



ZIMMER BIOMET

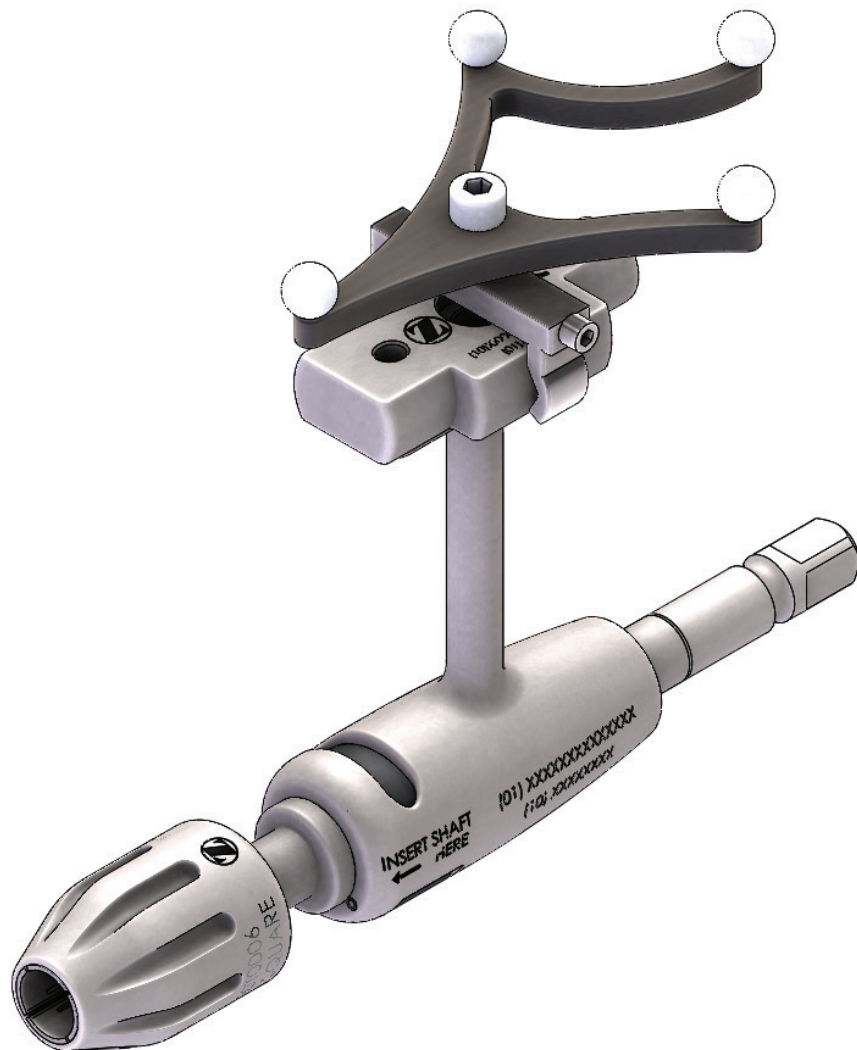
Your progress. Our promise.®



Universal Navigation System

Surgical Technique Guide

Compatible with the Medtronic® StealthStation®
Navigation System and SureTrak™ II Accessories



The Zimmer Biomet Universal Navigation System is intended to be used with instrumentation from Vitality[®] and Vital[™] Spinal Fixation System (including the Vital[™] Power Instrument Kit), PathFinder NXT[®] Minimally Invasive Pedicle Screw System, Cypher[™] MIS Screw System and the Polaris[™] Spinal Fixation System. It is specifically designed for use with the Zimmer Biomet ROSA ONE[®] System and Medtronic[®] StealthStation[®] System.

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Zimmer Biomet 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 Zimmer Biomet Universal Navigation System was designed for compatibility with the Medtronic StealthStation System and the SureTrak II clamps and arrays. The following Zimmer Biomet systems may be utilized with the Universal Navigation System: Vitality Spinal Fixation System, Vital Spinal Fixation System, PathFinder NXT Minimally Invasive Pedicle Screw System, Cypher MIS Screw System and the Polaris Spinal Fixation System.

This Surgical Technique Guide will focus on the compatibility with the Medtronic StealthStation System. Please refer to the ROSA ONE Universal Navigation Assembly Guide and ROSA ONE User Manual when utilizing the ROSA ONE System.

Users should follow instructions provided by the manufacturer of the navigation system utilized. The navigation company's arrays must be utilized for the manual calibration of general instruments.

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

Please refer to the following surgical technique guides, which can be found on zimmerbiomet.com, technical guiding principles for each system:

- Vitality Spinal Fixation System
- Vital Power Instrument Kit
- Vital Spinal Fixation System
- Polaris 5.5 Spinal System
- PathFinder NXT Minimally Invasive Pedicle Screw System
- Cypher MIS Screw System

UNIVERSAL NAVIGATION OVERVIEW

Universal Navigation Adaptor Overview

The Zimmer Biomet Universal Navigation Adaptor is ergonomically designed to facilitate rotation of the arrays relative to the instrument axis for uninterrupted navigation.

Compatibility with SureTrak II Array Kit

The Medtronic SureTrak II Universal Tracker, Small Passive Fighter shall not be used on any Zimmer Biomet instrumentation.

The Medtronic SureTrak II Universal Tracker, Medium Passive Fighter may be used for all instruments with the exception of drivers and iliac taps.

The Medtronic SureTrak II Universal Tracker, Large Passive Fighter may be used with all Zimmer Biomet instrumentation (including compatible screws mounted on screw inserter). See compatibility chart on page 15.

Features and benefits include:

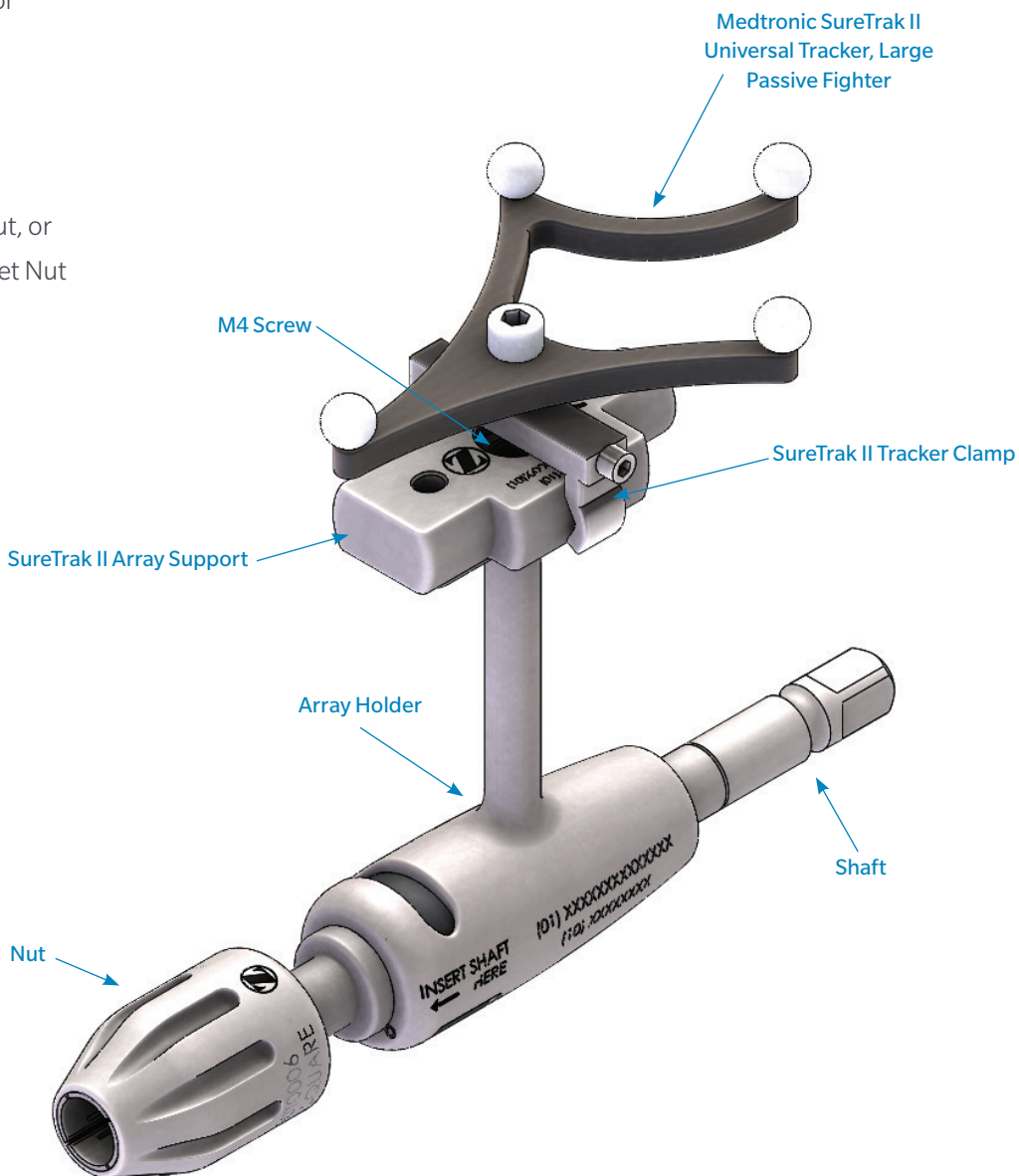
- Suitable for a MIS or Open Approach
- Uninterrupted navigation facilitated by a freely-rotating adaptor
- Ergonomically designed to facilitate the hand-held stabilization of the array relative to the instrument
- Compatible with multiple navigation-ready systems (Medtronic StealthStation Navigation System and ROSA ONE)
- The surgical instruments to be assembled and navigated using the Universal Adapter are:
 - PathFinder NXT taps and screwdrivers
 - Cypher taps and screwdrivers
 - Vitality/Vital taps and screwdrivers
 - Polaris taps, reamer probe and screwdrivers
 - Vital Power Reamer Probes

UNIVERSAL NAVIGATION ADAPTOR ASSEMBLY

Assembly of the Universal Navigation Adaptors should be completed prior to the start of the surgery. The Zimmer Biomet Universal Navigation System includes components for the assembly of three adaptors.

Each adaptor will require the following five components when utilized with Medtronic StealthStation Navigation System:

- Array Holder
 - ¼ Square- ¼ Square Shaft, or
 - ¼ Square- Tri-Flat Shaft, or
 - Large AO Shaft, or
 - Standard AO Shaft
- Nut
 - Square and Tri-Flat Collet Nut, or
 - Large and Standard AO Collet Nut
- Array Support
- M4 Screw



UNIVERSAL ADAPTER ASSEMBLY

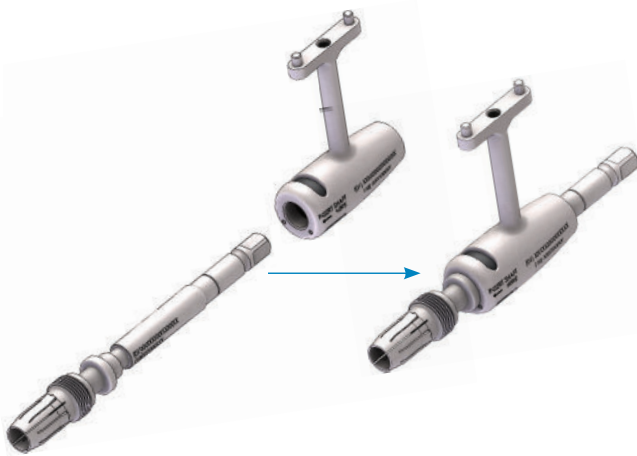


Figure 1

STEP 1: SHAFT ASSEMBLY

- Insert any of the four shafts into the array holder.
- To ensure proper assembly of the array adaptor, the shaft must be inserted from the end of the array holder where the button will be closest to the chuck end of the shaft (Figure 1). An "INSERT SHAFT HERE" laser marking can be seen on the holder to ensure proper assembly.
- During the assembly sequence, a hard point must be passed for the shaft to be fully inserted (Figure 2).
- The shaft will engage and lock into the array holder when fully inserted.

Note: The button must be flush with the cylindrical portion of the array holder to ensure the shaft has been fully inserted.

Note: If the adapter is correctly assembled, the array holder will rotate freely around the shaft.

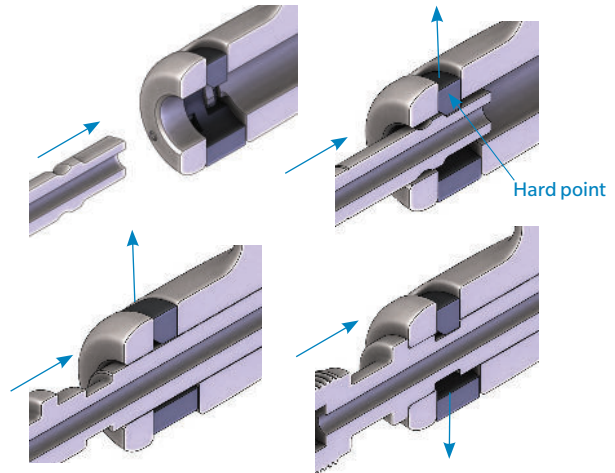


Figure 2

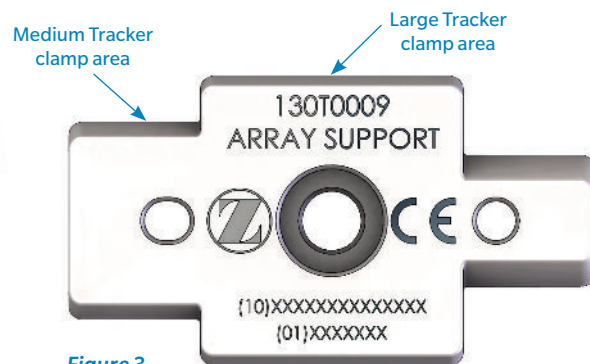


Figure 3

STEP 2: ARRAY ATTACHMENT

- Assembly of the Medtronic SureTrak II navigation array (Reflective Spheres, SureTrak II Universal Tracker Clamp and SureTrak II Tracker Fighter) can be found in Medtronic's SureTrak II user manual.
- There are two separate points of attachment on the array support that are dependent on the size of clamps selected (Figure 3).
 - The medium portion on the opposite end of the array support is dedicated to the SureTrak II Tracker, medium clamp.
 - The center and largest portion on the array support are dedicated to the SureTrak Tracker, large clamp.

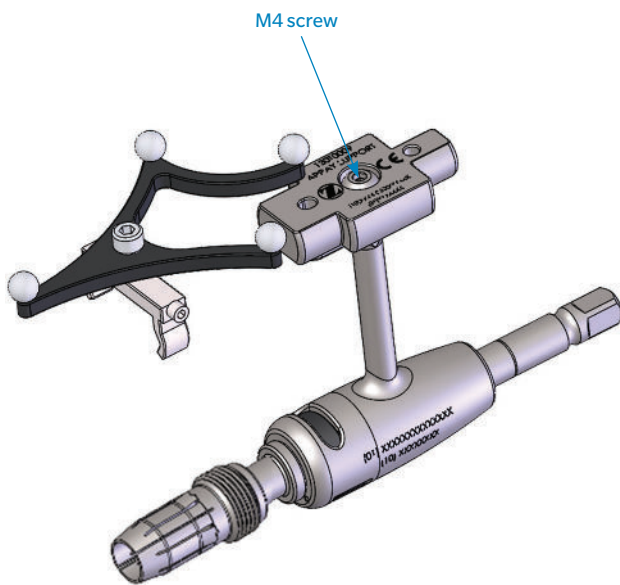


Figure 4

- Attach the array support to the array holder with a M4 screw utilizing the 2.5 hex driver until it is securely attached. (Figure 4).

Note: Make sure to properly tighten the M4 screw, no residual mobility between the array support and the array holder should remain if the M4 screw is properly tightened.

- Tighten and lock the array to the proper section of the array support (Figure 5) using Medtronic driver from SureTrak II kit.

Note: There is no incorrect orientation position for the array, however, it is critical that a secure connection is made between the clamp and the array support to prevent migration of the array during surgery.

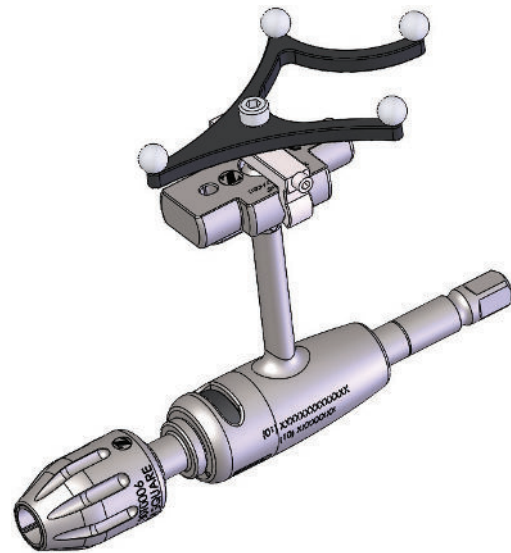


Figure 5

STEP 3: NUT ATTACHMENT

- Insert the appropriate nut and provisionally tighten on the chuck end of the shaft (Figure 5).

Note: The instrument cannot engage with the adapter if the nut is fully tightened to the shaft.

Tip: For ease of attachment, a handle can be attached at this stage for better grip and handling of the adapter.

- Prepare the patient reference and set up the Medtronic StealthStation System according to the standard procedures outlined in Medtronic's user manual.

INSTRUMENT ATTACHMENT



Figure 6

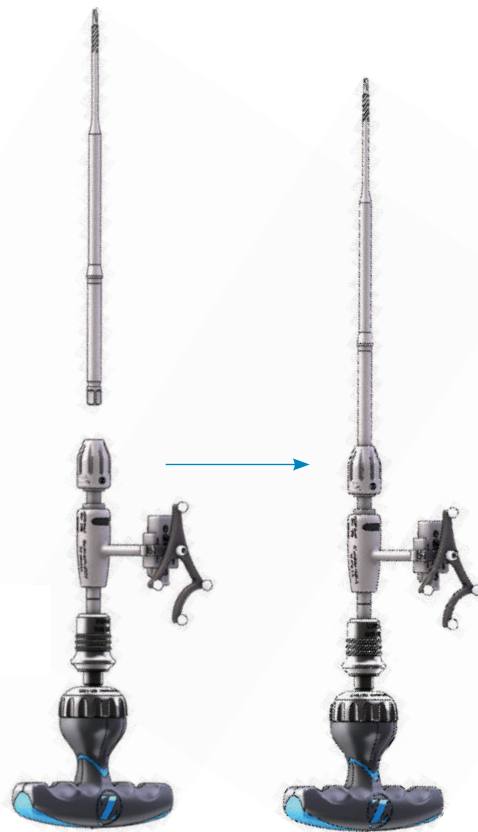


Figure 7

STEP 4

- If a handle has not been attached yet, connect the handle to the universal adapter with one hand supporting the handle and the other free hand introducing the adapter from a vertical position (Figure 6).
- At this step, it is **very important to maintain the assembly vertically** to guarantee a solid connection and accuracy of the end tip of the navigated instrument.
- Maintaining the assembly in the vertical position, insert the selected Zimmer Biomet instrument into the corresponding nut previously attached to the array holder and shaft assembly. A tactile stop will be felt when the instrument is fully inserted onto the nut of the array assembly (Figure 7).



Figure 8

- Utilizing the collet nut key, complete tightening of the nut until a secure connection is achieved (Figure 8).
 - When tightening the collet nut to rigidly affix the instrument into the adaptor shaft, the assembly should be held in a vertical position and the collet nut key should be held perpendicular to the shaft (Figure 8). Failure to assemble this instrument in the vertical orientation may lead to decreased accuracy of the the system during use.
- When using Power, connection to a Standard AO handle is necessary to apply counter-torque for the final tightening of the adapter nut.

Note: It is important to not exceed the instrument lengths stated for each array (see compatibility chart on page 15). If the arrays are used outside the scope, it could lead to decreased accuracy for the system.

Tip: For ease of tightening, slide the collet nut key along opposing grooves of the nut until a tactile stop is felt and then proceed with tightening.

INSTRUMENT CALIBRATION AND INSERTION

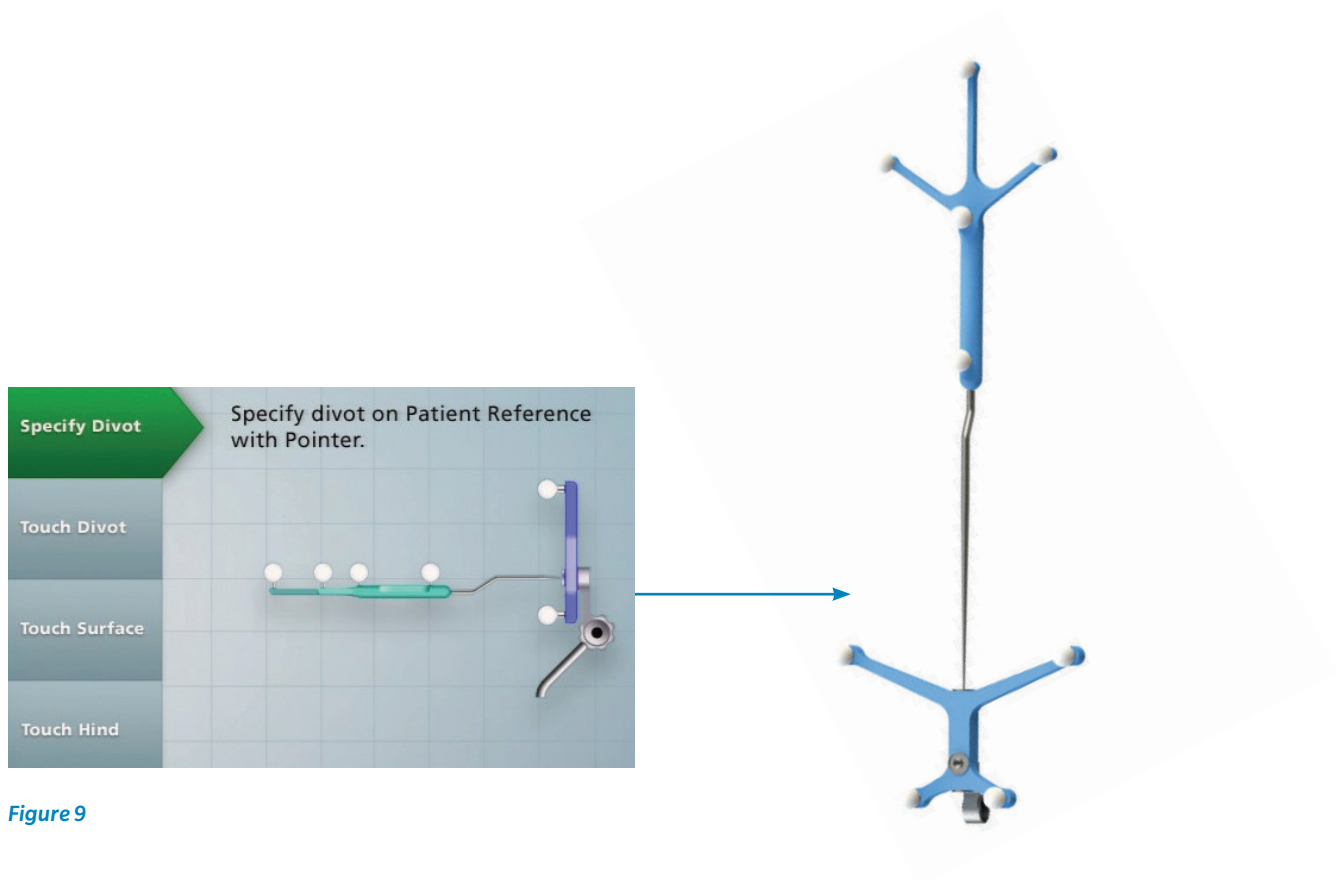


Figure 9

STEP 5

Medtronic StealthStation - Calibrate SureTrak

- Assemble instrumentation as listed above in steps 1-4.
- Prior to pedicle preparation, instrument calibration and verification of accuracy must be completed.
- The following steps outline the way Zimmer Biomet's instruments are used with the StealthStation. The Medtronic User Guide must be utilized throughout these steps.

- When utilizing a Zimmer Biomet System driver with screw, the appropriate screw must be selected and attached to the driver prior to instrument calibration.
- **Step 1** - Specify divot on patient reference with pointer (Passive Planar) (Figure 9).

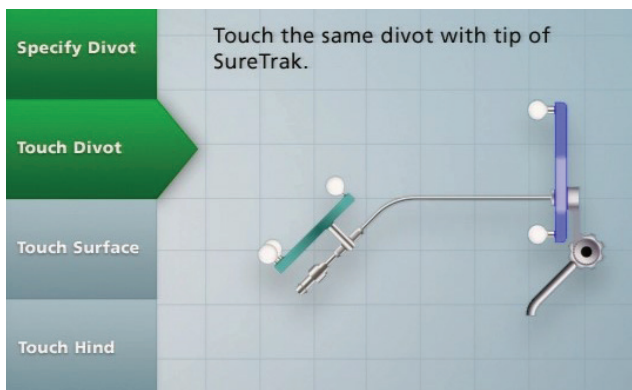


Figure 10

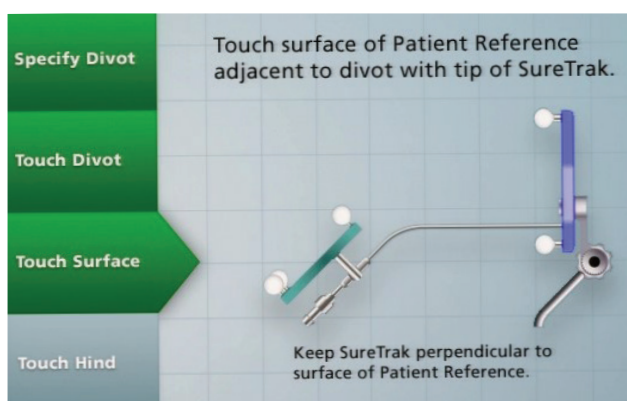
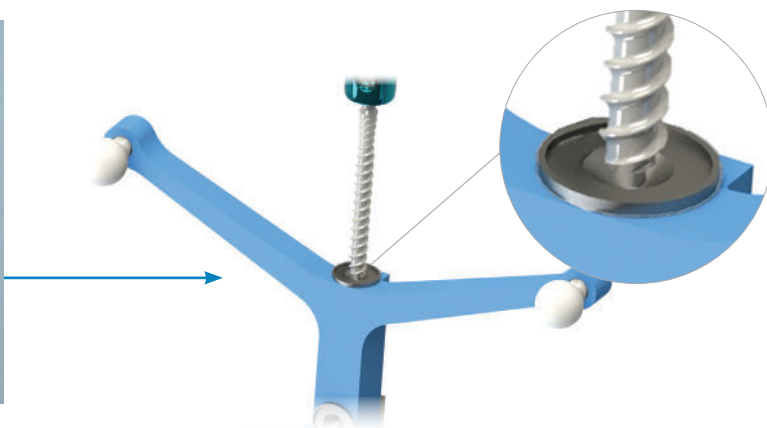
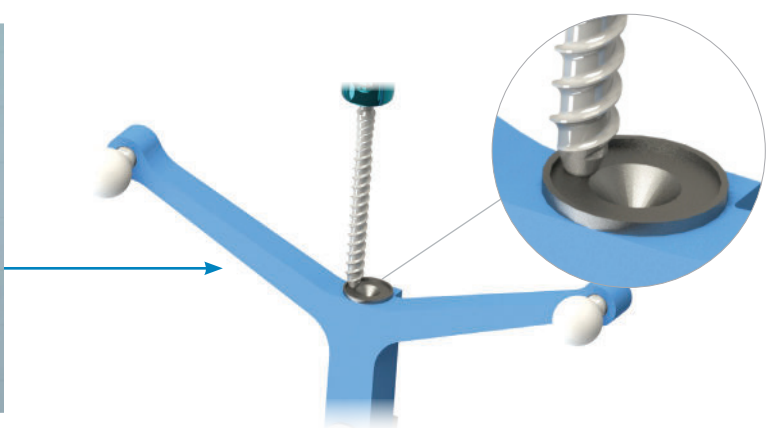


Figure 11



- **Step 2** - Touch the same divot with tip of the assembled Zimmer Biomet instrument with a SureTrak array (Figures 10).

- **Step 3** - Touch surface of patient reference adjacent to divot with tip of the assembled Zimmer Biomet instrument with a SureTrak array (Figures 11).

Tip: Keep SureTrak perpendicular to surface of patient reference.

Note: If using the driver with screw assembly, the tip of the screw will touch the divot in Step 2 and patient reference adjacent to divot in Step 3.

INSTRUMENT CALIBRATION AND INSERTION (*continued*)

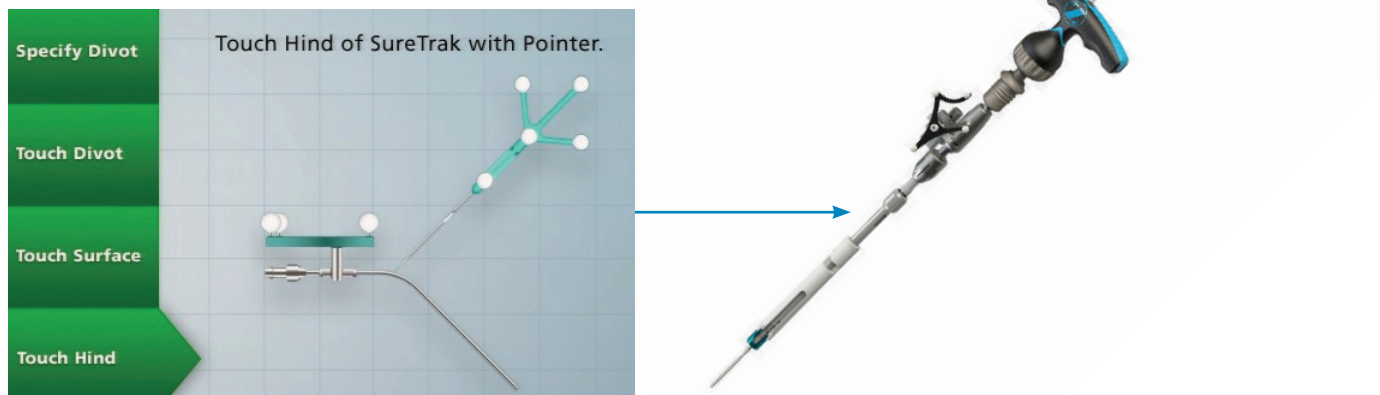


Figure 12

STEP 5 (*continued*)

- **Step 4** - Touch hind of the assembled Zimmer Biomet instrument with a SureTrak array with pointer (Figure 12).

Note: When guided to touch the passive planar to the back of the instrument, ensure that the point of the passive planar is touching the center point of the handle and is in line with the tip of the instrument. For cannulated instruments, the passive planar may be inserted into the cannula as these are central points in the instrument (Figure 13).

Note: Once calibration is complete, instruments are visualized as generic shapes in the navigation software.

Note: It is important that the patient reference array is covered from the camera at this step to ensure proper calibration.

- When adding a new instrument to an already calibrated array or a new implant to an instrument/implant assembly which has already been calibrated, the calibration step must be re-performed.

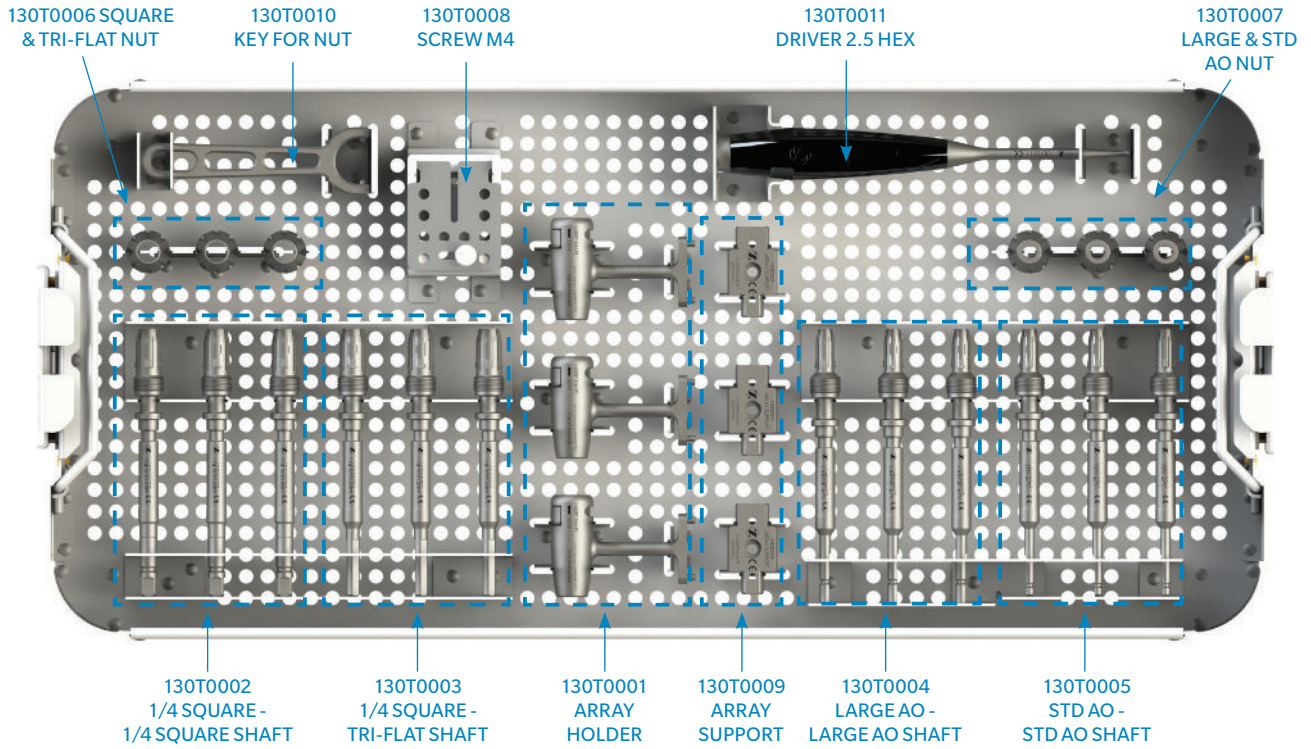
Note: Failure to re-calibrate instruments after changes to the instrument or instrument/implant assembly can lead to decreased accuracy for the assembly.



Figure 13: Top down views of standard instrument handles with red spots indicating the approximate location to touch the tip of the passive planar to the instrument during the calibration process.

INSTRUMENTS

Universal Navigation Instrument Kit Kit Number: PCR100T1100



Instruments



Array Holder PART NUMBER
130T0001



1/4 Square - Tri-Flat Shaft PART NUMBER
130T0003



Large AO Shaft PART NUMBER
130T0004



1/4 Square - 1/4 Square Shaft PART NUMBER
130T0002



Standard AO Shaft PART NUMBER
130T0005



Square & Tri-Flat Collet Nut PART NUMBER
130T0006



Array Support PART NUMBER
130T0009



Large & Standard AO Collet Nut PART NUMBER
130T0007



Collet Nut Key PART NUMBER
130T0010



Screw M4 PART NUMBER
130T0008



2.5 Hex Driver PART NUMBER
130T0011

ADAPTER COMPATIBILITY CHART WITH SURETRAK II ARRAYS

Zimmer Biomet MIS Percutaneous Screw Fixation Systems

PathFinder NXT (K132884)

INSTRUMENT TYPE	PART NUMBER	INSTRUMENT DESCRIPTION	MEDIUM	LARGE
Taps	3552-140	Cannulated Awl-Tap 4.0 mm	X	X
	3552-150	Cannulated Awl-Tap 5.0 mm	X	X
	3552-160	Cannulated Awl-Tap 6.0 mm	X	X
	3552-170	Cannulated Awl-Tap 7.0 mm	X	X
	3552-240	Cannulated Drill-Awl-Tap 4.0 mm	X	X
	3552-250	Cannulated Drill-Awl-Tap 5.0 mm	X	X
	3552-260	Cannulated Drill-Awl-Tap 6.0 mm	X	X
	3554-270	Cannulated Drill-Awl-Tap 7.0 mm	X	X
	3554-070	PAT TAP 4.0 mm	X	X
	3554-070	PAT TAP 5.0 mm	X	X
	3554-070	PAT TAP 6.0 mm	X	X
	3554-070	PAT TAP 7.0 mm	X	X
	Screwdrivers	3558-1	Classic Screwdriver + screws <35 mm	X
Classic Screwdriver + screws ≥35 mm				X
3558-2		Reduction Screwdriver + screws <35 mm	X	X
		Reduction Screwdriver + screws ≥35 mm		X

Cypher (K151974)

INSTRUMENT TYPE	PART NUMBER	INSTRUMENT DESCRIPTION	MEDIUM	LARGE
Taps	14-501684	Tap 4.5 mm	X	X
	14-501685	Tap 5.0 mm	X	X
	14-501686	Tap 5.5 mm	X	X
	14-501687	Tap 6.5 mm	X	X
	14-501688	Tap 7.5 mm	X	X
	14-501689	Tap 8.5 mm	X	X
	14-501690	Tap 9.5 mm	X	X
	14-501691	Tap 10.5 mm	X	X
	Screwdrivers	14-501669	Screw Insertor + all screws	
14-501801		Cypher Screw Insertor + all screws		X

ADAPTER COMPATIBILITY CHART (continued)

Vitality/Vital (K171907)

INSTRUMENT TYPE	PART NUMBER	INSTRUMENT DESCRIPTION	MEDIUM	LARGE
Taps	07.02088.001	Tap 3.5 mm	X	X
	07.02088.002	Tap 4.0 mm	X	X
	07.02088.003	Tap 4.5 mm	X	X
	07.02088.004	Tap 5.0 mm	X	X
	07.02088.005	Tap 5.5 mm	X	X
	07.02088.006	Tap 6.0 mm	X	X
	07.02088.007	Tap 6.5 mm	X	X
	07.02088.008	Tap 7.0 mm	X	X
	07.02088.009	Tap 7.5 mm	X	X
	07.02088.010	Tap 8.0 mm	X	X
	07.02088.011	Tap 8.5 mm	X	X
	07.02088.012	Tap 9.0 mm	X	X
	07.02088.013	Tap 9.5 mm	X	X
	07.02088.014	Tap 10 mm	X	X
	07.02088.015	Tap 10.5 mm	X	X
	730M3035	Tap 3.5 mm	X	X
	730M3040	Tap 4.0 mm	X	X
	730M3045	Tap 4.5 mm	X	X
	730M3050	Tap 5.0 mm	X	X
	730M3055	Tap 5.5 mm	X	X
	730M3060	Tap 6.0 mm	X	X
	730M3065	Tap 6.5 mm	X	X
	730M3070	Tap 7.0 mm	X	X
	730M3075	Tap 7.5 mm	X	X
	730M3080	Tap 8.0 mm	X	X
	730M3085	Tap 8.5 mm	X	X
	730M3090	Tap 9.0 mm	X	X
	730M3095	Tap 9.5 mm	X	X
	730M30100	Tap 10 mm	X	X
	730M30105	Tap 10.5 mm	X	X
	07.02114.006	Tap 6.0 mm - Iliac		X
	07.02114.007	Tap 6.5 mm - Iliac		X
	07.02114.008	Tap 7.0 mm - Iliac		X
	07.02114.009	Tap 7.5 mm - Iliac		X
	07.02114.010	Tap 8.0 mm - Iliac		X
	07.02114.011	Tap 8.5 mm - Iliac		X
	07.02114.012	Tap 9.0 mm - Iliac		X
	07.02114.013	Tap 9.5 mm - Iliac		X
	07.02114.014	Tap 10.0 mm - Iliac		X
	07.02114.015	Tap 10.5 mm - Iliac		X

Zimmer Biomet MIS Percutaneous Screw Fixation Systems (continued)**Vitality/Vital (K171907) continued**

INSTRUMENT TYPE	PART NUMBER	INSTRUMENT DESCRIPTION	MEDIUM	LARGE
Taps (continued)	730M5060	Cannulated Iliac Tap 6.0 mm		X
	730M5070	Cannulated Iliac Tap 7.0 mm		X
	730M5080	Cannulated Iliac Tap 8.0 mm		X
	730M5090	Cannulated Iliac Tap 9.0 mm		X
	730M5100	Cannulated Iliac Tap 10.0 mm		X
	730M5105	Cannulated Iliac Tap 10.5 mm		X
	Screwdrivers	07.02054.001	Screwdriver, Standard + screws < 35 mm	X
Screwdriver, Standard + screws ≥ 35 mm				X
07.02058.001		Reduction Screwdriver, Standard + screws < 35 mm	X	X
		Reduction Screwdriver, Standard + screws ≥ 35 mm		X
07.02128.001		Reduction Screwdriver, Short + screws < 85 mm	X	X
		Reduction Screwdriver, Short + screws ≥ 85 mm		X
07.02087.001		Screw Driver, Multi-piece		X
07.02055.001		Screw Driver, Short + screws < 85 mm	X	X
		Screw Driver, Short + screws ≥ 85 mm	X	X
730M0061		Cannulated Screwdriver, Short + screws < 85 mm	X	X
		Cannulated Screwdriver, Short + screws ≥ 85 mm	X	X

Vital Power (K172275)

INSTRUMENT TYPE	PART NUMBER	INSTRUMENT DESCRIPTION	MEDIUM	LARGE
Reamer Probe	731M0031	Reamer Probe - 3.0 mm	X	X
	731M0030	Reamer Probe - 3.2 mm	X	X

Polaris (K151974)

INSTRUMENT TYPE	PART NUMBER	INSTRUMENT DESCRIPTION	MEDIUM	LARGE
Taps	2000-9022	Tap 4.0 mm	X	X
	2000-9023	Tap 4.75 mm	X	X
	2000-9024	Tap 5.5 mm	X	X
	2000-9025	Tap 6.5 mm	X	X
	2000-9026	Tap 7.5 mm	X	X
	2000-9027	Tap 8.5 mm	X	X
	2000-9028	Tap 9.5 mm	X	X
	2000-9029	Tap 10.5 mm	X	X

Polaris (K151974) continued

INSTRUMENT TYPE	PART NUMBER	INSTRUMENT DESCRIPTION	MEDIUM	LARGE
Taps (continued)	14-500143	Tap 4.0 mm	X	X
	14-500144	Tap 4.75 mm	X	X
	14-500145	Tap 5.5 mm	X	X
	14-500146	Tap 6.5 mm	X	X
	14-500147	Tap 7.5 mm	X	X
	14-500148	Tap 8.5 mm	X	X
	14-500149	Tap 9.5mm	X	X
	14-500150	Tap 10.5 mm	X	X
Awl	594505	Pedicle Awl	X	X
Screwdrivers	14-500178	Translation Screwdriver + screws < 35 mm	X	X
		Translation Screwdriver + screws ≥ 35 mm		X
	14-500185	Multi-axial Screw Inserter + screws < 35 mm	X	X
		Multi-axial Screw Inserter + screws ≥ 35 mm		X
	14-500070	Translation Screwdriver + screws < 35 mm	X	X
		Translation Screwdriver + screws ≥ 35 mm		X
Reamer Probe	2000-9090	4.0 mm Reamer Probe	X	X
	2000-9091	4.75 mm Reamer Probe	X	X
	2000-9092	5.5 mm Reamer Probe	X	X
	2000-9093	6.5 mm Reamer Probe	X	X
	2000-9094	7.5 mm Reamer Probe	X	X
	14-500172	Iliac Reamer Probe 5.5 mm	X	X
	14-500173	Iliac Reamer Probe 6.5 mm	X	X
	14-500174	Iliac Reamer Probe 7.5 mm	X	X
	14-500175	Iliac Reamer Probe 8.5 mm	X	X
Taps	14-500085	Double Lead Tap, 4 mm	X	X
	14-500086	Double Lead Tap, 4.75 mm	X	X
	14-500088	Double Lead Tap, 5.5 mm	X	X
	14-500089	Double Lead Tap, 6.5 mm	X	X
	14-500090	Double Lead Tap, 7.5 mm	X	X
	14-500092	6.5 mm Doublelead Iliac Tap	X	X
	14-500093	7.5 mm Doublelead Iliac Tap	X	X
	14-500094	8.5 mm Doublelead Iliac Tap	X	X
	14-500097	9.5 mm Doublelead Iliac Tap	X	X
	14-500098	10.5 mm Doublelead Iliac Tap	X	X

IMPORTANT INFORMATION ON THE ZIMMER BIOMET UNIVERSAL NAVIGATION SYSTEM

DEVICE DESCRIPTION

When used with the ROSA ONE System, the Zimmer Biomet Universal Navigation System includes Universal Adapters that are intended to be used with instrumentation from Vital™ MIS Screw System, PathFinder NXT® Minimally Invasive Pedicle Screw System, and Cypher™ MIS Screw System to facilitate preparation and insertion of Zimmer Biomet screws using navigation.

When used with the Medtronic StealthStation System, the Zimmer Biomet Universal Navigation System includes Universal Adapters that are intended to be used with instrumentation from Vitality Spinal Fixation System (including Vital™ Power Instrument System), PathFinder NXT Minimally Invasive Pedicle Screw System, Cypher MIS Screw System and Polaris™ Spinal System to facilitate preparation and insertion of Zimmer Biomet screws using navigation.

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 multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays and 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.

INDICATIONS FOR USE

When used with the ROSA ONE System, the Zimmer Biomet Universal Navigation System is indicated for use during the preparation and insertion of Zimmer Biomet screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The universal adapters are specifically designed for use with the Zimmer Biomet ROSA ONE System, which is indicated for that the required fiducial markers and rigid patient anatomy can be identified on 3D CT scans. The ROSA ONE Spine System is intended for the placement of pedicle screws in vertebrae with a posterior approach in the thoracolumbar region.

Indications for compatible systems, Vital MIS Screw System, PathFinder NXT Minimally Invasive Pedicle Screw System, and the Cypher MIS Screw System can be found in their respective system IFUs.

When used with the Medtronic StealthStation System, the Zimmer Biomet Universal Navigation System is indicated for use during the preparation and insertion of Zimmer Biomet screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The universal adapters 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 pelvis or vertebra can be identified relative to an acquired image: CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Indications for compatible systems, Vitality Spinal Fixation System (including Vital Power Instrument System), PathFinder NXT Minimally Invasive Pedicle Screw System, Cypher MIS Screw System and Polaris Spinal System, can be found in their respective system IFUs.

IMPORTANT INFORMATION ON THE ZIMMER BIOMET UNIVERSAL NAVIGATION SYSTEM (continued)

WARNINGS AND PRECAUTIONS

Following are specific warnings, precautions, and adverse effects associated with use of the Universal Adaptors for Navigation non-sterile instrumentation that should be understood by the surgeon and explained to the patients. General surgical risk should be explained to the patients prior to surgery.

Warnings

- For use with the ROSA ONE system it is important not to exceed an instrument length of 360 mm for awls, taps and screwdriver/screw assemblies. The use of longer instrumentation could lead to a decrease in system accuracy.
- For use with the Medtronic StealthStation system, it is important not to exceed the instrument lengths stated for each array in Table 1. If the arrays are used outside of the scope of Table 1 it could lead to decreased accuracy for the system.

Table 1. Array compatibility chart for Universal Navigation Adaptor instruments

Arrays	Medium SureTrak II array	Large SureTrak II array
Maximum Instrument/ Implant Length to be Navigated	260mm	360mm

- When tightening the collet nut to rigidly affix the instrument into the adaptor shaft, the assembly should be held in a vertical position and the collet nut key should be held perpendicular to the shaft. Neglecting to assemble this instrument in this way could lead to decreased accuracy for the system.
- For use with the ROSA ONE system, when adding a new instrument to an already calibrated array, the calibration step must be re-performed. Failure to re-calibrate after changes to the instrument or instrument adapter assembly can lead to decreased accuracy for the assembly.
- For use with the Medtronic StealthStation system, when adding a new instrument to an already calibrated array or a new implant to an instrument/implant assembly which has already been calibrated,

the calibration step must be re-performed. Failure to re-calibrate after changes to the instrument or instrument/implant assembly can lead to decreased accuracy for the assembly.

- Breakage, slippage, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient or operative personnel.
- Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose or even dangerous to the patient or surgical staff.
- The physical characteristics required for many instruments does not permit them to be manufactured from implantable materials, and if any broken fragments of instruments remain in the body of a patient, the patient could have allergic or infectious consequences.
- It is important that the surgeon exercise extreme caution when working in close proximity to vital organs, nerves or vessels, and that the forces applied while correcting the position of the instrumentation is not excessive, such that it might cause injury to the patient.
- Zimmer Biomet does not warrant Medtronic Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or registration.
- Users must complete instrument registration 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 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, Navigation should be discontinued and the instruments should be inspected for damage before continuing with the traditional, non-navigated procedure.

Precautions

- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery, where many extenuating circumstances may compromise the results.
- Proper patient selection and operative care are critical to the success of the device and avoidance of injury during surgery.
- Read and follow the instructions for use and surgical technique guide provided by the manufacturer for this product.
- Under no circumstances are these instruments to be implanted.

Preoperative Precautions

- 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.
- Zimmer Biomet 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.

- Prior to use, instruments should be visually inspected for wear and tested to assure they are functioning properly. If instruments are discolored, show evidence of corrosion, have loose screws/pins, are out of alignment, are cracked or have other irregularities, DO NOT USE. Instrumentation that appears damaged should be returned to the manufacturer.

Intraoperative Precautions

- Over-bending, notching, striking and scratching with any instruments should be avoided to reduce the risk of breakage.
- If any instrument comes in contact with a non-sterile surface it should not be used.
- Extreme care must be taken when used near vital organs, nerves or vessels.

POSSIBLE COMPLICATIONS

- Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs or joints.
- Infection, if instruments are not properly cleaned and sterilized.
- Nerve damage due to surgical trauma.
- Impingement of close vessels, nerves, and organs by slippage or misplacement of the instrument.
- Cutting of skin or gloves of operating staff.
- Bony fracture in cases of deformed spine or weak bone.
- Involuntary crack, fracture or perforation of the bone.
- The methods of use of instruments are to be determined by the user's experience and training in surgical procedures.

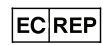
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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please see the product Instructions for Use for a complete listing of the indications, contraindications, precautions, warnings and adverse effects.



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