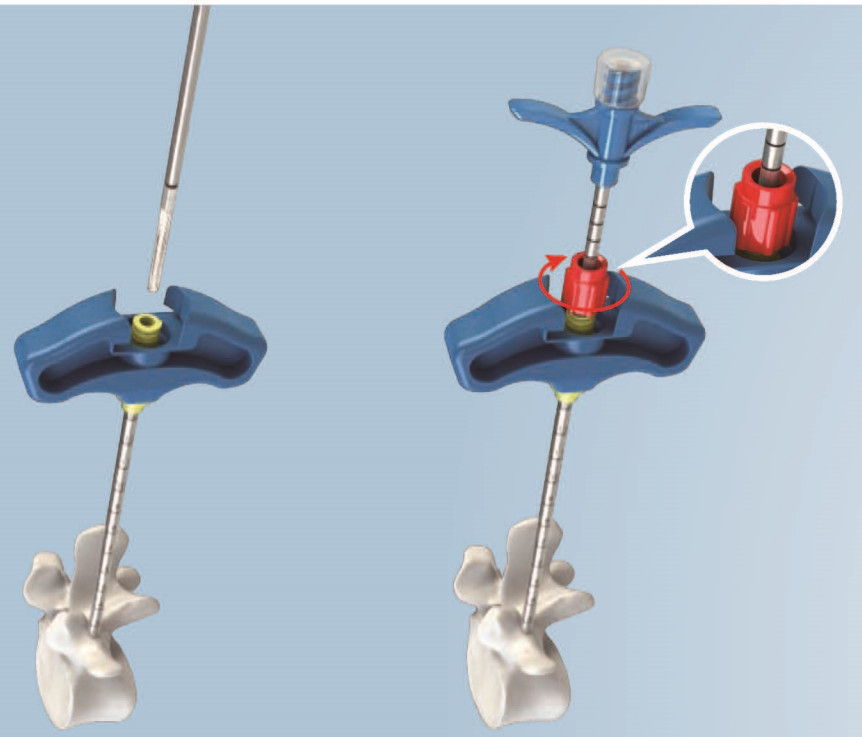
BVFX-D20/25/30
Vessel-X® Bone Filling Container
with cement Pushing Rod

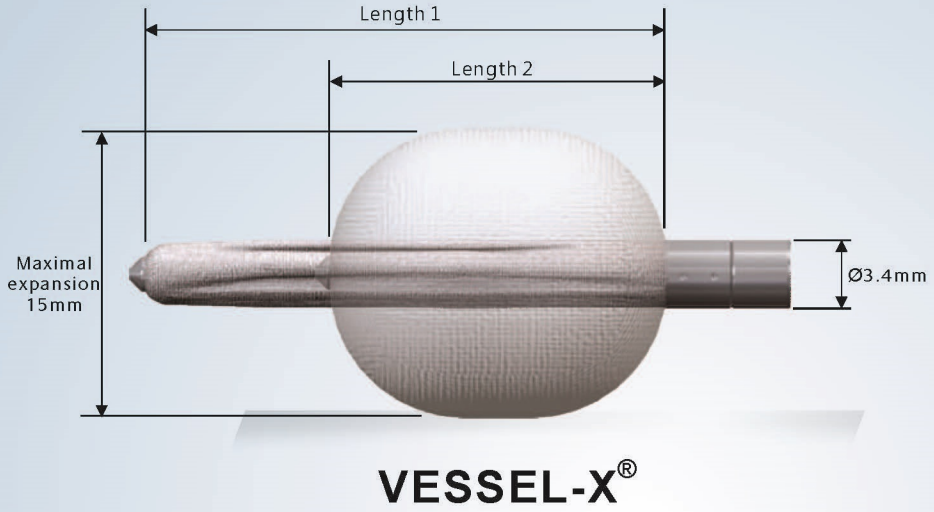
VESSEL-X®

9. Insert Vessel-X® Bone Filling Container along the cannula into the vertebral body. Confirm the depth of the Vessel-X® Bone Filling Container in the vertebral body.

10. Attach the cannula to the red Luer lock and rotate the red Luer lock ring and tighten to the cannula.

Filename	Length 1	Length 2
D20	20mm	12~15mm
D25	25mm	17~20mm
D30	30mm	22~25mm





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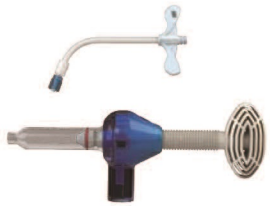


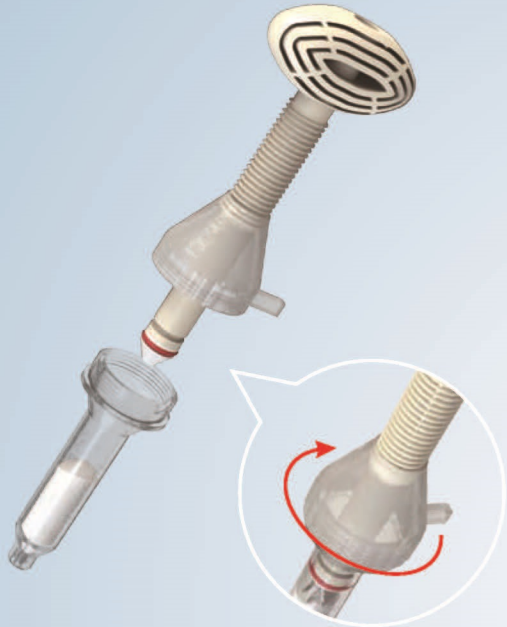
T-C301 Controllable Cement Delivery Device
with Extension Tube

11. Disconnect the syringe and the piston of the CCD according to the method demonstrated in the figure.

12. Pour the pre-mixed bone cement into the syringe.

13. Connect the syringe and pushing part of CCD.

14. Place the blue strengthening cover over CCD.

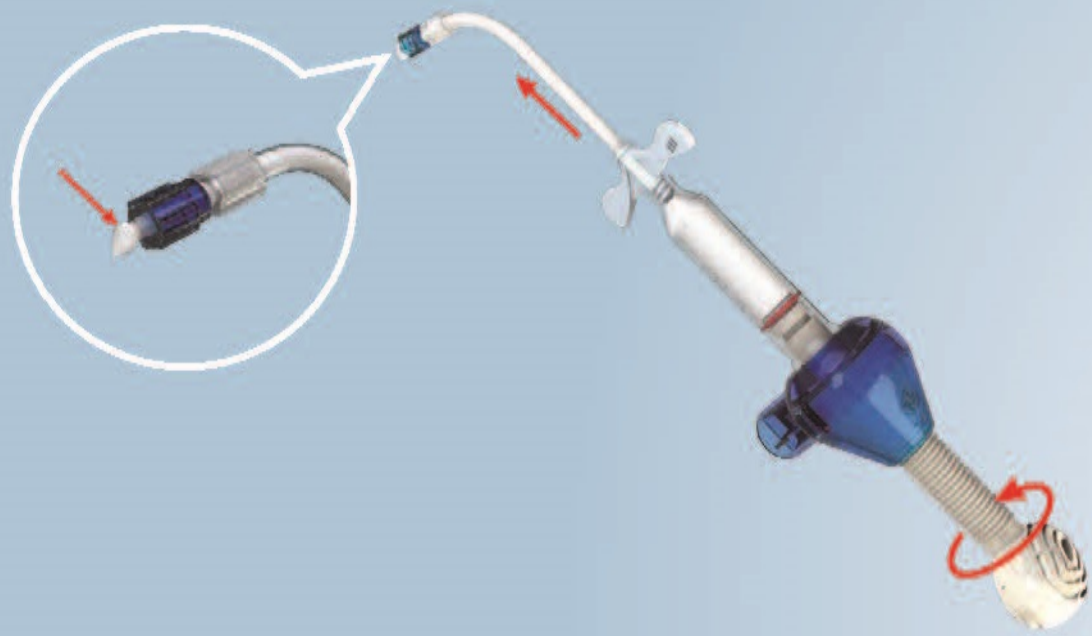


15. Slowly turn the oval piston handle on the syringe to expel air in the barrel.

16. Continue to turn the piston handle on the syringe until some bone cement is extruded at the tip. Check the condition of the bone cement.

17. Connect the extension tube with the syringe of the CCD when necessary.

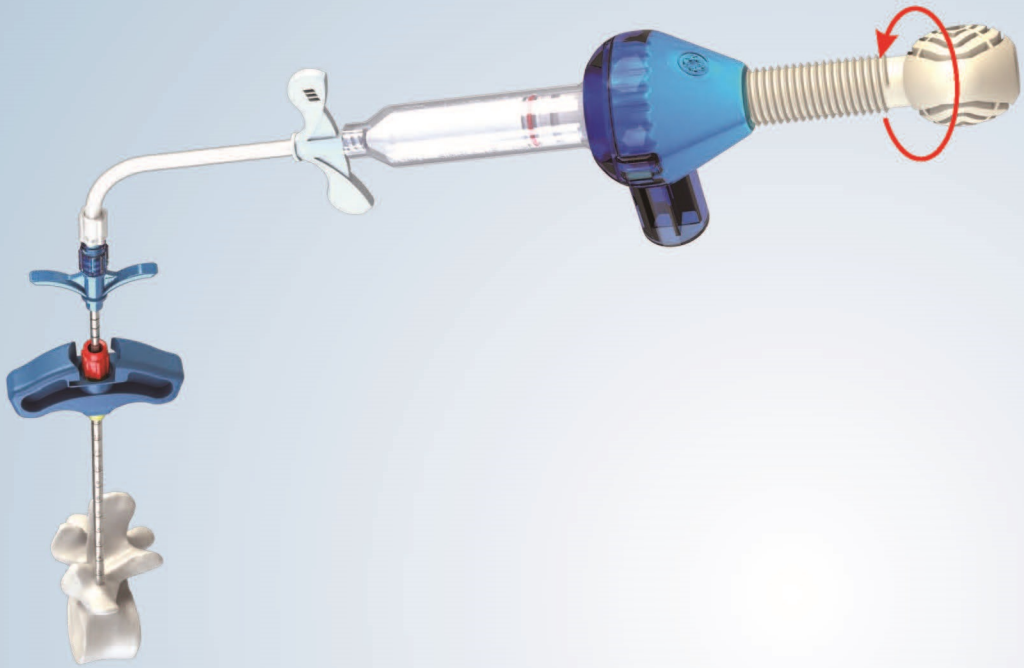
18. Rotate the oval piston handle to push the bone cement to fill the extension tube until some bone cement is extruded at the tip of the extension tube.



19. Remove the mini pin located in the middle of the Vessel-X® Bone Filling Container.

20. Connect and tighten the blue Luer lock of the extension tube to the Vessel-X® Introducer.

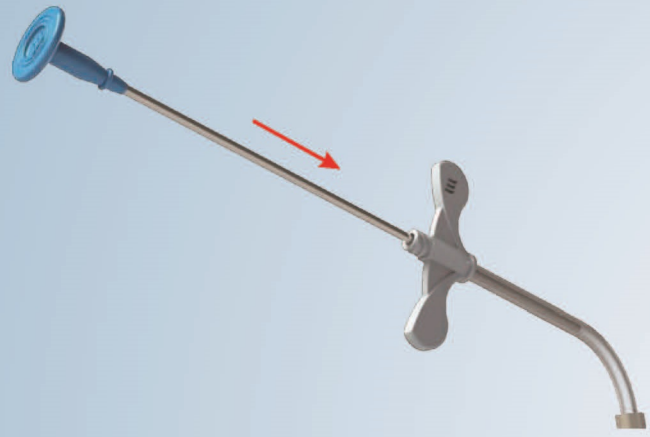
21. Rotate the oval piston handle of the CCD to push the bone cement into Vessel-X® Container. Each half turn (180 degrees) of the oval piston handle will inject approximately 0.18 ml (or cc) of bone cement. With every 0.36 ml bone filler material injection, monitor the Vessel-X® Container under fluoroscopy. Recommend bone cement injection volume respective of the Vessel-X® container size: 20mm is 2ml, 25mm is 2.5ml and 30mm is 3ml.



22. When the bone cement injection is completed, rotate counterclockwise the oval piston handle 90 degrees and then disconnect the extension tube from the syringe of CCD.

23. Under fluoroscopy guidance, insert the cement pushing rod into extension tube to push residual bone cement into the Vessel-X® Container.

24. Disconnect the blue Luer lock of the extension tube from the Vessel-X® Introducer.



25. Under fluoroscopy guidance, insert the cement pushing rod into Vessel-X® Introducer to push the residual bone cement (about 1.2 ml) into Vessel-X® Container.

26. When bone cement introduction is completed, rotate counterclockwise the red Luer lock ring to disconnect from the cannula and then rotate counter clockwise the Vessel-X® Introducer to disconnect from the Vessel-X® Container. Remove the Vessel-X® Introducer from the cannula.

27. Insert the stylet through the cannula to push the Vessel-X® Container further into the vertebral body.

28. When above steps are completed, remove the cannula and stylet from the vertebral body. Under fluoroscopy, confirm the result of the surgery. The surgical site can be closed per typical surgical procedure.

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Product Types

Title	Unit Kit	Standard Kit	Photos
Bone Access Needle	X1	X2	
Guide Pin	X1	X2	
Precision Drill	X1	X2	
Vessel-X® Bone Filling Container with cement Pushing Rod	X1	X2	
Controllable Cement Delivery Device with Extension Tube	X1	X2