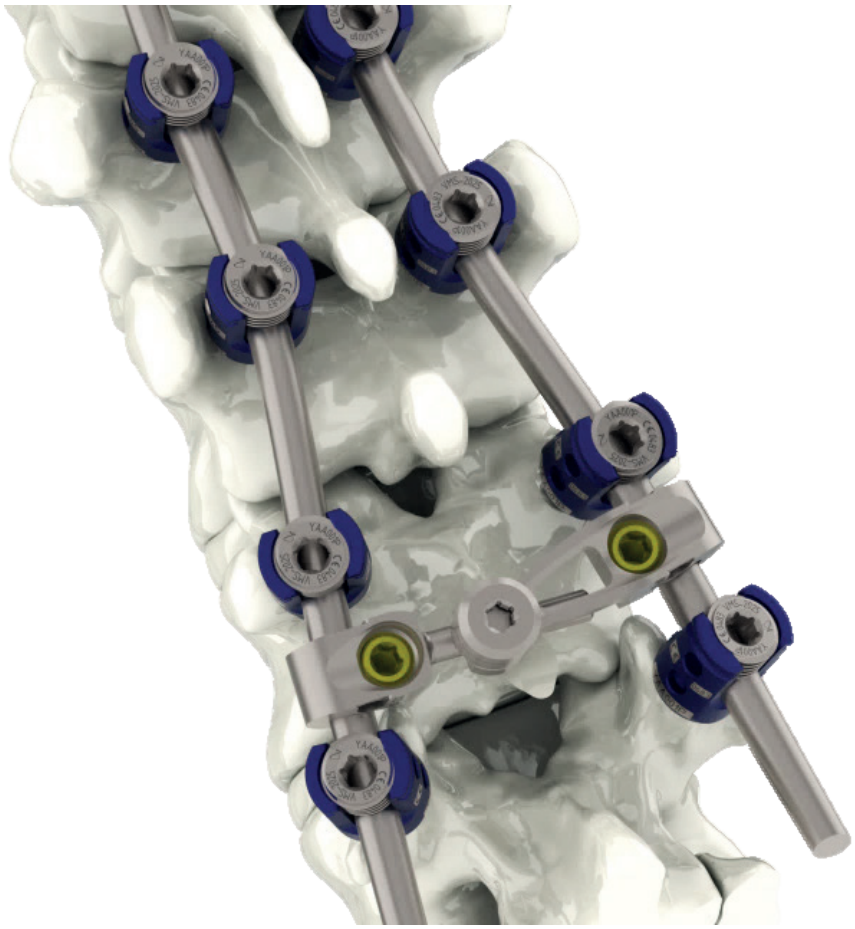
silony® SPINE

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.

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 Spine, 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.

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

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® 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).

Selecting the Cross-Connector

The VERTICALE Cross-Connectors have adjustable sizes and 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.

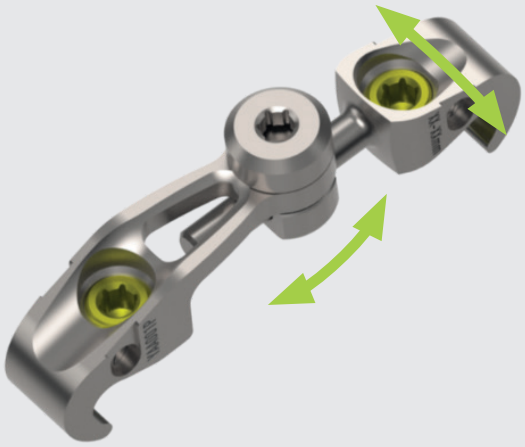

Fig. 2 Rotational and angular adjustment.

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.

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

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

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).

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.

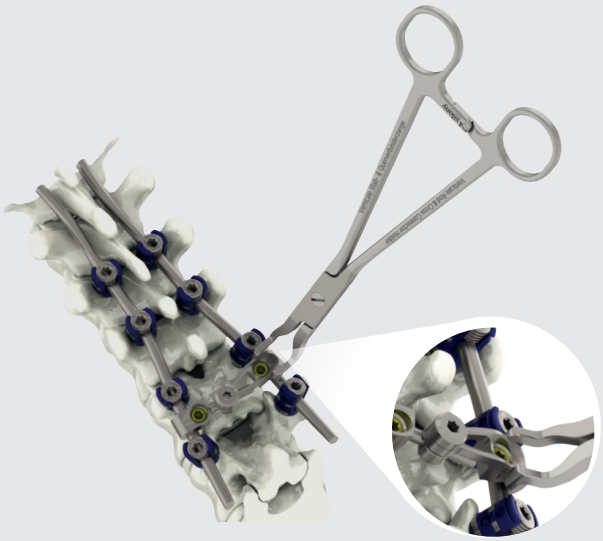

Fig. 6 Positioning of the cross-connector with the VERTICALE Rod and Cross-Connector Holder.

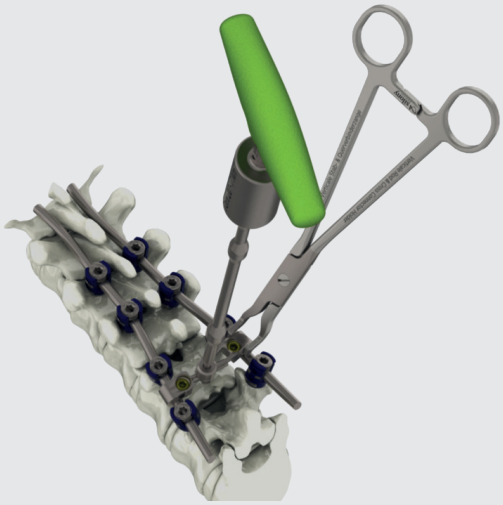

Fig. 7 Pre-fixing the medial screws with the VERTICALE T20 Screwdriver 7 Nm.

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.

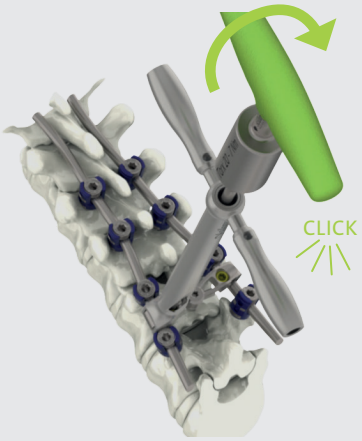

Fig. 8 Final fixation of the lateral set screws with the VERTICALE T20 Screwdriver 7 Nm and the VERTICALE Cross-Connector Counter Torque lat.

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.

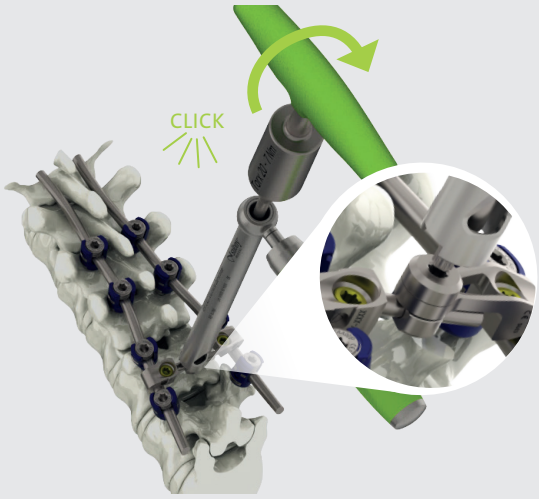

Fig. 9 Final fixation of the medial set screw with the VERTICALE T20 Screwdriver 7 Nm and the VERTICALE Cross-Connector Counter Torque med.

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

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	

All implants are single sterile packed.

VERTICALE® Cross-Connector Instruments

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

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