DePuy Synthes
COMPANIES OF Johnson & Johnson

# UNIVERSAL NAVIGATION INSTRUMENTS FOR EXPEDIUM® AND VIPER® MIS SPINE SYSTEMS

For manual-calibrated use with Medtronic StealthStation® Surgical Navigation System

This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

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# UNIVERSAL NAVIGATION INSTRUMENTS

**Universal Navigation Instruments for EXPEDIUM® and VIPER® Spine Systems**
The Universal Navigation Instruments for EXPEDIUM and VIPER are designed for compatibility with the Medtronic StealthStation Navigation System and the SureTrak®II clamps and arrays.

For full instructions on use, please refer to the following manuals and guides:
- EXPEDIUM 5.5 System Surgical Technique Guide
- VIPER 2 MIS Spine System System Guide
- Medtronic's software and user guides

**Universal Navigation Instruments for EXPEDIUM and VIPER Spine Systems meet Medtronic Navigation acceptance criteria for manual-calibrated instruments.**

**Note: For manual instrument calibration, the hospital's Medtronic navigation instrument set must include the SureTrakII clamps and arrays for general instrument calibration.**

See page 22 for list of compatible third-party navigation company instruments.

# FEATURES AND BENEFITS

**Compatible with Medtronic StealthStation Navigation System**

- Universal Navigation Instruments for EXPEDIUM 5.5 and VIPER Systems meet Medtronic Navigation's accuracy threshold for manual-calibrated instruments.

**Allows for Continuous Navigation**

- Specially designed Universal Navigation Adaptor instrument geometry accepts navigation adaptors for full rotation of array that allows for continuous visualization with the navigation camera.
- Dedicated placement of SureTrakII array allows for a smoother and more ergonomic handling of the instrument.

**Instrumentation Features**

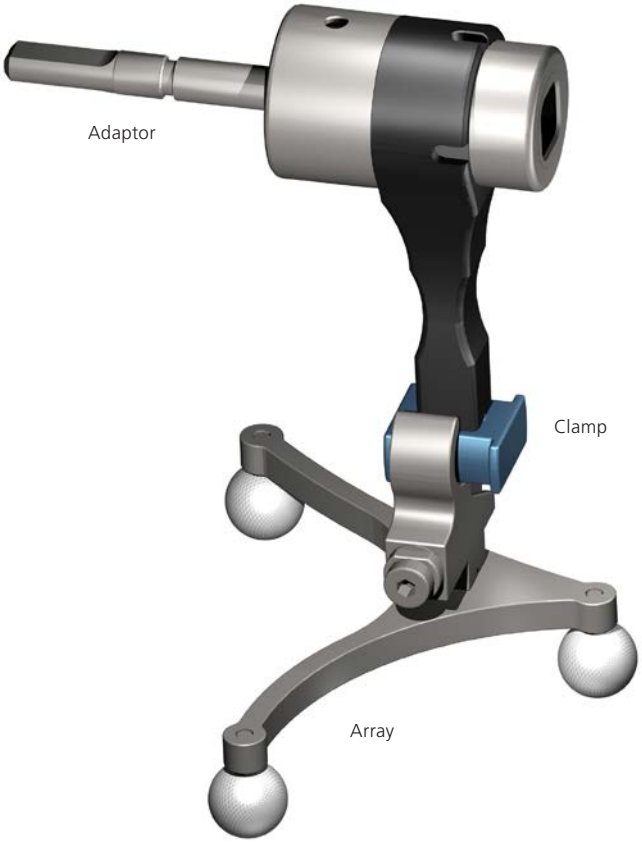
- Universal Navigation Instruments for EXPEDIUM 5.5 and VIPER Systems are manufactured with greater precision to meet the unique accuracy needs of navigated spine instruments.
- EXPEDIUM 5.5 or VIPER System screws: Instruments are manufactured with tighter tolerances compared to conventional instruments.
- Direct threaded connection point between the Universal adaptor and the SureTrakII array eliminates toggle; no clamp connection is necessary.

# UNIVERSAL NAVIGATION ADAPTOR OVERVIEW

**Features of *DePuy Synthes Spine* Universal Navigation System**

- The Universal Navigation Adaptor allows for rotation of arrays and clamps relative to the instrument axes for continuous visualization in the navigation system.

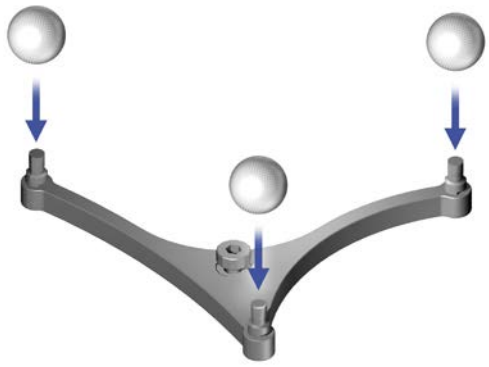
- The Universal Navigation Adaptor interface provides two attachment methods:
  - Direct attachment – Attach Array to Universal Navigation Adaptor Using Threaded Connection
  - Clamp attachment – Connect Array to Universal Navigation Adaptor Using Clamp and Clamp Attachment. Choose from two sizes of Universal Navigation Clamp Attachments to use with various size clamps and arrays.



# UNIVERSAL NAVIGATION ADAPTOR ASSEMBLY

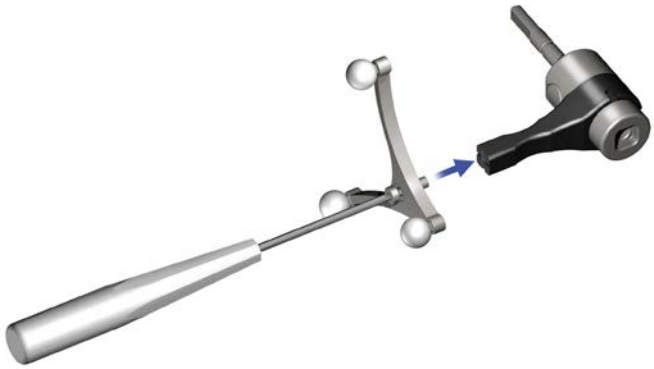
**Attach Reflective Spheres**

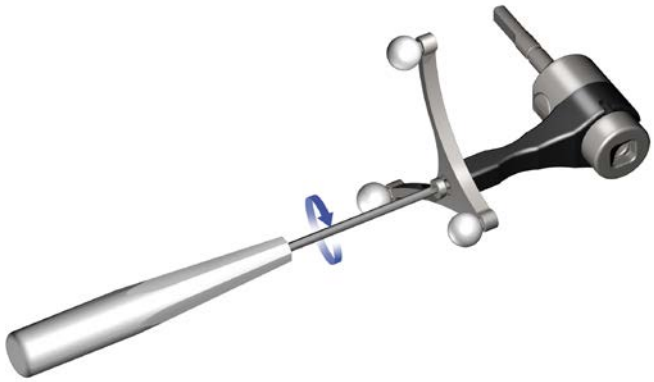
Assemble disposable reflective marker spheres according to Medtronic's instructions.



**Preferred Medtronic Compatibility:**

**Attach Array to Universal Navigation Adaptor Using Threaded Connection**
Tighten the Medtronic array to the Universal Navigation Adaptor until securely attached.





Final Assembly

**Alternate Medtronic Compatibility:**

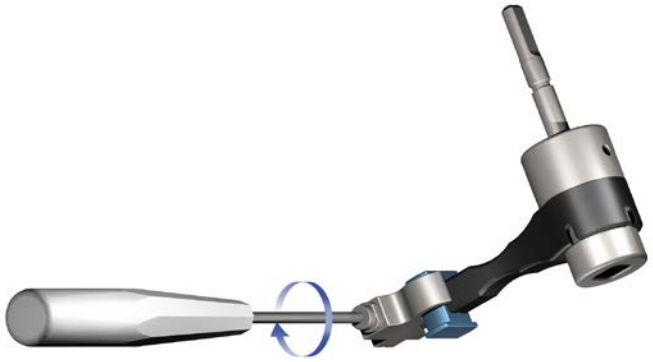
**Medtronic SureTrakII Universal Tracker Clamp Assembly**

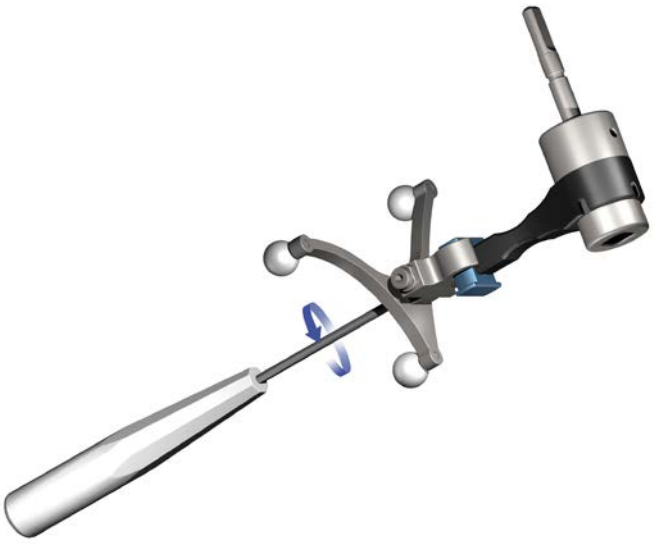
Tighten the SureTrakII Universal Tracker Clamp to the Universal Clamp Attachment until securely attached.

Reference the table for Compatibility Connections between the Universal Navigation Clamp Attachment and the Universal Clamps.

| | Medtronic Clamp, Small | Medtronic Clamp, Medium | Medtronic Clamp, Large |
|---|---|---|---|
| Small Clamp Attachment | YES | YES | NO |
| Large Clamp Attachment | NO | YES | YES |

**Caution:** **Ensure the clamps are assembled to the instruments in the absence of tissue and fluid to ensure rigid fixation.**





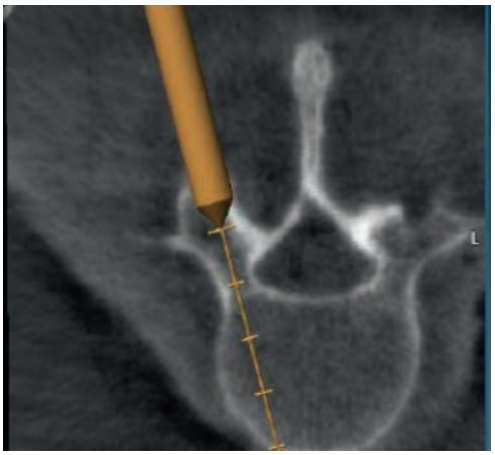
Attach the SureTrakII Universal Tracker Fighter array to the Clamp until securely fastened.

Final Assembly:
Universal Navigation Adaptor with SureTrakII Universal Tracker Clamp

# MANUAL-CALIBRATED INSTRUMENT ASSEMBLY AND USAGE

- Instruments must be calibrated each time prior to use, as no instrument geometry or dimensions are retained in the navigation software.

- After calibration, instruments are shown with generic shapes in the navigation software.



Brainlab navigation software screen showing manual-calibrated instrument representation.

**Instrument Assembly**

Slide your chosen instrument into the Universal Navigation Adaptor until it snaps into place.


Attach a *DePuy Synthes Spine* EXPEDIUM or VIPER System handle.


The instrument is now ready for calibration. Refer to the navigation manufacturer's user guides for general instrument calibration instructions.

**Warning:** **Each time the clamp attachment, clamp and/or array is changed or removed, the instrument must be re-calibrated for accuracy.**

# EXPEDIUM SPINE SYSTEM

**Pedicle Preparation**
Calibrate and verify accuracy per the navigation software and user guides.

**Navigation Note:** **The user can plan an ideal trajectory and a virtual screw can be optionally sized and planned to assist in aiming the navigation instruments. Refer to the navigation system user guides for more details.**

## 1
**Perforate Cortex of Pedicle with Awl and Open Pedicle Canal with Probe**

At this time, we do not offer Universal Adaptor compatibility with EXPEDIUM or VIPER System awls or probes.

If an EXPEDIUM System pedicle preparation instrument is desired, select desired instrument. Refer to the Guide for usage instructions.

## 2
**Tap**

Identify the desired size and lead tap. Assemble desired tap as described in assembly and usage section.

At this time, we do not offer a navigated single-lead tap. If uniplanar or monoaxial screws are desired, select the appropriately sized matching tap and refer to the Guide for usage instructions.

Locate pedicles and rotate the tap in a clockwise direction to continue down the pedicle canal. To remove the tap, rotate the tap in a counterclockwise direction.

**Note:** **Tap threads for Navigated EXPEDIUM Taps are undersized. The tap for the same size screw will result in under-tapping.**

**Screw Insertion**

To assemble quick-connect driver, insert the inner shaft into the outer sleeve. Push the collar of the inner shaft until an audible click is heard. Pull back on the inner shaft to ensure the components do not disassemble (A).


Place the tip of the screwdriver into the head of the screw (B). Rotate the outer sleeve clockwise until it is tight. Ensure the screw shaft is straight (C). For a full overview of the screw loading process, refer to the Guide.


Slide the driver shaft into the Universal Navigation Adaptor until it snaps into place. Attach a *DePuy Synthes Spine* handle onto the proximal end of the Universal Navigation Adaptor assembly.


**Note:** **If using monoaxial screws the EXPEDIUM Spine System 5.5 Monoaxial Driver is required.**

**Note:** **Prior to manually calibrating the attached screw, make sure that the screw is rigidly connected to the driver shaft.**

**Warning:** **If the screw type or size is changed, the instruments must be re-calibrated for accuracy prior to use.**

# VIPER SPINE SYSTEM

**Pedicle Preparation**
Calibrate and verify accuracy per the navigation software and user guides.

**Navigation Note:** **The user can plan an ideal trajectory and a virtual screw can be optionally sized and planned to assist in aiming the navigation instruments. Refer to the navigation system user guides for more details.**

## 1
**Perforate Cortex of Pedicle with Awl and Open Pedicle Canal**

At this time, we do not offer Universal Adaptor compatibility with EXPEDIUM or VIPER System awls or probes.

If a VIPER System pedicle preparation instrument is desired, select desired instrument. Refer to the VIPER 2 MIS Spine System System Guide for usage instructions.

**Warning:** **Probes and bone taps are marked but should not be used as measuring tools or to determine penetration depth. Screw length should be determined using the navigation software.**

## 2
### Insert Guide Wire

**Warning:** **The guide wire is not a navigated instrument. Ensure the guide wire remains securely in position throughout the entire duration of the procedure.**

Insert guide wire through the cannulated instrument. Sharp or blunt *DePuy Synthes Spine* guide wires can be used as desired.

**Note:** **Refer to Guide for compatible guide wire options.**

Advance the guide wire beyond the tip of the instrument to ensure adequate fixation into the cancellous bone.

**Note:** **To ensure proper depth and control, drive the guide wire by clamping a needle driver onto the guide wire at the desired distance proximal to the cannulated instrument and impact the needle driver until it contacts the top of the cannulated instrument.**

If necessary, use lateral fluoroscopy to monitor guide wire depth.

While maintaining the position of the guide wire within the pedicle, remove the cannulated instrument used to perforate the cortex of the pedicle.

**Caution:** **Markings on the guide wire should not be used as measurements and should not be used to determine penetration depth.**

## 3
### Tap

Identify the appropriate size tap. Assemble desired instrument as described in assembly and usage section.

Place the tip of the cannulated tap over the guide wire and rotate the tap in a clockwise direction to continue down the pedicle canal.

**Warning:** **To prevent inadvertent advancement of the guide wire, align the trajectory of the tap with the guide wire and monitor the guide wire position using fluoroscopy.**

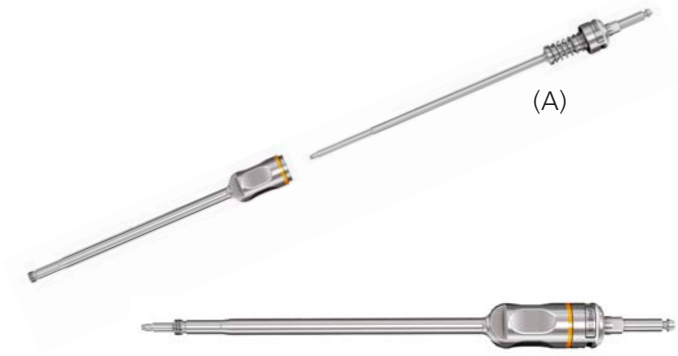
To remove the tap, while maintaining the position of the guide wire within the pedicle, rotate the tap in a counterclockwise direction.

**Note:** **Tap threads for Navigated VIPER Taps are undersized. The tap for the same size screw will result in under-tapping.**

If desired, use the VIPER System tap sheath to protect soft tissue during tapping. For a full overview of the use of the tap sheath, refer to the Guide.

**Screw Insertion**
Refer to screwdriver assembly and usage section as needed.

**Option A: VIPER Screws**
To assemble the 5.5 Universal Quick Connect Driver for use with polyaxial or uniplanar screws, insert the inner shaft into the outer sleeve. Push the collar of the inner shaft until an audible click is heard. Pull back on the inner shaft to ensure the components do not disassemble (A).


(A)

Attach the VIPER Screw to the screw extension, and secure by tightening the castle nut. Insert the screwdriver (B). Rotate the outer sleeve clockwise until it is tight.
Ensure the screw shaft is straight (C).


(B)


(C)

**Note:** **If using monoaxial screws, use the VIPER System 5.5 Cannulated Monoaxial Driver. For a full overview of the screw loading process, refer to the VIPER System Surgical Technique.**

Attach the Universal Navigation Adaptor assembly onto the driver shaft until it snaps into place. Attach a *DePuy Synthes Spine* handle onto the proximal end of the Universal Navigation Adaptor assembly. Calibrate as described in the assembly and usage sections.

**Option B: VIPER X-Tab Screws**
Guide an X-Tab sleeve over the tabs of the X-tab screw until it is fully seated against the screw head (D).


(D)

**Note:** **The X-Tab sleeve will help prevent unintentional separation of the tabs from the screw heads.**

Insert the screw driver and secure by turning clockwise until it is tight (E). For a full overview of the screw loading process, refer to the Guide.


(E)

Attach the Universal Navigation Adaptor assembly onto the driver shaft until it snaps into place. Attach a *DePuy Synthes Spine* handle onto the proximal end of the Universal Navigation Adaptor assembly. Calibrate as described in the assembly and usage sections.

**Caution:** **The screws are not pre-calibrated navigated implants and must be manual-calibrated attached to the screwdriver prior to use.**

**Warning:** **If the screw type or size is changed, the instrument must be re-validated/verified or re-calibrated prior to use.**

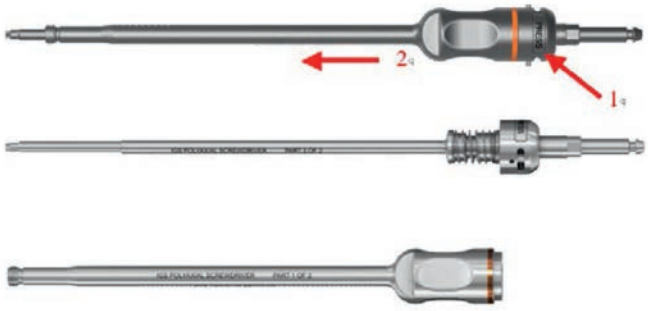
Place the tip of the screwdriver over the guide wire and insert the screw. Advance the screw into the pedicle by turning the ratchet handle clockwise.

Remove the guide wire once the tip of the screw enters the vertebral body.

**Warning:** **Do not advance the screw into the pedicle until the screw axis is aligned with the guide wire, to prevent kinking or unintended advancement. Monitor the tip of the guide wire under fluoroscopy to ensure it does not penetrate the anterior wall of the vertebral body.**

**Disassembly of 5.5 Universal Quick Connect Poly Driver (2797-34-000N)**

To disassemble the poly driver, press on the locking button (1) and pull the outer sleeve away from the inner shaft (2).



# INSTRUMENT RECOMMENDATIONS

**Warning:** **Between uses, lubricate moving parts including the button on the adaptor and the button on the 5.5 Quick Connect Poly Driver with a water-soluble lubricant in accordance with the manufacturer's instructions.**

Physicians and operators of the system, instruments and software should read the user guides carefully before handling the equipment and have access to the user guides at all times. Prior to using the Universal Navigation Instruments for EXPEDIUM and VIPER Spine Systems the physicians and operators should review the *DePuy Synthes Spine* system guides for their indications for use.

The following *DePuy Synthes Spine* user guides are available:

| > USER GUIDE | > CONTENTS | > LOCATION |
|---|---|---|
| *DePuy Synthes Spine* VIPER, VIPER 2, VIPER 3D MIS Correction Set and EXPEDIUM System Guides | Guides showing use of the EXPEDIUM and VIPER Spine Systems | Contact your *DePuy Synthes Spine* sales consultant to obtain copies of the system guide |

*DePuy Synthes Spine* Universal Navigation Instruments for EXPEDIUM and VIPER Spine Systems are NOT compatible with the implants from other manufacturers. The Universal Navigation Instruments for EXPEDIUM and VIPER Systems are intended for use with the following *DePuy Synthes Spine* implants:

- VIPER and VIPER 2 Systems
- EXPEDIUM 5.5 Spine System

# GLOSSARY

**Terms Used in this Surgical Technique**

**Clamps:** Refers to Medtronics SureTrakII Universal Tracker Clamp.

**Arrays:** Refers to Medtronic's SureTrakII Universal Tracker Passive Fighters.

**Manual-calibrated:** This type of instrument usage has the instrument dimensions acquired by the software through a calibration process. The Universal Navigation Instruments for EXPEDIUM and VIPER Systems can be used manual-calibrated by using Medtronic's clamps and arrays for general instrument calibration and following the instructions for use.

# INSTRUMENTS:
# UNIVERSAL NAVIGATION ADAPTOR

286755001N Universal Navigation Adaptor

286755010N Universal Navigation Clamp Attachment, Small

286755011N Universal Navigation Clamp Attachment, Large

# INSTRUMENTS: EXPEDIUM 5.5 SYSTEM

| | |
|---|---|
| 301020300N | Universal Navigation EXPEDIUM 5.5 Graphic Case |
| 301020301N | Universal Navigation EXPEDIUM 5.5 Tray |
| 279792109 | EXPEDIUM Instrument Case Generic Lid |

| | Dual-lead Taps |
|---|---|
| 279702400N | 4.35 mm |
| 279702500N | 5.00 mm |
| 279702600N | 6.00 mm |
| 279702700N | 7.00 mm |
| 279702800N | 8.00 mm |

| | |
|---|---|
| 279734000N | 5.5 Universal Quick Connect Poly Driver |

| | |
|---|---|
| 279600120 | SLIM-LOC Hex Head Screwdriver |

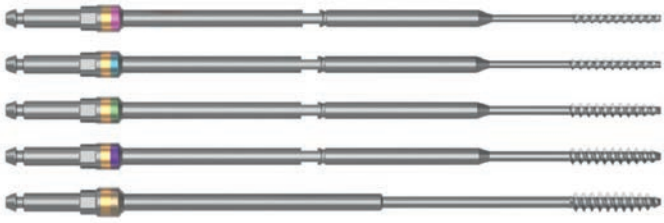

**Additionally Available EXPEDIUM Instruments:**

| | |
|---|---|
| 279712830N | EXPEDIUM Spine System 5.5 Monoaxial Driver |

# INSTRUMENTS: VIPER SYSTEM

| | |
|---|---|
| 301020400N | Universal Navigation VIPER Graphic Case |
| 301020401N | Universal Navigation VIPER Tray |
| 279792109 | EXPEDIUM Instrument Case Generic Lid |

| | Dual-lead Cannulated Taps |
|---|---|
| 286715450N | 4.35 mm |
| 286715500N | 5.00 mm |
| 286715600N | 6.00 mm |
| 286715700N | 7.00 mm |
| 286715800N | 8.00 mm |



| | |
|---|---|
| 279734000N | 5.5 Universal Quick Connect Poly Driver |

| | |
|---|---|
| 279600120 | SLIM-LOC Hex Head Screwdriver |

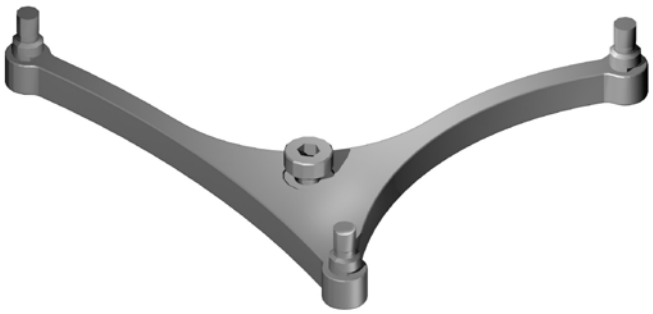

**Additionally Available VIPER Instruments:**

| | |
|---|---|
| 286720000N | VIPER System 5.5 Polyaxial Screw Driver Shaft, Cannulated |
| 286760010N | VIPER System 5.5 X-Tab Polyaxial Driver, 10 mm |
| 286760017N | VIPER System 5.5 X-Tab Polyaxial Driver, 25 mm |
| 286720100N | VIPER System 5.5 Cannulated Monoaxial Driver |

# INSTRUMENTS AVAILABLE THROUGH MEDTRONIC

**Medtronic SureTrakII Clamps and Arrays**

| | |
|---|---|
| 9731567 | SureTrakII Universal Tracker, Small Passive Fighter |
| 961-576 | SureTrakII Universal Tracker, Small Clamp |
| 961-578 | SureTrakII Universal Tracker, Medium Clamp |
| 961-579 | SureTrakII Universal Tracker, Medium Passive Fighter |
| 961-580 | SureTrakII Universal Tracker, Large Clamp |
| 961-581 | SureTrakII Universal Tracker, Large Passive Fighter |



# INDICATIONS

**Indications for Use**
The Universal Navigation Instruments for EXPEDIUM and VIPER MIS Spine Systems are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which the 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 tracking arrays provided by the navigation manufacturer. These procedures include but are not limited to spinal fusion. These devices can be pre-calibrated and/or manually calibrated with Brainlab Navigation system, where other navigation systems require 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 Universal Navigation Instruments for EXPEDIUM and VIPER MIS Spine Systems are indicated for spinal surgery and therefore are only appropriate for use with spinal navigation software packages. All other navigation software packages are contraindicated.

- DePuy Spine VIPER and EXPEDIUM navigated instruments are NOT compatible with implants from other manufacturers. The VIPER and EXPEDIUM navigated instruments are intended for use with the following DePuy Spine implants:
  - Product
  - VIPER and VIPER 2 Systems
  - EXPEDIUM 5.5 Spine System

**Warnings and Precautions**
Caution: DePuy Synthes is not a navigation provider. The instruments have been validated for use with Medtronic's StealthStation navigation system. 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. Compatible third-party navigation clamps and arrays are listed in the Surgical Technique. Ensure the hospital has the appropriate third-party navigation instruments prior to the case.

**Note:** **For information on use of disposable reflective marker spheres, refer to navigation manufacturers' user guides.**

**Warnings:**

- **The navigated instrument is a highly accurate and sensitive medical device. Handle it with extreme care. If you drop or otherwise damage it, verify its calibration accuracy. Failure to do so may lead to serious injury to the patient.**
- **Care should be taken to limit bending forces on calibrated instruments as deflection can influence navigation accuracy.**
- **Plan the setup of the OR and instrument array orientation prior to surgery. The navigation camera must have an unobstructed and simultaneous view of the instrument and navigation array.**

**Caution:** **The navigation system should be set up per the manufacturer's instructions.**

DePuy Synthes
COMPANIES OF Johnson&Johnson
People inspired™

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuysynthes.com

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