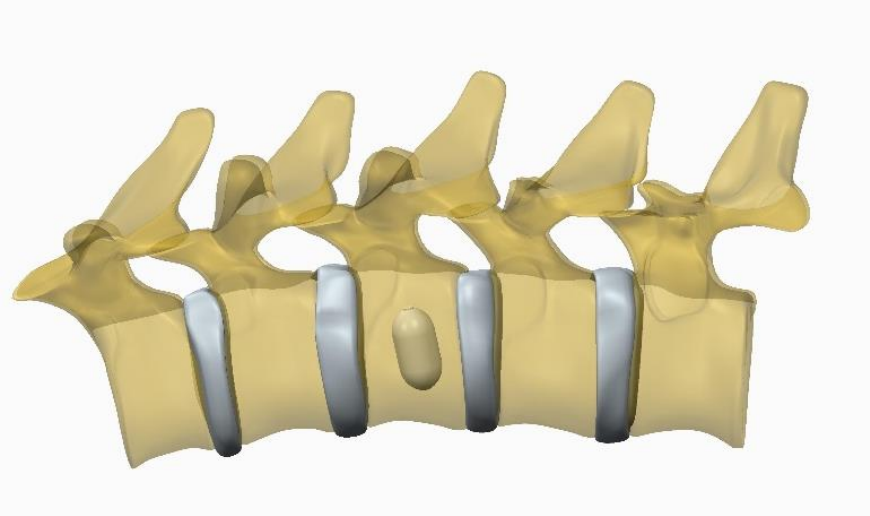
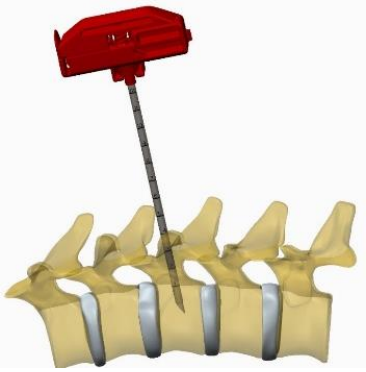
ZVplasty system Surgical Technique Guide



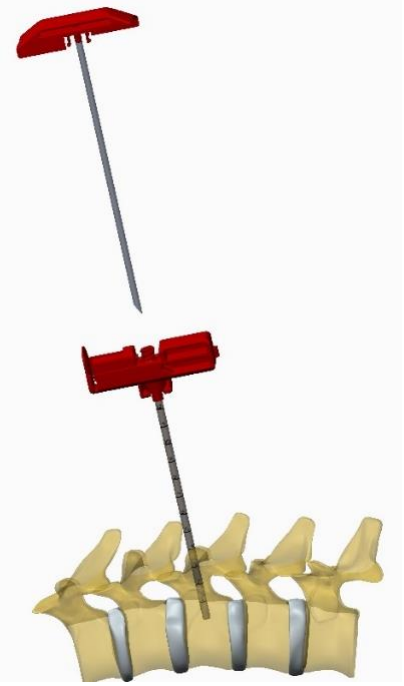
Procedure must be performed under the guidance of C-arm or equivalent imaging equipment.

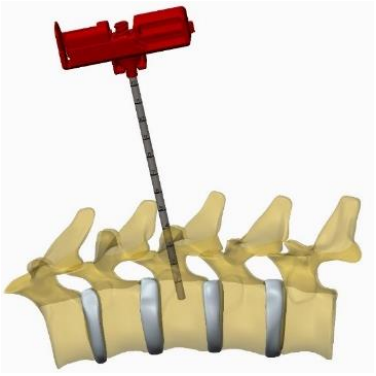
Step 1: Locate the insertion point of the Introducer cannula instrument and advance the Introducer to depth using imaging as a visual aid. Laser marking on the Introducer indicate the distance from the tip of the cannula. The system contains two introducers, one with a bevel tip and one diamond tip stylet. The diamond tip stylet can be used as an aid to penetrate hard cortical bone.



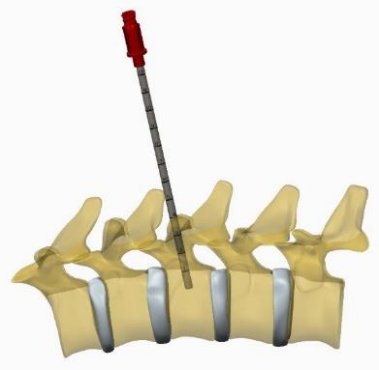
Bevel Tip Diamond Tip

Step 2: Unlock the stylet by securely holding the cannula handle and twist the stylet handle 90 degrees counter-clockwise. Remove the stylet by pulling the stylet handle outward.



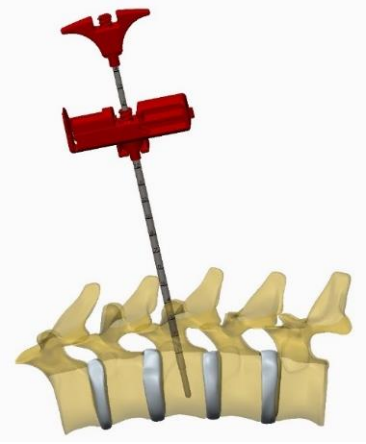


Step 3: Optional: The handle of the Introducer cannula can be removed by unlocking the handle tabs. Removing the handle will allow clearer A-P images and provide additional space for the physician during the procedure.

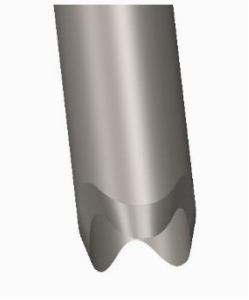


Step 4: Optional: If a bone sample is required insert the bone biopsy needle through the cannula up to the first laser mark on the outer shaft of the needle. Advance the needle by pushing and twisting the needle to the required depth. Laser marking on the needle indicate the distance the distal end of the needle has advance past the distal end of the introducer cannula. Remove the biopsy needle by pulling while twisting. The bone biopsy is removed from the needle by use of the bone biopsy needle stylet.

Bone Biopsy Needle

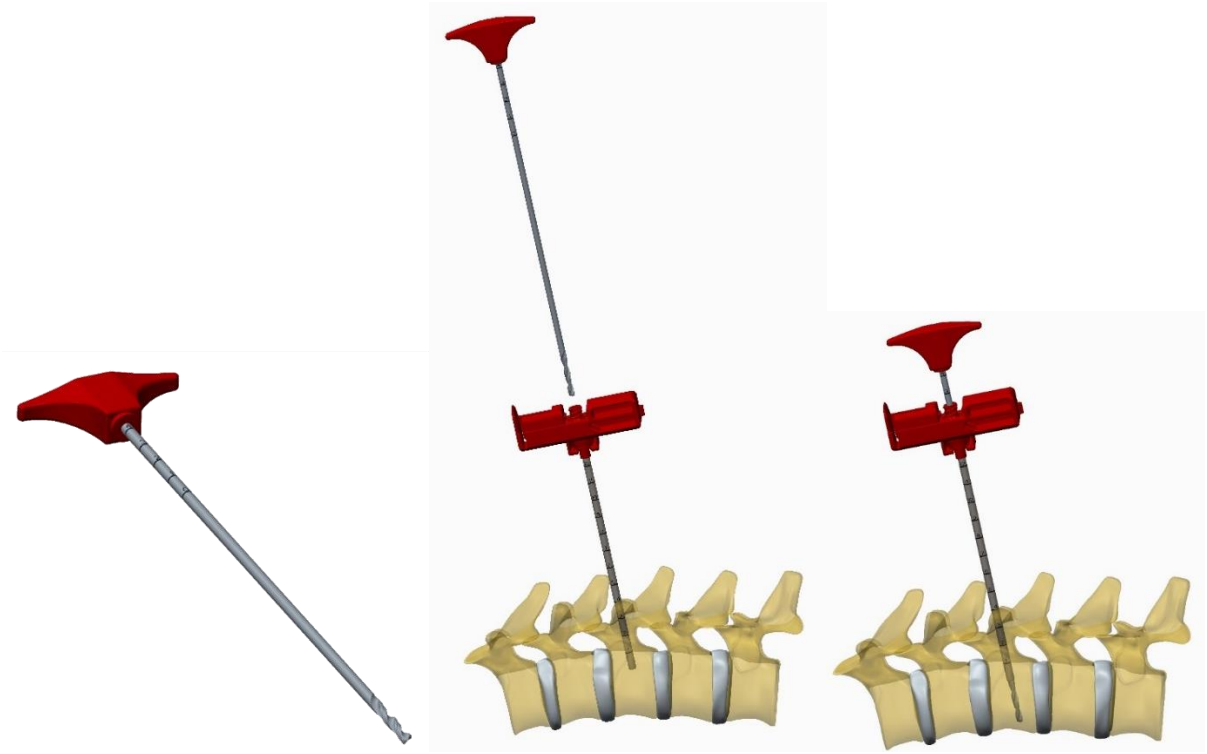


Bone Biopsy Needle Inserted



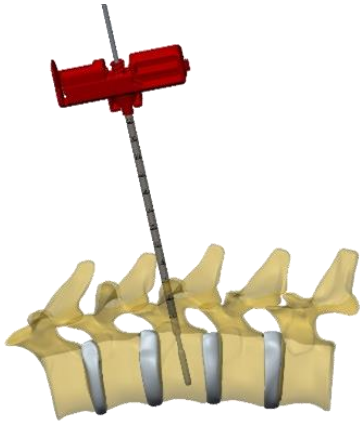
Cutting Tip

Step 5: Insert the drill into the introducer cannula up to the first laser marking on the shaft of the drill. The first marking on the drill indicates the distal end of the drill is in line with the distal end of the introducer cannula. Advance the drill by pushing while twisting the drill clockwise to the required depth. Remove the drill be pulling and twisting clockwise. The clockwise rotation of the drill during removal assures bone is removed from the cavity.

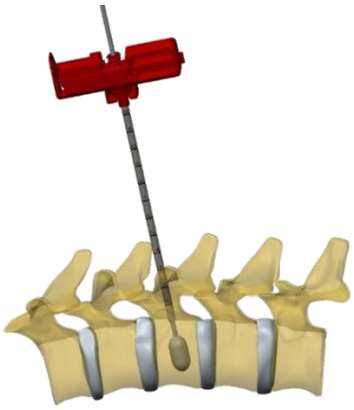


Drill Drill being introduced Drill introduced

Step 6: Prepare the balloon catheter as instructed in the balloon catheter *Instructions For Use*. Insert the balloon catheter through the introducer cannula using imaging to position the balloon catheter to the proper depth.

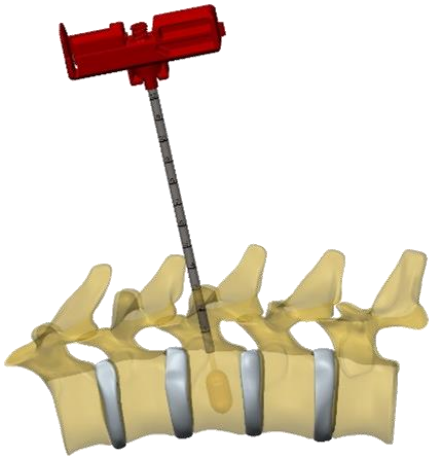


Step 7: Inflate the balloon under continuous image guidance. Inflate the balloon catheter as instructed in the inflation syringe *Instructions For Use*. Stop inflation when treatment goal is achieved or the balloon catheter inflation length contacts cortical bone or maximum inflation volume and/or maximum inflation pressure is achieved.

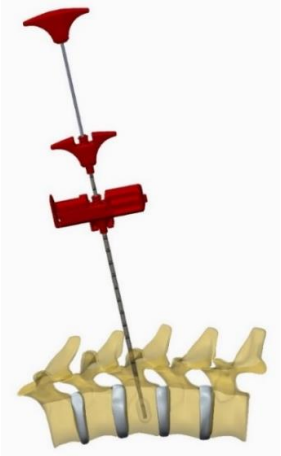


Step 8: Deflate the balloon catheter as instructed in the balloon catheter *Instructions For Use*. Remove the balloon catheter from the introducer cannula with a gentle twisting motion.

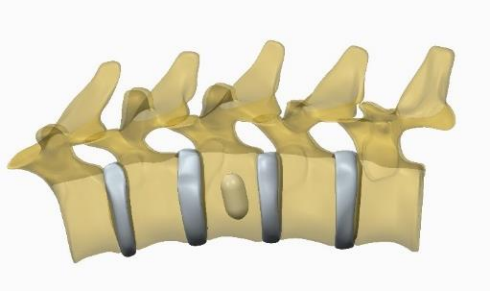
Caution: Do not attempt to withdraw the balloon catheter unless the inflatable component is fully deflated. Never withdraw the balloon catheter against resistance. If there is resistance, connect the 20mL Vac-Lock syringe to insertion port of the 3-way valve to create a vacuum, see the vacuum syringe *Instructions For Use*. Close the 3-way valve and resume the balloon catheter removal.



Step 9: Prepare the PMMA cement as instructed in the cement *Instructions For Use* using the cement mixing kit as instructed in its *Instructions For Use.* Fill each cement syringe with cement as instructed in the cement mixer *Instructions For Use*. Attach a syringe to each cement cannulas and load cannula with cement. Insert cement cannula through the introducer cannula using imaging to position the distal end of the cement cannula near the anterior side of the cavity created by the balloon catheter. Advance the cement cannula stylet to begin filling the cavity. Repeat until the cavity is filled. Do not reuse the cement cannula.



Step 10: Remove the introducer cannula with a twisting motion.



Device Description

Device View	Part #	Description

	VCF-1002	**Bevel Tip Introducer Cannula:**
		• 17cm Overall Length
		• 12cm Insertion Depth
		• 10 Gauge Cannula
		  ○ 3.4mm OD
		  ○ 2.9mm ID
		• Bevel Tip Style
		• Removable Handle
		• Luer Lock Syringe Connector
		• Depth Markings
		• Material:
		  ○ Handle: ABS, CYCOLAC HMG47MD
		  ○ Shaft: 304 Stainless Steel – ASTM A276

	VCF-1003	**Diamond Tip Introducer Cannula:**
		• 17cm Overall Length
		• 12cm Insertion Depth
		• 10 Gauge Cannula
		  ○ 3.4mm OD
		  ○ 2.9mm ID
		• Diamond Tip Style
		• Removable Handle
		• Luer Lock Syringe Connector
		• Depth Markings
		• Material:
		  ○ Handle: ABS, CYCOLAC HMG47MD
		  • Shaft: 304 Stainless Steel – ASTM A276

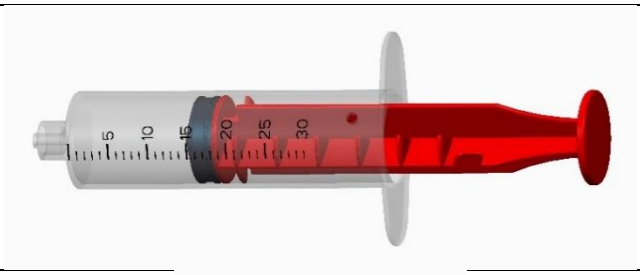
Device View	Part #	Description

	VCF-1006	**Drill:**
		• 22cm Overall Length
		• 2.7mm OD
		• 2 Flute Drill Tip
		• Depth Markings
		• Material:
		  ○ Handle: ABS, CYCOLAC HMG47MD
		  ○ Shaft: 17-4 Stainless Steel – ASTM F899

	VCF-1007	**Cement Cannula:**
		• 25cm Overall Length
		• 2.7mm OD
		• Depth Markings
		• Luer Lock Syringe Connector
		• Material:
		  ○ Handle: ABS, CYCOLAC HMG47MD
		  ○ Shaft: 304 Stainless Steel – ASTM A276

	VCF-1010	**Bone Biopsy Needle:**
		• 25cm Overall Length
		• 2.7mm OD
		• Depth Markings
		• Luer Lock Syringe Connector
		• Material:
		  ○ Handle: ABS, CYCOLAC HMG47MD
		  ○ Shaft: 304 Stainless Steel – ASTM A276

	VCF-1000-15 VCF-1000-20	**Previously FDA cleared Balloon Catheter** VCF-1000-15, 15mm length VCF-1000-20, 20mm length

Device View	Part #	Description
	VCF-1001	**Previously FDA cleared Inflation Syringe**
	VCF-1004	**Previously FDA cleared Vacuum Locking Syringe:**
	VCF-1005	**Previously FDA cleared Stopcock**
	VCF-1009	**Previously FDA cleared PMMA bone cement**
	VCF-1016	**510(k) exempt Cement Mixing Kit**

System Parts List

Part#	Qty	Description
VCF-1011	1	Instrument Kit (see kit components in table 2)
VCF-1000-15 VCF-1000-20	1	Previously FDA cleared Balloon Catheter
VCF-1017	1	Inflation Kit (see kit components in table 3)
VCF-1016	1	Previously FDA cleared PMMA bone cement
VCF-1009	1	510(k) exempt Cement Mixing Kit

VCF-1011 Instrument Kit Parts List

Part#	Qty	Description
VCF-1002	1	Bevel Tip Introducer Cannula
VCF-1003	1	Diamond Tip Introducer Cannula
VCF-1006	1	Drill
VCF-1007	5	Cement Cannula
VCF-1010	1	Bone Biopsy Needle

VCF-1017 Inflation Kit

Part#	Qty	Description
VCF-1001	1	Previously FDA cleared Inflation Syringe
VCF-1004	1	Previously FDA cleared Vacuum Syringe
VCF-1005	1	Previously FDA cleared Stopcock

Device Description:
The Zavation ZVplasty system is designed for use in vertebroplasty procedures for treatment of vertebral compression fractures in the lumbar or thoracic regions brought on by primary or secondary osteoporosis, cancer or trauma. The Zavation ZVplasty system consist of a variety of manual instruments which provide physicians with a means to access the vertebral body with a mechanical device in order to prepare a site for vertebroplasty. Once the site is prepared the Zavation ZVplasty system instruments are used to percutaneously deliver polymethylmethacrylate (PMMA) bone cement to the spine. The Zavation ZVplasty system instruments are to be used with the following previously FDA cleared items, balloon catheter, inflation syringe, vacuum syringe, stopcock, PMMA bone cement, cement mixing system.

Intended Use:
The Zavation ZVplasty system is intended to be used for reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during vertebroplasty procedures.

Materials: The ZVplasty system instruments are manufactured from stainless steel.

Contraindications:
-Instability
-Infection
-Severe Bleeding
-Known allergies to bone cement
-Pregnancy

Potential Adverse Events: Potential adverse events include, but are not limited to:
-Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae
-Deep or superficial wound infection
-Retropulsed vertebral body bone fragments which may cause injury to the spinal cord or nerve roots resulting in radiculopathy, paresis or paralysis
-Bleeding or hematoma
-Pneumothorax
-Pedicle fracture

Warnings and Precautions:
-Do no use if sterile package is opened or damaged.
-It is important to read the instructions for use, these precautions prior to device operation.
-Use the instrument kit prior to use by date noted on the package.
-Do not use damaged products. Before use, inspect the packaging to verify that no damage has occurred.
-Do not use this product if you have not been properly trained. Physicians using the device should be familiar with the physiology and pathology of the selected anatomy.
-The instruments should be manipulated only under fluoroscopic observation with radiographic equipment that provides high quality images.
-Do not re-sterilize and/or reuse. The instruments are for single use only. Reconditioning, refurbishing, repair, or resterilization of the device to enable further use is expressly prohibited.

Sterilization: The ZVplasty system will be received sterile in sealed sterile packaging.

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation LLC, 400 Liberty Park Dr., Flowood, MS 39232, USA, Telephone: 601-919-1119

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation LLC, 400 Liberty Park Dr., Flowood, MS 39232, USA, Telephone: 601-919-1119.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.