NAVIGATED INSTRUMENTS

Surgical Technique

Kalitec

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This surgical technique is for illustrative and demonstrative purposes only. Technique is dependent upon a surgeon's medical judgement to provide the best method of treatment for each patient. Please see Instructions for Use for the complete list of indications for use, warnings, precautions, and other important information concerning the use and guidance of Kalitec Medical's Navigated Instrumentation.

NAVIGATED INSTRUMENTATION
Kalitec Medical's Navigated Instruments System is designed specifically for use with StealthStation™ Navigation System by Medtronic Navigation, Inc. These instruments, comprised of probes, taps, and screwdrivers, are used with the StealthStation System to assist surgeons in locating anatomical structures for preparation and placement of pedicle screw implants. Please refer to the individual implant system's Instructions For Use (IFU) and Surgical Technique for complete system guide, descriptions, indications, and warnings.

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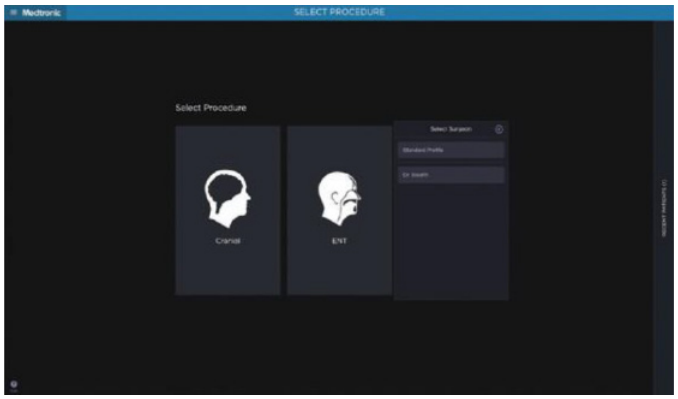
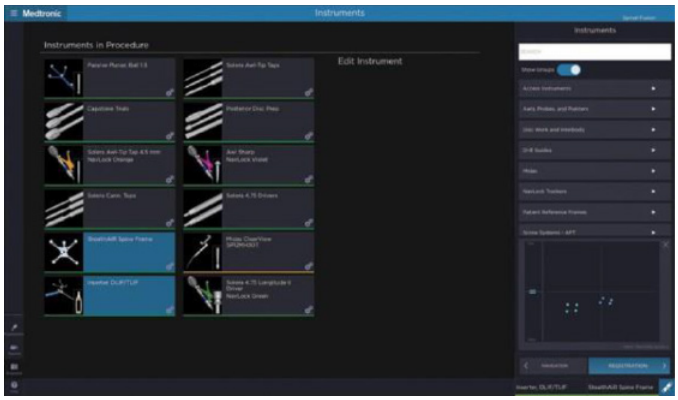
Step 1 Select Procedure and Surgeon

Open the “Select Surgeon” menu and select the Primary Surgeon and the Surgical Procedure to be performed.



Step 2 Verify Instruments

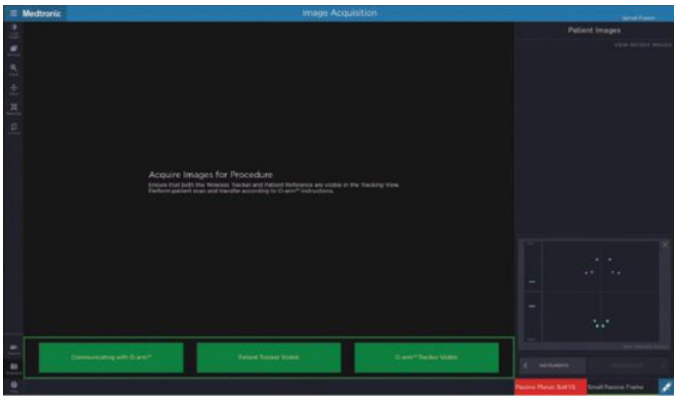
Check that the Tool Cards for all the navigated instruments needed for the procedure are shown on this screen. Instruments can be verified now or during a later step, but the Tool Card for the instrument must appear on this screen to be verified and tracked.



Step 3 Acquire Scan

The navigation system will remain on this screen until the O-arm™ System image acquisition step has been performed.

Reference Medtronic manual guides for further instructions.



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Step 4 Tool Card Assignment

Each navigated instrument to be used in the procedure must be assigned to an appropriate Tool Card.

Please use the following table for selecting the correct Medtronic Tool Card to use for each of Kalitec Medical's navigated instruments.

Instrument Description	Corresponding Tool Card
Probes	
Steffee Probe	NavLock™ - Lumbar Probe *(Requires Verification)*
Lenke Probe	
Taps	
CosmoLock© & Nido™ 4.75mm Tap, Non-Cannulated	NavLock - Solera™ X.Xmm Awl-Tip Tap *(Diameter Specific, Requires Verification)*
CosmoLock & Nido 5.5mm Tap, Non-Cannulated	
CosmoLock & Nido 6.5mm Tap, Non-Cannulated	
CosmoLock & Nido 7.5mm Tap, Non-Cannulated	
CosmoLock & Nido 8.5mm Tap, Non-Cannulated	
CosmoLock MIS 4.75mm Tap, Cannulated	
CosmoLock MIS 5.5mm Tap, Cannulated	
CosmoLock MIS 6.5mm Tap, Cannulated	
CosmoLock MIS 7.5mm Tap, Cannulated	
CosmoLock MIS 8.5mm Tap, Cannulated	
Screwdrivers	
Cosmolock, Cosmolock MIS, & Nido Screwdrivers, Non-Cannulated	NavLock - Solera 5.5/6.0 MAS Driver *(Requires Verification)*
Cosmolock, Cosmolock MIS, & Nido Screwdrivers, Cannulated	

Note: *In the event that the instrument width projection size cannot be obtained, use the next largest width size.*

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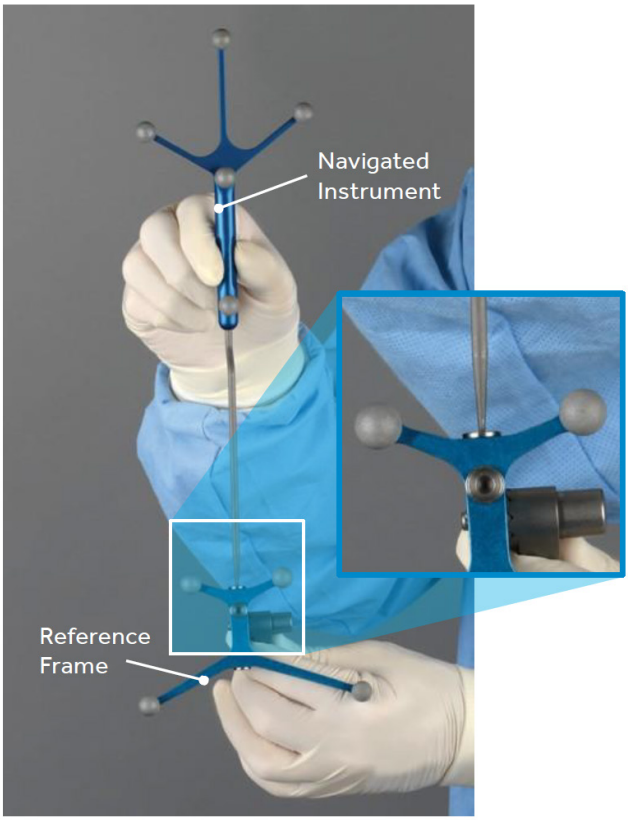
Step 5 Instrument Attachment

Attach the Spheres to a Reference Frame and the NavLock™ Trackers from the NavLock Set. Check the Spheres to ensure they are secure. Next, attach the NavLock Trackers to the instruments.
Place each instrument tip into the divot in the Reference Frame and hold perpendicular and visible to the camera until a confirmation color is visible. Use the tracking view in the lower right of the screen to ensure the camera is tracking the Reference Frame and instrument correctly.

- Successful verification is indicated by a chime and a transition to green on the instrument Tool Card.
- Failed verification is indicated by a “bonk” sound and indicates that the instrument may be positioned improperly in the divot or is bent/damaged. Inspect the instrument; if it is bent/damaged, do not use.
- If no sound is heard when the instrument is touched to the divot, this may indicate that the camera cannot see either the instrument or the frame.



Step 6 Screwdriver Verification

Secure a Tracker onto the desired Screwdriver. Confirm proper mating of the Screw to the Screwdriver and select the projection that matches the screw geometry. Use the following tables to cross-reference Kalitc and Medtronic Screw sizes.

In the event that the instrument width projection size cannot be obtained, use the next largest width size.

Confirm simulated and actual tip location relative to boney landmarks prior to proceeding. Reconfirm locations after every implant change.

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CosmoLock© Pedicle Screw System Cross-Reference					
Screw Size	Part Numbers			Corresponding StealthStation™ Tool Card	Corresponding Medtronic Part Number
	Polyaxial	Ext. Tabs	MIS		
4.75 x XXmm	10-SSP-47XX	10-SSE-47XX	10-SCT-47XX	Solera™ 5.5/6.0MAS 5.0 x XXmm*	558400050XX*
5.5 x XXmm	10-SSP-55XX	10-SSE-55XX	10-SCT-55XX	Solera 5.5/6.0MAS 5.5 x XXmm	558400055XX
6.5 x XXmm	10-SSP-65XX	10-SSE-65XX	10-SCT-65XX	Solera 5.5/6.0MAS 6.5 x XXmm	558400065XX
6.5 x 100mm	10-SSP-6500	10-SSE-6500	10-SCT-6500	Solera 5.5/6.0MAS 6.5 x 100mm	55840006500
7.5 x XXmm	10-SSP-75XX	10-SSE-75XX	10-SCT-75XX	Solera 5.5/6.0MAS 7.5 x XXmm	558400075XX
7.5 x 100mm	10-SSP-7500	10-SSE-7500	10-SCT-7500	Solera 5.5/6.0MAS 7.5 x 100mm	55840007500
8.5 x XXmm	10-SSP-85XX	10-SSE-85XX	10-SCT-85XX	Solera 5.5/6.0MAS 8.5 x XXmm	558400085XX
8.5 x 100mm	10-SSP-8500	10-SSE-8500	10-SCT-8500	Solera 5.5/6.0MAS 8.5 x 100mm	55840008500

NIDO™ Pedicle Screw System Cross-Reference				
Screw Size	Part Numbers		Corresponding StealthStation Tool Card	Corresponding Medtronic Part Number
	Solid	Cannulated		
4.75 x XXmm	15-BSC-47XX	15-BCC-47XX	Solera 5.5/6.0MAS 5.0 x XXmm*	558400050XX*
5.5 x XXmm	15-BSC-55XX	15-BCC-55XX	Solera 5.5/6.0MAS 5.5 x XXmm	558400055XX
6.5 x XXmm	15-BSC-65XX	15-BCC-65XX	Solera 5.5/6.0MAS 6.5 x XXmm	558400065XX
6.5 x 100mm	15-BSC-6500	15-BCC-6500	Solera 5.5/6.0MAS 6.5 x 100mm	55840006500
7.5 x XXmm	15-BSC-75XX	15-BCC-75XX	Solera 5.5/6.0MAS 7.5 x XXmm	558400075XX
7.5 x 100mm	15-BSC-7500	15-BCC-7500	Solera 5.5/6.0MAS 7.5 x 100mm	55840007500
8.5 x XXmm	15-BSC-85XX	15-BCC-85XX	Solera 5.5/6.0MAS 8.5 x XXmm	558400085XX
8.5 x 100mm	15-BSC-8500	15-BCC-8500	Solera 5.5/6.0MAS 8.5 x 100mm	55840008500
9.5 x XXmm	15-BSC-95XX	15-BCC-95XX	Solera 5.5/6.0MAS 9.5 x XXmm	558400095XX
9.5 x 100mm	15-BSC-9500	15-BCC-9500	Solera 5.5/6.0MAS 9.5 x 100mm	55840009500
10.5 x XXmm	15-BSC-05XX	15-BCC-05XX	Solera 5.5/6.0MAS 10.5 x XXmm	558400015XX
10.5 x 100mm	15-BSC-0500	15-BCC-0500	Solera 5.5/6.0MAS 10.5 x 100mm	55840001500

**4.75mm diameter implants are not offered as a StealthStation projection. Use of the 5.0mm Tool Card will simulate a 0.25mm larger diameter.*

Instructions For Use

Description:
The Kalitec Navigated Instrument System is comprised of manual surgical instruments for use with the StealthStation® Navigation System by Medtronic Navigation, Inc. “Medtronic Navigation” (denoted with MDT) to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures
Use of a navigation system provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement. Use of the Kalitec Navigated Instrument System is limited to Taps ranging in sizes of 4.5mm to 7.5mm and bone screws ranging in diameter from 4.75mm to 8.5mm with lengths ranging from 25mm to 110mm.
The Kalitec Navigated Instrument System instruments which are MDT compatible are comprised of Bone Awls, Bone Taps, Bone Probes and a variety of Screw Drivers.
The Kalitec Navigated Instrument System instruments were tested for compatibility utilizing the Medtronic Navigation StealthStation S8 Violet and Gray Navlock Trackers (PNs 9734682 and 9734590), Bone Clamp Array and Bone Clamp (PNs 973065 and 9735715), Medtronic Solera Cannulated Driver (PN 9735024), Medtronic Straight Lumbar Probe (PN 9734679), Medtronic Solera Awl Tip Tap 4.5mm (PN NAV202), Medtronic StealthStation Reference Probe (PN 960-559) while utilizing the Navigated CD Horizon Solera Operative Technique.

Indications for Use:
The Kalitec Navigated Instrument System is indicated for use during the preparation and placement of screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Kalitec Navigated Instruments System reusable instruments are specifically designed for use with the Medtronic Navigation StealthStation System which are 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 vertebra can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks for the anatomy.
Use of the Kalitec Navigated Instrument System instruments is limited to use only with Kalitec pedicle screw systems.

Contraindications:
The Kalitec Navigated Instrument System, as with other orthopedic implant systems, are contraindicated for use in patients with:
1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Pregnancy
5. Metal sensitivity/allergies
6. Severe osteopenia
7. Patients unwilling or unable to follow post-operative care instructions
8. Contraindications under the pedicle screw system in use and Medtronic Navigation StealthStation Systems are all applicable to the use of the Kalitec Navigated Instrument System instruments.
9. Any circumstances not listed under the heading “Indications for Use”.

Possible Adverse Effects:
Possible adverse effects include, but are not limited to:
1. Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy).
2. Pedicle screw malpositioning, with or without neurological or vascular injury.
3. Proximal or distal junctional kyphosis.
4. Pancreatitis.
5. Device component fracture.
6. Fracture of the vertebra.
7. Neurological injury.
8. Vascular or visceral injury.
9. Foreign body (allergic) reaction to instruments, debris and corrosion products, including metallosis, straining, tumor formation, and/or auto-immune disease.
10. Infection.
11. Pain, discomfort, or abnormal sensations due to the presence of the device.
12. Hemorrhage.
13. Death.
Note: As with any major surgical procedure, there are risks involved in orthopedic surgery.
Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.

Warnings and Precautions:
1. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth or may be at risk for rotational spinal deformities
(the “crankshaft phenomenon”) due to continued differential growth of the anterior spine.
2. The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.
3. Preoperative and operative procedures, including knowledge of surgical techniques, good reduction and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.
4. The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of the device in pediatric patients.
5. The safety and effectiveness of pedicle screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are: significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
6. The benefit of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
7. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of the pedicle screw spinal system because they are technically

demanding procedures presenting a risk of serious injury to the patient.
8. The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the Intended Use, Indications for Use or for use that in contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.
9. Kalitec Medical does not warrant Medtronic Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or registration.
10. The use of the Kalitec Navigated Instrument System instruments should only be used with Kalitec pedicle screw systems.
11. Users must complete verification steps as required per the Medtronic Navigation Operative Technique.
12. 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 (of which diameter and length are selected/entered in the software) 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.
13. In the event of a registration failure or suspected inaccuracy, the Kalitec Navigated Instrument System instruments should not be used with the Navigation System and the instruments should be inspected for damage before continuing with the traditional, non-navigated procedure.
If a reusable device is/was used in a patient with, or suspected of having, Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize and eliminate the risk of cross-contamination.

Packaging:
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Kalitec Medical.

Cleaning and Decontamination:
Instruments are supplied clean and NOT STERILE, and must be sterilized prior to use.

Notes

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