8. Inject the cement according to Instructions for Use provided by the cement manufacturer. The trocar can be used to eject the remaining bone cement from the injection needle into the vertebra, should this be clinically indicated.
   NOTE: It is important to observe the curing time of the cement to ensure safe removal of the instruments. Details can be found in the Technique Guide.
9. For removal of the needle assembly, close the side-opening window by turning the injection needle. This ensures that there is no contact between cement in the needle and that in the vertebral body. The needle can be loosened and pulled out.

Use: 03.702.219S, 03.702.220S and 03.702.221S

1. Insert needles at all levels where cement injection is planned. The needles are marked with equidistant depth markers. This allows monitoring of the insertion process.
   NOTE: The equidistant depth-markers are only for information and do not constitute a measuring system.
2. The color-coded needle assembly (side-opening needle with trocar or beveled tip needle with trocar) should be inserted with rotating movements and/or gentle hammer taps. The tip of the assembly must be inserted until it reaches the anterior half of the vertebral body. After insertion of the assembly, rotate it 360° around its axis. This movement will compress any excess bone tissue. Then remove the trocar.
3. Insert the injection needle and securely lock it in the handle of the needle.
4. The needle has a side-opening enabling the user to direct the cement flow into the desired location. The arrow on the needle handle marks the direction of the side-opening.
   NOTE: Verify that the arrow on the handle points in the desired direction.
5. Connect the designated cement delivery device (not included), containing PMMA-based bone cement, to the Luer-lock of the injection needle.
6. Inject the cement according to Instructions for Use provided by the cement manufacturer. The cement pusher can be used to eject the remaining bone cement from the injection needle into the vertebra, should this be clinically indicated.
   NOTE: It is important to observe the curing time of the cement to ensure safe removal of the instruments. Details can be found in the Technique Guide.
7. For removal of the needle assembly, close the side-opening window by turning the injection needle. This ensures that there is no contact between cement in the needle and that in the vertebral body. The needle can be loosened and pulled out.

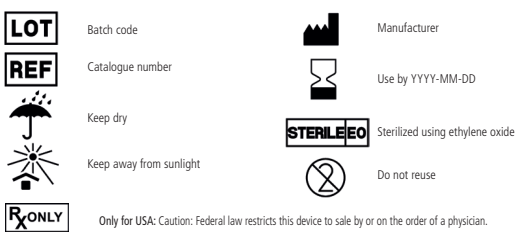
Sterility The device is supplied sterile. Before opening, check that the packaging is intact. Remove items from the packaging while maintaining aseptic conditions. Do not use if the packaging seal is broken or if the sterile barrier has been breached.

Single-use The device is intended for single-use only and may not under any circumstances be reused. The reuse of a single-use device poses an infection risk to patients and users. Contamination of the device can lead to injury, illness or death of the patient. Cleaning, disinfection and sterilization can adversely affect important material and design properties and device function.

Storage The device should be stored in a clean, dry environment and protected from direct sunlight. Do not use after the expiration date on the label.

Disposal Disposal takes place in accordance with the hospital ordinance or the applicable laws. Due to the risk of infection and injury, care must be taken to avoid all contact with the tips or sharp edges of the instruments. This is especially important for contaminated instruments.

Symbols



For further information about symbols used please refer to our homepage **www.moeller-medical.com/glossary-symbols**

MÖLLER

Distributed by
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en **Instruction leaflet**

Instructions for Use Vertebroplasty Needle Kit

Device in scope

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

Description The Vertebroplasty Needle Kit is a sterile packaged kit for Vertebroplasty procedures.

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Intended use The Vertebroplasty Needle Kit is intended for vertebral body access and injection of PMMA[1]-based bone cement into vertebral bodies during Vertebroplasty procedures and to be used in conjunction with the Vertecem Vertebroplasty System / Vertecem V+ System[2].
Refer to the corresponding instruction for use regarding indications, contraindications, compatibility, use, precautions, warnings and side effects of the bone cement used in conjunction with the Vertebroplasty Needle Kit. For information on compatibility with other devices or systems, consultation with a DePuy Synthes representative is recommended.

Indications The indications for the Vertebroplasty procedure using the Vertebroplasty Needle Kit are defined by the PMMA-based bone cement and can be found in the respective instructions for use.

Contraindications This device is not to be used in patients with coagulation disorders or infections. Further contraindications are defined by the PMMA-based bone cement and can be found in the respective instructions for use.

Patient Target Group The patient target group is defined by the PMMA-based bone cement and can be found in the respective instructions for use.

Warnings and precautions Since the device is used in technically complex procedures, the physicians should be familiar with the handling and use of the device, the other instrumentation and the procedure.
Before carrying out the procedure, the physician must ensure that the size of the available device is appropriate for the patient.
It is also necessary to check whether the patient has allergies to materials (e.g. nickel) contained in the device. Should this be the case, the use of the device is at the discretion of the attending physician.
The safe use of the device cannot be guaranteed if used in conjunction with MRI, which is associated with certain risks, including heating or migration of the device and artefacts on the MRI image.

[1] PMMA = Polymethyl Methacrylate
[2] Vertecem Vertebroplasty System is only available for sale in the United States. Vertecem V+ System is only available for sale outside the United States.

Side effects The side effects are defined by the PMMA-based bone cement and can be found in the respective instructions for use.

Materials The device contains the following materials:
– Stainless steel: Needles, trocars, cement pushers and guide wires
– Polybutylene terephthalate: Handles and other plastic components

Device variants and content The needles are available with blue (8G), yellow (10G) or green (12G) handles.

Part names	Diamond Tip			Beveled Tip	
	03.702.216S 8G, blue	03.702.218S 10G, yellow	03.702.220S 12G, green	03.702.219S 10G, yellow	03.702.221S 12G, green
Side-opening needle (with Luer-lock)	2 Units	2 Units	2 Units		
Beveled tip needle (with Luer-lock)				2 Units	2 Units
Cannulated trocar	2 Units	2 Units			
Trocar	2 Units	2 Units	2 Units	2 Units	2 Units
Cement pusher			2 Units	2 Units	2 Units
Injection needle (with side-opening and Luer-lock)	2 Units	2 Units	2 Units	2 Units	2 Units
Guide wire	2 Units	2 Units			

Mode of Use The correct placement of all instruments and needles must be performed with the aid of imaging procedures. Anterior/posterior and lateral views must be used.
CAUTION: When placing the instruments and needles it is essential to ensure that the anterior wall of each vertebral body is not penetrated.
Please refer to the Vertecem Vertebroplasty System / Vertecem V+ System Technique Guide for details.

Use: 03.702.216S and 03.702.218S

1. Insert guide wires at all levels where cement injection is planned. The guide wire is marked with equidistant depth-markers. This allows monitoring of the insertion process.
   NOTE: The equidistant depth-markers are only for information and do not constitute a measuring system.
2. In the lateral projection, the tip of the wire should reach the posterior border of the vertebral body. Next, cautiously advance the guide wire with gentle hammer taps and, if necessary, adjust the orientation (insertion direction) in order to reach the center of the vertebral body.
3. Insert the color-coded needle assembly (side-opening needle with cannulated trocar) over the guide wires using rotating movements. The tip of the assembly must be advanced until the posterior wall of the vertebral body is reached. After insertion of the needle, remove the guide wire.
   CAUTION: The guide wire is not to be pushed forward while inserting the needle.
4. The assembly must be further advanced until the anterior half of the vertebral body is reached; this may be performed with gentle hammer taps. After positioning of the assembly, remove the cannulated trocar.
5. Insert the injection needle and securely lock it in the handle of the needle.
6. The needle has a side-opening enabling the user to direct the cement flow into the desired location. The arrow on the needle handle marks the direction of the side-opening.
   NOTE: Verify that the arrow on the handle points in the desired direction.
7. Connect the designated cement delivery device (not included), containing PMMA-based bone cement, to the Luer-lock of the injection needle.