silony® MEDICAL

VERTICALE® HOOKS

INSTRUMENTATION GUIDE

MADE IN GERMANY

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NOTE: This instrumentation guide supplements the guide for the VERTICALE Posterior Spinal Fixation System and refers to the steps for implantation of hooks. 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. 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.

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

The VERTICALE system is indicated for use in the thoracic and lumbar spine, and 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 prohibited 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 successful result
- 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® 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 inside 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

VI-2010
VERTICALE Facet Rasp

VI-2020
VERTICALE Pedicle Elevator

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 Rasp (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 Elevator. To do so, place the instrument between the lower and the upper facet joint (Fig. 2). Ensure that the VERTICALE Pedicle Elevator 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 Rasp. Move the VERTICALE Pedicle Elevator 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.

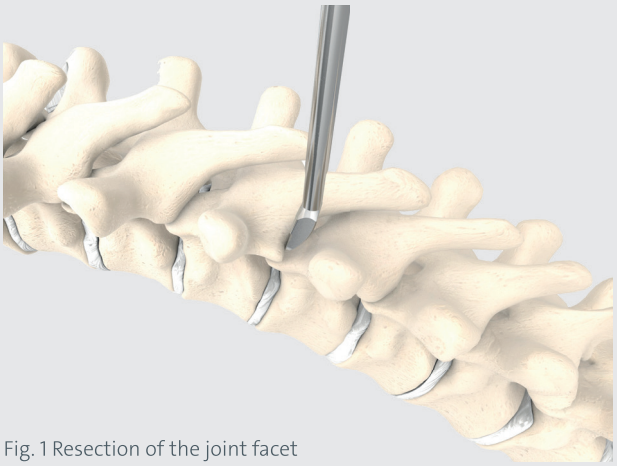

Fig. 1 Resection of the joint facet

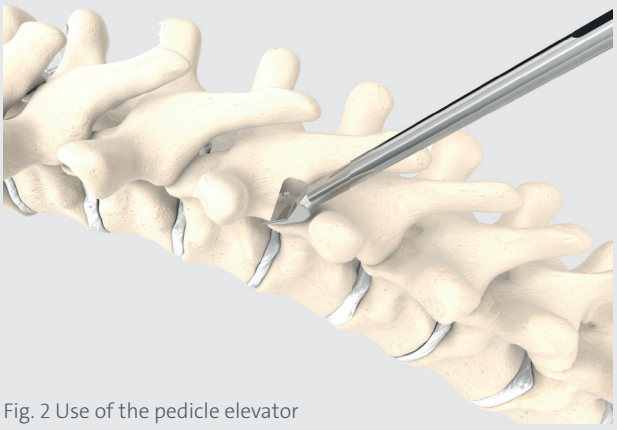

Fig. 2 Use of the pedicle elevator

Insertion and positioning of the pedicle hook

VI-2040
VERTICALE Hook
Pusher

VI-2050
VERTICALE Hook Holder

VI-2060
VERTICALE Hook Holder
Forceps

VI-2070
VERTICALE Hook Positioner

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. 3a Preparation of the hook holder

Fig. 3b Attachment of the hook in the hook holder

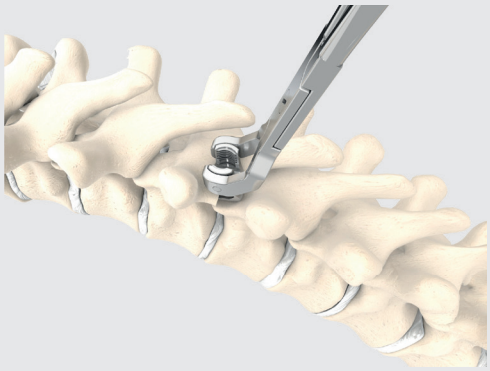

Fig. 4 Positioning the pedicle hook

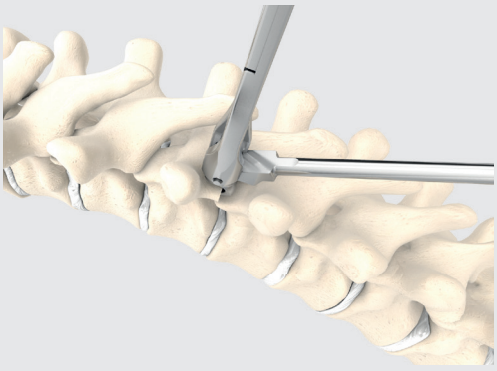

Fig. 5 Positioning the pedicle hook with straight holder forceps

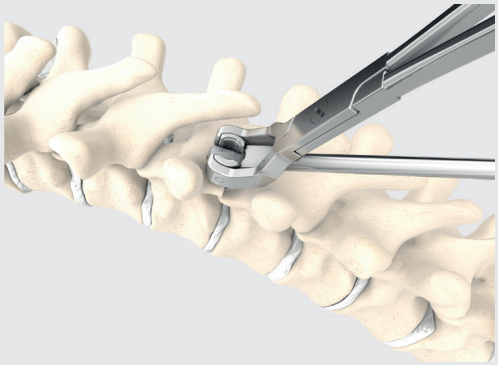

Fig. 6 Correction of the position using the pusher

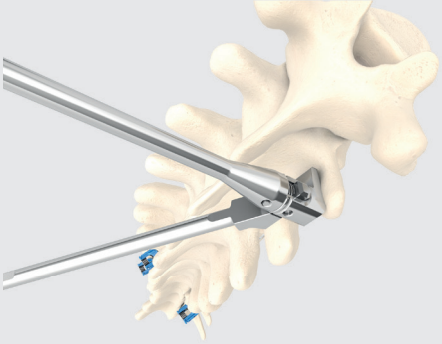

Fig. 7 Correction of the position using the positioner

Exposure of the transverse process

VI-2010
VERTICALE Facet Rasp

VI-2030
VERTICALE Lamina Elevator

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 Rasp.

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 Rasp.

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.

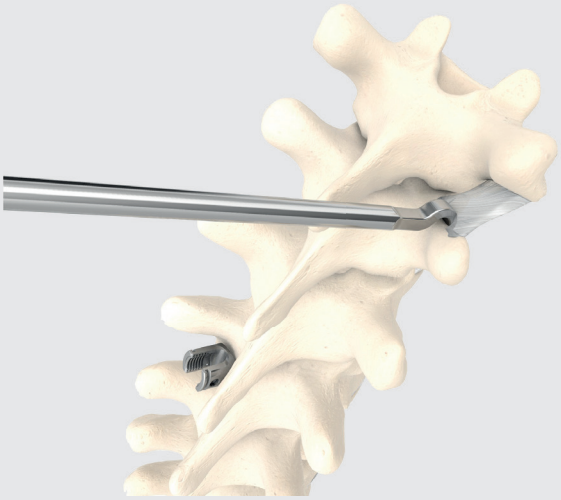

Fig. 8 Exposure of the transverse process

Insertion and positioning of the lamina hooks

VI-2040
VERTICALE Hook Pusher

VI-2050
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.

Positioning the sublamina hook and the supra-laminar hook

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.

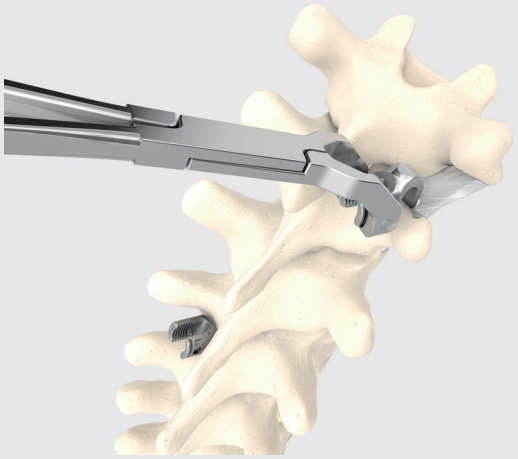

Fig. 9 Positioning the lamina hook

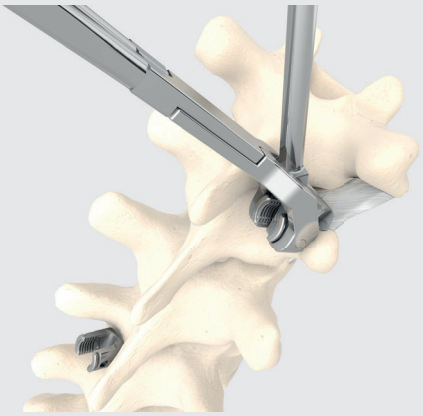

Fig. 10 Correction of the position using the pusher

Offset Hooks

VI-2040
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 Rasp.
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 Rasp.
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.

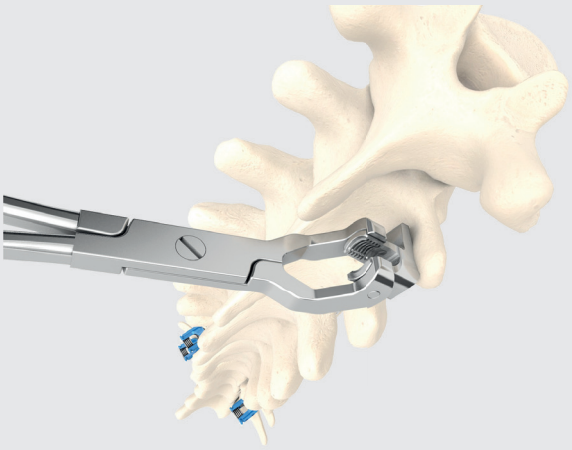

Fig. 11 Positioning the offset hook

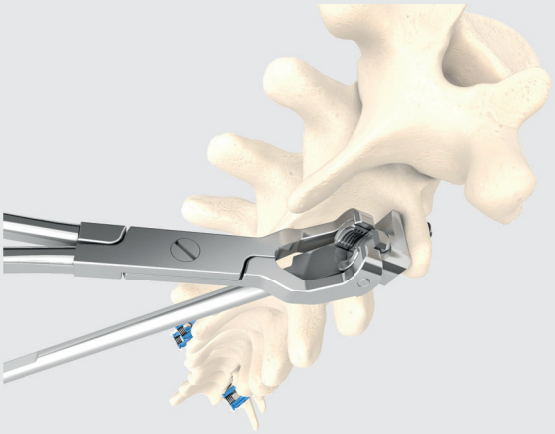

Fig. 12 Correction of the position using the pusher

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 screws.
A final check of the construction is carried out using x-ray verification images in two planes.
All other steps are described in the Standard Instrumentation Guide for VERTICALE products.

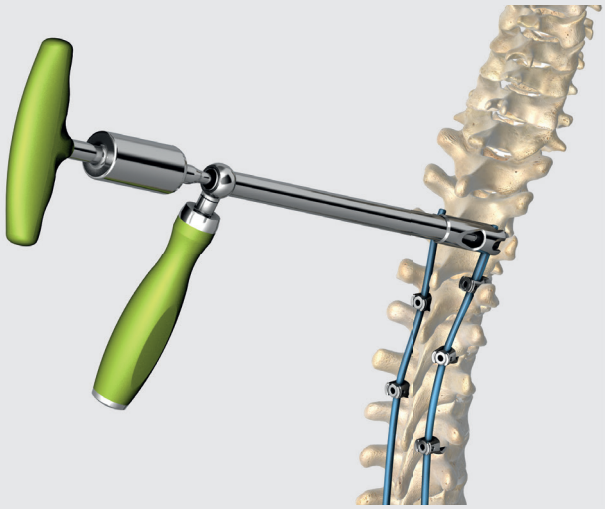

Fig. 13 Final tightening of the set screws

VERTICALE® PRODUCT INFORMATION

VERTICALE Implants
by article number ..... PI 02
VERTICALE Instruments
by article number ..... PI 03

VERTICALE® Implants

System:
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 Basis Instrumentation Guide D30000

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

Article number	Description	Illustration	Page
VI-2010	VERTICALE Facet Rasp		6, 8
VI-2020	VERTICALE Pedicle Elevator		6
VI-2030	VERTICALE Lamina Elevator		8
VI-2035	VERTICALE Lamina Elevator, small		8
VI-2040	VERTICALE Hook Pusher		7
VI-2050	VERTICALE Hook Holder		7
VI-2060	VERTICALE Hook Holder Forceps		7
VI-2070	VERTICALE Hook Positioner		7

Notes

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D30041.b.EN 15.09.2017