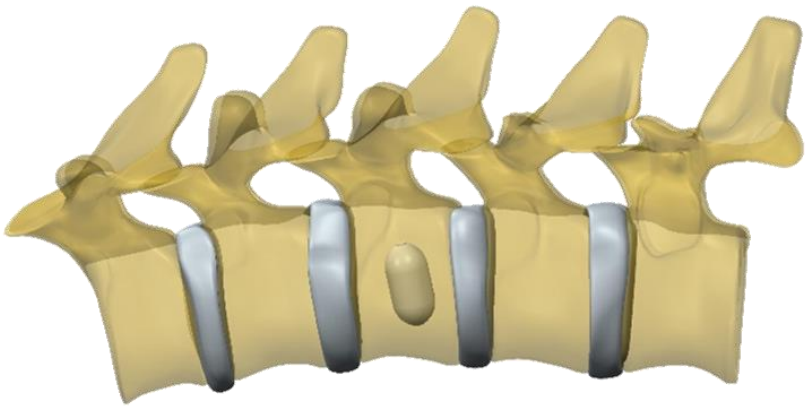
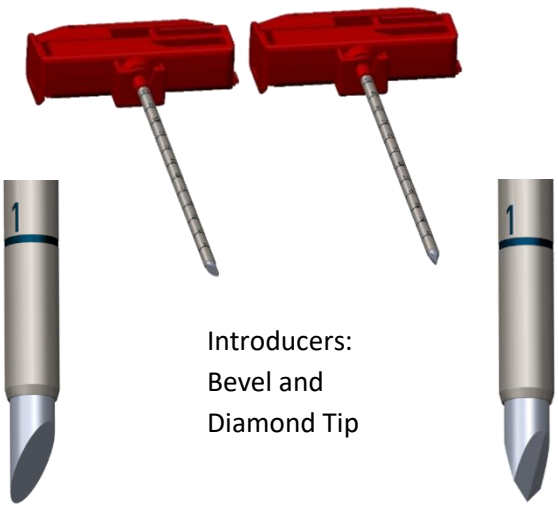
ZAVATION

# ZVplasty



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

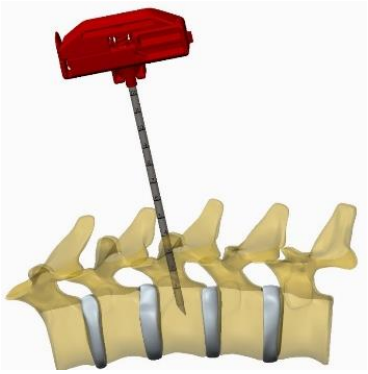



Introducers:
Bevel and
Diamond Tip

**Step 1: INTRODUCER PLACEMENT**

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 distal tip of the stylet extend 6.3mm past the distal end 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.

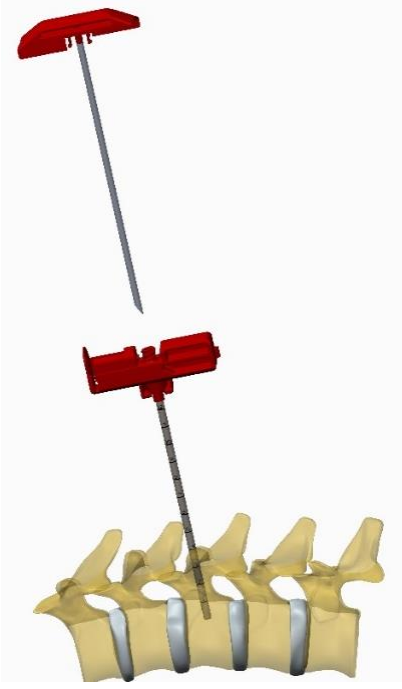
**Step 1**



**Step 2: STYLET REMOVAL**

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.

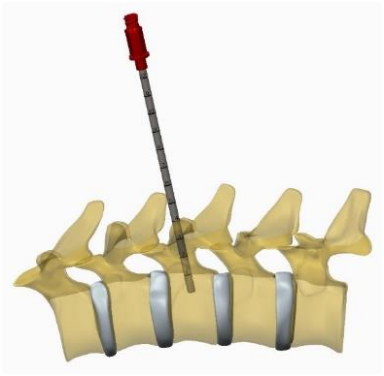
**Step 2**



**Step 3: OPTIONAL HANDLE REMOVAL**:

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.

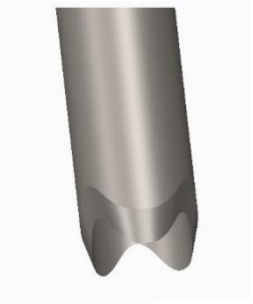
**Step 3**

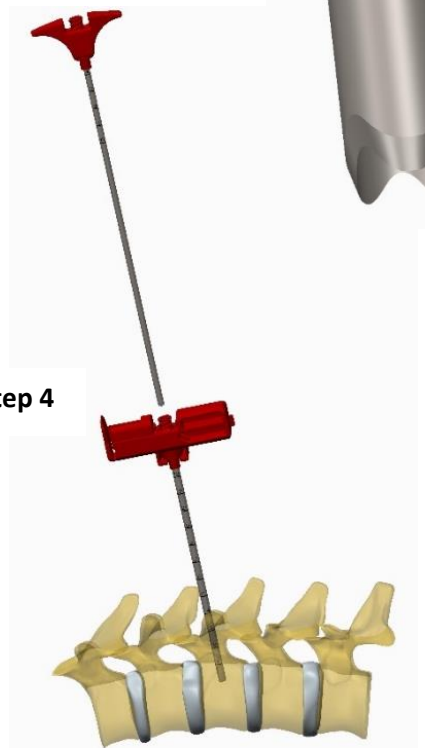


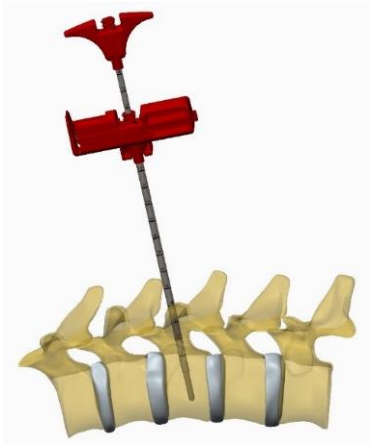
**Step 4: BONE BIOPSY**

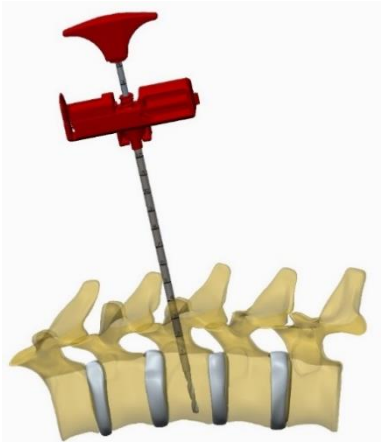
If a bone sample is required, insert the bone biopsy needle through the cannula up to the first laser mark on the outer shaft of the needle. Advance the needle by pushing and twisting the needle to the desired depth. Laser marking on the needle indicate the distance the distal end of the needle has advance 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.

**Step 4**







**Step 5: DRILLING**

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 desired depth. Remove the drill by pulling and twisting clockwise. The clockwise rotation of the drill during removal assures bone is removed from the cavity.

**Step 6: SELECTION OF THE BALLOON CATHETER**

- Select balloon catheter size based on the site and treatment goal.
- Table 1 defines the inflated diameter and inflated length of the balloon in 37ºC water at inflation volume increments to the maximum inflated volume. These dimensions may vary during product use due to local variation in bone structure.
- Table 2 gives the maximum recommended inflation pressure and volume values in constrained and unconstrained conditions. Also included are the pressure and volume values at burst in constrained and unconstrained conditions for guidance.

**Inflated Balloon Dimensions**

| **Catalog No.:** | **VCF-0015** | **Inflated Dimensions** | | |
|---|---|---|---|---|
| Size (Deflated Balloon Length): | 15 mm | **Volume** | **Diameter** | **Length** |
| Max. Inflation Volume: | 4 ml | 2 ml | 9 mm | 15 mm |
| | | 4 ml | 14 mm | 21 mm |
| **Catalog No.:** | **VCF-0020** | **Inflated Dimensions** | | |
| Size (Deflated Balloon Length): | 18 mm | **Volume** | **Diameter** | **Length** |
| Max Inflation Volume: | 6 ml | 2 ml | 8 mm | 18 mm |
| | | 4 ml | 12 mm | 24 mm |
| | | 6 ml | 16 mm | 29 mm |

**UNCONSTRAINED TEST CONDITION**

| **Catalog No.** | **Max. Recommended Inflation Pressure** | **Max. Recommended Inflation Volume** |
|---|---|---|
| VCF-0015 | 6.5 ATM | 4 ml |
| VCF-0020 | 6.5 ATM | 6 ml |

**CONSTRAINED TEST CONDITION** (Please note that the Inflation volume required to achieve a desired pressure in a constrained condition will vary during product use due to local variation in bone structure )

| **Catalog No.** | **Max. Recommended Inflation Pressure** | **Max. Recommended Inflation Volume** |
|---|---|---|
| VCF-0015 | 27 ATM | 4 ml |
| VCF-0020 | 27 ATM | 6 ml |

- Inflating the vertebral balloon beyond the maximum recommended inflation volume may cause the balloon to rupture before reaching the maximum inflation pressure and
- Inflating the vertebral balloon beyond the maximum recommended inflation pressure may cause the balloon to rupture before reaching the maximum inflation volume.

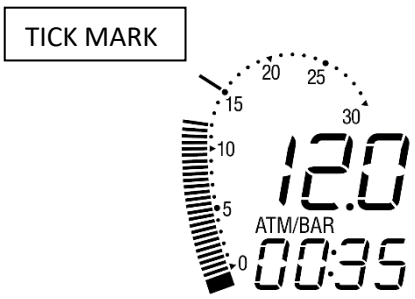
**Step 7: INFLATION SYRINGE PREPERATION**
Attach the stopcock to the line of the inflation syringe.

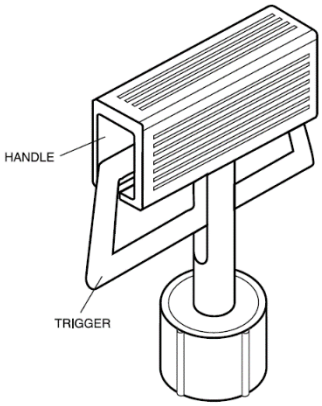
Ensure the line is open to atmospheric pressure by opening the stopcock. Press the blue button behind the LCD display near the tubing to power the device on. The LCD will display "Zero" for two seconds and then the device will be ready to use. At this point the syringe will begin its incremental time keeping.

The syringe will be set in the ATM/BAR mode when initially turned on. To change the pressure display to read in PSI, press and hold the blue button until "ATM/BAR" flashes four times. The user is now in "PSI" mode. To change back to ATM/BAR, press and hold the blue button once again.

NOTE: When in PSI mode, the tick marks on the left of the display that represent pressure will be limited to 300 PSI (20.4 ATM). If the ZVplasty is pressurized past 300 PSI, the grouping of tick marks on the left will flash. The numerical digits in the center of the display will continue to show actual pressure throughout the device's pressure range (-6 to 441 PSI).

After an inflation or pressure monitored injection has been made, a graph bar or tick mark will remain to mark the highest point of pressure. Pressing the blue button once quickly will display last inflation information and a "↩" indicator on the display. After the next inflation has been started, the last inflation tick mark will disappear.




**DEVICE PREPARATION:**
To engage PrimeLok, squeeze trigger and slide PrimeLok into slot.

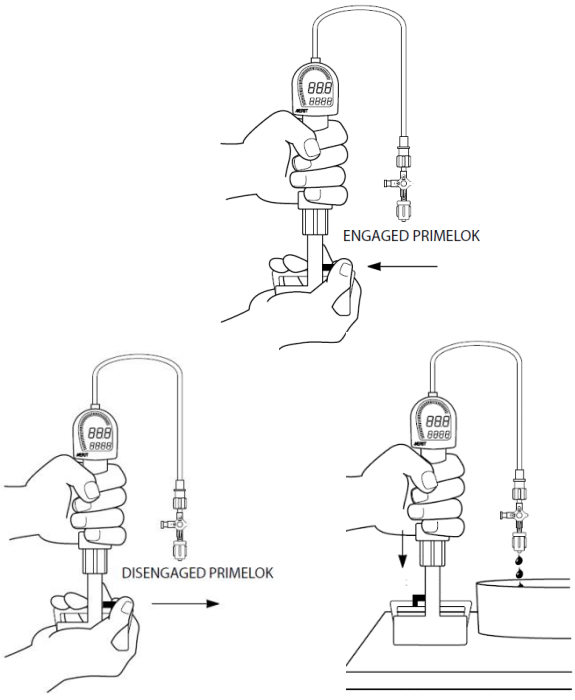
1. To prep syringe, simply aspirate up to 20ml of contrast solution or fluid to be dispensed into the inflation syringe by pulling back on the plunger handle.

   **CAUTION:** Inspect the syringe tubing and stopcock to insure that there is no air in the system.

2. Push handle against table to remove air in syringe.

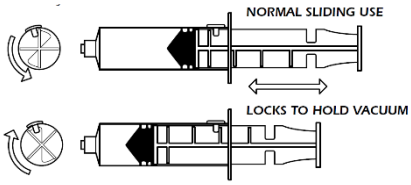
3. To disengage PrimeLok, squeeze trigger and slide PrimeLok out of slot. This will allow the plunger to lock in position and the device is now ready for use.

**NOTE:** The PrimeLok must be disengaged before pressure can be maintained by the lock/release mechanism.



**Step 8: ASSEMBLY AND PREPARATION OF THE BALLOON CATHETER**

- Attach the stopcock to the balloon catheter.
- Attach the VacLok syringe to the stopcock side port.
- Turn the stopcock valve handle toward the inflation syringe to open a passageway between the VacLok syringe and the balloon catheter.
- Using the VacLok syringe, purge the balloon fully.
- With the VacLok syringe locked to hold vacuum on the balloon catheter, rotate the handle of the stopcock toward the VacLok syringe opening a passageway between the inflation syringe and balloon catheter.
- Remove the VacLok syringe

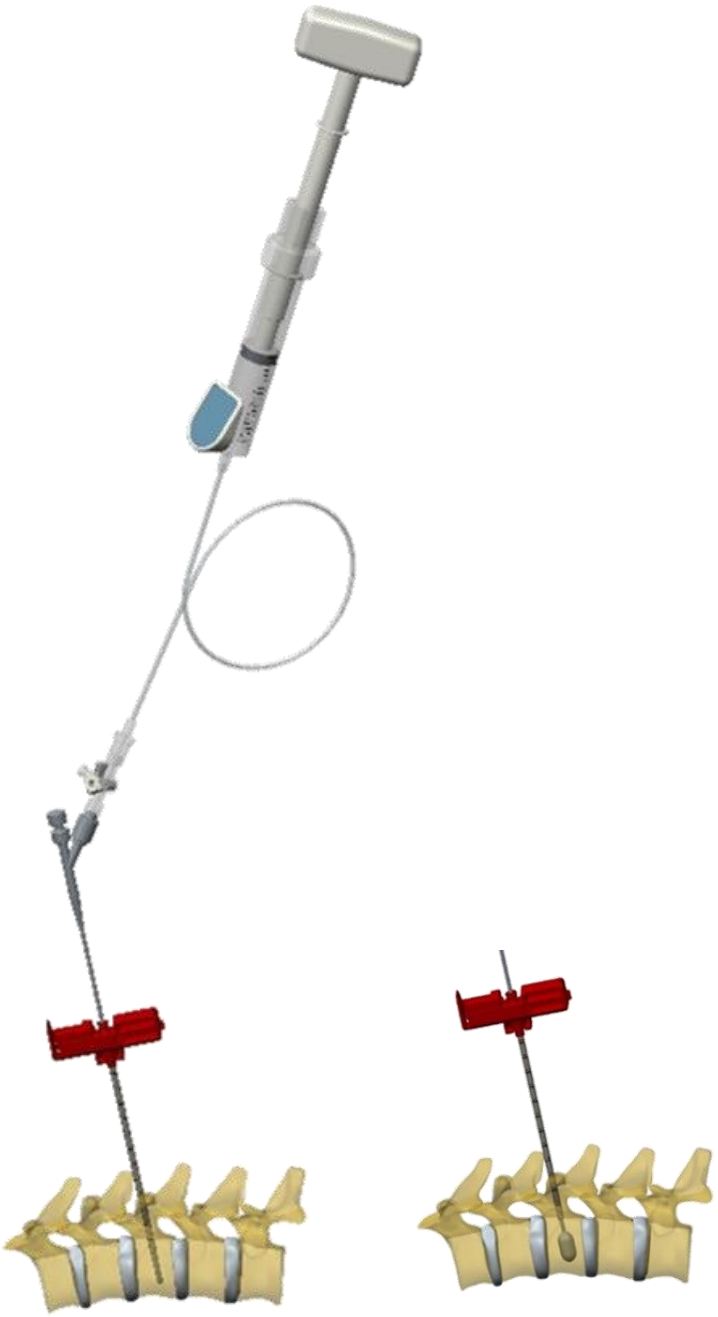



**Step 9: INSERTION AND INFLATION OF THE BALLOON CATHETER**

- Insert the deflated balloon catheter through the introducer. Continue insertion until the catheter reaches the desired location.

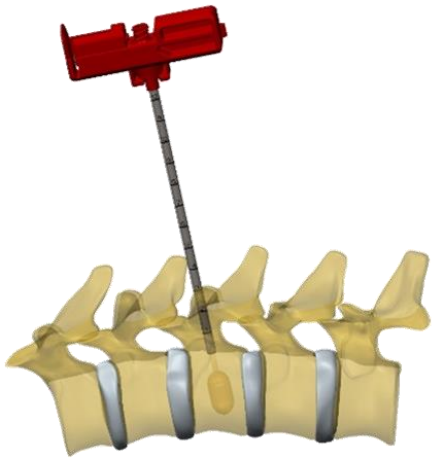
**BALLOON INFLATION**

- To inflate the balloon, squeeze the trigger allowing the plunger to return to a resting position (0 ATM/BAR or PSI). Release grip on the trigger, locking the plunger into position. To increase pressure, rotate handle clockwise until the desired pressure is achieved. Pressures above the maximum range will be indicated with flashing numbers.
- The tick mark will remain at the highest point of the last pressure reading. As the pressure decreases from the maximum pressure, the tick mark will begin to flash.
- **NOTE:** Significant loss of pressure may indicate a leak in the system.
- **CAUTION:** To protect the threads of the lock release handle, the pressure must be reduced to 25 ATM or lower before the quick release mechanism is used to deflate the balloon.
- Inflate the balloon under continuous image guidance. Stop when treatment goal is achieved or any part of the balloon inflated length comes into contact with the cortical bone or maximum recommended inflation volume and/or maximum recommended inflation pressure is attained.



**Step 10: CATHETER WITHDRAWAL**

- To deflate balloon, rotate handle counter clockwise to release pressure to 25 ATM or lower. Squeeze the trigger and pull back to generate a negative pressure. Release grip to lock the plunger in a negative pressure position. Pressures below the minimum range of the syringe will be indicated by flashing bars and a "NEg" in the pressure area.



**Caution:** Never withdraw the Balloon unless the inflatable component is fully deflated. Never withdraw the balloon against resistance. Determine the cause of resistance under fluoroscopy and take the necessary remedial actions.

- To deflate, pull the inflation syringe plunger all the way back and lock. Remove the Balloon from the bone through the cannula with a gentle twisting motion

- If there is resistance, connect the VacLok syringe to the side arm port of the three-way stopcock and move the stopcock so that the stopcock is closed to the inflation syringe and open to the 30 ml syringe. Pull the syringe back to the 30 ml mark to create a vacuum. Close the three way stopcock to the syringe. Resume the Balloon removal.

- Confirm entry of the inflatable portion of the Balloon into the cannula. If the inflatable component does not move into the cannula. Advance the cannula over the Balloon to the proximal radiopaque marker. Following cannula advancement, withdraw the Balloon through the cannula. If resistance is met, remove Balloon and cannula simultaneously.

**Step 11: CEMENT MIXING – Option 1** -using VCF-1051 kit.

1 – Remove the cap from the mixer container.

2 - Cut the corner of the cement powder pouch.

3-1 - Pour bone cement powder first.
3-2 - Then pour liquid monomer.

4 – Tighten the cap onto the mixer container.

5 - Shake up and down with three fingers for 30 seconds.

6 - Unscrew the small cap from the end of the mixer container.

7 - Luer-lock one syringe onto the mixing system.

8 - Put the container upside down (luer lock on bottom) and draw up the full quantity.

9 - Detach the syringe from the mixing system.

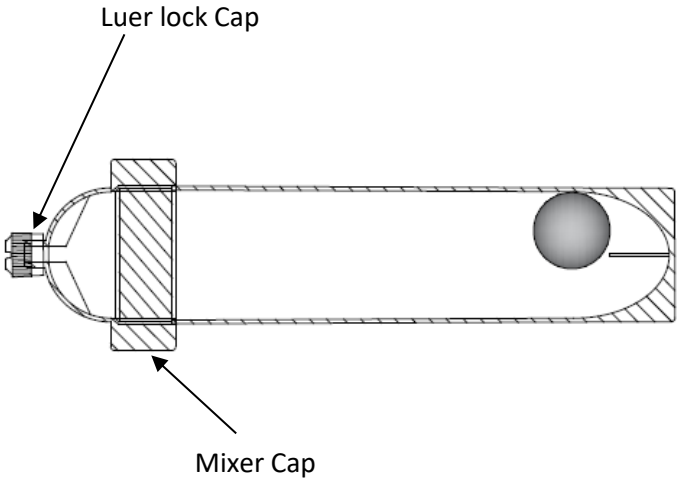
10 - Repeat operations 7, 8 and 9 with the other syringes.

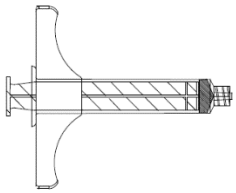
11 – Attach syringe to the cement cannula

12 – Inject cement into the cement cannula until completely filled

13 – Remove syringe from cannula

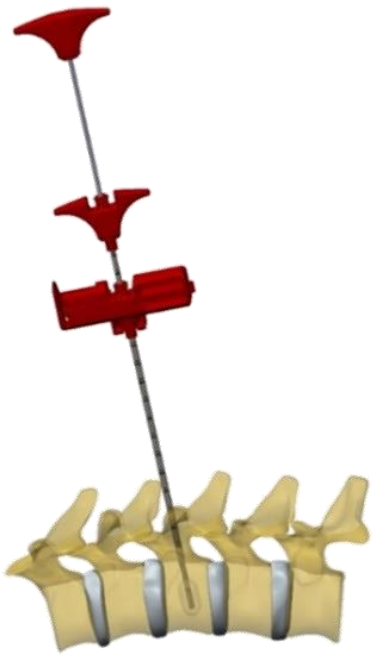
14 – Repeat operations 11, 12, 13 and 14 with the other cement cannulas



Syringe

**CEMENT MIXING – Option 2** -using VCF-1020 kit.
See the IFU for the injection/mixer device containted in the VCF-1020 box.



**Step 12: CEMENT INJECTION (using VCF-1016 kit only). See IFU contained in the VCF-1020 package for use of the injection gun kit)**

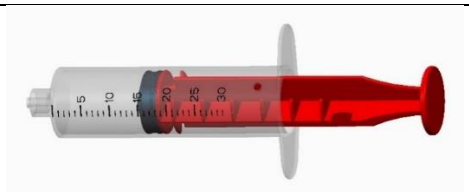
Insert filled cement cannula in the introducer to desired depth. The cement cannula contains marking in 1cm increments to indicate the distance the distal end of the cement cannula has exited the distal tip of the introducer. Repeat until the cavity created by the balloon catheter is completely filled.

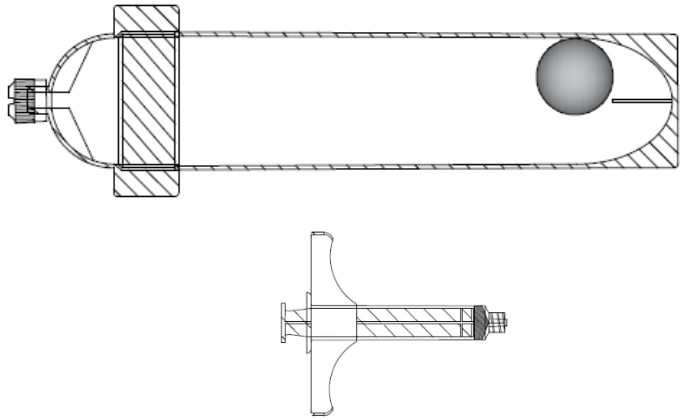
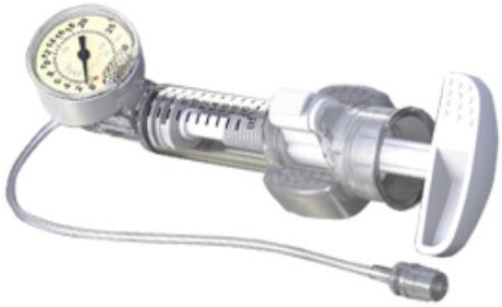
**Step 13: INTRODUCER REMOVAL**

Grasp the introducer handle and apply a twisting motion while pulling the introducer handle.

# Device Description

| Device View | Part # | Description |
|---|---|---|
|  | VCF-1002 | **Bevel Tip Introducer Cannula:**<br>• 17cm Overall Length<br>• 12cm Insertion Depth<br>• 10 Gauge Cannula<br>  ○ 3.4mm OD<br>  ○ 2.9mm ID<br>• Bevel Tip Style<br>• Removable Handle<br>• Luer Lock Syringe Connector<br>• Depth Markings |
|  | VCF-1003 | **Diamond Tip Introducer Cannula:**<br>• 17cm Overall Length<br>• 12cm Insertion Depth<br>• 10 Gauge Cannula<br>  ○ 3.4mm OD<br>  ○ 2.9mm ID<br>• Diamond Tip Style<br>• Removable Handle<br>• Luer Lock Syringe Connector<br>• Depth Markings |
|  | VCF-1006 | **Drill:**<br>• 22cm Overall Length<br>• 2.7mm OD<br>• 2 Flute Drill Tip<br>• Depth Markings |
|  | VCF-1007 | **Cement Cannula:**<br>• 25cm Overall Length<br>• 2.7mm OD<br>• Depth Markings<br>• Luer Lock Syringe Connector |
|  | VCF-1010 | **Bone Biopsy Needle:**<br>• 25cm Overall Length<br>• 2.7mm OD<br>• Depth Markings<br>• Luer Lock Syringe Connector |

| Device View | Part # | Description |
|---|---|---|
|  | VCF-1000-15<br>VCF-1000-20 | **Balloon Catheter**<br><br>VCF-1000-15, 15mm length<br>VCF-1000-20, 20mm length |
|  | VCF-1001 | **Inflation Syringe** |
|  | VCF-1004 | **Vacuum Locking Syringe:** |
|  | VCF-1005 | **Stopcock** |
|  | VCF-1009 | **PMMA bone cement** |
|  | VCF-1020 | **Cement Mixer and Injection Gun Kit** |

| Device View | Part # | Description |
|---|---|---|
|  | VCF-1051 | **Cement Mixing System** |
|  | VCF-1052 | **Inflation Device** |

## System Parts List

| Part# | Qty | Description |
|---|---|---|
| VCF-1011 | 1 | Instrument Kit (see kit components in table 2) |
| VCF-1000-15<br>VCF-1000-20 | 1 | Balloon Catheter |
| VCF-1017 | 1 | Inflation Kit (see kit components in table 3) |
| VCF-1016 | 1 | PMMA bone cement |
| VCF-1009<br>VCF-1020 | 1 | Cement Mixing Kit<br>Cement Mixer and Injection Gun 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 | Inflation Syringe |
| VCF-1004 | 1 | Vacuum Syringe |
| VCF-1005 | 1 | 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 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.

**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, 220 Lakeland Parkway, 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, 220 lakeland Parkway., 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.**