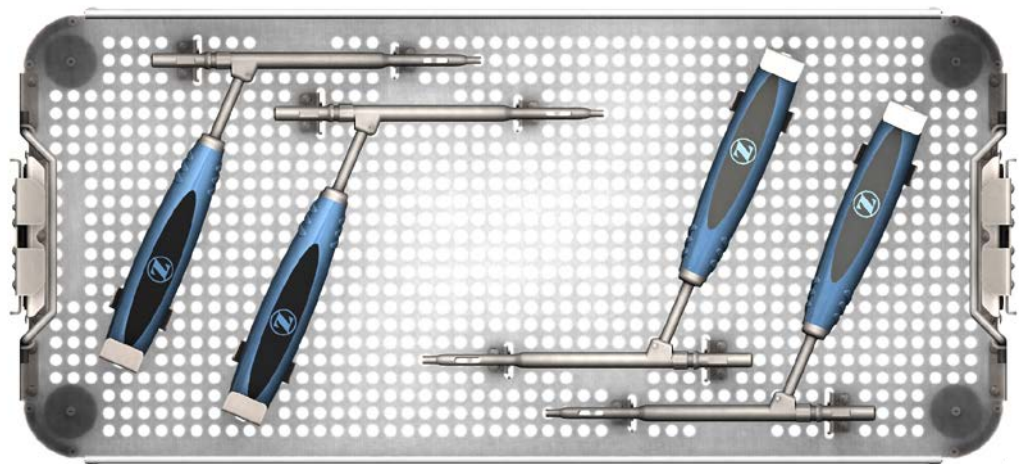
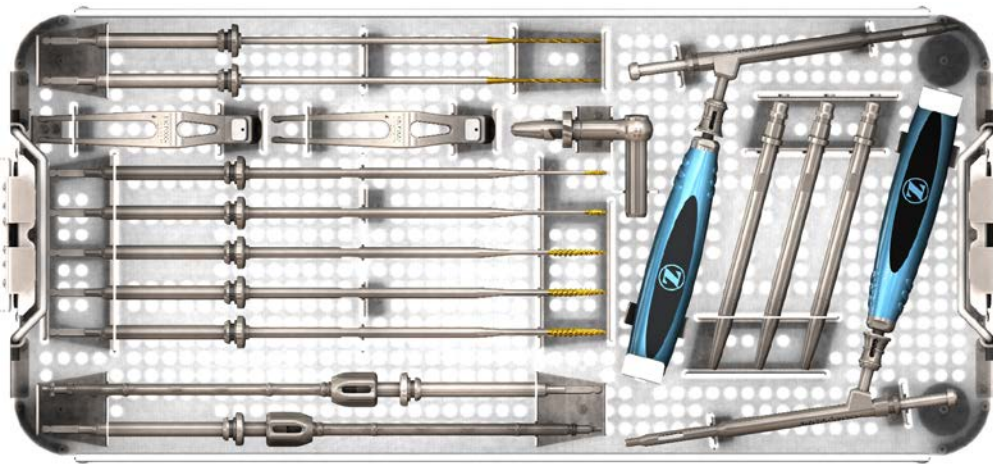




Surgical Technique Guide

Virage[®]

Navigation System



 **ZimVie**



Virage®

Navigation System



The Virage Navigation system is a series of instruments that are designed to be compatible with the Medtronic StealthStation® System S8 Version 1.2.0 and allow the navigation of bone preparation instruments and polyaxial screws in the spine.

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ZimVie does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Animations and virtual reality are provided as a visual guide based on surgical techniques. A written copy of the surgical technique is available at www.zimmerbiomet.com.

Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

INTRODUCTION

The Virage Navigation system is a series of instruments that are designed to be compatible with the Medtronic StealthStation System S8* Version 1.2.0 and allow the navigation of bone preparation instruments and polyaxial screws in the cervical spine.

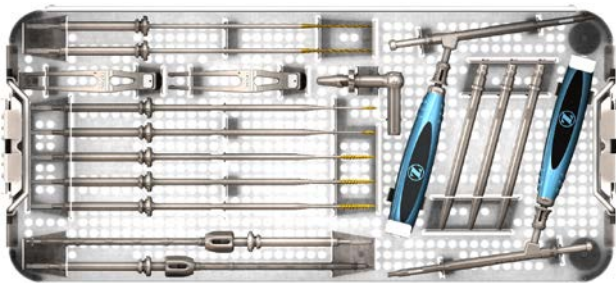
This surgical technique guide covers the verification and array assembly of the Virage Navigation instruments and implants that have been validated for use with Stealth Station.

For bone preparation, tapping and screw insertion surgical technique guide steps please refer to the following surgical technique guide for technical guiding principles:

Virage Spinal Fixation System Surgical Technique

The manufacturer of the Navigation system utilized should be responsible for the set up per their instructions. The navigation company's arrays must be utilized for verification of ZimVie instruments.

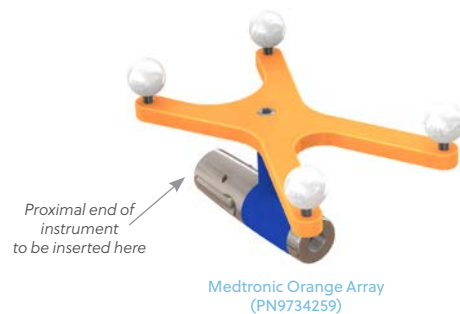
A manual technique can be utilized with the ZimVie screw system surgical technique guide listed above in the event that the third party tracking array is unavailable.



Virage Navigation Instrument
Kit Number: PCR 100P1101

Features and benefits include:

- Uninterrupted navigation facilitated by a fixed Array Orienter
- All instruments are compatible with the Virage System
- All Medtronic arrays within the NavLock® set are compatible with the Virage Navigation System instruments
- Instruments provided in the Virage Navigation System are for bone preparation, tapping, and screw insertion.
- Virage Navigation Instruments are compatible with ZimVie Universal Power System and WalterLorenz® Surgical Assist Arm.



* Virage Navigation instruments are backwards compatible with Medtronic Synergy Experience StealthStation System S7 Version 2.1.0

SURGICAL TECHNIQUE



INSTRUMENT CONNECTION TO ARRAY

Each instrument has been designed to be compatible with all NavLock arrays for Medtronic's Stealth Navigation System.

- Begin by sliding any of the NavLock arrays over the proximal end of the instrument until it clicks and comes to rest on the flange of the instrument.
- The metal portion end of the array should be introduced over the proximal end of the instrument first to ensure proper assembly.
- Any handle with a small AO connection may be attached after the array has been introduced.
- If use of Universal Power System is preferred, refer to Universal Power Compatibility section for compatible attachments references.
- When using drill bit with drill guides or taps with tap sleeves, slide the array orienter from the distal end of sleeve all the way to the proximal end of sleeve till the array orienter clicks. Now push the forked end of array orienter onto the Navlock array shaft so that it hugs the shaft. Use of array orienter would hold the Navlock array in a fixed position thus reducing the chances of interruption in navigation.

STEALTHSTATION SYSTEM SET UP

Please refer to Medtronic's StealthStation user guide for the following steps in the StealthStation System prior to the Verifying Instruments Stage:

- Start Spine Software
- Select Surgeon
- Select Procedure
- Set Up Equipment



INSTRUMENT REGISTRATION

The Virage Navigation System instruments utilize the toolcards present in the StealthStation and must be registered for use per the StealthStation User Manual. The following instructions are intended to be used as a guide for which toolcards to select and to give general instructions for how to register instrumentation.

- Table 1 below lists the toolcards which should be used for each of the Virage Navigation System instruments and provides a comparison of instrument length to the NavLock instruments.
- Table 2 below lists the ZimVie Virage screws which are compatible with the Virage Navigation system; and provides a comparison of screw length when attached to the NavLock drivers and Infinity screws.

Note: Compatible screws are listed in the Virage Screw compatibility chart in Table 2, screw sizes outside of the ranges listed in this chart are not compatible with the Medtronic StealthStation and should not be used with the Virage Navigation System.

Table 1: Toolcard selection and comparison for the Virage Navigation System Instruments

Part Number	Part Description	Instrument Length (mm)	Tool Card Selection	Instrument Length Range (mm)	Profile Comparison
130P0001	VIRAGE NAV POLY SCREW DRIVER	198	Infinity Driver or Solera 5.5/6.0 MAS Driver	198	Same Profile
130P2023	VIRAGE NAV D2.3MM DRILL BIT	201	Infinity Drill Bit	201	Same Profile
130P3030	VIRAGE NAV 3.0MM SMALL TAP	201	Infinity 3.0mm Tap	201	Same Profile, Infinity tap threading is longer
130P3035	VIRAGE NAV 3.5MM SMALL TAP	201	Infinity 3.5mm Tap	201	Same Profile, Infinity tap threading is longer
130P4040	VIRAGE NAV 4.0MM LARGE TAP	201	Infinity 4.0mm Tap	201	Same Profile, Infinity tap threading is shorter
130P4045	VIRAGE NAV 4.5MM LARGE TAP	201	Infinity 4.5mm Tap	201	Same Profile, Infinity tap threading is shorter
130P4050	VIRAGE NAV 5.0MM LARGE TAP	201	Infinity 5.0mm Tap	201	Same Profile, Infinity tap threading is shorter

Table 2: Compatible screws for the Virage Navigation System with Toolcard selection and a length comparison.

Screw Type	Length Range (mm)	Driver/Screw Length Range (mm)	Tool Card Selection	Tool Card Screw Length Range (mm)	Infinity or Solera Driver/Screw Length Range (mm)	Profile Comparison
Polyaxial Screws 3.5mm	10-34	211.04-235.04	Infinity screws (under Infinity 2.5mm Threaded Screwdriver)	10-34	209.72-233.72	Same Profile
Polyaxial Screws 4.0mm	10-34	211.04-235.04	Infinity screws (under Infinity 2.5mm Threaded Screwdriver)	10-34	209.72-233.72	Same Profile
Polyaxial Screws 4.5mm	20-45	221.04-246.04	Solera Screws (under Solera 5.5/6.0 MAS Driver)	20-45	220.70-245.70	Same Profile
Polyaxial Screws 5.0mm	20-45	221.04-246.04	Solera Screws (under Solera 5.5/6.0 MAS Driver)	20-45	220.70-245.70	Same Profile
Smooth Shank Screws 3.5mm	22-40	223.04-241.04	Infinity screws (under Infinity 2.5mm Threaded Screwdriver)	22-40	221.72-239.72	Same Profile
Smooth Shank Screws 4.0mm	22-40	223.04-241.04	Infinity screws (under Infinity 2.5mm Threaded Screwdriver)	22-40	221.72-239.72	Same Profile



Figure 1

PRELIMINARY SETUP

- Prior to navigation, the StealthStation must be set up to include the appropriate instrument toolcards.
- To add a toolcard to the case, navigate to the "Verify Instruments" screen and click the "Add or Remove Instruments" button (Figure 1).
- Search for the appropriate instrument toolcards and click the "Add" button for each.
 - Passive Planar Sharp
 - Passive Small frame
 - NavLock Array (varied colors)
 - Infinity Taps
 - Infinity Drill Bits
 - Infinity drivers
 - Solera 5.5/6.0 Drivers

Note: the toolcards for the Awls and Probes will be automatically added to the case when the NavLock arrays are added.

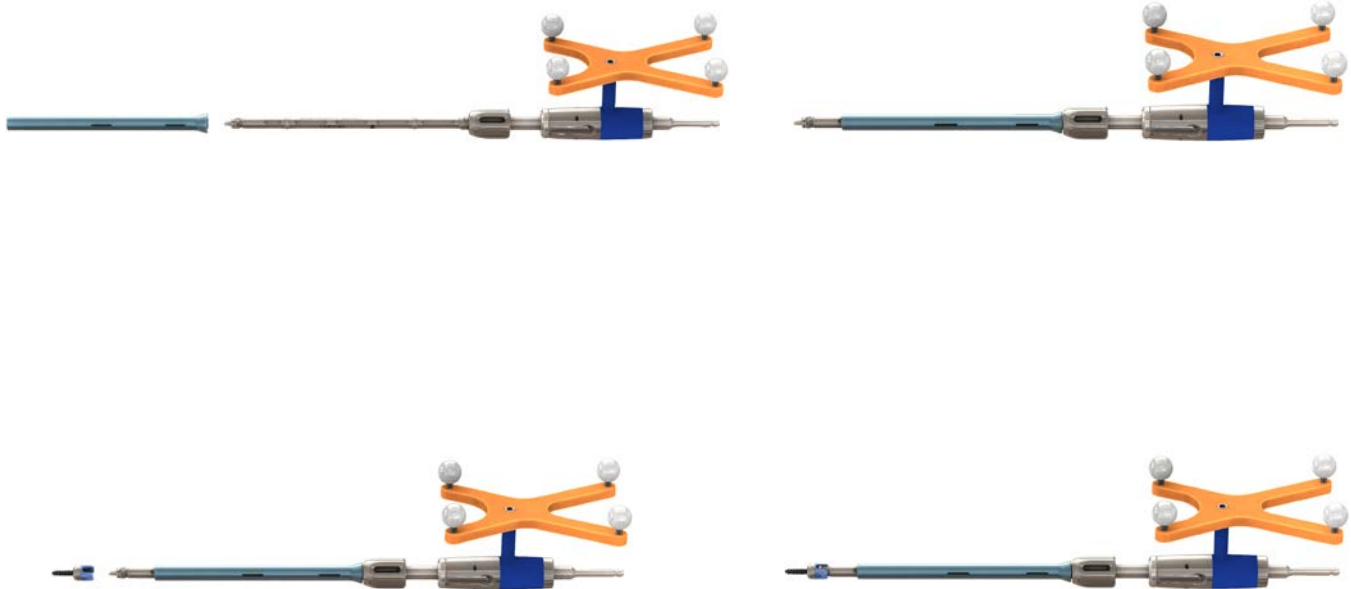
- Once all of the appropriate instrument toolcards have been added to the "Add or Remove Instruments" screen, click the "Add/Remove at this Site" button to add them to the case



Figure 2

INSTRUMENT REGISTRATION

- Prior to instrument registration be sure that the patient reference array is installed and registered to the patient according to Medtronic user manuals and surgical techniques.
- To register the instruments, move to the “Navigate” screen of the StealthStation.
- Once on the “Navigate” screen, click the “Select Tip” button and select the appropriate instrument toolcard for the Virage Navigation System instrument intended to be navigated per Table 1.
 - To select the appropriate toolcard, click the “View Categories” button in the “Select Tip” option and all of the instruments that were added in the Preliminary Setup step will be available.
- After selecting the appropriate instrument toolcard per Table 1, ensure that the selected NavLock array is firmly seated on the Virage Navigation System instrument and touch the instrument tip to the divot in the patient reference array while holding the instrument parallel to the camera for best visualization of the fiducials (Figure 2).
 - A beep will indicate that the instrument has been registered.



- The Taps toolcards will include options for tap sizes, using the specific options listed in Table 1 select the appropriate tap width from the menu.

Note:

- 1) When a new instrument is added to an array it is important to re-register the instrument following the steps above.
- 2) When using drill bit with drill guides or taps with tap sleeves, slide the array orienter from the distal end of sleeve all the way to the proximal end of sleeve till the array orienter clicks. Now push the forked end of array orienter onto the Navlock array shaft so that it hugs the shaft. Use of array orienter would hold the Navlock array in a fixed position thus reducing the changes of interruption in navigation.

SCREW SELECTION

- To select a screw, attach the NavLock array to the driver as instructed above and assemble the selected screw to the appropriate driver.
- Ensure that the driver tip is fully seated in the screw head and that the head capture system of the driver is fully tightened into the screw head.
 - All Virage Navigation System drivers feature a screw head capture system that must be fully engaged prior to the registration of the screw.
 - To properly operate the screw head capture system, the driver tip must fit into the screw head and the driver sleeve must be threaded into the screw head and tightened until the screw is rigidly fixed to the driver.
- To register the driver and screw, select the toolcard, as per Table 1, from the "View Categories" option within the "Select Tip" button.



Figure 3

PRELIMINARY SETUP

- Once the driver has been selected, click on the “Select Projection” button and use the plus and minus buttons to select the corresponding screw dimensions.
- Now that the screw projection has been selected, the instrument assembly including the Navlock array, driver and screw can be verified by touching the tip of the screw to the divot in the patient reference array (Figure 3).
 - A beep will indicate that the instrument has been registered.

Navigation and Other Steps

For usage and instruction on any additional features with the StealthStation software, please follow the standard procedures outlined in the user manual from Medtronic.

For bone preparation, tapping and screw insertion surgical technique guide steps please refer to the following surgical technique guide:

- Virage Spinal Fixation System Surgical Technique



UNIVERSAL POWER SYSTEM COMPATIBILITY

- When use of the Universal Power is preferred, the following attachments have to be used:



- Small AO 1000rpm
89-8509-410-20



- Drilling / Reaming Adapter
(1000rpm/250rpm)
89-8509-412-50



- Modular Small AO
Coupling
89-8509-460-20

- When drilling, a rotation speed of 1000rpm is recommended. Such rotation speed can be obtained using the 89-8509-410-20 Small AO attachment or 89-8509-460-20 Modular Small AO Coupling connected to 89-8509-412-50 Drilling / Reaming Adapter.
- For taping and screw insertion a 250rpm is preferable, by using 89-8509-460-20 Modular Small AO Coupling connected to 89-8509-412-50 Drilling / Reaming Adapter.

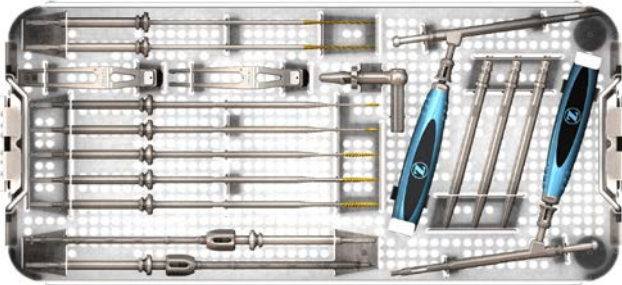


WALTERLORENTZ SURGICAL ASSIST ARM COMPATIBILITY

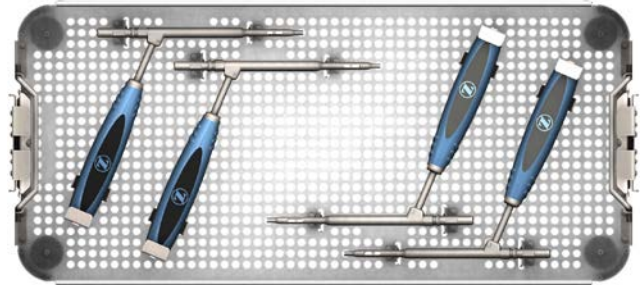
- A Water Guiding tube (130P7000) is provided in the Virage Navigation System to allow connection to the WalterLorentz Surgical Assist Arm.
- This guiding tube can fit to the drill guides, tap sleeves and Virage OCT spin grip sleeve (07-01764.003) to allow securing orientation of the instruments assembly.



INSTRUMENTS IMAGES



Virage Navigation Instrument
Kit Number: PCR 100P1101



Virage Navigation Fixed Drill Guides
Kit Number: PCR 100P2101



Virage Navigation Driver
P/N 130P0001



Virage Navigation D2.3mm Drill Bit
P/N 130P2023



Virage Navigation 3.0mm Small Tap
P/N 130P3030
Virage Navigation 3.5mm Small Tap
P/N 130P3035



Virage Navigation 4.0mm Large Tap
P/N 130P4040
Virage Navigation 4.5mm Large Tap
P/N 130P4045
Virage Navigation 5.0mm Large Tap
P/N 130P4050



Virage Navigation Ø3.5mm Tap Sleeve
P/N 130P5035
Virage Navigation Ø4.5mm Tap Sleeve
P/N 130P5045
Virage Navigation Ø5.0mm Tap Sleeve
P/N 130P5050



Virage Navigation Fix Drill Guide 10mm
P/N 130P8010
Virage Navigation Fix Drill Guide 12mm
P/N 130P8012
Virage Navigation Fix Drill Guide 14mm
P/N 130P8014
Virage Navigation Fix Drill Guide 16mm
P/N 130P8016



Virage Navigation Drill Guide
P/N 130P0003



Virage Navigation Array Orienter
P/N 130P0004



Virage Navigation Walter Tube
P/N 130P7000

IMPORTANT INFORMATION FOR THE VIRAGE NAVIGATION SYSTEM

Before using the Virage® Navigation non-sterile instruments, carefully study the following recommendations, warnings, and instructions; as well as all product labeling. ZimVie is not liable for complications that may arise from the use of the device in circumstances outside of ZimVie's control including, but not limited to, product selection or deviations from the device's intended uses or surgical technique.

Consult the Reusable Instrument Lifespan Manual (2741) to determine if an instrument is fit for surgical use.

For more information, visit <https://labeling.zimvie.com>

DEVICE DESCRIPTION

The Virage Navigation System is comprised of nonsterile, reusable instruments, including cases, drill bits, taps, and driver that can be operated manually. These instruments are intended to be used with the Medtronic StealthStation® System to assist surgeons in precisely locating anatomical structures in procedures for preparation and placement of Virage OCT Spinal Fixation System polyaxial screws. This surgical imaging technology provides surgeons visualization for complex procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.

As with all orthopedic surgical procedures, detailed preoperative planning is essential. Preoperative diagnostic evaluation, followed by carefully executed surgical technique is required. Postoperative care, individualized to suit the particular injury/disease requirements, is essential for optimum outcome. The surgeon must be fully aware of the risks and complications inherent to this type of surgery. Only those individuals with specialized training and experience in spinal surgery should attempt use of the instruments.

The instrument cases may be one-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may contain holders. The instrument cases are perforated to allow steam to penetrate these various materials and components. The instrument cases will allow for sterilization of the contents to occur in a steam sterilizer utilizing a cycle that has been validated by the user for the equipment and procedures employed at the user facility. Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap or rigid container to maintain sterility.

MATERIALS

Unless otherwise stated, the individual instruments and instrument cases are made out of a variety of materials commonly used in orthopedic and neurological procedures including stainless steel, and/or polymeric materials.

PRODUCT COMPATIBILITY

Only use Virage Navigation System instruments with the systems for which they are intended. Refer to the system Instructions for Use for system compatibility. The Virage Navigation System is only intended for use with the Virage OCT Spinal Fixation System, Medtronic StealthStation System, WalterLorenz Surgical Assist Arm and ZimVie Universal Power System.

INTENDED USE

These reusable instruments are intended to facilitate the implantation of the Virage OCT polyaxial screws during spinal surgery to assist the surgeon in precisely locating anatomical structures. The instrument cases are intended to facilitate the organization, identification, storage, transportation, sterilization, and reprocessing of the Virage Navigation System instruments. The WalterLorenz Surgical Assist Arm is only intended to be used in conjunction with the Virage Navigation System instruments.

INTENDED USERS

The Virage Navigation System instruments are intended to be used only by surgeons specialized in spinal surgery that have thorough knowledge of vertebral anatomy, regional vertebral morphology, and the biomechanical principles of the spine. The surgeon should also be familiar with the surgical techniques relative to the use of the device. Contact your local Zimmer Spine representative if product training is desired.

INDICATIONS FOR USE

The Virage® Navigation Instruments are to be used during the preparation and placement of Virage OCT polyaxial screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in open procedures. The Virage Navigation Instruments are specifically designed for use with the Medtronic StealthStation® System, which is 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 a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.

The Virage Navigation Instruments are also compatible with the ZimVie Universal Power System and the WalterLorenz® Surgical Assist Arm.

CONTRAINDICATIONS

The Virage Navigation System is not designed or sold for any use except as indicated. **DO NOT USE THE VIRAGE NAVIGATION SYSTEM INSTRUMENTS IN THE PRESENCE OF ANY CONTRAINDICATION.**

Contraindications include, but are not limited to:

1. Overt infection or distant foci of infections.
2. Local inflammation, with or without fever or leukocytosis.
3. Pregnancy.
4. Morbid obesity.
5. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis.
6. Suspected or documented metal allergy or intolerance.
7. Any time implant utilization would interfere with anatomical structures or expedited physiological performance, such as impinging on vital structures.
8. Severe comminuted fractures such that segments may not be maintained in satisfactory proximate reduction.
9. Use in displaced, non-reduced fractures with bone loss.
10. The presence of marked bone absorption or severe metabolic bone disease that could compromise the fixation achieved.
11. Poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency, and/or malnutrition).
12. Any case not needing a bone graft or fusion.
13. Any case not described in the indications.
14. The Virage Navigation System is contraindicated for any conditions listed as contraindications for the Medtronic Navigation System and the compatible Virage OCT Spinal Fixation System pedicle screws.

WARNINGS

- Refer to the Virage OCT system instructions for use for warnings related to use of the system during the surgical procedure.
- ZimVie does not warrant Medtronic Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or registration.
- The use of the Virage Navigation System should only be used with the indicated Virage OCT Spinal Fixation System pedicle screws.
- Users must complete verification steps as required per the Medtronic Navigation Operative Technique.
- Users must ensure that surgical accuracy be assessed before the procedure and repeatedly throughout the procedure by positioning the tip of each navigated instrument on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. When verifying the accuracy of the Navigated Drivers, the accuracy test must include the screw (of which diameter and length are selected/entered into the software) assembled securely onto the driver. The screw tip will be placed on an identifiable anatomical landmark and compared to the tip location as displayed on the screen.

- In the event of a registration failure or suspected inaccuracy, the Navigated Instruments should not be used with the Navigation System and the instruments should be inspected for damage before continuing with the traditional, non-navigated procedure.
- The Virage Navigation System instruments should not be bent or altered in any way as this could lead to a reduction in system accuracy.
- ZimVie does not specify the maximum number of times a re-usable instrument may be re-used. The useful life of these instruments is highly dependent on a number of factors including the frequency and manner in which they are used and the handling they experience in between uses.

POTENTIAL ADVERSE EFFECTS

Refer to the Virage OCT system instructions for use for adverse events related to use of the system during the surgical procedure.

PRECAUTIONS

Refer to the system Instructions for Use for precautions related to use of the instruments with other system components and during the surgical procedure.

- Make sure to read all Instructions for Use for the system. Failure to read all instructions may result in misuse of the instruments or complications during surgery, resulting in harm to the patient.
- Do not subject instruments to excessive force as this may damage or fracture the instruments, resulting in impaired functionality of the instruments or debris from the instrument entering the incision and not being retrieved.
- Do not store or clean instruments with aggressive chemicals or contaminants as this may lead to an allergic reaction or other complication requiring medical attention.
- Unless otherwise indicated, instruments are supplied nonsterile. Instruments must be thoroughly cleaned and sterilized prior to each use.
- Failure to clean and sterilize instruments may result in an allergic reaction, infection of the incision, or other complication requiring medical attention.
- Do not use an instrument that has come in contact with a nonsterile surface, as the instrument may become contaminated and lead to infection of the incision.
- Do not use with vertebral components or instruments from other manufacturers or other ZimVie Spine systems unless specified.

Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, precautions, warnings, adverse effects, and patient counseling information.

eLabeling: The Instructions for Use can be accessed online by visiting the website and using the KEY-CODE provided on the product label and as shown below. Additional translations are also available in electronic format for download. To request a paper copy of the Instructions for Use, contact ZimVie Spine at the phone number provided.



Consult Instructions for Use on this website:
labeling.zimvie.com Key-Code: IFU0005



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Rx only


Restoring Daily Life.™

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