VIPER PRIME™ System Navigation Instructions

Surgical Technique

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   - This device has not been evaluated for safety and compatibility in the MR environment.
   - This device has not been tested for heating or migration in the MR environment.

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### MR Information

This device has not been evaluated for safety and compatibility in the MR environment.
This device has not been tested for heating or migration in the MR environment.

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VIPER PRIME™ System Navigation Instructions  Surgical Technique  DePuy Synthes
Product Overview

Please refer to the VIPER PRIME™ System Surgical Technique Guide (DSEM/SPN/0717/0716) for full procedural instructions. The following guide outlines the steps specific to using the VIPER PRIME System with Navigation.

Navigation Instructions

The VIPER PRIME System can only be used with BrainLab, Medtronic StealthStation® Navigation System and Stryker SpineMap® 3D Navigation System. Set up of the Navigation system should be performed per manufacturer instructions. For manual instrument calibration the hospital's navigation instrument set must include the navigation company's universal clamps and arrays for general instrument calibration. If the respective third party universal tracking array set is not available at the hospital, the VIPER PRIME Navigated Inserter cannot be navigated. In the event that the respective third party tracking array set is unavailable, a manual technique using fluoroscopy, a Jamshidi needle, guidewire and the Navigated Inserter may be adopted.
Surgical Technique

Assembly of the VIPER PRIME Navigated Inserter

The Inserter is made up of 4 components:
1. Carrier (Fig 1)
2. Navigation Drive Tube (Fig 2)
3. Red Stylet Control Handle (Fig 3)
4. Navigation Shaft (Fig 4)
Surgical Technique

Step 1

- Insert the Carrier into the Navigation Drive Tube with the red line indicator facing into the tube. (Fig 5)

- Thread the Red Stylet Control Handle over the Carrier until it is seated on the Navigation Drive Tube. This is a reverse thread and should be rotated counterclockwise to assemble. (Fig 6)

- Insert the tabs of the Navigation Drive Tube into the Navigation Shaft. (Fig 7)

Ensure that the two set screws on the sides of the Navigation Shaft are fully backed out before trying to attach the Navigation Drive Tube. You will hear an audible click when the Navigation Drive Tube properly snaps into place.

- Using the Set Screw Driver, hand-tighten both set screws on the Navigation Shaft. (Fig 8)

- Select a VIPER PRIME Modular Handle (T-handle or Palm) and attach it to the proximal end of the Navigation Inserter. These will snap into place over the spring tabs of the Navigation Drive Tube.

The Modular Handle may be removed at any time for visualization.

There are 2 available adaptors:

1. BrainLab Adaptor (Fig 9)
2. Universal Navigation Adaptor (Fig 10)

Refer to the table below to select the correct adaptor and components based on your chosen navigation system. During the usage of any instrument, always ensure that the array is facing the camera.

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Surgical Technique

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1. BrainLab Adaptor (Fig 9)
2. Universal Navigation Adaptor (Fig 10)

Refer to the table below to select the correct adaptor and components based on your chosen navigation system. During the usage of any instrument, always ensure that the array is facing the camera.

### BrainLab Assembly Instructions

**Attach Reflective Spheres**
- Assemble disposable reflective marker spheres according to BrainLab’s instructions.
- Attach the adaptor and array to the shaft of the Navigation Inserter. The long arm of the array should be lined up with the axis of the instrument. (Fig 11)

<table>
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<tr>
<th>Navigation System</th>
<th>DePuy Synthes Adaptor Catalog No.(s)</th>
<th>Description</th>
<th>Universal Tracking Array Catalog No.(s)</th>
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<td>Universal Instrument Adaptor Array, StarLink, Size L</td>
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</table>
Medtronic Assembly Instructions

Attach Reflective Spheres
- Assemble disposable reflective marker spheres according to Medtronic’s instructions.
- Attach the adaptor and array to the shaft of the Navigation Inserter.

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<tr>
<th>Navigation System</th>
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<td></td>
<td>961-579</td>
<td>Medtronic SureTrak II® Universal Tracker, Medium Passive Fighter</td>
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<td></td>
<td>961-581</td>
<td>Medtronic SureTrak II® Universal Tracker, Large Passive Fighter</td>
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Stryker Assembly Instructions

The Stryker system does not require an adaptor.
- Attach the NavLock 13-20mm clamp (PN 6000-999-004) directly to the rotating sleeve on the VIPER PRIME Navigation Driver Shaft. (Fig 12)
- Attach the array to the clamp.

<table>
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<tr>
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<th>Universal Tracking Array Catalog No.(s)</th>
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<td>Navlock 13-20 mm</td>
<td>6000-014-000</td>
<td>Stryker NGenius® Universal Tracker</td>
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Step 2
Select Screw Length and Load Screw

- Select the screw size (length and diameter) based on pre-operative imaging and planning and load onto the VIPER PRIME Navigated Inserter. Ensure that the inserter is fully seated in the screw drive feature, and then tighten the green knob to the proximal threads on the screw tabs to secure the implant. The Inserter tip can strip if the Inserter is not fully seated during screw insertion. (Fig 13)

The dark etch line on the Navigation Inserter Shaft should line up with the most proximal etch line on the X-Tab. This ensures that the shaft drive feature is fully engaged with the implant screw shank.

Step 3
Calibration

- Prior to manually calibrating the attached screw, make sure that the screw and array are rigidly connected to the VIPER PRIME Navigated Inserter Shaft.

**Precaution:** If the universal tracking array cannot be rigidly connected to the respective VIPER PRIME adaptor and navigated inserter, a manual technique using fluoroscopy, a Jamshidi needle, guidewire and the navigated inserter should be adopted.

- The VIPER PRIME Navigated Inserter must be calibrated each time prior to use as no instrument geometry or dimensions are retained in the navigation software.

**Precaution:** For each new screw, the VIPER PRIME Navigated Inserter must be re-calibrated for accuracy prior to use.

Calibrate the VIPER PRIME Navigated Inserter without the stylet and verify accuracy per the navigation software and manufacturer user guides.
Brainlab Calibration Instructions

- Follow the instructions for the StarLink Universal Array to manually calibrate the screw. Use the instrument calibration block. Use the ICM 4 and only use the receptacle that corresponds to the screw diameter selected. (Fig 14)

Medtronic Calibration Instructions

- Follow the instructions for the SureTrak II Universal Tracker Array to manually calibrate the screw. Use the patient reference array to calibrate the screw.

Stryker Calibration Instructions

- Follow the instructions for the NGenius Universal Tracker to manually calibrate the screw. Use the VCD (Vector Calibration Device) to calibrate the screw.

Upon successful calibration, the axis, trajectory and location of the distal tip of the screw are visually represented by the virtual generic cylinder. If you desire to change the tip of the virtual representation to reflect the diameter and length of the screw, follow the instructions for the chosen navigation system. A projection is not required following manual calibration with the screw. For reference, VIPER PRIME X-Tab screw lengths are measured from the distal tip to the bottom of the screw head. (Fig 15)

Precaution: Each time the array is changed or removed, the VIPER PRIME Navigated Inserter must be re-calibrated for accuracy.

Warning: Care should be taken to limit bending forces on calibrated instruments during navigation as deflection can influence navigation accuracy. If you drop or otherwise damage the instrument, recalibrate it. Failure to do so may lead to serious injury to the patient.
Surgical Technique

Step 4

Load Stylet

- On the Stylet Depth Adjustor, identify the slot that corresponds to the chosen screw length. (Fig 16)

- Remove the Navigation Stylet from sterile packaging.

Ensure that the slot on the retaining sleeve is rotated into the “Open” position so that the slots are aligned. (Fig 17)

- Insert the distal tip of the Navigation Stylet through the distal ring on the Depth Adjustor and place the proximal flange of the Navigation Stylet in the slot for the identified screw length. (Fig 18)

- Rotate the retaining sleeve on the Depth Adjustor 180 degrees to capture the stylet and make sure it is properly retained. (Fig 19)
Surgical Technique

- Insert the Navigation Stylet and the Depth Adjustor into the top of the VIPER PRIME Navigation Inserter. (Fig 20)

- Use the X25 Set Screw Driver to thread the Depth Adjustor into the assembled Inserter until it is fully seated. (Fig 21)

It is recommended to use a Modular Handle at this point to provide countertorque during Depth Adjustor insertion.

- Turn the Red Stylet Control Handle counterclockwise until it stops to fully retract the Navigation Stylet. Confirm that the Navigation Stylet tip extends approximately 1 mm beyond the distal tip of the screw in this position as indicated by the red line visible through the Navigation Drive Tube window on the Stylet Depth Gauge. (Fig 22)

Precaution: If the Navigation Stylet is not visible beyond the screw tip or you cannot retract it to 1mm, disassemble the Depth Adjustor and confirm that the stylet flange is seated in the appropriate screw length.

The Navigation Stylet can be extended to a maximum of 5 mm beyond the tip of the screw.

Warning: The stylet of the VIPER PRIME Inserter is not navigated and will not be visible on the navigation screen. The stylet protrudes 1mm beyond the distal tip of the screw when fully retracted. The stylet can be advanced a maximum of 5mm beyond the tip of the screw.

Consider a traditional Jamshidi and guidewire technique if the Stylet cannot be advanced or retracted using the Red Stylet Control Handle at any point in the procedure.
Surgical Technique

OPTIONAL: Dilator Insertion

Determine the skin incision location using navigation software.

• Assemble the Dilator to the Dilator Sleeve. The instruments will snap together. (Fig 23)

• Advance the assembled instrument until the distal tip contacts the pedicle. (Fig 24)

• Push down on the Dilator Sleeve while pulling back on the Dilator until it separates from the Dilator and contacts the bone. Remove the Dilator while holding the Dilator Sleeve in place. (Fig 25)
Step 5

Pedicle Targeting

Follow manufacturer’s instructions for navigating pedicle targeting and screw insertion. Ensure that the array is facing the camera at all times.

- Insert the VIPER PRIME Navigation Inserter through the incision and dock the stylet tip on the bony anatomy of the desired level. At initial insertion, the Navigation Stylet should extend past the tip of the screw to dock onto the pedicle. The Navigation Stylet can be extended further if needed to adequately dock to the posterior anatomy. (Fig 26)

- To extend the Navigation Stylet relative to the screw tip, turn the Red Stylet Control Handle clockwise. As the handle is turned, each “click” represents approximately 1 mm of stylet extension. The Navigation Stylet can be extended up to 5 mm while applying gentle downward pressure to ensure the Stylet remains docked. (Fig 27 & 28)
Surgical Technique

Pedicle Targeting continued

The screw will rise as you extend the Stylet.

- Using a mallet, gently tap the Modular Handle to advance the Stylet into the pedicle. (Fig 29)

Use the etched markings on the X-Tabs to ensure that you do not mallet the screw tip into the pedicle. Observe where the etched lines are relative to the skin prior to extending the Navigation Stylet once it is docked. This is your reference for when the screw tip is docked on bone.

The distance between the tip of the Navigation Stylet and the tip of the screw is represented on the Stylet Depth Gauge at the proximal end of the inserter. This can be used to track the position of the Stylet while it is being advanced into the pedicle.

The 1 mm starting protrusion of the Navigation Stylet can vary ±1.8 mm due to allowable manufacturing tolerances.

**Warning:** The Navigation Stylet will not be visible on the navigation screen. The user must ensure awareness that the stylet could potentially extend a maximum of 5mm beyond the tip of the screw. If the Navigation Stylet is not properly monitored using the Stylet Depth Gauge, there is a potential for pedicle or anterior wall breach, potentially resulting in neurological damage or damage to the great vessels.
Step 6
Screw Insertion

Once the Navigation Stylet has been extended, HOLD THE RED STYLET CONTROL HANDLE while rotating the proximal handle of the Navigation Inserter clockwise to advance the screw into the pedicle over the extended Stylet. (Fig 30)

Warning: It is critical to hold the Red Stylet Control Handle at all times while advancing the screw. Holding the Red Stylet Control Handle will retract the Navigation Stylet at approximately the same rate that the screw is advancing into the pedicle. As a result, the tip of the Navigation Stylet will not advance further into vertebral body as the screw is inserted. If the Red Stylet Control Handle is not held, the Navigation Stylet will remain extended and advance in front of the screw, potentially leading to an anterior wall breach, neurological damage or damage to the great vessels.

Reference the etched lines on the X-Tab to check that they move relative to the skin to ensure the screw is advancing.

Once the Navigation Stylet is fully retracted, the Red Stylet Control Handle will no longer rotate independent of the Navigation Inserter assembly. The tip of the Navigation Stylet is now approximately 1 mm beyond the tip of the screw and can be confirmed by the red line position on the Stylet Depth Gauge. At this point, release the Red Stylet Control Handle and insert the screw the remaining distance using the proximal handle until the screw is fully seated. Be sure that the polyaxial head is still mobile when the screw is seated. (Fig 31)

Disengage the screw from the Navigation Inserter by fully unthreading the green knob from the proximal threads of the implant and remove the Navigation Inserter and Stylet using the Red Stylet Control Handle. Use caution when removing the Navigation Stylet from the screw. (Fig 32)
Surgical Technique

Step 6a
Insertion of Additional Screws
• Follow the previous steps for the remaining screws.

• If the length of the subsequent screw is the same, the Navigation Stylet and Depth Adjustor do not need to be changed. If the length of the subsequent screw is different, remove the Depth Adjustor using the Set Screw Driver. Open the retaining sleeve and move the Navigation Stylet flange to the appropriate slot for the new screw length.

After each screw, visually check the Navigation Stylet to ensure that it has not been damaged or bent during screw insertion. If it has, replace the Navigation Stylet with a new one before proceeding to the next screw.

Warning: Discontinue use if inaccuracy is suspected.
Removal Instructions

If a decision is made to remove the implants after solid fusion occurs, the following steps should be taken after the implant is exposed.

For set screw, rod and screw removal:
Clean debris/tissue from set screws
Connect the Torque Handle to the X25 Set Screw Inserter
Insert Counter Torque over targeted screw and engage Inserter with set screw
Turn the handle counter-clockwise to loosen set screw while applying counter torque
Once the set screws are removed, the rods can be removed
Engage Set Screw Inserter with screw shank and turn handle counter-clockwise to remove screw
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5. Once the set screws are removed, the rods can be removed.
6. Engage Set Screw Inserter with screw shank and turn handle counter-clockwise to remove screw.

Instruments:

- 2867-50-041 Stylet Depth Adjustor
- 2867-50-010 Dilator
- 2867-50-020 Dilator Sleeve
- 2867-50-033 Inserter Carrier
- 2867-50-032 Red Stylet Control Handle
- 2867-50-036 Palm Handle
- 2867-50-035 T Handle
- 2867-50-070 Set Screw Inserter
Instruments and Sterile Implants

| 2867-50-042 | Navigation Inserter Drive Tube |
| 2867-50-131N | Navigation Inserter Shaft |
| 2867-50-132N | BrainLab Adaptor |
| 2867-50-133N | Universal Navigation Adaptor |
| 2867-50-210S | Navigation Stylet |

Sterile Implants

Cases and Trays

| 286750510 | VIPER PRIME Instrument Case |
| 286750500 | VIPER PRIME Navigation Instrument Tray 1 |
| 286750512 | VIPER PRIME Instrument Tray 2 |
| 279792109 | Case Lid |
| 286750600 | VIPER PRIME Stylet Carry Case (Nav & Non Nav) |
### Sterile Implants

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Indications and Contraindications

Indications For Use
The VIPER PRIME Navigated Inserter is a navigated instrument for insertion of VIPER PRIME screws in open or percutaneous procedures. The VIPER PRIME Navigated Inserter is indicated for use in spinal surgical procedures, in which:
• use of the VIPER System is indicated,
• use of stereotactic surgery may be appropriate, and
• where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy using a navigation system which includes universal tracking arrays supplied by the navigation manufacturer.
These procedures include but are not limited to spinal fusion. The VIPER PRIME Navigated Inserter requires manual calibration.

Contraindications
Medical conditions which contraindicate the use of this instrument include any medical condition which may be contraindicative for the surgical procedure itself. For example, pregnancy would be a contraindication if surgery itself poses risks to the developing fetus. The VIPER PRIME Navigated Inserter is indicated for spinal surgery and therefore, is only appropriate for use with spinal navigation software packages. All other navigation software packages are contraindicated. Any contraindications to the Brainlab Navigation System, Medtronic StealthStation® System, Stryker SpineMap® 3D Navigation System and VIPER System are also contraindications to the VIPER PRIME navigated inserter.
The VIPER PRIME Navigated Inserter is NOT compatible with implants from other manufacturers.
The VIPER PRIME Navigated Inserter is intended for insertion of the VIPER PRIME screws of the VIPER System.

Warnings
DePuy Synthes is not a navigation provider. The VIPER PRIME navigated inserter has been validated for use with the third-party navigation systems of Brainlab, Medtronic and Stryker. Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and navigation company. Refer to the navigation company’s software and user guides for calibration and navigation guidance. The navigation system should be set up per the manufacturer’s instructions. Compatible third-party navigation clamps and universal tracking arrays are listed above. Ensure the hospital has the appropriate third-party navigation instruments prior to the case. In the event that the respective third party tracking array set is unavailable, a manual technique using fluoroscopy, a Jamshidi needle, guidewire and the navigated inserter may be adopted. Additional warnings and precautions are noted within the technique at the relevant surgical technique step. For complete labeling, please refer to the instructions for use available electronically at www.e-flu.com. For all indications, contraindications, warnings, precautions and possible adverse effects not specific to the navigation system, see the VIPER PRIME System Surgical Technique Guide.
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Ensure the hospital has the appropriate third-party navigation instruments prior to the case.

Care should be taken to limit bending forces on calibrated instruments as deflection can influence navigation accuracy.

The stylet of the VIPER PRIME Navigated Inserter is not navigated and will not be visible on the navigation screen. The stylet protrudes 1mm beyond the distal tip of the screw when fully retracted. The stylet can be advanced a maximum of 5mm beyond the tip of the screw.