

VERTEBRAL BODY BALLOON

For the reduction of fractures
and/or creation of a void in
cancellous bone in the spine



TABLE OF CONTENTS

| | | |
|--------------|-----------------------------------|---|
| INTRODUCTION | Vertebral Body Balloon | 2 |
| | AO Principles | 3 |
| | Product Ordering | 4 |
| | Indications and Contraindications | 4 |

| | | |
|--------------------|---|----|
| SURGICAL TECHNIQUE | Patient Positioning | 5 |
| | Surgical Technique | 6 |
| | Access | 8 |
| | Biopsy | 10 |
| | Create Channel and Determine Balloon Size | 13 |
| | Prepare Inflation System | 14 |
| | Inflate Balloon | 20 |
| | Deflate and Remove Balloon | 21 |
| | Inject PMMA Bone Cement | 22 |
| | Postoperative Care | 23 |

| | | |
|---------------------|-------------|----|
| PRODUCT INFORMATION | Instruments | 24 |
|---------------------|-------------|----|

VERTEBRAL BODY BALLOON

For the reduction of fractures and/or creation of a void in cancellous bone in the spine.

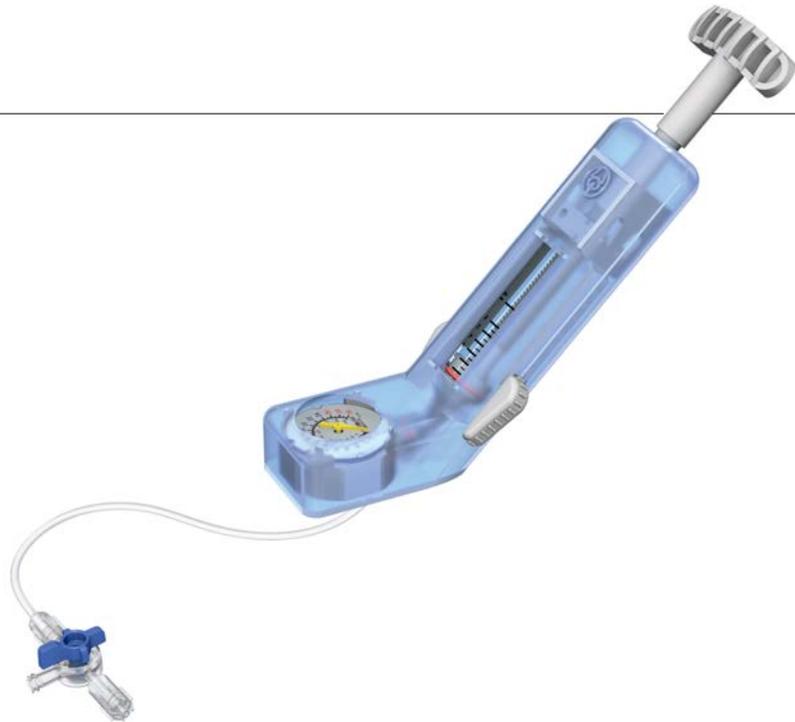
Vertebral Body Balloon

- Three sizes to fit varying patient anatomy
- For the reduction of fractures and/or creation of a void in the cancellous bone in the spine



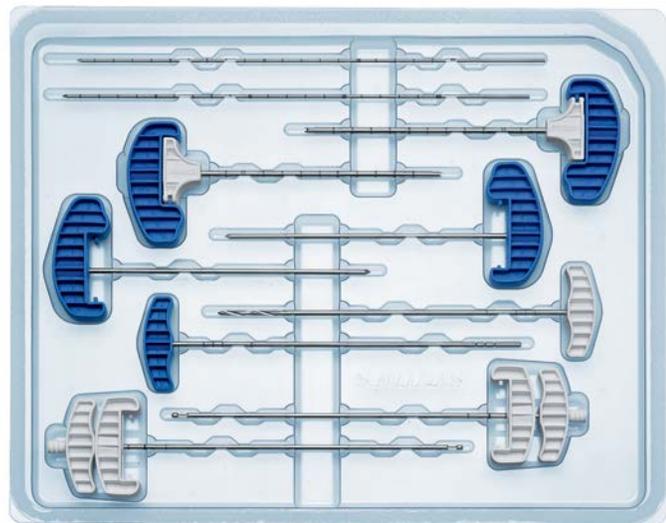
Inflation System

- Simple, easy-to-use inflation device
- Clear indication of volume and pressure during inflation



Access Kit

- Access options include guide wire and direct trocar approach
- Percutaneous, minimally invasive approach
- Intraoperative balloon sizing
- Optional biopsy



AO PRINCIPLES

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.¹ They are:

- Anatomic reduction
- Stable fixation
- Preservation of blood supply
- Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.^{2,3}

1. Müller ME, Allgöwer M, Schneider R, Willenegger H. *Manual of Internal Fixation: Techniques Recommended by the AO-ASIF Group*. 3rd ed. Berlin: Springer-Verlag; 1991.
2. Ibid.
3. Aebi M, Thalgott JS, Webb JK. *AO ASIF Principles in Spine Surgery*. Berlin: Springer-Verlag; 1998.

INDICATIONS AND CONTRAINDICATIONS

Indications

The Vertebral Body Balloon 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
- Systemic or local spinal infection
- Severe bleeding
- Known allergies to bone cement
- Pregnancy
- Fractures in which more than 75% of vertebral height is lost
- Any known severe allergy to contrast material
- Should not be used if vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon

Please refer to the Vertebral Body Balloon package insert for complete system descriptions, indications, and warnings.

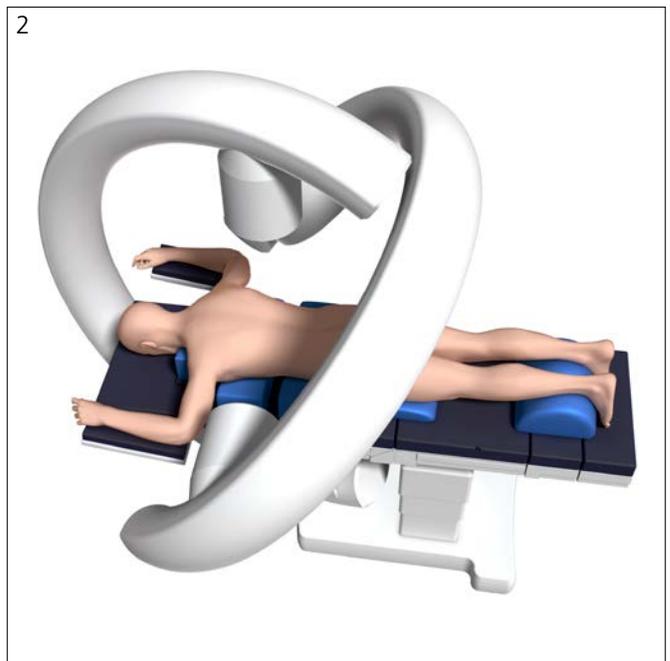
Refer to specific instructions for use of the cement being used for complete system specific information including indications, contraindications, warnings, precautions, and adverse reactions related to bone cement.

PATIENT POSITIONING

Position patient

Place the patient in the prone position on a radiolucent table to allow imaging of the targeted/affected levels (1).

- AP and lateral fluoroscopy are used frequently throughout the procedure. Biplanar fluoroscopy is recommended for the most efficient use of imaging (2). A single, freely mobile C-arm may also be used. Use of a device that offers a high-quality image is required. Set up the table, patient, and fluoroscopy to facilitate AP and lateral imaging throughout the procedure.



SURGICAL TECHNIQUE

Approach

Instruments

03.804.612S Access Kit, sterile

The access instruments can be inserted through either a transpedicular or extrapedicular approach. Identify the anatomical landmarks of the affected segment(s) under imaging.

Option A: Transpedicular

- 1 Under fluoroscopy, determine the location of the incision. The incision should facilitate insertion directly through the pedicle.

Important: Do not breach the pedicle wall or anterior cortical wall of the vertebral body during the approach.

Make a stab incision.

- 2 Under fluoroscopy, insert the tip of the access instrumentation through the incision until it contacts the pedicle. Confirm the proper trajectory, then advance the instrumentation through the pedicle and into the vertebral body.

Tip: Ensure that the tip of the access instrumentation does not pass the medial wall of the pedicle in the AP view until it has passed the posterior wall of the vertebral body in the lateral view to avoid entering the spinal canal.

Note: If considering a transpedicular approach, ensure that the diameter of the pedicle is at least 5.9 mm to accommodate access instruments with an outer diameter of 4.7 mm.



Transpedicular approach

Option B: Extrapedicular

- Under fluoroscopy, determine the location of the incision. The access instrumentation should enter the vertebral body lateral to the pedicle.

Important: Do not breach the anterior cortical wall of the vertebral body during the approach.

Make a stab incision.

- Under fluoroscopy, insert the tip of the access instrumentation through the incision until it contacts the posterolateral border of the vertebral body. Confirm the proper trajectory, and then advance the instrumentation into the vertebral body.



Extrapedicular approach

ACCESS

Determine access path

Access options include trocar or guide wire access. The trocar option allows access in a single step. The guide wire can be used to create a path for the access instruments.

Note: The guide wire access option may compromise the ability to collect a biopsy using the Biopsy Kit.

Option A: Trocar

To position the working sleeve, insert the access construct into the vertebral body in a single step.

Assemble the access construct from the instrument assembly as provided in the kit (working sleeve and cannulated trocar). Replace the cannulated trocar with the diamond tip trocar, and lock it into place with a clockwise rotation.

- 1 Under fluoroscopy, insert the access construct until the end of the working sleeve is positioned approximately 3 mm into the vertebral body (1). The end of the working sleeve can be viewed as a transition in diameter under fluoroscopy. For best visualization, temporarily slide the trocar partially out for fluoroscopic imaging. After imaging, slide the trocar fully forward into the working sleeve to adjust positioning of the access instrumentation as necessary.

The working sleeves are marked with equidistant depth markers to allow monitoring of the insertion process. If necessary, carefully hammer on the blue handle of the trocar to gently advance the trocar instrumentation. Do not hammer on the white plastic components.

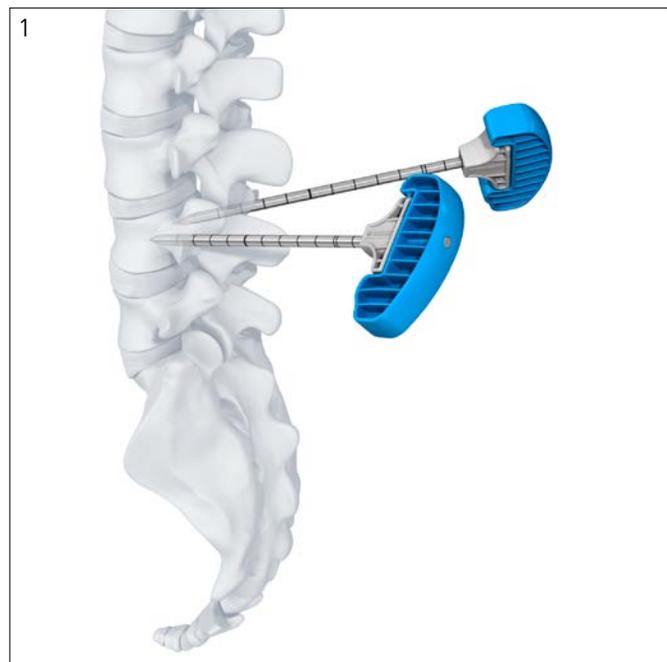
Important: Ensure that the trocar instrumentation does not breach the anterior wall of the vertebral body.

- 2 Confirm proper positioning of the access instrumentation under both AP and lateral fluoroscopy. Hold the working sleeve in place and carefully remove the trocar, leaving the working sleeve in the vertebral body (2).

For bilateral procedures, repeat on the contralateral side.

Warnings:

- Do not insert or advance the working sleeve in the bone without a trocar. This could damage the working sleeve and obstruct balloon insertion.
- Do not redirect the instrument assembly without removing it and re-accessing the vertebral body.



Option B: Guide Wire

Insert the guide wire to create the access path, and position appropriately. Insert the instrument assembly of working sleeve and cannulated trocar over the guide wire and into the vertebral body.

- 1 Under fluoroscopy, position the tip of the guide wire approximately 10 mm from the anterior wall of the vertebral body in the lateral view (1). The guide wires are marked with equidistant depth markers to allow monitoring of the insertion process. Monitor the guide wire position with fluoroscopy while inserting the instrument assembly of working sleeve and cannulated trocar over the guide wire, until the end of the working sleeve is positioned approximately 3 mm into the vertebral body (2). The end of the working sleeve can be viewed as a transition in diameter under fluoroscopy. For best visualization, temporarily slide the cannulated trocar partially out for fluoroscopic imaging. After imaging, slide the cannulated trocar fully forward into the working sleeve to adjust positioning of the access instrumentation as necessary. Ensure that the guide wire does not breach the anterior wall of the vertebral body.

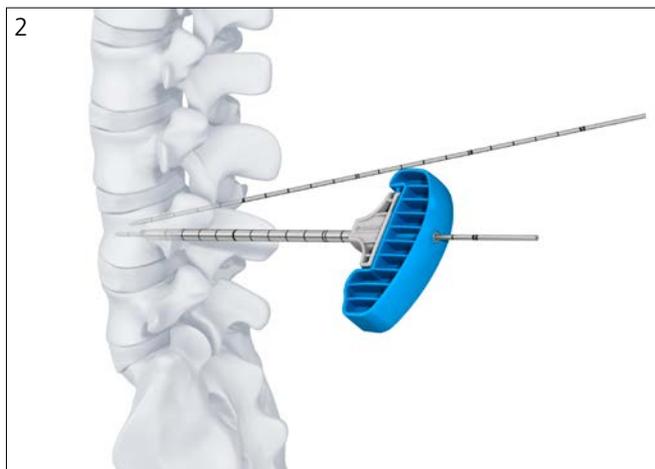
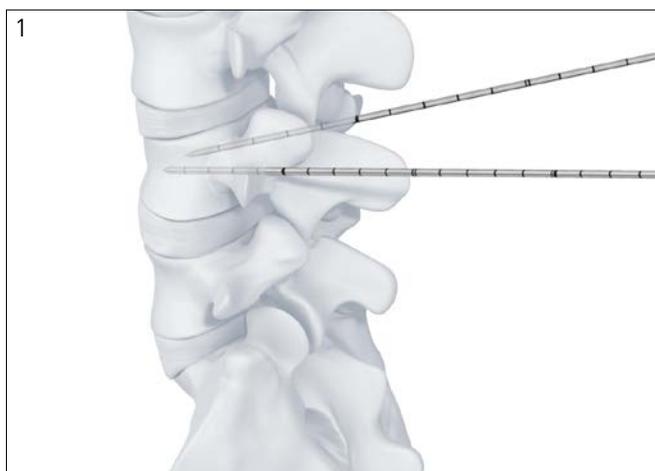
Important: The guide wire will extend out the back of the handle. Advance the instruments carefully, to avoid injury to the physician's hand.

- 2 Confirm proper positioning of the access instrumentation under both AP and lateral fluoroscopy. Hold the working sleeve in place and carefully remove the guide wire and cannulated trocar, leaving the working sleeve in the vertebral body (3).

For bilateral procedures, repeat on the contralateral side.

Warnings:

- Do not insert or advance the working sleeve in the bone without a trocar. This could damage the working sleeve.
- Do not redirect the instrument assembly without removing it and re-accessing the vertebral body.
- Do not use excessive force on the guide wire to avoid potentially deforming the guide wire.



BIOPSY

After placement of the working sleeve, a biopsy can be taken, if needed, using the biopsy kit.

Instruments

03.804.613S Biopsy Kit, sterile

Remove plunger from the biopsy needle.

- 1 Under fluoroscopy, insert the biopsy needle into the working sleeve until the first marker reaches the shaft of the working sleeve (1). In this position, the tip of the biopsy needle is at the tip of the working sleeve.

- 2 **Warning: Do not insert the biopsy needle beyond the anterior cortical wall of the vertebral body, as this could damage vascular structures.**

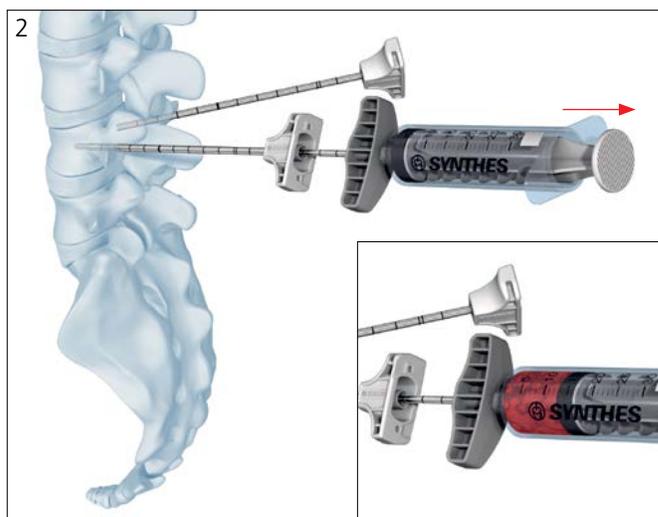
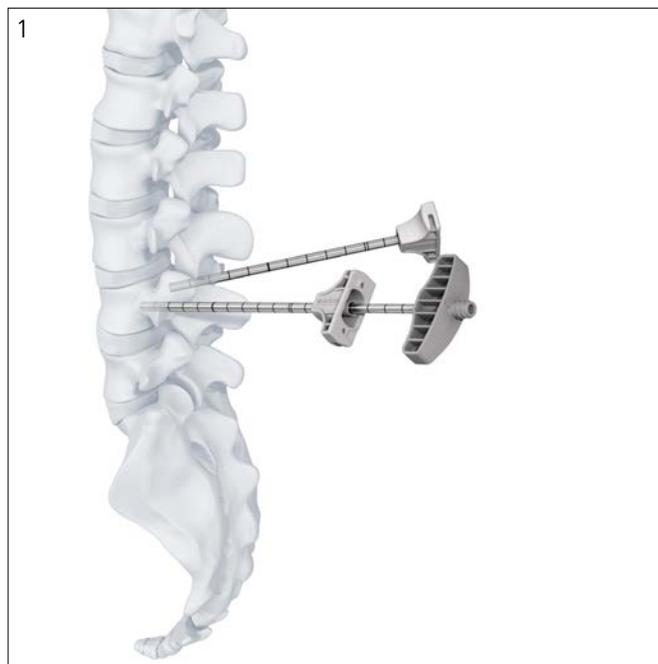
- 3 Under fluoroscopy, slowly advance the biopsy needle to the final position in the anterior half of the vertebral body. Do not use a hammer and take care not to perforate the anterior wall. Bone tissue will be captured in the biopsy needle.

Once the needle reaches the final position, rotate the biopsy needle one full turn (360°) to ensure that the bone biopsy is fully loosened from the surrounding bone.

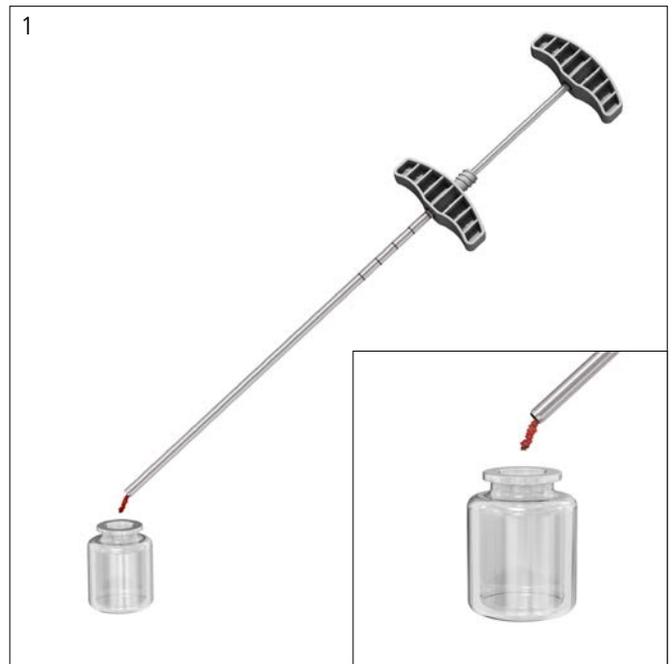
Optionally, attach a standard Luer lock syringe to the biopsy needle (at least 3 cc) and slowly draw the syringe (2).

Remove the biopsy needle with the attached syringe (if used) from the working sleeve.

Note: Hold the working sleeve in place and carefully remove the biopsy needle, leaving the working sleeve in the vertebral body.



If a syringe was used, remove it. Use the biopsy plunger to push the collected bone tissue out of the biopsy needle (1).



CREATE CHANNEL AND DETERMINE BALLOON SIZE

The plunger has two important uses:

- Create an access channel for balloon insertion
- Determine the appropriate balloon size

Create Channel

The access channel for the vertebral body balloon is created using the plunger.

- ① Under lateral fluoroscopy, insert the plunger through the working sleeve and into the vertebral body. The plunger may be advanced by hand pressure or gently hammering on the blue handle (1).

Optionally, the plunger can be removed and the access channel created with the drill. Advance the drill slowly by turning on the handle clockwise (2).

Remove the drill and insert the plunger to size and verify balloon position.

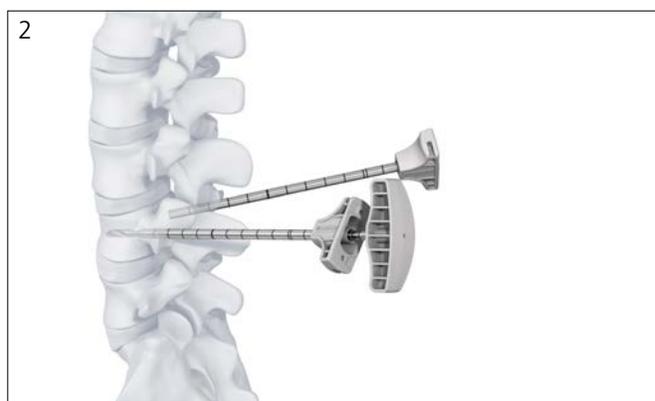
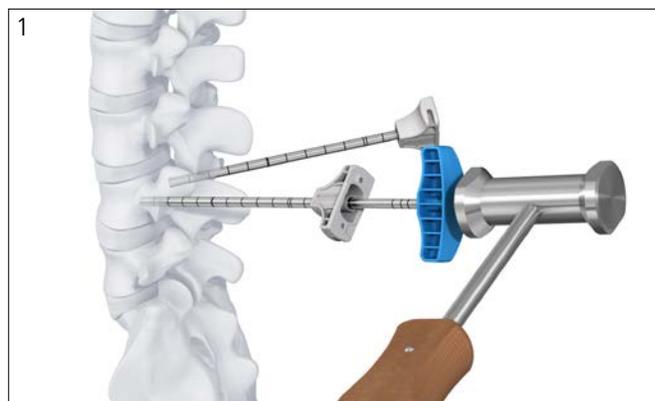
Note: The distal (first) marking on the plunger/drill indicates when the tip leaves the working sleeve whereas the three following markers show the initial lengths of sizes S/M/L respectively.

Warnings:

- Do not hammer on the drill.
- Do not insert the drill or plunger beyond the anterior cortical wall of the vertebral body, as this could damage vascular structures.

Important: When inserting or removing the plunger or drill, ensure the working sleeve does not move.

For bilateral procedures, repeat on the contralateral side.



Determine Balloon Size

The Vertebral Body Balloon is available in 3 sizes: small, medium and large.

Vertebral Body Balloons, sterile

| | | Max. Dia. (Inflated) (mm) | Pre-Inflated Length (mm) |
|-------------|--------|---------------------------|--------------------------|
| 03.804.500S | Small | 15 | 22 |
| 03.804.501S | Medium | 17 | 27 |
| 03.804.502S | Large | 17 | 31 |



The pre-inflated length is the unexpanded balloon length.

- Once the plunger has been positioned appropriately, use lateral fluoroscopy to determine the appropriate vertebral body balloon size. The plunger has 3 grooves near the distal tip that correspond to the 3 sizes:



From distal tip, the first groove visible:

Vertebral Body Balloon, small

From distal tip, the second groove visible:

Vertebral Body Balloon, medium

From distal tip, the third groove visible:

Vertebral Body Balloon, large



Note: If no plunger grooves are visible under fluoroscopy, adjust the working sleeve and/or the plunger if possible. If the instrumentation cannot be safely adjusted to reveal at least one groove, then the vertebral body balloon procedure will not be possible and an alternative augmentation procedure should be employed.

For bilateral procedures, repeat on the contralateral side.

PREPARE INFLATION SYSTEM

Instruments

| | |
|-------------|---|
| 03.804.413S | Inflation System, sterile |
| 03.804.500S | Vertebral Body Balloon, small, sterile |
| 03.804.501S | Vertebral Body Balloon, medium, sterile |
| 03.804.502S | Vertebral Body Balloon, large, sterile |

The following steps are required to prepare the inflation system and the Vertebral Body Balloon:

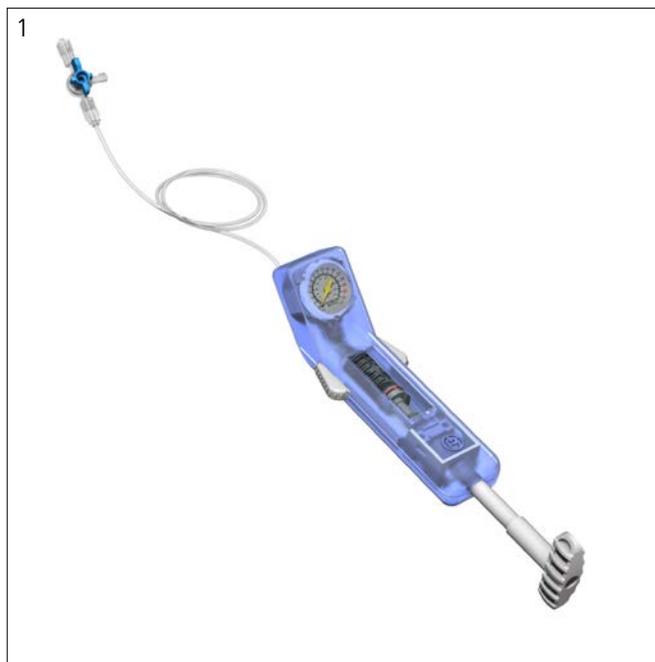
- Attach the stopcock to the inflation system
- Fill the inflation system
- Connect a balloon catheter to the inflation system and create a vacuum

For bilateral procedures, prepare two systems.

Note: The inflation system has an angled manometer that shows the pressure in the balloon in pounds/inch² (psi) and atmospheres (atm). The volume scale on the fluid chamber measures milliliters (mL).

Attach stopcock to inflation system

Attach the three-way stopcock to the inflation system tube via the Luer connector (1). The large arm of the stopcock knob (labeled "OFF") always points to the channel that is closed. Position the stopcock knob so the lateral channel is closed.



1a

Fill the inflation system, standard method

Prepare contrast medium. Contrast can be used alone, or a mixture can be used with a ratio of contrast medium to saline of up to 1:2.

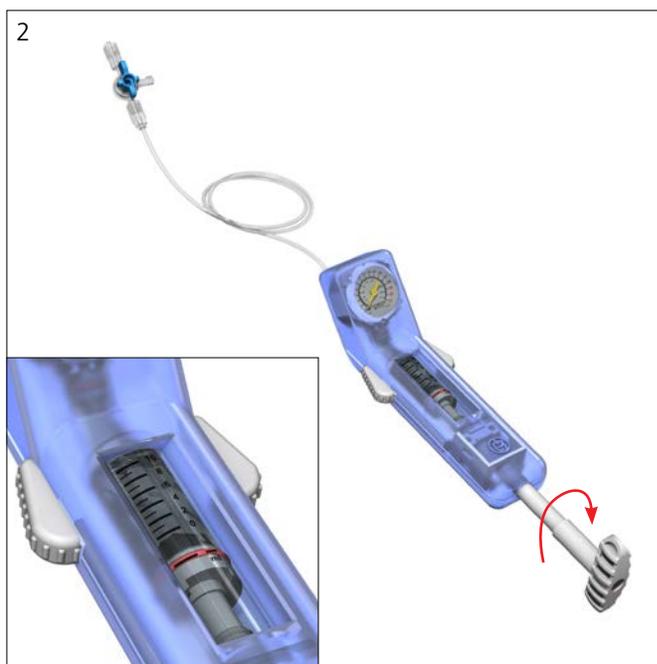
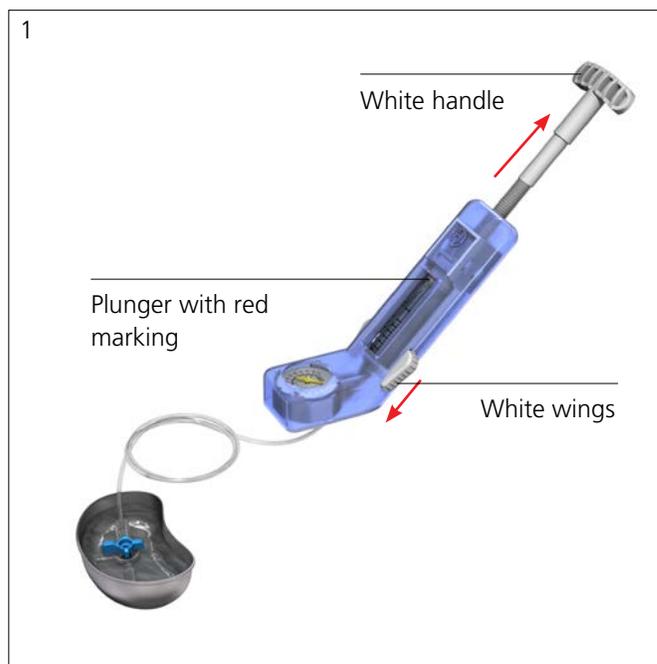
Notes:

- Check the patient for allergy to the contrast medium.
- Follow the manufacturer's recommendations for contrast medium use in the vertebral body.

Submerge/connect the distal end of the stopcock to the contrast solution source. Slide the white wings on the sides of the inflation system forward while pulling back on the white handle to fill the chamber with fluid (1). Release the wings when the plunger bottoms out and the chamber is filled with fluid. With the handle pointing up, tap the unit to clear air out of the gauge portion of the inflation system.

Hold the inflation system with the handle facing downward. While pushing forward on the handle, rotate the handle clockwise to expel all the air in the barrel (2). Continue turning the handle clockwise, until solution starts to emerge and the leading edge of the red ring on the plunger reaches approximately 3 to 4 mL below the "0" mark, or until the red ring is aligned with the black line above the mL sign, beneath the "0" mark (2, inset).

Tip: To make gross adjustments to the plunger, slide the wings forward to unlock the plunger.



2a

Connect balloon catheter and create vacuum, standard method

Remove the desired balloon from its packaging.

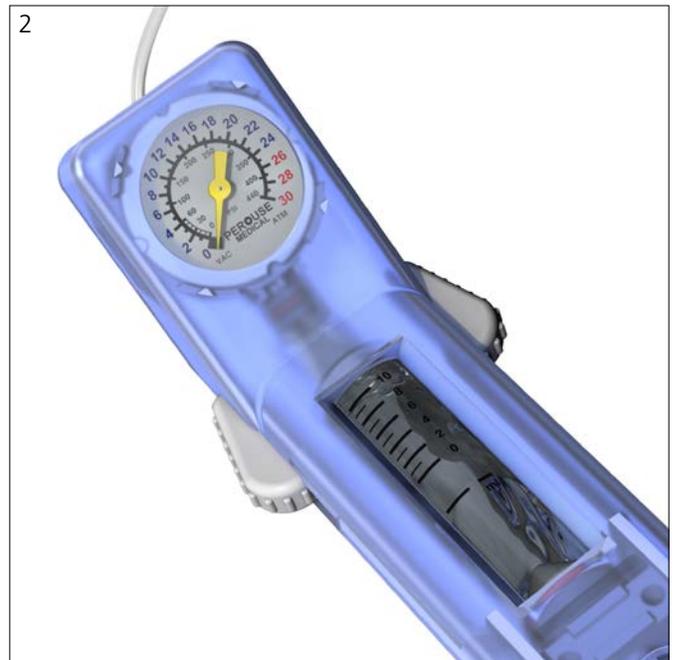
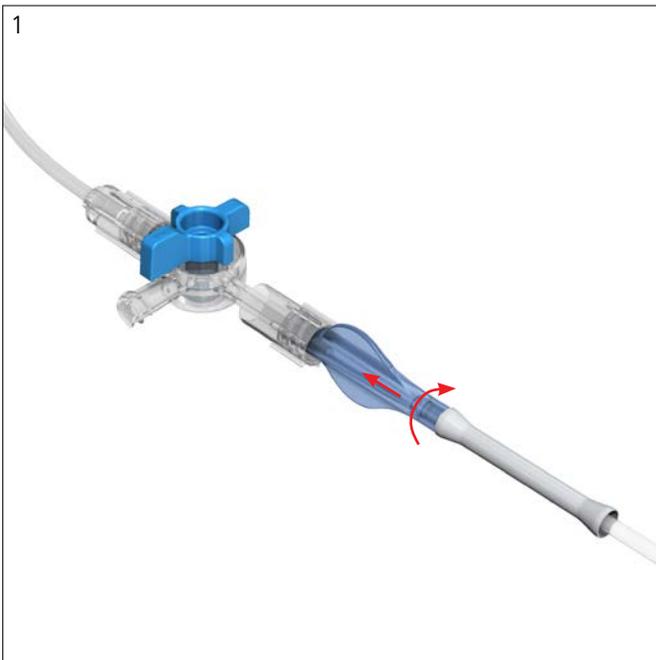
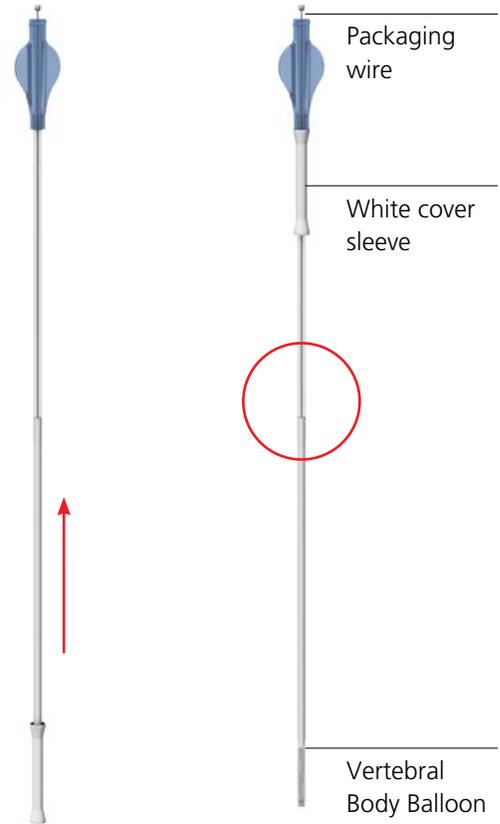
Slide the white cover sleeve covering the balloon toward the blue Luer connection and securely engage it to tip of the blue component.

Carefully remove the packaging wire from the catheter and discard.

Connect the vertebral body balloon to the three-way stopcock via the Luer connector (1).

Note: Ensure that all Luer connectors are securely attached. Loose connections may result in inaccurate filling volumes and pressures.

Slide the wings forward and pull the handle of the inflation system all the way back to pull the air out of the catheter, then release the wings while still holding the plunger back. This creates a vacuum in the catheter. The indicator on the manometer should point to "VAC." (2)



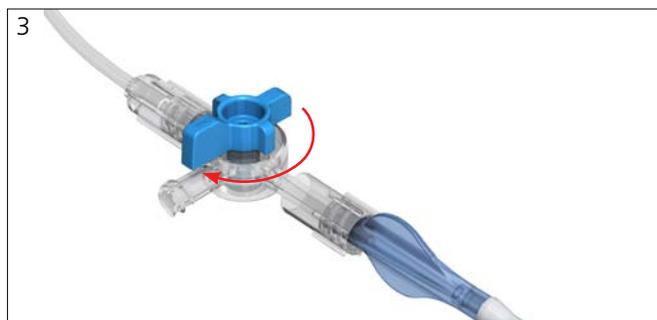
Prepare inflation system

Turn the stopcock knob to close the catheter channel (1). This retains the vacuum in the balloon catheter.

Hold the inflation system with the handle facing downward and turn the handle clockwise, to set the volume scale to "0." Turn the handle until the leading edge of the red ring on the plunger is precisely at "0." (2)

Tip: Suspend the three-way stopcock over a receptacle for all steps that involve expelling excess solution.

Turn the stopcock knob to close the lateral channel again (3).



1b

Fill the inflation system, alternate method

Prepare contrast medium. Contrast can be used alone, or a mixture can be used with a ratio of contrast medium to saline of up to 1:2.

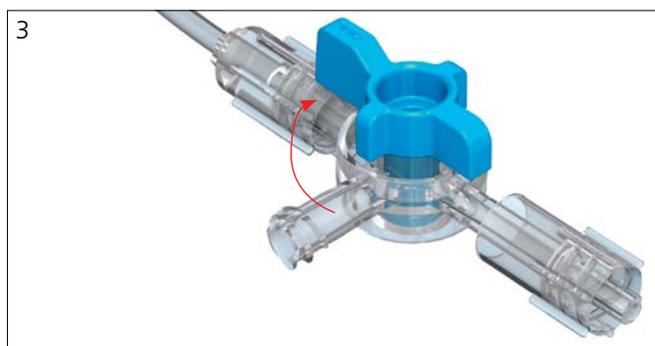
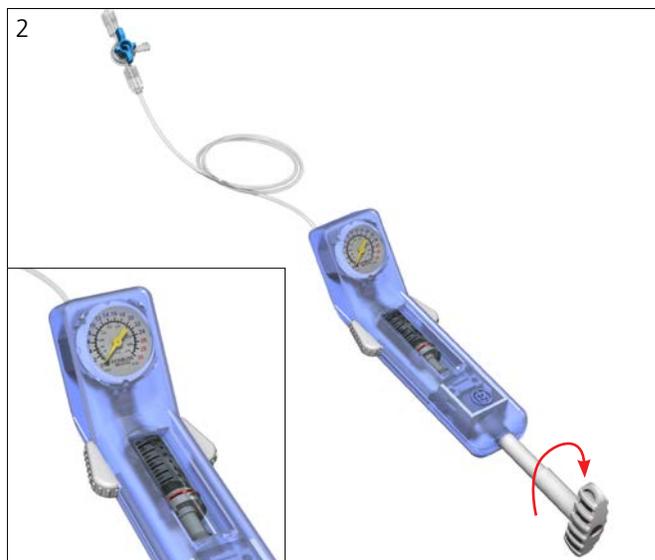
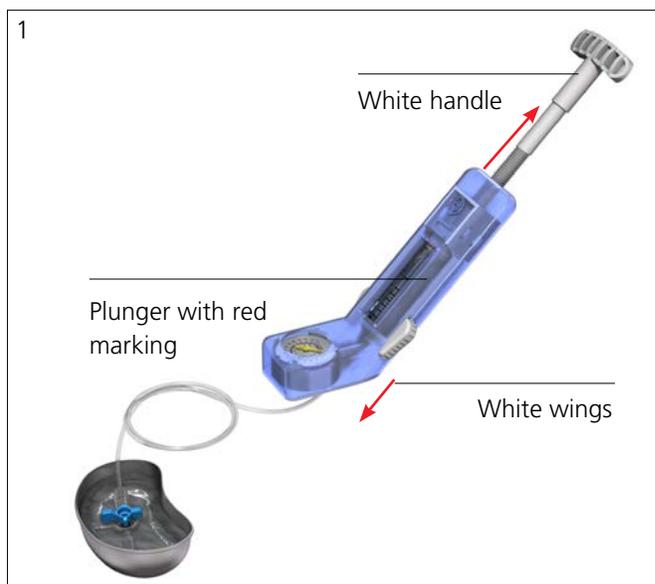
Notes:

- Check the patient for allergy to the contrast medium.
- Follow the manufacturer's recommendations for contrast medium use in the vertebral body.

Submerge/connect the distal end of the stopcock to the contrast solution source. Slide the white wings on the sides of the inflation system forward while pulling back on the white handle to fill the chamber with fluid (1). Release the wings when the plunger bottoms out and the chamber is filled with fluid. With the handle pointing up, tap the unit to clear air out of the gauge portion of the inflation system.

Hold the inflation system with the handle facing downward. While pushing forward on the handle, rotate the handle clockwise to expel all the air in the barrel (2). Continue turning the handle clockwise, until solution starts to emerge and the leading edge of the red ring on the plunger is precisely at "0".

Turn the stopcock knob to close the inflation tube channel (3).



2b

Connect balloon catheter and create vacuum, alternate method

Remove the desired balloon from its packaging.

Slide the white cover sleeve covering the balloon toward the blue Luer connection and securely engage it to the tip of the blue component. Carefully remove the packaging wire from the catheter and discard.

Connect the vertebral body balloon to the three-way stopcock via the Luer connector.

Note: Ensure that all Luer connectors are securely attached. Loose connections may result in inaccurate filling volumes and pressures.

Attach a locking syringe (10 mL–30 mL) with standard Luer connector to the lateral channel on the stopcock via the Luer connector.

Warnings:

- Only use syringes that are compatible with contrast material. Refer to the manufacturer's directions on appropriate syringes.
- Do not use syringes made from glass, rubber, and/or latex components.

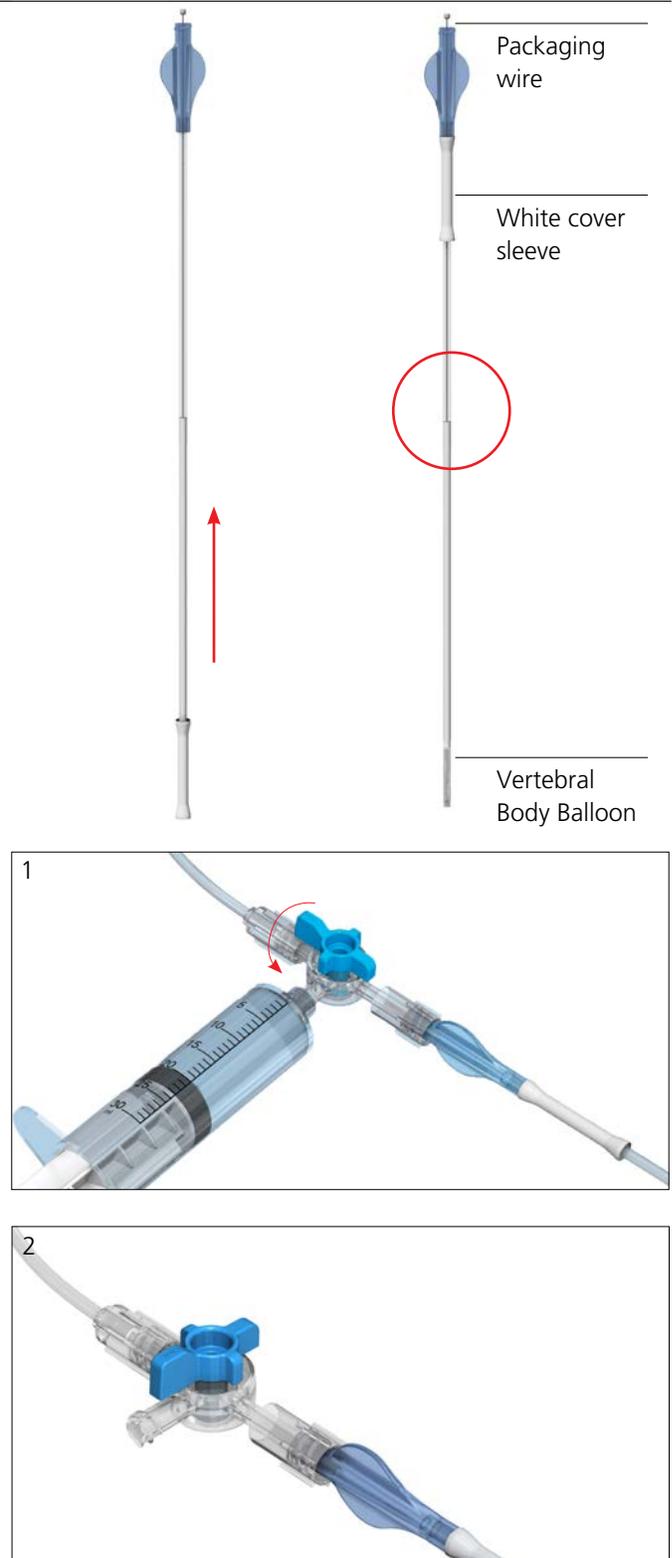
Note: A locking syringe is recommended for this option to more easily secure the created vacuum.

Pull and maintain vacuum on the syringe to at least 10 mL and no more than 30 mL.

Warnings:

- Exceeding 30 mL of vacuum may result in damage to the balloon catheter.
- Use syringe only to pull vacuum on the balloon catheter, do not inject any material into the balloon catheter.
- Only air should be in the syringe. In the case that contrast material gets in the syringe and then is injected into the balloon catheter, discard the entire system (syringe, contrast, inflation system, and balloon catheter if attached).

While maintaining vacuum, turn the stopcock knob to close the lateral channel where the syringe is connected (1). Remove the syringe (2).



INFLATE VERTEBRAL BODY BALLOON

Inflate balloons with fluid

- 1 The white sleeve aids in balloon insertion. Slide the white sleeve back over the balloon. While continuing to hold the white sleeve, use it to aid in balloon catheter insertion into the working sleeve under lateral radiographic control. After inserting the balloon catheter into the working cannula, carefully slide the white sleeve back toward the blue Luer connection and secure it in place. The full release (initial) length of the balloon is outside the working sleeve when the proximal end of the white portion of the catheter shaft disappears into the working sleeve (1). Check the position under radiographic control and confirm the desired position.

Note: If it is not possible to completely insert the balloon catheter so that the white portion of the catheter shaft disappears, it may be necessary to clear the path again using the plunger.

- 2 To inflate the balloon, slowly rotate the handle of the inflation system clockwise while monitoring the pressure and volume. Proceed with inflation slowly, stopping every few seconds to allow the bone to adjust to the pressure/volume changes. Use fluoroscopy to monitor balloon inflation (2).

Stop increasing pressure when any of the following happen:

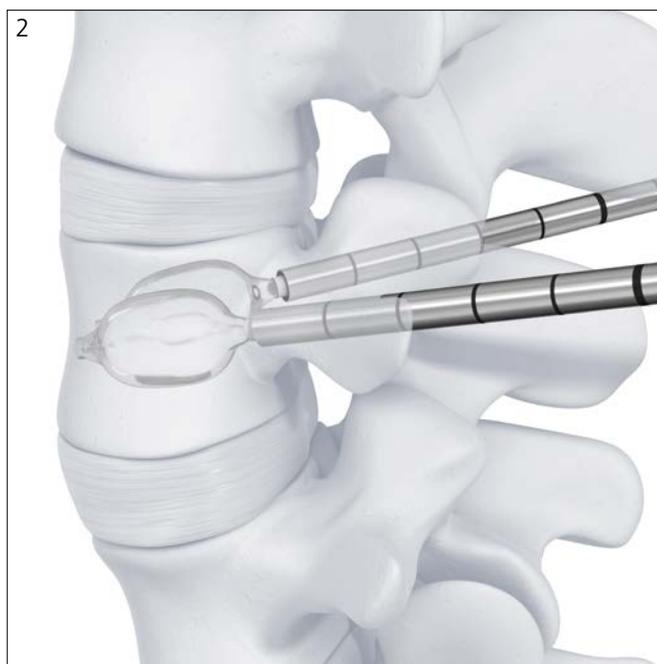
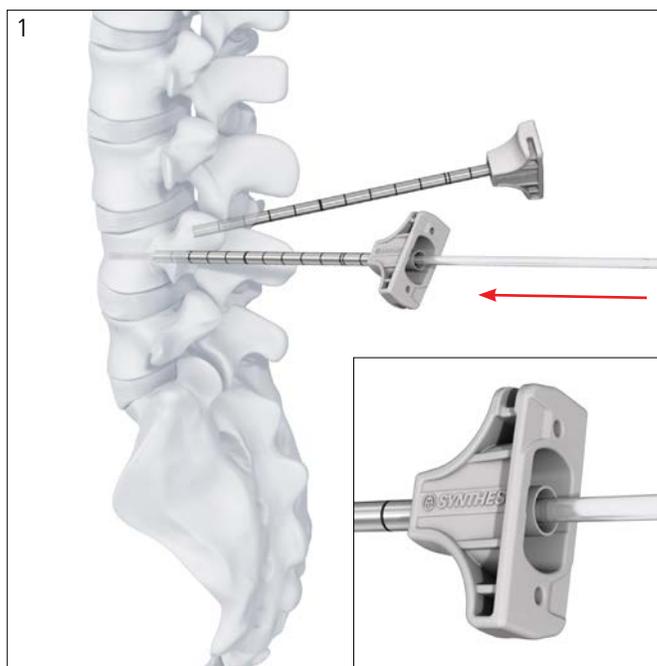
- The desired clinical outcome is reached
- The pressure reaches 30 atm (440 psi)
- The maximum volume is achieved
 - 4.0 mL for the small balloon
 - 4.5 mL for the medium balloon
 - 5.0 mL for the large balloon

Important: The balloons may leak if they are filled beyond their maximum volume or pressure. If balloon leakage does occur, a new balloon should be used.

For bilateral procedures, inflate each balloon alternately in increments.

Notes:

- For bilateral procedures, it is important to ensure balloon inflation does not induce misalignment. However, it may be desirable to inflate the balloons to different volumes to prevent or correct misalignment.
- Each balloon is for single use only and should not be reinserted or inflated after the initial use.



DEFLATE AND REMOVE VERTEBRAL BODY BALLOON

Gradually decrease the pressure by turning the handle of the inflation system counterclockwise, until the manometer indicates approximately 10 atm (150 psi) (1). Slide the wings forward while pulling the handle all the way back slowly, to fully collapse the balloon and draw a vacuum. Release the wings with the handle pulled all the way back, to seal the vacuum.

Hold the working sleeves in place and remove the catheters to retrieve the balloons.

Note: If the balloon does not deflate, check the connections to the inflation system, draw a vacuum again, or assemble a new inflation system to draw a vacuum and collapse the balloon.

Important: The balloon material is not implant-grade material. If balloon rupture occurs, visually inspect the ruptured balloon to confirm no fragment is missing from it. If any portion of the balloon is missing, it must be retrieved from the patient.

Note: If it becomes difficult to remove the balloon catheters through the working sleeves, twist the catheter while firmly pulling the catheter. If removal is still difficult, remove the balloon catheters together with the working sleeves, then re-access the vertebral body using the working sleeve trocar assembly. Once re-access is complete, remove the trocar.

For bilateral procedures, deflate each balloon alternately in increments.



INJECT PMMA BONE CEMENT

Instrument

03.804.612S Access Kit, sterile

Follow the manufacturers' recommendations for PMMA use in the vertebral body.

Remove the injection needle with clip from the package. Move the clip to the starting marker position. In this position, the distal tip of the injection needle is in line with the distal end of the working sleeve after insertion.

Under fluoroscopy, insert the injection needle with clip into the working sleeve and rotate the clip clock-wise to lock it to working sleeve (1). Connect a PMMA delivery system via the Luer lock.

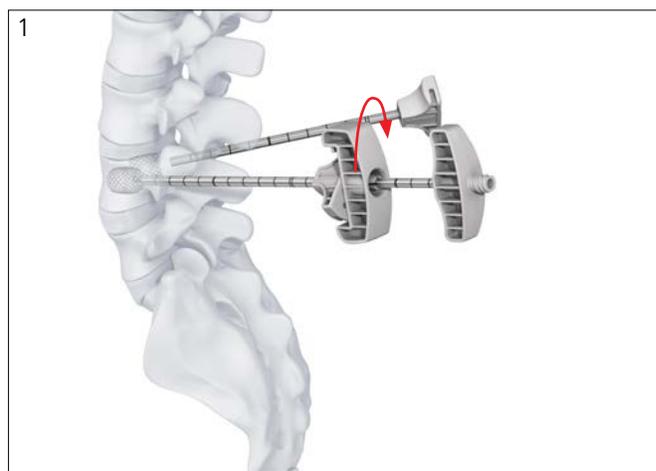
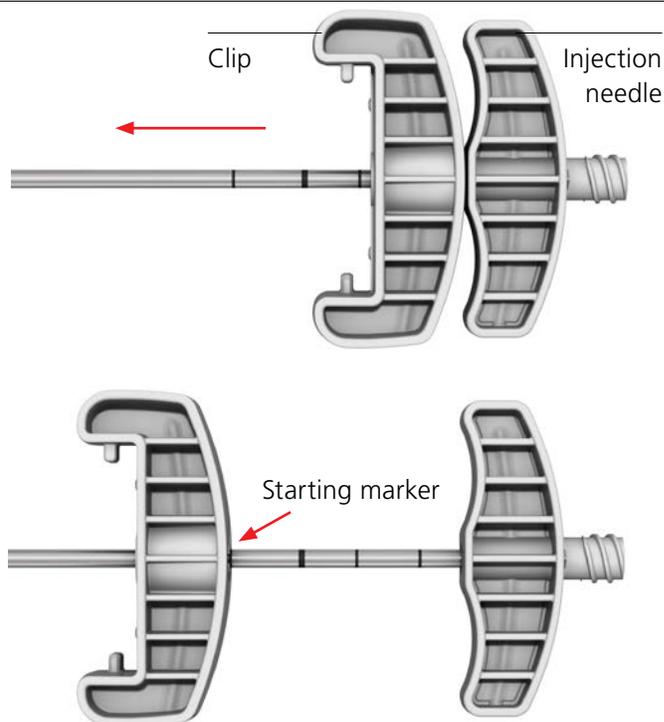
Note: Do not use the biopsy kit for cement application.

For bilateral procedures, repeat on the contralateral side.

- Under lateral fluoroscopy, inject PMMA cement. The direction of the PMMA flow can be changed by orienting the handle of the side-opening needle to correspond to the direction of PMMA cement flow. The arrow on the handle of the side opening needle corresponds to the side of the opening. The PMMA should be contained within the vertebral body.

Notes:

- Hold the injection needle while connecting and disconnecting the PMMA delivery system to prevent the injection needle from moving.
- When using an injection system, confirm that the system is compatible with the standard Luer lock on the injection needle.
- If using a bilateral approach, alternately fill both sides in increments. It is important to see the filling behavior of both needles. Once the filling of one side is accomplished, the lateral view of the opposite side is hidden by the cement, which makes monitoring the flow more difficult.



- Warning:** Closely monitor the PMMA injection under fluoroscopy to reduce the risk of cement leakage. Severe leakage can cause death or paralysis. If cement leakage is observed during the procedure, STOP cement injection and consider: waiting for the cement already injected to harden, repositioning the needle, adjusting the needle direction, or stopping the procedure. If desired, continue cement injection slowly, and carefully evaluate for further leakage. If further leakage is observed, cease cement injection.

Refer to the manufacturer's instructions for proper waiting times required prior to the removal of side-opening needle(s) and working sleeve(s).

Note: If the working sleeves are removed before the cement is sufficiently hardened, there is risk of pulling cement fibers into the muscle tissue. If this happens, cement residue should be removed from the soft tissues.

Close wound.

POSTOPERATIVE CARE

Place the patient in the supine position after surgery to compress the wound. Bruising may occur at the puncture sites. The patient may then be mobilized at the physician's discretion.

INSTRUMENTS

Vertebral Body Balloons, sterile

| | | Pre-Inflated Length (mm) | Max. Dia. (Inflated) (mm) | Max. Volume (ml) | Max. Pressure (atm) |
|-------------|--------|--------------------------|---------------------------|------------------|---------------------|
| 03.804.500S | Small | 22 | 15 | 4.0 | 30 |
| 03.804.501S | Medium | 27 | 17 | 4.5 | 30 |
| 03.804.502S | Large | 31 | 17 | 5.0 | 30 |



03.804.413S Inflation System, sterile

Contains:

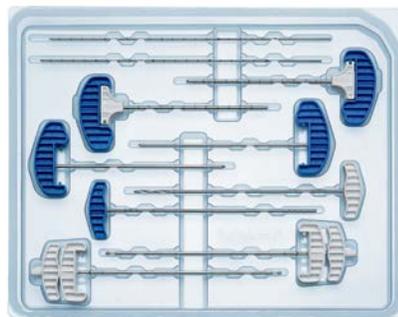
1 Stopcock

1 Inflation device



Note: For additional information, please refer to package insert.

03.804.612S Access Kit, sterile



Contains:

2 Injection Needles with clip



2 Guide Wires, with depth markings



2 Trocars



2 Cannulated Trocars



2 Working Sleeves



1 Access Drill



1 Access Plunger



OPTIONAL IMPLANTS AND INSTRUMENTS

03.804.613S Biopsy Kit, sterile (optional)



Limited Warranty and Disclaimer: DePuy Synthes Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

To order in the U.S. call, Johnson & Johnson Health Care Systems Inc. Customer Support Services at 800-255-2500.

Not all products are currently available in all markets.

This surgical technique is not intended for distribution in Canada

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