SI-LUTION® NAVIGATION SYSTEM

SI-LUTION NAVIGATION SYSTEM

Surgical Technique Guide

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Part Number	Description
C645-100	Navigation Pilot Drill
C645-200	Navigation 7mm Drill
C645-201	Navigation 7mm Cannulated Drill
C645-210	Navigation 9.5mm Drill
C645-211	Navigation 9.5mm Cannulated Drill
C645-220	Navigation 12mm Drill
C645-221	Navigation 12mm Cannulated Drill
C645-300	Navigation 7mm Tap
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C645-310	Navigation 9.5mm Tap
C645-311	Navigation 9.5mm Cannulated Tap
C645-320	Navigation 12mm Tap
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C645-400	Navigation 9.5 & 12mm Screw Inserter
C645-401	Navigation Cannulated 9.5 & 12mm Screw Inserter
C645-410	Navigation 7mm Screw Inserter
C645-411	Navigation Cannulated 7mm Screw Inserter

SI-LUTION® NAVIGATION SYSTEM

Surgical Technique

DISCLAIMER: Curiteva is not a navigation provider. The SI-LUTION Navigation System surgical instruments have been validated for use with a third-party navigation system, the Medtronic® StealthStation®. 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.

A. Initial Setup

- Power on the Medtronic StealthStation and log in.
- Choose “SPINE & TRAUMA” to begin 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 Medtronic StealthStation.

B. Instrument Setup and Registration

- Attach four disposable reflective marker spheres (Balls) to NavLock Trackers.

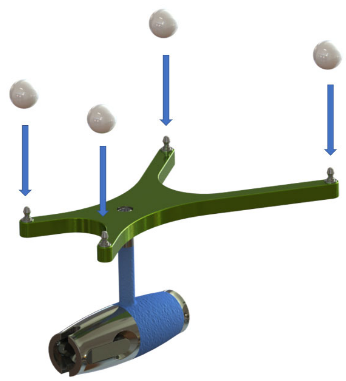

Figure 1 - NavLock Tracker sphere assembly

- Insert the appropriate NavLock Tracker onto the instrument shaft such that the NavLock Tracker latch properly engages and mates with the stepped undercut geometry of the instrument. If a NavLock Tracker fails to properly lock onto an instrument (minimal up and down movement), correct the issue or do not navigate the instrument. Ensure the NavLock Tracker spins freely prior to use.

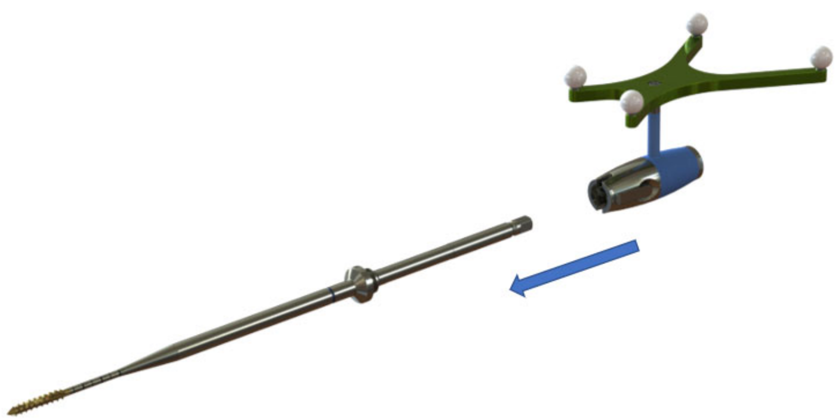

Figure 2 - NavLock Tracker instrument assembly

- On the “VERIFY INSTRUMENTS” tab on the Medtronic StealthStation, confirm that the necessary tool cards for instruments, NavLock arrays, and reference frames are available and can be selected.
- If the tool cards are not listed, add the appropriate instrument Tool Cards for the surgery type by selecting them from the “ADD/REMOVE INSTRUMENTS” window.
- When using the SI-LUTION Navigation Instruments, add the corresponding Medtronic Tool Cards from the cross-reference table below.
- Additionally, add one NavLock Tracker for each instrument being used in the surgery. Assign the NavLock Tracker to an instrument using the dropdown menu.

SI-LUTION NAVIGATION INSTRUMENT CROSS-REFERENCE TABLE

Part Number	Description	StealthStation Tool Card	Medtronic Part Number
C645-100	Navigation Pilot Drill	Pilot Drill	NAV7426002
C645-200	Navigation 7mm Drill	Pilot Drill	NAV7426002
C645-201	Navigation 7mm Cannulated Drill	Pilot Drill	NAV7426002
C645-210	Navigation 9.5mm Drill	Pilot Drill	NAV7426002
C645-211	Navigation 9.5mm Cannulated Drill	Pilot Drill	NAV7426002
C645-220	Navigation 12mm Drill	Pilot Drill	NAV7426002
C645-221	Navigation 12mm Cannulated Drill	Pilot Drill	NAV7426002
C645-300	Navigation 7mm Tap	Rialto Awl Tip Tap	NAV7426000
C645-301	Navigation 7mm Cannulated Tap	Rialto Awl Tip Tap	NAV7426000
C645-310	Navigation 9.5mm Tap	Rialto Awl Tip Tap	NAV7426000
C645-311	Navigation 9.5mm Cannulated Tap	Rialto Awl Tip Tap	NAV7426000
C645-320	Navigation 12mm Tap	Rialto Awl Tip Tap	NAV7426000
C645-321	Navigation 12mm Cannulated Tap	Rialto Awl Tip Tap	NAV7426000
C645-400	Navigation 9.5 & 12mm Screw Inserter	Rialto Driver	NAV7426001
C645-401	Navigation Cannulated 9.5 & 12mm Screw Inserter	Rialto Driver	NAV7426001
C645-410	Navigation 7mm Screw Inserter	Rialto Driver	NAV7426001
C645-411	Navigation Cannulated 7mm Screw Inserter	Rialto Driver	NAV7426001

- Place the distal tip of each instrument, one at a time, into the divot on the reference frame. Hold the instrument as perpendicular to the reference frame as possible.
- Aim the camera in the direction of the 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. Blue dots indicate successful tracking and yellow dots indicate blocked and/or malfunctioning spheres. The blue triangle indicates how close/far the camera is from the reference frame.
- Successful verification is indicated on the instrument tool card on the VERIFY INSTRUMENTS screen. The card transitions from blue to green once verified, and an audible notification is heard.

- If verification is unsuccessful, the card remains blue and an audible notification will play. 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 verified. If verification is not achieved discontinue navigation. Simulated instrument and implant tip locations and / or projected tip locations need to be compared to actual locations on bone landmarks prior to use.

  CAUTION: Only the identified Tool Card is to be selected for each instrument to prevent patient injury from inaccurate navigation.

  The SI-LUTION Navigation System instruments are compatible with the Medtronic S7 System v2.1.0 & Medtronic S8 System v1.2.0 (1.2.0-20). Use with other version or systems may cause patient injury.

C. 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.
- Placement of the patient reference frame should be performed according to the manufacturer's procedure.

D. Acquiring Scans

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

E. Navigating Instruments

- Perform surgery as indicated by the surgical technique for the corresponding implant system (SI-LUTION).

CAUTION: Instrument verification and accuracy checks need to be assessed prior to every use! Accuracy assessments can be accomplished by placing each navigated instrument at known anatomical landmarks and confirming that the instrument tip location and orientation is in agreement with the simulated depiction in the Navigation screen.

Reassessing system accuracy should be performed throughout the procedure including whenever any changes are made to the instrument being navigated, or the manner in which the instrument is depicted in the simulation (Ex. Change in implant size or change in projection or change from navigate tip to navigate projection, etc.). Be cognizant of what is being navigated (the simulated instrument or the projection).

Care should be taken to limit bending forces on navigated instruments as instrument deflection can influence navigational accuracy. Do not use bent or otherwise damaged instrumentation. Patient repositioning, spinal manipulation, reference frame movement all can affect navigational accuracy. Follow the manufacturer's (Medtronic) instructions for system setup, use, trouble shooting, and all warnings and precautions. If the navigation system does not appear to be accurate despite troubleshooting (e.g., resetting the system), do not rely on the navigation system**.**

F. StealthStation Implant Tool Cards and References

- Refer to the chart below for SI-LUTION screw sizes, designated with check marks, that are compatible with navigation. All other sizes are NOT compatible with navigation.

Screw Length (mm)	Screw Diameter (mm) 7	9.5	12
30	×	×	×
35	×	×	×
40	✓	✓	✓
45	×	×	×
50	✓	✓	✓
55	×	×	×
60	✓	✓	✓
65	×	×	×
70	×	×	×

- The table on the following page may be used to cross-reference the corresponding SI-LUTION System implants available for registration within Medtronic StealthStation. The SI-LUTION implants must be properly mated with the 7mm Screw Inserters (C645-410, C645-411) or the 9.5 & 12mm Screw Inserters (C645-400, C645-401).

SI-LUTION IMPLANT CROSS-REFERENCE TABLE

Curiteva SI-LUTION Screw Size (Ø x Length)	Curiteva SI-LUTION Screw Part Numbers	StealthStation Tool Card, Rialto System	Medtronic Part Numbers, Rialto System
Ø7mm x 40mm	C614-7040	Rialto Driver, 12mm x 40mm	74200001240
Ø7mm x 50mm	C614-7050	Rialto Driver, 12mm x 50mm	74200001250
Ø7mm x 60mm	C614-7060	Rialto Driver, 12mm x 60mm	74200001260
Ø9.5mm x 40mm	C614-9540	Rialto Driver, 12mm x 40mm	74200001240
Ø9.5mm x 50mm	C614-9550	Rialto Driver, 12mm x 50mm	74200001250
Ø9.5mm x 60mm	C614-9560	Rialto Driver, 12mm x 60mm	74200001260
Ø12mm x 40mm	C614-1240	Rialto Driver, 12mm x 40mm	74200001240
Ø12mm x 50mm	C614-1250	Rialto Driver, 12mm x 50mm	74200001250
Ø12mm x 60mm	C614-1260	Rialto Driver, 12mm x 60mm	74200001260

G. Instructions For Use

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION:

The SI-LUTION Navigation System Instruments are manual surgical instruments that are designed to function with the Medtronic® StealthStation® System S7 V2.1.0 and S8 V1.2.0 (1.2.0-20) to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures.

The SI-LUTION Navigation System surgical instruments are manufactured from stainless steel that conforms to ASTM F899.

INDICATIONS FOR USE:

The SI-LUTION Navigation System is intended to be used in the preparation and placement of SI-LUTION sacroiliac screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The SI-LUTION Navigation System is 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 skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS:

Refer to the contraindications for specific Spinal Systems and implants that may be used with these surgical instruments. The SI-LUTION Navigation System contraindications include, but are not limited to:

- Patients with probable intolerance to the materials used in the manufacture of this device.
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, substance abuse, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
- Patients unwilling or unable to follow post-operative restrictions on movement, especially in athletic and occupational activities.
- Use with components from other systems, or in any case requiring the mixing of metals from different components.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing process.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any case not described in the indications for use.

CAUTIONS, PRECAUTIONS, WARNINGS and POSSIBLE ADVERSE EFFECTS:

Cautions:

Assess navigational accuracy repeatedly throughout a procedure when using a surgical navigation system.

Reconfirm accuracy by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system.

Precautions:

- Curiteva is not a navigation provider. The Navigation instruments have been validated for use with a third-party navigation system, the Medtronic® StealthStation®. 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.
- A navigation 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.
- The navigation system should be set up per the manufacturer's instructions.
- The Curiteva navigation system instruments should only be used with Curiteva implants. Do not attempt to use with other competitive devices.
- Avoid application of excessive stress on surgical instrumentation.
- Carefully read and follow any package insert which accompanies the implants to be used with this instrumentation.
- Instruments must be cleaned and decontaminated before they are returned to the manufacturer for any reason.

Warnings:

The SI-LUTION Navigation System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the SI-LUTION Navigation System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

The physician is the learned intermediary between the company and the patient. Curiteva intends that the navigation system instruments should be used only by physicians having received proper training in the use of the instruments and Medtronic® StealthStation®. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through Curiteva customer support representatives.

Possible Adverse Effects:

Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects, including but not limited to:

- Early or late loosening of any or all of the components
- Disassembly, bending, and/or breakage of any or all of the components
- Foreign body (allergic) reaction to the implants including possible tumor migration
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site which may result in skin breakdown and/or wound complications
- Pressure on the skin from components where there is inadequate tissue coverage
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Hemorrhage of blood vessels and/or hematomas
- Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone at, above, and/or below the level of surgery
- Non-union (pseudarthrosis), mal-union or delayed union
- Loss of neurological function (e.g., bowel or bladder dysfunction), appearance of radiculopathy, and/or development of pain
- Neurovascular compromise including paralysis or other types of serious injuries
- Gastrointestinal and/or reproductive system compromise, including sterility
- Cessation of growth of the fused portion of the spine
- Death

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All products are not currently available in all markets

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