

VERTICALE® MIS SCREW ROD SYSTEM

INSTRUMENTATION GUIDE

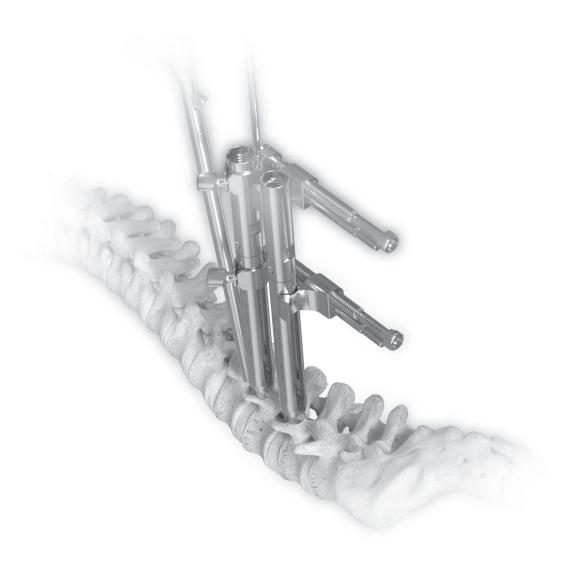


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NOTE: This guide describes the instrumentation of the VERTICALE® MIS System. - This guide does not replace briefing by a physician experienced in the instrumentation used in spinal surgery.

We would be happy to assist you in finding a hospital that provides an opportunity to observe surgical procedures.

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PRFFACE

VERTICALE® MIS SCREW ROD SYSTEM

The VERTICALE MIS System is an extension of the posterior screw rod system.

VERTICALE MIS is a posterior double rod fixation system for stabilizing the thoracic and lumbar spine.

The system was developed in close cooperation with experienced and qualified spinal surgeons as well as specialist staff from OR and sterilization departments. As a result, VERTICALE MIS is a well-designed, modular and versatile screw rod system.

VERTICALE MIS is a system enhancement (instruments and implants) that allows the VERTICALE Screw Rod System to be used in minimally invasive techniques. As such, the system supports both percutaneous and paraspinal access. Like all other implants and instruments developed by Silony Medical, VERTICALE MIS is a living system. Whether instrument or implant device – we are constantly working to expand and improve the system in order to optimally meet the needs of patients, physicians, and nursing staff.

To meet the needs of surgeons in the best possible manner we are collaborating in every product development project with a group of renowned surgeons, the Medical Advisory Board (MAB). Based on the initial concept of product design, the MAB is involved throughout the entire product development process and provides our team of engineers with expert advice.

To ensure that we fulfill our claim to be "clinically driven" we also appoint, in addition to the MAB, a Process Advisory Board (PAB) for each development project. The PAB is made up of experienced and competent medical professionals, especially nursing staff and sterilization experts.

They not only play a key role in product development but also ensure that our products, services, and solutions meet all requirements both at the operating table and throughout everyday clinical routine.

Our top priority is the health and safety of your patients. Silony Medical supports you in your capacity as a physician and clinician with our products and solutions.

We would like to thank the following individual MAB surgeons and PAB clinicians who were involved in this development.

COOPERATING MAB MEMBERS

Quante, Markus Rohrsen. Johannes Schneider, Sascha Wiese. Dirk Wimmer. Cornelius Wolfs, Jasper

COOPERATING PAB MEMBERS

Harmel, Klaus Dieter Krug, Florian Lange, Roswitha Maass, Thorsten Piske. Elke



Indications

The VERTICALE MIS System is indicated for use in the thoracic and lumbar spine as well as for iliosacral fixation procedures (T1–S2 / ilium). This includes all kinds of thoracic and lumbar instabilities that require comprehensive posterior pedicle screw fixation:

- Degenerative disc diseases
- Spondylolisthesis of all etiologies
- Stenosis
- Deformities such as scoliosis and kyphosis
- Fractures
- Spondylitis
- Tumors
- Revisions
- Pseudarthrosis

Contraindications

Under certain circumstances, implantation is contraindicated or associated with substantial risks, even though there may be an indication for it. These include in particular:

- · Anticipated or documented allergy or intolerance to the materials used (e.g. titanium or cobalt chromium)
- · Any case in which the chosen implants would be too large or too small to achieve a success-
- Any patient for whom the use of the implant would conflict with anatomical structures
- · Missing bony structures that make solid anchoring of the implant impossible (e.g. in the case of fractures, tumors or osteoporosis).

NOTE: Anterior, interbody support in the form of an intervertebral implant device, such as a ROCCIA Cage, is recommended for treating instabilities of the anterior 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.

VERTICALE® MISSISSIPPORT STANDARD INSTRU-MENTATION

In the following section, we begin by describing a monosegmental posterior VERTICALE standard instrumentation that forms the basis for all subsequent steps with additional instruments and implant devices Multisegmental instrumentations are also performed according to these instructions.

Position and approach

The patient is positioned in the prone position, as is common for the posterior approach. Corresponding bearing frames or padding underneath the pelvis and thorax can be used for this purpose. The VERTICALE MIS System supports both percutaneous and paraspinal access. It is the responsibility of the attending surgeon to select the approach in accordance with experience and preference. Using an image intensifier for verification, the pedicles are localized and the position of the incision determined on the skin. The required incisions of the skin and fasciae are carried out in accordance with the selected approach. Blunt dissection of the soft tissue is then carried out in order to establish initial access to the pedicle.

Localization of the pedicle



Localization of the pedicle is performed using the VERTICA-LE MIS Pedicle Awl. To mount the complete VERTICALE MIS Pedicle Awl, the VERTICALE MIS Sleeve f. Awl (1) is inserted through the first MIS Dilator (2) and screwed tight (Fig. 1a). The VERTICALE MIS Awl (3) is then secured by rotating it into the awl sleeve (Figs. 1a and 1b).

Using an image intensifier for verification, the pedicle entry point is first identified through the incision with the mounted VERTICALE MIS Pedicle Awl (Fig. 1c).

Once the cortex has been drilled through using the tip of the awl, the awl is guided through the pedicle while using an image intensifier for verification. The dilator prevents the tip of the awl from being inserted too deeply. In order to hold the VERTICALE MIS Pedicle Awl, either the VERTICALE MIS X-Ray Positioning Bar can be secured to the awl sleeve and/or the VERTICALE MIS Dilator 1 Holder can be attached to the dilator.

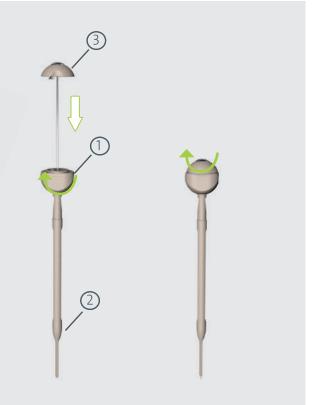


Fig. 1a Assembly of the MIS Pedicle Awl

Fig. 1b Closing and securing the pedicle awl

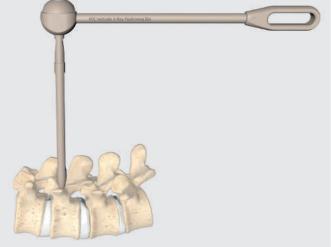


Fig. 1c Identification of the pedicle entry point with the VERTICALE MIS Pedicle Awl using the MIS X-Ray Positioning Bar

Localization of the pedicle

VI-4010 Verticale MIS Pedicle Awl VI-1060 Guide Wire with Trocar Tip

Once the pedicle awl is in the required position, the awl is removed from the awl sleeve and replaced by a guide wire. The guide wire is inserted into the vertebral body while using an image intensifier for verification (Fig. 2a). The awl sleeve is then unscrewed and removed from the first dilator (Fig. 2b).

* Additional guide wires are listed in the chapter "Accessories".



Fig. 2a Replacement of the MIS Awl with a guide wire



Fig. 2b Removal of MIS Sleeve f. Awl

NOTE: Alternatively, the guide wire can also be placed using a Jamshidi needle. This depends on the preference of the attending surgeon.

It is very important to ensure that the inserted guide wires remain in position throughout the entire instrumentation. This should be monitored using an image intensifier for verification in order to prevent perforation of the anterior wall of the vertebral body and injury to the vessels in front.

Dilation of the incision



For further dilation, the individual VERTICALE MIS Dilators 2 to 4 are placed in sequence on top of one another (Fig. 3).

To ensure that the inserted guide wires remain in position, the dilators are inserted while using an image intensifier for verification. Once the incision has been fully dilated, the inner dilators are removed by pulling the first dilator (Fig. 4). In doing so, ensure that the guide wire remains in its position. The external VERTICALE MIS Dilator 4 (20 mm) should remain in position. It provides protection for the surrounding soft tissue during the subsequent instrumentation steps.

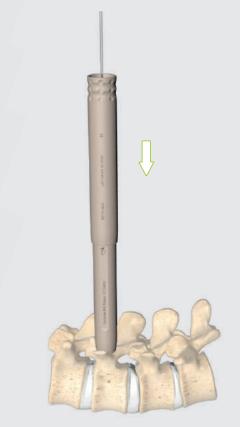


Fig. 3 Dilation from 9 mm to 20 mm



Fig. 4 Removal of the inner MIS dilators: pulling dilator 1 automatically

Pedicle preparation



To additionally open up the pedicle down to the cancellous bone of the vertebral body, the cannulated VERTICALE MIS Probe is used. The probe is guided via the wire and the pedicle opened up into the vertebral body while using an image intensifier for verification (Fig. 5). Laser markings on the probe aid orientation in this respect with regard to the insertion depth.

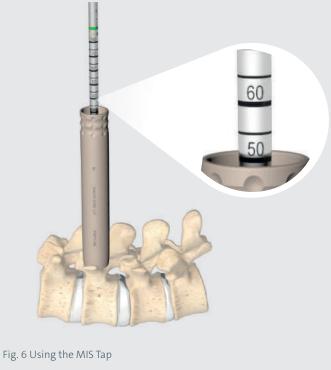
Hard bone structures (e.g. sclerotic bone) may make it necessary to pre-tap the thread. Cannulated taps are available for this purpose that are guided via the wire.

The screw channel is prepared clockwise. Laser markings on the tap provide orientation with regard to the depth of the thread (Fig. 6).

The thread on the cannulated VERTICALE MIS Tap is 25 mm long. The laser markings indicate increments of 5 mm each (Fig. 6, inset). After cutting, the tap is disengaged by turning it counterclockwise.



Fig. 5 Opening of the pedicle using the VERTICALE MIS Probe

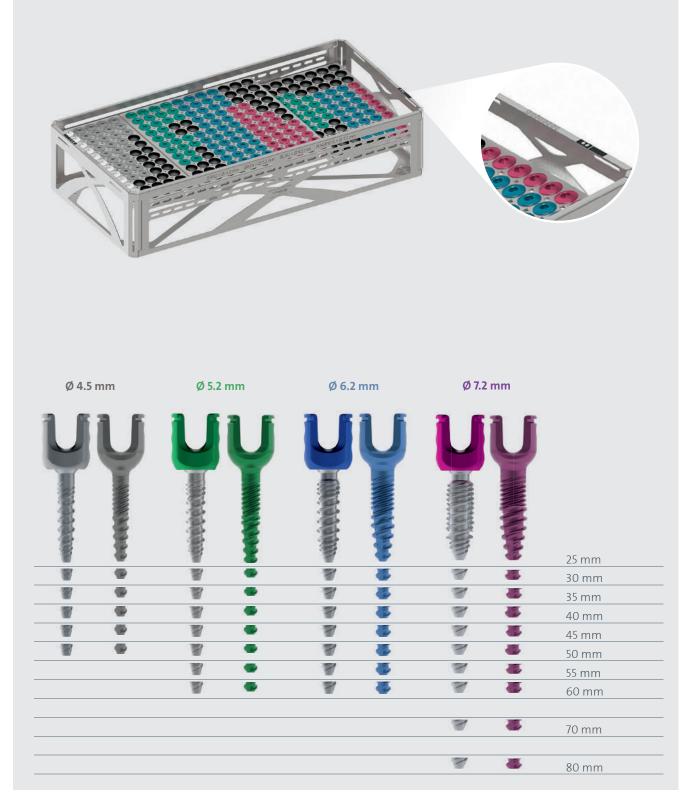


Selection of pedicle screws

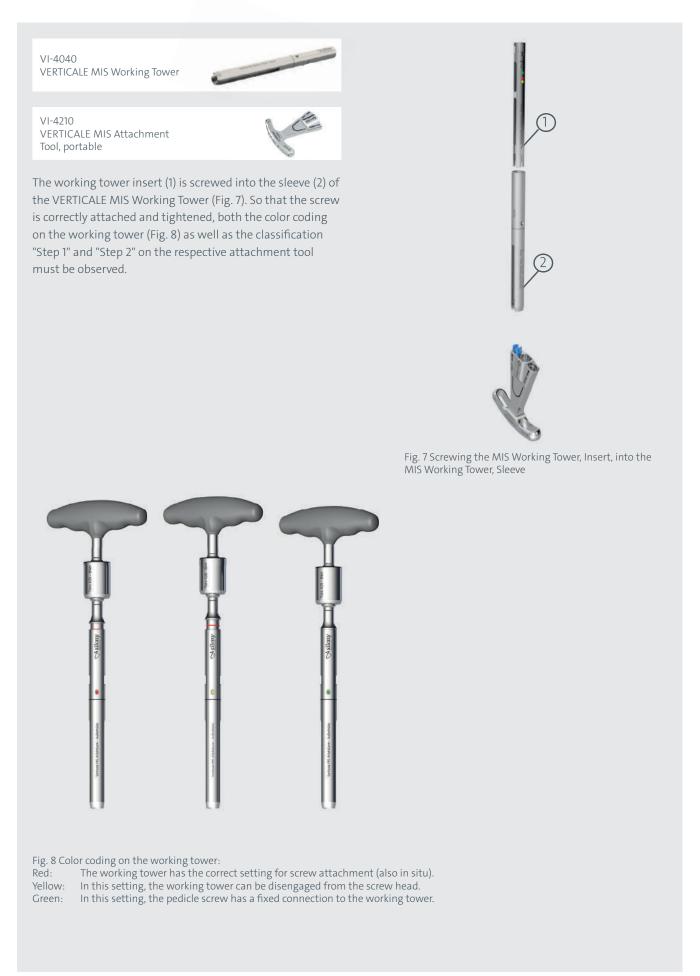
NOTE: To enable fast and easy identification, all VERTICA-LE Pedicle Screws are color-coded by diameter.

The VERTICALE MIS System can be used with cannulated polyaxial and monoaxial screws.

NOTE: Using an image intensifier to perform anterior verification, select pedicle screws with the largest possible diameter, based on the pedicle diameter. It is recommended that the length of the screw be selected such that it extends to at least 2/3 of the diameter of the vertebral body, ideally up to the anterior edge of the vertebral body.



Screw attachment using the attachment tool



Screw attachment using the attachment tool



In the attachment tool, the screw is initially inserted into the opening labeled STEP 1. In doing so, you must distinguish between the STEP 1 opening for monoaxial screws, and STEP 1 for all polyaxial screws (Fig. 9). The working tower is now placed onto the screw in straight alignment (Fig. 10). For this purpose, it must be in the "red" position (Fig. 10, inset). An audible click confirms that each side of the working tower is correctly locked into the hook slot of the screw.

In order to ensure that the working tower does not slip out of the hook slot of the screw on final tightening, the screw and the working tower are placed in STEP 2 of the attachment tool and the working tower screwed tight to the final position using the MIS Torque Limiter. For this purpose the attachment tool should be held firmly at the opposite end (Fig. 11). The final position of the working tower is achieved when the green dot on the working tower is visible (Fig. 11, inset). This is confirmed by an audible click. The working tower is now correctly prepared for the connection to the screw driver and insertion of the screw into the vertebral body.



Fig. 9 Attachment tool STEP 1 with a VERTICALE Poly Screw

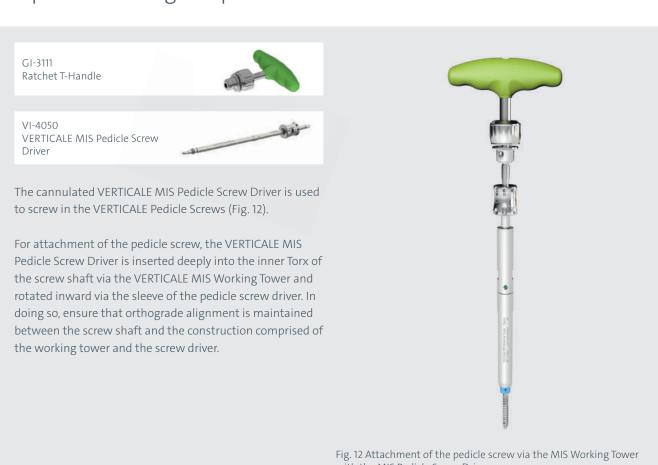


Fig. 10 Placement of the working tower on the polyaxial pedicle

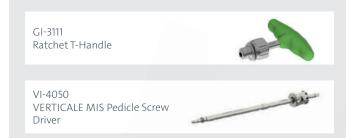


Fig. 11 MIS Attachment Tool STEP 2 (final tightening of the screw)

Preparation using the pedicle screw driver



Pedicle screw insertion



The mounted VERTICALE MIS Working Tower and VERTICALE MIS Pedicle Screw Driver with the attached pedicle screw are guided via the wire. While doing so, the VERTICALE MIS Dilator 4 (20 mm) protects the tissue (Fig. 13a). When inserting the screw, ensure that the insertion axis of the pedicle screw corresponds with the guide wire.

Using an image intensifier for verification, the VERTICALE MIS Pedicle Screws are screwed into the prepared screw channel until the screw shaft is fully inserted into the pedicle. While doing so, it is important that the position and alignment of the guide wire are verified.

The pedicle screw driver is disengaged from the mounted VERTICALE MIS Working Tower with the pedicle screw by rotating the lower part of the handle counterclockwise. Then the VERTICALE MIS Dilator 4 can be removed (Fig. 13b). This process is repeated until all the pedicle screws have been placed with the respective VERTICALE MIS Working Towers. Verifying the correct positioning of the pedicle screws by means of an image intensifier in frontal and sagittal projection is strongly recommended.



Fig. 13a Screwing the pedicle screw (secured to the VERTICALE MIS Working Tower) into the vertebral body

NOTE: In the case of polyaxial screws, it is important that the polyaxiality of the screw head not be blocked. When using monoaxial screws, it is important that the screw head be positioned in superior-inferior alignment. If necessary, the screw must be turned back a little.

NOTE: Using monoaxial screws may hinder the procedure using the VERTICALE MIS System, as the VERTICALE MIS Working Towers are always aligned orthograde to the pedicle screw. In the event of severe lordosis, for example, this may result in the alignment of MIS Working Towers preventing the application of an additional MIS Working Tower.



Fig. 13b Removing the Dilator 4

Rod selection



Various rod lengths with a diameter of 5.5 mm are available. All VERTICALE MIS Rods have a conical tip for application that is gentle on tissue. By default, the system comes with straight and pre-curved titanium rods and straight CoCr rods.

The required rod length is determined using the VERTICALE MIS Rod Gauge.

1. The fixed measuring rod of the rod gauge is inserted fully into the inferior VERTICALE MIS Working Tower until the tip of the shaft is placed inside the pedicle screw head. Here, the adjustment rail is positioned on top of the working tower.

II. The variable rod of the rod gauge is inserted fully into the superior MIS Working Tower and into the screw head (Fig. 14a). When doing so, do not secure the adjustment rail. The adjustable unit is now fixed into position using the rotary knob. The movable measuring rod must be pulled back fully. If this step is not completed, the rod gauge becomes incorrectly adjusted on removal. The rod gauge can be removed from the working towers, the movable measuring rod pushed downwards until the green marking is reached, and the appropriate rod read on the MIS Rod Length Verifier (Fig. 14b). The rod length verifier has two sides for reading so it can be used both for curved rods and for straight rods.

The MIS Rods can be placed on the rod length verifier so that the length can be checked quickly (Fig. 14c).

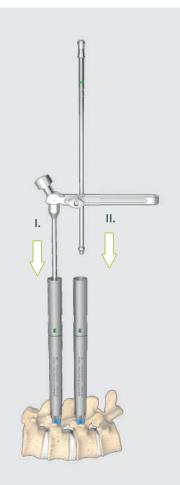


Fig. 14a Inserting the rod gauge into the working towers



Fig. 14b Reading the rod length on the rod length verifier



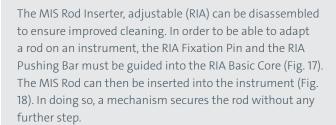
Fig. 14c Verifying the length of the MIS Rods on the rod length verifier

Preparation of the MIS Rod Inserter



The VERTICALE MIS System offers two options for rod insertion. The rod can be inserted at a fixed angle of approx. 95°, or placed into the screw head via an adjustable rod holder with different insertion angles. Here, eight positions are possible between 0° and 90°.

In order to mount the rod to the MIS Rod Inserter (RIF), the RIF Fixation Pin must be inserted into the RIF Basic Core (Fig. 15). A VERTICALE MIS Rod can then be inserted. In order to ensure a secure connection, final tightening of the RIF Fixation Pin is performed using the MIS Torque Limiter (Fig. 16). An audible click indicates that the torque is reached.



In order to disengage the rod following fixation in the pedicle screw head, the RIF Fixation Pin of the rod inserter (RIF) must be disengaged using the MIS Torque Limiter. The instrument can then be removed.

In the case of the adjustable rod inserter, the lever on the RIA Fixation Pin is used to disengage the rod. The instrument can then be removed.

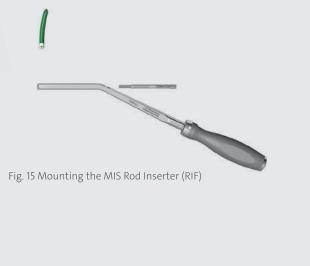


Fig. 16 MIS Rod Inserter including MIS Torque Limiter 5Nm



Fig. 17 Mounting the MIS Rod Inserter, adjustable



Fig. 18 MIS Rod Inserter, adjustable with adapted rod

Inserting the rods



Prior to insertion of the rod, it is important for the rod slots of the VERTICALE MIS Working Towers to be in superiorinferior alignment. The rod is then inserted at a steep angle through the rod slots of the superior or inferior working tower and under the fasciae (Fig. 19).

When using the adjustable VERTICALE MIS Rod Inserter, the required angle of the rod is locked by pressing the handle. The rod is then guided via the adjacent MIS Working Towers (Fig. 20).

Lateral verification of the final positioning of the rod is recommended using an image intensifier. In doing so, it is important to ensure that both the rod attachment coupling as well as the conical tip of the rod extend laterally out of the respective VERTICALE MIS Working Tower (overlap at least 3 mm, which roughly corresponds to half of the conical tip).

When selecting the rod using the rod gauge and length verifier, taking the ideal overlapping length into consideration is recommended. Correct placement of the rod can be verified using the VERTICALE MIS Rod Feeler. To do so, the rod feeler is inserted via the VERTICALE MIS Working Towers (Fig. 21). If a rod is located in the pedicle screw head, this is confirmed by the green marking on the rod feeler. If the red marking is visible on the rod feeler, the rod feeler will not encounter resistance until it is deeper, which in turn means that as yet, there is no rod at this location in the screw

When selecting the rod connection, make sure the rod length is adequate.

NOTE: It is recommended that the rod should already be inserted as deeply as possible into the pedicle screw head during insertion. It is important for lateral verification of the insertion depth of the tip of the rod to be carried out using an image intensifier.

NOTE: To enable permanent verification of the rod (rotation and positioning), leaving the VERTICALE MIS Rod Inserter on the rod until final tightening of the set screws is recommended. In situ attachment of the rod is not possible.



Fig. 19 Insertion of the rod with the MIS Rod Inserter (approx.

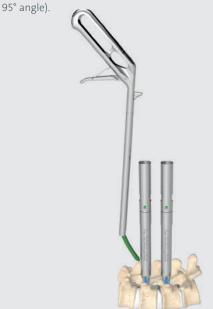
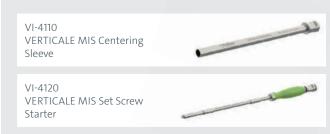


Fig. 20 Insertion of the rod with the MIS Rod Inserter, adjustable



Fig. 21 Verification of the placement of the rod using the MIS Rod Feeler

Temporary fixation of the set screw



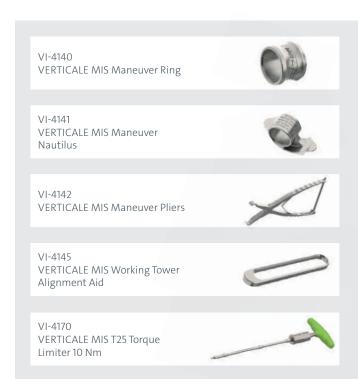
The set screw is inserted using the VERTICALE MIS Set Screw Starter. For this purpose, the MIS Starter Inner Shaft is inserted into the MIS Starter Basic Core and secured using the MIS Starter Turning Knob. Using the VERTICALE MIS Set Screw Starter, the set screw is attached and guided via the VERTICALE MIS Working Towers (Fig. 22) together with the MIS Centering Aid. Temporary fixation of the rod is achieved by gently turning the set screw.



Fig. 22 Temporary fixation of the set screw with the MIS Set Screw Starter

NOTE: Set screws should always be inserted with a smooth clockwise rotation. To prevent tilting, a brief prior counterclockwise rotation can facilitate insertion of the set screw into the first thread.

Distraction using the Nautilus



The VERTICALE MIS System offers two options for carrying out the compression or distraction maneuver: In the case of adjacent segments, distraction or compression can be carried out using the VERTICALE MIS Maneuver Nautilus. The VERTICALE MIS Maneuver Rack can be used for both monosegmental as well as multisegmental distraction or compression.

The MIS Working Tower Alignment Aid is available for both maneuver options. This prevents the working towers from tipping over, thus stabilizing the working construction. It is recommended that the set screw at the end with the rod inserter should be tightened using the MIS T25 Torque Limiter 10Nm before each maneuver.

To perform distraction, the VERTICALE MIS Maneuver Ring (1) is guided via the MIS Working Tower and placed as close to the skin as possible. The VERTICALE MIS Maneuver Nautilus (2) is guided on the superior or inferior adjacent MIS Working Tower and placed at the same height as the ring (Fig. 23a).

The VERTICALE MIS Maneuver Ring and the MIS Maneuver Nautilus provide the point of rotation of the MIS Working Towers. By using the VERTICALE MIS Maneuver Pliers (3) at the distal ends of the MIS Working Towers, distraction (4) of the screw heads is achieved (Fig. 23b).

NOTE: So that the rod can move freely in the screw head, the set screw must not be securely tightened in the working tower without a rod inserter during the compression and distraction maneuver. To ensure appropriate manipulation of the spinal segment, it is recommended that the correction maneuver be performed while using an image intensifier to carry out lateral verification.



Fig. 23a Placement of the VERTICALE MIS Maneuver Ring and Nautilus for a distraction maneuver

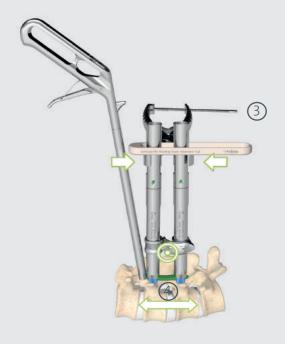
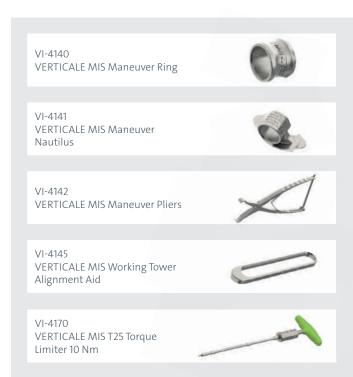


Fig. 23b Pedicle screw head distraction through compression of the VERTICALE MIS Working Towers (Nautilus is positioned beneath the pliers)

Compression using the Nautilus



To perform compression, the VERTICALE MIS Maneuver Ring (1) is guided via the MIS Working Tower and placed as far away from the skin as possible. The VERTICALE MIS Maneuver Nautilus (2) is guided on the superior or inferior adjacent MIS Working Tower and placed at the same height as the ring (Fig. 24a).

The VERTICALE MIS Maneuver Ring and the MIS Maneuver Nautilus provide the point of rotation of the MIS Working Towers. By using the VERTICALE MIS Maneuver Pliers (3) at the proximal ends of the MIS Working Towers, compression (4) of the screw heads is achieved (Fig. 24b).

The pliers should be left in this position, first to lock the set screw by hand using the VERTICALE MIS Set Screw Starter and then to tighten it using the MIS T25 Torque Limiter 10Nm. The MIS Maneuver Pliers, MIS Maneuver Ring and the MIS Maneuver Nautilus are then removed.



Fig. 24a Placement of the VERTICALE MIS Maneuver Ring and Nautilus for a compression maneuver

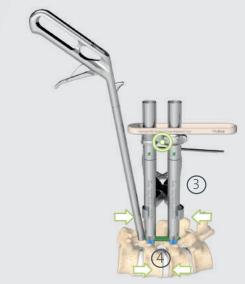


Fig. 24b Pedicle screw head compression through compression of the VERTICALE MIS Working Towers (Nautilus is positioned above the

NOTE: So that the rod can move freely in the screw head, the set screw must not be securely tightened in the working tower without a rod inserter during the compression and distraction maneuver. To ensure appropriate manipulation of the spinal segment, it is recommended that the correction maneuver be performed while using an image intensifier to carry out lateral verification.

Distraction using the maneuver rack



The VERTICALE MIS Maneuver Racks are available for highly precise monosegmental and multisegmental correction maneuvers. For this purpose, the VERTICALE MIS Maneuver Racks are guided via the superior and inferior MIS Working Tower. It is best to place one rack close to the skin, with the second rack in a distal position. The MIS Working Tower Alignment Aid can help here to prevent the working towers from tipping over.

I. The rack is secured to the working tower via the rotary handle on the side.

II. For distraction, the slider of the Maneuver Rack next to the skin is located flush on the inside between the working

III. For distraction, the slider of the maneuver rack away from the skin is located flush on the outside of the working

IV. The distraction length is set manually via the handle on the maneuver rack.

V. Distraction can also be adjusted using the MIS Maneuver Rack Adjuster.

Distraction of the spinal segments using the maneuver racks is achieved by arranging the maneuver racks as shown in Fig. 25 and then compressing the ends of the working towers that are not adjacent to the skin.

The racks should be left in this position, first to lock the set screw by hand using the MIS Set Screw Starter and then to tighten it using the MIS T25 Torque Limiter 10Nm. The MIS Maneuver Racks are then removed.

NOTE: So that the rod can move freely in the screw head, the set screw must not be securely tightened in the working tower without a rod inserter during the compression and distraction maneuver. To ensure appropriate manipulation of the spinal segment, it is recommended that the correction maneuver be performed while using an image intensifier to carry out lateral verification.

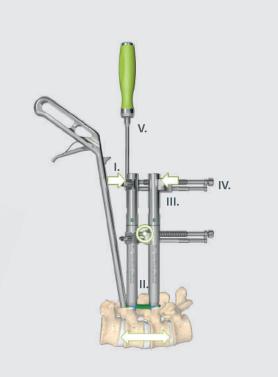


Fig. 25 Arrangement of the sliders belonging to the maneuver racks for distraction of the spinal segment

Compression using the maneuver rack



To achieve compression of the spinal segment, the position of the slider of the MIS Maneuver Rack is modified (Fig. 26).

- 1. The rack is secured to the working tower via the rotary handle on the side.
- II. For compression, the slider of the MIS Maneuver Rack next to the skin is located flush on the outside of the working
- III. For compression, the slider of the MIS Maneuver Rack away from the skin is located flush on the inside between the working towers.
- IV. The compression length is set manually via the handle on the maneuver rack.
- V. Compression can also be adjusted using the MIS Maneuver Rack Adjuster.

Compression of the spinal segments using the maneuver racks is achieved by arranging the maneuver racks as shown in Fig. 26 and then distracting the ends of the working towers that are not adjacent to the skin.

The racks should be left in this position, first to lock the set screw by hand using the MIS Set Screw Starter and then to tighten it using the MIS T25 Torque Limiter 10Nm. The MIS Maneuver Racks are then removed.

NOTE: So that the rod can move freely in the screw head, the set screw must not be securely tightened in the working tower without a rod inserter during the compression and distraction maneuver. To ensure appropriate manipulation of the spinal segment, it is recommended that the correction maneuver be performed while using an image intensifier to carry out lateral verification.

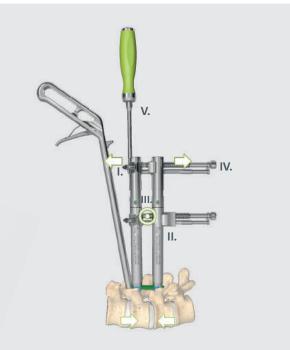


Fig. 26 Arrangement of the sliders belonging to the maneuver racks for compression of the spinal segment

Reduction maneuver



The VERTICALE MIS Reduction Instrument in combination with the VERTICALE MIS Reduction Adapter is used to push the rod into the base of the pedicle screw head.

I. The MIS Reduction Instrument is inserted into the working tower. (Fig. 27a).

II. The MIS Reduction Adapter and the T-Handle are placed onto the MIS Reduction Instrument.



Fig. 27a Insertion of the MIS Reduction Instrument into the MIS Working Tower

Reduction maneuver



III. By turning the VERTICALE MIS Reduction Adapter, the rod is pressed into the screw head in controlled fashion (Fig. 27b). At the same time, the position of the vertebral body is corrected to posterior. It is recommended that the reduction maneuver be performed while using an image intensifier for verification.

IV. It is recommended that the VERTICALE MIS Counter Torque be used to counteract rotational forces (Fig. 27b). V. The markings on the VERTICALE MIS Reduction Adapter show which reduction distance is required until the final position is reached (Fig. 27b, inset). The maximum possible reduction length is 20 mm. Reduction has only been fully completed and the rod can only be secured (Fig. 27b, inset) when sufficient reduction has been performed so that the scale shows MAX.

Fixation of the rod is achieved using the VERTICALE Set Screw. It is screwed in using the VERTICALE MIS Set Screw Starter. For this purpose, the VERTICALE MIS Reduction Adapter is disengaged from the reduction instrument and the set screw mounted on the MIS Set Screw Starter is guided by the VERTICALE MIS Reduction Instrument. Temporary fixation of the rod is achieved by turning the set screw. Final tightening is carried out using the MIS T25 Torque Limiter 10Nm. The reduction instrument can then be removed.

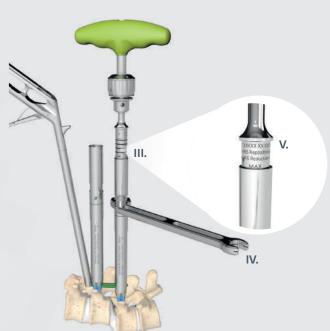


Fig. 27b Reduction maneuver with the VERTICALE MIS Reduction Instrument and Adapter

Final tightening using the counter torque



Centering Sleeve followed by the VERTICALE MIS T25 Torque Limiter is guided via the MIS Working Tower and final tightening of the set screw is performed with a torque of 10Nm. In doing so, it is important to use the VERTICALE MIS Counter Torque to stabilize the rotation when tightening the set screw (Fig. 28).

An audible click indicates that the torque is reached. The same procedure must be repeated with all other set screws. If the set screw was already tightened after a maneuver, it is recommended that this procedure be repeated following removal of the maneuver instruments. It is recommended that all the set screws be checked again to ensure the construction is postoperatively stable. Also make sure the screws have been fitted properly by tightening them again with a torque limiter (confirmation by two audible clicks)

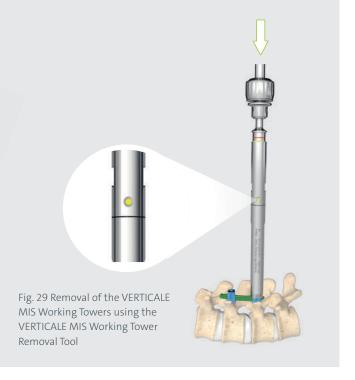


Fig. 28 Final tightening of the set screws with the MIS T25 Torque Limiter 10Nm

Removal of the instruments



Working Tower Removal Tool must be connected with the handle and inserted into the MIS Working Tower (Fig. 29). The working tower is disengaged from the pedicle screw head by turning counterclockwise with slight downward pressure. The working tower is only fully disengaged from the screw and can be removed when the yellow marking on the working tower becomes visible (Fig. 29, inset). In doing so, the VERTICALE MIS Counter Torque can be used to stabilize the rotation when disengaging the MIS Working Towers.



VERIFICATION

The result of the instrumentation is verified using images in two planes from an image intensifier.

Lateral verification of the final positioning of the rod is recommended using an image intensifier. In doing so, it is important to ensure that both the rod attachment coupling as well as the conical tip of the rod extend laterally out of the screw head.

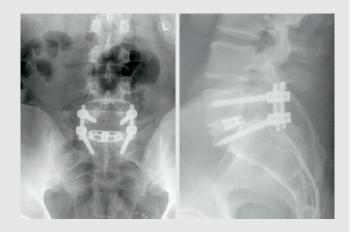


Fig. 30 Verification (using an image intensifier) of the final instrumentation result

Reconnection of the working tower

VERTICALE MIS Tower Reconnecting Tool



The tower reconnecting tool can be used to reattach a previously removed working tower to a screw in situ. For this purpose, the reconnector insert (1) is rotated into the reconnector sleeve (2) (Fig. 31a). The reconnector insert must then first be secured to the set screw followed by final tightening. The working tower must be turned back again until the red marking is visible and is then guided via the tower reconnecting tool. With a sharp tug, the working tower is then connected with the pedicle screw head (Fig. 31b). Alternatively, the basic core of the pedicle screw driver can be rotated into the head of the pedicle screw. To do so, the working tower must be guided first via the screw driver. The MIS Tower Reconnecting Tool can then be disengaged from the set screw via the reconnector insert. The MIS Dilator 4 should be guided via the working tower in order to ensure a secure connection of the working tower on the pedicle screw head (green position). Final attachment is carried out using the MIS Torque Limiter 5Nm.

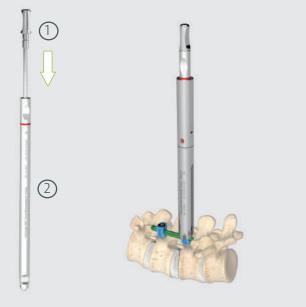


Fig. 31a Assembly of the MIS Tower Reconnecting Tool

Fig. 31b Placement of the MIS Tower Reconnecting Tool onto the set screw

Contouring of the rods

VI-1270 **VERTICALE** French Bender



For individual anatomic adjustment of the rod, the VERTI-CALE French Bender can be used (Fig. 33). The straight rods have two (CoCr) or multiple (titanium) longitudinal marks (Fig. 34), which provide assistance for aligning the contouring properly. The interfacing, and hence the alignment of the bend toward the superior-inferior line, is predefined by the instrument mount. Any bending back of the rod decreases the fatigue life of the material and should be avoided. For this reason, bending of the rod should be performed gradually until the desired curvature is attained.



Fig. 33 Bending the rod with the VERTICALE French

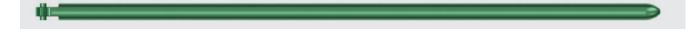




Fig. 34 Marks on the rods

NOTE: It is recommended that the rod should already be inserted as deeply as possible into the pedicle screw head during insertion. It is important for lateral verification of the insertion depth of the tip of the rod to be carried out using an image intensifier.

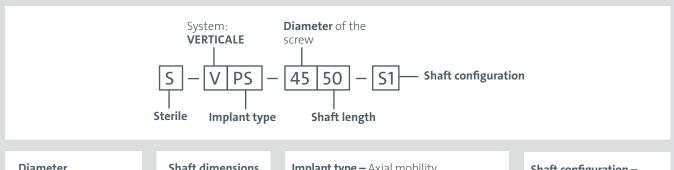
NOTE: To enable permanent verification of the rod (rotation and positioning), leaving the VERTICALE MIS Rod Inserter on the rod until final tightening of the set screws is recommended. In situ attachment of the rod is not possible.

VERTICALE® MIS PRODUCT INFORMATION

VERTICALE MIS Implants by article number	Ы	02	— (07
VERTICALE MIS Instruments by article number	ΡI	08	-	10
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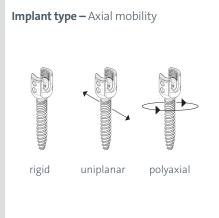
Article number explanation for screws, as an example

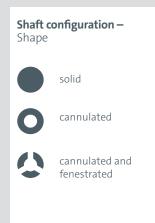
VERTICALE Poly Screw Ø 4.5 x 25 mm, solid











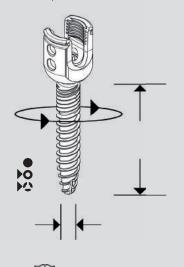
System: VERTICALE

Implant type: Pedicle screw

Configuration: Polyaxial, cannulated and fenestrated shaft

Material: Ti6Al4V ELI

All articles are also available as a sterile variant. The article number is then preceded by the prefix S-.





Article number	Description	Illustration
VPS-4525-K1	VERTICALE Poly Screw 4.5 x 25 mm, can	2.5
VPS-4530-K1	VERTICALE Poly Screw 4.5 x 30 mm, can	u
VPS-4535-K1	VERTICALE Poly Screw 4.5 x 35 mm, can	
VPS-4540-K1	VERTICALE Poly Screw 4.5 x 40 mm, can	89000
VPS-4545-K1	VERTICALE Poly Screw 4.5 x 45 mm, can	9999
VPS-4550-K1	VERTICALE Poly Screw 4.5 x 50 mm, can	9
VPS-5225-K1	VERTICALE Poly Screw 5.2 x 25 mm, can	
VPS-5230-K1	VERTICALE Poly Screw 5.2 x 30 mm, can	
VPS-5235-KF1	VERTICALE Poly Screw 5.2 x 35 mm, can+fen	u
VPS-5240-KF1	VERTICALE Poly Screw 5.2 x 40 mm, can+fen	I
VPS-5245-KF1	VERTICALE Poly Screw 5.2 x 45 mm, can+fen	- 8
VPS-5250-KF1	VERTICALE Poly Screw 5.2 x 50 mm, can+fen	866
VPS-5255-KF1	VERTICALE Poly Screw 5.2 x 55 mm, can+fen	
VPS-5260-KF1	VERTICALE Poly Screw 5.2 x 60 mm, can+fen	
VPS-6225-K1	VERTICALE Poly Screw 6.2 x 25 mm, can	
VPS-6230-K1	VERTICALE Poly Screw 6.2 x 30 mm, can	
VPS-6235-KF1	VERTICALE Poly Screw 6.2 x 35 mm, can+fen	u
VPS-6240-KF1	VERTICALE Poly Screw 6.2 x 40 mm, can+fen	
VPS-6245-KF1	VERTICALE Poly Screw 6.2 x 45 mm, can+fen	8000
VPS-6250-KF1	VERTICALE Poly Screw 6.2 x 50 mm, can+fen	55
VPS-6255-KF1	VERTICALE Poly Screw 6.2 x 55 mm, can+fen	
VPS-6260-KF1	VERTICALE Poly Screw 6.2 x 60 mm, can+fen	
VPS-7225-K1	VERTICALE Poly Screw 7.2 x 25 mm, can	
VPS-7230-K1	VERTICALE Poly Screw 7.2 x 30 mm, can	
VPS-7235-KF1	VERTICALE Poly Screw 7.2 x 35 mm, can+fen	
VPS-7240-KF1	VERTICALE Poly Screw 7.2 x 40 mm, can+fen	u
VPS-7245-KF1	VERTICALE Poly Screw 7.2 x 45 mm, can+fen	
VPS-7250-KF1	VERTICALE Poly Screw 7.2 x 50 mm, can+fen	
VPS-7255-KF1	VERTICALE Poly Screw 7.2 x 55 mm, can+fen	-
VPS-7260-KF1	VERTICALE Poly Screw 7.2 x 60 mm, can+fen	₹
VPS-7270-KF1	VERTICALE Poly Screw 7.2 x 70 mm, can+fen	
VPS-7280-KF1	VERTICALE Poly Screw 7.2 x 80 mm, can+fen	
VMS-2025	VERTICALE Set Screw 1S Torx 25	

Article number	Description	Illustration
VPS-4525-K2	VERTICALE Poly Screw ST 4.5 x 25 mm, can	
VPS-4530-K2	VERTICALE Poly Screw ST 4.5 x 30 mm, can	u
VPS-4535-K2	VERTICALE Poly Screw ST 4.5 x 35 mm, can	T
VPS-4540-K2	VERTICALE Poly Screw ST 4.5 x 40 mm, can	800
VPS-4545-K2	VERTICALE Poly Screw ST 4.5 x 45 mm, can	30
VPS-4550-K2	VERTICALE Poly Screw ST 4.5 x 50 mm, can	8
VPS-5225-K2	VERTICALE Poly Screw ST 5.2 x 25 mm, can	
VPS-5230-K2	VERTICALE Poly Screw ST 5.2 x 30 mm, can	11
VPS-5235-KF2	VERTICALE Poly Screw ST 5.2 x 35 mm, can+fen	¥
VPS-5240-KF2	VERTICALE Poly Screw ST 5.2 x 40 mm, can+fen	
VPS-5245-KF2	VERTICALE Poly Screw ST 5.2 x 45 mm, can+fen	9950
VPS-5250-KF2	VERTICALE Poly Screw ST 5.2 x 50 mm, can+fen	9000
VPS-5255-KF2	VERTICALE Poly Screw ST 5.2 x 55 mm, can+fen	
VPS-5260-KF2	VERTICALE Poly Screw ST 5.2 x 60 mm, can+fen	
VPS-6225-K2	VERTICALE Poly Screw ST 6.2 x 25 mm, can	
VPS-6230-K2	VERTICALE Poly Screw ST 6.2 x 30 mm, can	3.5
VPS-6235-KF2	VERTICALE Poly Screw ST 6.2 x 35 mm, can+fen	U .
VPS-6240-KF2	VERTICALE Poly Screw ST 6.2 x 40 mm, can+fen	
VPS-6245-KF2	VERTICALE Poly Screw ST 6.2 x 45 mm, can+fen	3
VPS-6250-KF2	VERTICALE Poly Screw ST 6.2 x 50 mm, can+fen	-
VPS-6255-KF2	VERTICALE Poly Screw ST 6.2 x 55 mm, can+fen	8
VPS-6260-KF2	VERTICALE Poly Screw ST 6.2 x 60 mm, can+fen	
VPS-7225-K2	VERTICALE Poly Screw ST 7.2 x 25 mm, can	
VPS-7230-K2	VERTICALE Poly Screw ST 7.2 x 30 mm, can	
VPS-7235-KF2	VERTICALE Poly Screw ST 7.2 x 35 mm, can+fen	11
VPS-7240-KF2	VERTICALE Poly Screw ST 7.2 x 40 mm, can+fen	Ų
VPS-7245-KF2	VERTICALE Poly Screw ST 7.2 x 45 mm, can+fen	
VPS-7250-KF2	VERTICALE Poly Screw ST 7.2 x 50 mm, can+fen	3
VPS-7255-KF2	VERTICALE Poly Screw ST 7.2 x 55 mm, can+fen	*
VPS-7260-KF2	VERTICALE Poly Screw ST 7.2 x 60 mm, can+fen	
VPS-7270-KF2	VERTICALE Poly Screw ST 7.2 x 70 mm, can+fen	
VPS-7280-KF2	VERTICALE Poly Screw ST 7.2 x 80 mm, can+fen	
VMS-2025	VERTICALE Set Screw 1S Torx 25	

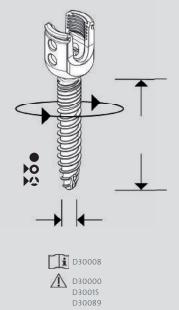
System: VERTICALE

Implant type: Pedicle screw

Configuration: Polyaxial ST, cannulated and fenestrated shaft

Material: Ti6Al4V ELI

All articles are also available as a sterile variant. The article number is then preceded by the prefix S-.



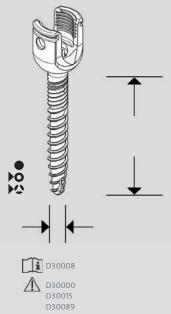
System: VERTICALE

Implant type: Pedicle screw

Configuration: Monoaxial, cannulated and fenestrated shaft

Material: Ti6Al4V ELI

All articles are also available as a sterile variant.
The article number is then preceded by the prefix S-.



Article number	Description	Illustration
VFS-4525-K2	VERTICALE Mono Screw 4.5 x 25 mm, can	3.6
VFS-4530-K2	VERTICALE Mono Screw 4.5 x 30 mm, can	U
VFS-4535-K2	VERTICALE Mono Screw 4.5 x 35 mm, can	T
VFS-4540-K2	VERTICALE Mono Screw 4.5 x 40 mm, can	8
VFS-4545-K2	VERTICALE Mono Screw 4.5 x 45 mm, can	•
VFS-4550-K2	VERTICALE Mono Screw 4.5 x 50 mm, can	*
VFS-5225-K2	VERTICALE Mono Screw 5.2 x 25 mm, can	
VFS-5230-K2	VERTICALE Mono Screw 5.2 x 30 mm, can	3.6
VFS-5235-KF2	VERTICALE Mono Screw 5.2 x 35 mm, can+fen	Ų
VFS-5240-KF2	VERTICALE Mono Screw 5.2 x 40 mm, can+fen	
VFS-5245-KF2	VERTICALE Mono Screw 5.2 x 45 mm, can+fen	
VFS-5250-KF2	VERTICALE Mono Screw 5.2 x 50 mm, can+fen	
VFS-5255-KF2	VERTICALE Mono Screw 5.2 x 55 mm, can+fen	
VFS-5260-KF2	VERTICALE Mono Screw 5.2 x 60 mm, can+fen	
VFS-6225-K2	VERTICALE Mono Screw 6.2 x 25 mm, can	
VFS-6230-K2	VERTICALE Mono Screw 6.2 x 30 mm, can	3.6
VFS-6235-KF2	VERTICALE Mono Screw 6.2 x 35 mm, can+fen	Ų
VFS-6240-KF2	VERTICALE Mono Screw 6.2 x 40 mm, can+fen	
VFS-6245-KF2	VERTICALE Mono Screw 6.2 x 45 mm, can+fen	
VFS-6250-KF2	VERTICALE Mono Screw 6.2 x 50 mm, can+fen	
VFS-6255-KF2	VERTICALE Mono Screw 6.2 x 55 mm, can+fen	\$
VFS-6260-KF2	VERTICALE Mono Screw 6.2 x 60 mm, can+fen	
VFS-7225-K2	VERTICALE Mono Screw 7.2 x 25 mm, can	
VFS-7230-K2	VERTICALE Mono Screw 7.2 x 30 mm, can	
VFS-7235-KF2	VERTICALE Mono Screw 7.2 x 35 mm, can+fen	11
VFS-7240-KF2	VERTICALE Mono Screw 7.2 x 40 mm, can+fen	Y
VFS-7245-KF2	VERTICALE Mono Screw 7.2 x 45 mm, can+fen	
VFS-7250-KF2	VERTICALE Mono Screw 7.2 x 50 mm, can+fen	
VFS-7255-KF2	VERTICALE Mono Screw 7.2 x 55 mm, can+fen	
VFS-7260-KF2	VERTICALE Mono Screw 7.2 x 60 mm, can+fen	훃
VFS-7270-KF2	VERTICALE Mono Screw 7.2 x 70 mm, can+fen	1
VFS-7280-KF2	VERTICALE Mono Screw 7.2 x 80 mm, can+fen	
VMS-2025	VERTICALE Set Screw 1S Torx 25	

Article number	Description	Illustration
VST-4040-T	VERTICALE MIS Rod curved 5.5 / 40 mm Ti	
VST-4045-T	VERTICALE MIS Rod curved 5.5 / 45 mm Ti	
VST-4050-T	VERTICALE MIS Rod curved 5.5 / 50 mm Ti	
VST-4055-T	VERTICALE MIS Rod curved 5.5 / 55 mm Ti	
VST-4065-T	VERTICALE MIS Rod curved 5.5 / 65 mm Ti	110.
VST-4075-T	VERTICALE MIS Rod curved 5.5 / 75 mm Ti	1//////
VST-4085-T	VERTICALE MIS Rod curved 5.5 / 85 mm Ti	"
VST-4095-T	VERTICALE MIS Rod curved 5.5 / 95 mm Ti	"/////
VST-4105-T	VERTICALE MIS Rod curved 5.5 / 105 mm Ti	'///
VST-4115-T	VERTICALE MIS Rod curved 5.5 / 115 mm Ti	-11
VST-4125-T	VERTICALE MIS Rod curved 5.5 / 125 mm Ti	
VST-4135-T	VERTICALE MIS Rod curved 5.5 / 135 mm Ti	

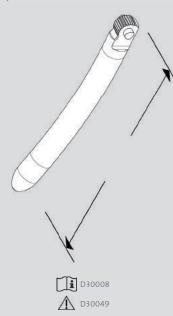
System: VERTICALE

Implant type: Rod

Configuration: curved

Material: Ti6Al4V ELI

All articles are also available as a sterile variant. The article number is then preceded by the prefix S-.

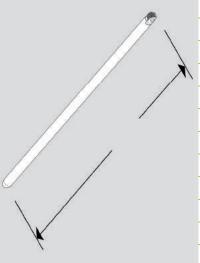


System: VERTICALE

Implant type: Rod

Configuration: straight

Material: Ti6Al4V ELI





Article number	Description	Illustration
VST-4080-T	VERTICALE MIS Rod straight 5.5 / 80 mm Ti	
VST-4090-T	VERTICALE MIS Rod straight 5.5 / 90 mm Ti	
VST-4100-T	VERTICALE MIS Rod straight 5.5 / 100 mm Ti	Acces (
VST-4110-T	VERTICALE MIS Rod straight 5.5 / 110 mm Ti	Ħ
VST-4120-T	VERTICALE MIS Rod straight 5.5 / 120 mm Ti	
VST-4130-T	VERTICALE MIS Rod straight 5.5 / 130 mm Ti	
VST-4140-T	VERTICALE MIS Rod straight 5.5 / 140 mm Ti	
VST-4150-T	VERTICALE MIS Rod straight 5.5 / 150 mm Ti	
VST-4160-T	VERTICALE MIS Rod straight 5.5 / 160 mm Ti	
VST-4170-T	VERTICALE MIS Rod straight 5.5 / 170 mm Ti	
VST-4180-T	VERTICALE MIS Rod straight 5.5 / 180 mm Ti	
VST-4190-T	VERTICALE MIS Rod straight 5.5 / 190 mm Ti	
VST-4200-T	VERTICALE MIS Rod straight 5.5 / 200 mm Ti	
VST-4210-T	VERTICALE MIS Rod straight 5.5 / 210 mm Ti	
VST-4220-T	VERTICALE MIS Rod straight 5.5 / 220 mm Ti	
VST-4230-T	VERTICALE MIS Rod straight 5.5 / 230 mm Ti	
VST-4240-T	VERTICALE MIS Rod straight 5.5 / 240 mm Ti	
VST-4250-T	VERTICALE MIS Rod straight 5.5 / 250 mm Ti	
VST-4260-T	VERTICALE MIS Rod straight 5.5 / 260 mm Ti	
VST-4270-T	VERTICALE MIS Rod straight 5.5 / 270 mm Ti	
VST-4280-T	VERTICALE MIS Rod straight 5.5 / 280 mm Ti	
VST-4290-T	VERTICALE MIS Rod straight 5.5 / 290 mm Ti	
VST-4300-T	VERTICALE MIS Rod straight 5.5 / 300 mm Ti	
VST-4310-T	VERTICALE MIS Rod straight 5.5 / 310 mm Ti	
VST-4320-T	VERTICALE MIS Rod straight 5.5 / 320 mm Ti	
VST-4330-T	VERTICALE MIS Rod straight 5.5 / 330 mm Ti	U.
VST-4340-T	VERTICALE MIS Rod straight 5.5 / 340 mm Ti	•
VST-4350-T	VERTICALE MIS Rod straight 5.5 / 350 mm Ti	
VST-4360-T	VERTICALE MIS Rod straight 5.5 / 360 mm Ti	
VST-4370-T	VERTICALE MIS Rod straight 5.5 / 370 mm Ti	
VST-4380-T	VERTICALE MIS Rod straight 5.5 / 380 mm Ti	
VST-4390-T	VERTICALE MIS Rod straight 5.5 / 390 mm Ti	
VST-4400-T	VERTICALE MIS Rod straight 5.5 / 400 mm Ti	
VST-4410-T	VERTICALE MIS Rod straight 5.5 / 410 mm Ti	
VST-4420-T	VERTICALE MIS Rod straight 5.5 / 420 mm Ti	
VST-4430-T	VERTICALE MIS Rod straight 5.5 / 430 mm Ti	
VST-4440-T	VERTICALE MIS Rod straight 5.5 / 440 mm Ti	
VST-4450-T	VERTICALE MIS Rod straight 5.5 / 450 mm Ti	
VST-4460-T	VERTICALE MIS Rod straight 5.5 / 460 mm Ti	
VST-4470-T	VERTICALE MIS Rod straight 5.5 / 470 mm Ti	

Article number	Description	Illustration	System: VERTICALE
VST-4200-C	VERTICALE MIS Rod straight 5.5 / 200 mm CoCr		Implant type
VST-4210-C	VERTICALE MIS Rod straight 5.5 / 210 mm CoCr		Implant type: Rod
VST-4220-C	VERTICALE MIS Rod straight 5.5 / 220 mm CoCr		
VST-4230-C	VERTICALE MIS Rod straight 5.5 / 230 mm CoCr		Configuration: straight
VST-4240-C	VERTICALE MIS Rod straight 5.5 / 240 mm CoCr		<u> </u>
VST-4250-C	VERTICALE MIS Rod straight 5.5 / 250 mm CoCr		Material: CoCr
VST-4260-C	VERTICALE MIS Rod straight 5.5 / 260 mm CoCr		COCI
VST-4270-C	VERTICALE MIS Rod straight 5.5 / 270 mm CoCr		
VST-4280-C	VERTICALE MIS Rod straight 5.5 / 280 mm CoCr		
VST-4290-C	VERTICALE MIS Rod straight 5.5 / 290 mm CoCr		/9 \
VST-4300-C	VERTICALE MIS Rod straight 5.5 / 300 mm CoCr		// \
VST-4310-C	VERTICALE MIS Rod straight 5.5 / 310 mm CoCr		
VST-4320-C	VERTICALE MIS Rod straight 5.5 / 320 mm CoCr		
VST-4330-C	VERTICALE MIS Rod straight 5.5 / 330 mm CoCr		
VST-4340-C	VERTICALE MIS Rod straight 5.5 / 340 mm CoCr		
VST-4350-C	VERTICALE MIS Rod straight 5.5 / 350 mm CoCr		
VST-4360-C	VERTICALE MIS Rod straight 5.5 / 360 mm CoCr		
VST-4370-C	VERTICALE MIS Rod straight 5.5 / 370 mm CoCr		
VST-4380-C	VERTICALE MIS Rod straight 5.5 / 380 mm CoCr		X
VST-4390-C	VERTICALE MIS Rod straight 5.5 / 390 mm CoCr		330
VST-4400-C	VERTICALE MIS Rod straight 5.5 / 400 mm CoCr		D30008
VST-4410-C	VERTICALE MIS Rod straight 5.5 / 410 mm CoCr		⚠ D30049
VST-4420-C	VERTICALE MIS Rod straight 5.5 / 420 mm CoCr		
VST-4430-C	VERTICALE MIS Rod straight 5.5 / 430 mm CoCr		
VST-4440-C	VERTICALE MIS Rod straight 5.5 / 440 mm CoCr	ī	
VST-4450-C	VERTICALE MIS Rod straight 5.5 / 450 mm CoCr	\forall	
VST-4460-C	VERTICALE MIS Rod straight 5.5 / 460 mm CoCr		
VST-4470-C	VERTICALE MIS Rod straight 5.5 / 470 mm CoCr		

VERTICALE® MIS Instruments

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VI-4061	VERTICALE MIS Rod Length Verifier		15
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VERTICALE® MIS Instruments

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VI-4130	VERTICALE MIS Reduction Instrument	1	23
VI-4131	VERTICALE MIS Reduction Adapter		23
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VI-1070	VERTICALE Guide Wire with Round Tip
VI-1270	VERTICALE French Bender
KG.065.01*	Hand Drilling Chuck Ergo small, free passage 2.5 mm

^{*} Manufacturer: MEDE Technik

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Notes

Notes

Distributed in:

Netherlands and Belgium

Silony Medical Europe GmbH

Bahnhofstraße 1 28195 Bremen, Germany Phone +49 421 24 69 56 0 Fax +49 421 24 69 56 55 United Kingdom

Silony Medical Ltd.

5 The Beacons Beaconsfield Road Hatfield, Herts, AL10 8RS Phone +44 (0)1707 32 84 77 Fax +44 (0)1707 37 60 73



Silony Medical Europe GmbH

Silony Medical GmbH