ZimVie SURGICAL TECHNIQUE GUIDE

Vital™ Navigation System

ZimVie

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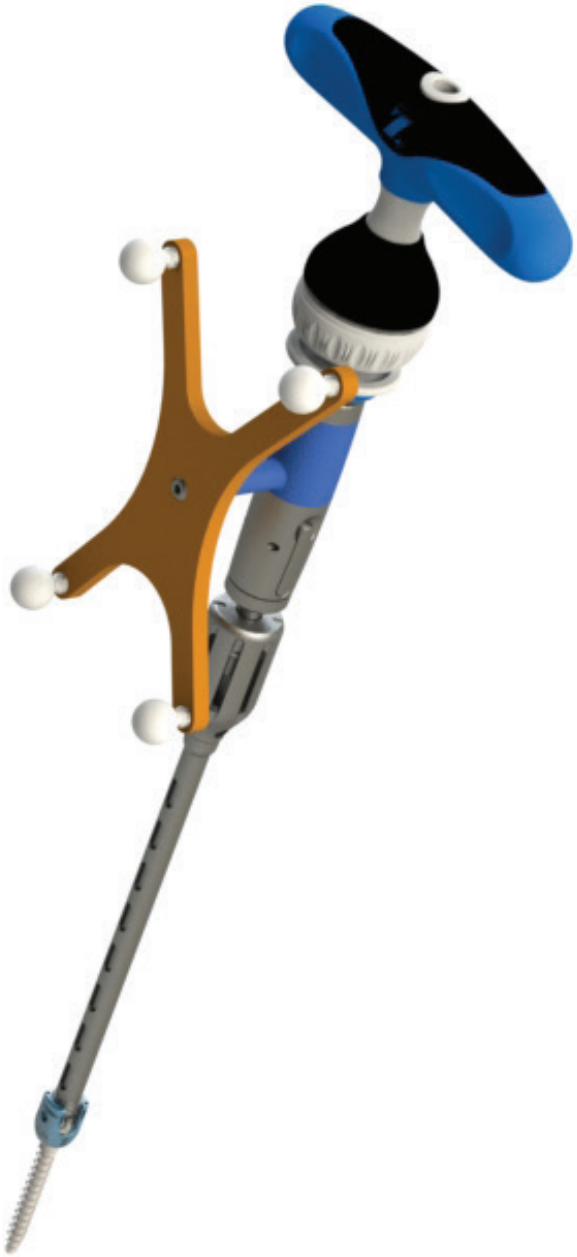
The Vital Navigation system is a series of instruments that are designed to be compatible with the Medtronic Synergy Experience StealthStation® System S7 Version 2.1.0 and allow the navigation of bone preparation instruments and pedicle screws in the spine.



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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.zimvie.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 Vital Navigation system is a series of instruments that are designed to be compatible with the Medtronic Synergy Experience StealthStation System S7 Version 2.1.0 and allow the navigation of bone preparation instruments and pedicle screws in the spine.

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

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

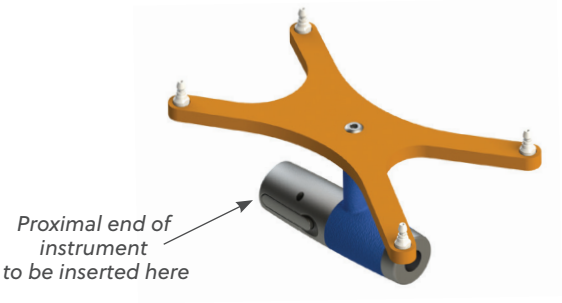
- Vital™ MIS Spinal Fixation System Surgical Technique
- Vitality® Spinal Fixation System Surgical Technique

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.

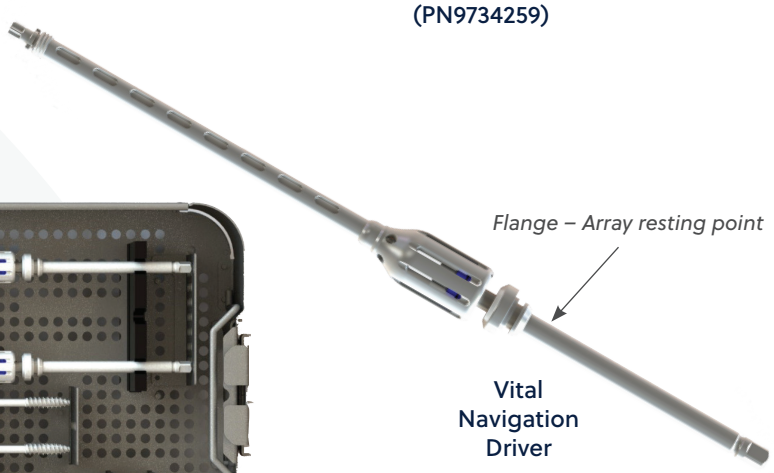
A manual technique can be utilized with assistance with any of the ZimVie screw system surgical technique guides listed above in the event that the third party tracking array is unavailable.

Features and benefits include:

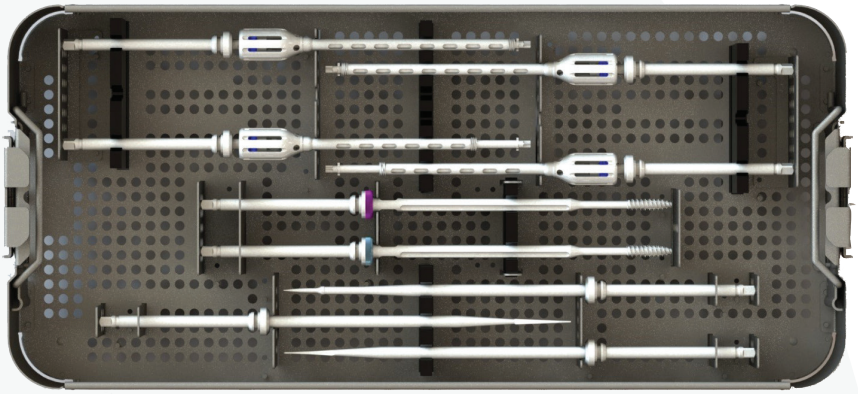
- Uninterrupted navigation facilitated by a freely rotating adaptor
- Compatible with multiple navigation-ready systems
- All instruments are compatible with the Vitality and Vital Systems
- All Medtronic arrays within the NavLock® set are compatible with the Vital Navigation System instruments
- Instruments provided in the Vital Navigation System are for bone preparation, tapping, and screw insertion.
- Nav PAT and Nav PASIT Styluses for use with the Vital MIS PAT Handle for MIS direct tapping or Direct-to-screw option.



Medtronic Orange Array (PN9734259)



Vital Navigation Driver



Vital Navigation Kit

Surgical Technique

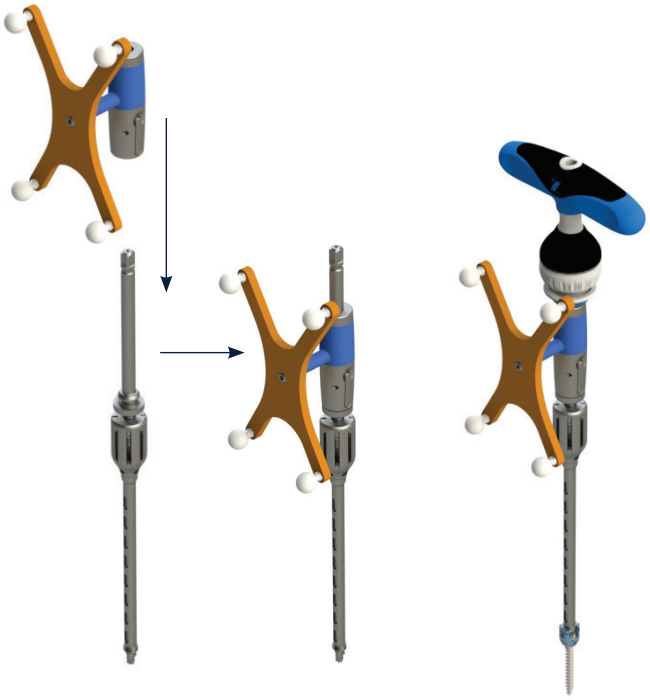


Figure 1

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 ¼ inch square connection may be attached after the array has been introduced.

The array should move freely around the instrument. The free rotation of the array allows the fiducials to always be facing the camera while instruments are
in use.

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 Vital 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 Vital Navigation System instruments and provides a comparison of instrument length to the NavLock instruments.
- Table 2 below lists the ZimVie Vitality screws which are compatible with the Vital Navigation system and provides a comparison of screw length when attached to a driver to the NavLock drivers and Solera® screws.

Note: *Compatible screws are listed in the Vitality and Vital 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 Vital Navigation System.*

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

PART NUMBER	PART DESCRIPTION	INSTRUMENT LENGTH (mm)	TOOLCARD SELECTION	INSTRUMENT LENGTH RANGE (mm)	PROFILE COMPARISON
854M0021	Vital Navigation Driver	198	Solera 5.5/ 6.0 MAS Driver	198	Same Profile
854M0022	Vital Navigation Reduction Driver	198	Solera 5.5/ 6.0 MAS Driver	198	Same Profile
854M1045	Navigation Tap 4.5 mm	200	Solera 4.5 mm Tap Solid	201	Same Profile, Solera tap threading is longer
854M1055	Navigation Tap 5.5 mm	200	Solera 5.5 mm Tap Solid	201	Same Profile, Solera tap threading is longer
854M1065	Navigation Tap 6.5 mm	200	Solera 6.5 mm Tap Solid	201	Same Profile, Solera tap threading is longer
854M1075	Navigation Tap 7.5 mm	200	Solera 7.5 mm Iliac Taps	201	Same Profile, Solera tap threading is longer
854M0001	Vital Navigation Awl	200	Awl Sharp	201	Same Profile
854M0002	Navigation Thoracic Probe	200	Probe Thoracic	201	Same Profile
854M0003	Navigation Lumbar Probe	200	Probe Lumbar	201	Same Profile

Note: *If implanting a Vital MIS screw, the Vital Navigation Reduction Driver should be used.*

Table 2: Compatible Vitality screws for Vital Navigation System with Toolcard selection and length comparison

SCREW TYPE	LENGTH RANGE (mm)	DRIVER/SCREW LENGTH RANGE (mm)	TOOLCARD SELECTION	TOOLCARD SCREW LENGTH RANGE (mm)	SOLERA DRIVER/ SCREW LENGTH RANGE (MM)	PROFILE COMPARISON
Vital /Vital MIS - Cannulated Polyaxial \and Uniplanar Screws	20-110	218.83-308.83	Solera Screws (under Solera 5.5/6.0 MAS Driver)	15 - 110	220.70-310.70	Same Profile
Vital - Cannulated Monoaxial Screws	20-110	220.46-310.46	Solera Screws (under Solera 5.5/6.0 MAS Driver)	15 - 110	220.70-310.70	Same Profile
Vital - Polyaxial and Uniplanar Screws	20-110	219.27-309.27	Solera Screws (under Solera 5.5/6.0 MAS Driver)	15 - 110	220.70-310.70	Same Profile
Vital Monoaxial Screws	20-110	220.90-310.90	Solera Screws (under Solera 5.5/6.0 MAS Driver)	15 - 110	220.70-310.70	Same Profile
Vitality Polyaxial, Uniplanar and Iliac Screws	20-110	221.82-311.82	Solera Screws (under Solera 5.5/6.0 MAS Driver)	15 - 110	220.70-310.70	Same Profile
Vitality Monoaxial Screws	20-110	220.91-310.91	Solera Screws (under Solera 5.5/6.0 MAS Driver)	15 - 110	220.70-310.70	Same Profile

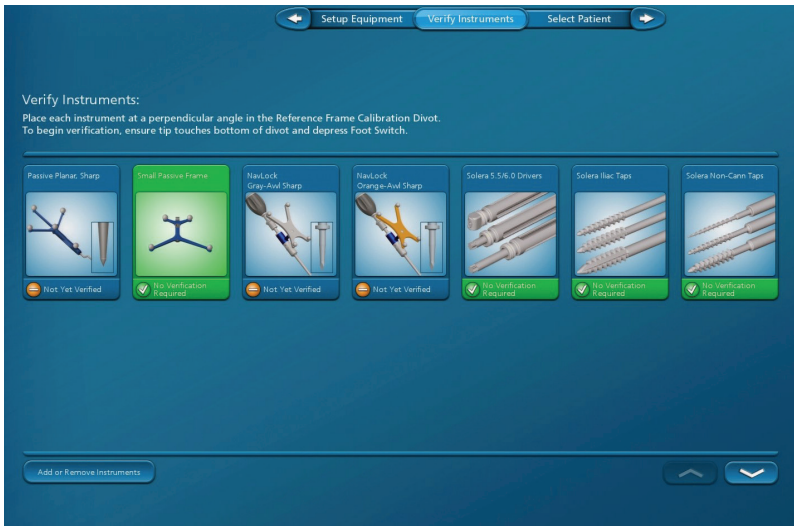


Figure 2

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 2).
- Search for the appropriate instrument toolcards and click the "Add" button for each.
  - Passive Planar Sharp
  - Passive Small frame
  - NavLock Array-Awl Sharp
  - NavLock Array-Awl Sharp
  - Solera 5.5/6.0 drivers
  - Solera Non-Cann Taps
  - Solera Iliac Taps

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

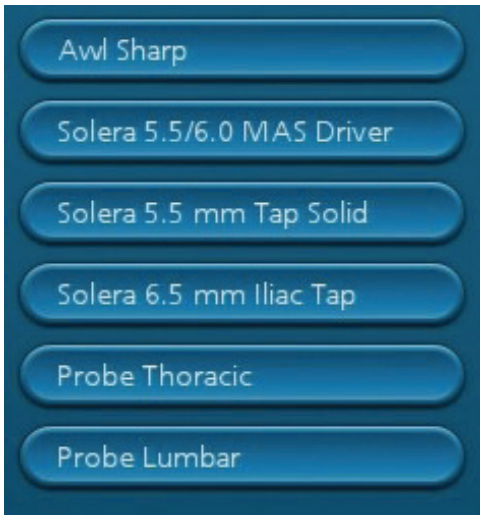


Figure 3

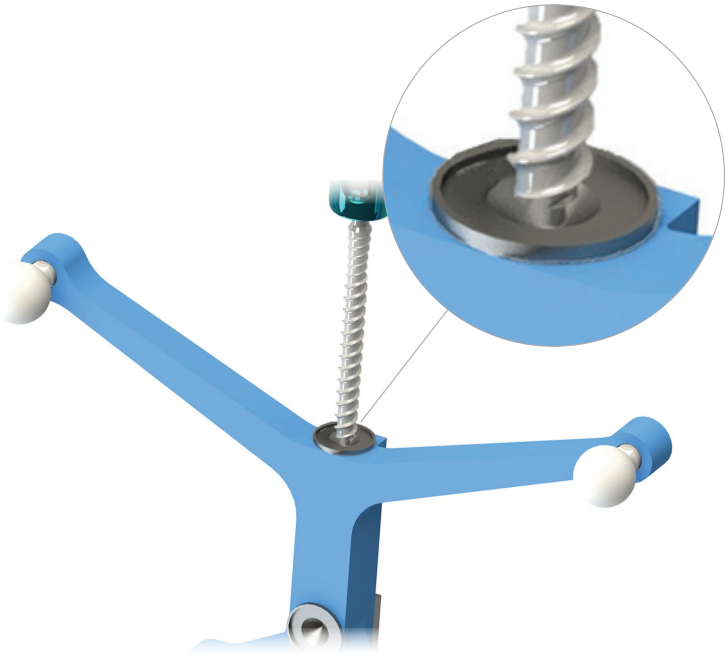


Figure 4

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 Vital Navigation System instrument intended to be navigated per Table 1 (Figure 3).
  - 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 Vital 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 4).

- A beep will indicate that the instrument has been registered
- The Taps toolcards will include options for tip sizes, using the specific options listed in Table 1 select the appropriate tap width from the menu (Figure 5).

  Note: *When a new instrument is added to an array it is important to re-register the instrument following the steps above.*

  Note: *For Vital MIS Pedicle Screws the Vital Nav Reduction Driver should be used.*

Figure 5

Figure 6

Alternative Pedicle Prep Solution

The Vital Navigated Pedicle Access Tool (Nav PAT) can be used to combine the traditional steps of using a pedicle targeting needle to place a guidewire and tapping.

The Vital Nav PAT instrument combines a cortex-breaking stylus with the navigated tap so that direct tapping may occur.

- After navigated tap selection and registration, assemble the Vital MIS PAT handle to the navigated tap. Slide the Vital Nav PAT stylus down through the Vital MIS PAT handle and thread the Vital Nav PAT stylus into the top of the Vital MIS PAT handle. Check that the tip of the Vital Nav PAT stylus is protruding from the tip of the navigated tap. There should be approximately 3.5 mm of protrusion (Figure 6).

  Warning: *When using the Vital Nav PAT Stylus, the stylus protrusion will not be visible under navigation.*

  Note: *Due to allowable manufacturing tolerances when assembled to the Vital Navigated PAT tool, the protrusion of the stylus can vary ± 2.7 mm.*

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 Vital 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 "Solera 5.5/6.0 MAS Driver" toolcard from the "View Categories" option within the "Select Tip" button.

Figure 7

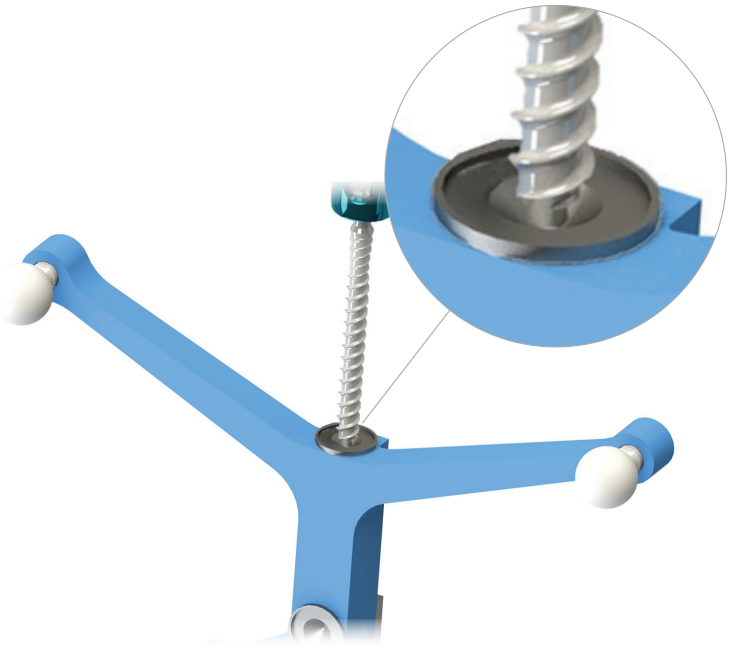


Figure 8

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 (Figure 7).
- 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 8).
  - 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 guides for technical guiding principles for each system:

- Vital MIS Spinal Fixation System Surgical Technique
- Vitality Spinal Fixation System Surgical Technique

Figure 9

Figure 10

Alternative Screw Insertion Technique: PASIT Direct-to-Screw

The Vital Navigated Pedicle Access Screw Insertion Tool (Nav PASIT) instrument combines a cortex-breaking stylus with the screwdriver so direct-to-screw insertion may occur with the Vital MIS or Vital Cannulated screws.

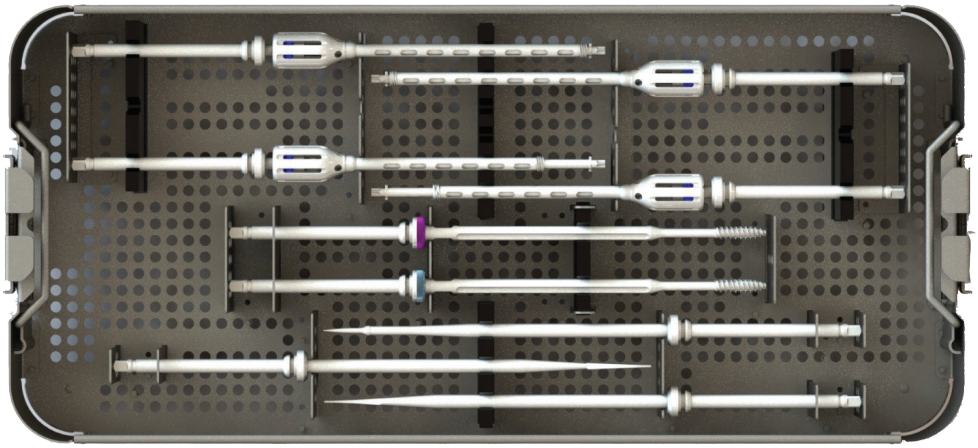
- After screw selection, assembly to driver and registration, select the appropriate size Vital Nav PASIT stylus (Figure 9) that corresponds to the length of the pedicle screw intended for insertion.
- Assemble the Vital MIS PAT handle to the navigated screwdriver. Slide the Vital Nav PASIT stylus down through the Vital MIS PAT handle and thread the Vital Nav PASIT stylus into the top of the Vital MIS PAT handle. Check that the tip of the Vital Nav PASIT stylus is protruding from the tip of the pedicle screw. There should be approximately 3.5 mm of protrusion (Figure 10).

Warning: *When using the Vital Nav PASIT Stylus, the stylus protrusion will not be visible under navigation.*

Note: *Due to allowable manufacturing tolerances when assembled to the Vital Navigated PASIT tool, the protrusion of the stylus can vary ± 3.1 mm.*

Instruments

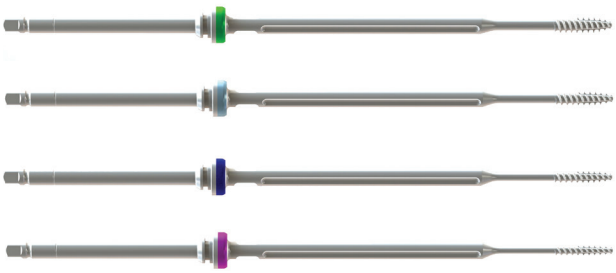
Vital Navigation Instrument Kit
Kit Number: PCR800M2000



Vital Navigation Driver	PART NUMBER
	854M0021

Vital Navigation Reduction Driver	PART NUMBER
	854M0022

Vital Navigation Awl	PART NUMBER
	854M0001

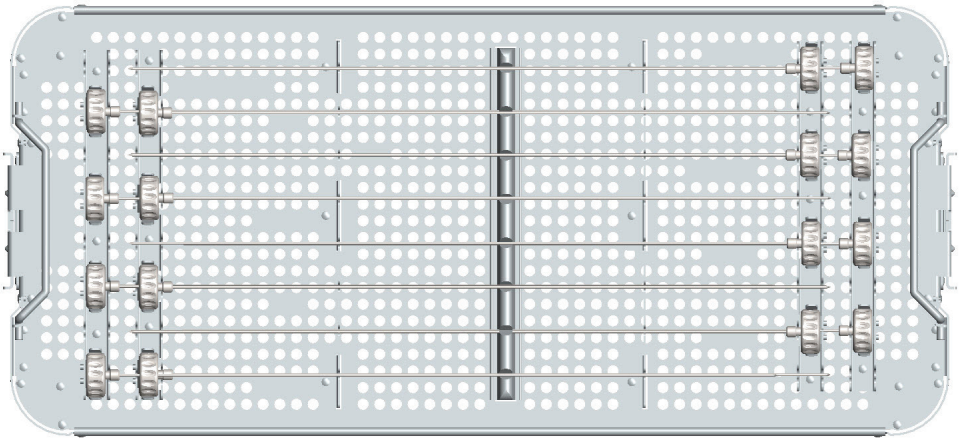


Navigation Taps	PART NUMBER
Navigation Tap 4.5 mm	854M1045
Navigation Tap 5.5 mm	854M1055
Navigation Tap 6.5 mm	854M1065
Navigation Tap 7.5 mm	854M1075

Navigation Thoracic Probe	PART NUMBER
	854M0002

Navigation Lumbar Probe	PART NUMBER
	854M0003

Vital Nav PAT/PASIT Kit
Kit Number: PCR800M1401



DESCRIPTION	QTY	PART NUMBER
PAT Tap Stylus	2	854M4000
PASIT Stylus - 30 mm	2	854M4030
PASIT Stylus - 35 mm	2	854M4035
PASIT Stylus - 40 mm	2	854M4040
PASIT Stylus - 45 mm	2	854M4045
PASIT Stylus - 50 mm	2	854M4050
PASIT Stylus - 55 mm	2	854M4055
PASIT Stylus - 60 mm	2	854M4060

PAT/PASIT Stylus	PART NUMBER
PAT Tap; 30 mm - 60 mm	854M4XXX

Important Information on the Vital Navigation System

Indications for Use

Vital Navigation instruments are to be used during the preparation and placement of Vital and Vitality screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. Vital 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.

Contraindications

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

- Insufficient bone quantity, severe osteoporosis, or other condition that might compromise rigid fixation of the device.
- A history of infection, active systemic infection or infection localized to the site of the proposed implantation.
- Suspected or documented metal allergy or intolerance.
- A disorder affecting the normal process of bone remodeling, including but not limited to severe osteoporosis involving the spine, excessive bone reabsorption, osteopenia, a primary or metastatic tumor involving the spine, or certain metabolic disorders of osteogenesis.
- Iliac screws and offset connectors should not be used in cases of tumor or trauma of the sacrum, when additional screw fixation in S1 is not possible.
- Other relative contraindications include obesity, pregnancy, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.
- The Vital Navigation System is contraindicated for any conditions listed for the Medtronic Navigation System and the compatible Vital and Vitality implant systems.

Warnings and Precautions

Following are specific warnings, precautions, and adverse effects associated with use of the Vital Navigation System that should be understood by the surgeon and explained to the patients. Surgeons should be thoroughly familiar with these instructions, in addition to all other product labeling. General surgical risk should be explained to the patients prior to surgery.

- Implantation of the Vitality System should be performed only by experienced spinal surgeons.
- All implants are intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single-use devices include:
  - Mechanical malfunction
  - Transmission of infectious agents
- Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.
- Universal precautions should be observed by all end users that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges to prevent injuries during and after surgical procedures and reprocessing.
- 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 Vital Navigation System should only be used with the indicated Vital and Vitality screw systems.

- 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 Vital Navigation System instruments should not be bent or altered in any way as this could lead to a reduction in system accuracy.
- ***Warning:*** The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5 S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- ***Warning:*** The safety and effectiveness of this device has not been established for use as part of a growing rod construct. The device is only intended to be used when definitive fusion is being performed at all instrumented levels.

Additional Warnings for Pediatric Patients:

- The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.
- ***Precaution:*** The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Additional Precautions for Pediatric Patients:

- The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.
- The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

Important Information on the Vital Navigation System *(continued)*

Preoperative

- Usage of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments.
- Proper handling, decontamination (including pre-rinsing, washing, rinsing and sterilization), storage and utilization are important for the long and useful life of all surgical instruments. Even with correct use, care and maintenance, they should not be expected to last indefinitely. This is especially true for cutting instruments (e.g., bone awls/drills) and driving instruments (e.g., drivers). These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.
- Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct; otherwise, galvanic corrosion may occur.
- 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.

Intraoperative

- If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant surface. Do not repeatedly or excessively bend the implant. Do not reverse bend the rods.
- Pedicle bone integrity should be verified.
- Care should be taken during pedicle preparation to avoid penetrating too deep.
- Care should be taken during bone preparation to avoid damage to the pedicle and to the surgical instruments.
- Care should be taken to minimize soft tissue damage during surgery.
- Care should be taken to avoid removing excess material from the lamina.
- Care should be taken to avoid cross-threading screws and closure tops.
- If any implant or instrument comes in contact with a non-sterile surface it should not be used.

Postoperative

- Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in fracture. The patient should understand that an implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
- The Vitality System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture.

Adverse Effects

Complications and adverse reactions have been reported with the use of similar spinal instrumentation systems. These adverse effects, including the possibility of death, should be discussed with the patient prior to surgery.

- Non-union, delayed union
- Bending or fracture of implant. Fraying, kinking, loosening, bending or breaking of any or all implant components
- Loosening of or migration of the implant

- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Loss of the natural curvature of the spine
- Modification of the spinal geometric corrections of the vertebral and/or intervertebral height and/or of the reduction in spinal deformities
- Vascular and/or nerve damage due to surgical trauma or presence of the device.
- Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation and paraesthesia.
- Bursitis
- Dural leak
- Paralysis
- Death
- Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death
- Additional surgery may be required to correct any of these potential adverse effects

Additional Potential Adverse Effects for Pediatric Patients:

1. Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
2. Pedicle screw malpositioning, with or without neurological or vascular injury
3. Proximal or distal junctional kyphosis
4. Pancreatitis

Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients, and pediatric patients may be at increased risk for device-related injury because of their smaller stature.

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