Biomet® Verteoplasty System

Surgical Technique
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Introduction

This technique manual has been developed to provide the physician with an effective technique for gaining percutaneous access to the vertebral body. The method presented here is similar to those utilized for discography or for percutaneous/arthroscopic disc excisions. There is a larger target area on the postlateral corner of the vertebral body as compared to the disc space.

In both the thoracic and lumbar regions, an extrapedicular technique can be utilized for gaining access to the vertebral body through a single percutaneous incision. The angles for the technique, however, are quite different in each region of the spine, and are therefore addressed separately.

The angles of access in the thoracic region are different from the lumbar spine. They are much more vertical, and the starting points are more medial to reduce the possibility of pneumothorax. In thoracic cases the patient should be apprised of this additional potential risk and the possible need for a chest tube. Also, since the bone is often in a weakened condition, special care must be taken to avoid over penetration of the bone by the guidewire through the opposing cortex and into the adjacent anatomy.
**System Design Features**

- Radiolucent cannulae to enhance visualization under fluoroscopy
- Highly viscous material delivered under low-pressure
- Material flow that responds directly to the physician’s tactile pressure
- Optional Stainless Steel cannulae to access cortical-like bone

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**High Viscosity**

- Aluminum Delivery Cannula
- Stainless Steel Delivery Cannula
- Gold Plated Tips
- Low-Pressure Delivery
**Instruments**

- Holding Forceps
- Injector Gun
- Guidewire Driver
- Biopsy Cannula
- Tamp Cap T-Handle
- Biopsy Punch
- Mallet
- Osteo Probe
- Trephine Cannula
Pre-Operative Planning And Patient Positioning

Prior to the procedure, A/P and Lateral Plain films, MRI, CT and bone scans may be helpful to determine bone pathology, the amount of kyphosis, lordosis, and presence of any deformity, such as scoliosis. If scoliosis is present, the procedure should be planned from the convex side.

The positioning of the patient can be either prone, or in a lateral decubitus position. A Jackson Table or similar radiolucent procedural table is necessary to facilitate fluoroscopy. When utilizing the prone position, the abdominal cavity and viscera should be allowed to fall away from the spine, as this provides a larger access area. This also minimizes the epidural venous engorgement and collateral blood flow near the nerve roots. Patient positioning will depend on table availability and the physician preference.

Subsequent to positioning the patient and padding all dependent and vital areas, the patient is prepped and draped to facilitate bilateral access. Under fluoroscopic guidance, markings are made in the lumbar and/or thoracic region corresponding to the trajectories, as described in the illustrations to follow.

For the proper execution of any percutaneous procedure and specifically for this approach, a high quality fluoroscopy system is required. This system should provide precise localization and identification of the patient’s anatomy, as well as the guidewire needle.

This document is intended as a guide. The final choice of technique depends upon patient anatomy, pathology, health status, and the physician’s preference and judgment.

Cross-Section Through The Lumbar Area

![Cross-Section Through The Lumbar Area](image)
Lumbar Entry Points

1. Identify the midline with a guidewire while under fluoroscopy.

2. Draw a line on the skin down the midline with a marker.

3. Draw a transverse line on the inferior margin of the transverse process and the pedicle.

4. Measure 8-10cm off the midline and draw a parallel line.

5. For patients with a high iliac crest, the transpedicular technique may be more appropriate at L5.

6. At L1-L2 identify or palpate the 12th rib. Entry point should be 5mm medial to the rib.

7. Make a punch incision with scalpel.

8. Using A/P fluoroscopy, insert the guidewire at a 45-60° angle from the vertical axis of the midline (see Fig. 2)
   - L1 – L3 – 45-50°
   - L4 – 50-55°
   - L5 – 55-60°

9. Dock on the vertebral body/pedicle junction and verify placement under lateral fluoroscopy.

10. Advance the guidewire to a depth of 50% of the vertebral body under lateral fluoroscopy, and verify trajectory using A/P fluoroscopy. Adjust the trajectory as needed using the aligning cannula. Upon trajectory confirmation, return to lateral and advance the guidewire to a depth of 70% of the vertebral body.

11. Confirm final placement under A/P fluoroscopy.

The position of the guidewire on the pedicle can be visualized as the hours on the face of a clock. The desired zone is 1 through 5 o’clock on the right pedicle and 7 through 11 o’clock on the left pedicle.

The 12 o’clock position risks entry into the posterior intervertebral foramen. The 6 o’clock position risks entry into the caudal intervertebral foramen, putting the nerve root at risk.
Lumbar Wire Placement

*Alternative approach is to position guidewire next to transverse process

Figure 4
Thoracic Entry Points

1. Identify the lateral edge of the pedicle with a guidewire while under A/P fluoroscopy.

2. Draw a vertical line on the skin with a marker.

3. Draw a line parallel to this vertical line 2 to 2.5cm lateral.

4. Identify the inferior edge of the pedicle by making a small reference mark (this is not a target point).

5. Identify soft tissue between the rib structures using fluoroscopy or palpation.

6. Make a punch incision with a scalpel.

7. Using A/P fluoroscopy, insert the guidewire at a 20-30° angle off the vertical line, targeting and docking on the lamina.

8. Using tactile sensory feedback, walk the guidewire along the lamina. Use caution, as the guidewire will drop off the lamina approximately 1cm onto the vertebral ridge.

9. Securely dock onto the vertebral ridge. This may be difficult to visualize on fluoroscopy.

10. Subsequently adjust trajectory 5-10° lateral.

11. Advance the guidewire to a depth of 50% of the vertebral body under lateral fluoroscopy, and verify trajectory using A/P fluoro. Adjust the trajectory as needed using the aligning cannula. Upon trajectory confirmation, return to lateral and advance the guidewire to a depth of 70% of the vertebral body.

12. Confirm final placement under A/P fluoroscopy.

Figure 5
Thoracic Wire Placement

Initial Entry Options

Initial

Final

20-30°

Axial

A/P

Figure 6

Initial Entry Options

50%

Final

Lateral
Trajectory Verification

50% Penetration  70% Penetration

Too Steep  Correct  Too Flat

Figure 7
Surgical Technique

**CDV™ System**

After guidewire is in position on the vertebral body, place the guidewire driver on the distal end of the guidewire and use the mallet to aid in driving the guidewire into the vertebral body. It is important to use the guidewire driver to help minimize bending of the guidewire.

The modular tamp handle can be used to facilitate the insertion of the inner aligning cannula and dilation of the surrounding tissue. Holding the modular tamp handle horizontal, thread the guidewire through the small hole in the modular tamp handle. The modular tamp handle will now slide down the guidewire and provide a surface to strike with the mallet to drive the inner aligning cannula into place inside the vertebral body. An alternative to using the modular tamp handle would be to use the holding forceps.

The inner aligning cannula is placed over the guidewire.

Attach the modular tamp handle to the delivery cannula via the luer lock connection. Slide the delivery cannula over the inner aligning cannula until resistance is met. The mallet is used to drive the delivery cannula into place.
Notice the fenestrations in the modular tamp handle. These fenestrations will allow visualization of the inner aligning cannula while driving in the delivery cannula. The fenestrations will also indicate the depth and alignment of both the inner aligning cannula and the delivery cannula. While driving the delivery cannula into the vertebral body, notice the rings on the distal end of the inner aligning cannula shaft. When the rings on the inner aligning cannula shaft stop and smooth shaft appears, this will indicate that both the tip of the inner aligning cannula and delivery cannula have met.

With the guidewire and inner aligning cannula removed, two alternate ways of charging the delivery cannula will be described.

A.) The osteo-syringe attaches via luer lock to the delivery cannula.

B.) The osteo-syringe is loaded into the injector gun and then attached to the delivery cannula via the connector hose luer lock.

After the guidewire and inner aligning cannula have been removed from inside the delivery cannula, the osteo probe can be placed down the shaft to check for any bony obstructions.

Once the cannula is charged with material (the CDV System delivery Cannula holds approximately 3.5cc’s of material) the syringe can be disconnected and removed to prepare for final delivery of material via the plunger.
Surgical Technique (Continued)

CDV™ System (Continued)

If the delivery of additional materials is needed, the Dual Chamber Delivery System can be added to increase volume by 4.5cc’s.

With the delivery cannula in place the dual chamber delivery cannula is attached via luer lock to the distal end of the delivery cannula. The osteo-syringe is then attached to fill both dual chamber and delivery cannula via the double male-ended connector.

After the delivery cannula has been charged with material the plunger can be introduced for final delivery. The plunger is designed to deliver materials into the vertebral body without any pressure buildup. The plunger will give tactile feedback to the surgeon and respond by delivering cement only when advanced further down the cannula shaft.

After the materials have been delivered into the vertebral body the cannula can be removed by rotating the cannula a few times in clockwise fashion to loosen any cement that may be starting to harden around the delivery cannula. The holding forceps can be placed under the luer lock connection on the delivery cannula shaft and the mallet can be used to persuade the cannula out of the body.
After the guidewire is docked in position, place the guidewire driver on the distal end of the guidewire and use the mallet to aid in driving the guidewire into the vertebral body. It is important to use the guidewire driver to help minimize bending of the guidewire.

The delivery cannula and modular tamp handle are placed over the guidewire. The mallet is used to drive the cannula into the vertebral body. Depth markings on the guidewire will allow for visual confirmation of final depth and placement.
Once the delivery cannula is in place the hand held delivery syringe can charge the cannula with material (the LP² System Delivery Cannula can hold approximately 1.5cc’s of material) to be delivered into the vertebral body. The connector hose can be added for flexibility to get into tighter spaces and around C-arm machines.

After the delivery cannula has been charged with material the plunger can be introduced for final delivery. The plunger is designed to deliver materials into the vertebral body without any pressure buildup. The plunger will give tactile feedback to the surgeon and respond by delivering cement only when advanced further down the cannula shaft.
Removal of the cannula starts by rotating the delivery cannula in a clockwise fashion to make sure it is free of any material that may be hardening around the tip. The holding forceps are placed under the luer lock connection of the delivery cannula and the mallet is used to persuade the cannula out of the body.
Mixing Instructions

Cobalt™ V Bone Cement Mixing Instructions

Pour the liquid into a sterile mixing bowl and add the powder. Stir with a spatula vigorously, but carefully, for about 30 seconds. The working time will be affected by temperature (see chart and table for working and hardening times). The ideal working consistency of the Cobalt V Bone Cement for application is best determined by the surgeon based upon experience in using the preparation.

Application of the cement should be performed during a pasty condition phase of the cement to avoid vascular migration. For the method of application consult the instructions for use provided with the vertebroplasty or kyphoplasty system to be used with the Cobalt V Bone Cement.

During intravertebral application a strict latero-lateral real time radioscopy is necessary. After vertebral augmentation a stylet should be placed into the vertebroplasty injection cannulae (if applicable) to avoid cement residues being deposited in the soft tissues on withdrawal of the application cannulae. The patient should be kept immobilized until the end of the setting time (see charts and table below).

Typical Working Data For Cobalt™ V Bone Cement

The following chart shows dough- and set-times for Cobalt V Bone Cement measured according to ASTM and ISO methods. The chart indicates when the cement reaches a doughy state, and when it can be expected to set when maintained in a constant temperature environment throughout mixing and hardening. It is not predictive of in vivo cement hardening times.

ASTM/ISO Dough- and Set-Times vs. Temperature for Cobalt™ V Acrylic Cement

Diagram showing dough-time and set-time values for different temperatures.
The following table and chart provide guidance for use of **Cobalt V** in percutaneous vertebroplasty or kyphoplasty. Start of delivery cannula delivery times will vary with surgeon viscosity preference and end of cannula delivery times will vary with vertebroplasty or kyphoplasty system used. The reference data below was obtained using the LP² System (Biomet Spine), which employs a cannula of 3.0 mm internal diameter.

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**Cannula Delivery- and *in vivo* Cure-times vs. Ambient Temperature for Cobalt™ V Acrylic Cement**

![Graph showing the relationship between temperature and time for different phases of the procedure.]

- **I - Mixing**
- **II - Waiting Phase**
- **III - Cannula Delivery Phase**
- **IV - Pre-hardening Phase**
- **V - Range of Hardening** (Depending on time of delivery)
**Indications For Use**

This brochure describes a surgical technique used by ______________________, M.D. Biomet Spine as the manufacturer of this device, does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient. The contents of this manual are intended to be only a guide and are not intended to set a standard of care.

The Biomet Vertebroplasty Systems are indicated to deliver bone cement legally cleared for use in the spine for the treatment of compression fractures of a vertebral body.

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**Precautions**

**CDV System, LP² System, DCD System, LP² Cortical Bone Accessories, and Modular Tamp:**

Instruments that are labeled or designated as single use devices should not be resterilized, or re-used, and should be disposed of properly after use. This device is labeled as single use to ensure quality patient care.
Further Information

For further information, please contact the Customer Service Department at:

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