

VERTICALE® HOOKS

INSTRUMENTATION GUIDE



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NOTE: The following instructions are intended to familiarize you with the surgical procedure and the use of the VERTICALE hooks and the associated instruments. This instrumentation guide supplements the instructions for the VERTICALE OPEN Screw Rod 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.



PREFACE

VERTICALE® HOOKS

VERTICALE Hooks are an application option available for use with the VERTICALE system. Hooks are a suitable alternative when it is not possible to insert screws due to the anatomical situation.

In the development process, particular attention was paid to enabling an easy surgical procedure and to achieving high primary stability. The prerequisites for permanent fusion are achieved with the use of a titanium alloy (Ti6Al4V). Mechanical tests have demonstrated high primary stability. The tests focused in particular on the tendency to sink in and on the stabilizing effect.





Indications / Contraindications

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

NOTE: An interbody support in the form of an intervertebral implant device, such as a cage, is recommended for treating instabilities of the 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. All instrumentation guides and Instructions for Use can be found on our eLabeling portal under the following link (https://elabeling.silony-medical. com).

VERTICALE® HOOKS INSTRUMENTATION

Important advice:

Hooks do not provide three-dimensional stability, which is why using a cross-connector as a brace across both rods is recommended in order to achieve primary stability.

Ensure that the hooks are not placed in too deep a position and that they do not press against the spinal cord. Pressure on the spinal cord or on the nerve roots should be avoided.

Using a hook can reduce the risk of injury to nerves when determining the location of the pedicle or placing a screw in a pedicle that is difficult to identify.

On the other hand, using a hook increases the risk of neurological damage.

Lamina hooks are inserted with their shoe along the spinal canal and can therefore cause compression to be applied to the spinal cord and / or nerve roots, resulting in neurological damage.

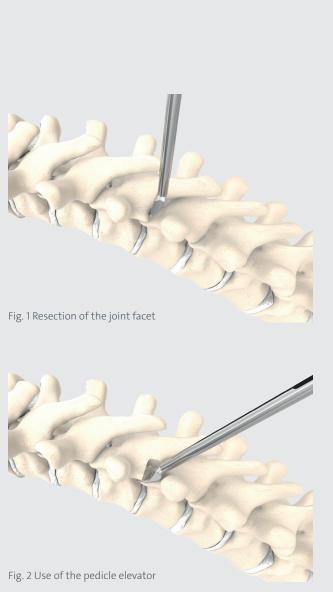
Exposure of the facet joint and the pedicle



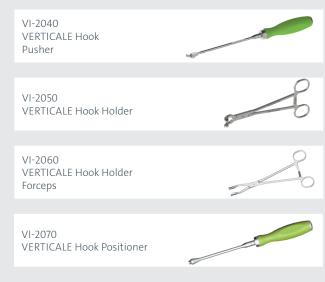
In the thoracic region, the pedicle hook is generally used in the superior direction.

To this end, the inferior joint facet is resected at a right angle using the VERTICALE Facet Finder (Fig. 1). Underneath, the superior joint facet of the inferior vertebra is exposed. The pedicle is identified by moving underneath the facet of the superior vertebra while on the facet that has been exposed.

Expose the pedicle using the VERTICALE Pedicle Finder. To do so, place the instrument between the lower and the upper facet joint (Fig. 2). Ensure that the VERTICALE Pedicle Finder is seated in the joint line and not in the bone of the lower facet. In order to simplify insertion of the pedicle hook, a small part of the lower facet should be removed using the VERTICALE Facet Finder. Move the VERTICALE Pedicle Finder in the lateral and superior direction in order to verify the ideal position. In doing so, the instrument should not be pressed in the medial direction. Then remove the instrument.



Insertion and positioning of the pedicle hook



Once a suitable pedicle hook has been selected, it is attached to the VERTICALE Hook Holder (Fig. 3a + 3b). The pedicle hook is then inserted at the required location. This can be done either with a hook holder with a lateral attachment (Fig. 4) or with holding forceps held perpendicular to the hook (Fig. 5).

The VERTICALE Hook Pusher simplifies correct placement (Fig. 6). Together with the VERTICALE Positioner, the hook can be precisely placed in the required position (Fig. 7). This procedure is repeated for the insertion of the other pedicle hooks.

* Additional pedicle hooks are described in the chapter on implants.



Fig. 4 Positioning the pedicle hook

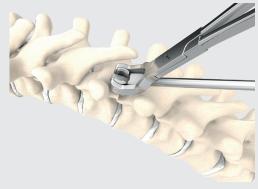
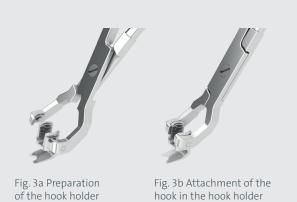


Fig. 6 Correction of the position using the pusher



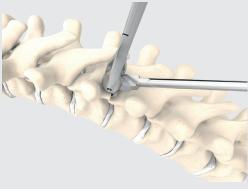






Fig. 7 Correction of the position using the positioner

Exposure of the transverse process



Lamina hooks are inserted at the lamina both in the lumbar and in the thoracic spine (inferior-superior, superior-inferior or at the transverse processes).

For this purpose, the transverse process is exposed by circling the VERTICALE Lamina Elevator (Fig. 8) in the superior area.

For inferior placement of lamina hooks, the hook is positioned in the supralaminar, thoracic or lumbar area following partial removal of the ligamentum flavum using the VERTICALE Facet Finder.

If necessary, the spinous processes are shortened until the ligamentum flavum becomes visible.

To ensure secure anchoring of the lamina hook, the ligamentum flavum and a part of the lamina can be carefully removed using the VERTICALE Facet Finder.

Supralamina hooks are used in segments T1-L5. Superior or inferior alignment can be selected in this case.

A laminotomy may be required to expose the area where the supralamina hook is to be seated. Partial resection of the ligamentum flavum is required. For this purpose, the VERTICALE Lamina Elevator can be used. As little of the bony structure as possible should be removed to ensure stable anchoring of the implant. The inferior part of the lamina must also be resected if required in order to ensure appropriate placement of the hook.



Fig. 8 Exposure of the transverse process

Insertion and positioning of the lamina hooks

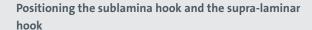


VERTICALE Hook Holder



The lamina hook is attached to the VERTICALE Hook Holder and then inserted at the required location (Fig. 9). The VERTICALE Hook Pusher facilitates correct placement (Fig. 10). You can repeat this procedure for each lamina hook.

NOTE: Ensure that the lamina hook is not placed in too deep a position and that it does not press against the spinal cord.



For this purpose, the sublamina hook / supralamina hook is attached to the VERTICALE Hook Holder in the same way as the lamina hook.

The sublamina hook / supralamina hook can then be inserted at the required location.

The VERTICALE Hook Pusher facilitates correct placement. You can repeat this procedure for each sublamina hook / supralamina hook.

NOTE: Ensure that the sublamina hook is not placed in too deep a position and that it does not press against the spinal cord.

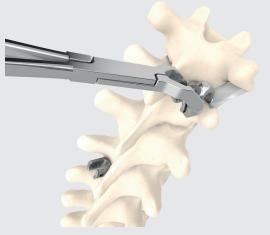


Fig. 9 Positioning the lamina hook



Fig. 10 Correction of the position using the pusher

Offset Hooks

VERTICALE Hook Pusher

VI-2050 **VERTICALE** Hook Holder



When using hooks in the lumbar spine, hooks known as Offset Hooks are generally required. The hooks can be positioned using superior or inferior alignment. In individual situations (e.g. when an adjacent pedicle screw is used), the Offset Hook can also be placed on the lateral process.

For this purpose, the transverse process is exposed by circling the lamina elevator in the superior area. For inferior placement of Offset Hooks, the hook is positioned in the supralaminar area following partial removal of the ligamentum flavum using the VERTICALE Facet Finder. If necessary, the spinous processes are shortened until the ligamentum flavum becomes visible. To ensure secure anchoring of the Offset Hook, the ligamentum flavum and a part of the lamina can be carefully removed using the VERTICALE Facet Finder.

Attach the Offset Hook to the VERTICALE Hook Holder. You can then insert the Offset Hook at the required location (Fig. 11). The VERTICALE Hook Pusher facilitates correct placement (Fig. 12). This procedure is repeated for each Offset Hook.

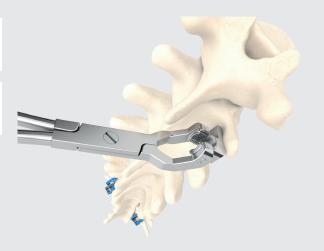


Fig. 11 Positioning the Offset Hook

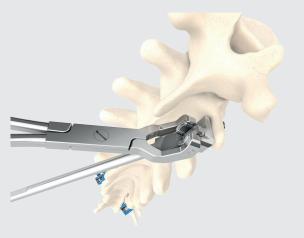


Fig. 12 Correction of the position using the pusher

Final tightening and final check

Following rod insertion, the set screws are inserted into the hooks. The VERTICALE Counter Torque is used to stabilize the rotation when tightening the set screw. In order to position the set screw with guidance, the counter torque is placed directly onto the head. The VERTICALE T25 Torque Limiter can then be guided by the counter torque and the set screw tightened in its final position with a torque of 10 Nm (Fig. 13). An audible click indicates that the torque is reached.

The same procedure must be repeated with all other set

A final check of the instrumentation is carried out using x-ray verification images in two planes.

All other steps are described in the Standard Instrumentation Guide for VERTICALE OPEN.

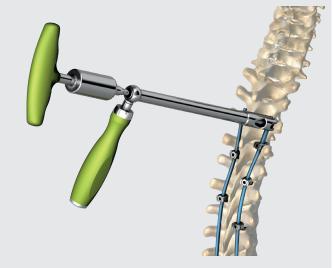


Fig. 13 Final tightening of the set screws

VERTICALE® PRODUCT INFORMATION

VERTICALE Implants by ar	ticle number	PI 02
VERTICALE Instruments by	y article number	PI 03

VERTICALE® Implants

VERTICALE
Implant type: Hook
Material: Ti6Al4V ELI

For all other system components such as pedicle screws, rods, standard pedicle screws, and cross connectors, see VERTICALE OPEN Screw Rod System Instrumentation Guide D30000.

Article number	Description	Illustration
S-VPH-1000	VERTICALE Pedicle Hook, small	
S-VPH-1005	VERTICALE Pedicle Hook, large	
S-VPH-1010	VERTICALE Lamina Hook, small	
S-VPH-1015	VERTICALE Lamina Hook, large	
S-VPH-1020	VERTICALE Supralamina Hook, small	
S-VPH-1025	VERTICALE Supralamina Hook, large	
S-VPH-1030	VERTICALE Offset Hook, left	
S-VPH-1035	VERTICALE Offset Hook, right	
S-VPH-1040	VERTICALE Sublamina Hook, small	
S-VPH-1045	VERTICALE Sublamina Hook, large	
Il implants are single :	sterile packed.	
S-VMS-2025	VERTICALE Set Screw 1S Torx 25	

Set screws are double sterile packed.

VERTICALE® Instruments

Article number	Description	Illustration
VI-2010	VERTICALE Facet Finder	
VI-2020	VERTICALE Pedicle Finder	
VI-2030	VERTICALE Lamina Elevator	
VI-2035	VERTICALE Lamina Elevator, small	
VI-2040	VERTICALE Hook Pusher	
VI-2050	VERTICALE Hook Holder	
VI-2060	VERTICALE Hook Holder Forceps	
VI-2070	VERTICALE Hook Positioner	

Notes



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