

VERTICALE[®] AUGMENTATION

INSTRUMENTATION GUIDE



MADE IN GERMANY

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NOTE: The following guide is intended to familiarise you with the surgical procedure and use of the instruments and implants required for screw augmentation with the VERTICALE system. This instrumentation guide supplements the guide for the VERTICALE – Dorsal Spinal Fixation System and refers to the steps of augmentation of screws. Instruments from Silony Spine are processed, serviced and cared for in accordance with the information given in the instructions for use. Please read this guide and the instructions for use accompanying the implants carefully before using the implant, and also pay particular attention to the information provided in the appendix of this guide.

PREFACE

VERTICALE[®] – AUGMENTATION

The VERTICALE system is a posterior rod-screw fixation system for stabilizing the thoracic, lumbar and iliosacral spine.

The system was developed in close cooperation with experienced and qualified spinal surgeons as well as theatre and sterilisation staff in surgical environments. As a result, VERTICALE is a well-designed, modular and versatile fixation system.

The addition of augmentable screws also ensures better fixation of the screws in the VERTICALE system. This is particularly necessary if the fixation of the screws in the vertebral body is not sufficiently stable. The VERTICALE augmentation system is therefore especially suited for revisions after screw loosening or screw cutout as well as for patients with reduced bone density (e.g. osteoporosis).

The VERTICALE augmentation system includes fenestrated short and long-head screws in a variety of lengths and diameters so that implants can be selected on the basis of individual and anatomically optimal requirements.

Like all other implants and instruments developed by Silony Spine, the VERTICALE augmentation system is a living system. Whether instrument or implant device – we are constantly working to expand and improve systems in order to optimally meet the needs of patients, doctors, and other medical personnel.

Indications / Contraindications

For indications, contraindications and further safety information, please refer to the respective instrumentation guides and Instructions for Use.

NOTE: A ventral interbody support in the form of a intervertebral disc implant, such as a cage, is recommended for treating instabilities of the ventral spine and is used at the discretion of the operating surgeon and in accordance with the respective indication.

NOTE: Please also note the Instructions for Use provided with each product. They may include additional advice that leads to exclusion of the implant procedure. All instrumentation guides and Instructions for Use can be found on our eLabeling portal under the following link: <https://elabeling.silony-medical.com/>

VERTICALE® AUGMENTATION – INSTRUMENTATION

In the following section we describe only those particular steps that must be carried out when using augmentable screws. For a general instrumentation guide for a dorsal VERTICALE standard instrumentation that forms the basis of all subsequent work steps with additional instruments and implants, please follow the relevant instrumentation guide.

Position and approach

The patient is positioned in the prone position, as is common for the dorsal approach. The skin incision is performed medially above the spinous processes corresponding to the spinal segment to be treated. After that, the soft tissue is dissected until the anatomical structures of the spinal column can be clearly seen.

The VERTICALE® augmentation system can also be used for minimally invasive approaches.

Selection of the pedicle screw for augmentation

To facilitate rapid and easy identification, all VERTICALE pedicle screws are colour coded by diameter.

Using the A-P X-ray image, choose pedicle screws according to the pedicle diameter with the largest possible diameter.

Determine the length of the screw using the lateral X-ray image.

The VERTICALE augmentation screws have a perforation for cementation in the anterior third of the screw. Therefore, the screw should be selected such that its length extends to at least $\frac{2}{3}$ of the diameter of the vertebral body, and in the best case the anterior edge of the vertebral body (Fig. 1).

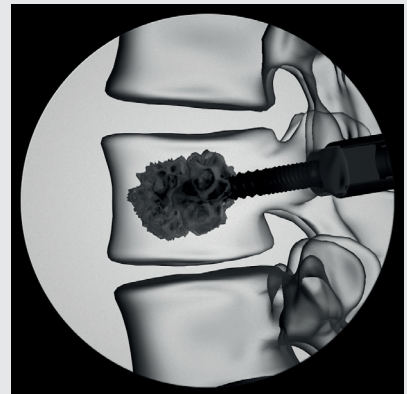
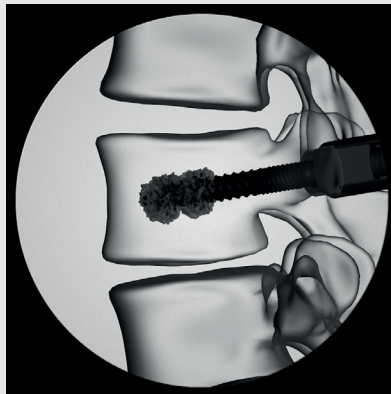
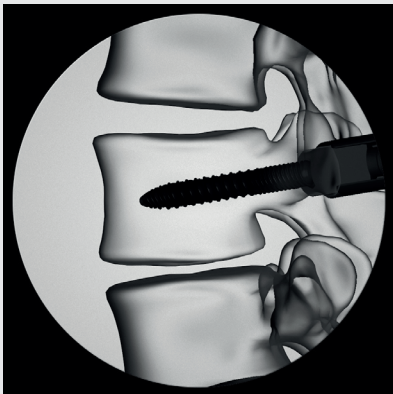
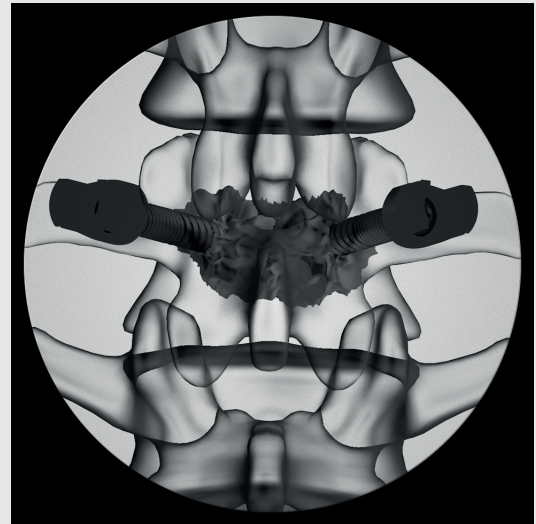







Fig. 1 Augmented pedicle screw

If augmentation of the screw is planned, this should be done straight after insertion of all screws. It may already be necessary to have the screws firmly fixed for subsequent surgical steps to prevent loosening or cutout of the screw. During distraction or compression and lordosis or rotation of a segment, forces are generated that can be transmitted to the screws. In patients with reduced bone density this can lead to screw loosening.

The procedure for inserting the pedicle screws can be found in the respective system-specific instrumentation guide.











Other pedicle screws can be found for the implants in the associated instrumentation guides.

Augmentation for open surgical applications

VERTICALE OPEN augmentation system	
	<p>S-VI-3100 VERTICALE OPEN VERTICALE OPEN Cement Cannula, sterile</p> <p>VI-3100 VERTICALE OPEN Cement delivery needle, sterile</p> 
<p>Preparing the augmentation systems and connecting them to the pedicle screw</p>	<p>Prior to applying cement, the augmentation systems must be connected to the respective pedicle screw system. Depending on the augmentation system, a different procedure is required here. A different procedure is described as follows depending on the augmentation system.</p>
<p>Cement delivery adapter</p>	<div style="display: flex; justify-content: space-around;"> <div style="width: 45%;"> <p>VI-3014 VERTICALE OPEN Cement delivery adapter, short</p>  </div> <div style="width: 45%;"> <p>VI-3016 VERTICALE OPEN Cement delivery adapter, long</p>  </div> </div>
<p>Counter torque</p>	<p>VI-3022 VERTICALE OPEN Cement delivery counter torque</p> 
<p>Alignment tool</p>	<p>VI-3052 VERTICALE OPEN Alignment tool for the cement delivery adapter</p> 

NOTE: For cement augmentation, make sure that the respective cementing instruments are fully screwed into the screw head. Only when the cement delivery adapter has completely reversed the polyaxiality of the screw is it adequately positioned in the screw head. This requires an orthograde alignment of the adapter to the screw shaft. The appropriate alignment tool or a guide wire must be used for this purpose.

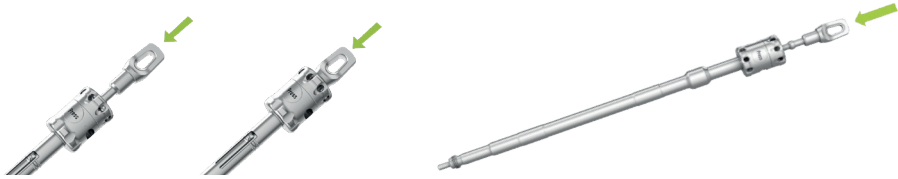




Augmentation for minimally invasive applications

VERTICALE MIS augmentation system				
	S-VI-3400 VERTICALE MIS VERTICALE MIS Cement Cannula, sterile			
				
Preparing the augmentation systems and connecting them to the pedicle screw	Prior to applying cement, the augmentation systems must be connected to the respective pedicle screw system. Depending on the augmentation system, a different procedure is required here. A different procedure is described as follows depending on the augmentation system.			
Cement delivery adapter	VI-3414 VERTICALE MIS Cement delivery adapter, short	VI-3416 VERTICALE MIS Cement delivery adapter, long		
				
Instrumentation system/counter torque	VI-5440 VERTICALE ML Locking and Reduction Tower	VI-4040 VERTICALE MIS Working Tower	VI-4412 VERTICALE WINX Blade 2.0	
				
	VI-5441 VERTICALE ML LRT Insert Quick Release	VI-5442 VERTICALE ML LRT Insert, adjustable	VI-4422 VERTICALE WINX Tower 2.0	
				
Alignment tool	VI-3420 VERTICALE MIS Alignment tool for the cement delivery adapter			
				

NOTE: For cement augmentation, make sure that the respective cementing instruments are fully screwed into the screw head. Only when the cement delivery adapter has completely reversed the polyaxiality of the screw is it adequately positioned in the screw head. This requires an orthograde alignment of the adapter to the screw shaft. The appropriate alignment tool or a guide wire must be used for this purpose.

Augmentation for open surgical applications


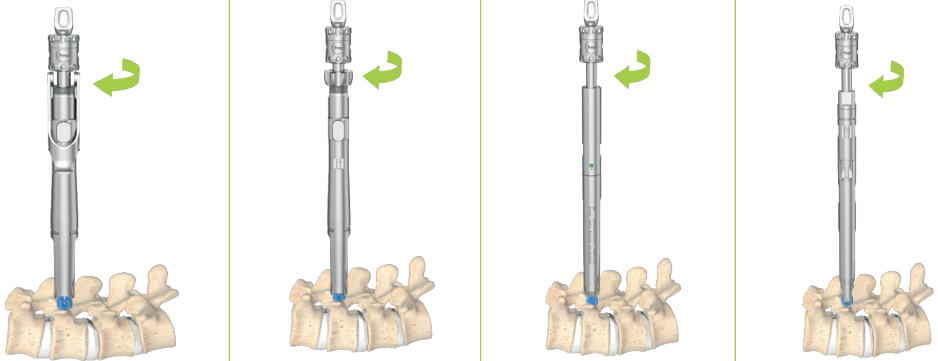
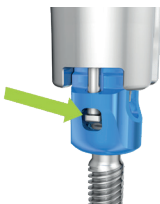



VERTICALE OPEN augmentation system

<p>Preparing the cement delivery adapter with the alignment tool</p>	<p>The alignment tool is used for orthograde alignment. The cement delivery adapters have a mechanical locking mechanism (push button) to allow easy connection and disconnection of the alignment tool and the sterile cement delivery needle.</p> <div style="text-align: center;">  </div>		
<p>Use with instrumentation system/counter torque</p>	<p>The alignment tool is then mounted onto the screw which has already been inserted into the pedicle, as a unit with the cement delivery adapter and counter torque.</p> <div style="text-align: center;">  </div>		
<p>Connecting to the pedicle screw</p>	<p>Short-head pedicle screw</p> <div style="text-align: center;">  </div>	<p>Reduction screw</p> <div style="text-align: center;">  </div>	<p>ML reduction screw</p> <div style="text-align: center;">  </div>
<p>Removing the alignment tool</p>	<p>The alignment tool is removed from the cementing adapter after screwing in the cement delivery adapter by actuation of the push-button mechanism.</p> <div style="text-align: center;">  </div>		

NOTE: The VERTICALE MultiLocking screws offer the possibility of temporarily fixing the polyaxiality. Temporary fixation must not be activated for cementation, otherwise orthograde alignment cannot be performed. The fixation must be completely released prior to inserting the cementation adapter. Refer to the VERTICALE MultiLocking instrumentation guide for more information about setting and releasing the polyaxiality.





Augmentation for minimally invasive applications

VERTICALE MIS augmentation system





<p>Preparing the cement delivery adapter with the alignment tool</p>	<p>The alignment tool is used for orthograde alignment. The cement delivery adapters have a mechanical locking mechanism (push button) to allow easy connection and disconnection of the alignment tool and the sterile cement delivery needle.</p> <div style="text-align: center;">  </div>		
	<p>The alignment tool is then inserted into the cement delivery adapter until it clicks into place and is then mounted on the screw which has already been inserted into the pedicle, as a unit. The MIS cement delivery adapter can be used with the VERTICALE MIS, the VERTICALE MultiLocking, and the VERTICALE WINX system.</p>		
<p>Use with instrumentation system/counter torque</p>	<div style="display: flex; justify-content: space-around;">  </div> <p style="background-color: #92d050; color: white; padding: 5px; margin-top: 5px;">NOTE: For the correct handling of the associated instrumentation for VERTICALE MIS, VERTICALE MultiLocking and VERTICALE WINX, please refer to the corresponding instrumentation guide of the respective system.</p>		
<p>Connecting to the pedicle screw</p>	<p>MultiLocking short-head screw</p> 	<p>Short-head pedicle screw</p> 	<p>Reduction pedicle screw</p> 
<p>Removing the alignment tool</p>	<p>The alignment tool is removed from the cementing adapter after screwing in the cement delivery adapter by actuation of the push-button mechanism.</p> <div style="text-align: center;">  </div>		

NOTE: The VERTICALE MultiLocking screws offer the possibility of temporarily fixing the polyaxiality. Temporary fixation must not be activated for cementation, otherwise orthograde alignment cannot be performed. The fixation must be completely released prior to inserting the cementation adapter. Refer to the VERTICALE MultiLocking instrumentation guide for more information about setting and releasing the polyaxiality.

Augmentation for open surgical applications

VERTICALE OPEN augmentation system	
Application of bone cement	<p>Before starting the augmentation, the cement delivery adapters must be mounted onto all the pedicle screws that are to be augmented. The VERTICALE OPEN Cement Cannula, when using the cement delivery adapter, controls the flow of cement into the screws and prevents leakage of cement into the screw head. One cement cannula is required for each screw. The VERTICALE OPEN Cement Cannula is inserted into the cement delivery adapter until it clicks into place. The cement cannula is freely rotatable in the cement delivery adapter, allowing flexible orientation of the cement application system independent of the orientation of the cement adapter.</p> <p>The cement cannula fits flush with the OPEN cement adapter. After preparing the bone cement that will be used, the cement application can now be started. The cement cannula is released by simply pressing the push button on the cement adapter.</p> 
	<p>S-VI-3100 VERTICALE OPEN Cement delivery needle, sterile</p> <p>VI-3100 VERTICALE OPEN VERTICALE OPEN Cement Cannula, sterile</p> 
	<p>NOTE: Visually check that the cannula is in the correct position. It is recommended to constantly monitor the cement flow radiographically (AP and lateral). If the cement escapes uncontrolled, the application must be stopped.</p>
Plunger used	<p>The VERTICALE OPEN cement delivery plunger is used to push the excess bone cement remaining in the needle into the vertebral body. The lumen (0.8 ml) of the cement delivery needle must be taken into account. The cement must also be compacted under fluoroscopic guidance.</p> 
	<p>VI-3101 VERTICALE OPEN Cement Delivery Plunger</p>
Disassembling the cement delivery needle	<p>The cement cannula is released by simply pressing the push button on the cement adapter as well as the alignment tool.</p>
Disassembling the augmentation system	<p>Once the cement injection is complete and the cement has fully cured, the cement application system is first removed from the cement delivery needle. The respective cement delivery adapter is then released by unscrewing it from the pedicle screw head and removing it from the screw. The VERTICALE OPEN cement cannulas are designed so that they can be loosened from the screw and the bone cement by simply rotating.</p> 
	<p>NOTE: If cement escapes from the screw head, this can have a negative effect on the function of the screw. Therefore, the needle must be left securely anchored in the screw head until the cement has fully cured. The screw head must be checked for traces of cement. Any cement residue must be removed.</p>

Augmentation for minimally invasive applications

VERTICALE MIS augmentation system	
Application of bone cement	<p>Before starting the augmentation, the cement delivery adapters must be mounted onto all the pedicle screws that are to be augmented. The VERTICALE MIS Cement Cannula, when using the cement delivery adapter, controls the flow of cement into the screws and prevents leakage of cement into the screw head. One cement cannula is required for each screw. The VERTICALE MIS Cement Cannula is inserted into the cement delivery adapter until it clicks into place. The cement cannula is freely rotatable in the cement delivery adapter, allowing flexible orientation of the cement application system independent of the orientation of the cement adapter.</p> <p>The cement cannula fits flush with the MIS cement adapter. After preparing the bone cement that will be used, the cement application can now be started. The delivery needle is released by simply pressing the push button on the cement adapter.</p> <div style="text-align: right;">  </div>
	<p>S-VI-3400 VERTICAL MIS VERTICALE MIS Cement Cannula, sterile</p> <div style="text-align: center;">  </div>
<p>NOTE: Visually check that the cannula is in the correct position. It is recommended to constantly monitor the cement flow radiographically (AP and lateral). If the cement escapes uncontrolled, the application must be stopped.</p>	
Plunger used	<p>The VERTICALE MIS cement delivery plunger is used to push the excess bone cement remaining in the cannula into the vertebral body. The lumen (1.6 ml) of the cement cannula must be taken into account. The cement must also be compacted under fluoroscopic guidance.</p> <div style="text-align: right;">  </div>
	<p>VI-3401 VERTICALE MIS Cement Delivery Plunger</p>
Disassembling the cement delivery needle	<p>The cement cannula is released by simply pressing the push button on the cement adapter as well as the alignment tool.</p>
Disassembling the augmentation system	<p>Once the cement injection is complete and the cement has fully cured, the cement application system is first removed from the cement cannula. The respective cement delivery adapter is then released by unscrewing it from the pedicle screw head and removing it from the screw. The VERTICALE MIS cement cannula are designed so that they can be loosened from the screw and the bone cement by simply rotating.</p> <div style="text-align: right;">  </div>
	<p>NOTE: If cement escapes from the screw head, this can have a negative effect on the function of the screw. Therefore, the cannula must be left securely anchored in the screw head until the cement has fully cured. The screw head must be checked for traces of cement. Any cement residue must be removed.</p>

Continuing the instrumentation steps

The other instrumentation steps (insertion of the rod, insertion of the set screw, any segmental corrections required such as distraction or compression, lordosis or kyphosis as well as segmental or global rotation) are carried out in accordance with the instrumentation guide of the respective VERTICALE screw system.

NOTE: In patients with reduced bone density (T-Score < -2,5) or poor screw anchorage, screws can become loose despite the augmentation procedure. Therefore, all active corrections should be made with additional monitoring.

VERTICALE®
PRODUCT
INFORMATION

VERTICALE® Instruments

Article number	Description	Illustration	Page
VI-3014	VERTICALE OPEN Cement Delivery Adapter, short		6, 10
VI-3016	VERTICALE OPEN Cement Delivery Adapter, long		6, 10
VI-3022	VERTICALE OPEN Cement Delivery Counter Torque		6, 10
VI-3052	VERTICALE OPEN Alignment for Cement Adapter		6, 8
VI-3100*	VERTICALE OPEN Cement Delivery Needle, sterile		6, 10
S-VI-3100*	VERTICALE OPEN Cement Cannula, sterile		6, 10
VI-3101	VERTICALE OPEN Cement Delivery Plunger		10
S-VI-3400*	VERTICALE MIS Cement Cannula, sterile		7, 11
VI-3401	VERTICALE MIS Cement Delivery Plunger		7, 11
VI-3414	VERTICALE MIS Cement Delivery Adapter, short		7, 11
VI-3416	VERTICALE MIS Cement Delivery Adapter, long		7, 11
VI-3420	VERTICALE MIS Alignment for Cement Delivery Adapter		7, 9

* Single sterile packaged



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