silony® MEDICAL

VERTICALE® AUGMENTATION

INSTRUMENTATION GUIDE

MADE IN GERMANY

TABLE OF CONTENTS

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 Medical 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.

VERTICALE® – AUGMENTATION

The VERTICALE system is a dorsal rod-screw fixation system for stabilising the thoracic and lumbar 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 ideally 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 Medical, 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 the 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 2/3 of the diameter of the vertebral body, and in the best case the anterior edge of the vertebral body (Fig. 1).

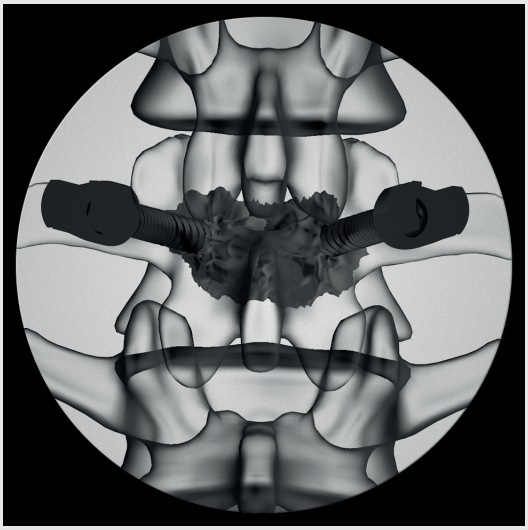

Fig. 1 Augmented pedicle screw

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 cut-out 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		
	VI-3100 VERTICALE OPEN Cement delivery needle, 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-3014 VERTICALE OPEN Cement delivery adapter, short 	VI-3016 VERTICALE OPEN Cement delivery adapter, long 
Instrumentation system/counter torque	VI-3022 VERTICALE OPEN Cement delivery counter torque 	
Centring tool	VI-3052 VERTICALE OPEN Centring 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 centring tool or a guide wire must be used for this purpose.

Augmentation for minimally invasive applications

<table>
<tr><th colspan="5">VERTICALE MIS
augmentation system</th></tr>
<tr><td></td><td colspan="4">S-VI-3400 VERTICALE MIS
Cement delivery needle, sterile
  </td></tr>
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<tr><td>Cement delivery adapter</td><td colspan="2">VI-3414 VERTICALE MIS
Cement delivery adapter, short
  </td><td colspan="2">VI-3416 VERTICALE MIS
Cement delivery adapter, long
  </td></tr>
<tr><td rowspan="3">Instrumentation system/counter torque</td><td colspan="2">VI-5440 VERTICALE ML Locking and Reduction Tower
  </td><td rowspan="3">VI-4040 VERTICALE MIS Working Tower
  </td><td>VI-4410 VERTICALE WINX Blade
  </td></tr>
<tr><td>VI-5441 VERTICALE ML LRT Insert Quick Release
  </td><td>VI-5442 VERTICALE ML LRT Insert, adjustable
  </td><td>VI-4420 VERTICALE WINX Tower
  </td></tr>
<tr><td>VI-4430 VERTICALE WINX Nut
  </td></tr>
<tr><td>Centring tool</td><td colspan="4">VI-3420 VERTICALE MIS
Centring tool for the cement delivery adapter
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Augmentation for open surgical applications

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<tr><td rowspan="2">Preparing the cement delivery adapter with the centring tool</td><td colspan="3">The centring 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 centring tool and the sterile cement delivery needle.
  </td></tr>
<tr><td colspan="3">The centring 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.</td></tr>
<tr><td>Use with instrumentation system/counter torque</td><td colspan="3">The cement delivery counter torque is necessary to prevent concurrent turning of the screw head when inserting the cement deli
  </td></tr>
<tr><td>Connecting to the pedicle screw</td><td>Short-head pedicle screw
  </td><td>Long-head pedicle screw
  </td><td>ML long-head screw
  </td></tr>
<tr><td>Removing the centring tool</td><td colspan="3">The centring tool is removed from the cementing adapter after screwing in the cement delivery adapter by actuation of the push-button mechanism.
  </td></tr>
</table>

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

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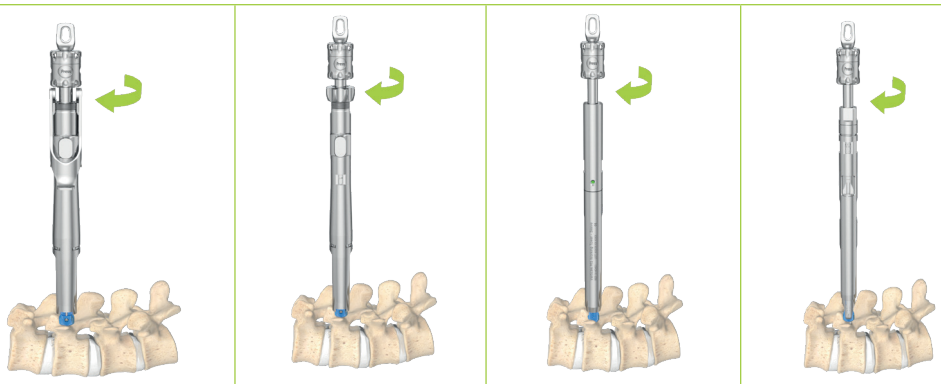
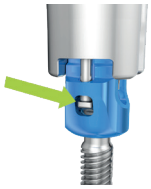
The centring tool is then inserted into the cement delivery adapter until it clicks into place and is then mounted on the screw which has already been inserted into the pedicle, as a unit. The MIS cement delivery adapter can be used with the VERTICALE MultiLocking, and the VERTICALE WINX system.</td></tr>
<tr><td>Use with instrumentation system/counter torque</td><td colspan="3"> 
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.</td></tr>
<tr><td>Connecting to the pedicle screw</td><td>MultiLocking short-head screw
  </td><td>Short-head pedicle screw
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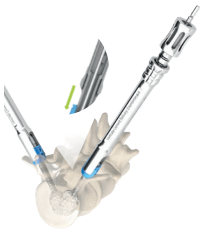
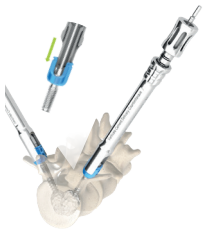
Augmentation for open surgical applications

VERTICALE OPEN augmentation system	
Application of bone cement	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 delivery needle, 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 delivery needle is required for each screw. The VERTICALE OPEN needle is inserted into the cement delivery adapter until it clicks into place. The cement delivery needle is freely rotatable in the cement delivery adapter, allowing flexible orientation of the cement application system independent of the orientation of the cement adapter. The cement delivery needle fits flush with the OPEN 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. 
	VI-3100 VERTICALE OPEN Cement delivery needle, sterile 
	NOTE: Visually check that the needle 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.
Plunger used	The VERTICALE OPEN cement delivery plunger is used to push the excess bone cement remaining in the needle into the vertebral body. The lumen of the cement delivery needle must be taken into account. The cement must also be compacted under fluoroscopic guidance. 
	VI-3101 VERTICALE OPEN Cement Delivery Plunger (lumen 0.8 mL)
Disassembling the cement delivery needle	The delivery needle is released by simply pressing the push button on the cement adapter as well as the centring tool.
Disassembling the augmentation system	The cement application system is first removed from the cement delivery needle Once the cement injection is complete and the cement has fully cured. 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 delivery needles are designed so that they can be loosened from the screw and the bone cement by simply rotating.  **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.

Augmentation for minimally invasive applications

VERTICALE MIS augmentation system	
Application of bone cement	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 delivery needle, 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 delivery needle is required for each screw. The VERTICALE MIS delivery needle is inserted into the cement delivery adapter until it clicks into place. The cement delivery needle is freely rotatable in the cement delivery adapter, allowing flexible orientation of the cement application system independent of the orientation of the cement adapter. The cement delivery needle 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. 
	S-VI-3400 VERTICAL MIS Cement delivery needle, sterile 
	NOTE: Visually check that the needle 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.
Plunger used	The VERTICALE MIS cement delivery plunger is used to push the excess bone cement remaining in the needle into the vertebral body. The lumen of the cement delivery needle must be taken into account. The cement must also be compacted under fluoroscopic guidance. 
	VI-3401 VERTICALE MIS Cement Delivery Plunger (lumen 1.2 mL)
Disassembling the cement delivery needle	The delivery needle is released by simply pressing the push button on the cement adapter as well as the centring tool.
Disassembling the augmentation system	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 MIS cement delivery needles are designed so that they can be loosened from the screw and the bone cement by simply rotating. 
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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 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

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D60079.a.EN 10.02.2023