iVAS
Inflatable Vertebral Augmentation System

Procedure Overview
Stryker Interventional Spine
iVAS Procedure Overview

During vertebral augmentation utilizing the iVAS System, a balloon catheter is used to create a void in the collapsed vertebra, helping to allow for controlled and contained cement delivery.\textsuperscript{1,2} The hardened cement creates an internal cast that is thought to stabilize the fracture, thereby alleviating pain in approximately 90 percent of patients.\textsuperscript{1}

**STEP 1**
Preparing inflator.

To begin a vertebral augmentation procedure using iVAS, first prepare the inflator.

Unlock the inflator handle, pull the handle back and fill the inflator with contrast.

Now connect the stopcock and open.

Then, holding the inflator in an upright position, push the handle to purge air from the inflator.

When all the air bubbles have been eliminated, close the stopcock and lock the inflator handle.

iVAS is a complete system for performing vertebral augmentation procedures. The kit consists of a balloon catheter, access cannula with diamond tip stylet, bevel tip stylet, locking syringe, inflator and stopcock. Supplementary products are also available.

**STEP 6**
Inflating balloon.

Paying close attention to the fluoroscopic images, pressure gauge and volume of contrast, slowly turn the inflator handle to inflate the balloon with contrast.

Slow inflation of the balloon allows time for it to expand and compact bone while limiting the pressure within the balloon.

**Bipedicular Approach**

Vertebral augmentation can be accomplished by utilizing either a unipedicular or bipedicular approach. \textbf{If performing bipedicularly, repeat each of the following steps on both sides of the vertebra.}

Do not use if vertebral height is compromised by more than 68 percent or if there is instability of the posterior wall and/or pedicles.
**STEP 2**  
*Inserting access cannula.*

Next, under fluoroscopic guidance, insert and advance the access cannula into the cortical bone of the vertebral body.

Once the cannula has reached the desired position, unlock and remove the stylet.

**STEP 3**  
*Optional: Placing access needle and inserting hand drill to anterior third.*

While rotating, insert the Stryker hand drill (reference: 0306-810-000) into the access cannula.

Once you have established an adequate pathway, remove the hand drill by continuing to rotate clockwise while retracting.

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**STEP 7**  
*Deflating balloon and removing balloon catheter.*

When the balloon catheter is inflated to desired size, pressure and volume, unlock the inflator handle and pull it back to deflate and remove the balloon.

A void has now been created for the injection of bone cement.

**STEP 8**  
*Injecting bone cement.*

After deflating and removing the balloon, insert the VertePort cement cannula through the access needle.

Slowly inject VertaPlex HV, VertaPlex or SpinePlex bone cement while carefully monitoring the fluoroscopic imaging.

The hardened cement creates an internal cast that stabilizes the fracture. Clinical results for vertebral augmentation show the potential for substantial pain relief, increased mobility and improved quality of life.
**STEP 4**  
**Inserting balloon catheter.**

Next, insert a deflated balloon catheter through the access cannula and into the pathway that has been created.

Under fluoroscopic guidance, move the balloon catheter into the desired location for balloon inflation. Radiopaque markers provide accurate visualization of the balloon’s distal and proximal boundaries to aid in placement.

**STEP 5**  
**Connecting inflator.**

Once the iVAS balloon catheter is properly positioned, connect it to the stopcock on the prepared inflator.

Insert the locking syringe into the side port of the stopcock, confirming that its handle is turned toward the inflator to ensure an open path.

Next, pull the plunger on the locking syringe to remove air from the balloon catheter. Turn the stopcock handle to open a path between the balloon catheter and the inflator and then disconnect the locking syringe.

Unlock the inflator to allow the handle to move forward until the pressure equals. Then, re-lock the inflator handle.

**STEP 9**  
**Removing VertePort.**

Once an adequate fill has been achieved, remove the VertePort from the access needle and replace the original access stylet.

Slowly remove the access needle to complete the procedure.

**Indications For Use**

The Stryker iVAS Inflatable Vertebral Augmentation System is intended to be used for the reduction 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 procedures, such as kyphoplasty.

**Contraindications**

- Instability of posterior wall and/or pedicles
- Infection
- Severe bleeding
- Known allergies to bone cement
- Pregnancy
- Fractures in which more than 68 percent of vertebral height is lost
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iVAS
Inflatable Vertebral Augmentation System
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Learn more about iVAS, our latest technology for VCFs.

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Footnotes

This document is not meant to replace the Instruction for Use. Carefully review and understand the IFU, including all warnings.