
Technique Guide

DePuy Synthes

This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation.
Warning
This description alone does not provide sufficient background for direct use of the product. Instruction by a surgeon experienced in handling this product 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.depuysynthes.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.depuysynthes.com/hcp/reprocessing-care-maintenance
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Ready-to-use viscosity
Vertecem V+ Cement requires no waiting time before injectable cement viscosity is reached. The application time of the ready-to-use cement is approximately 27 minutes at room temperature and offers physicians the freedom to use cement with greatly reduced time constraints.

Easy and efficient
The Vertecem V+ System is a closed, clean and easy-to-use vertebroplasty system. The modularity of the available kits enables physicians to perform surgeries efficiently.

Cement specific syringes
Vertecem V+ Syringes have wide integrated wings and reinforced syringe plungers to guarantee excellent force transfer, combined with good tactile feedback.

Wide portfolio of vertebroplasty needles
A wide portfolio with both diamond and beveled tip needles offers a solution for every preference. All needles can be used for injection of cement through the front or through a side opening. The side-opening needles make it possible to guide cement flow in-situ.

1 See Instruction for Use for specific information
Vertebroplasty Needle Kit
- Side-opening needles, 2-pack
- Diamond and beveled tip
- 8G/14 cm (blue)
- 10G/12 cm (yellow)
- 12G/12 cm (green)
- Optional 8G and 10G biopsy solution

Bone Access Needle
- Front-opening needle, 1-pack
- Diamond and beveled tip
- 8G/14 cm (blue)
- 11G/10 cm (violet)
- 11G/15 cm (violet)
- 13G/10 cm (orange)
- Optional 8G and 11G biopsy solution

Vertecem V+ Syringe Kit
Vertecem V+ Syringe Kit includes a stop-cock for simple, clean and quick filling of the 1 mL and 2 mL syringes.

Vertecem V+ Cement Kit
For good visual control during cement application under x-ray imaging, the Vertecem V+ powder contains 40% zirconium dioxide and 15% hydroxyapatite. Therefore Vertecem V+ powder contains 55% ceramic components and only 45% PMMA.

Direction of cement through side-opening

Comparison of flow behaviour between a front-opening (A) and a side-opening (B) needle. The needles are placed identically. After the injection of 2 mL, the cement is clearly directed into the medial part of the vertebral body with the side-opening needle.
In 1958, the AO formulated four basic principles which have become the guidelines for internal fixation. These principles are also valid for spinal surgery:

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

In Vertebroplasty (VP) these principles can be interpreted as follows:

**Stable internal fixation**
The injection of Vertecem V+ Cement allows an infiltration of the cancellous bone. Thereby, the trabecular cohesion is enhanced and micromovements within the vertebra are avoided.

**Pain relief**
Quick pain relief is achieved in the vast majority of vertebroplasty procedures (80% – 90%) due to the restoration of the mechanical properties of the vertebrae. Therefore, vertebroplasty represents an effective pain treatment.

**Minimal invasive access**
The applied percutaneous techniques allow for a minimal invasive access to the vertebral body.

**Reduction of the fracture / height restoration**
Vertebroplasty alone does not permit an active reduction of the fractured vertebrae. The spontaneous reduction resulting from proper bodily positioning can, however, be preserved through augmentation with bone cement. This stabilizes the fracture and stops further collapse of the vertebral body.

**Early mobilization**
The minimally invasive injection of Vertecem V+ Cement provides immediate stability that allows patients to be mobilized as soon as tolerated and to return to daily activities and functions.

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Vertecem V+ Cement Kit

Intended use
The Vertecem V+ Cement Kit bone cement component is a radiopaque, injectable polymethyl methacrylate cement, indicated for use in spine pathologies being treated using vertebroplasty or kyphoplasty procedures. It should only be used with devices or systems with which it has been tested and validated. For information on compatibility, consultation with a DePuy Synthes representative is recommended.

Indications
- Vertebral compression fractures (VCF)
- Progressive compression fractures of one or multiple vertebrae with subsequent development of increasing kyphosis
- Patients with persisting instability after a vertebral fracture
- Combined procedures with internal fixation in osteoporosis
- Osteolysis
- Metastatic lesions
- Aggressive type of haemangioma

Contraindications
- Infections
- Patients with clotting disorders
- Patients with severe cardiac and/or pulmonary insufficiency
- Patients with known hypersensitivity or allergy to any of the components of Vertecem V+ bone cement
- Vertebra plana or circumstances where safe percutaneous access to the vertebra cannot be guaranteed
- Unstable vertebral fractures with involvement of the posterior wall in standalone vertebral augmentation procedures (e.g. vertebroplasty)
- Previous damage to the pedicle wall (transpedicular access)
- Lesions that feature narrowing of the spinal canal (more than 20%), including fracture or neoplasm, with or without myelopathy
- Retropulsing vertebral fragments with myelopathy
- A satisfactory response to conservative treatment
- Asymptomatic stable vertebral fractures
- Vertecem V+ bone cement is contraindicated for use in arthroplasty procedures

Vertecem V+ Syringe Kit

Intended use
The “Vertecem V+ Syringe Kit” is solely intended for the application of PMMA-based bone cement with the intent to augment cancellous bone. Refer to the corresponding directions regarding indications, contraindications, compatibility, use, precautions, warnings and side effects of the PMMA-based bone cement and access solution used in conjunction with the “Vertecem V+ Syringe Kit”. For information on compatibility with other devices or systems, consultation with a DePuy Synthes representative is recommended.

Vertebroplasty Needle Kit

Intended use
The “Vertebroplasty Needle Kit” is intended to be used to inject PMMA cement into vertebral bodies during Vertebroplasty procedures.

The “Vertebroplasty Needle Kit” is intended to be used in conjunction with the Vertecem/Vertecem V+ System.

Biopsy Kit

Intended use
The biopsy kit is designed for taking vertebral body bone biopsies.

The vertebroplasty biopsy kit is intended to only be used in combination with the vertebroplasty needle of the Vertecem/Vertecem V+ system.

Biopsy Needle

Intended use
The Biopsy Needle is a sterile-packed kit used for taking bone biopsy. The Biopsy Needle is inserted into the bone with the aid of imaging procedures. The Biopsy Needle is used exclusively in connection with the Synthes Bone Access Needle.

Bone Access Needle

Intended use
The bone access needle is a sterile-packed kit used in procedures where access to bone is required. The bone access needle is inserted into the bone with the aid of imaging procedures.

The bone access needle can also be used for providing access for appropriate guide wires, for obtaining bone marrow by aspiration technique and for inserting therapeutic materials, including bone cements. When using the bone access needle in connection with outer instruments and/or therapeutic materials, the Surgical Technique and/or the Instruction for Use issued by the relevant manufacturer should be observed.
Vertecem V+ Cement Kit

Precautions
- A thorough preoperative check-up of the patient must be carried out.
- Store this package between 0 °C and 25 °C and protect it from light to prevent premature polymerization of the monomer fluid. Always check the condition of the monomer before use; if it shows any sign of thickening or premature polymerization, do not use.
- If stored below OR temperature, always allow the product to equilibrate to OR temperature prior to use.
- Make sure to follow preparation and handling instructions for the Vertecem V+ Cement Kit carefully.
- The monomer liquid is a powerful lipid solvent; it should not be allowed to come into direct contact with sensitive tissue or rubber or latex gloves. Wearing of a second pair of gloves and strictly adhering to the mixing instructions may reduce the risk of hypersensitivity reactions.
- Always use the full amounts of monomer liquid and polymer powder provided in the kit, respectively, when mixing Vertecem V+ Cement Kit bone cement. Otherwise the behavior of the Vertecem V+ Cement Kit can no longer be guaranteed. Using only one of the components is not permitted.
- Ensure that the powder and liquid component are thoroughly mixed before starting cement transfer.
- The mixing device is designed for mixing of Vertecem V+ Cement Kit bone cement and transferring it to a compatible application system. It is not designed for the injection of mixed cement directly into a vertebra. Such use is strictly prohibited. For information on compatibility, consultation with a DePuy Synthes representative is recommended.
- The formation of large air pockets within the cement should be avoided when filling the application system.
- The physician should have specific training and experience in performing a vertebroplasty or kyphoplasty procedure. She or he should also be thoroughly familiar with the properties, handling characteristics and application of the Vertecem V+ Cement Kit, as well as with percutaneous cement delivery.
- The use of Vertecem V+ Cement Kit bone cement during pregnancy or lactation is not recommended. In considering use of Vertecem V+ Cement Kit bone cement in a pregnant patient, the responsible physician should weigh the benefits of the application of Vertecem V+ Cement Kit bone cement against the potential risks to the patient and the pregnancy.
- Long-term efficacy data for Vertecem V+ Cement Kit bone cement is limited. The responsible physician should weigh the benefits of using Vertecem V+ Cement Kit bone cement in painful non-osteoporotic, acute traumatic fractures against the potential risks, especially when treating younger patients.
- Exercise caution in cases involving significant fragmentation and collapse of the vertebral body (i.e. a fractured vertebral body height corresponding to less than 1/3 of the original height). Such cases may require treatment with a more technically complex procedure.
- Application of Vertecem V+ Cement Kit bone cement should be monitored using real time imaging procedures capable of delivering high quality images. Use appropriate imaging techniques to confirm correct needle placement, the absence of damage to surrounding structures and appropriate location and quantity of injected material.
- After last cement injection, the patient should remain immobile for 15 minutes to facilitate proper cement curing.
- If repeated access is required within a single vertebral body, the access needle should be closed with a trocar to maintain access and to prevent bone cement from leaking out of the vertebra through said needle.

Warnings
- Use of Vertecem V+ Cement Kit bone cement is not established for prophylactic augmentation of non-fractured vertebral bodies.
- Percutaneous application of polymethyl methacrylate should only be performed in medical settings where emergency decompressive surgery is available.
- During surgery Vertecem V+ Cement Kit bone cement may spread beyond the region of its intended use (i.e. outside of the vertebral body or into the circulatory system). If this occurs, injection should be halted immediately.
- Extravasation of bone cement can result in cement entering fracture cracks or venous circulation, but is not necessarily limited to said areas.
- Additives (such as antibiotics) are not to be mixed with the Vertecem V+ Cement Kit bone cement, as this will alter cement properties.
Vertecem V+ Syringe Kit

Precautions
- The “Vertecem V+ Syringe Kit” is used in technically demanding procedures. Therefore only physicians familiar with the proper technique and instrumentation used for the delivery and use of PMMA-based bone cement should use the “Vertecem V+ Syringe Kit”.
- The “Vertecem V+ Syringe Kit” should only be used to deliver PMMA-based bone cement in conjunction with the use of fluoroscopy imaging equipment capable of delivering high-quality images.
- Ensure a good fit between “Vertecem V+ Syringe Kit” syringe and “Vertecem V+ Syringe Kit” stop-cock/used access solution, but make sure to be on axis and avoid using excessive force when coupling them. They are both made of plastic and could otherwise break.
- After filling a “Vertecem V+ Syringe Kit” syringe with cement, grip it by its wings. Gripping it anywhere else could transfer heat from your hand to the cement, shortening the working time of the PMMA-based bone cement.
- Always fill all “Vertecem V+ Syringe Kit” syringes with PMMA-based bone cement directly after mixing.
- Always make sure the PMMA-based bone cement has reached the preferred viscosity prior to injection.
- To halt the flow of cement out of the “Vertecem V+ Syringe Kit” syringe at any given time, simply stop pushing the plunger.
- Make sure to always inject cement in a slow, controlled fashion.
- If cement flow is hindered at any time during injection, halt, investigate and correct the reason for the flow hindrance.
- Do not use tools or excessive force to operate the “Vertecem V+ Syringe Kit”.
- Federal law restricts this device to sale in the US by or on the order of a physician.

Warnings
- The purpose of the milliliter (mL) scale on the side of the “Vertecem V+ Syringe Kit” syringes is to give physicians an indication of how much PMMA-based bone cement has been injected. This scale is for information purposes only.

Vertebroplasty Needle Kit

Cautions and restrictions
Since the “Vertebroplasty Needle Kit” is used in technically demanding procedures, the physician should be familiar with the use of the needle kit along with the rest of the instrumentation.

Biopsy Kit

Cautions and restrictions
The biopsy kit is used in technically complex surgery. The physician should therefore be familiar with handling and using the biopsy kit and the other instrumentation.

Biopsy Needle

Notes, cautions and restrictions
Since the biopsy needle is used in technically complex procedures, the doctor should be familiar with the handling and use of the kit and the taking of bone biopsies.

Bone Access Needle

Notes, cautions and restrictions
Since the bone access needle is used in technically complex procedures, the doctor should be familiar with the handling and use of the kit, the access techniques, the use of therapeutic materials and aspiration.

The bone access needle can be inserted into the bone with gentle taps of the hammer. Strong hammer blows should be avoided, even if sclerotic or thicker cortical bone is involved. Under certain circumstances, there might be a risk of splitting the bone.

The safe use of the bone access needle cannot be guaranteed if used in conjunction with MRI, which is associated with certain risks, including:
- Heating or migration of the product and
- Artifacts on the MRI image.
Preoperative Planning

1

Clinical

The preoperative evaluation consists of a careful assessment of the patient, including:

– Patient history (type and time of pain appearance)
– Current X-ray images, if possible in standing position, of the thoracic and lumbar spine in two planes to assess the fracture and spinal alignment
– A spinal CT or MRI scan (ideally with STIR frequency) of the painful region of the spine if X-rays are ambiguous. In patients with a contraindication for an MRI, a bone scan may be used alternatively.
– Pain location and pain severity
– Feasibility of surgery and use of anesthesia

As recommended in the AO-Spine manual, take into consideration:

– Cumarine-like anticoagulants must be stopped prior to procedure and a minimal INR value of 1.5 (= Quick >50) should be respected
– Aspirin-like medication can be continued

2

Instrument and implant planning

The Vertecem V+ System is a modular system. All implants and instruments are provided separately. This allows for an economically efficient and precise operation planning. See page 29 for images and more comprehensive descriptions of the different products.

**Patient Positioning**

**1**  
**Position the patient**

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

There are several different imaging systems on the market. In this Surgical Technique they are exemplified by the C-arm.

If a C-arm is used the OR table should allow for free manipulation over the operative site in both planes.
Both the guide wire 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 bipedicicular 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

Guide wire technique

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

<table>
<thead>
<tr>
<th>Instruments</th>
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<tbody>
<tr>
<td>03.702.216S Vertebroplasty Needle Kit, 8-Gauge, Diamond Tip</td>
</tr>
<tr>
<td>03.702.218S Vertebroplasty Needle Kit, 10-Gauge, Diamond Tip</td>
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</tbody>
</table>

The C-arm is installed in the AP projection. Plan the exact site of incision with the C-arm.

Use the C-arm to localize the stab incision. Push the guide wire through the soft tissue until you can touch the bony surface of the spine. Use the C-arm for a controlled placement.

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

The orientation of the guide wire 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 guide wire convergent in projection of the pedicle.
In order to penetrate the surface of the bone, some gentle blows with a hammer are necessary. Adjust the direction of the guide wire 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. This is time saving and avoids problems with contamination due to repeated change of the C-arm projection. Of 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 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 with gentle hammer blows 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, inject local anesthetic, advance needle under C-arm control.

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 guide wire is marked with 1 cm dashes. This allows monitoring the insertion progress.

The guide wire is approx. 4 cm 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 guide wire by rotating movements. This procedure can be painful and the anesthesiologist should be informed to administer appropriate analgesia. Use again C-arm control during the final needle placement.

If a biopsy is needed, please respect 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 guide wire and the cannulated trocar.

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 inner sleeve with side-opening is inserted in order to close off the front-opening of the outer needle. The side-opening enables to direct the cement flow into the needed direction. Place the sleeve properly and check it with 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. This guarantees that the side-opening window is opened for cement injection.

The side-opening needle is marked with 1 cm dashes. This allows monitoring the insertion progress. If there is any doubt about the location, the C-arm should be switched to the AP projection.
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**

<table>
<thead>
<tr>
<th>Instrument Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>03.702.219S</td>
<td>Vertebroplasty Needle Kit, 10-Gauge, Beveled Tip</td>
</tr>
<tr>
<td>03.702.220S</td>
<td>Vertebroplasty Needle Kit, 12-Gauge, Diamond Tip</td>
</tr>
<tr>
<td>03.702.221S</td>
<td>Vertebroplasty Needle Kit, 12-Gauge, Beveled Tip</td>
</tr>
</tbody>
</table>

- The C-arm is installed in the AP projection. Plan the exact site of incision with the C-arm.

- Use the C-arm to localize the stab incision. Push the needle through the soft tissue until you can touch the bony surface of the spine. Use the C-arm for a controlled placement. 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.
In order to penetrate the surface of the bone, use controlled pressure combined with turning movements (also gentle hammer blows are suitable). To adjust the direction of the needle turn the beveled tip into the desired direction and continuously advance it under AP C-arm control. This procedure can be painful and the anesthesiologist should be informed to administer appropriate analgesia. 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. This is time saving and avoids problems with contamination due to repeated change of the C-arm projection. Of each vertebra where the needle 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 use article 03.702.219S and respect section C page 17 for the biopsy technique.

If the needle tip reaches the posterior wall use again C-arm control during the final needle placement. 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 inner sleeve with side-opening is inserted in order to close off the front-opening of the outer needle. The side-opening enables to direct the cement flow into the needed direction. Place the sleeve properly and check it with the closing mechanism on the handle.
### Biopsy technique

<table>
<thead>
<tr>
<th>Instruments</th>
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<tbody>
<tr>
<td>03.702.222S Biopsy Kit, for 8-Gauge Vertebroplasty Needle Kit</td>
</tr>
<tr>
<td>03.702.223S Biopsy Kit, for 10-Gauge Vertebroplasty Needle Kit</td>
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</tbody>
</table>

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 guide wire 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 (see page 18). During this insertion bone tissue is captured in the biopsy needle. Rotate the assembly at least one full turn (360°). This will help to loosen the biopsy.
Attach a standard luer lock syringe (1–3 mL, not included) 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.
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.

During preparation, mixing and injection make sure to always handle the mixing device by gripping the blue part located directly below the transparent cartridge. If the transparent part is used as gripping surface, the body heat provided by the users hand might result in a shorter working time than intended.

Open the glass ampoule by breaking off its neck with the plastic cap ①. 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 (seen in picture above) from the mixing device and dispose of it. Pour the full content of the ampoule ② into the mixer and close it tightly with the separate mixing and transfer lid ③. Make sure that both mixing lid and the small sealing plug on top of it are securely tightened.
Grip the mixer by the blue part 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 (1 and 4 combined). Once properly mixed, the blue handle 2 must be left in its outmost position.
2

Fill injection syringes

| Instrument | 03.702.215S 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. 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, do not push.

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). We recommend using the 2 mL 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. 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 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. The anesthesiologist needs to be informed of the injection in order to give analgesics.

Attach the 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.

Continue injecting after the cement appears at the opening of the needle. The cement should behave like a growing cloud. The flow of the cement needs to be monitored with continuous fluoroscopic control. Cement always flows in the direction where it encounters the least resistance. If cement leakage or uncontrolled cement flow is observed, the injection must be stopped immediately. By making a pause in the injection, the cement has a chance to set further and thereby occlude the blood vessels involved in the leakage. After this pause the needle should be slightly relocated to change the cement flow direction, after which the injection of cement can commonly be resumed. Due to the generous working time in comparison to other cements, the surgeon may have to make a longer pause with Vertecem V+ before continuing the 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.
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. Avoid a needle displacement in anterior direction when applying force to the trocar.

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

8 Ga (Ø = 4.2 mm) ~1.42 mL
10 Ga (Ø = 3.4 mm) ~0.70 mL
12 Ga (Ø = 2.7 mm) ~0.35 mL

This technique allows the application of high viscous cement. Viscosity is the key for safety, as the risk for leakage decreases with increasing viscosity.\(^4\)

**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. Often, if one side shows cement leakage, filling via the opposite pedicle is still possible.

Cement flow towards the posterior wall of the vertebral body can be monitored more reliably than lateral flow. If the cement is not clearly visible, the injection must be stopped immediately.

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.
No cement injection must be performed with an AP projection only! If a fresh fracture is reinforced, the flow along a fracture gap toward the disc space is frequent. In this case, a bilateral approach may be helpful. The amount of cement used to fill one level depends on the location, size and state of the vertebral body, as well as surgeon preference and type of approach (uni- or bipedicular). In clinical literature for Vertebroplasty the reported amount of cement injected per vertebrae varies typically from 1 mL to 9 mL with an average of around 4.1 mL. Any cement leakage must lead to an immediate stop of the injection.

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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. This guarantees that there is no contact between cement in the needle and vertebral body. This feature of the Vertecem V+ System ensures that no cement “spikes” will result during the removal of the needle. With a simple twist, the needle can be loosened and be pulled out. Wound closure is done with tight suture.

The setting time for Vertecem V+ at room temperature is approximately 27 minutes. At body temperature the setting time is 15 minutes. After last cement injection, the patient should remain immobile for 15 minutes to facilitate proper cement curing.
Postoperative Procedure

After the procedure, the patient is placed in a supine position for one hour for wound compression. Haematoma at the puncture sites may occur. Subsequently, mobilization is allowed according to the surgeon’s decision. The effect of the procedure can be evaluated immediately as the usual pain level should be reduced and only the discomfort due to the puncture should remain.
### Product Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>07.702.016S</td>
<td><strong>Vertecem V+ Cement Kit</strong> containing:</td>
</tr>
<tr>
<td></td>
<td>1x Vertecem V+ Mixer</td>
</tr>
<tr>
<td></td>
<td>prefilled with cement powder</td>
</tr>
<tr>
<td></td>
<td>1x Monomer glass ampoule</td>
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<table>
<thead>
<tr>
<th>Code</th>
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<tbody>
<tr>
<td>03.702.215S</td>
<td><strong>Vertecem V+ Syringe Kit</strong> containing:</td>
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<tr>
<td></td>
<td>8x 1 mL syringes (blue)</td>
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<tr>
<td></td>
<td>5x 2 mL syringes (white)</td>
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<tr>
<td></td>
<td>1x stop cock</td>
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<td>Code</td>
<td>Description</td>
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<td>--------------------------------------------------</td>
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<tr>
<td>03.702.216S</td>
<td>Vertebroplasty Needle Kit®, 8 Gauge, Diamond Tip, 2 units</td>
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<tr>
<td>03.702.218S</td>
<td>Vertebroplasty Needle Kit®, 10 Gauge, Diamond Tip, 2 units</td>
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<tr>
<td>03.702.219S</td>
<td>Vertebroplasty Needle Kit®, 10 Gauge, Beveled Tip, 2 units</td>
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<tr>
<td>03.702.220S</td>
<td>Vertebroplasty Needle Kit®, 12 Gauge, Diamond Tip, 2 units</td>
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<tr>
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<tr>
<td>03.702.222S</td>
<td>Biopsy Needle Kit®, for 8 Gauge Vertebroplasty Needle Kit, 1 unit</td>
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<tr>
<td>03.702.223S</td>
<td>Biopsy Needle Kit®, 10 Gauge, 1 unit</td>
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ें Vertebralplasty Needle Kit, Biopsy Needle Kit: CE0482
Manufactured by: Möller Medical GmbH, Wasserkerpenstrasse 29-31, 36043 Fulda, Germany
Distributed by: Synthes GmbH, Eimattstrasse 3, 4436 Oberdorf, Switzerland
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<tr>
<th>Code</th>
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<th>Dimensions</th>
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<tr>
<td>03.702.240S</td>
<td>Bone Access Needle 7, 8G, Diamond Tip, 140 mm</td>
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<tr>
<td>03.702.241S</td>
<td>Bone Access Needle 7, 11G, Diamond Tip, 100 mm</td>
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<tr>
<td>03.702.243S</td>
<td>Bone Access Needle 7, 11G, Beveled Tip, 100 mm</td>
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<tr>
<td>03.702.244S</td>
<td>Bone Access Needle 7, 11G, Diamond Tip, 150 mm</td>
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<tr>
<td>03.702.245S</td>
<td>Bone Access Needle 7, 11G, Beveled Tip, 150 mm</td>
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<td>03.702.246S</td>
<td>Bone Access Needle 7, 13G, Diamond Tip, 100 mm</td>
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<td>03.702.247S</td>
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<td>03.702.250S</td>
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<tr>
<td>03.702.251S</td>
<td>Biopsy Needle 7, for Needle 11G, 100 mm</td>
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<td>Biopsy Needle 7, for Needle 11G, 150 mm</td>
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</table>

Bone Access Needle, Biopsy Needle: CE0482
Manufactured by: Möller Medical GmbH, Wasserkuppenstrasse 29-31, 36043 Fulda, Germany
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