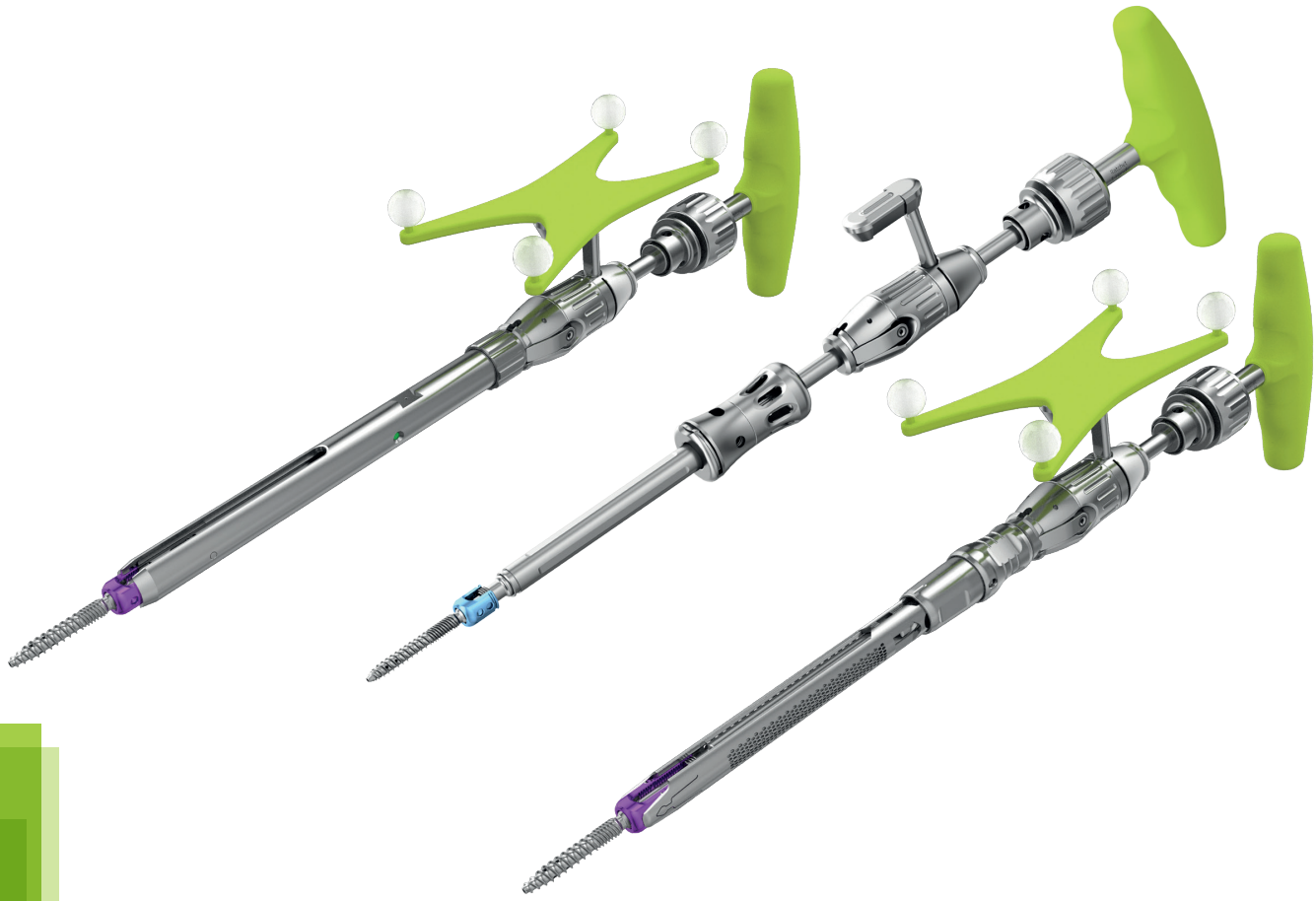
silony® SPINE

VERTICALE® Navigation

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® Navigation Instrumentation. This instrumentation guide supplements the guides for the VERTICALE® Screw Rod System. Instruments from Silony Spine 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 appended to 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.

NOTE: Silony Spine is not a manufacturer of navigation systems or equipment. Please refer to the navigation company's software and user guides for instructions for use and training prerequisites on the navigation system. Instructions for use and handling of any third-party navigation systems in combination with Silony instruments are the responsibility of the hospital and navigation company. The navigation system should be set up per the manufacturer's instructions.

INTRODUCTION / PREFACE

Navigation Instruments for Silony Spine VERTICALE® Screw Rod Systems

The Navigation Instruments for VERTICALE® are designed for compatibility with
- the Medtronic StealthStation® Navigation System and the Medtronic NavLock™ tracker,
- the Brainlab Navigation System and the Brainlab Universal Instrument Adapters (StarLink™).

For general instructions on use, indications, contraindications and warnings please refer to the following manuals and guides:

VERTICALE® OPEN and MultiLocking Screw Rod System Instrumentation Guide
Instructions for Use VERTICALE implants
Instructions for Use Silony surgical instruments
Medtronic's current navigation system software and user guides (StealthStation®, NavLock™)
Brainlab's current navigation system software and user guides (StarLink™)

Physicians and operators of the system, instruments and software should read all related (Silony Spine and third-party) user guides carefully before handling the equipment and have access to the user guides at all times. Prior to using the VERTICALE® Navigated Instruments for VERTICALE® Screw Rod Systems, the physicians and operators should review the Silony Spine VERTICALE® System guides for their indications for use.
Silony Spine navigation instruments for VERTICALE® Screw Rod Systems are NOT compatible with the implants from other manufacturers. The VERTICALE® Navigation Instruments are intended for use with Silony Spine VERTICALE® implants only:
- VERTICALE® Pedicle screws with short & reduction head
  - VERTICALE® Polyaxial screw
  - VERTICALE® Monoaxial screw
  - VERTICALE® Uniplanar screw
  - VERTICALE® Revision / Iliac screw
  - VERTICALE® MultiLocking screw

INDICATIONS / CONTRAINDICATIONS

Please refer to the supplemental VERTICALE® system guides and Instructions for Use for general procedural instructions, indications, contraindications and warnings.

Please consider the following additional information for Navigation use:

Additional Indications for Navigation use

Silony Spine Navigation Instruments are intended to be used during the preparation and placement of VERTICALE® pedicle screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in open procedures. These instruments are designed for use with third-party stereotactic navigation systems, which are indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Additional Contraindications for Navigation use

Medical conditions which contraindicate the use of a computer-assisted surgery system and its associated applications with Silony Spine VERTICALE® system include any medical conditions which may contraindicate the medical procedure itself.

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.
All instrumentation guides and Instructions for Use can be found on our eLabeling portal (https://elabeling.silony-medical.com/)

NOTE: A navigated percutaneous procedure using VERTICALE MultiLocking short-head screws isn't possible with the existing instruments.

PREPARATION OF NAVIGATION SYSTEM AND INSTRUMENTATION

Prerequisites on Navigation System and tracker

Note: For navigated instrumentation with Medtronic StealthStation®, the hospital's Medtronic navigation instrument set must include the Medtronic NavLock™ trackers. For navigated instrumentation with Brainlab Navigation System, the hospital's instrument set must include the Brainlab universal instrument adapters (StarLink™). Silony Navigation Instruments require following the instructions for use for the respective third-party navigation system and its navigation instruments, which are provided by the navigation system manufacturer. If the respective third-party navigation instrument set is not available at the hospital, the VERTICALE® Navigation Instruments cannot be navigated. In the event that the respective third-party navigation instrument set is unavailable, a non-navigated technique using fluoroscopy and respective Silony Spine instrumentation may be adopted as per Silony Spine Instrumentation guides.

Navigation System	Respective Instrument tracker / Array
Medtronic StealthStation® System S8*	Medtronic NavLock™ tracker
Brainlab	Brainlab Universal Instrument Adapters (StarLink™)

*Note: Position verification was performed with Medtronic StealthStation® System S8 and Software Version 1.2.0.

Assembly of instruments

Medtronic: Follow the instructions for NavLock™ tracker.

Brainlab: Follow the instructions for universal instrument adapter clamps and arrays (StarLink™) for manual calibration of third-party instruments.

Note: For selection on tracker type, clamp or array size please refer to the third-party's user guides. It is recommended to use the largest array size feasible for the instrument.

Pre-assembly of navigation tracker using third-party universal adapter clamps and arrays (e.g. Brainlab).

1) Assemble the third-party universal instrument adapter clamps and arrays according to the respective navigation manufacturer's instructions.

2) Rigidly connect the clamp of the third-party universal adapter to the prismatic interface of the VERTICALE® Nav Adapter VI-7030 according to the respective navigation manufacturer's instructions. Always make sure that the clamp-array-assembly is fully seated on the prismatic interface and the array is oriented in line with VERTICALE® Nav adapter's axis such that the array is pointing down to the instrument's working end when assembled in the next step.

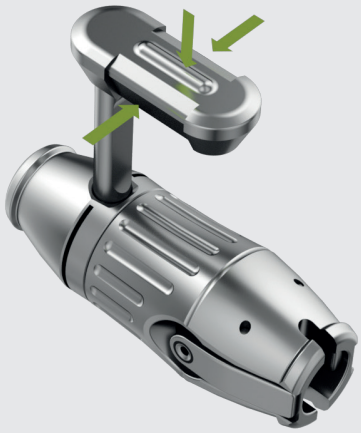


Fig. 1 VERTICALE® Nav Adapter with prismatic interface for universal clamps.

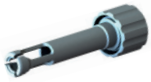
Both the VERTICALE® Navigation Adapter with connected third-party universal clamps or the NavLock™ tracker are further denoted by 'navigation tracker' (short 'tracker').

Assembly of Navigated Shaft Instruments

GI-3111
Ratchet T-Handle**

VI-7130
VERTICALE Nav SD Inner Shaft

VI-7135
VERTICALE Nav Insert MIS



VI-7136
VERTICALE NAv Insert WINX

1) Attach the corresponding tracker to the respective Navigation Instrument (Awl, Probe, Tap or SD Inner Shaft)* until it snaps into place, make sure that the Navigation Tracker is securely connected to the respective instrument.

Fig. 2 Attaching Navigation tracker to navigated shaft instrument.

2) Attach Silony handle according to your preference to the proximal interface of the instrument shaft*.

3) Additional Steps for Navigated Screwdriver

OPEN Navigated Screwdriver (Fig. 3)
The navigated screwdriver consists of a Navigated Driver Shaft VI-7130 in combination with modular components of the VERTICALE® Screwdriver VI-1130. Please refer to the instrument list section at the end of this guide for combination options, e.g., with SI-0024. For further (dis-) assembly instructions of the modular screwdriver VI-1130 or SI-0024, please refer to the supplemental information provided with the instruments.

3.1) Attach your desired outer sleeve option onto the basic core
3.2) Instead of a non-navigated driver shaft, insert the VI-7130 SD Inner Shaft into the respective screwdriver basic core options

*Further instrument options can be found in the instrument list section at the end of this guide.

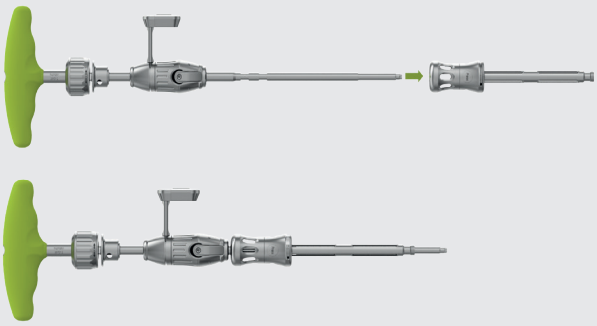


Fig 3: Assembling Navigated Screwdriver Shaft with Basic Core of e.g., VI-1130.

Assembly of Navigated Shaft Instruments

4) Additional Steps for Navigated Screwdriver

MIS Navigated Screwdriver (Fig. 4)
The navigated screwdriver consists of a Navigated Driver Shaft VI-7130 in combination with Nav Insert MIS VI-7135 and the Working Tower VI-4040. For (dis-)assembly instructions of the Working Tower, please refer to the VERTICALE MIS System Instrumentation Guide D30049:

Attach the Nav Insert MIS onto the Navigated Driver Shaft until it clicks into the designated groove in the shaft.

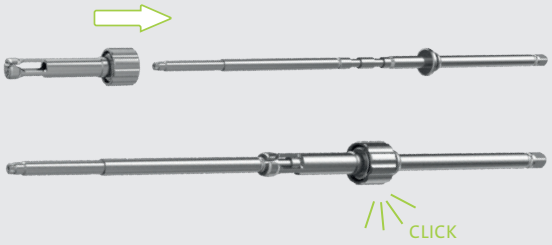


Fig. 4: Assembling Navigated Screwdriver Shaft with Nav Insert MIS.

WINX Navigated Screwdriver (Fig.5)
The navigated screwdriver consists of a Navigated Driver Shaft VI-7130 in combination with Nav Insert WINX VI-7136 and the WINX Blades 2.0 VI-4412. For (dis-)assembly instructions of the WINX Blades construct, please refer to the VERTICALE WINX Instrumentation Guide D30214.

Attach the Nav Insert WINX onto the Navigated Driver Shaft until it clicks into the designated groove in the shaft.

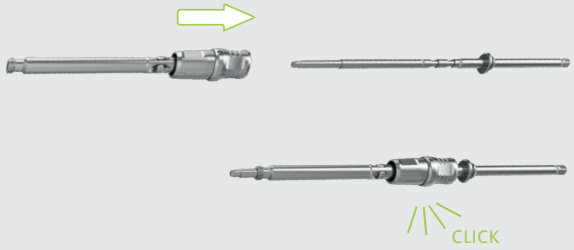


Fig. 5: Assembling Navigated Screwdriver Shaft with Nav Insert WINX.

NOTE: Do not use the same tracker type/geometry on two different instruments without new registration procedure.

NOTE: If the tracker cannot be rigidly connected to the respective Silony Navigation Instrument, utilize Silony standard non-navigated surgical technique as described in the VERTICALE® system guides. For registration instructions, please refer to the registration section.

Instrument Registration Instructions

Refer to the navigation manufacturer's current navigation software and user guides for patient referencing and instrument registration.

Medtronic: Follow the instructions for StealthStation® and NavLock™ tracker.

For each instrument to be navigated with Medtronic StealthStation®, assign the appropriate instrument tool card and NavLock™ tracker type/geometry (and screw size when using screw driver) in the navigation software that has been attached to the respective instrument.

Upon successful registration, the trajectory and location of the distal tip of the instrument or screw are visually represented within the software by the third-party instrument or screw selected from the corresponding tool cards. If you desire to change the tip of the virtual representation to reflect the diameter and length of the screw, follow the instructions of the chosen navigation system.

Brainlab: Follow the instructions for universal instrument adapter clamps and arrays (StarLink™) and manual calibration of third-party instruments with ICM4.

Using the VERTICALE® Navigation shaft instruments with the VERTICALE® Navigation adapter, requires manual registration and calibration. This means the respective Silony navigation instrument dimensions need to be acquired by the Navigation Software through a manual calibration process. VERTICALE® Navigation Instruments can be used for manual calibration by using the respective navigation system manufacturer's clamps and arrays for general instrument calibration and following their instructions for use.

For each instrument to be navigated with Navigation Systems based on a manual calibration process, assign the appropriate generic instrument tool card and perform manual calibration according to the navigation manufacturer's instructions. For the screw driver always manually calibrate the instrument with each attached screw and re-calibrate after any change to the calibrated instrumentation assembly.

Upon successful manual calibration, the trajectory and location of the distal tip of the instrument or screw are visually represented within the software by the chosen generic instrument or screw selected from the corresponding tool cards. If you desire to change the tip of the virtual representation to reflect the diameter and length of the screw, follow the instructions of the chosen navigation system.

Instrumentation / Surgical Steps

General Notes on use of Navigation instruments

The following section describes only the specific steps for the use of VERTICALE® Navigation instruments. For a general instrumentation guide for a dorsal VERTICALE® standard instrumentation that forms the basis of all subsequent work steps, we ask you to study the appropriate instrumentation guide for the VERTICALE® Screw Rod System.

Please review the following notes prior to using VERTICALE® Navigation instruments.

- Prior to navigation, always confirm that accuracy of the instrument tip or tip of screw driver with rigidly connected screw is in an acceptable range for the intended use by positioning the navigated tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system.
- Assess navigational accuracy repeatedly throughout a procedure.
- After each change to the navigated instrumentation assembly in use (e.g. for each new screw; after re-attachment of tracker including array and spherical markers) when using a surgical navigation system, the navigated instrumentation assembly must be re-verified for accuracy. For manually calibrated systems, the calibrated instrumentation assembly in use must always be re-calibrated after each change to the assembly (e.g. for each new screw; after re-attachment of tracker including adapter, clamp, array and spherical markers).
- Discontinue use if inaccuracy is suspected.
- If the stereotactic navigation system does not appear to be accurate or registration of Silony instruments fails despite troubleshooting (e.g. resetting the system), do not rely on the navigation system. A non-navigated technique using fluoroscopy and respective Silony Spine instrumentation should be used as per Silony Spine Instrumentation guides.
- If the desired virtual screw or instrument diameter is not available in the software, use the next larger available size in diameter (e.g. Ø 5.2 mm screws → Software: select Ø 5.5 mm screw projection).
- At all times during use, ensure the navigation tracker is visible to the camera of the respective navigation system in use.
  - For probes, taps and the screw driver, the navigation tracker will rotate around the instrument shaft. Please hold the tracker with the hand for permanent camera visibility of the array markers while using the instrument.
  - For inserting taps and screws rotate proximal instrument handle clockwise, for removal rotate anti-clockwise.
  - Some instruments are equipped with an anti-rotation pin. For these instruments, the navigation tracker will not rotate around the instrument shaft during use (only back and forth rotation allowed for permanent camera visibility).
- Care should be taken to avoid bending forces on registered instruments during navigation procedure as deflection can influence navigation accuracy.
- If instruments drop or may otherwise be damaged, re-verify them with respect to anatomical landmarks or use another instrument. Do not use any instrument if verification of anatomical landmarks fails. Omission to do so may lead to serious injury to the patient.
- Do not use the tracker and/or Silony Navigation instruments if any components appear to be loose, bent or otherwise damaged.
- Cannulated instruments (taps, screw driver) are available for using guide wires
  - The guide wires are not navigated instruments.
  - Ensure that the length of the guide wire exceeds the length of implant, instrument and additional handle.
  - Push the instrument over the placed guide wire
  - Ensure the guide wire remains securely in position throughout the entire duration of the procedure.
  - Remove the guide wire after screw insertion and confirming final screw position.

Position and approach

Please refer to the VERTICALE® Instrumentation Guide for information on patient position and approach.

Opening the cortex of the pedicle

VI-7010
VERTICALE Nav Awl with Stop*

Assemble and register respective awl as described in assembly and registration section. Please refer to general notes section prior to navigation.
Please refer to the VERTICALE® Instrumentation Guide for information on opening the pedicle with an awl.

* Further instrument options at the end of this guide.

Open the pedicle canal with a probe

VI-7024
VERTICALE Nav Thoracic Probe*

VI-7025
VERTICALE Nav Lumbar Probe*

Assemble and register respective probe as described in assembly and registration section. Please refer to general notes section prior to navigation.
Please refer to the VERTICALE® Instrumentation Guide for information on opening up the cancellous bone of the vertebral body with a probe.

* Further instrument options at the end of this guide.

Tapping (optional)

VI-7045
VERTICALE Nav Tap
4.5 + 5.2 mm*

VI-7067
VERTICALE Nav Tap
6.2 + 7.2 mm*

Assemble and register respective tap as described in assembly and registration section. Please refer to general notes section prior to navigation.
Please refer to the VERTICALE® Instrumentation Guide for information on tapping with solid taps or cannulated taps in combination with guide wires for guided insertion.

* Further instrument options at the end of this guide.

Selection of screw

Select the VERTICALE® pedicle screw type and size (length and diameter) based on pre-operative planning and fluoroscopic imaging. VERTICALE® Pedicle screws with short & reduction head are compatible with VERTICALE® Navigation Instruments:

- VERTICALE® Polyaxial screw
- VERTICALE® Monoaxial screw
- VERTICALE® Uniplanar screw
- VERTICALE® Revision / Iliac screw
- VERTICALE® MultiLocking screw

Screw loading onto Navigated Screwdriver

VI-7130
VERTICALE Nav SD Inner Shaft

1) Assemble and register screwdriver shaft as described in assembly and registration section.
2) Adjust for short or long head screws, in analogy to VI-1130, by pressing the button on the middle part of the handle of the screwdriver basic core and pulling or pushing the driver shaft into its dedicated position.
3) Loading screw

Open procedure, in analogy to VI-1130 (Fig. 6)
The VERTICALE® pedicle screwdriver tip is first inserted deeply into the inner drive feature of the screw shaft. After that, the internal thread of the screw head is connected to the external thread of the instrument by rotating clockwise and applying gentle downward force with the instrument shaft.
➔ For full instructions please refer to VERTICALE® OPEN Instrumentation Guide D30000 and supplemental information provided with the instrument.

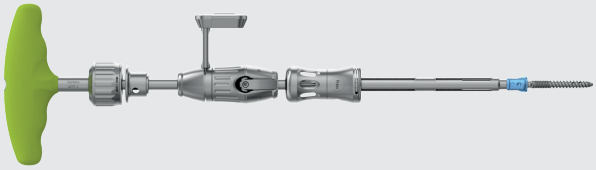


Fig. 6 Navigated screwdriver with loaded screw.

MIS procedure (Fig.7)
1) Assemble the desired pedicle screw on the Working Tower VI-4040 according to VERTICALE MIS System Instrumentation Guide D30049.
2) Insert the assembled navigated screwdriver shaft into the assembled Working Tower and fixate it by turning the Nav Insert MIS in.

Fig. 7 MIS Working Tower with loaded screw.

WINX procedure (Fig.8)
1) Assemble the Winx Blades 2.0 onto the desired pedicle screw according to VERTICALE WINX Instrumentation Guide D30214.
2) Insert the assembled navigated screwdriver shaft into the assembled WINX Blades 2.0 construct and fixate it by turning in the Nav Insert WINX.

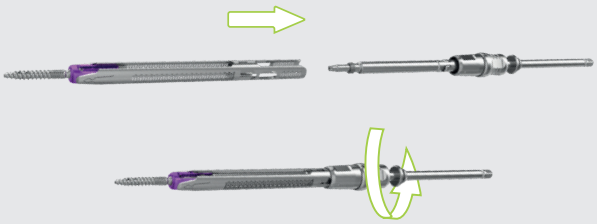


Fig. 8 Assembled WINX Blades 2.0 with loaded screw.

NOTE: Please ensure the screw driver tip is fully seated in the screw drive feature and the connection is rigid after tightening.

Screw insertion

NOTE: The tip position of the navigated instrument with loaded screw must be verified for accuracy prior to use when using a navigation system. Please refer to general notes section prior navigation.

Please refer to the VERTICALE® Instrumentation Guide for information on inserting the pedicle screw and disengaging the screw driver.

NOTE: Do not hold the middle handle of the screw driver VI-1130 basic core until disengaging the screw driver from the screw.

For insertion of additional screws, follow the previous steps for the remaining screws.

NOTE: If the screw is changed, the tip position of the navigated instrument with loaded new screw must be re-verified for accuracy prior to use. Please refer to general notes section.

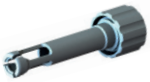
Further surgical steps

Please refer to the VERTICALE® system instrumentation guides for information on further surgical steps after screw placement or the implant removal procedure to complete surgery.

VERTICALE® NAVIGATION PRODUCT INFORMATION

The following section gives an overview on compatible instruments of the VERTICALE® Screw Rod System.

VERTICALE® Navigation Instruments

Article number	Description	Illustration	Page
VI-1130*	VERTICALE Screw Driver T25		7, 13
VI-7010	VERTICALE Nav Awl with stop		11
VI-7020	VERTICALE Nav Awl Starter		11
VI-7024	VERTICALE Nav Thoracic Probe		11
VI-7025	VERTICALE Nav Lumbar Probe		11
VI-7028	VERTICALE Nav Iliac Probe		11
VI-7030	VERTICALE Nav Adapter		6, 7, 13
VI-7034	VERTICALE Nav Awl Tap 4.5 mm		11
VI-7045	VERTICALE Nav Tap 4.5 + 5.2 mm		
VI-7135	VERTICALE Nav Insert MIS		8, 13
VI-7136	VERTICALE Nav Insert WINX		8, 13

VERTICALE® Navigation Instruments

Article number	Description	Illustration	Page
VI-7067	VERTICALE Nav Tap 6.2 + 7.2 mm		11
VI-7089	VERTICALE Nav Tap 8.2 + 9.2 mm		11
VI-7102	VERTICALE Nav Tap 10.2 mm		11
VI-7124**	VERTICALE Nav Thoracic Probe, short		11
VI-7125**	VERTICALE Nav Lumbar Probe, short		11
VI-7128**	VERTICALE Nav Iliac Probe, short		11
VI-7130	VERTICALE Nav SD Inner Shaft		7, 13
VI-7145	VERTICALE Nav Tap 4.5 + 5.2 mm, can		11
VI-7167	VERTICALE Nav Tap 6.2 + 7.2 mm, can		11
VI-7189	VERTICALE Nav Tap 8.2 + 9.2 mm, can		11
VI-7202	VERTICALE Nav Tap 10.2 mm, can		11

* Note: VERTICALE OPEN Screwdriver options compatible with VI-7130
• Basic Core VI-1130.1 or VI-1131.1 or SI-0024.1 with
a) Outer Sleeve VI-1130.2 or
b) Outer Sleeve SI-0024.2
** Note: Short instrument versions are only designed for use with Navigation Systems based on manual calibration of navigated instruments and are NOT compatible with Medtronic StealthStation® using NavLock™ tracker which is based on a proprietary instrument length.

Notes

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