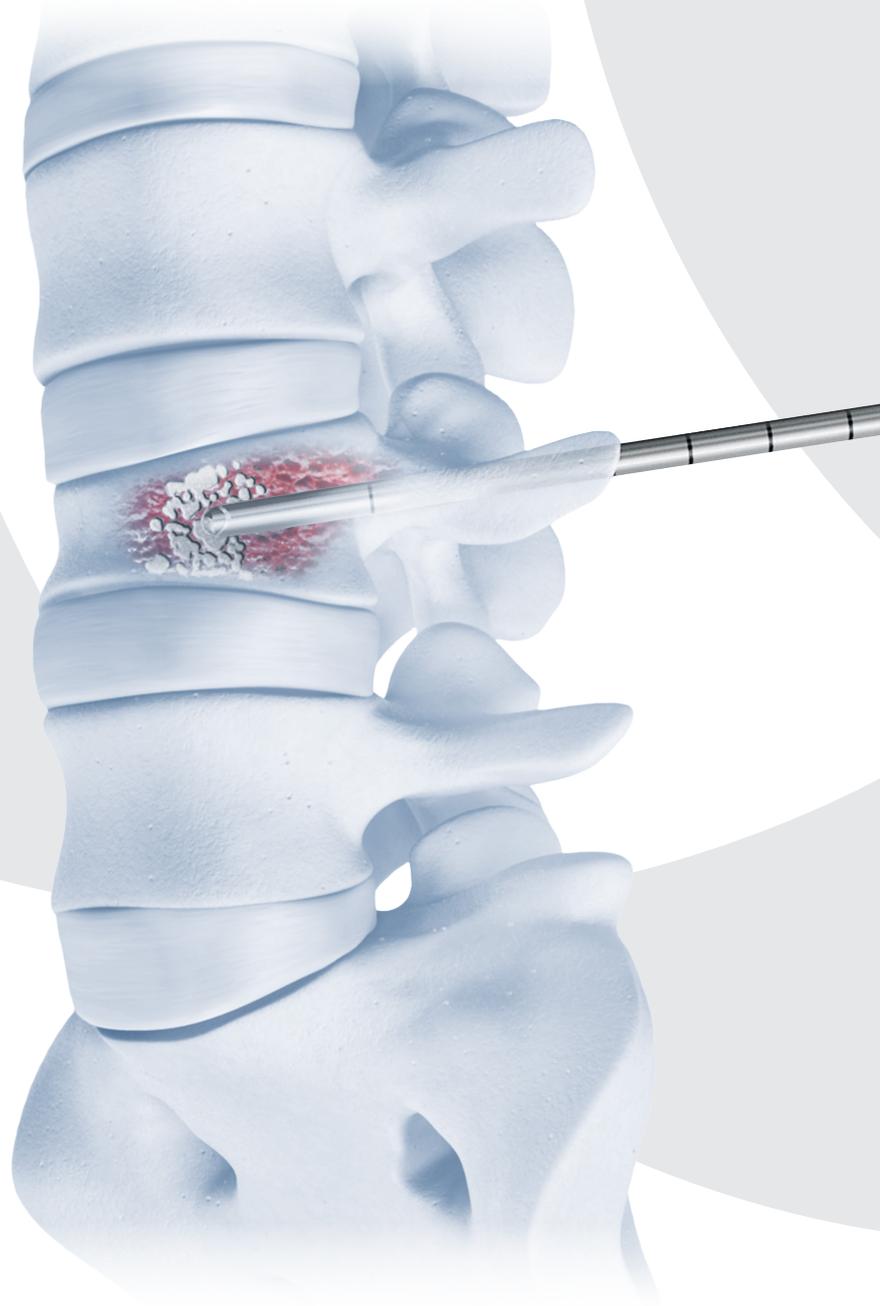


# VERTECEM™ V+

## Surgical Technique



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 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

**Processing, Reprocessing, Care and Maintenance**

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

<http://emea.depuyshnthes.com/hcp/reprocessing-care-maintenance>

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE\_023827) or refer to:

<http://emea.depuyshnthes.com/hcp/reprocessing-care-maintenance>

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# AO Spine Principles

The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.<sup>1,2</sup>

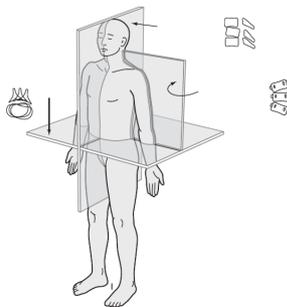
## Stability

Stabilization to achieve a specific therapeutic outcome



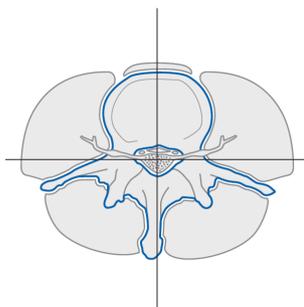
## Alignment

Balancing the spine in three dimensions



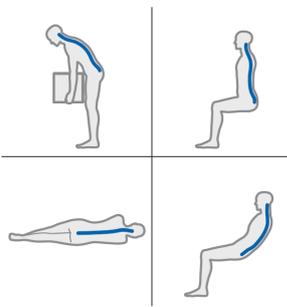
## Biology

Etiology, pathogenesis, neural protection, and tissue healing



## Function

Preservations and restoration of function to prevent disability



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# Preoperative Planning

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## **Instrument and implant planning**

VERTECEM V+ is a modular system and all implants and instruments are provided separately. Please refer to the Product Catalogue for images and more comprehensive descriptions of the different products

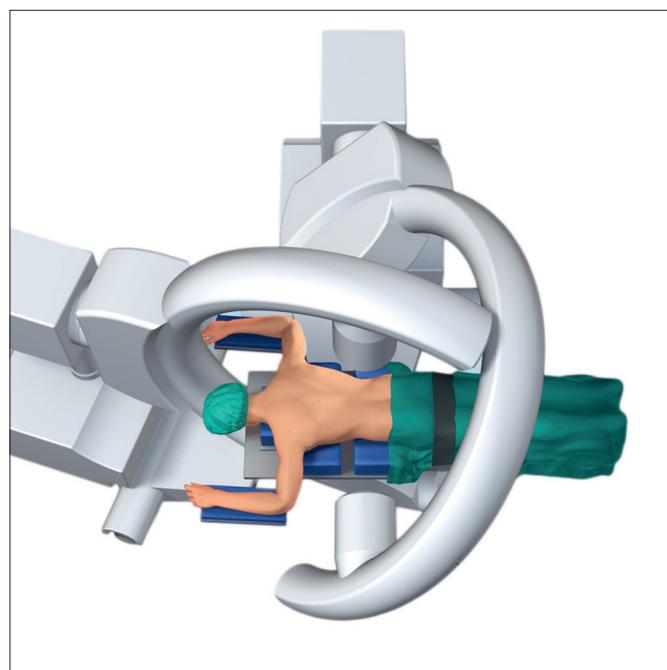
# Patient Positioning

## 1. Position the patient

- 1 Place the patient in the prone position on a lumbar support. The table must be radiolucent in both planes.



The OR table should allow free manipulation of the C-arm over the operative site in both planes



# Access Options

Both the guidewire and direct access techniques described in the following sections are based on a minimally invasive approach. In both cases access can be established combining the following options.

- Trans- or parapedicular access
- Mono- or bipedicular access

In the following, the use of the Vertebroplasty Needle Kits featuring a side-opening window is described, making it possible to guide cement flow in-situ. DePuy Synthes also offers the Bone Access Needle line which is front-opening only. The physician needs to take the difference in cement flow behavior between the two into account during needle placement and cement injection.

## A. Guidewire technique

The technique is based on a minimally invasive approach to the vertebral body either trans- or parapedicular. Hereafter the transpedicular approach is described.

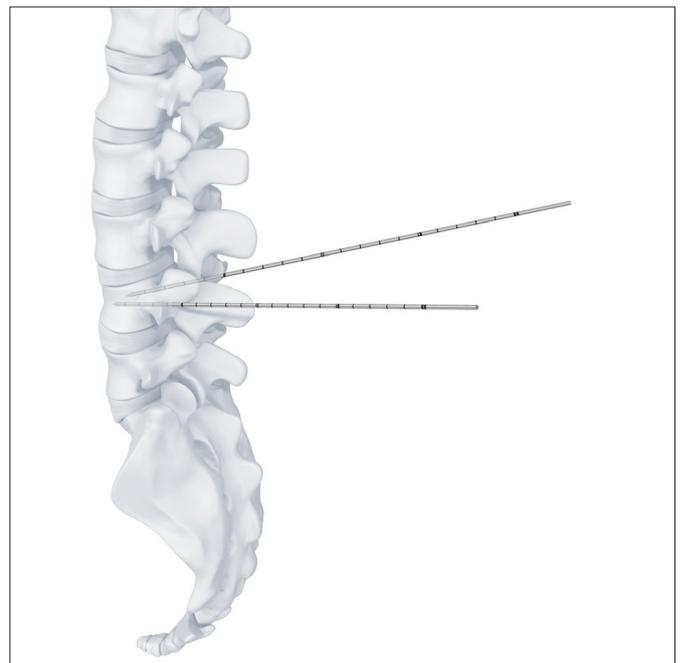
### Instruments

03.702.216S	Vertebroplasty Needle Kit, 8-Gauge, Diamond Tip
03.702.218S	Vertebroplasty Needle Kit, 10-Gauge, Diamond Tip
03.702.219S	Vertebroplasty Needle Kit, 10-Gauge, Beveled Tip
03.702.220S	Vertebroplasty Needle Kit, 12-Gauge, Diamond Tip
03.702.221S	Vertebroplasty Needle Kit, 12-Gauge, Beveled Tip

- 1 With the C-arm in the AP view, plan the site of the stab incision.

Complete the stab incision, then push the guide wire (supplied within the needle kits referred to above) through the soft tissue until you touch the bony surface of the spine. Use the C-arm to verify placement of the guide wire tip.

Use a wire holder in order to avoid radiation exposure to your fingers



Transpedicular approach in the lumbar spine using the guidewire technique.

The orientation of the guidewire is made with the C-arm in the AP view: Once you touch the bony surface, the tip of the wire should be located lateral of the “eye” of the pedicle at its upper third. At the thoracic spine the wire sits on the costo-transverse process and at the lumbar spine it sits in the edge of the lateral facet and the transverse process.

Then advance the guidewire convergent in projection of the pedicle.

**Warning: True AP and lateral images are required to ensure accurate positional and dimensional assessments**

In order to penetrate the surface of the bone, some light taps with a mallet/hammer may be necessary. Adjust the direction of the guidewire as required and continuously advance it under AP C-arm control. As soon as the tip of the wire reaches the medial border of the pedicle, the depth of the wire needs to be verified in the lateral projection.

Preliminarily insert the wires at all levels where cement injection is planned. For each vertebra where the wire has been placed preliminarily, store its position in your image intensifier.

- ① The C-arm projection is now changed to lateral: In the lateral projection, the tip of the wires must be positioned at least at the level of the posterior wall of the vertebral body, otherwise the wire needs to be relocated by switching back to the AP view. Then cautiously advance the guide wire using light taps with a mallet/hammer and if necessary, redirect in order to reach the centre of the vertebral body.

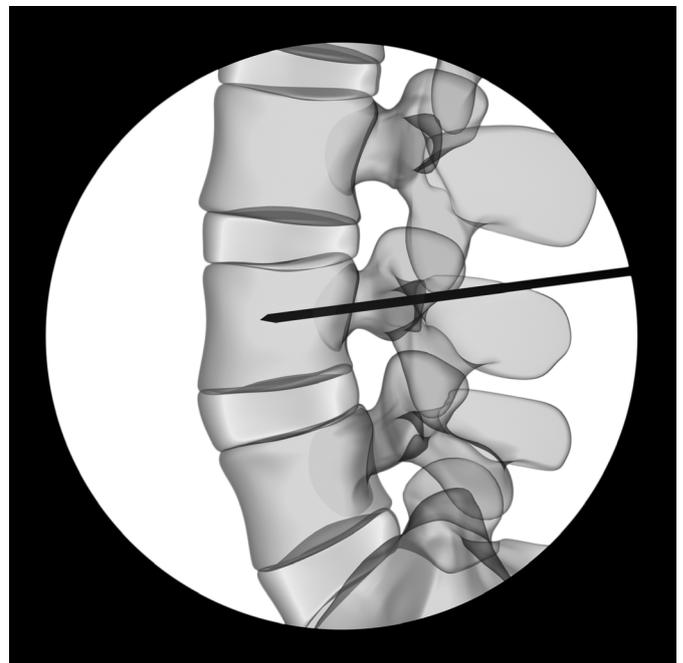
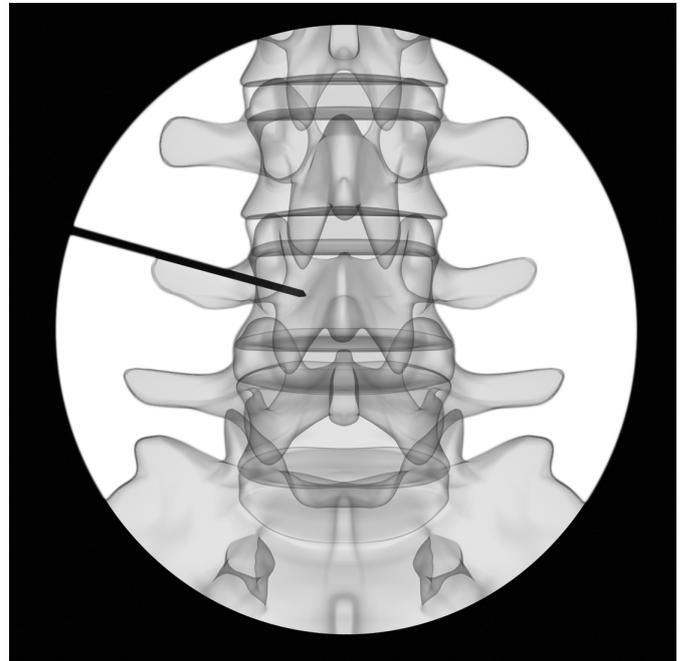
- First, align the X-ray beam parallel to endplates. Plan the insertion of the beveled tip needle based on the AP view, advance needle under C-arm control.

- ① Store the native pictures of the part to be injected in your C-arm and depict the picture on your right screen as a reference.

The guidewire is marked with 1 cm dashes. This allows monitoring the insertion progress.

**Warning: Be sure to maintain the position of the guide wire to prevent it from advancing or backing out inadvertently.**

The guide wire is approx 4cm longer than the needle assembly. If the guide wire does not instantly protrude from the handle of the needle, an uncontrolled advancement of the guide wire should be suspected.



**Insert needles**

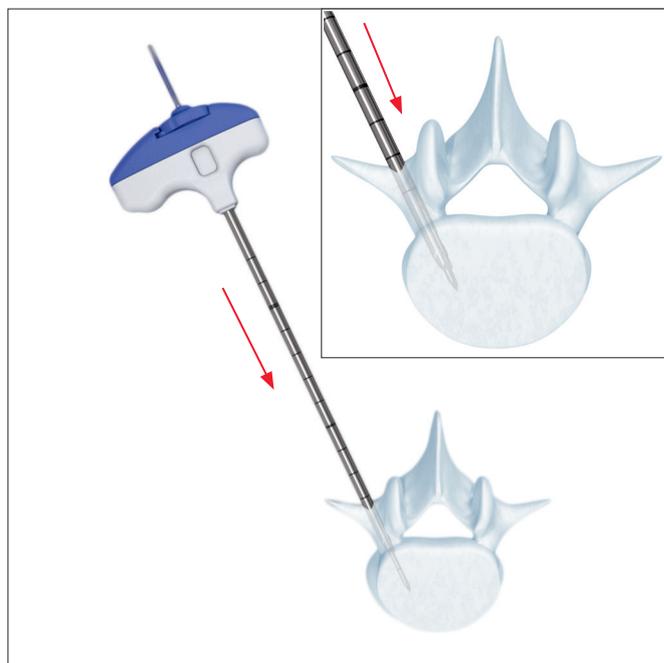
Slide the side-opening needle assembled with the cannulated trocar together over the guidewire by rotating movements. Again, use C-arm control during the final placement of the needle.

If a biopsy is needed, please refer to section C page 17 for the biopsy technique.

The tip of the needle should be advanced until the anterior half of the vertebral body is reached. As soon as the needle has reached the final position remove the guidewire and the cannulated trocar.

**Warning:**

- Be sure to maintain the position of the guide wire to prevent it from advancing or backing out inadvertently.
- Be careful not to perforate the anterior wall when placing the guide wire or the needle.



**Insert inner sleeve**

Prior to inserting the inner sleeve ensure that all bone tissue has been cleared out of the outer needle using the trocar.

The side opening inner sleeve is inserted in order to close off the front opening of the outer needle.

Engage the sleeve fully and check the closing mechanism on the handle.



The arrow on the handle indicates the side-opening of the needle.

Ensure that the dash on the inner sleeve and the arrow on the outer cannula are aligned at all times to allow the cement to be injected via the side-opening window.

The side-opening needle is marked with 1 cm dashes. This allows the depth of insertion to be monitored. During placement of the needle, the position of it should be checked with the C-Arm.



## B. Direct access technique

The technique is based on a minimally invasive approach to the vertebral body either trans- or parapedicular. Hereafter the transpedicular approach is described.

### Instruments

03.702.216S	Vertebroplasty Needle Kit, 8-Gauge, Diamond Tip
03.702.218S	Vertebroplasty Needle Kit, 10-Gauge, Diamond Tip
03.702.219S	Vertebroplasty Needle Kit, 10-Gauge, Beveled Tip
03.702.220S	Vertebroplasty Needle Kit, 12-Gauge, Diamond Tip
03.702.221S	Vertebroplasty Needle Kit, 12-Gauge, Beveled Tip

- With the C-arm in the AP view, plan the site of the stab incision.

Complete the stab incision, then push the guide wire (supplied within the needle kits referred to above) through the soft tissue until you touch the bony surface of the spine. Use the C-arm to verify placement of the guide wire tip. Use a needle holder in order to avoid radiation exposure to your fingers.

The orientation of the needle is made with the C-arm in the AP view: Once you touch the bony surface, the tip of the needle should be located lateral of the "eye" of the pedicle at its upper third. At the thoracic spine the needle sits on the costo-transverse process and at the lumbar spine it sits in the edge of the lateral facet and the transverse process. Then advance the needle convergent in projection of the pedicle.

**Warning: Be sure to maintain the position of the guide wire to prevent it from advancing or backing out inadvertently.**

Be careful not to perforate the anterior wall when placing the guide wire or the needle.



Transpedicular approach in the lumbar spine.

In order to penetrate the surface of the bone, use controlled pressure combined with turning movements (some light taps with a mallet/hammer may be necessary.) To adjust the direction of the needle turn the beveled tip into the desired direction and continuously advance it under AP C-arm control. As soon as the tip of the needle reaches the medial border of the pedicle, the depth of the needle needs to be verified in the lateral projection.

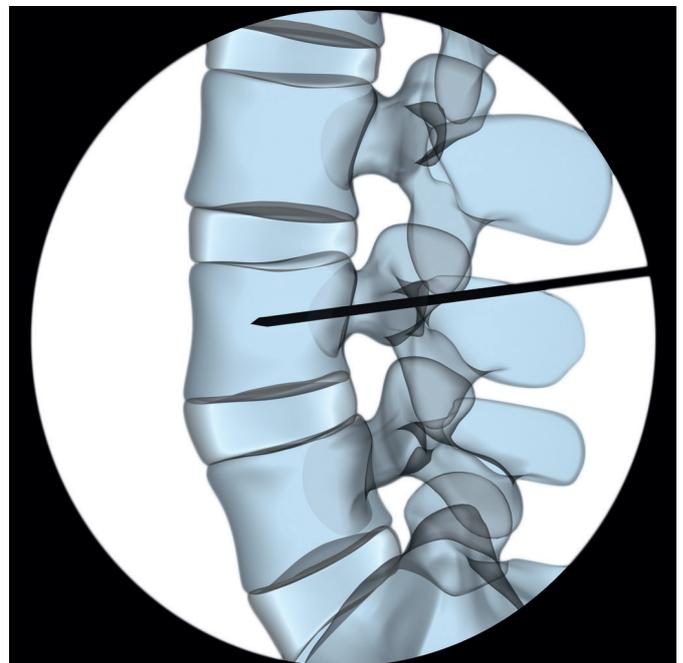
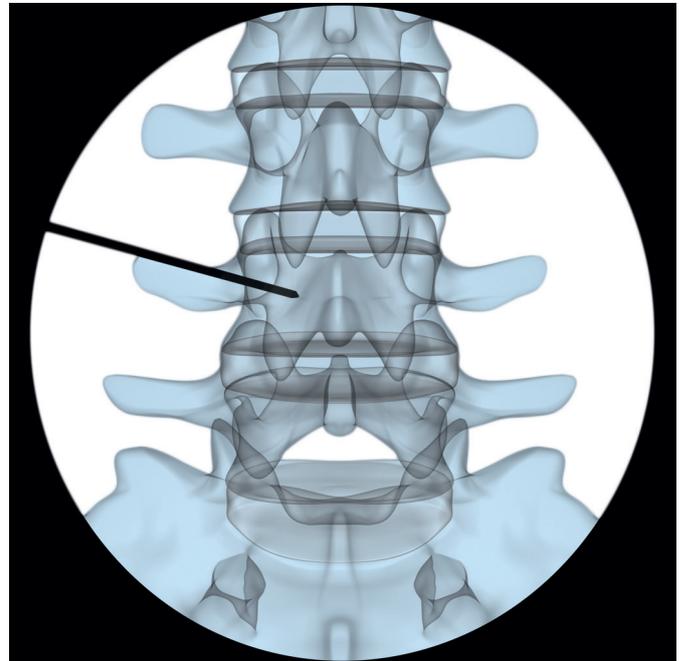
Preliminarily insert the needles at all levels under AP C-arm control where cement injection is planned. For each vertebra where the wire has been placed preliminarily, store its position in your image intensifier.

The C-arm projection is now changed to lateral: In the lateral projection, the tip of the needle must be positioned at least at the level of the posterior wall of the vertebral body, otherwise the needle needs to be relocated by switching back to the AP view.

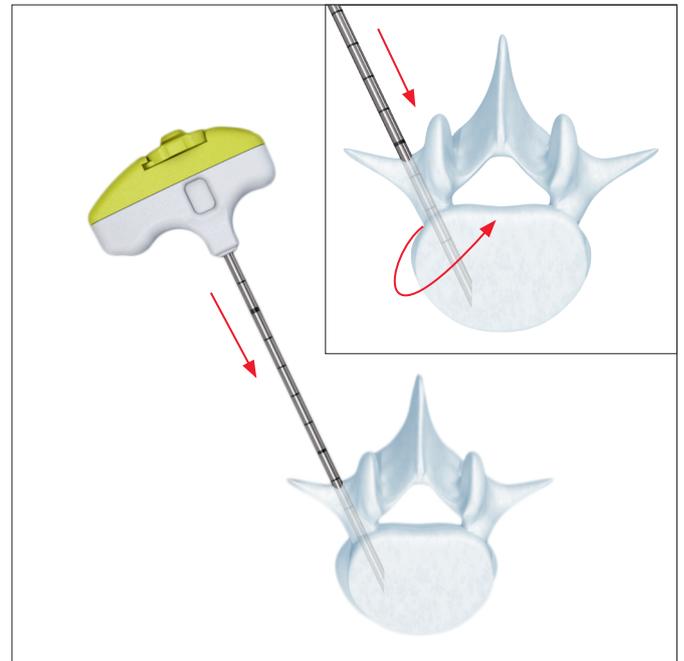
"If a biopsy is needed, please refer to section C page 17 for the biopsy technique.

The tip of the needle should be advanced until the anterior half of the vertebral body is reached.

Store the native pictures of the part to be injected in your C-arm and depict the picture on your right screen as a reference.



In order to make room for the inner sleeve, it is required to compress the bone tissue at the tip of the needle. To do this, turn the needle together with the trocar assembly 360°. Then remove the trocar. This needs to be done if the inner sleeve is used for cement injection.

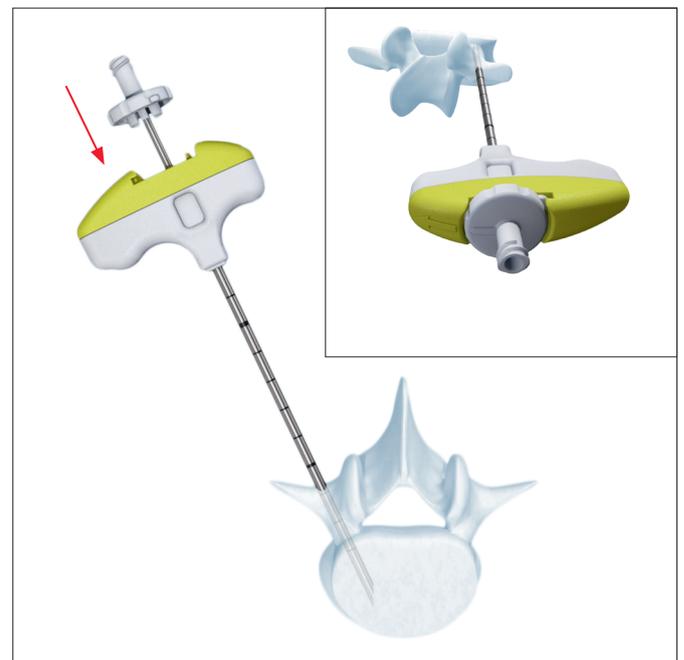


**Insert inner sleeve**

Prior to inserting the inner sleeve ensure with the trocar that all bone tissue has been cleared out of the outer cannula.

The side opening inner sleeve is inserted in order to close off the front opening of the outer needle.

Engage the sleeve fully and check the closing mechanism on the handle.



## C. Biopsy technique

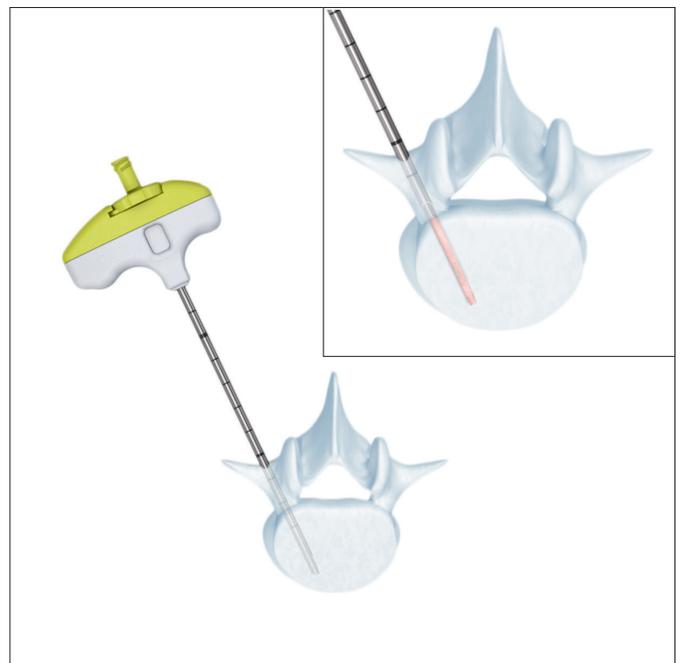
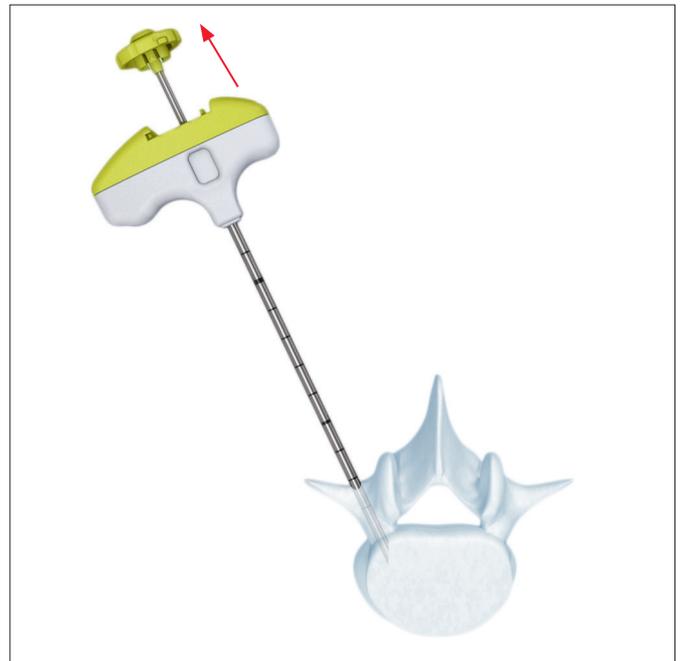
### Instruments

03.702.222S	Biopsy Kit, for 8-Gauge Vertebroplasty Needle Kit
03.702.223S	Biopsy Kit, for 10-Gauge Vertebroplasty Needle Kit

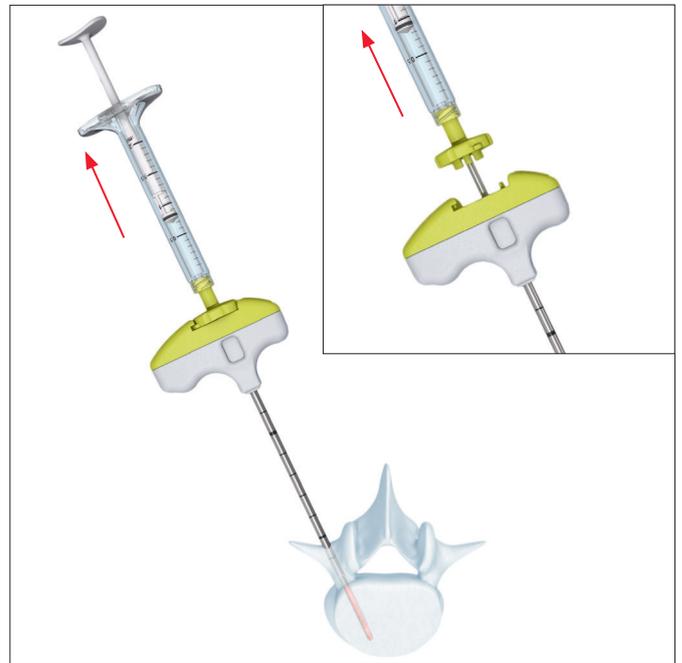
When the inserted needle (here shown for the beveled 10 gauge needle) has passed the posterior wall, remove the beveled trocar.

This technique is also applicable using the 8 or 10 gauge diamond tip needle. Instead of removing only the beveled trocar, as described above, the cannulated trocar together with the guidewire needs to be removed.

Insert the biopsy needle and lock it into the handle of the outer cannula. Advance the outer cannula assembled with the biopsy needle to the final position in the vertebral body (INSERT CORRECT PAGE NUMBER ONCE STG IS AMENDED). During this insertion bone tissue is captured in the biopsy needle. Rotate the assembly at least one full turn (360°), to loosen the biopsy.



Attach a standard Luer lock syringe (1–3 mL, not included within any of the VERTECEM V+ system) to the biopsy needle, and create a vacuum to retain the bone biopsy in the needle. Remove the biopsy needle with the attached syringe from the outer needle.



Remove the syringe and use the stylet to push the collected bone tissue out of the biopsy needle.



# Cement Handling

## 1. Prepare cement

### Implant

07.702.016S VERTECEM V+ Cement Kit

Hold the VERTECEM V+ Cement Kit upright and gently tap with the finger tip at the top of the mixing device in order to ensure no cement powder sticks to the cartridge and transportation lid.

**Precaution:** During preparation, mixing and injection, always hold the mixing device by gripping the blue tube section located directly below the transparent cartridge.

If the transparent part is held, the body heat provided by the users hand might speed up polymerisation and decrease the working time of the cement.

Open the glass ampoule by breaking off its neck with the plastic cap ❶. Place the opened ampoule in the ampoule holder in the VERTECEM V+ Cement Kit inner blister or on a flat, sterile surface. Hold the mixing device upright and make sure the blue handle is in its outmost position. Tap gently on its lid with your finger to ensure that no powder sticks to transportation lid or mixer walls. Remove the transportation lid (see Fig 1) from the mixing device and dispose of it. Pour the full content of the ampoule ❷ into the mixer and close it tightly with the separate mixing and transfer lid ❸. Make sure that both mixing lid and the small sealing plug on top of it are securely tightened (see Fig 2).

Fig. 1



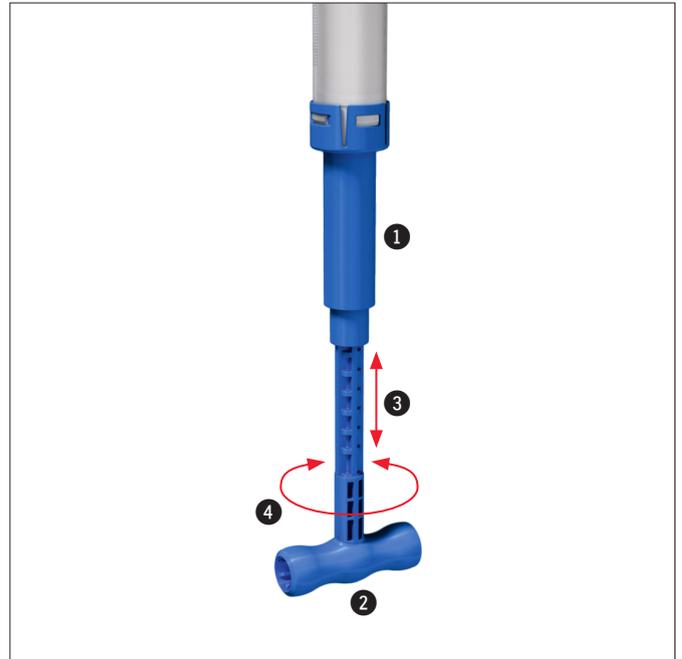
Fig. 2



Grip the mixer by the blue tube section ①. Start mixing the VERTECEM V+ cement by pushing and pulling the handle ② from endpoint to endpoint ③ for 20 seconds (1–2 strokes per second). Perform the first few mixing strokes slowly with an oscillating-rotating movement (③ and ④ combined).

Once properly mixed, the blue handle ② must be left in its outmost position.

If syringes are used instead of SynJect, go directly to page 31, section 3b “Fill injection syringes”.



## 2. Fill injection syringes

### Instrument

03.702.2155 VERTECEM V+ Syringe Kit

Once cement has been mixed, remove the sealing plug and connect the stop cock. Use the side without the funnel when connecting the stop-cock to the mixer.

The handle in the initial position is turned 90° away from the mixer and the "off" sign is on the opposite side from the funnel.

**Precaution:** Ensure a tight fit between the stop-cock and mixing device, but avoid breakage of the stop-cock due to the application of excessive torque.

First, the air has to be removed from the system. Hold the cement mixer in a vertical position and gently turn its handle clockwise.

Turn the handle clockwise to extrude cement from the mixer.

**Precaution:** Do not push the handle.

You will see the piston of the mixer advancing in the translucent cartridge and a steady flow of cement moving into the stop-cock. As soon as the cement is visible at the funnel end of the stop-cock, close the stop-cock by turning the handle ("off") toward the mixer (90°).



Attach a syringe to the stop-cock (funnel side). It is suggested to use the 2ml syringes first.

Open the stop-cock by turning the handle (90° turn), back to its original position.



Use slow, controlled turning movements on the mixer handle to fill the syringe. As soon as the syringe is filled turn the valve of the stop-cock again (90°) towards the mixer. The "off" sign is directed toward the mixer, stopping the cement flow.

To transfer cement, simply rotate the handle.

**Precaution: Do not push.**



Disconnect the full syringe and attach the next one. Continue until all syringes are filled. Always fill all syringes directly after mixing.



### 3. Inject cement with side-opening needle

VERTECEM V+ is a ready to use cement. This means that after the cement has been transferred into the cartridge or the syringes the injection may be commenced carefully. Always make sure to verify the cement viscosity prior to first injection.

- For the injection the C-arm is in the lateral projection. Before injecting any cement, store the images of the vertebrae to be reinforced on the image intensifier and show them on the second screen as a reference.

Attach the SynJect cartridge or syringe to the inner sleeve of the needle. Avoid a needle displacement in anterior direction during the attachment.

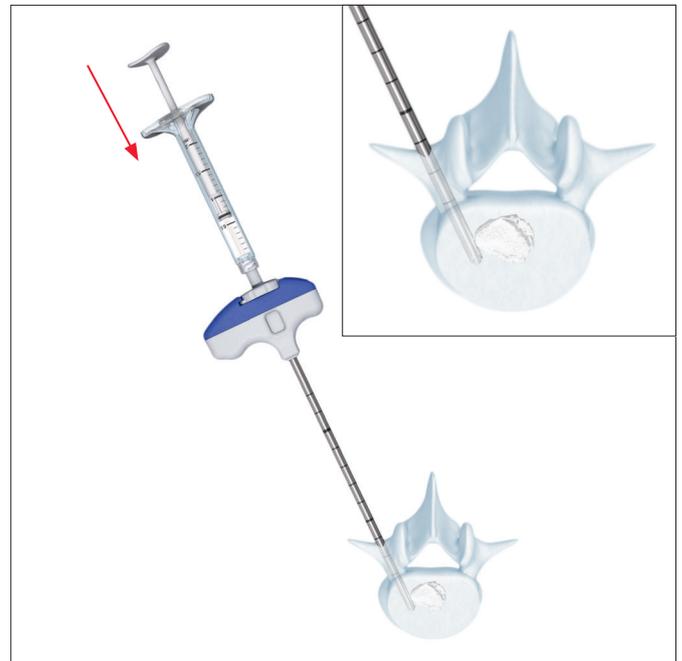
The cement injection starts with filling of the needles. For this purpose, we recommend to use the 2 mL syringes.

Apply a careful stepwise injection technique and closely monitor the cement flow with real time fluoroscopy.

**Warning:** Closely monitor the cement injection under fluoroscopy to reduce the risk of cement leakage. Severe leakage can result in death or paralysis. If cement leakage is observed during the procedure, STOP injecting and consider the following: wait for the cement to harden, reposition the needle, adjust the needle direction, or stop the procedure. If desired, continue cement injection slowly and carefully evaluate for further leakage. If further leakage is observed, cease cement injection.

It is important to note that the force necessary to inject the cement increases with time. Moreover, the force necessary to inject the cement with the smaller syringe is lower. It is therefore advised to use the 2 mL syringe first.

**Note:** The VERTECEM V+ powder contains 40% zirconium dioxide and 15% hydroxyapatite. Therefore, VERTECEM V+ powder contains 55% ceramic components and only 45% PMMA



Switch to the 1 mL syringe as soon as the force with the 2 mL syringe seems to be too high to inject the cement. At the very end of the injection phase, the trocar can be used to carefully push the cement volume present in the needle forward.

**Warning: Avoid a needle displacement in anterior direction when applying force to the trocar.**

The remaining cement volume in the needle (inner sleeve) is as follows:

- 8 Ga ( $\varnothing = 4.2$  mm) ~1.42 mL
- 10 Ga ( $\varnothing = 3.4$  mm) ~0.70 mL
- 12 Ga ( $\varnothing = 2.7$  mm) ~0.35 mL

### **Bilateral approach**

If a bilateral approach is used, simultaneously fill the contralateral side as well. It is important to see the filling behaviour of both needles. Once the filling of one side is accomplished, the other side is hidden by the cement, which makes monitoring the flow more difficult. Therefore, when a bilateral approach is chosen, the injection is performed stepwise and simultaneously.

If the cement is not clearly visible, the injection must be stopped immediately.

- ⓘ **Warning: It is mandatory during the whole injection procedure to have real-time fluoroscopic control in the lateral projection. It can be necessary to check the cement distribution in the AP projection from time to time unless a biplanar control with two C-arms is given. For this purpose the C-arm is switched back into the AP projection.**

# Removal of the Needle

The needles are removed once the cement has completely cured. Close the side-opening window on the needle by turning the inner sleeve.

The setting time for VERTECEM V+ at room temperature is approximately 27 minutes.



# Bibliography

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- 1 Aebi M, Arlet V, Webb JK, (2007): AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.
- 2 Aebi M, Thalgott JS, Webb JK (1998): AO ASIF Principles in Spine Surgery. Berlin: Springer.

# Intended Use, Indications and Contraindications

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Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks.

Instructions for Use are available at [www.e-ifu.com](http://www.e-ifu.com) and/or [www.depuysynthes.com/ifu](http://www.depuysynthes.com/ifu)

