

NAVIGATION

Medtronic® NavLock® Navigation Instruments



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NAVIGATION

Medtronic NavLock® Navigation Instruments

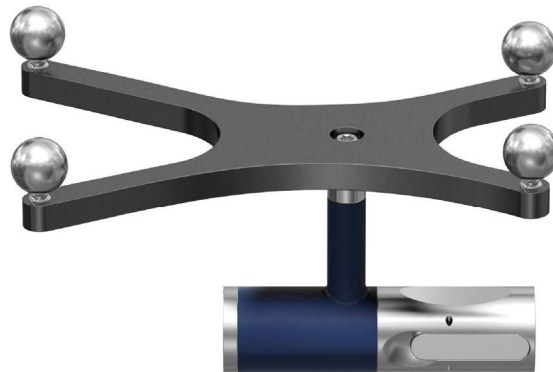
Introduction

The ChoiceSpine Navigation instruments are non-sterile, reusable instruments designed to function with the Medtronic® StealthStation® System. This technique describes how to register Navigation instruments to the S7 (V2.1.0) and S8 (V1.2.0) StealthStation®. Refer to the appropriate navigation system Instructions for Use and/or StealthStation® Surgical Technique Guide for details regarding navigation system use.

Use of ChoiceSpine Navigation Instrumentation is limited to the intended use and purpose of the system they were designed for. This surgical technique guide contains only information regarding the ChoiceSpine Navigation instruments. For surgical technique information regarding ChoiceSpine systems, please refer to the appropriate system surgical technique guide.

Navigation Instrument Setup with NavLock® System:

Assembly



Step 1:

To attach the NavLock Tracker to the instrument, slide the Tracker over the proximal end of the instrument.

Step 2:

Keep sliding the NavLock Tracker distally until it snaps into the recess geometry.

Step 3:

The Tracker should not slide axially but will freely rotate.

Navigation Setup and Registration

NavLock Preliminary Setup:

All preliminary set-up steps for S7 and S8 StealthStation should be done in accordance with the Medtronic technique guide. These steps listed below are for reference only.

- Turn on StealthStation and log in.
- Select “SYNERGY SPINE” to start setup for spine navigation.
- Select the desired surgeon profile from the “SURGEON PROFILE” tab.
- Select the desired procedure from the “SELECT PROCEDURE” tab.
- Ensure that all necessary equipment (monitors, O-arm, etc.) are connected to the StealthStation.

Patient Reference Setup:

- There are several reference frame options available to accommodate the preferred access to the patient: the Percutaneous Reference pin, the Open Spine clamp, the Thoracic Spine Clamp, and the Mast Clamp. Install the desired patient reference frame according to the manufacturer’s instructions.
- Attach 4 reflective spheres onto the patient reference frame.

Instrument Setup:

- Select an individual NavLock Tracker for each instrument you choose to navigate, and attach the four reflective spheres to each Tracker.
- Attach the NavLock Tracker to the selected instrument.
- To assign a NavLock Tracker to the desired instrument:
 1. S7 software: Select a tip from the pop-up menu.
 2. S8 software: Select the appropriate category and then the tip from the drop-down menu.
- On the “VERIFY INSTRUMENTS” tab on the StealthStation S7 or the “INSTRUMENTS” tab on the StealthStation S8, add one NavLock Tracker for each instrument being used in the surgery by selecting it from the “ADD/REMOVE INSTRUMENTS” window.
- Select a default category (driver, tap, or probe) and then the tip (tap size, driver type, or probe) for that NavLock tracker. Assign the tracker to an instrument by choosing one of the tool cards listed in Table 1

Table 1

| ChoiceSpine Navigation Instruments | Corresponding Medtronic Tool Card |
|----------------------------------------------------------|------------------------------------------|
| Cervical | |
| ChoiceSpine Posterior Cervical/Thoracic 3.5mm System Tap | Vertex® 3.0mm Tap |
| ChoiceSpine Posterior Cervical/Thoracic 4.0mm System Tap | Vertex® 4.0mm Tap |
| ChoiceSpine Posterior Cervical/Thoracic System Tap | Vertex® 3.0mm Tap or Vertex 4.0mm Tap |
| ChoiceSpine Posterior Cervical/Thoracic System Drill | Vertex® 3.0mm Tap or Vertex 4.0mm Tap |
| ChoiceSpine Posterior Cervical/Thoracic System Awl | Vertex® 3.0mm Tap or Vertex 4.0mm Tap |
| ChoiceSpine Posterior Cervical/Thoracic System Probe | Vertex® 3.0mm Tap or Vertex 4.0mm Tap |
| ChoiceSpine Posterior Cervical/Thoracic System Driver | Vertex® Standard Driver |
| Thoracolumbar | |
| ChoiceSpine Posterior Thoracolumbar 4.5mm System Tap | Solera® Non-Cannulated 4.5mm Tap |
| ChoiceSpine Posterior Thoracolumbar 5.5mm System Tap | Solera® Non-Cannulated 5.5mm Tap |
| ChoiceSpine Posterior Thoracolumbar 6.5mm System Tap | Solera® Non-Cannulated 6.5mm Tap |
| ChoiceSpine Posterior Thoracolumbar 7.5mm System Tap | Solera® Non-Cannulated 7.5mm Tap |
| ChoiceSpine Posterior Thoracolumbar 8.5mm System Tap | Solera® Non-Cannulated 8.5mm Tap |
| ChoiceSpine Posterior Thoracolumbar System Probe | Any Solera® Non-Cannulated Tap |
| ChoiceSpine Posterior Thoracolumbar System Driver | Solera® 4.75 Standard Driver |
| Sacroiliac Joint Fixation | |
| ChoiceSpine Sacroiliac System Ø8mm Tap | Ballast™ Probe |
| ChoiceSpine Sacroiliac System Ø12mm Tap | |
| ChoiceSpine Sacroiliac System Ø14mm Tap | |
| ChoiceSpine Sacroiliac System Ø8mm Drill | |
| ChoiceSpine Sacroiliac System Ø12mm Drill | |
| ChoiceSpine Sacroiliac System Ø14mm Drill | |
| ChoiceSpine Sacroiliac System T50 Screwdriver | |

Registering Instruments to the StealthStation:

- Aim the camera in the direction of the patient reference frame. Use the Tracking View window to confirm that the reference frame and trackers are in range and can be tracked by the system (Figure 3). Blue dots indicate successful tracking and yellow(S7)/red(S8) dots indicate blocked/malfunctioning spheres. The blue triangle(S7)/line(S8) indicates how close/far the camera is from the reference frame. Place the distal tip of the instrument (with the NavLock Tracker attached) into the divot on the patient reference frame. Hold the instrument perpendicular to the reference frame with the spheres of the NavLock Tracker facing towards the camera until registration of the NavLock Tracker is successful.
- Successful registration is indicated on the instrument tool card on the “VERIFY INSTRUMENTS” (S7) or “INSTRUMENTS” (S8) tab. The tool card transitions from blue(S7)/orange(S8) to green once registered, and an audible notification is heard (Figure 4).
- If registration is unsuccessful, the card remains blue(S7)/orange(S8). Ensure sterile spheres are clean and that both the instrument and reference frame are visible in the tracking view. Repeat steps until the instrument is successfully registered (Figure 5).

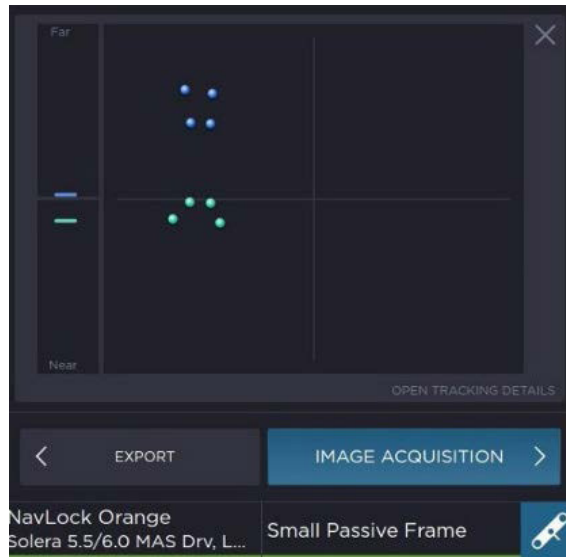


Figure 3: Tracking View window (S8).

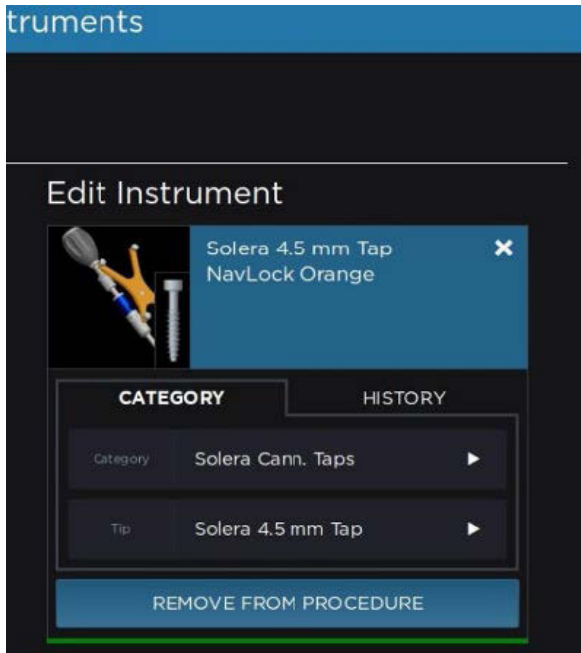


Figure 4: Instrument Registration Incomplete (S8).

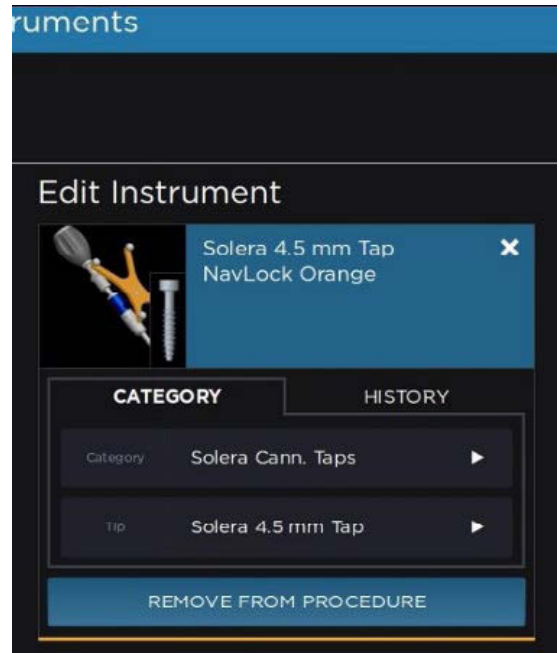


Figure 5: Instrument Registration Complete (S8).

Navigation Usage After Setup

Acquiring Scans:

- After installing patient reference frame, obtain 3D CT images of the desired anatomical area.
- Transfer images to the StealthStation

Navigating Instruments:

- Perform surgery as indicated by the surgical technique for the corresponding implant system.
- **When using the Triton Navigation System:** To correct for screw pocket depth, adjust the projected implant cylinder to selected implant length minus 5mm (ex. desired implant size of 50mm would utilize a 45mm projected cylinder within the StealthStation software).

Compatibility Confirmation:

After calibration and verification of the ChoiceSpine Navigation instrumentation with the NavLock Trackers and StealthStation, field assessment must be performed. This is done by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system.

If the actual and virtual locations of the instrument do not correctly match, recalibrate the ChoiceSpine instrument and NavLock tracker with the StealthStation. Repeat the field assessment steps to verify correct functionality. If the actual and virtual locations of the instrument do not correctly match again, do not use the navigation system in conjunction with the ChoiceSpine Navigation instrumentation. Contact your ChoiceSpine representative.

Disassembly

Step 1:

- NavLock Tracker: First remove the proximal quick connect handle. Then, push the two metal buttons on each side of the NavLock Tracker, and pull the attachment off of the instrument shaft.

Notes:

For Instructions for Use please visit <https://choicespine-eifu.com/>



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