stryker®

iVAS

Inflatable Vertebral Augmentation System

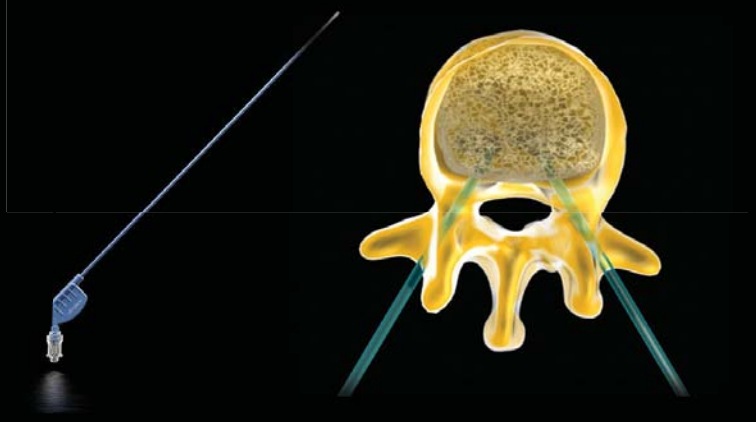
Procedure Overview

International

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.[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.[1]

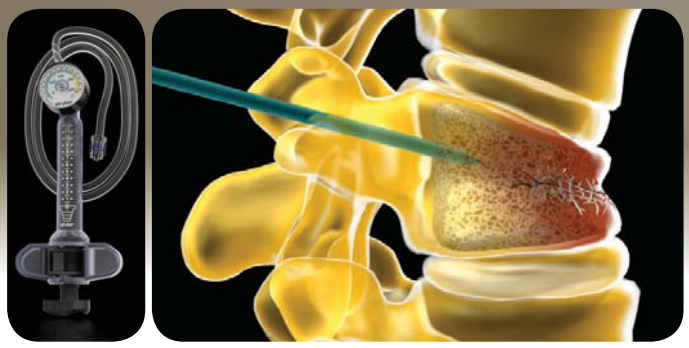
iVAS is a complete system for performing vertebral augmentation procedures. The kit consists of a balloon catheter, access cannula with diamond tip stylet, bevel tip stylet, locking syringe, inflater and stopcock. Supplementary products are also available.



Bipedicular Approach

Vertebral augmentation can be accomplished by utilizing either a unipedicular or bipedicular approach. **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 1
Preparing inflator.

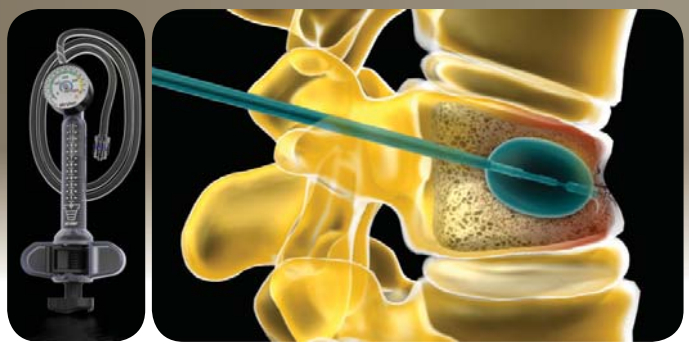
To begin a vertebral augmentation procedure using iVAS, first prepare the inflator.

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.

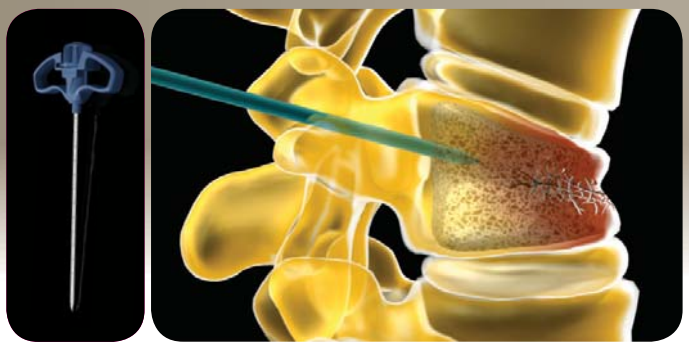
When all the air bubbles have been eliminated, close the stopcock and lock the inflator handle.



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.

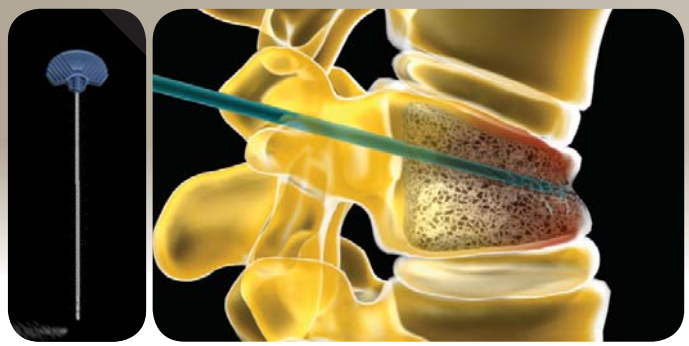


STEP 2

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.

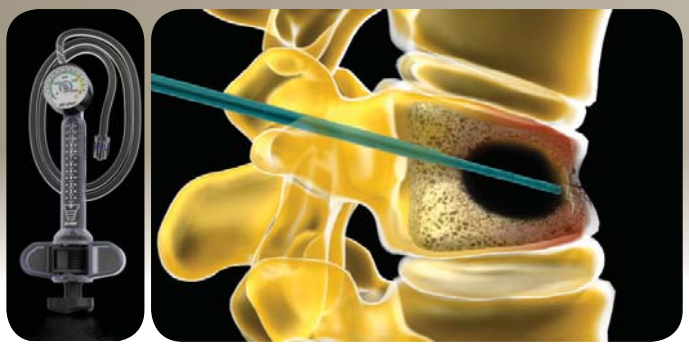


STEP 3

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.

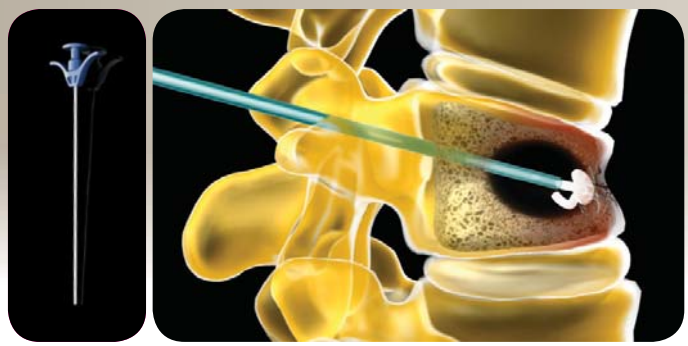


STEP 7

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.



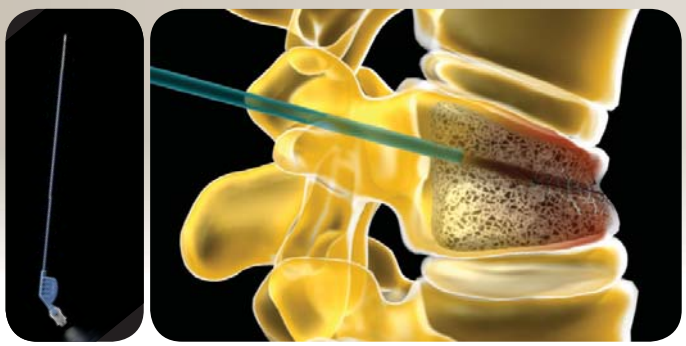
STEP 8

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.[3,4,5,6,7] Clinical results for vertebral augmentation show the potential for substantial pain relief, increased mobility and improved quality of life.[3,4,5,6,7]

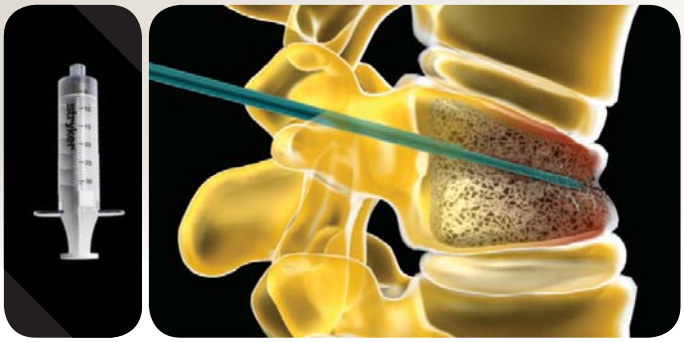


STEP 4

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

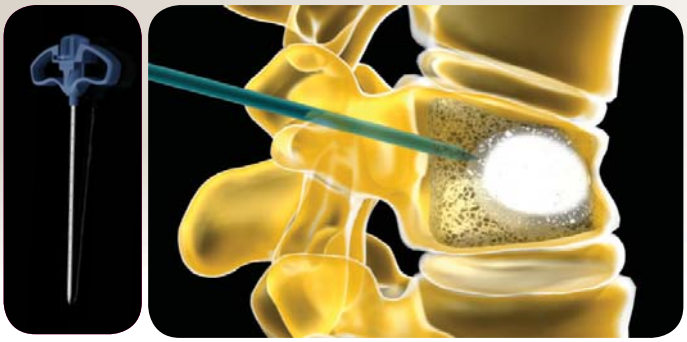
Connecting inflator.

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 equalizes. 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
VertaPlex HV
High Viscosity Radiopaque Bone Cement

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iVAS Inflatable Vertebral Augmentation System

0705-115-000
10g iVAS System Kit (Sterile; 3 per box)
(2-15 mm)
Includes: Balloon catheter, access cannula with diamond tip stylet, bevel tip stylet, locking syringe, inflater, stopcock

0705-115-500
10g iVAS Balloon Catheter (Sterile; 3 per box)
(2-15 mm) A la carte

0306-810-000
10g Hand Drill (Sterile; 6 per box)

Mixers and Delivery Systems

AutoPlex (Sterile; 2 per box)

0605-887-000
AutoPlex System Kit without Cement or Needles
Includes: One AutoPlex mixer and delivery system

PCD (Sterile; 4 per box)

0506-482-000
10g PCD System Kit without Cement
Includes: One PCD mixer and delivery system, one 10g 5" diamond tip match-ground introduction needle, one 10g 5" interchangeable bevel stylet

0506-486-000
PCD System Kit without Needles
Includes: One PCD mixer and delivery system

0506-489-000
PCD System Kit with Straight Short Extension Tube and without Needles
Includes: One PCD mixer and delivery system with straight short extension tube

0507-589-000
VertaPlex HV / PCD System Kit with Straight Short Extension Tube and without Needles
Includes: One half dose of VertaPlex HV Bone Cement, one PCD mixer and delivery system with straight short extension tube

Bone Cements

VertaPlex HV

Offered only with mixing devices. See Mixers and Delivery Systems.

VertaPlex (Sterile; 2 per box)

0406-422-000
VertaPlex 20 Gram Twin Pack (one-half dose)

SpinePlex (Sterile; 2 per box)

0406-222-000
SpinePlex 20 Gram Twin Pack (one-half dose)

VertePort

Access Cannulae (Sterile; 6 per box)

0306-400-000
10g 5.75" Long Stylet Access Cannula

0306-430-000
10g 5" Short Stylet Access Cannula

Cement Cannulae (Sterile; 18 per box)

0306-410-000
10g Cement Cannula (for use with 10g long and short access needles 0306-400-000 and 0306-430-000)

Needles

(Sterile; 6 per box)

10g

0306-100-000
10g 5" Diamond Tip Match-Ground Introduction Needle

0306-101-000
10g 5" Bevel Tip Match-Ground Introduction Needle

0306-190-000
10g 9" Diamond Tip Match-Ground Introduction Needle

0306-191-000
10g 9" Bevel Tip Match-Ground Introduction Needle

Bone Biopsy Kits

(Sterile; 6 per box)

0306-105-000
10g 5" Bone Biopsy Kit

0306-195-000
10g 9" Bone Biopsy Kit

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What is this?
Scan this QR Code with your smartphone to be directed to a website with more information about Stryker Interventional Spine.

You can download a QR Code Reader application for your smartphone at getscanlife.com (supports most smartphones).

This document is intended solely for the use of healthcare professionals.

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The products listed above are CE marked according to the Medical Device Directive 93/42/EEC.

Footnotes

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3. Lavelle W, Carl A, Lavelle ED, Khaleel MA. Vertebroplasty and Kyphoplasty, Anesthesiol Clin. 2007 Dec;25 (4):913-28.
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5. Passias PG, Li Gang, Wood, KB. SRS Position Paper: The Results of Vertebral Augmentation Procedures Department of Orthopaedic Spine Surgery Massachusetts General Hospital and Harvard Medical School Boston, MA Sept. 8, 2008.
6. Jensen ME, McGraw JK, Cardella JF, Hirsch JA. Position statement on percutaneous vertebral augmentation: A consensus statement developed by the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and American Society of Spine Radiology. J Vasc Interv Radiol 2009; 20:S326–S331.
7. Eck JC, Nachtigall D, Humphreys SC, Hodges SD. Comparison of vertebroplasty and balloon kyphoplasty for treatment of vertebral compression fractures: a meta-analysis of the literature. The Spine Journal 2008; 8:488-497.

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