# VERTEBREX™ Surgical Technique Guide

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**Disclaimer:**
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon before and during surgery as to the best mode of treatment for each patient. Please reference the 510K or package insert for additional information and a complete list of intended indications, warnings, precautions, and other medical information.
If it’s easier to use, stick with it.

The Vertebrex™ Inflatable Bone Expander System offers easy handling and familiar instrumentation. The system is available in ten gauge unilateral and bilateral kits and three different balloon sizes. Familiar handling and a quick to dough cement with excelling handling characteristics combine to create ease of use for surgeons.

Features & Benefits

• Designed to help restore sagittal alignment
• Aides in reduction and fixation of fractures and/or creation of void in cancellous bone
• Designed for use with PMMA bone cements
• Small cannula for comfort
• High tolerance balloon pressure of 800 psi
• Balloon sizes of 10, 15, and 20mm

Vertebrex™ Inflatable Bone Expander System

Vertebrex™ Bilateral Kits

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Vertebrex™ Unilateral Kits

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*Please ask about a la carte items.
Instrument Guide
# Instrument Guide

**VERTEBREX™ INFLATABLE BONE EXPANDER SYSTEM**

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## New Parts

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For more information or to place an order call 1-877-755-3329, email accountservices@amendia.com or visit amendia.com
Preparing the Balloon

The VERTEBREX™ balloons are required to have a negative pressure before use. The balloons should not be inflated with air or type of gas for the procedure. The balloons are intended for single use only.

*Note: The maximum PSI for the balloons is 800 PSI.*

1. Advance the plunger in the 30-mL syringe to purge air from chamber.

2. Firmly attach the 30-mL vacuum syringe to the inflation port on balloon catheter.

3. Retract vacuum syringe plunger.

4. While retracted, rotate the plunger to lock in the rear position, then detach from the balloon catheter (Figure 1a, 1b).

5. Finally, remove the balloon protector from the distal tip of the balloon catheter while being sure not to slide it towards the proximal end and discard.
Primming the Inflation Device

**Note:** For bilateral procedures an inflation device for each balloon is necessary. It is necessary for the balloon inflation device to be filled with saline/contrast solution to make the balloon visible under fluoroscopy. The mixture should be prepared in a sterile bowl with no less than 60% contrast solution.

Patient should be checked for allergies to contrast medium.

1. Submerge the luer connector of the inflation device in a specimen cup of contrast solution *(Figure 2)*.

2. Squeeze the spring loaded handle and slowly pull until the threaded plunger is fully retracted *(Figure 3)*.

3. Tilt device up, keeping handle angled toward floor.

4. Prior to advancing the plunger, verify any air bubbles are at the surface of the contrast.

5. Advance the threaded inflation device plunger into barrel until the internal stopper aligns with the zero mark on the barrel *(Figure 4)*.

6. Verify there are no bubbles in the hose or barrel.

7. Once the inflation device is purged of any air, attach the balloon catheter.
Trocar Placement

1. The skin incision(s) for the transpedicular approach is usually 1-2cm lateral and up to 1cm cranial to the lateral aspect of the pedicle.

2. Make skin incision.

3. Insert the instrument assembly using AP and lateral live fluoroscopy. Confirm anatomical location of the introducer assembly using fluoroscopy. Once in right location, apply slight manual pressure or controlled blows with a surgical mallet to advance the introducer assembly (Figure 5a, 5b, 5c).

Note: Using fluoroscopy, confirm the distal tip of the cannula is approximately 3 mm in the bone to minimize the risk of the cannula coming out of the vertebrae. The working cannula will appear slightly larger than the trocar under fluoroscopy.

Note: If using a surgical mallet to advance the introducer assembly make sure the trocar and cannula handles are locked together.

Note: If applying both balloon catheters, repeat these steps for the contra-lateral side.

WARNING: It is essential that the trocar tip does not penetrate into the spinal canal or vascular structures beyond the anterior cortical wall. Avoid inserting the trocar tip too far medially as this could penetrate the spinal canal. If you need to redirect the instrument assembly, remove it, and re-access the pedicle.

In order for the distal tip of the introducer assembly to cross midline in the AP view, the distal tip of the introducer assembly must have passed the posterior wall in lateral view. The tip of the introducer assembly should not be closer than 0.5 cm to the anterior cortical wall of the vertebral body.

WARNING: Do not insert the starter cannula without the trocar, as this could damage the cannula.
Channel Creation

1. Separate the introducer trocar from the introducer cannula and remove (Figure 6).

2. Using fluoroscopy in the lateral view, insert the drill through the introducer cannula to prepare a pathway for the placement of the balloon catheter by rotating the handle clockwise (Figure 7a, 7b). This protects the balloon from being damaged by sharp bony fragments that may be encountered during access and inflation.

Note: When performing a bipedicular approach, repeat steps 1 & 2 for the contralateral side.

WARNING: The drill must not be overdriven into vascular structures beyond the anterior cortical wall. Apply lateral fluoroscopy intensification to avoid the penetration of the anterior cortex of the vertebral body.

WARNING: Do not use the surgical mallet to drive the drill forward. This can cause aggressive advancement.

WARNING: Ensure that the introducer tube does not move due to the application of the drill. Do not use the drill to change the direction of the introducer tube.
Balloon Inflation

1. Insert the balloon catheter through the introducer tube into the prepared vertebral body. Use lateral fluoroscopy to ensure correct placement of the catheter (Figure 8a, 8b). The entire balloon portion must be completely inside the vertebra and have passed completely through the introducer cannula to allow inflation.

Note: The balloon is fully through the working cannula when both the distal and proximal balloon radio-opaque markers are seen outside the working cannula.

2. Check balloon placement using both lateral and AP fluoroscopy. Once the catheter is in place, slowly inflate the balloon by rotating the handle of the inflation syringe clockwise. Monitor the balloon under fluoroscopy, and make sure to stop inflation every several seconds to maximize the balloon’s working potential. Additionally, inflate the balloon until either the patient-specific desired height, maximum pressure, maximum inflation volume is achieved or desired outcome is reached (Figure 9).

3. The balloon pressure and volume must be monitored during use. The maximum volume for the 10 and 15mm balloons is 4cc and the 6mm balloon is 6cc.

PRECAUTION:
Stop inflation when:
- Desired outcome is reached
- Max pressure is reached
- Max volume is reached
- Pressure dramatically drops (most likely due to balloon burst)
- Balloon contacts any part of the cortical bone

Note:
- The maximum inflation pressure for the balloon catheter is 800PSI.
- Use of the balloon catheters is most effective when dilation of bilateral catheters occurs simultaneously.
- Do not connect the inflation device to the stylet.
- The balloon cannot come in contact with PMMA bone cement.
Deflation & Removal of the Balloon Catheter

Once the balloon catheter has been inflated, deflate and remove the catheter to prepare for the insertion of the cement delivery device.

1. Stabilize syringe barrel with one hand.

2. With the other hand, slowly deflate the balloon catheter by rotating the handle of the inflation device counter-clockwise to reduce the pressure.

3. Retract plunger to generate negative pressure, deflating the balloon.

4. Using lateral fluoroscopy verify the balloon has completely deflated prior to attempting to remove (Figure 10a).

5. Hold the introducer cannula in place, and carefully pull on the catheter(s) to retrieve from the vertebral body. Slight rotation can be applied to help facilitate removal (Figure 10b).

**WARNING:**
*If balloon catheter material detaches and remains in the vertebral body, it must be retrieved.*

**Note:** *If the balloon catheter does not move into the access cannula, advance the cannula over the catheter to the proximal radiopaque marker. If resistance still occurs, remove catheter and cannula simultaneously.*
Filling the Cavity

The PMMA-based bone cement selected for the procedure will determine the specific details of this phase. Follow the manufacturer’s specifications to ensure that bone cement is applied optimally.

1. Mix the PMMA-based bone cement according to the manufacturer’s specifications.
2. Fill the cement delivery devices.
3. Wait for the cement to achieve the optimal viscosity for the procedure.
4. Using fluoroscopy, insert the cement delivery device into the introducer tube.
5. Advance the cement delivery device into the vertebral body so that the distal tip is just posterior to the anterior cortex (Figure 11).
6. Begin injecting the bone cement into the cavity in the vertebral body using the plunger (Figure 12a). Monitor the cement flow under live fluoroscopy in both the AP and lateral views.
7. Continue injection until the bone cement infiltrates the cancellous bone surrounding the cavity and fill from anterior to posterior (Figure 12b).
Filling the Cavity (Continued)

8. Once competed, reinsert the blue introducer needle into the working cannula and lock. (This will prevent the cement from trailing out of the pedicle.

9. Carefully remove the introducer cannula.


**Note:** If using a bilateral approach, alternate between filling each cavity, and leave the long plunger in the cannula not currently being using to avoid cement from flowing into the contralateral cannula.

**Note:** Make sure cement has sufficiently hardened prior to removing the cannula.

**Note:** During cement injection, monitor bone cement to make sure it does not extravasate from the vertebral body as leakage of bone cement can cause death or paralysis.
INDICATIONS

The VERTEBREX™ Inflatable Bone Expander System (IBES) is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

CONTRAINDICATIONS

Include, but are not limited to:
• Bleeding disorder or treatment that increases the chance of excessive bleeding.
• Any known severe allergy to contrast material.
• Vertebral dimensions or fracture pattern that do not allow safe placement and inflation of the balloon.
• Instability of posterior vertebral wall and/or pedicles.

WARNINGS

• For a transpedicular approach, if the pedicle is not large enough or stable enough to withstand the procedure, pedicle fracture may occur.
• Complications that may occur during a parapedicular approach include pneumothorax and bleeding.
• Avoid contact between the balloon and bone cement.
• The balloon component of the VERTEBREX™ IBES may fail due to bone splinters and/or surgical tool contact.
• Do not inflate the balloon until it has been fully deployed in the vertebral body. Inflating the balloon prior to full deployment may result in premature balloon failure due to contact between the balloon and the access cannula.
• Do not use this product after the expiration date printed on the package. The device may not be safe or effective beyond its expiration date.
• One balloon catheter must be used in the only one pedicle approach. Do not reuse in the other pedicle approach.