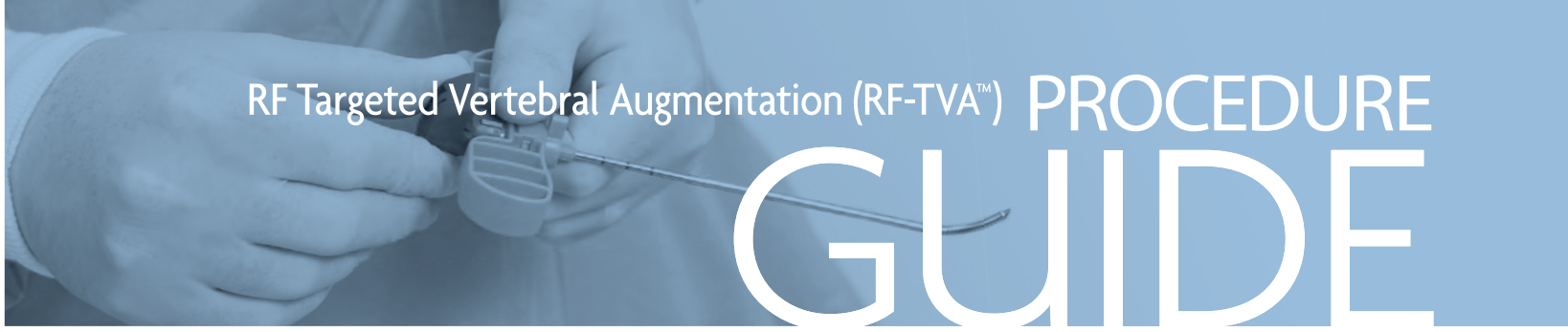
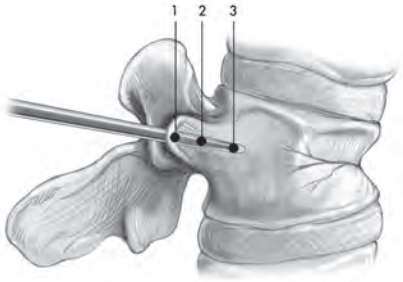


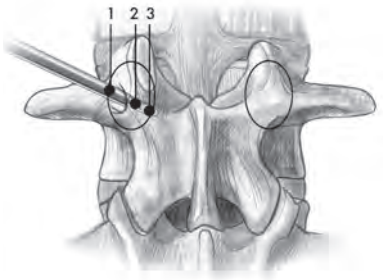
RF Targeted Vertebral Augmentation (RF-TVA™) PROCEDURE GUIDE

StabiliT® Introducer Approaches

Transpedicular

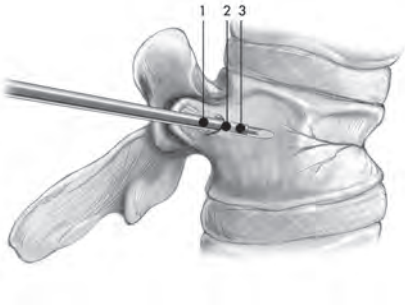
The transpedicular approach is commonly utilized in lower thoracic and lumbar vertebra where access through the pedicle allows for needle placement toward the midline of the vertebra.

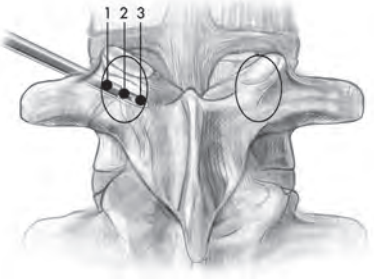




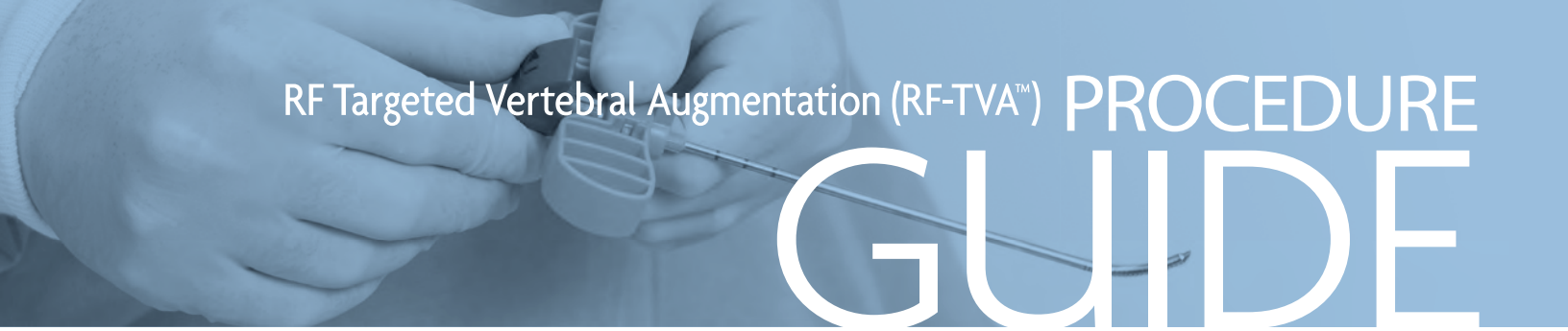
Extrapedicular

The extrapedicular approach is commonly utilized in higher thoracic vertebra where access outside of the pedicle through the costo vertebral junction with a more angled approach allows for needle placement toward the midline of the vertebra.





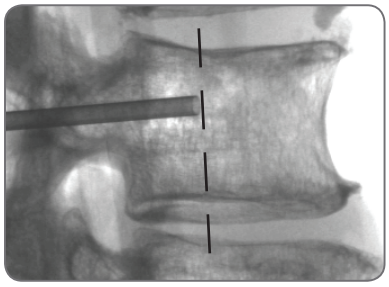
STABILIT® Vertebral Augmentation System



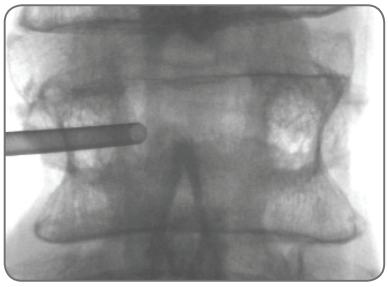
RF Targeted Vertebral Augmentation (RF-TVA™) PROCEDURE GUIDE

Part 1 - StabiliT® Introducer Placement

StabiliT® Introducer



Lateral View: Distal tip of Working Cannula should be in the posterior 1/3 of the vertebral body (VB).



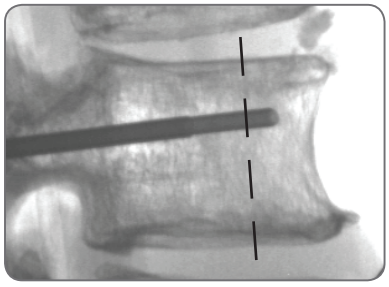
AP View: Distal tip of Working Cannula should be between medial cortex of pedicle and midline of VB.

Part 2 - Initial Cavity Creation

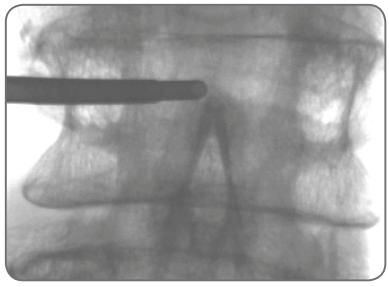
Initial Cavity Creation

Insert the VertecoR® StraightLine Osteotome (SLO) and create cavity into anterior 1/3 of the vertebral body. Advance SLO and Working Cannula together until SLO is in the anterior 1/3 of the VB. The Working Cannula tip should be positioned near the middle of the VB. Rotate SLO when fully inserted. Aspirate to retrieve biopsy if needed.

VertecoR®
StraightLine
Osteotome



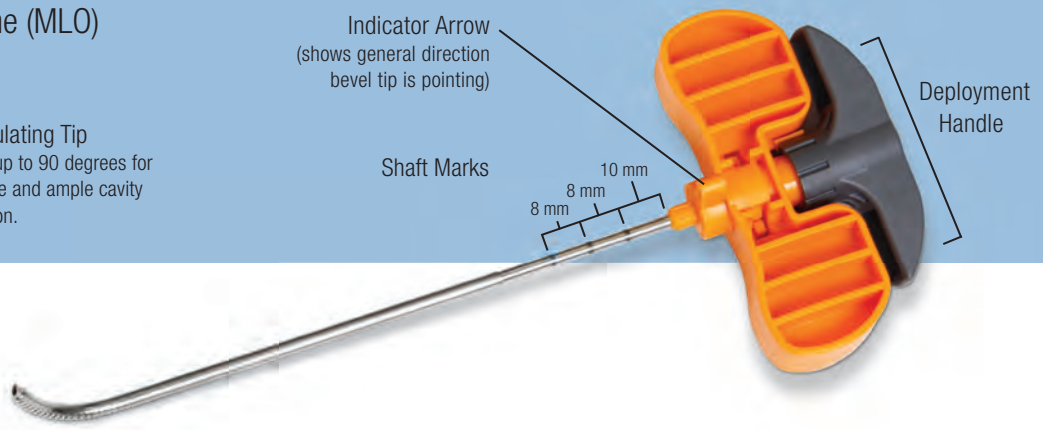
Lateral View: SLO advanced with Working Cannula into anterior 1/3.



AP View: SLO advanced with Working Cannula.

VertecoR® MidLine Osteotome (MLO)

Articulating Tip
curls up to 90 degrees for precise and ample cavity creation.



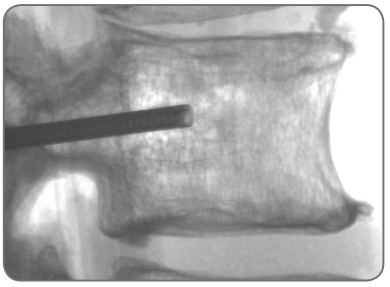
Part 3 - Site And Size Specific Cavity Creation

Site And Size Specific Cavity Creation

Follow the steps below to create site and size specific cavities using the VertecoR® MidLine Osteotome (MLO).

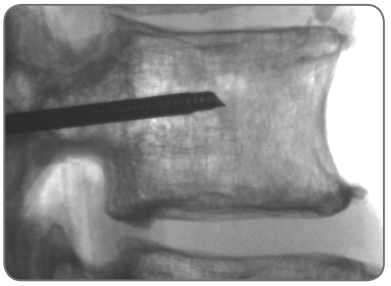
Due to bone quality, the MLO may not traverse across the midline. A bipedicular approach in this case may be needed to ensure a symmetric cement fill.

Step 1



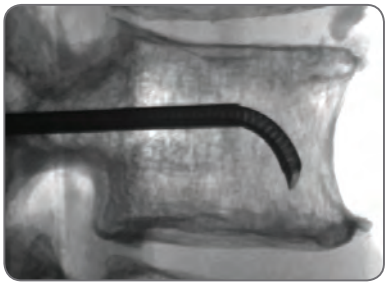
Insert the MLO to the most distal mark on its shaft. This positions the distal tip of the MLO flush with the distal tip of the Working Cannula.

Step 2



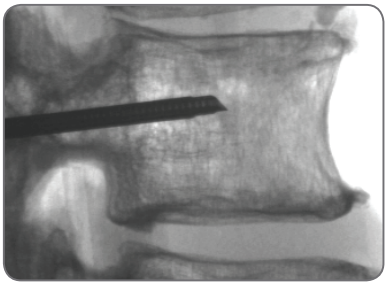
Advance the MLO to the middle laser mark. Rotate the Deployment Handle ¼ turn. MLO distal tip will articulate in direction of bevel tip and Indicator Arrow.

Step 3



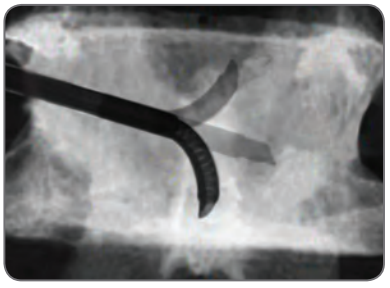
Advance the MLO to the proximal laser mark and rotate the Deployment Handle another ¼ turn. Advance to the hub of the MLO.

Step 4



Holding the Working Cannula in place, withdraw MLO until resistance is felt. Then turn Deployment Handle counter-clockwise ¼ turn. Continue withdrawing and turning until MLO is back inside the Working Cannula.

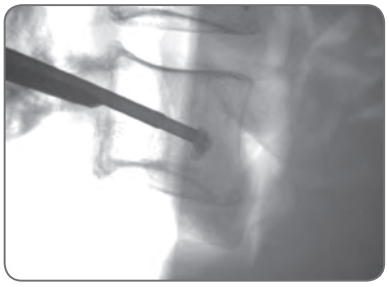
Step 5



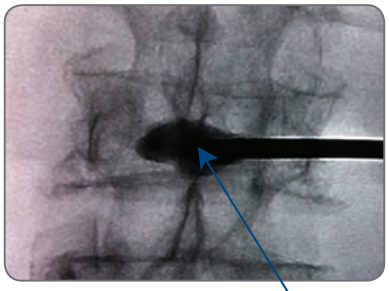
Multiple channels can be created within the VB by repeating steps 1-4 while advancing the MLO in a new direction utilizing the bevel tip and Indicator Arrow. The number of channels created will depend on fracture morphology and physician preference.

Part 4 - **Cement Delivery**

Deliver StabiliT® ER² Bone Cement into the anterior ⅓ of the VB filling the MLO created channels to allow cement to interdigitate in a controlled fashion to adjacent regions.



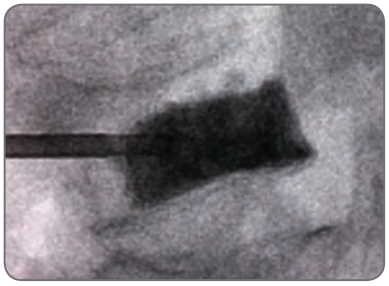
Lateral View: Distal tip of Locking Delivery Cannula (LDC) should be in the anterior ⅓ of the VB.



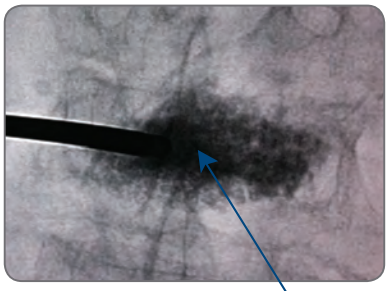
AP View: Cement fills cavity.

Ultra high viscosity cement predictably and preferentially fills regions of compromised bone resulting from cavities created or fractures.

As cement fills the anterior ⅓ of the VB, the Working Cannula may be repositioned to allow cement to fill site specific regions of the VB.



Lateral View: Final fill.



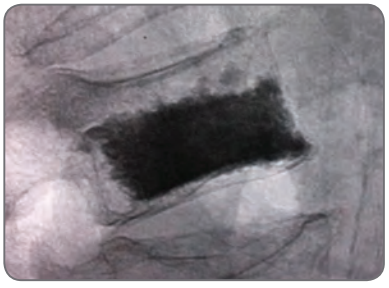
AP View: Final fill.

System drives cement to interdigitate into surrounding trabecular bone allowing for uniform cement interdigitation across entire VB.

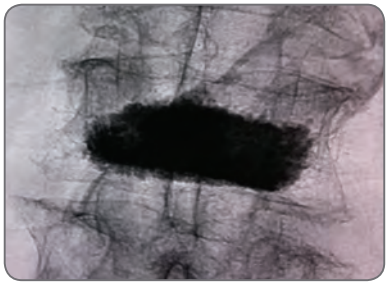
Part 5 - **Working Cannula Removal**

After removing the LDC immediately insert the Stylet into the Working Cannula to ensure cement does not track up the Working Cannula.

Next, remove the StabiliT® Introducer from the VB while checking the lateral image to ensure there is a small gap between the distal tip of the Working Cannula and cement.



Lateral View: Final fill.



AP View: Final fill.

Risks Statement

As with most surgical procedures, serious adverse events, some of which can be fatal, can occur. Although RF-TVA™ is designed to minimize these risks as much as possible, potential serious adverse events that can occur include:

- myocardial infarction *(heart attack)*
- pulmonary embolism *(cement leakage that migrates to the lungs)*
- cerebrovascular accident *(stroke)*
- cardiac arrest *(heart stops beating)*
- paralysis or muscle weakness
- death

A prescription is required. Please consult your physician for a discussion of these and other risks and if this procedure is right for you.