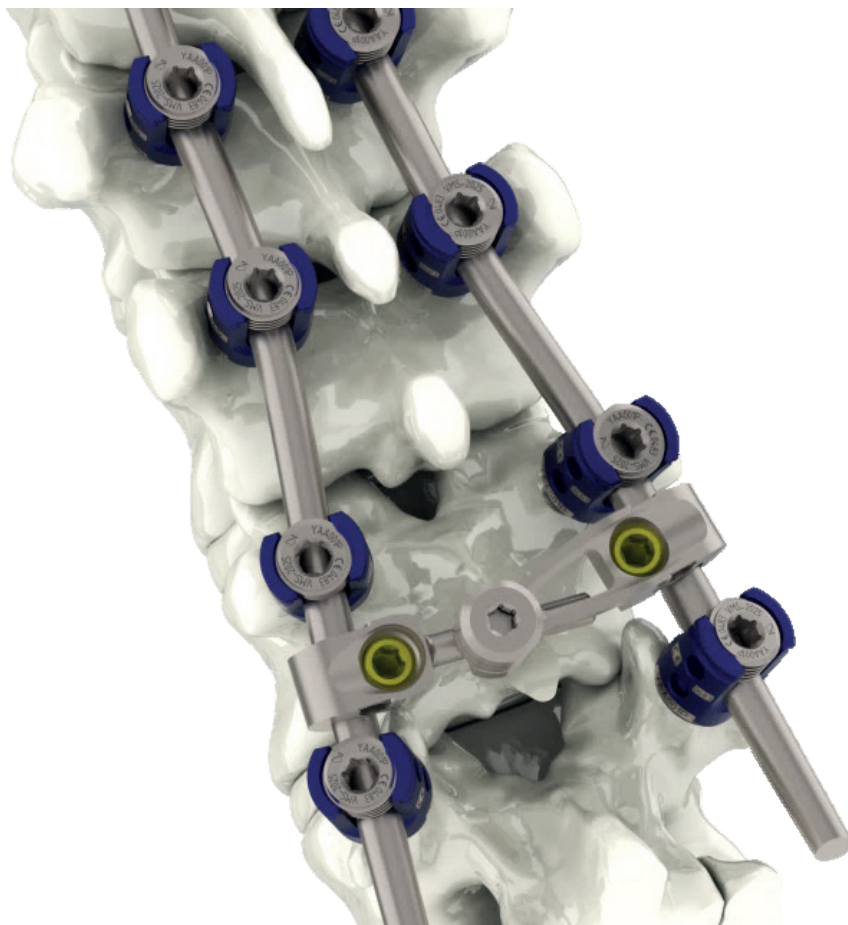


VERTICALE[®] CROSS-CONNECTOR

INSTRUMENTATION GUIDE



MADE IN GERMANY

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NOTE: The following guide is intended to familiarize you with the surgical procedure and use of the VERTICALE Cross-Connector and the associated instruments. This instrumentation guide supplements the guide for the VERTICALE Screw Rod System. 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 in the appendix of this guide.

This guide does not replace briefing by a surgeon 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[®] – CROSS-CONNECTOR

The VERTICALE Cross-Connector is an extension to the dorsal VERTICALE Screw Rod System with the addition of pre-mounted lumbar cross-connectors. Compared to cross-connectors that are mounted intraoperatively, the VERTICALE Cross-Connector is quick and easy to use. The optimized design ensures rotational stability between the rods.

Like all other implants and instruments developed by Silony Medical, the VERTICALE Cross-Connector is a "living system". Whether instrument or implant—we are constantly working to expand and improve our systems in order to optimally meet the needs of patients, physicians, and hospital nursing staff.

To meet the needs of surgeons in the best possible manner, we collaborate as part of every product development project with a group of renowned surgeons, the Medical Advisory Board (MAB). Starting from the initial concept for the 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 a Process Advisory Board (PAB) for every development project in addition to the MAB. 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 all the MAB surgeons and PAB clinicians who were involved in this development.

Indications

The VERTICALE 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 dorsal pedicle screw fixation:

- Degenerative disc diseases
- Spondylolisthesis of all etiologies
- Stenoses
- 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. 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: Ventral interbody support in the form of an intervertebral implant device, such as a ROCCIA 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.

VERTICALE® CROSS-CONNECTOR INSTRUMENTATION

In the following section, only those specific steps that are required to insert the lumbar cross-connectors are described. For a general instrumentation guide for dorsal VERTICALE standard instrumentation that forms the basis of all subsequent work steps with additional instruments and implants, we ask that you study the current guide for the VERTICALE OPEN Screw Rod System (D30000). The use of the cross-connector that is mounted intraoperatively and multisegmental instrumentations are also explained in this guide.

Selecting the cross-connector

The VERTICALE Cross-Connectors have adjustable sizes that mean they can be individually selected according to the patient's anatomy. To enable faster and easier identification, the VERTICALE Cross-Connectors are color coded by size (Fig. 1). Individual alignment of the implant on the screw-rod construction is enabled by two rotational axes (Fig. 2).



Fig. 1 Cross-connector sizes incl. color coding.

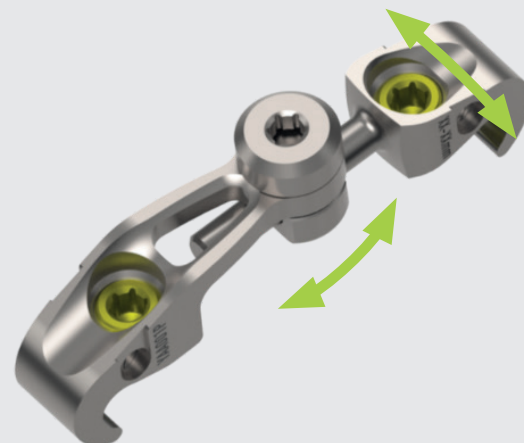


Fig. 2 Rotational and angular adjustment.

Determining the size

VI-1840
VERTICALE Cross-Connector
Size Indicator



To determine the size, the VERTICALE Cross-Connector Size Indicator is used; the ends of the jaws of the size indicator correspond to the size of the cross-connector ends. This enables the user to check if the implant fits between the heads of the pedicle screws. To determine the distance between two rods, the wider jaw end of the VERTICALE Cross-Connector Size Indicator is placed at the desired point on a rod. By then spreading the instrument arms apart, the narrower jaw end is placed on the opposing rod (Fig. 3).



Fig. 3 Determining the cross-connector size using the VERTICALE Cross-Connector Size Indicator.

The appropriate cross-connector size is identified using the color markings on the handle area of the instrument which correspond to the color coding of the cross-connectors (Fig. 4). If several color stripes are visible at the same time in the viewing window, the following procedure is recommended for selecting the size of the implant:

- Two color stripes: Select the implant using the larger color stripe
- Three color stripes: Select the implant using the middle color stripe

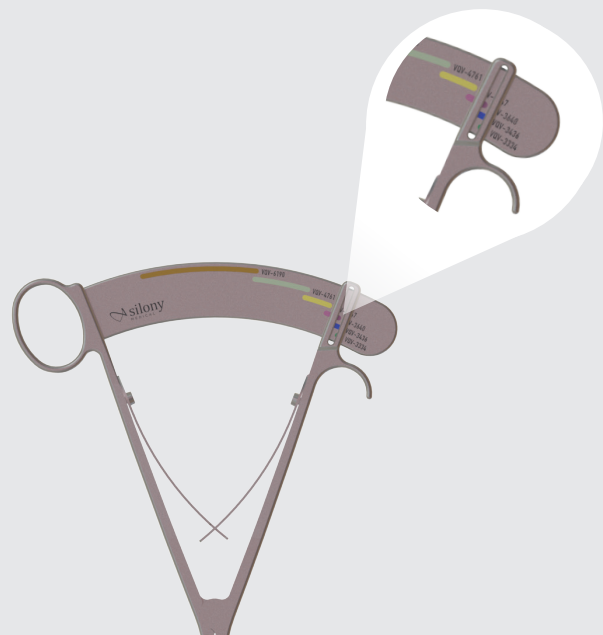


Fig. 4 VERTICALE Cross-Connector Size Indicator color scale.

NOTE: Ensure that no force is applied to the catch of the size indicator when determining the size of the implant. The result may otherwise be imprecise and indicate the use of an implant that is too large!

Preparing the cross-connector

VI-1810
VERTICALE T20 Screwdriver
7 Nm



After removing the pre-mounted cross-connector from the sterile packaging, the set screws must first be screwed out counter-clockwise using the VERTICALE T20 Screwdriver 7 Nm until they are at about the height of the upper edge of the particular catch (Fig. 5). The cross-connector can then be inserted.



Fig. 5 Preparing the cross-connector by screwing out the set screws.

NOTE: Ensure that the set screws are not completely removed from the catch when screwing them out.

Inserting and pre-fixing the cross-connector

VI-1810
VERTICALE T20 Screwdriver
7 Nm



VI-1830
VERTICALE Rod and
Cross-Connector Holder



The pre-mounted cross-connector is picked up with the VERTICALE Rod and Cross-Connector Holder and placed at the required position on the rods (Fig. 6). After positioning the cross-connector on the rods, first the lateral set screws and then the medial screw are temporarily fixed using the VERTICALE T20 Screwdriver 7 Nm (Fig. 7).

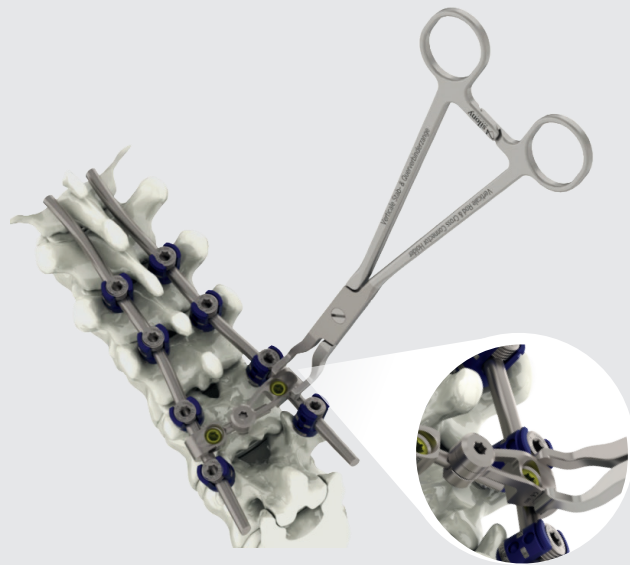


Fig. 6 Positioning of the cross-connector with the VERTICALE Rod and Cross-Connector Holder.

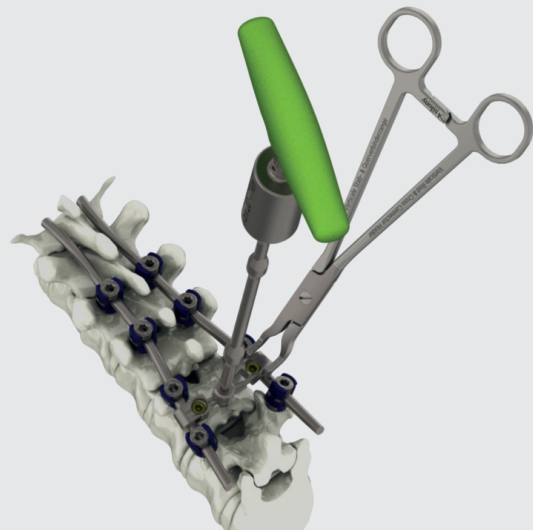


Fig. 7 Pre-fixing the medial screws with the VERTICALE T20 Screwdriver 7 Nm.

NOTE: The cross-connector must be able to be placed on the rods with no tension during the assembly. Otherwise, the next larger size must be used.

Final tightening of the set screws

VI-1810
VERTICALE T20 Screwdriver
7 Nm



VI-1850
VERTICALE Cross-Connector
Counter Torque lat.



VI-1860
VERTICALE Cross-Connector
Counter Torque med.



The VERTICALE T20 Screwdriver 7 Nm is guided through the VERTICALE Cross-Connector Counter Torque until the tip of the screwdriver protrudes over the working end of the counter torque. Then the screwdriver tip is inserted into one of the two lateral set screws of the cross-connector and the counter torque is pushed downward over the cross-connector (Fig. 8). The outwardly curved surface on the working end of the VERTICALE Cross-Connector Counter Torque lat. must be placed on the cross-connector facing the lateral direction. The set screws are finally tightened with the VERTICALE T20 Screwdriver 7 Nm by turning the screwdriver clockwise. An audible click indicates that the torque has been reached. This process is repeated for the contra-lateral screw.

Then the medial screw is also tightened with the VERTICALE T20 Screwdriver 7 Nm using the VERTICALE Cross-Connector Counter Torque med. until a clear click indicates that the screw has been securely fixed (Fig. 9). It is also recommended here to first guide the VERTICALE T20 Screwdriver 7 Nm through the VERTICALE Cross-Connector Counter Torque med. until the torx (star tip) of the screwdriver protrudes over the working end of the VERTICALE Cross-Connector Counter Torque med. We recommend ensuring that the screw is correctly seated by repeatedly tightening with the torque limiter. This is confirmed by two clicking sounds.

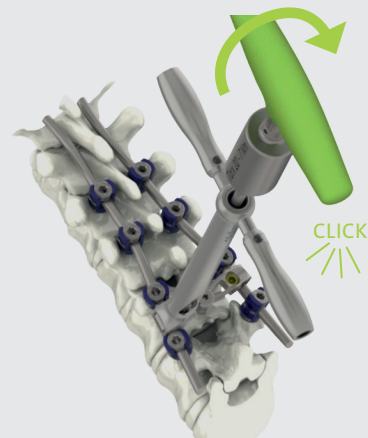


Fig. 8 Final fixation of the lateral set screws with the VERTICALE T20 Screwdriver 7 Nm and the VERTICALE Cross-Connector Counter Torque lat.

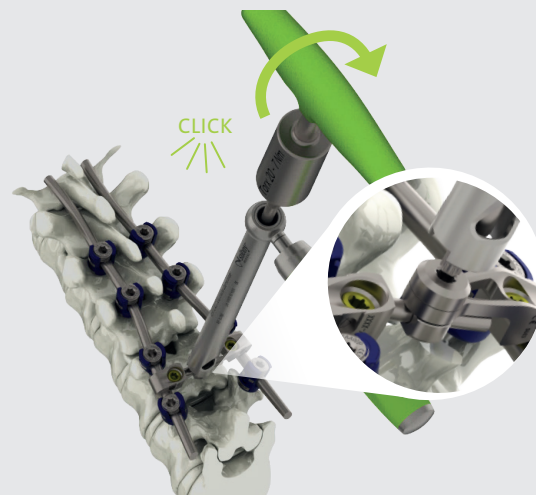


Fig. 9 Final fixation of the medial set screw with the VERTICALE T20 Screwdriver 7 Nm and the VERTICALE Cross-Connector Counter Torque med.

Removing the implants

VI-1810
VERTICALE T20 Screwdriver
7 Nm



VI-1830
VERTICALE Rod and
Cross-Connector Holder



VI-1850
VERTICALE Cross-Connector
Counter Torque lat.



VI-1860
VERTICALE Cross-Connector
Counter Torque med.



To remove the cross-connector, proceed by reversing the implantation sequence. To do so, first loosen the lateral set screws and then the medial screw. For this step it is recommended to use both counter torques. The two lateral set screws are screwed out counter-clockwise using the VERTICALE T20 Screwdriver 7 Nm until they are approximately flush with the upper edge of the particular catch (Fig. 10). After the screws have been loosened, the implant can be picked up and removed with the VERTICALE Rod and Cross-Connector Holder.









Fig. 10 Loosening the set screws counter-clockwise.

NOTE: Ensure that the set screws are not completely removed from the catch when screwing them out.

VERTICALE® CROSS-CONNECTOR PRODUCT INFORMATION

VERTICALE Cross-Connector Implants by article number	PI 02
VERTICALE Cross-Connector Instruments by article number.....	PI 03

VERTICALE[®] Cross-Connector Implants

Article number	Description	Illustration
S-VQV-3334	VERTICALE Cross-Connector, 33–34 mm	
S-VQV-3436	VERTICALE Cross-Connector, 34–36 mm	
S-VQV-3640	VERTICALE Cross-Connector, 36–40 mm	
S-VQV-3947	VERTICALE Cross-Connector, 39–47 mm	
S-VQV-4761	VERTICALE Cross-Connector, 47–61 mm	
S-VQV-6190	VERTICALE Cross-Connector, 61–90 mm	

Product classification: All implants listed here correspond to class IIb (CE₀₄₈₃) as defined by the Medical Device Directive (MDD 93/42/EEC) unless otherwise explicitly indicated.


VERTICALE® Cross-Connector Instruments

Article number	Description	Illustration	Page
VI-1810	VERTICALE T20 Screwdriver 7 Nm		8, 9, 10, 11
VI-1830	VERTICALE Rod and Cross-Connector Holder		9, 11
VI-1840	VERTICALE Cross-Connector Size Indicator		7
VI-1850	VERTICALE Cross-Connector Counter Torque lat.		10, 11
VI-1860	VERTICALE Cross-Connector Counter Torque med.		10, 11

Product classification: All instruments listed here correspond to class I (CE) as defined by the Medical Device Directive (MDD 93/42/EEC) unless otherwise explicitly indicated.



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