

# VERTICALE<sup>®</sup> SI FIXATION SYSTEM

INSTRUMENTATION GUIDE



MADE IN GERMANY

# TABLE OF CONTENTS

Preface .....	3
Indications / contraindications .....	4
INSTRUMENTATION .....	5
Position and planning .....	6
Intraoperative C-arm imaging .....	7
Landmarks for stab incision .....	8
Placement of guide wire .....	9
Placement of an SI screw with washer .....	11
Placement of screw .....	13
Placement of an SI screw with plate .....	16
Augmentation of the SI screw .....	23
PRODUCT INFORMATION	
Implants .....	PI 02
Instruments .....	PI 04
Alphabetical index .....	PI 06

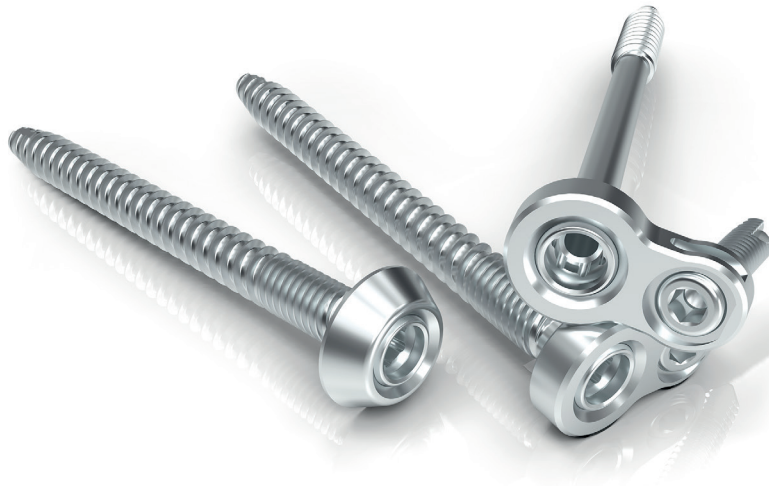
**NOTE:** This guide describes the instrumentation of the VERTICALE® SI Fixation System. - This guide does not replace briefing by a physician experienced in the instrumentation used in spinal surgery.

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

## INTRODUCTION

# VERTICALE® SI FIXATION SYSTEM

The VERTICALE® SI Fixation system is intended for use in posterior pelvic ring and iliosacral stabilization procedures.



### Benefits and features:

- 7.2 mm SI-screws with preassembled polyaxial plate or washer to fit anatomical and pathological requirements
- Fixed-angle locking plate screw to enhance primary fixation of the SI-Screw
- Screw augmentation option
- Quattro-lead thread at proximal screw shaft for enhanced fixation in iliac cortex
- Wide screw selection to fit anatomical and pathological requirements
- Full threaded screw in 70-140mm with preassembled plate or washer
- Lag-screw in 70-140mm with preassembled plate

## Indications

The VERTICALE® SI Fixation System is intended to be used in the following medical indications:

- Pelvic ring instabilities
- Iliosacral instabilities

## Contraindications

- Anticipated or documented allergy or intolerance to the materials (e.g. titanium)
- 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 structure
- Missing bone structures that render good anchoring of the implant impossible (e.g. in fractures, tumours or osteoporosis)

**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® SI FIXATION STANDARD INSTRUMENTATION

## Position and planning

The prone position is used for access to the sacrum and posterior SI regions.

Prior to starting the procedure fluoroscopic AP, inlet and outlet x-rays should be obtained to ensure adequate visualization.

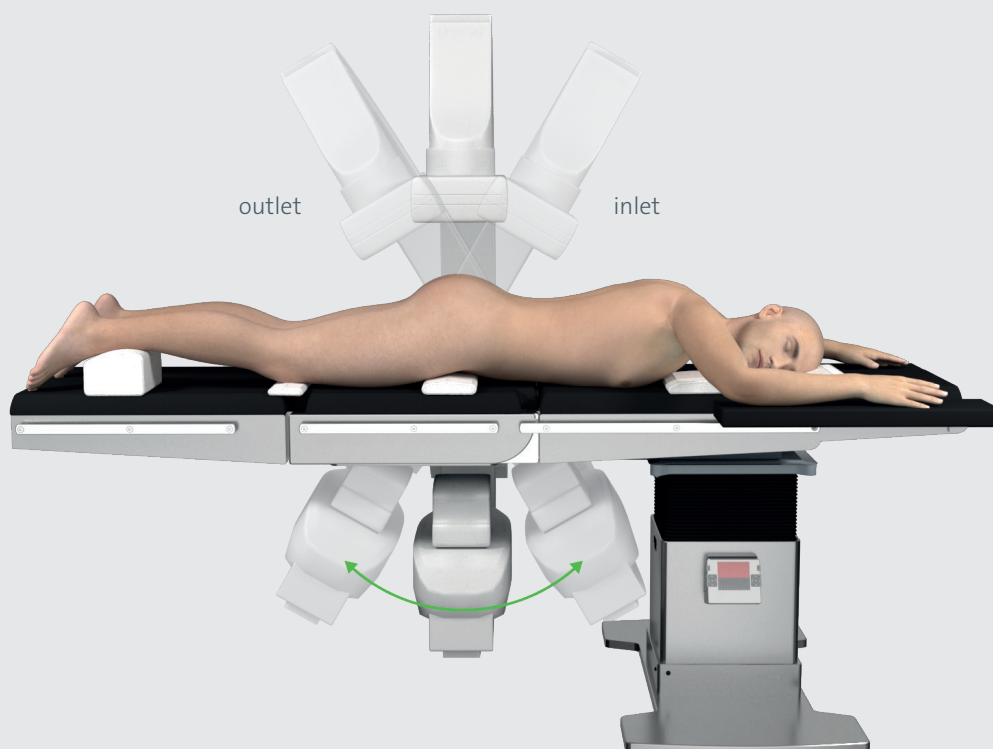


Fig. 1 Intra-operative imaging control

# Intraoperative C-arm imaging

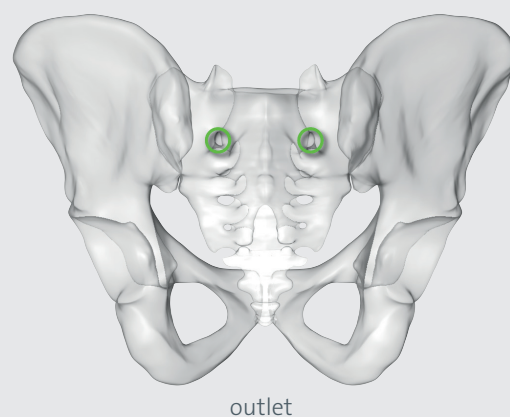
During setup for surgery, it is important to confirm the adequacy of fluoroscopic imaging. This is essential to avoid errors in SI-screw placement.

The following should be clearly identifiable:

- sacral foramina (outlet view)
- spinal canal (inlet view)
- S1 body (inlet view)

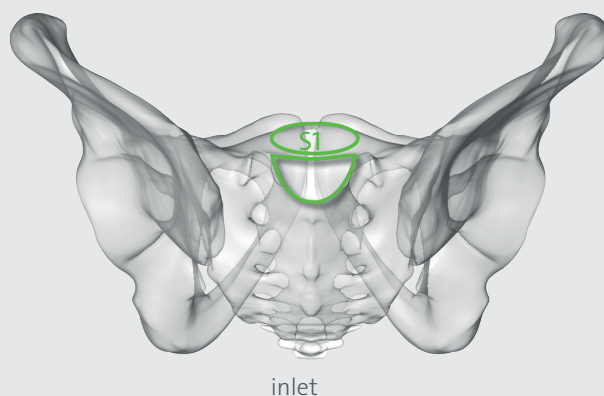
If these structures cannot be clearly seen, a safe trajectory for the SI screw cannot be determined.

It is recommended that before beginning an SI screw fixation procedure, appropriate preoperative planning for screw length, trajectory and location needs to be verified.



outlet

Fig. 2 Intra-operative imaging - outlet view



inlet

Fig. 3 Intra-operative imaging - inlet view

## Landmarks for stab incision

On a lateral projection, identify the S1 body and iliac cortical densities (ICDs), here overlapping correctly.

The entry point should be posterior in S1 and inferior to the ICD, which parallels the sacral alar slope. The direction of the entry point is usually slightly caudal and posterior. The ICD thus marks the antero-superior boundary of the safe zone for an iliosacral screw. Having a safe entry point avoids injuring the L5 nerve root if it penetrates this cortex.

A 3-4 cm incision is made at the identified site

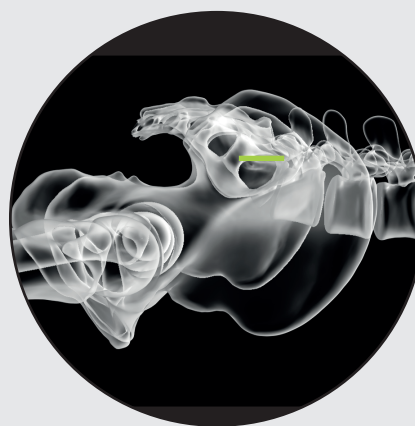


Fig. 4 Intra-operative imaging - lateral view



# Placement of guide wire

RI-1355  
ROCCIA Slotted Mallet, solid



VI-6050  
VERTICALE Guide wire blunt



VI-6051  
VERTICALE Guide wire trocar



VI-6052  
VERTICALE Guide wire threaded



When the desired entry position is identified, the 3.2mm guide wire is tapped 2-3 mm into the planned screw entry point. Confirmation of position is recommended using imaging intensifier in a lateral view.

If correct entry point is identified the guide wire is advanced 1 cm into the sacral ala according to chosen screw channel.

**NOTE:** If you use a hammer to advance the guide wire the guide wire protection sleeve must be used. Do not hammer on the guide wire tip to avoid damaging the wire.

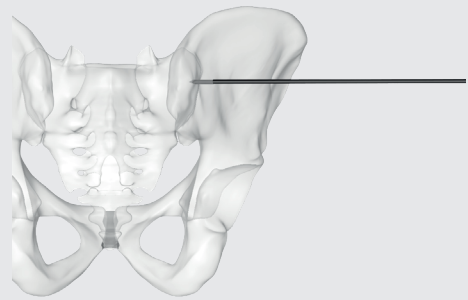


Fig. 5 Placement of guide wire - outlet view

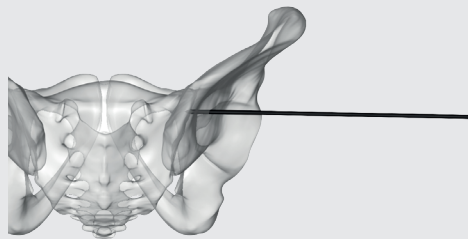


Fig. 6 Placement of guide wire - inlet view

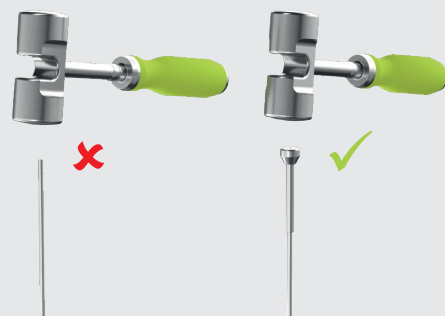


Fig. 7 Do not use a hammer with the guidewire without protection sleeve

## Placement of guide wire

Once the guidewire tip is lateral to the neural foramen in the outlet view, confirm that it is in the desired position using fluoroscopic imaging.

The desired trajectory is within, but close to the anterior alar cortex on the inlet view, and cranial to the ventral foramen of the 1st sacral nerve root.

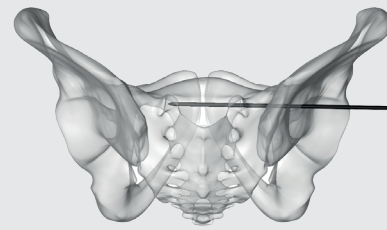
If the trajectory of the guidewire would compromise either the sacral foramen or the spinal canal, the guidewire is removed and then reinserted from a similar entry point but in a corrected trajectory.

When the correct trajectory for the guidewire is confirmed, it is further advanced to the S1 vertebral body.

When the guide wire reaches the centre of S1, the position is again verified in lateral, inlet, and outlet view.

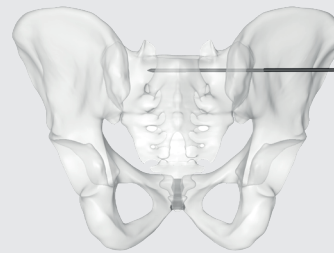
Advance the guide wire into the desired position for the SI-screw placement and length.

The wire must be far enough from cortices and neural foramina to accommodate the desired SI-screw.



inlet.

Fig. 8 Placement of guide wire - inlet view



outlet.

Fig. 9 Placement of guide wire - outlet view

## Placement of an SI screw with washer

VI-6023  
VERTICALE Dilator 17



VI-4024  
VERTICALE MIS Dilator 4  
(20 mm)



For blunt preparation of the tissue to access the iliac cortex, the 17mm Dilatation tube is placed over the wire. Slide the VERTICALE MIS Dilator (20 mm) over the 17 mm Dilatation Tube and push it down onto the iliac cortex. The 17 mm Dilatation Tube is removed. The Working Tube provides sufficient room for a protective screw bed preparation using an awl or drill and for the insertion of the SI-screw with washer.

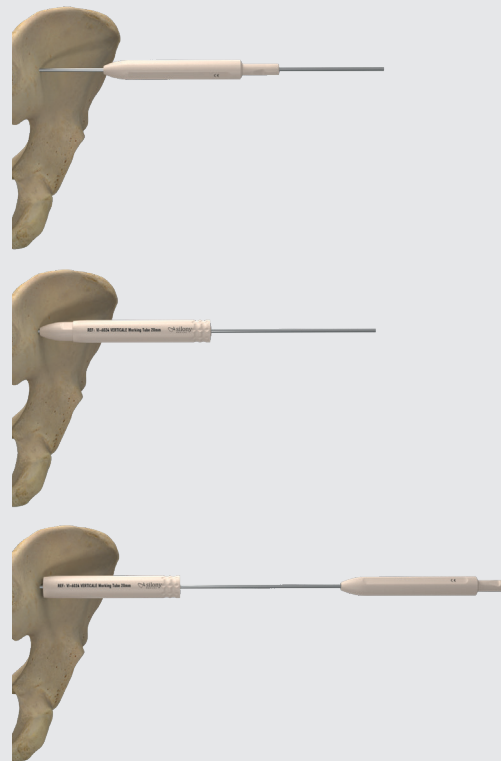


Fig. 10 Dilatation of soft tissues to perform lateral access to the os ilium

VI-6860  
VERTICALE SI Screw Indicator



The screw length is measured using the VERTICALE SI Screw Indicator, which is guided over the guide wire and pushed onto the iliac cortex. The end of the guide wire indicates to the appropriate length of the SI-screw.

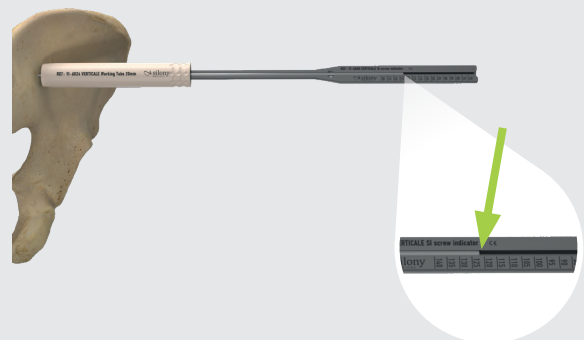


Fig. 11 Identification of screw length.

## Placement of an SI screw with washer

VI-6070  
VERTICLE Probe with ball



VI-6192  
VERTICLE Drill Bit, cannulated



In normal bone the screw bed may be prepared for correct screw insertion using the VERTICLE Probe with ball tip to open the iliac cortex and the cannulated VERTICLE Drill Bit, to over-drill the guide wire to enhance SI-screw insertion.

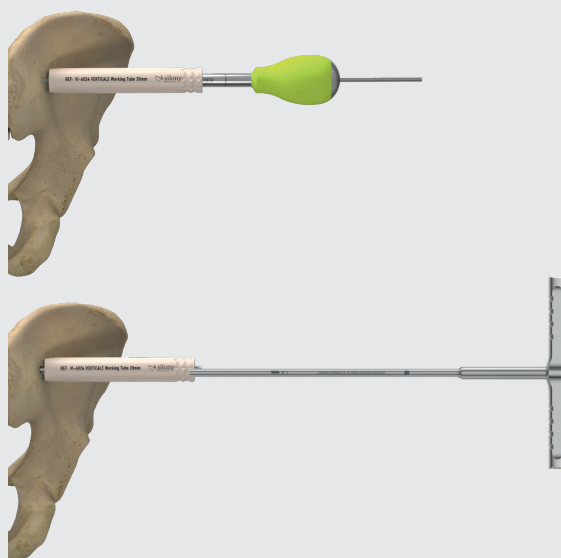


Fig. 12 Preparation of bone bed with probe and drill.

## Placement of screw

VI-6700.1  
VERTICALE Screw Driver shaft



VI-6700.2  
VERTICALE Screw Driver outer sleeve



VI-6700.3  
VERTICALE Screw Driver sleeve lock



VI-6730 I  
VERTICALE SI Screw Loading Tool



The selected VERTICALE SI-Screw with washer is attached to the VERTICALE SI Screw Driver. Insert the screw loading tool through the Screw driver shaft. The pin guides the SI-screw driver aligned to the screw interface to aid/improve attachment. Insert the screw driver shaft into the screw driver outer sleeve first. The tip (1) of the screw driver shaft must be placed into the torx interface of the SI-screw head and the outer sleeve is screwed completely into the thread of the SI-screw head (2). Attach the VERTICALE Screw Driver Sleeve Lock and mount it tight (3). A green line indicates that the SI screw driver is fully mounted onto the SI-screw.



Fig. 14 Assembly of the SI screw driver step 2.



Fig. 15 Assembly of the SI screw driver step 3.



Fig. 16 Assembly of the SI screw driver step 4.



Fig. 13 Assembly of the SI screw driver step 1.

## Placement of screw

GI-2111  
Ratchet T-Handle, short



Attach the T-handle and guide the screw over the guide wire. Control screw insertion and guide wire position using imaging intensive control.

In normal bone the force for screw insertion will increase as the washer reaches the iliac cortex.

Tactile feed-back may not be observed in soft bones. It is therefore recommended to control the positioning of the washer onto the iliac cortex in an oblique inlet view.

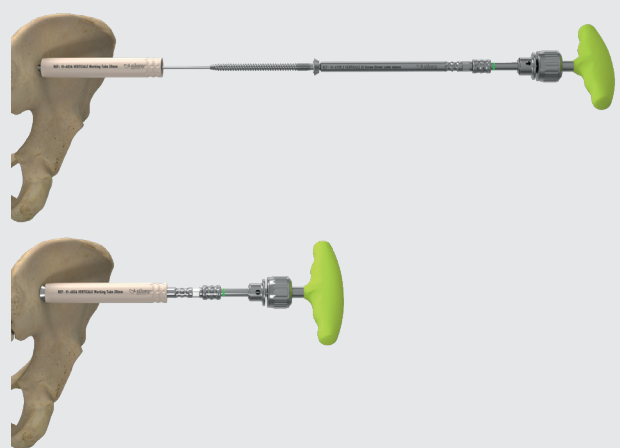


Fig. 17 Insertion of SI screw

VI-6000  
VERTICALE Holding Clamp



When the SI-screw reaches the desired position the guide wire is removed.

If indicated the SI-screw may be augmented (see page 23).

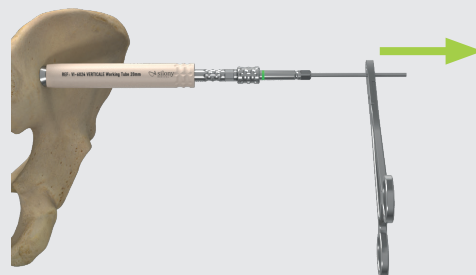


Fig. 18 Removal of guide wire.

**NOTE:** The SI screw driver is maintained in place if screw augmentation is planned.

## Placement of screw

VI-6720  
VERTICALE SI Wrench



To remove the SI-screw driver, firstly the sleeve lock is removed. Secondly, unscrew the SI-screw driver outer sleeve. The VERTICALE SI Screw Driver Removal Tool may be used to detach the outer sleeve if necessary. If the outer sleeve is fully unthreaded the SI-screw driver can be removed without resistance.

Remove the 20mm working tube.

Upon completion of the SI-screw procedure, use fluoroscopy images to confirm the correct placement of the SI-screw. This should include AP, inlet, outlet, and lateral images of the posterior pelvis.

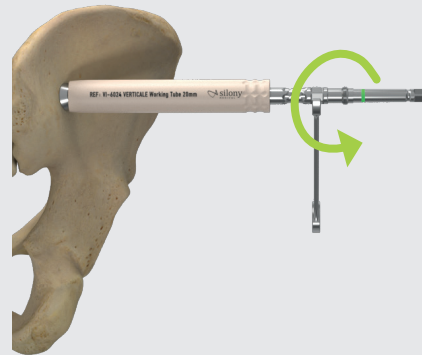


Fig. 19 Removal of SI screw driver

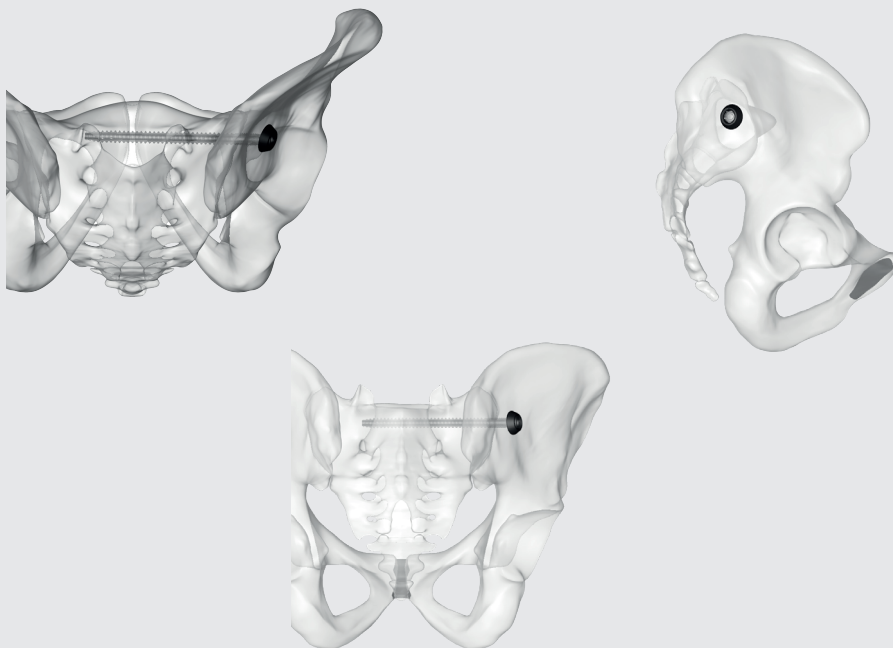


Fig. 20 Verification of final implantation using imaging intensifier control in inlet, outlet and lateral view.

## Placement of an SI screw with plate

VI-6070  
VERTICALE Probe with ball tip



VI-6192  
VERTICALE Drill Bit, cannulated



VI-6860  
VERTICALE SI Screw Indicator



After placement of the guide wire in the desired position the tissues are dissected down to bone, by spreading with an appropriate blunt clamp, or with scissors to ensure a 3-4 cm access to the iliac cortex for a protective screw bed preparation using the awl with stop or the drill.

The screw length is measured with the VERTICALE SI Screw Indicator, which is guided over the guide wire and pushed onto the iliac cortex. The end of the guide wire indicates the appropriate length of the SI-screw.

In normal bone the screw bed may be prepared for proper screw insertion using the VERTICALE Probe with ball tip to open the iliac cortex and the cannulated VERTICALE Drill Bit with T-handle to over-drill the guide wire to enhance SI-screw insertion.



Fig. 21 Identification of screw length.

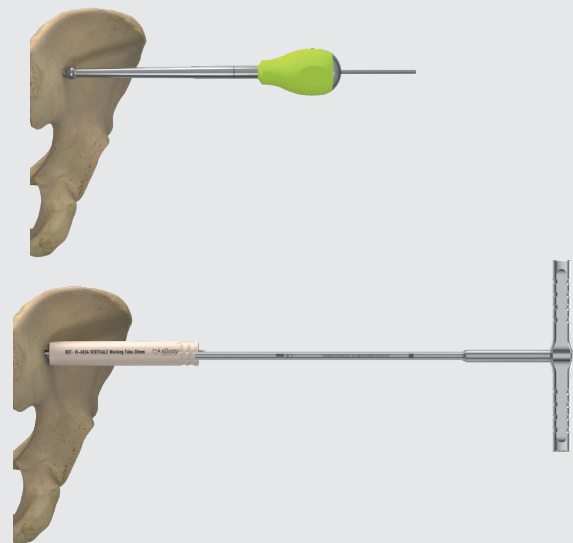


Fig. 22 Preparation of bone using probe and drill.



# Placement of an SI screw with plate

VI-6700.1 VERTICALE SI Screw  
Driver shaft



VI-6700.2 VERTICALE SI Screw  
Driver outer sleeve



VI-6700.3 VERTICALE SI Screw  
Driver sleeve lock



VI-6751.1 VERTICALE Plate  
inserter inner sleeve



VI-6751.2 VERTICALE Plate  
inserter outer sleeve



The selected SI-screw with plate is attached to the VERTICALE SI Screw Driver: Insert the screw loading tool through the Screw driver shaft. The pin guides the SI-screw driver aligned to the screw interface to enhance attachment. Insert the screw driver shaft into the screw driver outer sleeve first. The torx (1) of the screw driver shaft must be placed into the torx interface of the SI-screw head and the outer sleeve is screwed completely into the thread of the SI-screw head (2). Attach the VERTICALE SI Screw Driver Sleeve Lock and mount it tight (3). A green line indicates that the SI screw driver is fully mounted onto the SI-screw.

Slide the VERTICALE SI Plate inserter outer sleeve from lateral onto the plate (4). Insert the VERTICALE SI Plate inserter inner sleeve (5) and lock it to the outer sleeve by a quarter turn (6).



Fig. 23 Assembly of SI Screw driver onto the SI screw step 1.



Fig. 24: Assembly of SI Screw driver onto the SI screw step 2.

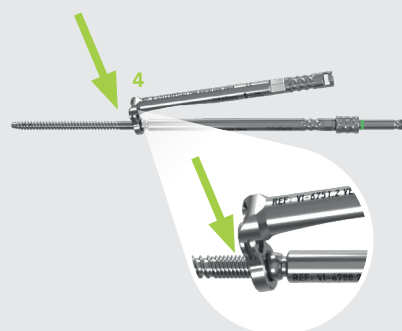


Fig. 25 Assembly of the Plateholder onto the SI plate - Step 1.

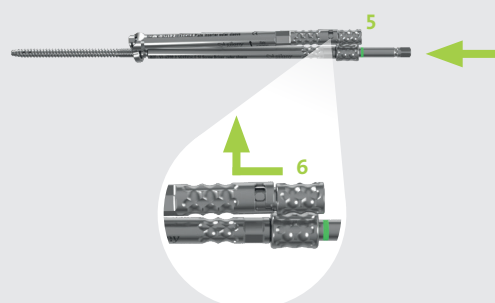


Fig. 26 Assembly of the Plateholder onto the SI plate - Step 2.

# Placement of an SI screw with plate

Attach the T-handle and guide the screw over the guide wire. Control the screw insertion and guide wire position using imaging intensive control.

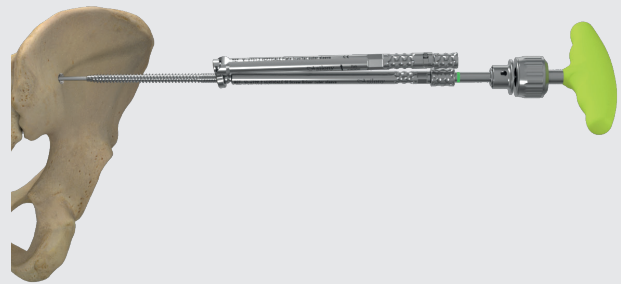


Fig. 27 Insertion of SI screw with plate

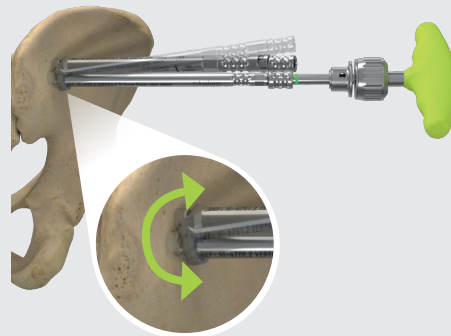


Fig. 28 Orientation of Plate

In a normal bone the force for screw insertion will increase when the plate reaches the iliac cortex. This tactile feed-back may not be observed in soft bones. Therefore it is recommended to control the positioning of the plate onto the iliac cortex in an oblique inlet view until the plate is firmly attached on the iliac cortex. The SI screw should not be inserted completely until the plate is guided into the desired position. If needed unscrew the SI screw until the plate can be moved. A marking on the Plate Insertor outer sleeve indicates the orientation of the plate.

Position the plate into the desired position and enhance the SI screw until the plate is positioned firmly onto the iliac cortex.



Fig. 29 Define final position of the plate.

## Placement of an SI screw with plate

VI-6000  
VERTICALE Holding Clamp



The correct position of the plate onto the cortex can be verified using the VERTICALE SI Plate Indicator. Also the length of the plate fixation screw can be identified. If the line of the plate indicator is visible it indicates that the plate is fully seated onto the iliac cortex.

Remove the guide wire.

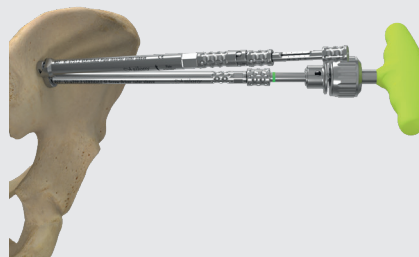


Fig. 30 Determin position of plate onto the os ilium.



Fig. 31 Removal of guide wire.

## Placement of an SI screw with plate

VI-6870.1  
VERTICALE Plate Indicator



VI-6870.2  
VERTICALE Plate Fixation Screw  
Indicator



VI-6720  
VERTICALE SI Wrench

VERTICALE Screwdriver Hex 3.5

VI-6141  
VERTICALE Ratchet T-Handle,  
4Nm



Using the Plate Fixation Screw Indicator the length and position of the plate fixation screw can be verified. The length is indicated on the plate indicator.

Remove the plate indicator and the plate fixation screw indicator.

Attach the selected plate fixation screw to the VERTICALE Screw Driver Hex 3.5. Attach the T-handle with 4Nm torque and guide the Plate fixation screw through the SI Plate inserter. Use the VERTICALE SI Wrench as counter-torque. The screw must be inserted into the bone and the plate using the torque limiting T-Handle 4Nm until there is a tactile release which indicates that the required torque has been applied.

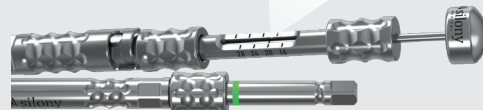
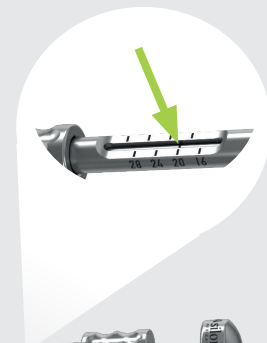


Fig. 32 Indicate required length of the plate fixation screw.



Fig. 33 Insertion of plate fixation screw.

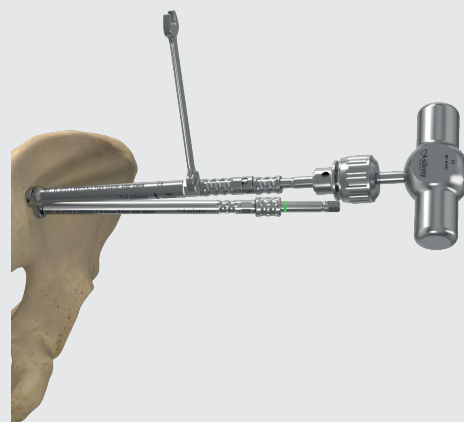


Fig. 34 final tightening of plate fixation screw

## Placement of an SI screw with plate

VI-6720  
VERTICALE SI Wrench



Remove the Screwdriver Hex 3.5.  
If indicated the SI-screw may be augmented (see chapter 8).

**NOTE:** The SI screw driver is maintained if screw augmentation is planned.

To remove the SI-screw driver, firstly remove the sleeve lock. Secondly, unscrew the SI-screw driver outer sleeve. The SI screw driver removal tool may be used to detach the outer sleeve. If the outer sleeve is fully unthreaded, the SI-screw driver can be removed without resistance.

**NOTE:** Remove the SI screw driver before removal of the Plate inserter sleeve.

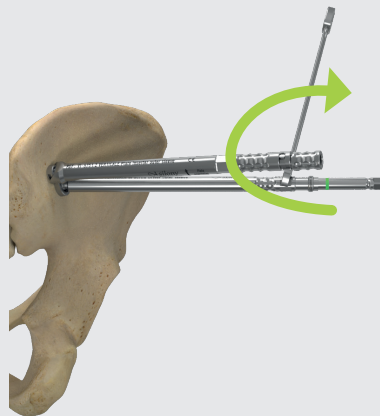


Fig. 35 Removal of SI Screw driver

## Placement of an SI screw with plate

Now unlock the Plate inserter inner sleeve from the outer sleeve by a quarter turn and remove it. The plate inserter outer sleeve must be slipped off the plate. The marking on the sleeve indicates the direction of movement.

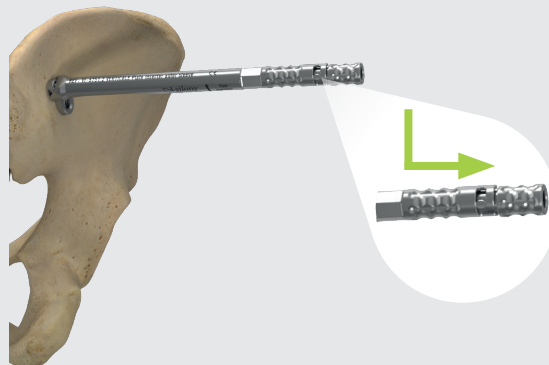


Fig. 36 Removal of SI plate holder - Step 1

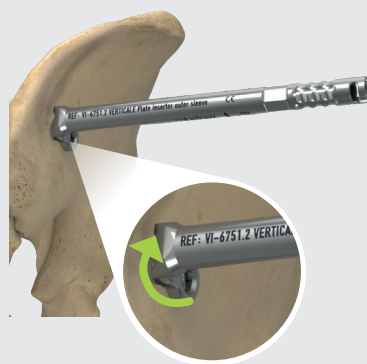


Fig. 37 Removal of SI plate holder - Step 2

Upon completion of the SI-screw with plate procedure, use appropriate imaging to confirm the correct placement of the SI screw. This should include AP, inlet, outlet, and true lateral images of the posterior pelvis.

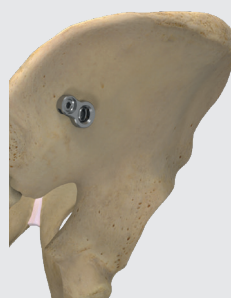


Fig. 38. Final Position of SI screw with plate

# Augmentation of the SI-screw

VI-6510 VERTICALE SI Cement Adapter



S-VI-6500 VERTICALE SI Cement Kit



If required the SI-Screw can be augmented using PMMA bone cement.

For cement augmentation of the VERTICALE SI Screw the VERTICALE SI Cement Kit is needed. The kit contains:

- VERTICALE SI Cement Plug
- VERTICALE SI Cement Cannula
- VERTICALE SI Cement Pusher

When the SI-screw is placed in its desired position the guide wire and T-Handle are removed. The screw driver should remain in position.

To avoid cement extrusion at the distal tip of the SI-screw a plug is applied first. Guide the SI Cement Plug through the screw driver until it reaches the screw-bone interface. Push the plug firmly to the front and turn the handle of the Cement Plug. The tip of the plug breaks off and closes the distal cannulation of the screw.

Now attach the VERTICALE SI Cement Adapter on the screw driver shaft.

The SI Cement Cannula is mounted through the SI Cement Adapter until it firmly locks.

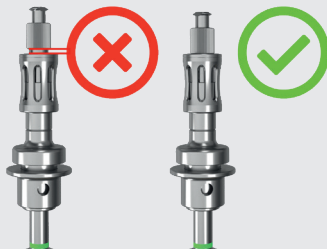


Fig. 39 Insertion of SI screw

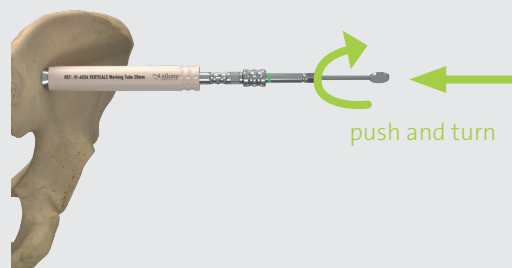


Fig. 40 Close the tip of the SI screw shaft using the SI cement plug.

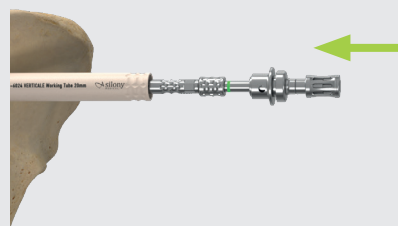


Fig. 41 Attach the SI cement adapter on the SI screw driver shaft.

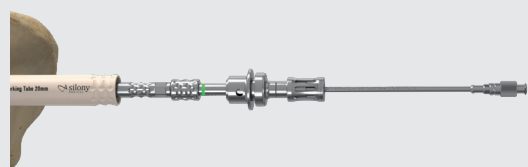


Fig. 42 Insert and lock the SI cement cannula in the SI cement adapter

## Augmentation of the SI-screw

Prepare the cement following appropriate manufacturer guideline and connect the application system to the Luer lock of the cement cannula. Cement application should be performed using imaging intensifier control.

To apply the cement which remains inside the Cement Cannula the Cement Pusher can be used. Remove all instruments.

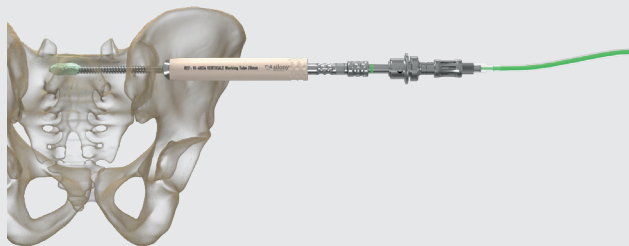


Fig. 43 Application of PMMA cement.

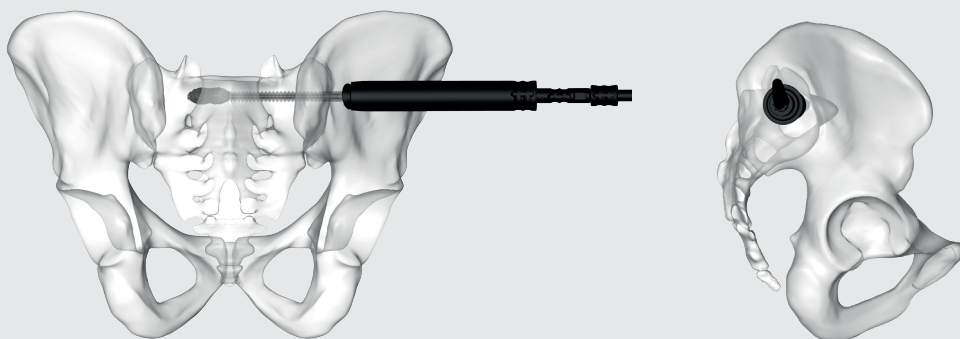


Fig. 44 Control of cement application in outlet and lateral view.



# VERTICALE® SI FIXATION PRODUCT INFORMATION

VERTICALE SI Fixation Implants by article number .....	PI 02 – 07
VERTICALE SI Fixation Instruments by article number .....	PI 08 – 10
VERTICALE SI Fixation Index .....	PI 10 – 11

# VERTICALE® SI Fixation Implants

System:  
VERTICALE

Implant type:  
SI Screw with Washer

Screw shaft diameter:  
7.2 mm

Configuration:  
Polyaxial, cannulated  
and fenestrated shaft,  
full threaded

Material:  
Ti6Al4V ELI

Article number	Description	Illustration
S-VOW-7070-CL1	VERTICALE SI screw with washer 7,2 x 70	
S-VOW-7075-CL1	VERTICALE SI screw with washer 7,2 x 75	
S-VOW-7080-CL1	VERTICALE SI screw with washer 7,2 x 80	
S-VOW-7085-CL1	VERTICALE SI screw with washer 7,2 x 85	
S-VOW-7090-CL1	VERTICALE SI screw with washer 7,2 x 90	
S-VOW-7095-CL1	VERTICALE SI screw with washer 7,2 x 95	
S-VOW-7100-CL1	VERTICALE SI screw with washer 7,2 x 100	
S-VOW-7105-CL1	VERTICALE SI screw with washer 7,2 x 105	
S-VOW-7110-CL1	VERTICALE SI screw with washer 7,2 x 110	
S-VOW-7115-CL1	VERTICALE SI screw with washer 7,2 x 115	
S-VOW-7120-CL1	VERTICALE SI screw with washer 7,2 x 120	
S-VOW-7125-CL1	VERTICALE SI screw with washer 7,2 x 125	
S-VOW-7130-CL1	VERTICALE SI screw with washer 7,2 x 130	
S-VOW-7135-CL1	VERTICALE SI screw with washer 7,2 x 135	
S-VOW-7140-CL1	VERTICALE SI screw with washer 7,2 x 140	

System:  
VERTICALE

Implant type:  
SI Screw with Plate

Screw shaft diameter:  
7.2 mm

Configuration:  
Polyaxial, cannulated  
and fenestrated shaft,  
full threaded

Material:  
Ti6Al4V ELI

Article number	Description	Illustration
S-VOP-7070-CL1	VERTICALE SI screw w. plate 7,2 x 70	
S-VOP-7075-CL1	VERTICALE SI screw w. plate 7,2 x 75	
S-VOP-7080-CL1	VERTICALE SI screw w. plate 7,2 x 80	
S-VOP-7085-CL1	VERTICALE SI screw w. plate 7,2 x 85	
S-VOP-7090-CL1	VERTICALE SI screw w. plate 7,2 x 90	
S-VOP-7095-CL1	VERTICALE SI screw w. plate 7,2 x 95	
S-VOP-7100-CL1	VERTICALE SI screw w. plate 7,2 x 100	
S-VOP-7105-CL1	VERTICALE SI screw w. plate 7,2 x 105	
S-VOP-7110-CL1	VERTICALE SI screw w. plate 7,2 x 110	
S-VOP-7115-CL1	VERTICALE SI screw w. plate 7,2 x 115	
S-VOP-7120-CL1	VERTICALE SI screw w. plate 7,2 x 120	
S-VOP-7125-CL1	VERTICALE SI screw w. plate 7,2 x 125	
S-VOP-7130-CL1	VERTICALE SI screw w. plate 7,2 x 130	
S-VOP-7135-CL1	VERTICALE SI screw w. plate 7,2 x 135	
S-VOP-7140-CL1	VERTICALE SI screw w. plate 7,2 x 140	

# VERTICALE®SI Fixation Implants

Article number	Description	Illustration
S-VOP-7070-CS1	VERTICALE SI lag screw w. plate 7,2 x 70	
S-VOP-7075-CS1	VERTICALE SI lag screw w. plate 7,2 x 75	
S-VOP-7080-CS1	VERTICALE SI lag screw w. plate 7,2 x 80	
S-VOP-7085-CS1	VERTICALE SI lag screw w. plate 7,2 x 85	
S-VOP-7090-CS1	VERTICALE SI lag screw w. plate 7,2 x 90	
S-VOP-7095-CS1	VERTICALE SI lag screw w. plate 7,2 x 95	
S-VOP-7100-CS1	VERTICALE SI lag screw w. plate 7,2 x 100	
S-VOP-7105-CS1	VERTICALE SI lag screw w. plate 7,2 x 105	
S-VOP-7110-CS1	VERTICALE SI lag screw w. plate 7,2 x 110	
S-VOP-7115-CS1	VERTICALE SI lag screw w. plate 7,2 x 115	
S-VOP-7120-CS1	VERTICALE SI lag screw w. plate 7,2 x 120	
S-VOP-7125-CS1	VERTICALE SI lag screw w. plate 7,2 x 125	
S-VOP-7130-CS1	VERTICALE SI lag screw w. plate 7,2 x 130	
S-VOP-7135-CS1	VERTICALE SI lag screw w. plate 7,2 x 135	
S-VOP-7140-CS1	VERTICALE SI lag screw w. plate 7,2 x 140	

System:  
VERTICALE


Implant type:  
SI Lag Screw with Plate

Screw shaft diameter:  
7.2 mm

Configuration:  
Polyaxial, cannulated and fenestrated shaft, partially threaded

Length of thread:  
20 mm for screws in length 70-90 mm  
32 mm for screws in length 95-140 mm

Material:  
Ti6Al4V ELI

Article number	Description	Illustration
S-VOP-0016-X1	VERTICALE SI Plate fixation screw 16 mm	
S-VOP-0018-X1	VERTICALE SI Plate fixation screw 18 mm	
S-VOP-0020-X1	VERTICALE SI Plate fixation screw 20 mm	
S-VOP-0022-X1	VERTICALE SI Plate fixation screw 22 mm	
S-VOP-0024-X1	VERTICALE SI Plate fixation screw 24 mm	
S-VOP-0026-X1	VERTICALE SI Plate fixation screw 26 mm	
S-VOP-0028-X1	VERTICALE SI Plate fixation screw 28 mm	
S-VOP-0030-X1	VERTICALE SI Plate fixation screw 30 mm	

System:  
VERTICALE

Implant type:  
Plate Fixation Screw









Configuration:  
Solid, locking, self-tapping

Material:  
Ti6Al4V ELI

# VERTICALE® SI FIXATION Instruments

Article number	Description	Illustration	Page
GI-2111	Ratchet T-Handle, short		14
GI-6141	Ratchet T-Handle, 4Nm		-
RI-1355	ROCCIA Slotted Mallet, solid		9
VI-4024	VERTICALE MIS Dilator 4 (20 mm)		11
VI-6000	VERTICALE Holding Clamp		14, 19
VI-6023	VERTICALE Dilator 17 mm		11
VI-6050	VERTICALE Guide wire blunt, 3.2 x 400 mm		9
VI-6051	VERTICALE Guide wire trocar, 3.2 x 400 mm		9
VI-6052	VERTICALE Guide wire threaded 3.2 x 400 mm		9
VI-6059	VERTICALE Guide wire protection sleeve		-
VI-6070	VERTICALE Probe with ball tip		12, 16
VI-6192	VERTICALE Drill Bit, cannulated		12, 16
S-VI-6500	VERTICALE SI Cement Kit		23
VI-6510	VERTICALE SI Cement Adapter		23
VI-6700.1	VERTICALE SI Screw Driver shaft		13, 17
VI-6700.2	VERTICALE SI Screw Driver outer sleeve		13, 17
VI-6700.3	VERTICALE SI Screw Driver sleeve lock		13, 17

# VERTICALE® MIS Instruments

Article number	Description	Illustration	Page
VI-6710	VERTICALE Screwdriver Hex 3.5		-
VI-6720	VERTICALE SI Wrench		15, 20, 21
VI-6730	VERTICALE SI Screw Loading Tool		13
VI-6751.1	VERTICALE Plate inserter inner sleeve		17
VI-6751.2	VERTICALE Plate inserter outer sleeve		17
VI-6860	VERTICALE SI screw indicator		11, 16
VI-6870.1	VERTICALE Plate Indicator		20
VI-6870.2	VERTICALE Plate Fixation Screw Indicator		20

# VERTICALE® Alphabetical Index

A–Z	Description	Article number	Page
C	VERTICALE SI Cement Adapter	VI-6510	23, PI 04
	VERTICALE SI Cement Kit	VI-6500	PI 04
D	VERTICALE MIS Dilator 4 (20 mm)	VI-4024	11, PI 04
	VERTICALE Dilator 17 mm	VI-6023	11, PI 04
	VERTICALE Drill Bit, cannulated	VI-6192	12, 16, PI 04
G	VERTICALE Guide wire blunt, 3.2 x 400 mm	VI-6050	9, PI 04
	VERTICALE Guide wire trocar, 3.2 x 400 mm	VI-6051	9, PI 04
	VERTICALE Guide wire threaded 3.2 x 400 mm	VI-6052	9, PI 04
	VERTICALE Guide wire protection sleeve	VI-6059	PI 04
H	VERTICALE Holding Clamp	VI-6000	14, 19, PI 04
P	VERTICALE Plate Fixation Screw Indicator	VI-6870.2	20, PI 05
	VERTICALE Plate Indicator	VI-6870.1	20, PI 05
	VERTICALE Plate inserter inner sleeve	VI-6751.1	17, PI 05
	VERTICALE Plate inserter outer sleeve	VI-6751.2	17, PI 05
	VERTICALE Probe with ball tip	VI-6070	12, 16, PI 04
T	Ratchet T-Handle, short	GI-2111	14, PI 04
	Ratchet T-Handle, 4Nm	GI-6141	PI 04
S	VERTICALE Screwdriver Hex 3.5	VI-6710	PI 04
	VERTICALE SI Screw Driver outer sleeve	VI-6700.2	13, 17, PI 04
	VERTICALE SI Screw Driver shaft	VI-6700.1	13, 17, PI 04
	VERTICALE SI Screw Driver sleeve lock	VI-6700.3	13, 17, PI 04
	VERTICALE SI Screw indicator	VI-6860	11, 16, PI 05
	VERTICALE SI Screw Loading Tool	VI-6730	13,, PI 05
	ROCCIA Slotted Mallet, solid	RI-1355	9, PI 04
W	VERTICALE SI Wrench	VI-6720	15, 20, 21, PI 05





[www.silony-medical.com](http://www.silony-medical.com)

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

 **Silony Medical GmbH**  
Leinfelder Strasse 60  
70771 Leinfelden-Echterdingen, Germany  
Tel. +49 711 78 25 25 0  
Fax: +49 711 78 25 25 11

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