CD Horizon™ Solera™ Voyager™ 5.5/6.0mm Spinal System

SURGICAL TECHNIQUE

Medtronic

MICHELSON TECHNOLOGY AT WORK

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INSTRUMENTS

Set Screw Driver
(6550006)

Multi-Axial Screw Driver
(6550002)

Rod Holder
(8350312)

MAS Rod Template
(6550013)

Plier Compressor
(6550009)

Compressor/Distractor Arm A*
(6550007)

Compressor/Distractor Arm B*
(6550008)

*Available as an extra item.

Cannulated One-Step Taps
(4.5mm 6551004) (6.5mm 6551006)
(5.5mm 6551005) (7.5mm 6551007)

(8.5mm 5484840)
(9.5mm 5484841)

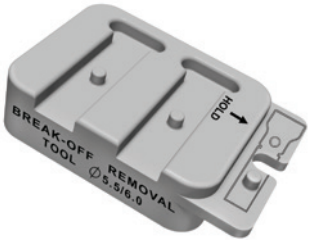
One-Step Tap Sleeve*
(6550000)

One-Step Drill Tap
(4.5mm to 5.5mm 6551045)
(5.5mm to 6.5mm 6551056)

T27 Removal Driver
(7480147)

Tab Breaker
(6550019)

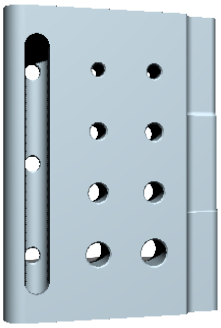
Tab Extender
(6550017)



Tab Removal Tool
(6550020)

Quick Connect Ratcheting Egg Handle
(9098120)

Extender Cap
(6550016)



Screw Gauge
(5584007)

*Compatible with 6551004, 6551005, 6551006, 6551007, 6551045, 6551056

5.5/6.0mm Non-Retaining Screwdriver
(6550003)

5.5/6.0mm Ball-Ended Driver
(6550004)

PAK Needle

2 Bevel Tips
(PK1001)

2 Trocar Tips
(PK1002)

1 Trocar/
1 Bevel Tip
(PK1003)

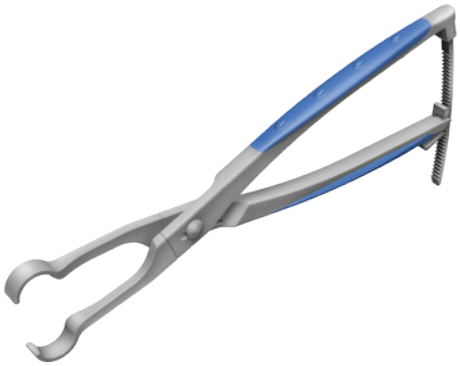
NIM™ Pedicle Access Needle
(9450020)

Guidewires
Sharp (8670002)
Blunt (8670001)

5.5/6.0mm Reinforcement Sleeve
(6550034)

5.5/6.0mm Threaded Rod Reducer
(6550027)

5.5/6.0mm Nut Driver
(6550031)



5.5/6.0mm Fulcrum Pliers
(6550035)

5.5/6.0mm Fulcrum
(6550036)

5.5/6.0mm Rod Gripper
(6550014)

Quick Connect
Ratcheting T-Handle
(7579000)

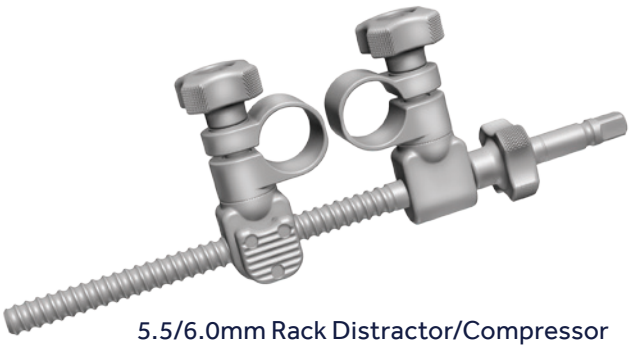
5.5/6.0mm Ring Counter Torque
(6550022)

Percutaneous Inserter
(9010000849)

5.5/6.0mm Reducer Counter Torque
(6550021)

Break Off T-Handle
(7570090)

Navigated MAS Retaining Driver
(NAV6550005)



5.5/6.0mm Rack Distractor/Compressor
(6550011)

French Bender
(7480162)

IMPLANTS

5.5mm CD Horizon Solera Voyager
Cobalt Chrome Capped Rod

5.5mm CD Horizon Solera Voyager
Cobalt Chrome Percutaneous Rod

5.5mm CD Horizon Solera Voyager
Titanium Percutaneous Rod

Set Screw
(6540530)

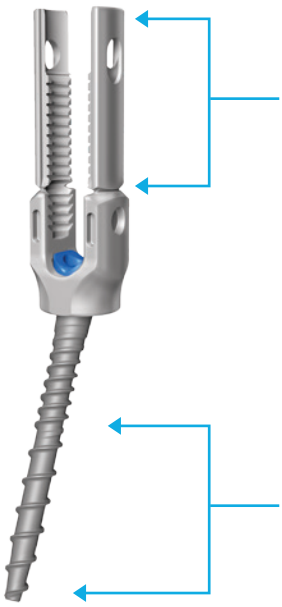
5.5/6.0mm CD Horizon Solera
Voyager Extended Tab Cannulated
Multi-Axial Screw

5.5/6.0mm CD Horizon
Solera Voyager Extended
Tab ATS Multi-Axial Screw

IMPLANT ASSEMBLY
AND SCREW OVERVIEW

Cap:
- Aligns tab to avoid Extender splay
- Works as a guide for placing instruments

Tab Extenders:
- Guide Capped Rod
- Reusable



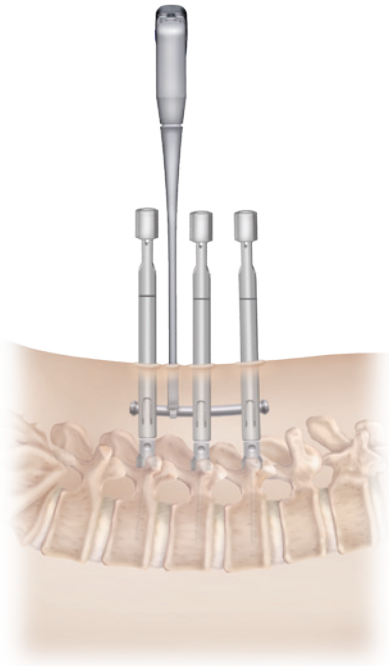
Break-off section allows for 16.5mm of reduction

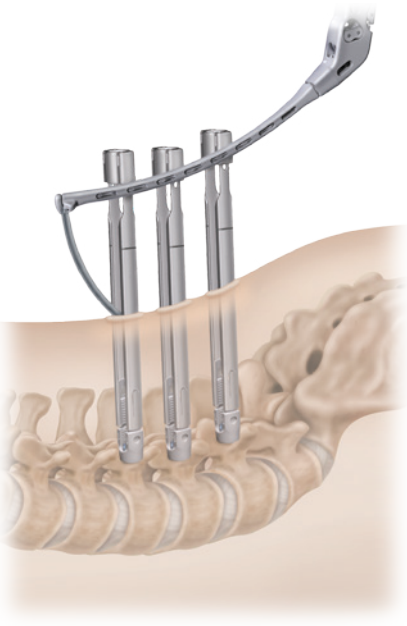
Dual lead thread form offers enhanced fixation

5.5/6.0mm CD Horizon Solera Voyager Extended Tab Cannulated Multi-Axial Screw

5.5/6.0mm CD Horizon Solera Voyager Extended Tab ATS Multi-Axial Screw

Two Rod Insertion Methods:
- Mini-Open
- Percutaneous

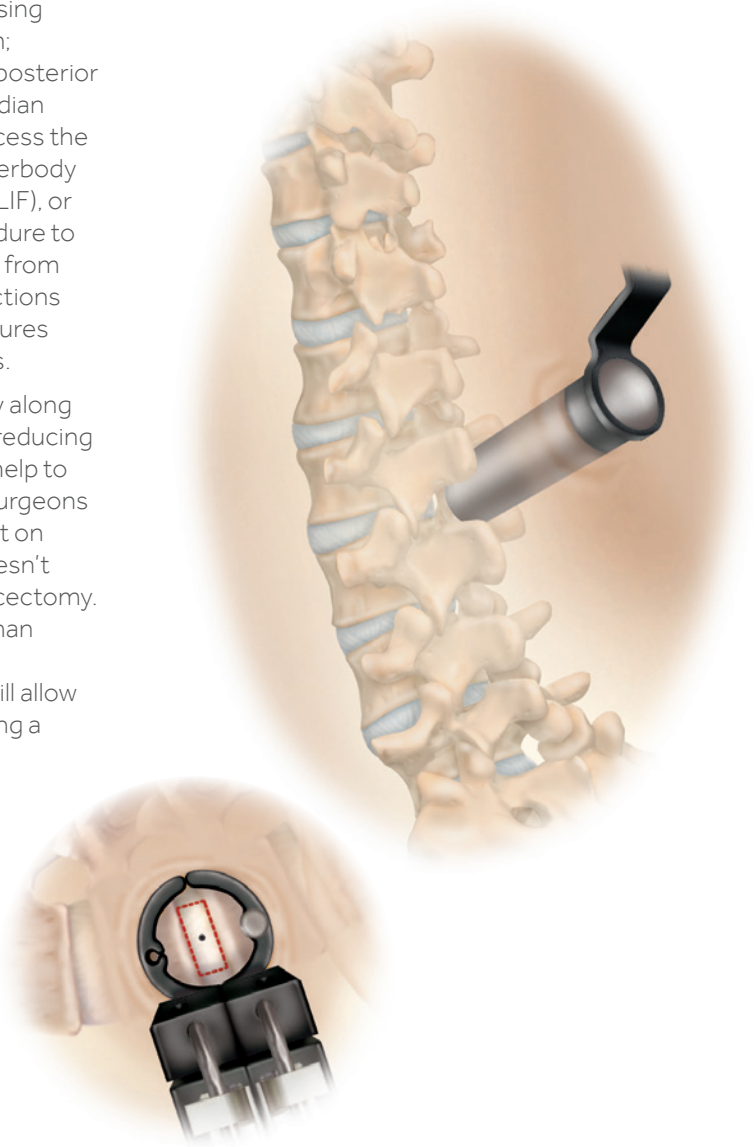




INTERBODY ACCESS AND PREPARATION

Posterior access to the surgical site for discectomy and interbody graft placement can be facilitated using the METRx™ II System or MAST Quadrant™ System; alternatively surgeons may choose to expose the posterior spinal elements via a traditional midline or paramedian approach. In addition, surgeons may choose to access the intervertebral disc space via an Oblique Lateral Interbody Fusion (OLIF), a Direct Lateral Interbody Fusion (DLIF), or an Anterior Lumbar Interbody Fusion (ALIF) procedure to perform the discectomy and interbody placement from an anterior or lateral approach. For detailed instructions regarding the use of these systems and/or procedures please refer to their respective surgical techniques.

Perform either a unilateral or bilateral facetectomy along with a total discectomy for each operative level. If reducing a spondylolisthesis, releasing these elements will help to reduce the spondylolisthesis. Additionally, some surgeons may prefer to do these procedures with the patient on a Wilson frame in the down position, so the slip doesn't worsen after performing the facetectomy and discectomy. A bilateral facetectomy will create more mobility than a unilateral facetectomy. Once the discectomy is performed, placing a distractor in the disc space will allow access for final endplate preparation and, if reducing a spondylolisthesis, will also facilitate its reduction.



PREOPERATIVE PLANNING AND SETUP

Review of preoperative imaging is useful in determining the optimal starting point and screw trajectory. Suggested skin incisions, measured laterally from the anatomic midline, can be found in **(Figure 1)**.

Important
The starting point is rarely directly over the pedicle. Some tables have pedestals that make it difficult to get a true AP view of the pedicles, especially at the S1 level. While adjustments in patient positioning can be made, tables that limit good AP fluoroscopy should generally be avoided.

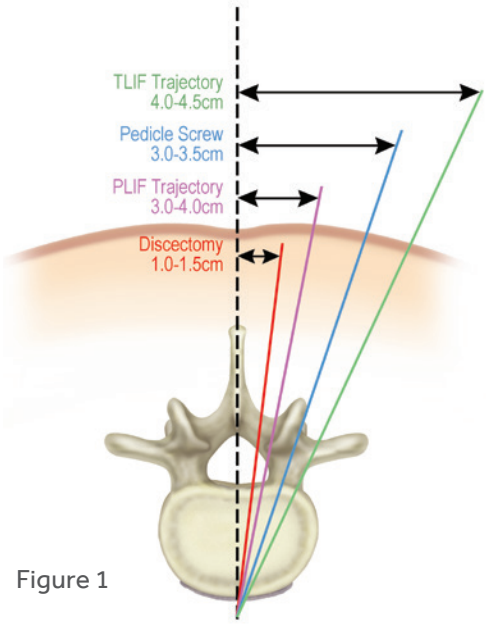


Figure 1

When using the CD Horizon Solera Voyager 5.5/6.0mm Spinal System, the patient should be placed in either the prone or the lateral position **(Figure 2a)** and efforts should be made to maximize lordosis in the spine. Prior to skin incision, it is recommended to verify that adequate fluoroscopic images of the pedicles can be obtained in both the anterior/posterior (AP) and lateral views. If difficulty is encountered when attempting to identify the S1 pedicles on the AP view, the Ferguson C-Arm view can be useful **(Figure 2b)**. To assist with accurate pedicle cannulation, the spinous process should be positioned midway between the pedicles on the AP view and the vertebral body endplates and pedicles should be crisp and single on the lateral views.

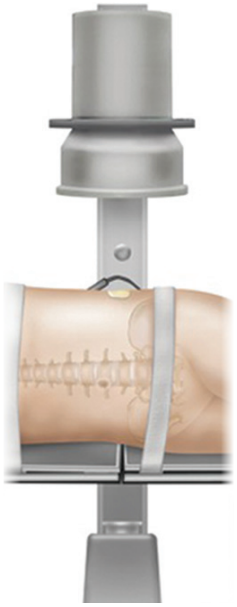


Figure 2a

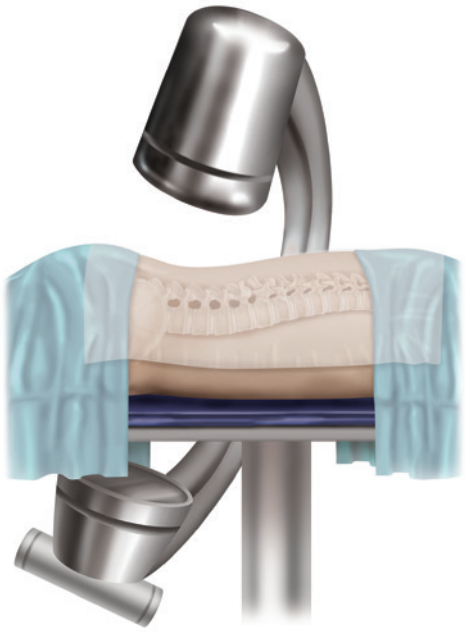


Figure 2b

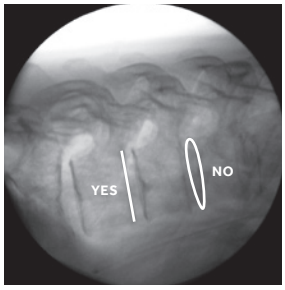


Figure 2c

Important
On AP fluoroscopy, the spinous processes should be located midway between both pedicles.

On lateral fluoroscopy, the end plates should be linear and not rounded.

POSITIONING OF **SKIN INCISIONS**

A 22-gauge spinal needle may be used to verify the appropriate location of the skin incisions. The needle is positioned on the skin directly over the pedicle on an AP image. The needle is then moved laterally 1cm to 2cm and inserted through the skin to the intersection of the facet and transverse process **(Figures 3a and 3b)**.

Important
The skin incision is slightly lateral to the pedicle (~1cm) on fluoroscopy. This will help to ensure the needle follows the normal lateral to medial trajectory of the pedicle.

Both AP and lateral images confirm that the appropriate starting place has been determined **(Figures 4a and 4b)**.

Important
Incise the skin approximately 15mm to allow the Tap Sleeve to advance to the bony anatomy.

Helpful Hint
Either measure baseline segmental lordosis at the desired operative level manually or by leveraging a mobile-device based measurement application.

Based upon the surgeon preference for the rod insertion method and number of levels instrumented, different incision techniques may be considered.

If using the percutaneous rod insertion method, make separate skin incisions over the intersection of the facet and the transverse process where each screw will be inserted **(Figure 5a)**.

If using the mini-open capped rod insertion technique, create a paramedian incision (in plane with the junction of the lateral facet and the transverse process on the AP image). Extend the incision from the most superior to the most inferior pedicle to be instrumented. It is important to open the spinal muscular fascia to permit passage of the Capped Rod down the incision and through the muscular plane. Once the pedicle is identified, sweep the PAK Needle or another general instrument to the next pedicle. This step will create a pathway through the muscle plane and also allow for easier access during rod insertion. With this method, all Screw Extenders to be connected via the Capped Rod will need to be contained within a single incision.

Alternatively, a posterior midline incision technique can be used if an open method is preferred and direct visualization of the pedicles is required **(Figure 5b)**.

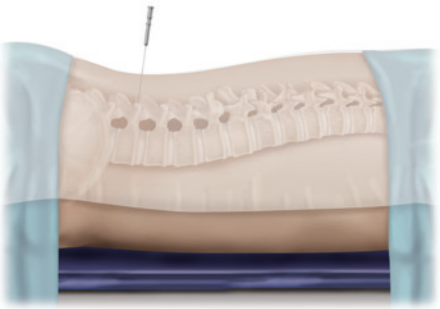


Figure 3a

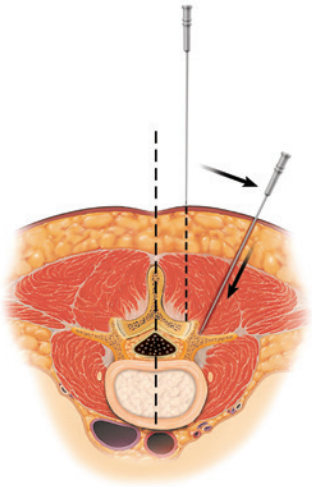


Figure 3b

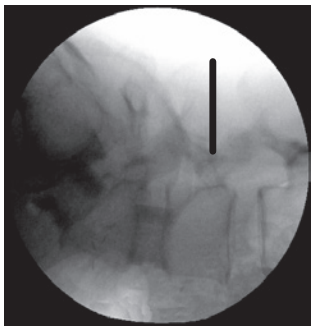


Figure 4a

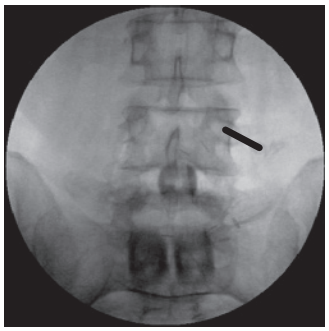


Figure 4b

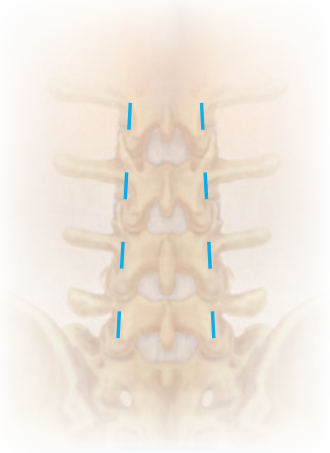


Figure 5a

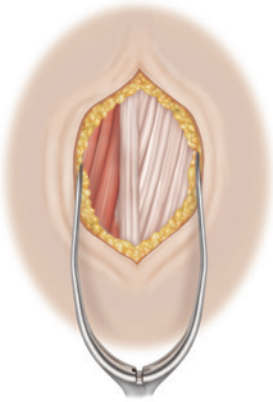


Figure 5b

CONSIDERING
PEDICLE ANATOMY

Consider the pedicle as roughly a cylindrical structure. As the pedicle is traversed, the trajectory should allow the needle or screw to remain lateral to the medial pedicle wall **(Figure 6a)**.

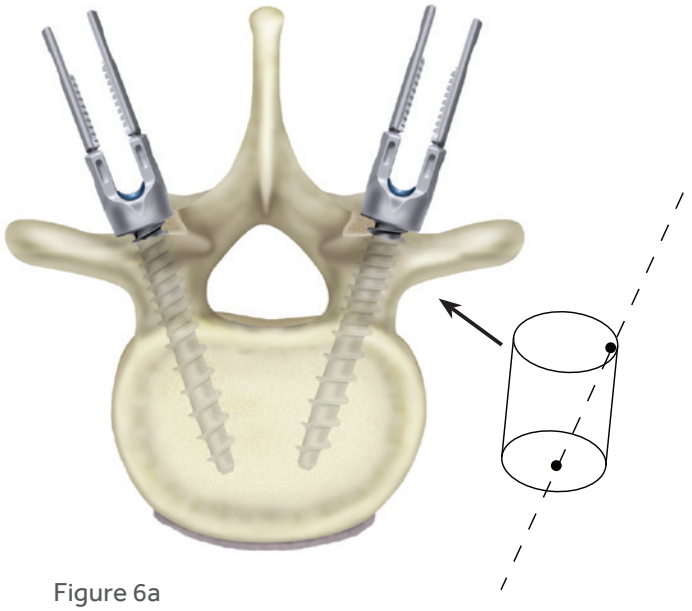


Figure 6a

Important
The ideal starting point is at the intersection of the facet and the transverse process (the lateral edge of the cylinder) **(Figures 6b and 6c)**.

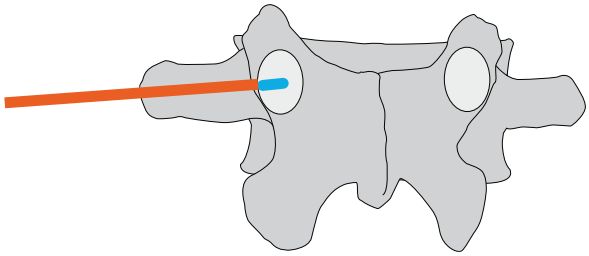


Figure 6b

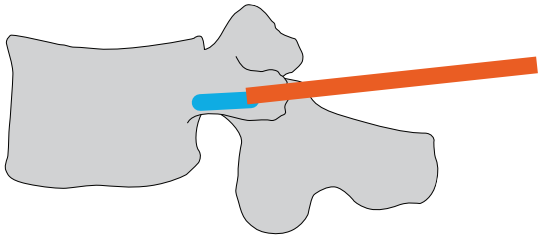


Figure 6c

EXTENDED TAB CANNULATED **MULTI-AXIAL SCREWS**

ACCESSING
THE PEDICLE

PAK Needle Insertion

A PAK (Pedicle Access Kit) Needle is used to gain access to the pedicle. After placing the PAK Needle at the intersection of the facet and the transverse process, the needle is advanced in a lateral-to-medial trajectory **(Figure 7)**.

An AP image should show the needle tip at the lateral margin of the pedicle initially. As the needle advances toward the base of the pedicle on the lateral image, it should approach the pedicle center on the AP image **(Figures 8a and 8b)**.

For neuromonitoring, a NIM PAK Needle **(Figure 8c)** may be used to access the pedicle. Triggered EMG monitoring **(Figure 8d)** can be performed during advancement of the needle into the pedicle to ensure proper placement.

Figure 7

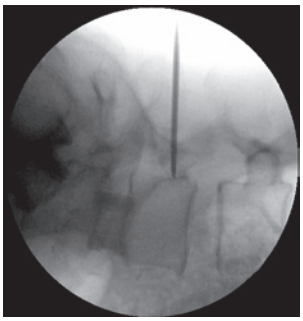


Figure 8a

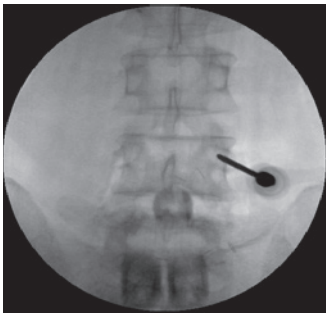


Figure 8b

Important

The PAK Needle should be advanced across the junction of the pedicle and the vertebral body to allow placement of the Guidewire.

The NIM-Eclipse Spinal System Surgeon Directed (SD) configuration is intended for use to record, monitor, and stimulate/record biopotential signals including electromyograph (EMG), evoked response and nerve/muscle potentials, and for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The system provides feedback to the surgeon and OR team to assist in the localization and assessment of spinal nerves and verification of placement of spinal instrumentation to avoid injury to at-risk nerve roots.

Figure 8c

Figure 8d

Important

Please see the NIM-Eclipse™ E4 Spinal System package insert and user's manual for complete instructions and a list of warnings, precautions, and other medical information.

NIM-Eclipse E4 System is manufactured by Medtronic Xomed, Inc. and distributed in the USA by Medtronic Sofamor Danek USA, Inc.

For the complete labeling for the navigation products please contact Medtronic Navigation, General Business at 800-580-8860 or visit www.medtronic.com .

Guidewire Insertion

The inner stylet of the needle is removed to allow the Guidewire to be inserted into the pedicle **(Figures 9a and 9b)**.

Important
Be extremely careful with regard to the position of the Guidewire. Unintentional advancement of the wire can potentially be very dangerous. Once the Guidewire is inserted, the Cannula may be removed using a rotation technique, leaving only the Guidewire in place. The Guidewire insertion steps should be repeated for each Guidewire that is placed.

Note
Guidewire, Screw Extender placement and rod passage steps are illustrated in this technique on one side only for clarity purposes.

Note
Care should be taken when removing the Cannula to ensure the Guidewire is not also removed. A heavy needle holder may be used to assist with the Cannula removal.

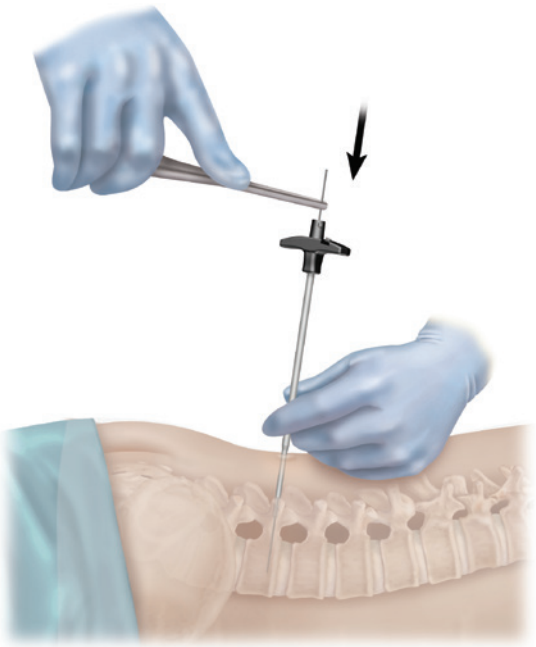


Figure 9a

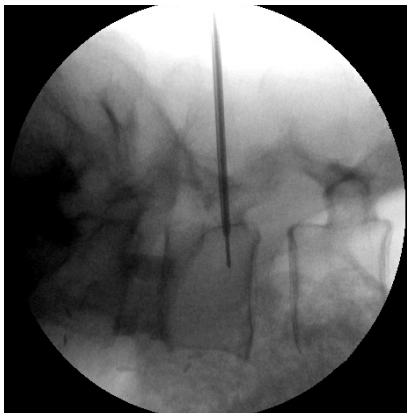


Figure 9b

Dilating the Fascia

The fascia and muscle must be dilated to allow for screw placement. Place the Tap Sleeve over the Tap and lock it into position by pushing the button **(Figure 10)**. Once it is locked in, there are two stops, one at 10mm and a second stop that allows the Tap to be fully extended. Insert both the Tap and Tap Sleeve into the stab incision over the Guidewire to dilate the fascia and muscle. The Tap Sleeve should be docked on bony anatomy to minimize tissue creep **(Figure 11)**.

Figure 10

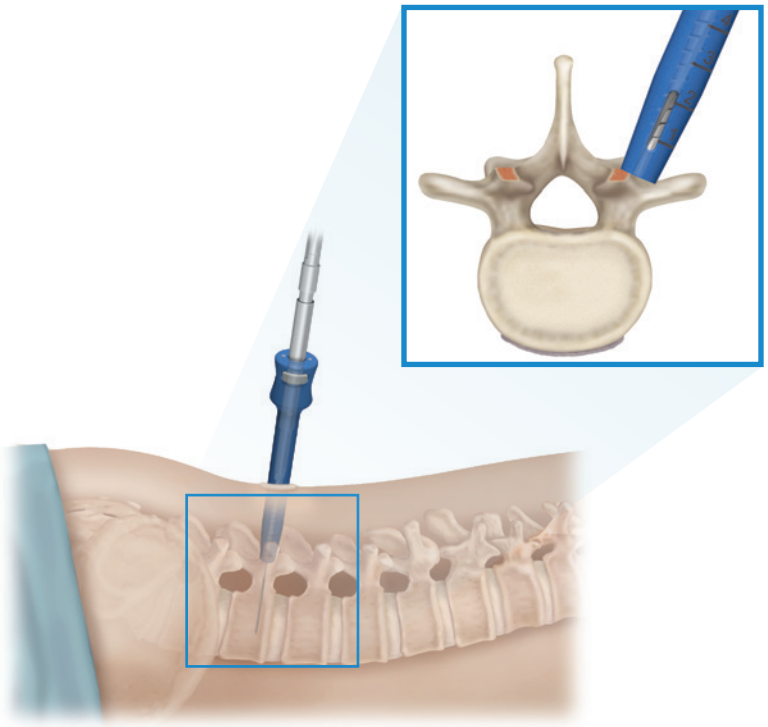


Figure 11

PEDICLE PREPARATION

The pedicle is prepared by advancing the Tap along the Guidewire to the desired depth **(Figure 13)**. In dense bone, where the Screw may be difficult to advance, ensure that the pedicle is fully prepared by using a Tap the same size as the Screw to be inserted. Use the Self-Drilling Tap option if particularly hard bone is encountered.

Alternatively, the IPC™ Powerease™ System may be used for tapping **(Figure 14)**. The IPC Powerease System is a system of powered surgical instruments designed specifically for spine surgery. The IPC Powerease System Taps and Screwdrivers are cannulated to enable use over a Guidewire. The integrated design allows the Powerease Driver to connect directly to the NIM-Eclipse System. For comprehensive instructions refer to the Powerease User Manual.

Further evaluation of the tapped pedicle can be performed by using the NIM-Eclipse System Surgeon directed Ball-Tip Probe (945SPK1004) **(Figure 15)**. Free-running EMG will monitor any nerve root irritation during this procedure **(Figure 16)**.

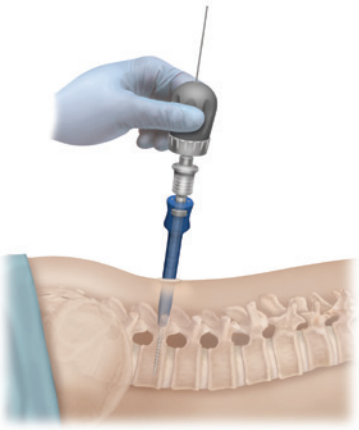


Figure 13

Figure 14

Note

It is important to keep the Tap along the same axis as the Guidewire. If a change in trajectory is required, the PAK Needle should be reinserted over the Guidewire, the Guidewire removed, and the inner stylet replaced.

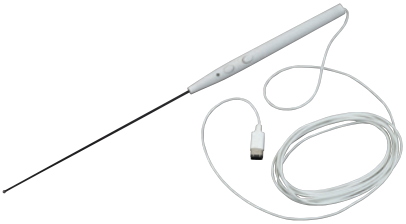


Figure 15

Figure 16

Important

Unintentional advancement of the Guidewire should be monitored during this step. To avoid this, ensure the direction of the Tap is in the same plane as the Guidewire. Cleaning the Guidewire prior to tapping can be helpful.

To assemble an instrument with the Powerease™ Driver align the connection end with the Quick Connect on the Powerease™ Driver and insert until the connection end of the instrument is fully seated within the Quick Connect of the Driver **(Figures 17a and 17b)**.

Figure 17a

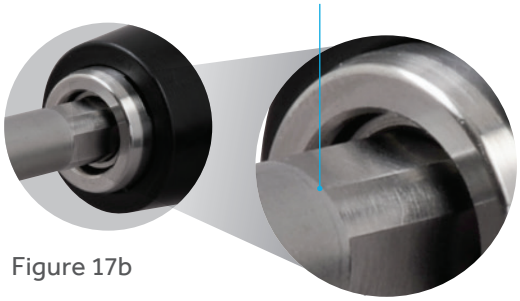


Figure 17b

Flat sides should be fully inserted and not be visible.

Screw length can be estimated by referencing the depth marks on the Tap with the rim of the Tap Sleeve **(Figure 18)**. To ensure accuracy, the Tap Sleeve must be docked on bone.

Fluoroscopy should be used to verify the position of the Guidewire and the Tap during this step, After tapping, remove the Dilator but leave the Guidewire in place.

Helpful Information

If you tap beyond the tip of the Guidewire, bone within the end of the Tap may cause the Guidewire to pull out as you remove the Tap. To avoid this, advance the Guidewire through the Tap before you remove the Tap from the vertebral body. If the Guidewire becomes bent, place a PAK Cannula over the bent Guidewire, then replace it with a new Guidewire.

Important

Care should be taken when removing the Tap Sleeve and Tap not to inadvertently remove the Guidewire.

Figure 18

EXTENDER, CAP, AND **SCREW ASSEMBLY**

Before a Screw can be inserted into the pedicle, the Tab Extenders and Cap **(Figure 19a)** must be assembled with the Extended Tab Multi-Axial Screws. To assemble the Screw Extenders, insert the Extended Tab Multi-Axial Screw Head into the Tab Extenders until locked with an audible click and tactile feedback. With both Tab Extenders locked onto the Extended Tab Multi-Axial Screw Head, insert the Cap into the forked tips of the Tab Extenders **(Figure 19b)**.

Note
To ensure Cap is locked onto Tab Extenders, listen for an audible click.

Figure 19a

Figure 19b

SCREW INSERTION

If using the Cannulated CD Horizon Solera Voyager 5.5/6.0mm Screws, insert the Cannulated Retaining Bonescrew Driver into the Screw Extender Assembly. The tip of the driver passes into the head of the Multi-Axial Extended Tab Screw until the driver fully engages the Screw **(Figure 20)**.

Thread the Sleeve of the Retaining Driver into the head of the Screw before inserting over the Guidewire **(Figure 21)**.

The entire Screw Extender Assembly is inserted over the Guidewire and into the pedicle **(Figure 22)**. If the Screw is difficult to advance, remove the assembly while leaving the Guidewire in place, and ensure the pedicle is fully prepared by using a Tap the same diameter as the inserted Screw. After driving the Screw Assembly through the pedicle, remove the Guidewire to prevent it from being advanced. Be certain that the Screw Assembly is not inserted too far. If the multi-axial head of the CD Horizon Solera Voyager Cannulated Extended Tab Multi-Axial Screw is driven too forcefully against the bone, it will lose its multi-axial capabilities, making it difficult to connect the assemblies during subsequent steps.

Figure 20

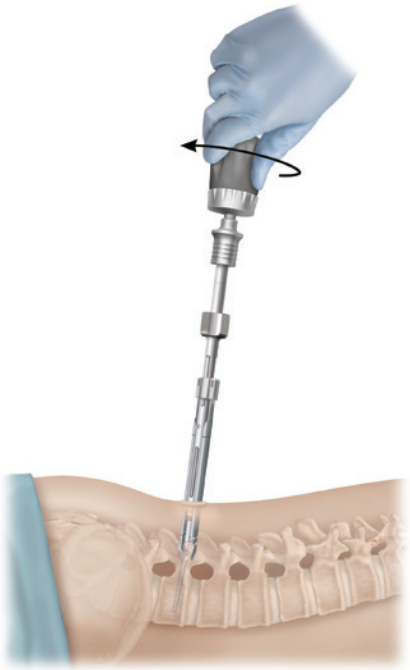


Figure 21

Note

The IPC Powerease System may be used for insertion of CD Horizon Solera Voyager 5.5/6.0mm System Screws. The IPC Powerease System is a system of powered surgical instruments designed specifically for use in spine surgery. The Powerease System Taps and Screwdrivers are cannulated to enable use over a Guidewire. These Taps and Screwdrivers can be used manually or with the IPC Powerease System. For comprehensive instructions refer to the Powerease User Manual.

The process is repeated for additional Screws on the same side. After inserting the assemblies, the Screw Extenders should be at approximately the same height outside the patient. The assemblies should move freely following Screw insertion.

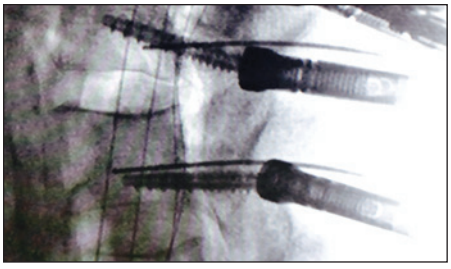
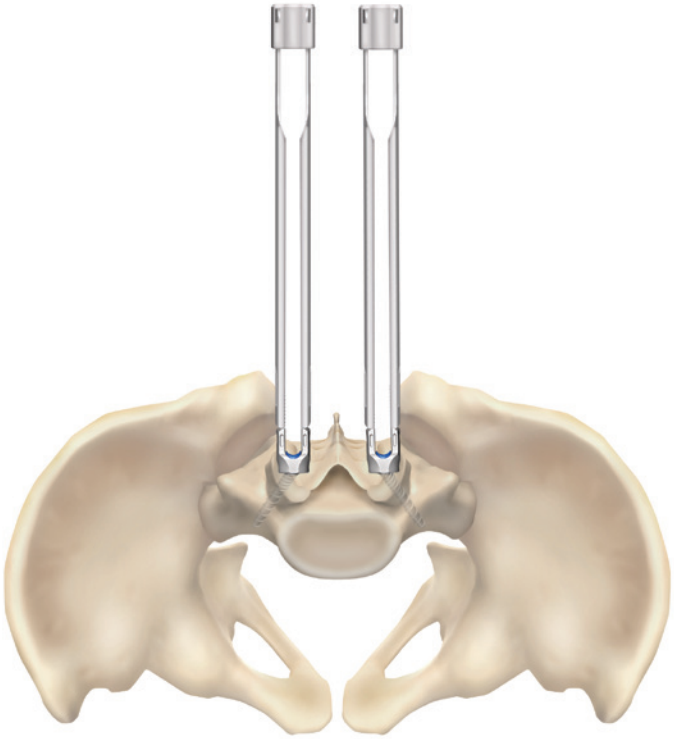


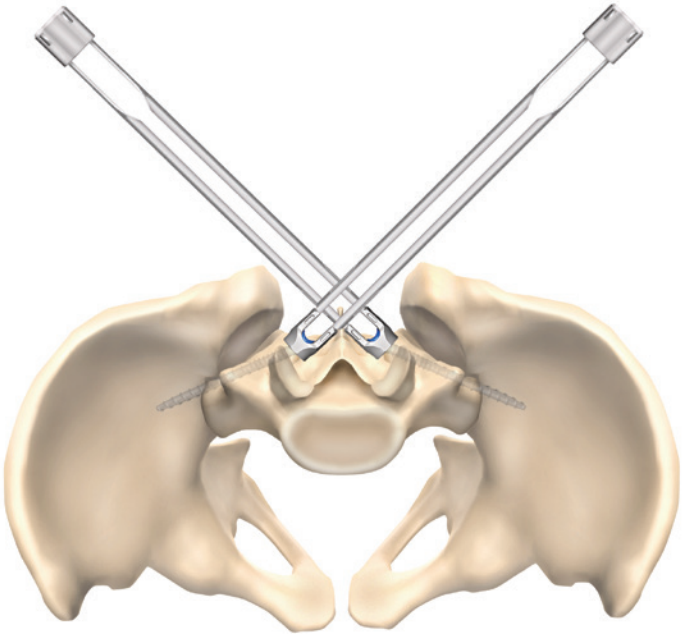
Figure 22

ILIAC
FIXATION

The goals of iliac fixation include leveling pelvic obliquity, correcting coronal and sagittal imbalance, and providing rigid fixation to help prevent pseudoarthrosis, dislodgement of instrumentation, and recurrence of deformity. The implants and instruments featured in this guide are versatile and can be used according to surgeon preference. Following are two different trajectories for performing sacropelvic fixation.



S1 Alar Trajectory



S2 Alar Iliac Trajectory

S2 ALAR ILIAC TRAJECTORY (S2AI)

Exposure and Starting Point Selection

A midline incision should be extended to expose the S1 and S2 foramens. It is not necessary to dissect to the iliac crest for this trajectory. The S1 and S2 dorsal foramen are your anatomical landmarks for the S2AI trajectory. Find the midpoint between the S1 and S2 dorsal foramen and the lateral border of the foramen, as the intersection of these two places is your starting point **(Figure 23)**. The entry point may vary with pathology. The advantage of this starting point is that it should be in line with a S1 Pedicle Screw, or slightly lateral to the S1 Pedicle Screw to allow maximum ease of in-line rod connection without rod bending or use of connectors.

Fluoroscopy is recommended to help identify the appropriate trajectory. Direct the C-arm in the intended trajectory of the implant.

- Angled 20-30 degrees caudal and 40-50 degrees to the transverse plane **(Figures 24a and 24b)**.
- The iliac teardrop should be visible on the AP fluoroscopic image **(Figure 25)**.

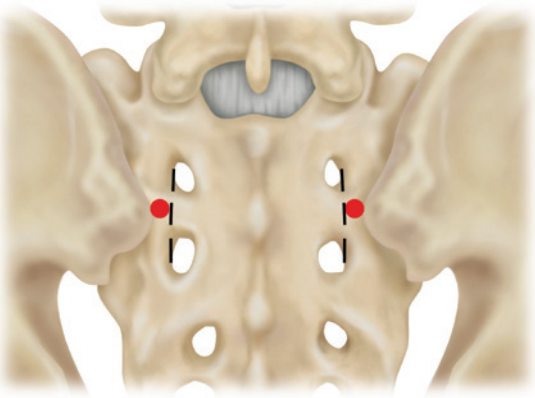


Figure 23

Note
If the pelvis is asymmetrical in the transverse plane, the starting point may need to vary in the mediolateral plane. This is common in patients with genetic or neuromuscular disorders.

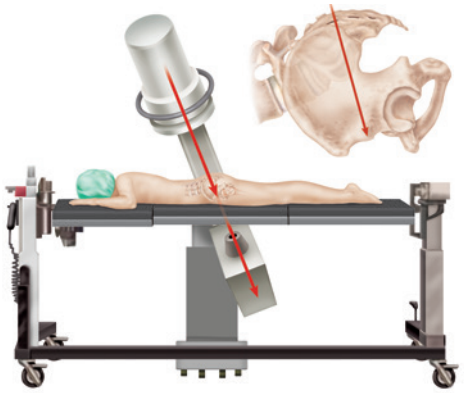


Figure 24a

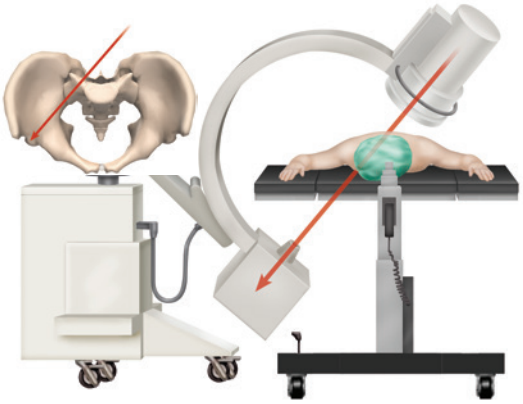


Figure 24b

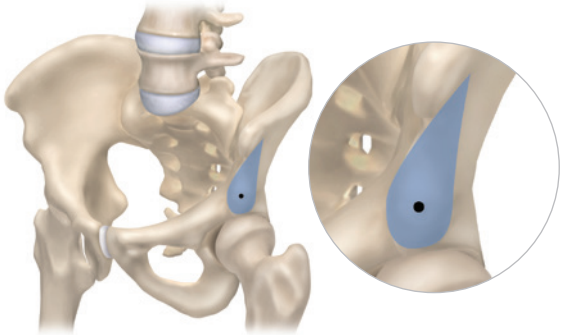
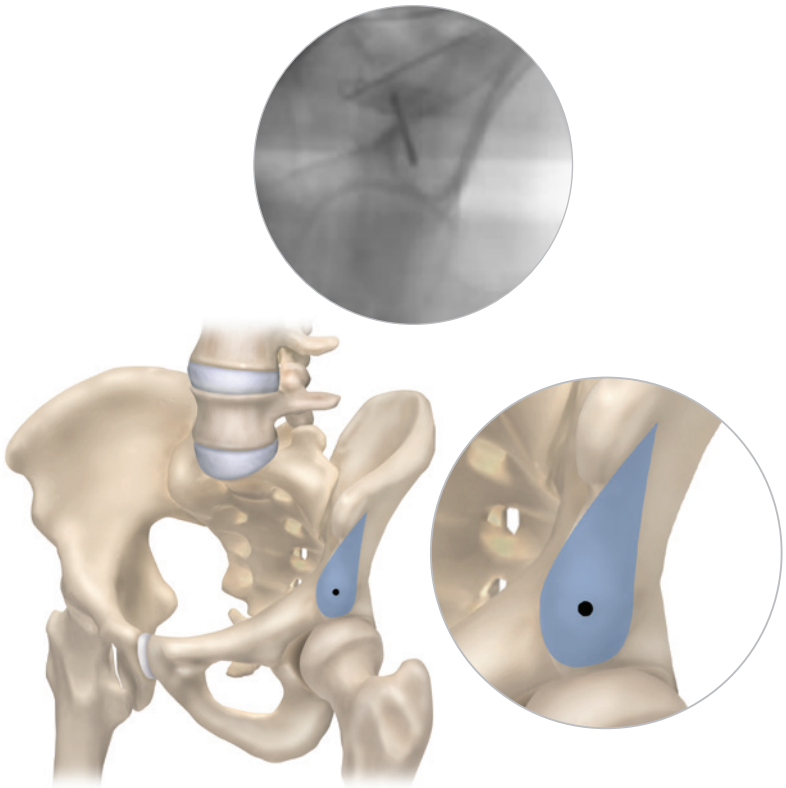


Figure 25

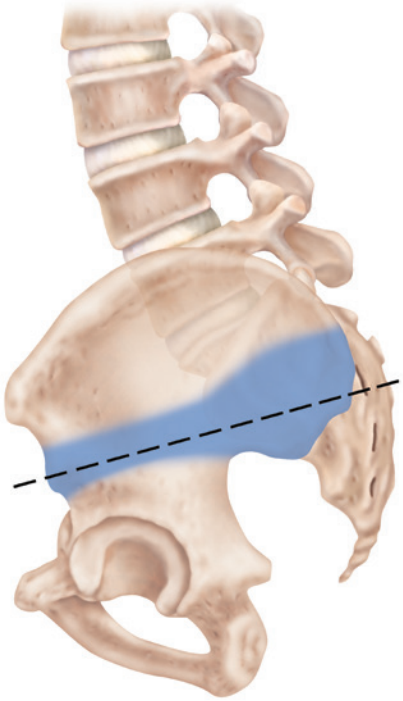
Screw Site Preparation

Using an appropriate size drill, the chosen trajectory should be lateral and approximately 40-50 degrees relative to the horizontal line connecting the posterior superior iliac spine (PSIS) and 20-30 degrees caudal from straight lateral. This trajectory will vary with pelvic obliquity and lumbar lordosis. Again, fluoroscopy can be very helpful when utilizing the iliac teardrop and sciatic notch views **(Figures 26 and 27)**. The sciatic notch view is obtained by placing the fluoroscopy unit 90 degrees to the iliac teardrop view. This will show the sciatic notch, posterior superior iliac spine (PSIS), and anterior inferior iliac spine (AIIS).



Iliac Teardrop View

Figure 26



Sciatic Notch View

Figure 27

The path of the probe or drill should be within 20mm of the greater sciatic notch and aiming toward the anterior inferior iliac spine (AIIS). If using a drill, feel for the bony endpoint following each advancement of the drill. Once the drill crosses the sacroiliac joint, a 3.2mm drill bit is used to guard against breaking the smaller bit in the ilium. A teardrop fluoroscopic image at this stage will help ensure the anterior-posterior trajectory within the thickest part of the ilium, without cortical breach. Use a Ball-Tip Probe to palpate the course of the Screw and confirm the bony end point. Note the appropriate Screw length as denoted on the Ball-Tip Probe or on the drill. Placing a Screw slightly (<10 mm) less than measured permits the Screw to be hubbed down into the dorsal sacral bone while not penetrating the AIIS or acetabulum.

- A Guidewire can be used to ensure proper Screw placement by placing the Guidewire through the probed hole to preserve the trajectory established **(Figure 28)**. Confirm Guidewire position with fluoroscopy in the iliac teardrop and sciatic notch views.

Next, tap the hole using the appropriate size pedicle Tap for the intended Screw diameter. While advancing the Tap, ensure that the Guidewire does not also advance.

Note
Tapping is the key to successfully implanting Screws into the ilium in either a percutaneous or open fashion.

Note
As the pelvic wing tends to be a highly cortical structure, it is important to tap the full distance for the Screw. Tapping the full distance will help to avoid imparting high torsional forces onto the implant.

Note
Due to the higher torsional forces when placing large Screws in the ilium, it is recommended to tap "line-to-line" rather than under tapping.

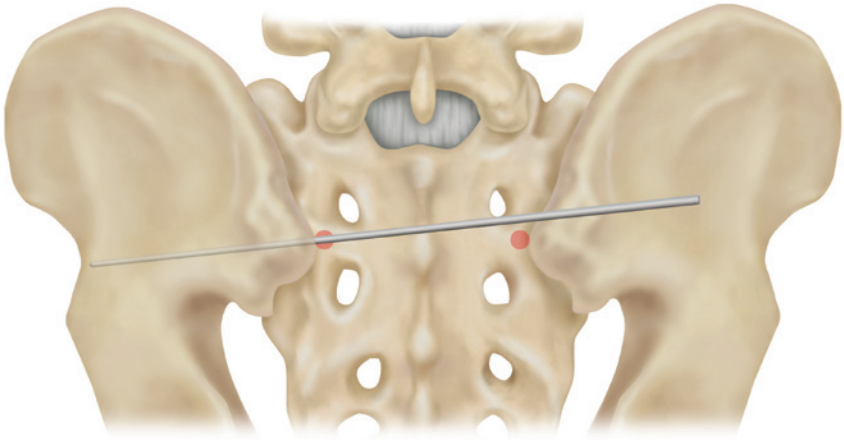


Figure 28

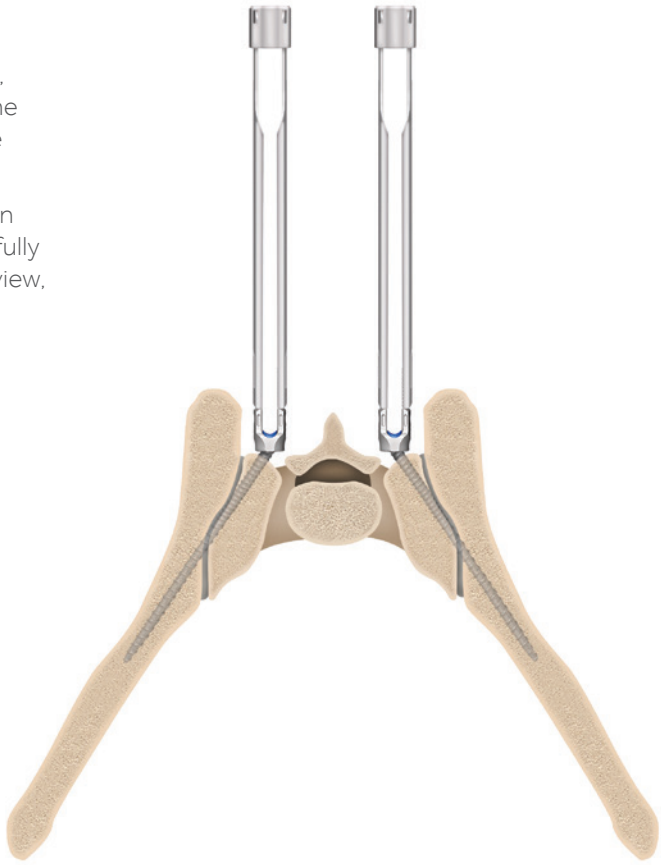
SCREW
SELECTION

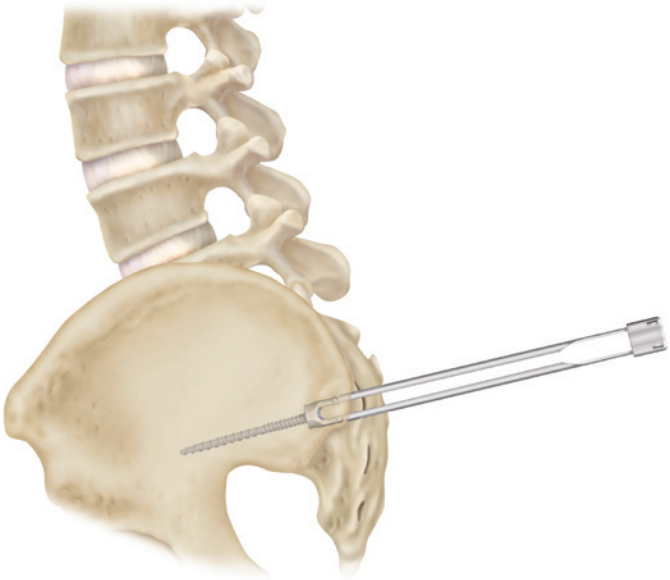
Once the hole is prepared, the appropriate Screw size is selected. In general, this is the longest, largest diameter Screw that will fit the anatomy. The CD Horizon Solera Voyager 5.5/6.0mm Spinal System Screw is placed using the Screwdriver with the Ratchet Handle or the Powerease™ System. If the Powerease System is used during iliac Screw placement, the Torque Multiplier instrument may be used for increased torque.

SCREW
PLACEMENT

When performing the S2AI trajectory, place the Screw approximately 40-50 degrees lateral to the horizontal plane, and 20-30 degrees caudal (guided by posterior surface of the sacrum). Target the anterior inferior iliac spine, which can be found by palpating the top of the greater trochanter.

Insert the Screw aiming for the AIIS with the trajectory within 20mm above the greater sciatic notch. Before the Screw is fully seated, remove the Guidewire (if used). Using the teardrop view, confirm Screw placement with fluoroscopy.

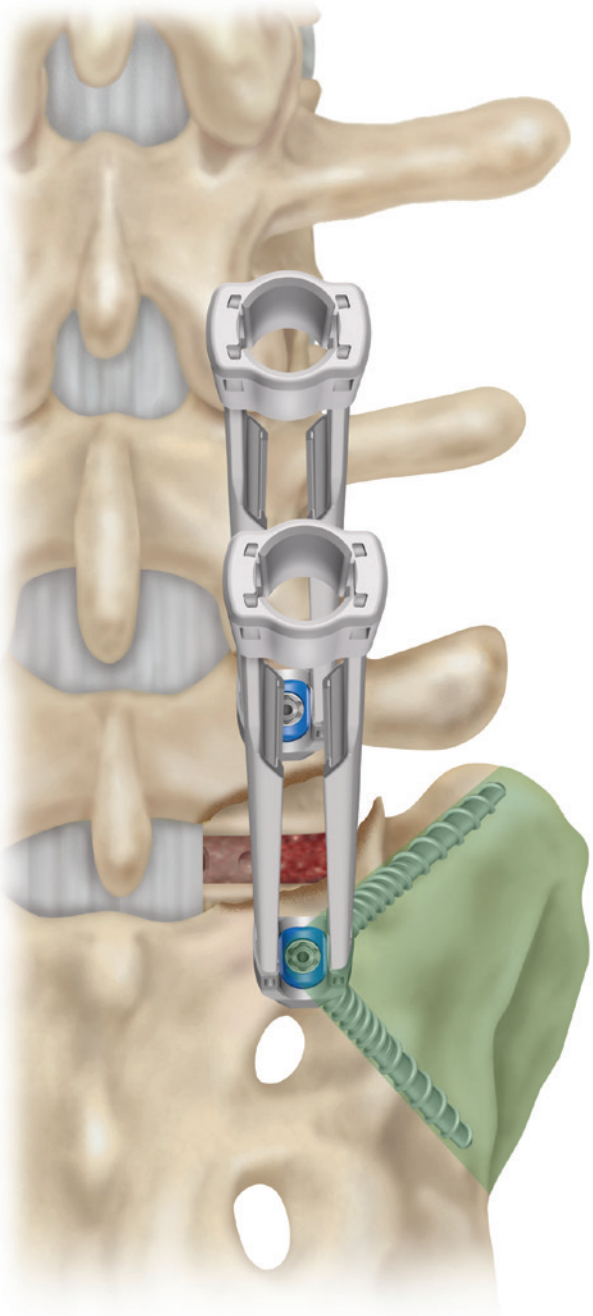




S1 ALAR
TRAJECTORY

Exposure and Starting Point Selection

Lateral dissection is done underneath the spinal fascia to reach the medial aspect of the iliac wing at its very distal aspect. The starting point for a S1 Alar Screw is midway between the L5/S1 facet and the first dorsal foramen.



Screw Site Preparation

The trajectory for a S1 Alar Screw is flexible within the alar zone. This sacral strategy allows either a down-and-away or up-and-out trajectory. Both enable bicortical purchase (by selecting the appropriate length of Screw) and construct alignment of the medially-placed Screws.

Screw Selection and Placement, Rod Placement

The key factors of S1 Alar Screw placement are:

- Lateral to the medial wall of the S1 foramen
- 1mm to 2mm superior to the cephalad border of the S1 foramen

Select the appropriate size Screw. In general, this is the longest, largest diameter Screw that will fit the anatomy. The CD Horizon Solera Voyager 5.5/6.0 Spinal System Screw is placed using the Screwdriver and the Ratchet Handle or the Powerease System. The Screw Head is positioned facing directly cephalocaudal to allow proper seating of the Rod.

NAVIGATION

- Cannulated CD Horizon Solera Voyager 5.5/6.0 Extended Tab Multi-Axial Screws
- CD Horizon Solera Voyager 5.5/6.0 Extended Tab ATS Multi-Axial Screws

TECHNOLOGY
OVERVIEW

O-arm™ Image Acquisition System

Mobile Viewing Station

Main Cart

Camera Cart

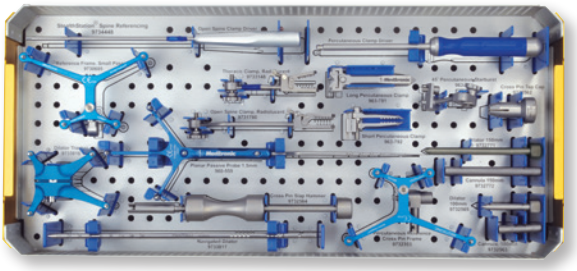
O-arm Imaging System

StealthStation™ S8 Surgical Navigation

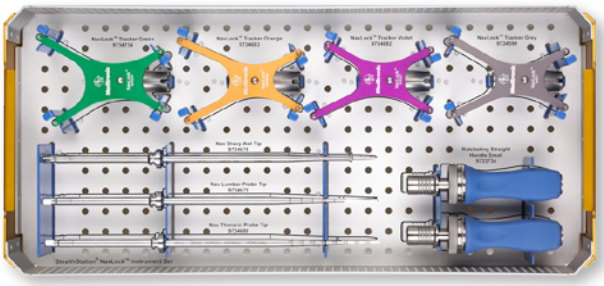
Navigated Stealth-Midas™ Powered Drilling System

CD Horizon Solera Voyager 5.5 System

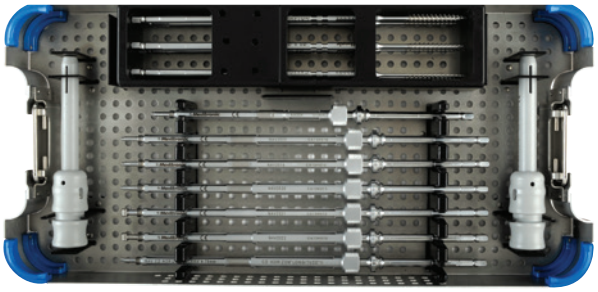
INSTRUMENTS
AND EQUIPMENT



StealthStation Spine Referencing Set
(9734495)



StealthStation NavLock™ Instrument Set
(9734833)



Navigated CD Horizon™ Solera™ Complete Percutaneous Taps/Drivers Set

Spheres
(8801074)

Disposable Perc Pin
100mm (9733235)
150mm (9733236)

Navigated PAK Needle
(9733498)

O-arm Sterile Tube Drape (optional)
(9732722)

NAVIGATION EQUIPMENT
AND ROOM SETUP

For a navigated surgery, the OR should be equipped with the O-arm Image Acquisition System, the Mobile Viewing Station (MVS), and the StealthStation S8 System **(Figure 29)**. Plug the MVS into a power source; connect the MVS to the O-arm System, and power on the system. Power on the StealthStation S8 System and start the Spine software. Connect the MVS to the StealthStation S8 System network port with a network cable or a crossover cable.

The equipment setup for Navigated Posterior Fixation Procedure has the StealthStation S8 Camera Cart positioned near the patient's feet.

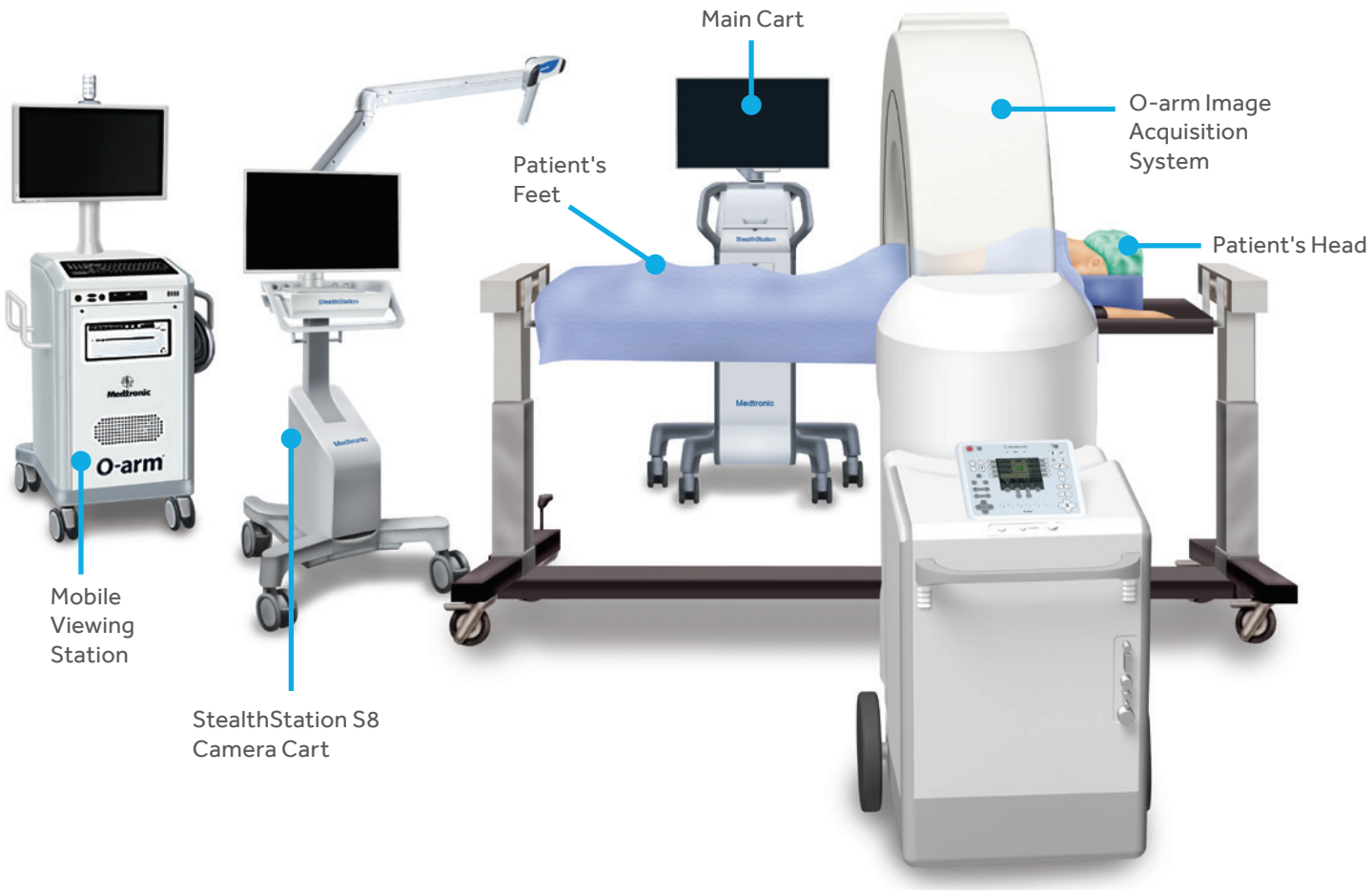


Figure 29

When positioning the O-arm System for the procedure, place it around the patient table approximately seven inches closer cephalad from the anatomy to be imaged **(Figure 30a)**. The gantry should then be translated in the direction of the patient's feet for imaging. This will allow the gantry to be placed in a "park" position and remain in the sterile field throughout the procedure, if desired **(Figure 30b)**.

The camera should be positioned at the foot end of the patient table so that the camera has an unobstructed line-of-sight to the Reference Frame which will be placed into the patient. Position the surgeon's monitor near the patient's side, opposite from the surgeon.

Place the patient in the prone position, lying flat on a Jackson spine top table or a Jackson table with the Wilson frame.

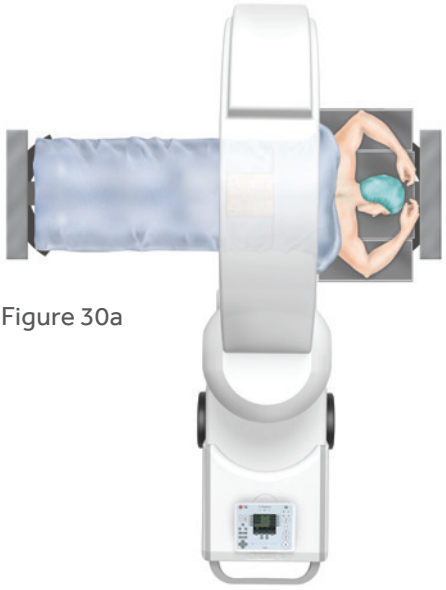


Figure 30a

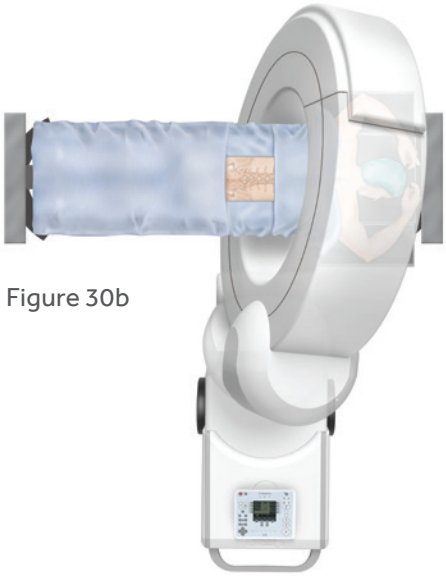
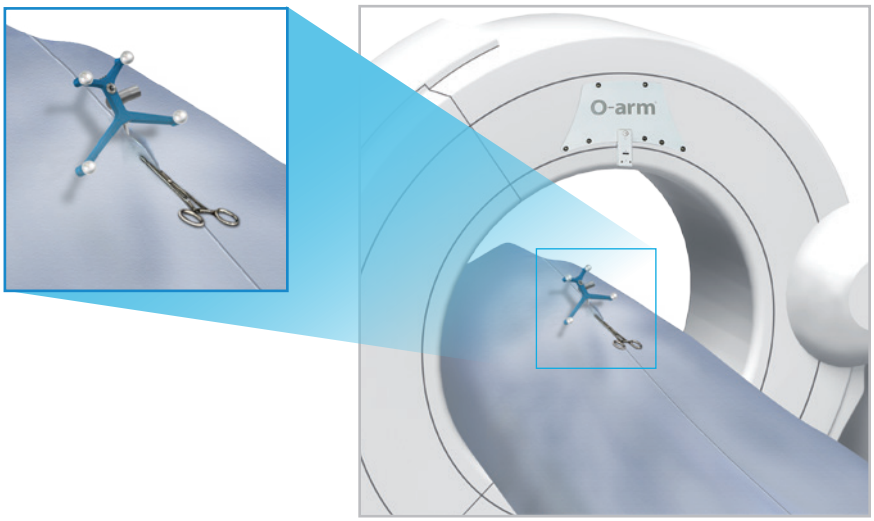


Figure 30b

Helpful Information

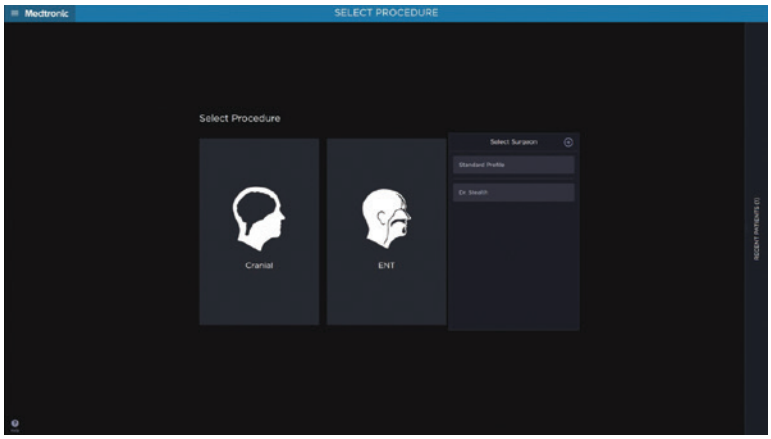
If the O-arm System will remain in the sterile field during the procedure, drape the O-arm System gantry using the O-arm IAS Sterile Tube Drape during the positioning of the system. If the O-arm System will be removed from the sterile field, place and clamp two half-drapes over the sides of the patient prior to positioning in the sterile field maintaining sterility around the patient while closing the gantry of the O-arm System.

Be sure that the reference frame is visible to the StealthStation camera after draping and be sure that any clamps placed on the drapes do not interfere with O-arm acquisition.



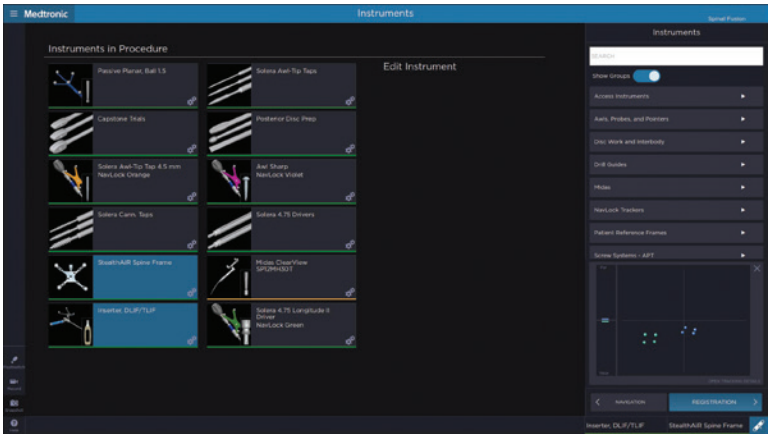
In the StealthStation S8 Spine Software, complete the "Select Surgeon" and then "Select Procedure" tasks. Continue through the software by completing the "Set-Up Equipment" and "Verify Instruments" tasks to reach the "Acquire Scan" screen.

StealthStation S8 Spine Software Workflow



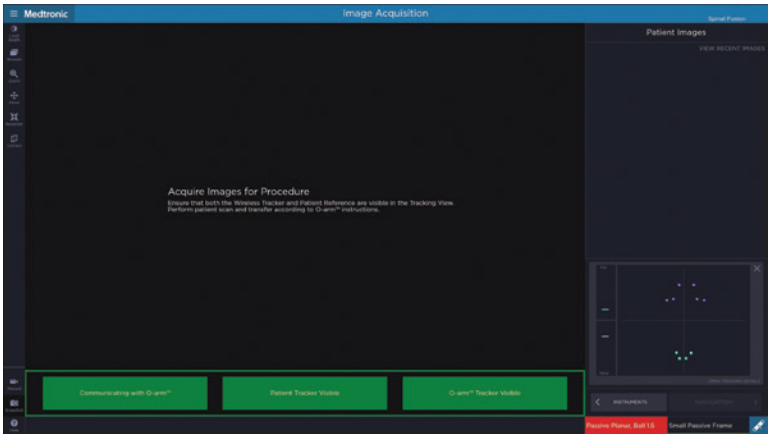
1. Select Procedure

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



2. Verify Instruments

Check that the toolcards 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 toolcard for the instrument must appear on this screen to be verified and tracked.



3. Acquire Scan

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

INSTRUMENT **VERIFICATION**

Attach the Sphere to a blue Reference Frame from the Spine Referencing Set 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 blue Reference Frame and hold perpendicular **(Figure 31a)** and visible to the camera until a confirmation color is seen. Use the tracking view in the lower right of the screen to ensure the camera is tracking the Reference Frame and instrument correctly **(Figure 31b)**.

- Successful verification is indicated by a chime and a transition to green on the instrument toolcard.
- 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.

Helpful Hint
Assigning an instrument to a specific colored NavLock Tracker will eliminate the need to switch the tracker from one instrument to the next instrument throughout the procedure. As an example, the grey tracker could be assigned to the tap and the orange tracker could be assigned to the driver.

Helpful Hint
OR staff can verify instruments before the surgeon enters prior to reference frame placement.

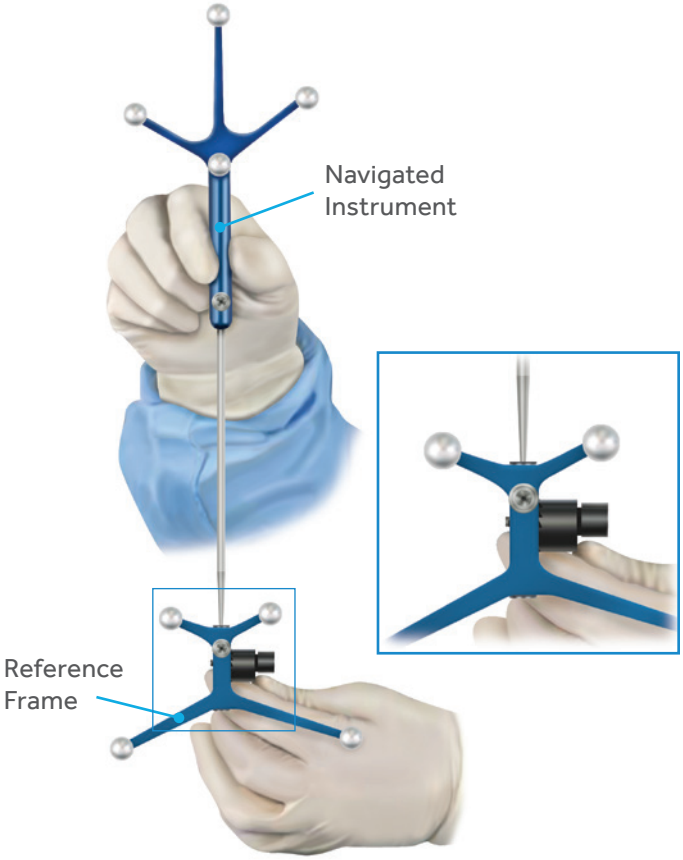


Figure 31a

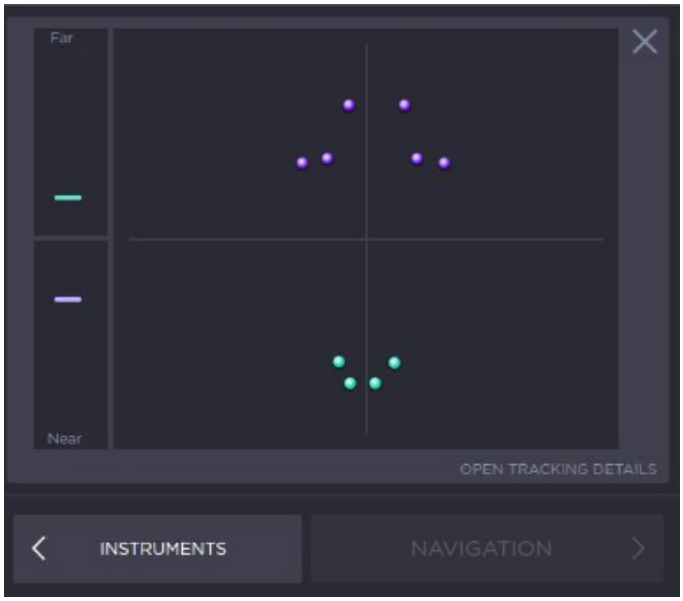


Figure 31b

REFERENCE FRAME PLACEMENT

When performing a SynergyTLIF℠ Procedure, use of the Percutaneous Reference Pin with the Percutaneous Reference Frame is recommended. Pins are available in 100mm and 150mm lengths. For L5-S1 procedures, the surgeon should consider medializing the pin to avoid line-of-sight obstructions between the camera and the navigated instruments.

The preferred method places the pin down the posterior superior iliac spine (PSIS) much like the trajectory of an iliac screw, which drops the reference frame out of the way and does not pose potential line-of-sight obstacles between the camera and the screw placement **(Figure 32a)**. This option is described below.

Upon palpation, locate the PSIS on the patient. Mark the skin a little medial and inferior to the PSIS to verify the appropriate location to place the pin.

Make a stab incision and locate the Cannula with the Dilator over the PSIS. Place the Dilator/Cannulas into the incision through the tissue until it contacts bone. Once docked, the Dilator/Cannula assembly is tapped with a mallet to make an indentation in the bone for the pin. While holding the Cannula in place, remove the Dilator and insert the pin through the Cannula. Place the Tap Cap on the pin and rotate the cap so the arrow on the Tap Cap points toward the camera. Orient the Pin/Tap Cap assembly approximately 30 degrees toward the midline of the patient and then angle it 30 degrees toward the foot of the patient.

Use an impactor to drive the pin into the bone until the Tap Cap contacts the top of the Cannula **(Figure 32b)**. Remove the Tap Cap from the pin and attach the Percutaneous Reference Frame to the pin **(Figure 32c)**.

Alternatively, the Spinous Process Clamp with the Small Passive Reference Frame can also be used. The clamp should be firmly attached to the spinous process inferior to the planned instrumented levels. With the camera positioned at the patient's feet, the clamp should be within an unobstructed view of the camera and the instruments.

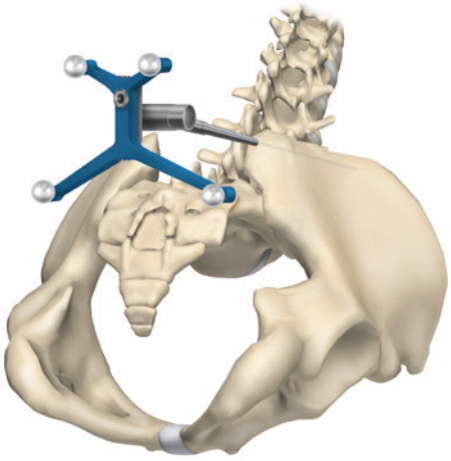


Figure 32a

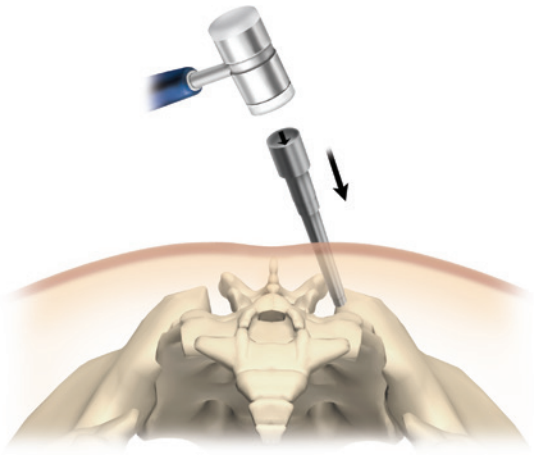


Figure 32b

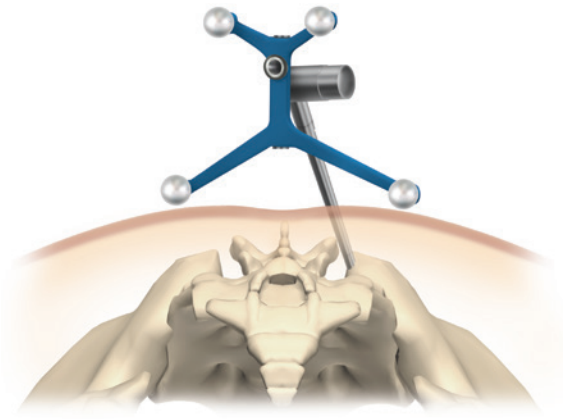


Figure 32c

Helpful Hint
To keep the frame close to the patient and out of the way of surgical instruments, use the 100mm Percutaneous Reference Pin, if possible.

Important
Ensure the Reference Frame is properly secured to the anatomy. Neglecting to verify that the Reference Frame is secured could result in navigational inaccuracy if the hardware moves in relation to the anatomy after registration is complete.

IMAGE ACQUISITION

At any time when fluoroscopy is used (2D or 3D acquisition) all personnel who are not wearing protective lead apparel should stand at least 15 feet (457.2cm) from the O-arm System with a certified moveable lead shield between themselves and the O-arm System to avoid unnecessary radiation exposure (**Figure 4**).

Establish the surgery site using 2D fluoroscopy scout images as needed. On the control panel, select the patient size, anatomy, and orientation. With the patient isocenter, position the O-arm System gantry to perform a 3D spin. Following the 3D spin, the images are transferred automatically to the StealthStation System. Should 2D images or a second 3D spin be desired, four preset O-arm System gantry positions may be set up and saved. Once the images are transferred, the O-arm System can be moved out of the way and into the park position.

O-arm System Isodose Curve

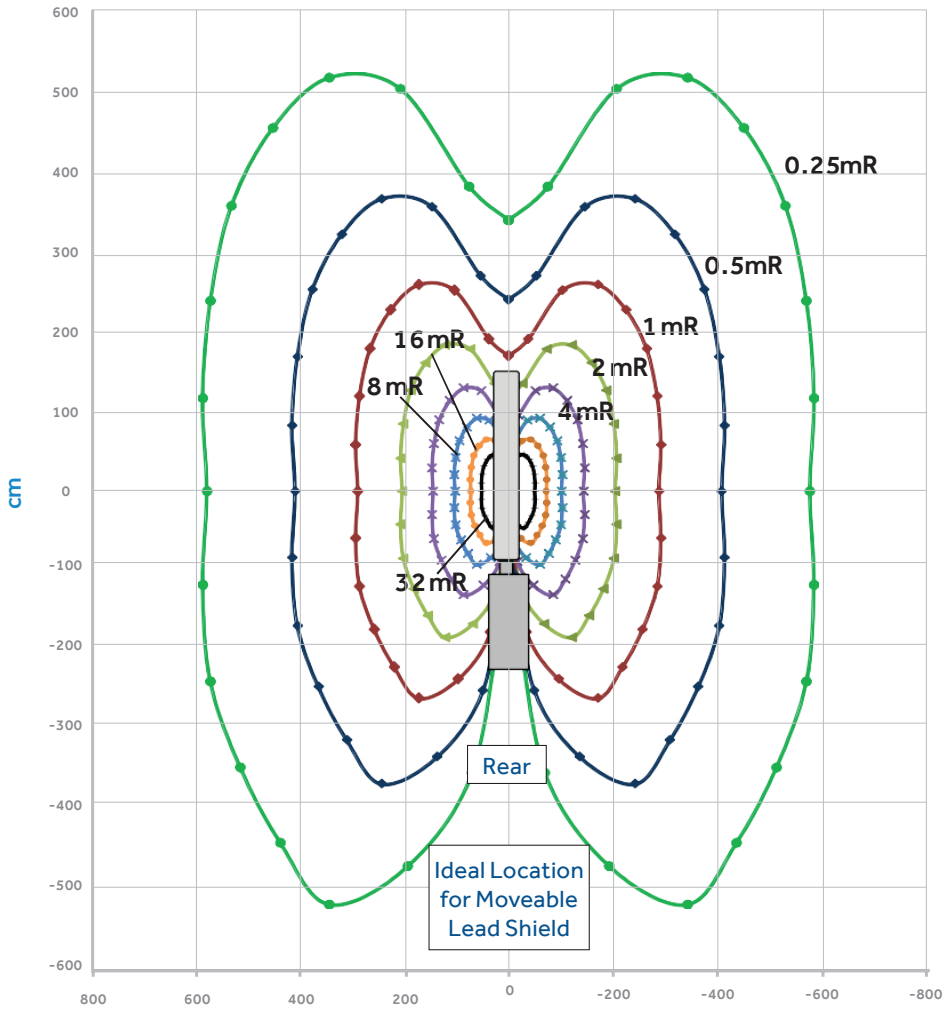


Figure 4

Scatter plot showing the shape of isodose curves for the maximum technique factors for the O-arm 02 Imaging System. Please refer to the end of this surgical technique for more information on the shape of isodose curves for the O-arm 1000.

- Protocol: Abdomen Standard Large
- Technique: 120 kVp, 330 mAs

PROCEDURAL STEPS OVERVIEW
USING EXTENDED TAB MULTI-AXIAL SCREWS

VERIFY INSTRUMENTS

- Navigated Probe
- Navigated Driver

PLACE REFERENCE FRAME

- Percutaneous Reference Pin with Percutaneous Reference Frame

– OR –

- Spinous Process Clamp with Small Passive Reference Frame

ACQUIRE 3D IMAGE

- Drape patient, bring O-arm System in field, and remove after image acquisition

– OR –

- Drape O-arm System, bring in and leave in field after image acquisition

TAP/PLACE SCREWS ON CONTRALATERAL SIDE

- Tap and use reverse projection to determine screw length and diameter
- Save projection to mark entry point
- Place screw on contralateral side only
- Repeat for other levels (contralateral side only)

TAP ON IPSILATERAL SIDE

- Tap and use reverse projection to determine screw length and diameter
- Save projection to mark entry point
- Repeat steps for other levels (ipsilateral side)

DECOMPRESS/ DISCECTOMY

- Decompress after tapping so anatomy is maintained

PLACE IPSILATERAL SCREWS

- Place screws in previously drilled and tapped holes using previously saved projection
- Repeat steps for other levels (ipsilateral side)

ROD AND SET SCREW PLACEMENT

- Place rods and set screws on the contralateral side

ACQUIRE 3D CONFIRMATION IMAGE

- Assess implant placement

PROCEDURAL STEPS OVERVIEW
USING EXTENDED TAB ATS MULTI-AXIAL SCREWS

VERIFY INSTRUMENTS

- Navigated Probe
- Navigated Driver

PLACE REFERENCE FRAME

- Percutaneous Reference Pin with Percutaneous Reference Frame

– OR –

- Spinous Process Clamp with Small Passive Reference Frame

ACQUIRE 3D IMAGE

- Drape patient, bring O-arm System in field, and remove after image acquisition

– OR –

- Drape O-arm System, bring in and leave in field after image acquisition

PEDICLE PREPARATION

- Determine entry points
- Mark skin
- Make skin incisions
- Visualize the pedicle
- Determine screw size by both pre-op measurements and intra-op evaluations with Navigated Probe

PLACE SCREWS

- Select the appropriate diameter and length ATS Implant. Attach the ATS Implant to the Navigated Multi-Axial Screw Driver. Slowly advance the ATS Implant down the pedicle to ensure proper tracking while allowing for viscoelastic expansion. Repeat for subsequent levels.

PLACE SCREWS ON CONTRALATERAL SIDE

- Use reverse projection to determine screw length and diameter
- Save projection to mark entry point
- Place screw
- Repeat for other levels

ROD AND SET SCREW PLACEMENT

- Place rods and set screws on the contralateral side

ACQUIRE 3D CONFIRMATION IMAGE

- Assess implant placement

PEDICLE ACCESS
PREPARATION

If using Cannulated Multi-Axial Screws, determine the trajectory for pedicle tapping and mark the skin bilaterally at each level to be instrumented. Use the Navigated Dilator/Dilator Tracker or the Navigated PAK Needle to identify the trajectory for tapping and mark the skin bilaterally directly over where the screws will be placed. Under the "Projection" tab of the MAST Dilator instruments on the StealthStation System, add a tip extension, such as 1mm × 100mm, to the tip of the instrument. The projection may be lengthened as needed to accommodate patient size **(Figures 34a and 34b)**.

Make the skin incision on the side contralateral to the planned TLIF **(Figure 34c)**. The ipsilateral incision is made in a subsequent step.

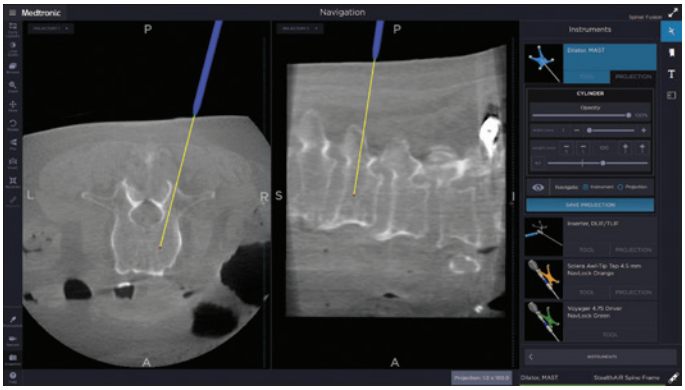


Figure 34a

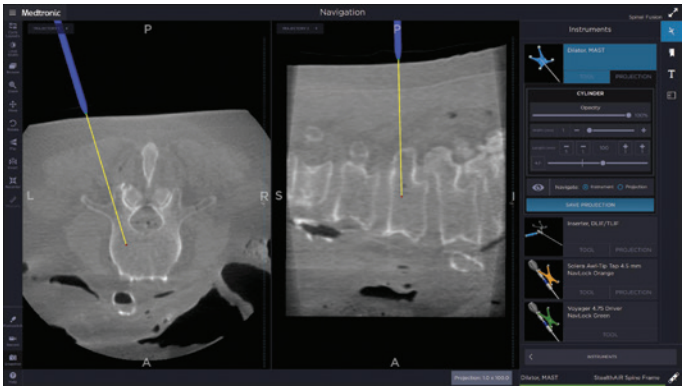


Figure 34b

OPTIONAL
STEP

On the StealthStation System, choose the "Tool" tab to select the appropriate Stealth-Midas tip to display the Stealth-Midas dissecting tool. Use the Stealth-Midas to drill at the desired trajectory. Choose the "Projection" tab on the StealthStation System to create a projection and select "Save Projection" to save your plan **(Figure 34d)**.

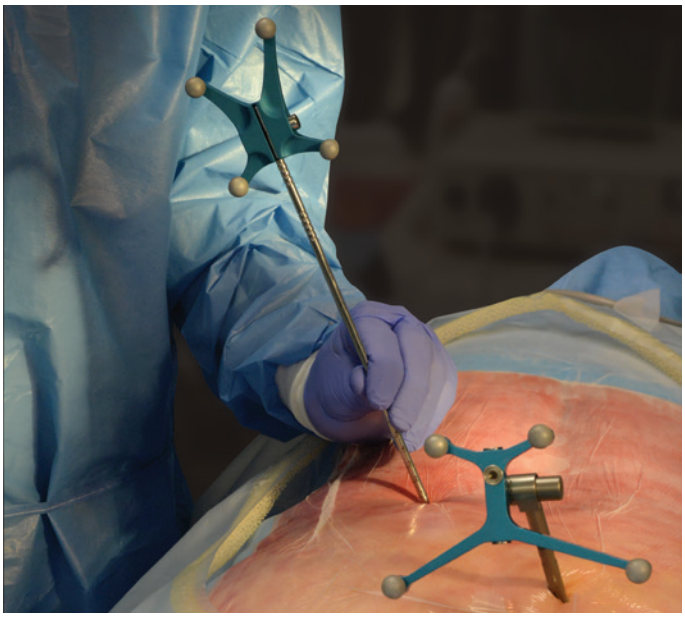


Figure 34c

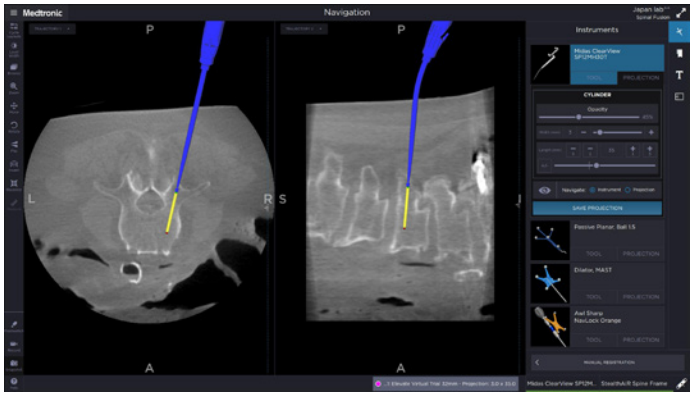


Figure 34d

Based upon the surgeon preference for the rod insertion method and number of levels instrumented, different incision techniques may be considered.

If using the percutaneous rod insertion method, make separate skin incisions over the intersection of the facet and the transverse process where each Screw will be inserted **(Figure 35a)**.

If using the Mini-Open Capped Rod Insertion Technique, create a paramedian incision (in plane with the junction of the lateral facet and the transverse process on the AP image) that extends from the most superior to the most inferior pedicle to be instrumented. It is important to open the spinal muscular fascia to permit passage of the Capped Rod down the incision and through the muscular plane. Once the pedicle has been identified, sweep the PAK Needle or another blunt instrument to the next pedicle. This step will create a pathway through the muscle plane and allow for easier access during rod insertion. With this method, all Screw Extenders to be connected via the Capped Rod will need to be contained within a single insertion.

Alternatively, a posterior midline incision technique can be used if an open method is preferred and direct visualization of the pedicles is required **(Figure 35b)**.

Figure 35a

Figure 35b

EXTENDER, CAP, AND **SCREW ASSEMBLY**

Before a Screw can be inserted in to the pedicle, the Tab Extenders and Cap **(Figure 36a)** must be assembled with either the Extended Tab Cannulated Multi-Axial Screws or the Extended Tab ATS Screws. To assemble the Screw Extenders, insert the Tab Extenders into either the Extended Tab Cannulated Multi-Axial Screw Head or the Extended Tab ATS Head until locked with an audible click and tactile feedback. With both Tab Extenders locked onto the Screw Head, insert the Cap into the forked tips of the Tab Extenders **(Figure 36b)**.

Note

To ensure Cap is locked onto Tab Extenders, listen for an audible click.

Figure 36a

Figure 36b

CONTRALATERAL PEDICLE PREPARATION **AND SCREW LENGTH MEASUREMENT**

If using Cannulated Extended Tab Multi-Axial Screws, assemble the Awl-Tip Tap with the Tissue Protector. Insert the Awl-Tip Tap. The Tissue Protector can be retained on the Tap by locking it in the first position **(Figure 37a)**.

Insert the assembly into the skin incision and verify the trajectory on the surgeon monitor **(Figure 37b)**. Advance the assembly until it contacts the bone. A virtual tip projection can be selected under the "Projection" button to provide additional guidance **(Figures 37c)**. Advance the Tap to its desired depth. Once the Tap has been advanced to the ideal depth, create a reverse projection under the "Projection" tab and then select "Save Projection" **(Figure 37d)**. This will save the trajectory to be used as a virtual guidewire which may be recalled during subsequent Screw placement. This projection also indicates the Screw length and diameter for subsequent Screw placement. Remove the Awl-Tip Tap and Tissue Protector for Screw placement. The Tissue Protector can be held down against the bone to cover the Tap threads and re-lock the Tissue Protector to the Tap during removal.

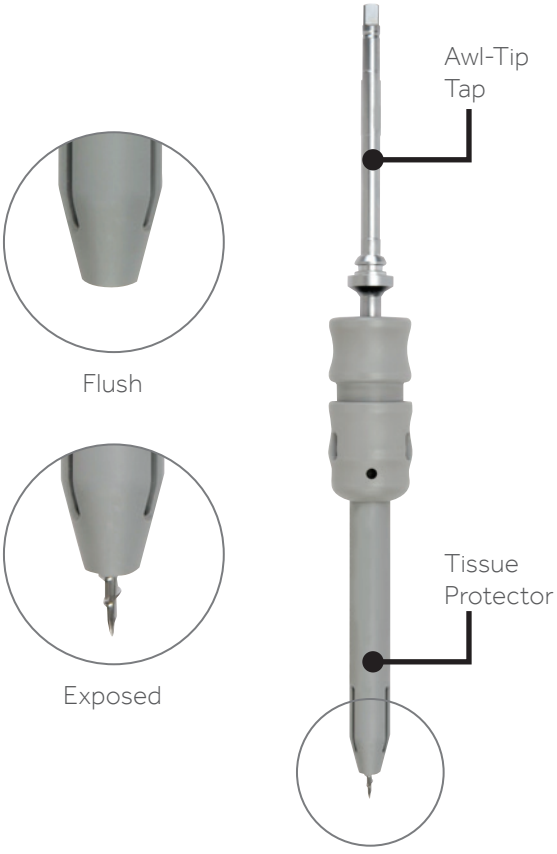


Figure 37a

Figure 37b

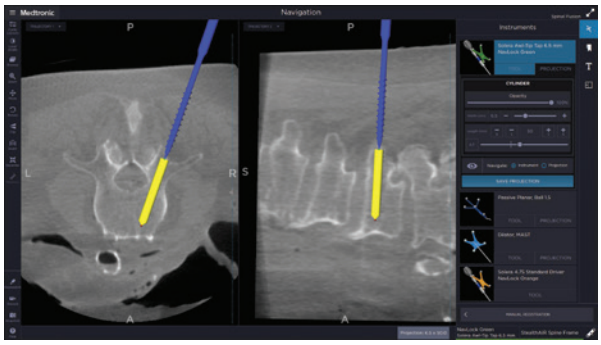


Figure 37c

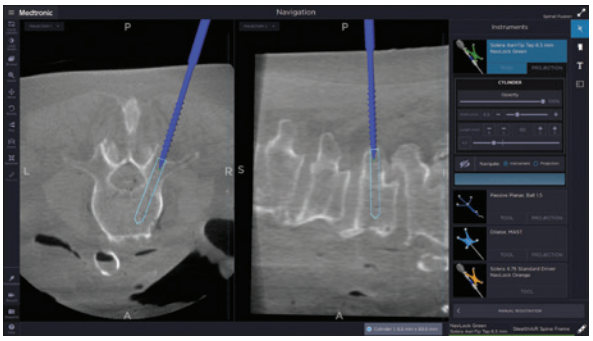


Figure 37d

CONTRALATERAL **SCREW INSERTION**

Screw insertion contralateral to the planned TLIF may be performed at this time. Thread the navigated driver into the head of the Screw. Remove the Tissue Protector, if still in place, and recall the virtual guidewire if saved during pedicle preparation **(Figure 38a)**. Under "Tool" select the appropriate Screw width and length. Align the Screw Extender and driver with the virtual guidewire and advance the Screw being careful that the Screw Assembly is not advanced too far **(Figure 38b)**. If the Screw Head is placed against the bone, it will lose its multi-axial capabilities and make it difficult to connect the Screw Assemblies during subsequent steps.

Place the remaining Screw Extender Assemblies for the contralateral side of the construct. After inserting the Assemblies, the Screw Extenders should be at approximately the same height outside the patient **(Figure 38c)**. The Assemblies should move freely following Screw insertion.

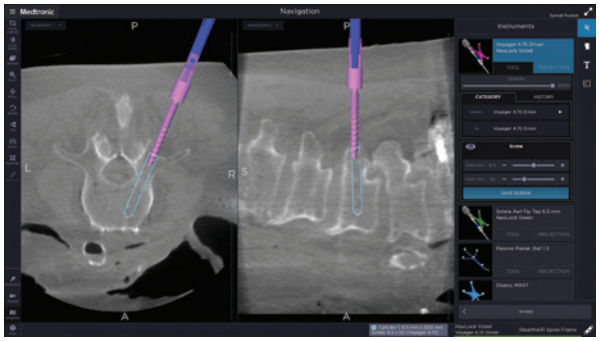


Figure 38a

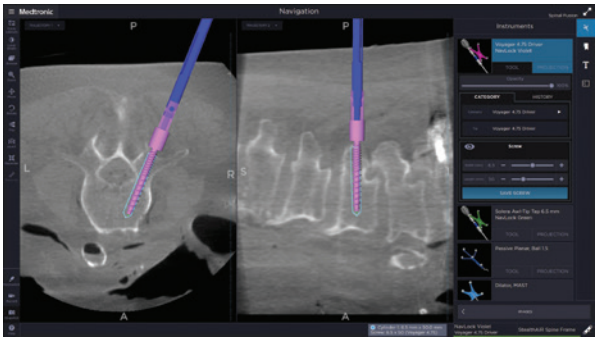


Figure 38b

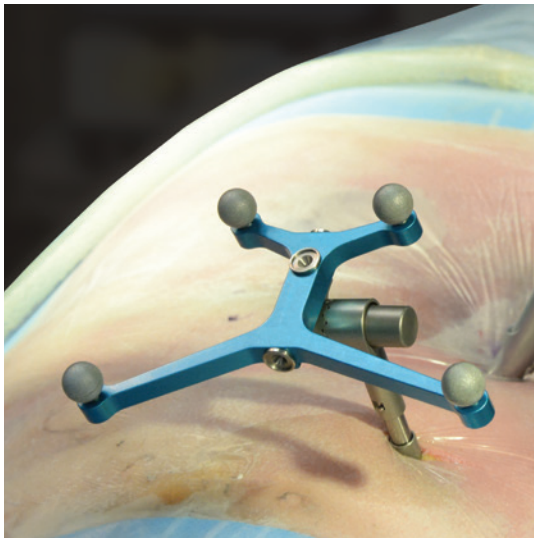


Figure 38c

IPSILATERAL
PEDICLE PREPARATION

Once the Screws are placed contralateral to the planned TLIF, pedicle preparation on the ipsilateral side should be performed as described in the Contralateral Pedicle Preparation section of this guide. Take into consideration the Screw placement and TLIF locations when making the incision for the TLIF, as one incision may be used for both procedural steps **(Figures 39a and 39b)**.

Figure 39a

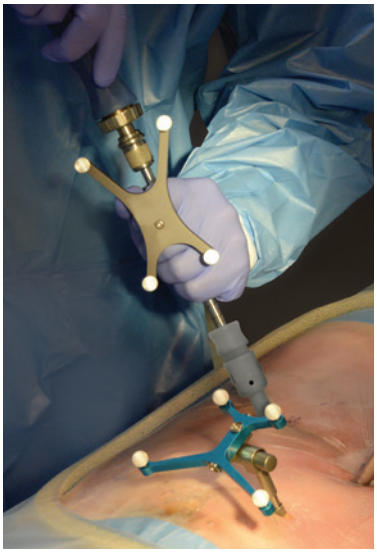


Figure 39b

Helpful Hint

After ipsilateral pedicle preparation is completed, a hemostatic agent may be placed into the prepared pedicles to prevent excess bleeding until subsequent Screw placement.

PLACEMENT OF IPSILATERAL **PEDICLE SCREWS**

Recall the virtual guidewire that was saved during the pedicle preparation on the ipsilateral side of the TLIF. It is important to note that the superior vertebral body may be slightly elevated from the original trajectory due to the interbody device placement. As an alternative method to using the original virtual guidewire, place the Passive Planar Ball-Tipped Probe or the NavLock straight thoracic pedicle probe tip into the previously prepared pedicle and save a reverse projection. Next, place the Screws following the previously described steps **(Figures 40a and 40b)**.

To save an image of the Screw in the software, leave the driver in the Screw following placement and choose the "Tool" tab; then choose "Save Screw".

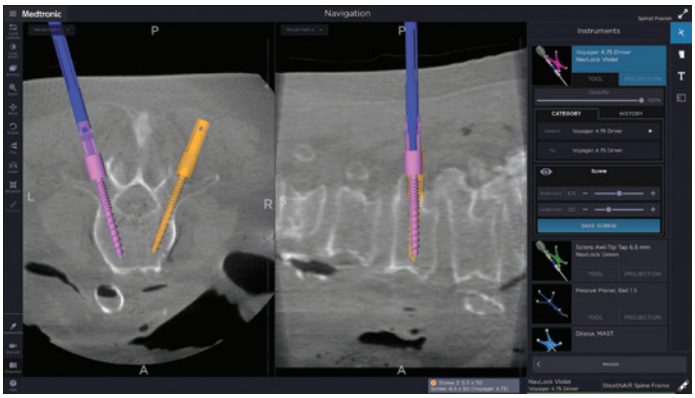


Figure 40a

Figure 40b

Helpful Hint

During Screw placement, be careful that the Screw Assembly is not advanced too far. If the Screw Head is placed against the bone, it will lose its multi-axial capabilities and could make it difficult to connect the Screw Assemblies during subsequent steps.

ATS AWL TAP MULT-AXIAL SCREW
IMPLANT PLACEMENT TECHNIQUE

The ATS Bone Screw has a tapered awl tip with cutting flutes which obviates the probing and tapping steps prior to Screw placement. It also eliminates the need for a Guidewire thru the use of the virtual guidewire available on the Stealth Station S8 Navigation System. Due to the sharp tip design, use of intraoperative imaging is recommended. The implant can be used with Stealth Station S8 Navigation System with O-arm integration and the navigation-compatible Powerease System. The ATS Bone Screw is compatible with triggered intraoperative EMG monitoring, such as the NIM-Eclipse Spinal System, which may be used to verify the trajectory within the pedicle. It may be helpful to prepare the pedicle by creating a cortical breach at the pedicle entry point as per the surgeon's standard technique (such as with an awl or burr) prior to placing the ATS implant.

When used with the Stealth Station S8 Navigation System with O-arm integration, the Screw size is measured intraoperatively. Assess the pedicle per the surgeon's common technique. Use the measurements on the navigated probe to verify the Screw length as well as the trajectory. The tip of the Screw should be 1cm short of the anterior cortical wall of the vertebral body. Thread the navigated driver into the head of the Screw thru the Extender Assembly. Dock the implant in the bone **(Figures 41a and 41b)**. Slowly advance the ATS implant down the pedicle to ensure proper tracking while allowing for viscoelastic expansion. If using the Powerease System for Screw placement, please refer to the Powerease System user manual. Repeat the steps on all levels.

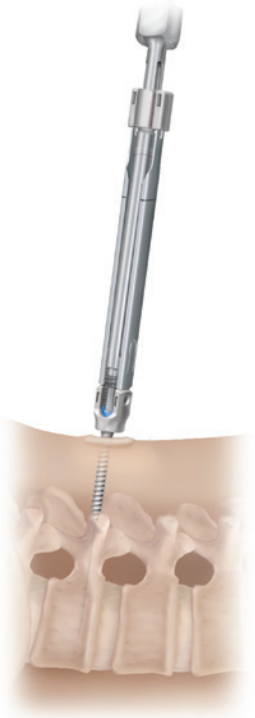


Figure 41a

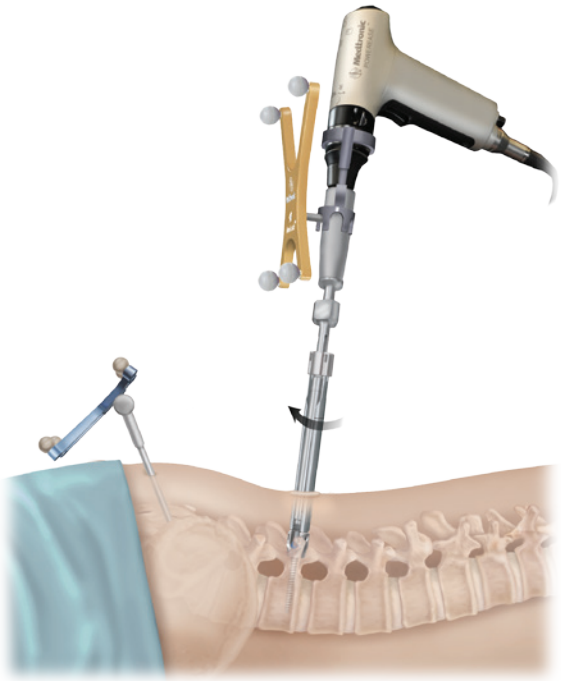


Figure 41b

Note

If particularly hard bone is encountered (for example dense, sclerotic bone), it might be helpful to prepare the pedicle by creating a cortical breach at the pedicle entry point as per the surgeon's standard technique prior to placing ATS implant.

CONFIRMATION
IMAGE ACQUISITION

The Reference Frame should be left in place during the confirmation image acquisition to ensure that navigation can still be performed if any changes are required.

With the patient isocenter, position the O-arm System to perform a 3D image acquisition **(Figure 42a)**.
During the acquisition process all personnel who are not wearing protective lead apparel should stand at least 15 feet from the O-arm System with a certified moveable lead shield between themselves and the O-arm System to avoid unnecessary radiation exposure. Perform the image acquisition to confirm screws, rods, and interbody placement **(Figure 42b)**. Following confirmation, the Reference Frame should be removed.

Final 3D O-arm images may be obtained prior to final screw tab break-off to permit easier screw repositioning if needed.

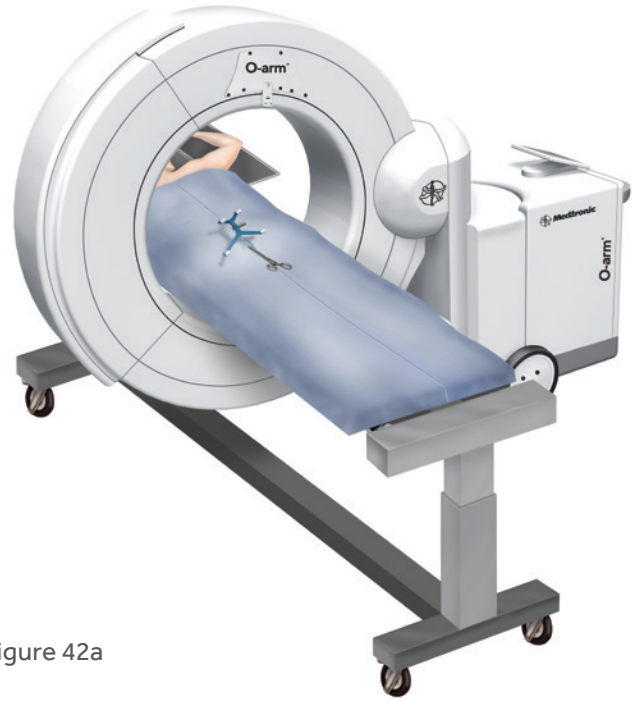


Figure 42a

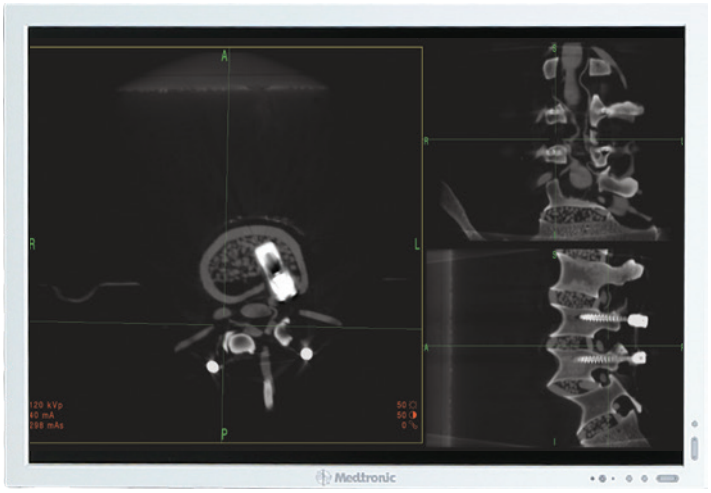


Figure 42b

ROD **PLACEMENT**

MEASURING THE ROD

To determine the appropriate Rod length, place the Rod Template into the cephalad and caudal Screw Extenders. The Rod Template Scale reads the minimum Rod length required **(Figure 43)**.

Note
The Rod Template should be fully seated in the Screw Extender Assemblies to obtain an accurate reading. Make sure that the top of the Extender Cap is aligned with the ledge on the Rod Template.

Figure 43

EXTENDERS ALIGNMENT

Begin the Rod insertion step by rotating the Tab Extenders, as needed, until the Rod slots are aligned for Rod passage **(Figure 44)**.

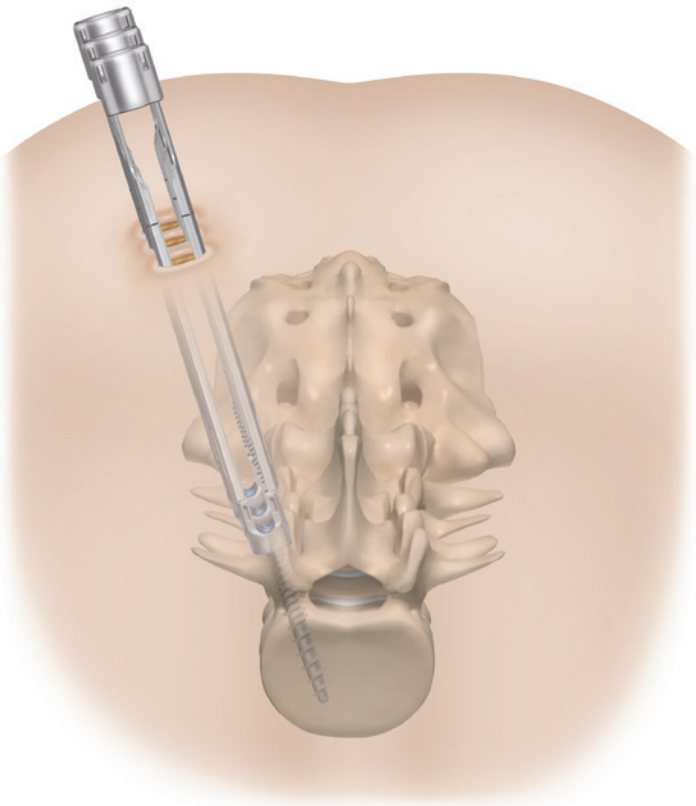


Figure 44

ROD INSERTION:
PERCUTANEOUS TECHNIQUE

To attach the Rod to the Percutaneous Rod Inserter, press the button behind the clasp to open the secondary lock stage **(Figure 45a)**. Next, lift the clasp further to open the primary lock stage **(Figure 45b)**. Insert the appropriate length Rod with the Medtronic part number on the Rod facing right. Press the clasp closed until it clicks to lock the Rod in the Inserter.

If needed, use the Rod Bender to bend the Rod according to patient anatomy **(Figure 45c)**. Do not bend the Rod prior to placing it in the Percutaneous Rod Inserter.
To estimate any bend for the Rod, place the Percutaneous Rod Inserter lateral to the patient and take a lateral fluoroscopy. Next, compare the bend in the Rod-to-Screw trajectory and alter as needed.

Note
Capped Rods cannot be used for this Rod insertion method.

Note
When the clasp is open, a T25 Driver may be used to adjust the tension of the Inserter's locking mechanism, if needed.

Note
Do not adjust the tension while clamping a rod.

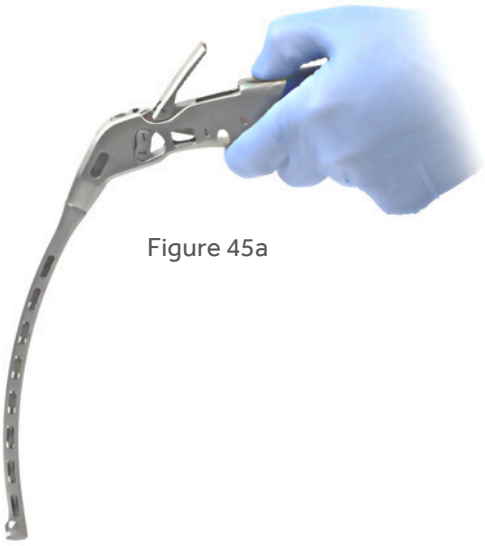


Figure 45a

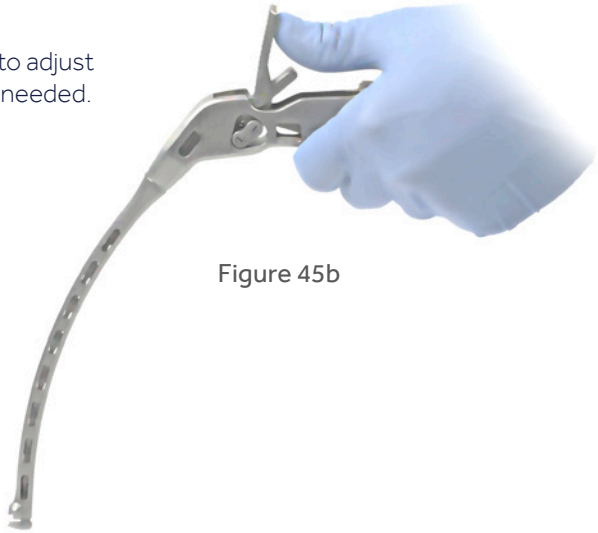


Figure 45b

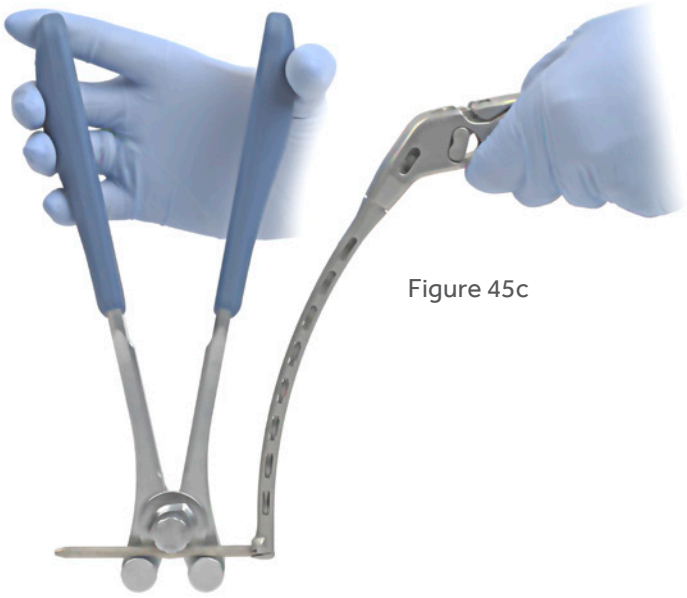


Figure 45c

Rod Passage Through First Extender — Cephalad to Caudal

With the Rod securely attached to the Percutaneous Rod Inserter, pass the Rod through the same incision as the most cephalad Extender. The Rod will enter through the Extender Rod Channel by inserting the Rod at an angle inclined relative to the Extender **(Figure 46)**. Use AP and lateral fluoroscopy as necessary in combination with tactile and visual feedback to find the path through the remaining Extenders.

Important
It is very important to pass the Rod cephalad to caudal to allow laminar shingling to serve as an additional safety measure for protecting the spinal canal.

Note
If needed, appropriately extend the incision to ensure that the Rod can be completely seated.

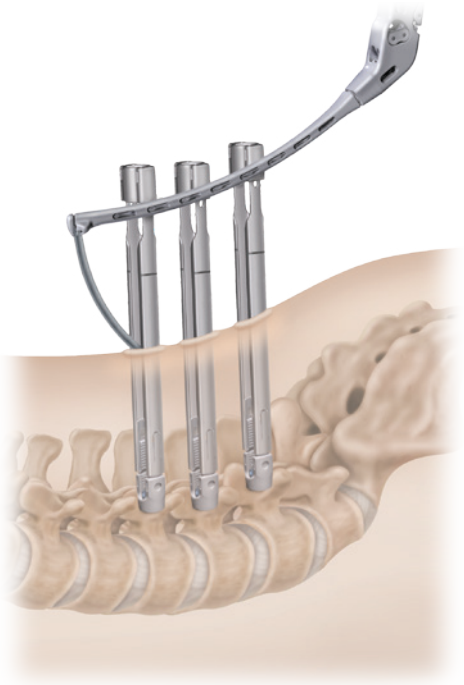


Figure 46

Rod Passage

After the Rod is through the first Extender, guide it via the steering handle of the Rod Inserter through the remaining Extenders using tactile feel, and AP and lateral fluoroscopy, as necessary. The Rod Inserter is designed so it cannot pass through the first Extender. The Rod Inserter Tip should be inserted until it is against the cephalad Screw Extender **(Figure 47a)**. A sliver of Rod should be visible from the most caudal Screw of the construct on fluoroscopy **(Figure 47b)**.

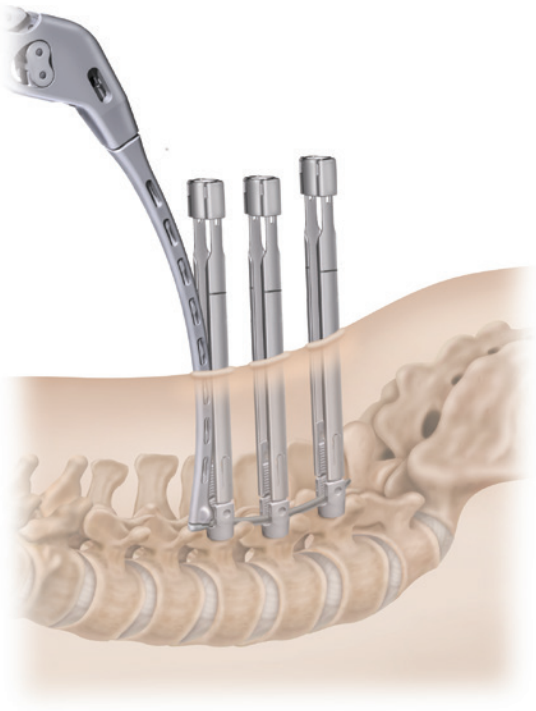


Figure 47a

Note
During Rod passage, the Rod should be below the fascia at all levels. The lordosis in the Rod may allow the Rod to sit proud above the fascia distally, and if this is not recognized the Rod may not reduce into the Screw.

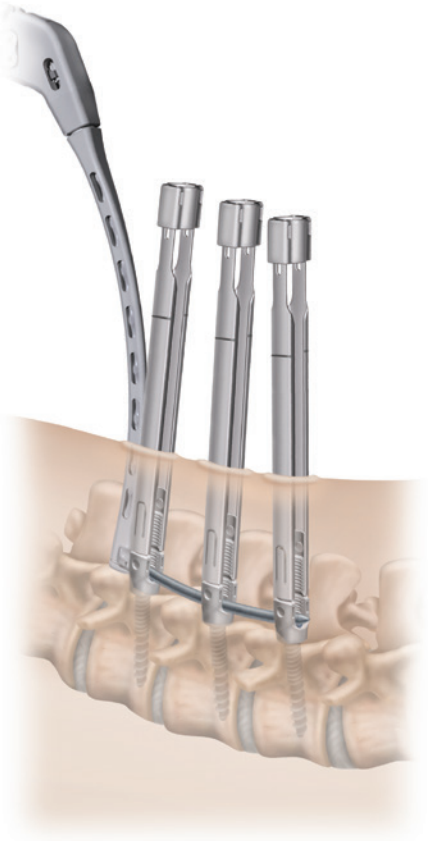


Figure 47b

Rod Verification

Once the Rod is passed through the Rod Channels of the Extenders, additional methods may be used to verify Rod passage such as rotating each of the Extenders by hand. If the Extenders rotate freely, then the Rod has not passed through the Extenders.

The Ball-Ended Driver or the Non-Retaining Driver may also be used to confirm Rod passage by placing the Driver into each Extender. The Rod has passed correctly into the Screw Head if the laser marked line on the Driver is visible above the Extender Cap **(Figure 48)**.

With the Rod confirmed through all of the Extenders, lateral fluoroscopy may be used to ensure there is Rod overhang from the most cephalad and caudal Extenders **(Figure 49)**.

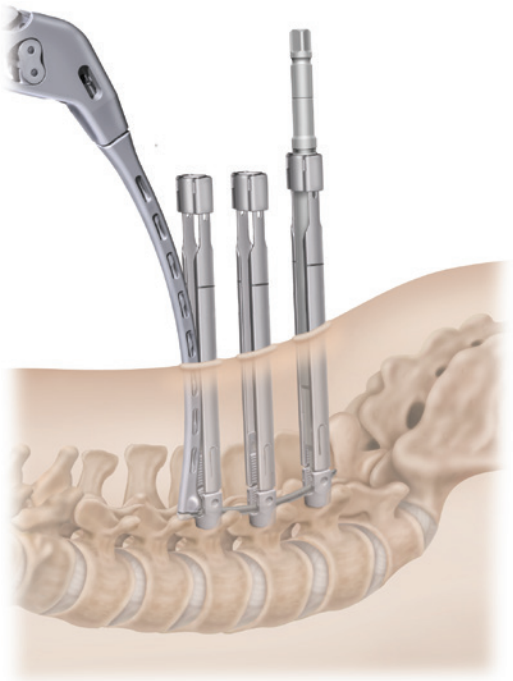


Figure 48

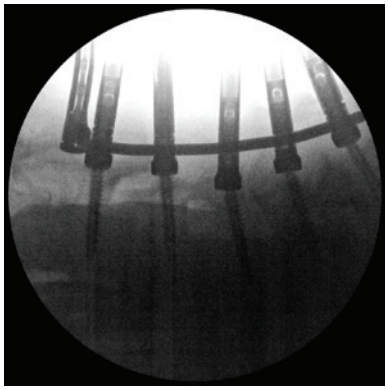


Figure 49

ROD INSERTION:
MINI-OPEN TECHNIQUE

If the Mini-Open Rod Insertion Technique is chosen, the fascia between the Screw Extenders must be incised if it has not already been done. Start by dissecting the soft tissue and muscle between the Screw Extender Assemblies to create a channel for the placement of the Rod. With this insertion method, it is recommended that the Capped Rod be used.

Press the button behind the clasp to open the secondary lock stage. Next, lift the clasp further to open the primary lock stage **(Figure 50a)**. Load the appropriate size Rod as determined by the Rod Template into the Rod Gripper. Press the clasp closed until it clicks to lock the Rod in the Rod Gripper **(Figure 50b)**.

Note
Pull on the Rod to ensure the Rod is securely attached to the Rod Gripper.

Note
For single-level constructs, place the Rod Gripper in the middle of the Rod. For multi-level constructs, place the Rod Gripper near the caudal end leaving about 15–20mm of Rod visible.

Note
When the clasp is open, a T25 Driver may be used to adjust the tension of the Inserter's locking mechanism, if needed.

Figure 50a

Figure 50b

Pass the Rod into the openings on the top of the Tab Extenders **(Figure 51a)**. Align Rod so the End Caps of the Rod extend to both sides of the Tab Extenders **(Figure 51b)**. Push Rod down to fully seat in the Screw Heads **(Figure 51c)**. Rod confirmation can be made using fluoroscopy **(Figure 52)**.

Helpful Hint

Measure segmental lordosis either at the operative level to confirm maintenance or restoration relative to baseline measurements manually or by leveraging a mobile-device based measurement application.

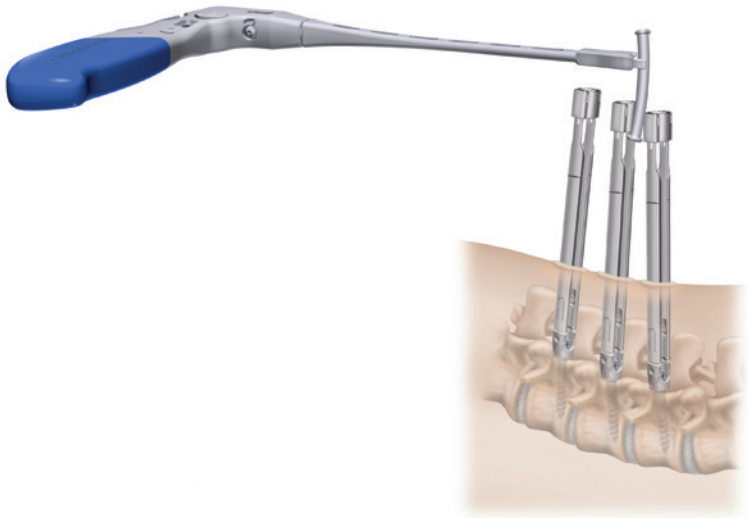


Figure 51a

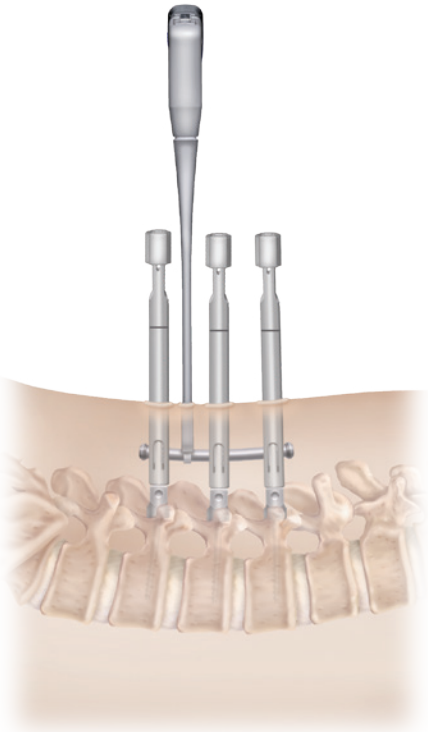


Figure 51b

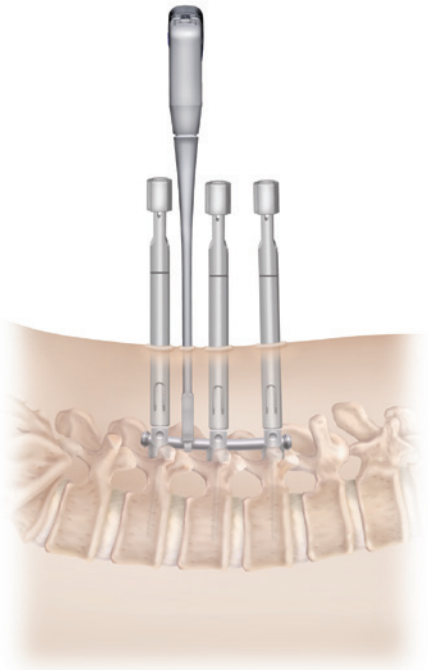


Figure 51c

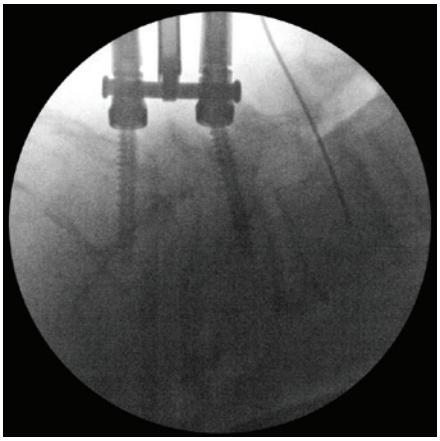


Figure 52

OPTIONAL ROD REDUCTION

If needed the Rod Reducers **(Figure 53)** may be used to sequentially reduce the Rod into the Screw Heads. Make sure the marked line in the window lines up with LD by unscrewing the top portion of the Rod Reducer. Remove the Cap from the Extender and slide the Reducer over the Extenders. The Extender Tabs should be visible in the lower window on the Rod Reducer **(Figure 54a)**.

Once the Rod Reducers are in position, sequentially tighten them until the the marked line in the window lines up with RD. The Nut Driver and Quick Connect Ratcheting Egg Handle may be attached to the top of the Rod Reducer to more easily reduce the Rod. RD indicates that the Rod is fully reduced into the Screw Head **(Figure 54b)**.

Note
The line visible in the window during reduction indicates how close the Rod is to being fully reduced.

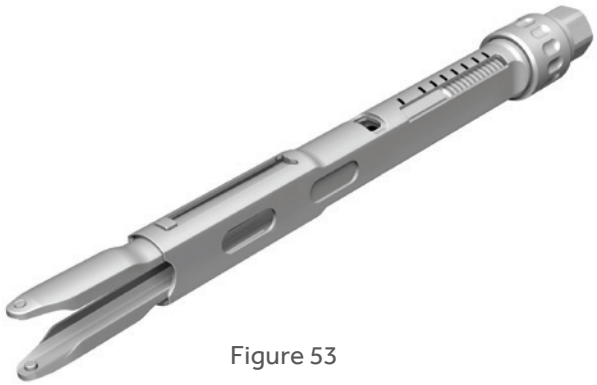


Figure 53

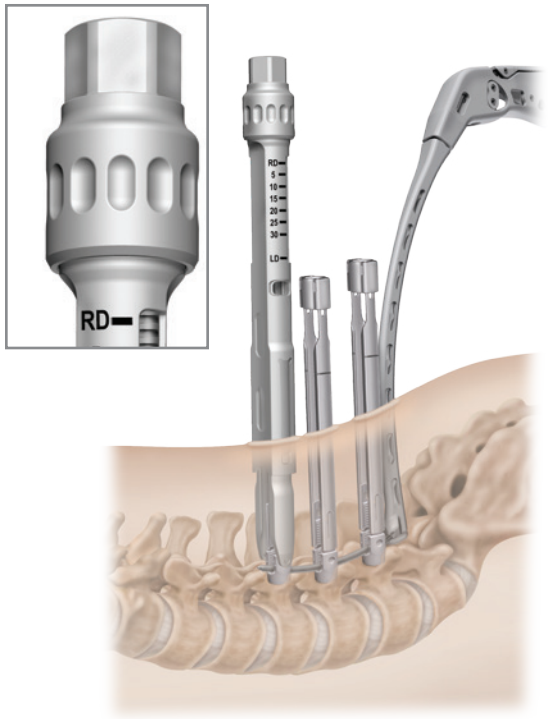


Figure 54a

Figure 54b

INITIAL SET SCREW INSERTION

After verifying that the Rod is seated in all the Screws, the Set Screws can be inserted with the Set Screw Retaining Driver. Begin by loading the Set Screw on the tip of the Set Screw Retaining Driver. Push the button of the Set Screw Retaining Driver Handle **(Figure 55)**. While pushing the button, insert the Set Screw on the distal tip of the Set Screw Retaining Driver **(Figure 56)**. Release the button and tug on the Set Screw to ensure a secure connection.

Note
The button on the Set Screw Retaining Driver Handle should be proud once the Set Screw is loaded.

Figure 55

Figure 56

Provisionally tighten the Set Screws by inserting the Set Screw Assembly down the Tab Extenders **(Figure 57)**. If the black line on the Set Screw Retaining Driver is visible, the Rod is not fully seated **(Figure 58)**.

Provisionally tighten all Set Screws to secure the Rod.

Figure 57

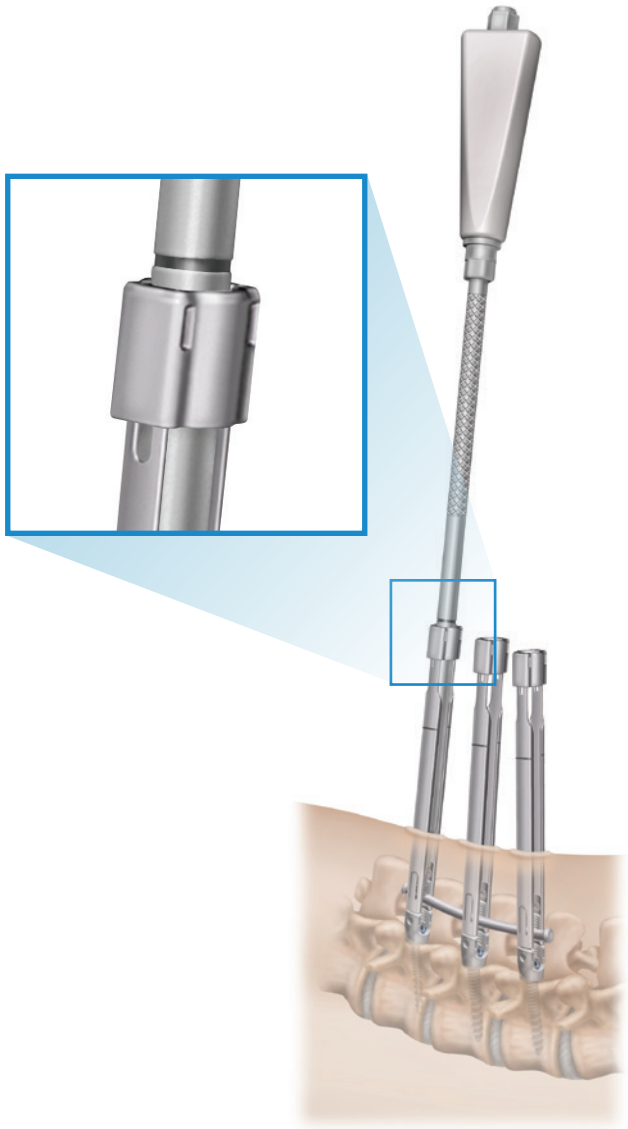


Figure 58

ADDITIONAL COMPRESSION OR DISTRACTION OPTIONS

The CD Horizon Solera Voyager 5.5/6.0mm System offers multiple compression and distraction options.

Compression/Distraction with the Fulcrum

The first option for compression and distraction is the Fulcrum Method. To use the Fulcrum Method, first remove the Caps from the Screw Assembly. Next, place the Reinforcement Sleeve over the Extender, taking care to ensure that the Reinforcement Sleeve is fully seated on the Extenders **(Figure 59)**. The extender tips will be visible in the windows. Lock the Reinforcement Sleeve into place by placing downward pressure on the top of the Reinforcement Sleeve. When the Reinforcement Sleeve locks, there is an audible click. To ensure that the Reinforcement Sleeve is locked gently pull up on the middle of the Reinforcement Sleeve. Repeat the placement of the Reinforcement Sleeve on the second Screw Assembly.

After placing the Reinforcement Sleeves, place the Fulcrum on top of the Reinforcement Sleeves. The Fulcrum must be placed past the locking cap of the Reinforcement Sleeve and above the flat portion of the Reinforcement Sleeve **(Figure 60)**. Loosen the Set Screws on the Screw Assemblies you wish to be mobile. To adjust the Fulcrum, unscrew the back thumbscrew and slide the rack body so that it will slide over the Screw Extenders with the Reinforcement Sleeves. Lock the Fulcrum in place by tightening the back thumbscrew. To distract, position the Fulcrum Pliers above the Fulcrum. To compress, position the Fulcrum Pliers below the Fulcrum. Once the Fulcrum Pliers are positioned, squeeze the pliers to compress or distract **(Figure 61)**. Once the surgeon has compressed or distracted the desired amount, insert and provisionally re-tighten the Set Screws to hold the achieved correction. Remove the Fulcrum and the Reinforcement Sleeves.

Note
When the cap is removed the screw extender tabs are vulnerable to tab break off; minimal medial-lateral forces should be placed on the tab extenders prior to attaching the reinforcement sleeve.

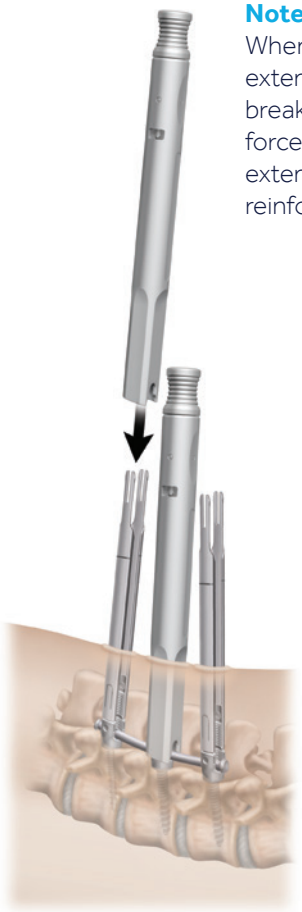


Figure 59

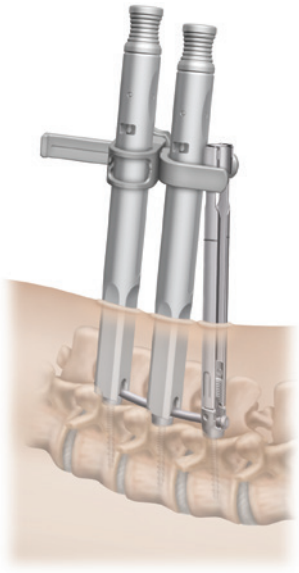


Figure 60

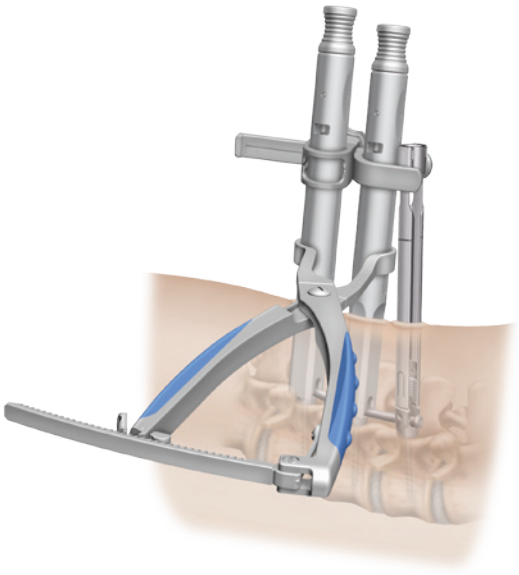


Figure 61

Compression with the Pliers

The second option for achieving compression is to use the Pliers Compressor. The Caps do not have to be removed to use the Pliers Compressor. Slide the compressor instrument along the outside of the Extenders and down to the Rod of the Screws to be compressed **(Figure 62)**. Loosen the Set Screws on the Screw Assemblies you wish to be mobile. Perform the compression and then tighten the Set Screws to maintain the compression **(Figure 63)**.

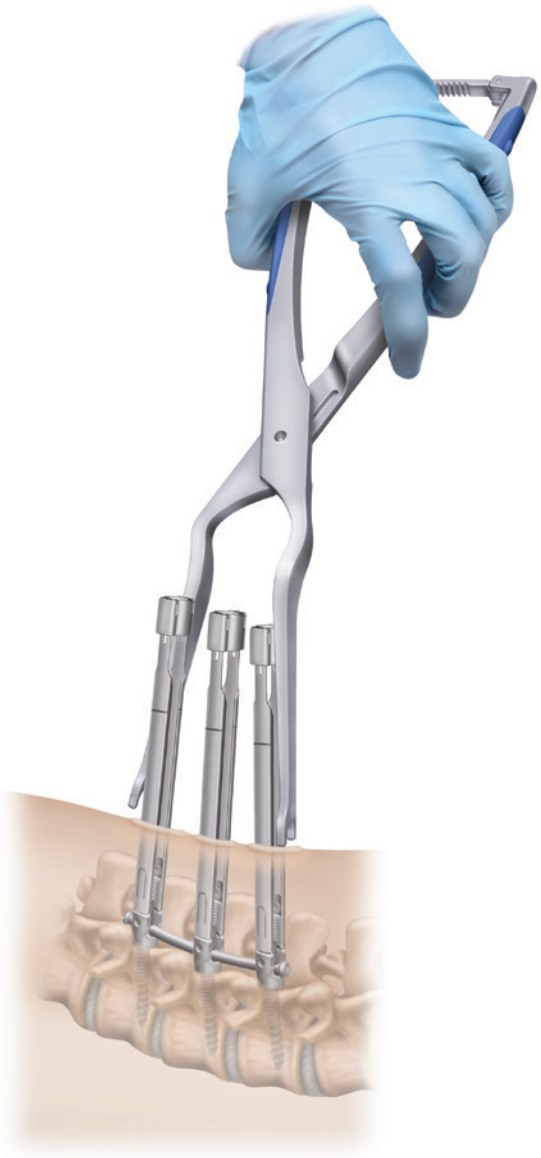


Figure 62

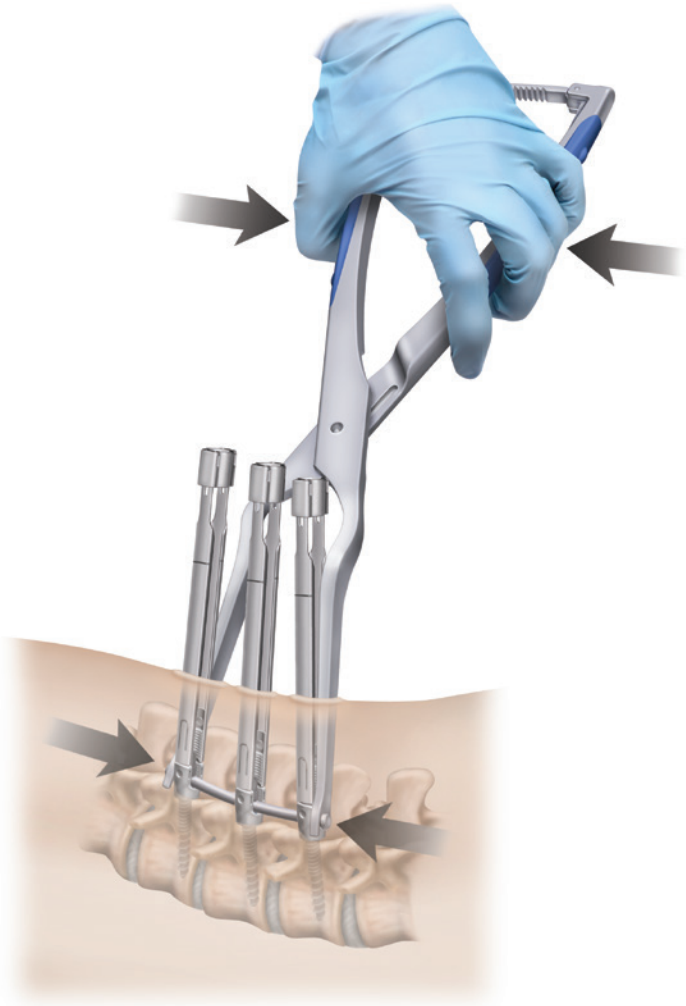


Figure 63

Compression/Distraction with the Rack

The third option for compression and distraction is the Rack Compressor/Distractor. It is only available in the long rod instrument set. To use the Rack Compressor/Distractor, place the Reinforcement Sleeves on the Screw Assembly as previously described. Next, place the Rack on the Reinforcement Sleeves taking care to ensure that it is positioned below the locking cap of the Reinforcement Sleeve **(Figure 64)**. Loosen the Set Screws on the Screw Assemblies you wish to be mobile. Twist the knob on the Rack to compress or distract. The Quick Connect Ratcheting Egg Handle may be attached to the end of the Rack for ease of use **(Figure 65)**. Once the surgeon has compressed or distracted the desired amount, provisionally re-tighten the Set Screws to hold the compression or distraction and then remove the Rack Compressor/Distractor and the Reinforcement Sleeves.

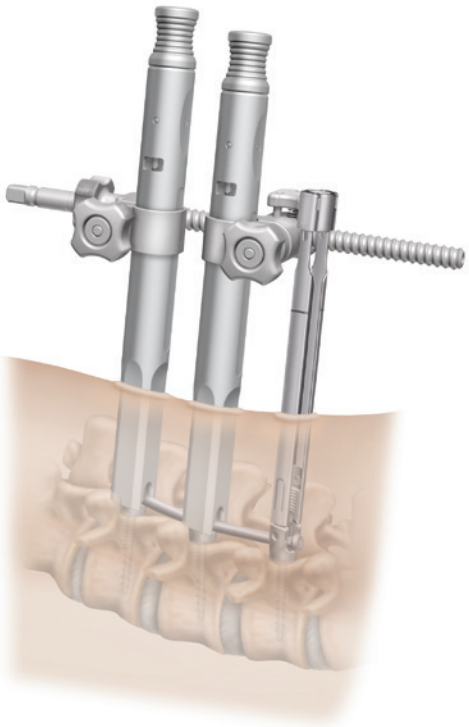


Figure 64

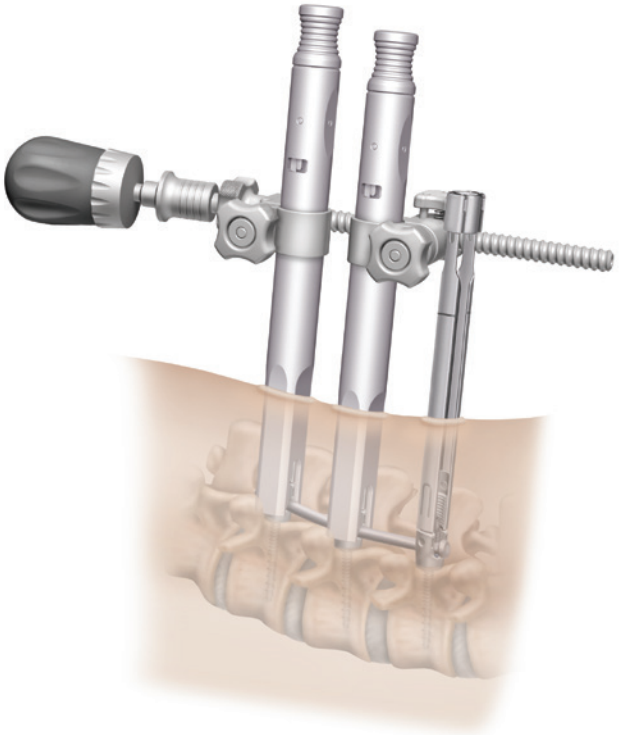


Figure 65

Compression/Distractor with the A/B Compressor Arms

Begin by loosening the Set Screw from the Screw in the vertebral body that needs to be adjusted.

To use the A/B Compressor/Distractor Arms remove the Caps from the Tab Extenders **(Figure 66)**. Compressor/Distractor Arms should be assembled with Tab Extenders one arm at a time and then locked together. Align Compressor/Distractor Arm A over the Tab Extender and slide down until contact is made with Rod **(Figure 67)**. If the black line on the Tab Extender is visible through the Compressor/Distractor Arm window, the Compressor/Distractor Arm is fully seated **(Figure 68)**. Next, align Compressor/Distractor Arm B over the Tab Extender and slide down until contact is made with the Rod. At this point the two arms should lock together.

To compress, squeeze the two arms together **(Figure 69)**. To distract, pull the two arms apart **(Figure 70)**.

Note
Compressor Arm A should always be placed first, with the noted opening facing the opposing Screw. (The Screw that Compressor Arm B will be placed on).

Note
The A/B Compressor is not in the set configuration and must be ordered separately.

Figure 66

Figure 67

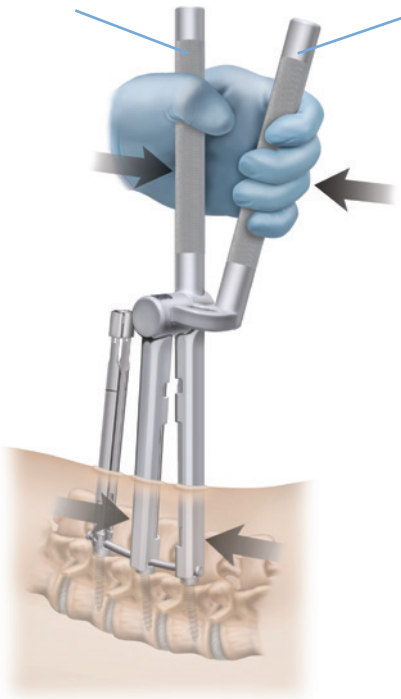


Figure 68

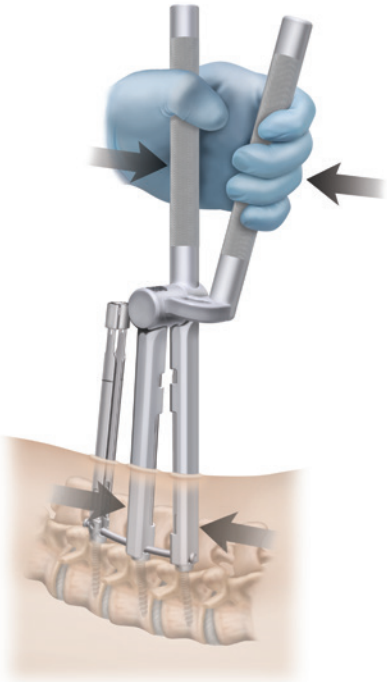


Figure 69

Figure 70

REMOVING ASSEMBLY

To break-off the Extender Tabs, slide the Tab Breaker over each of the Tab Extenders. Ensure that the button slides upward to engage the Extender. Apply downward pressure to the Tab Breaker while simultaneously moving it medial-to-lateral **(Figure 74)**. The tabs will break-off and be retained in the Tab Breaker along with the Extender. Flip the Tab Breaker and repeat on the second Extender.

Once the Tab Breaker is removed from the surgical site, remove the Tab Extender from the Tab Breaker by sliding the button down and the Extender will slide out.

To remove and dispose of the Break-Off Tab from the Tab Extender, use the Break-Off Removal Tool **(Figure 75)**.

Note
Once the break-off portion of the Screw is removed from the Tab Extender, "screw portion" must be discarded. Place Tab Extender back in loaner kit so that it can be used for future surgeries.

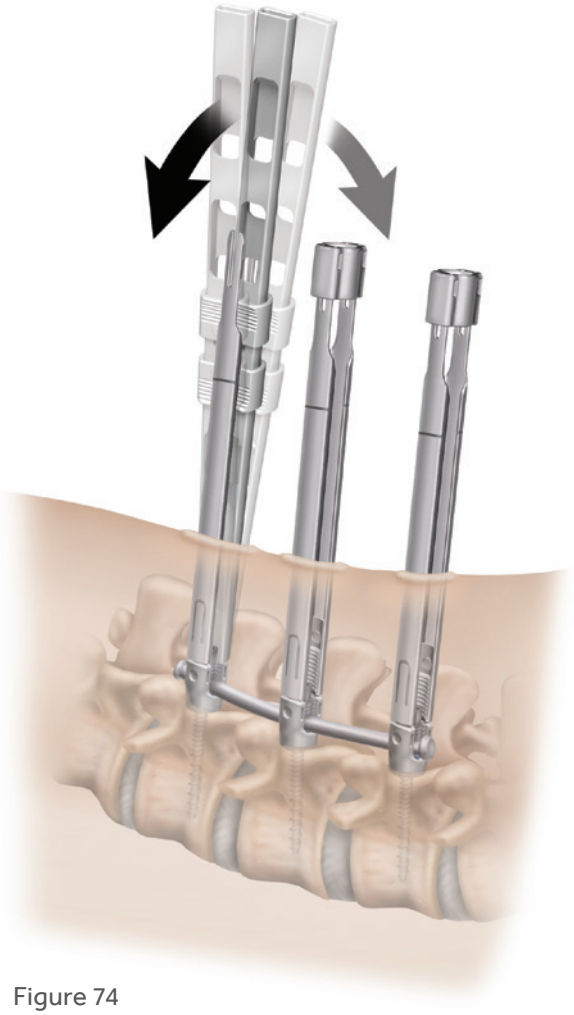


Figure 74

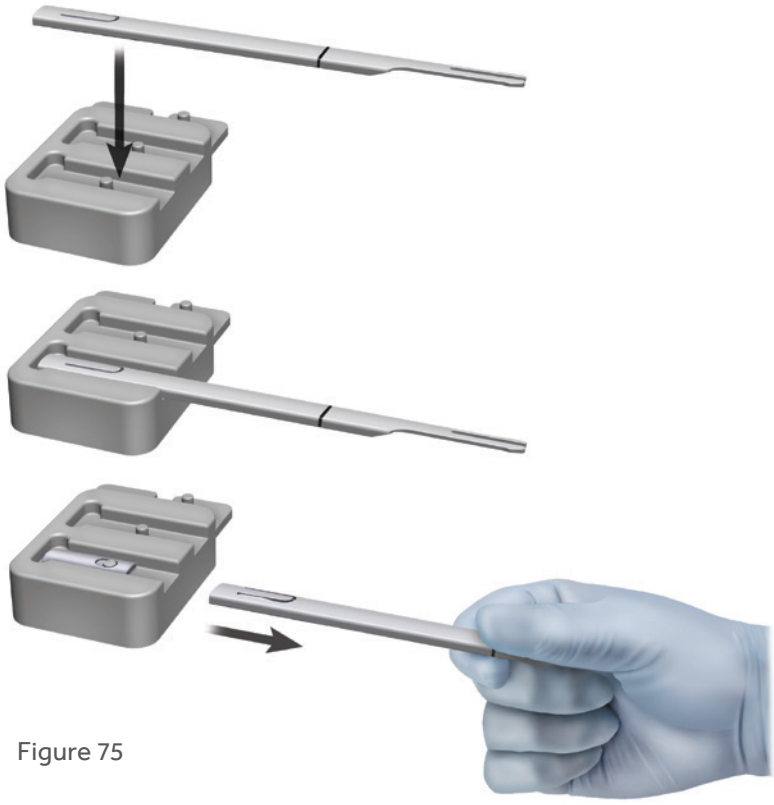


Figure 75

To remove the Tab Extenders from an unused Tab Extender Screw Assembly, use the side portion of the Break-Off Removal Tool **(Figure 76)**.

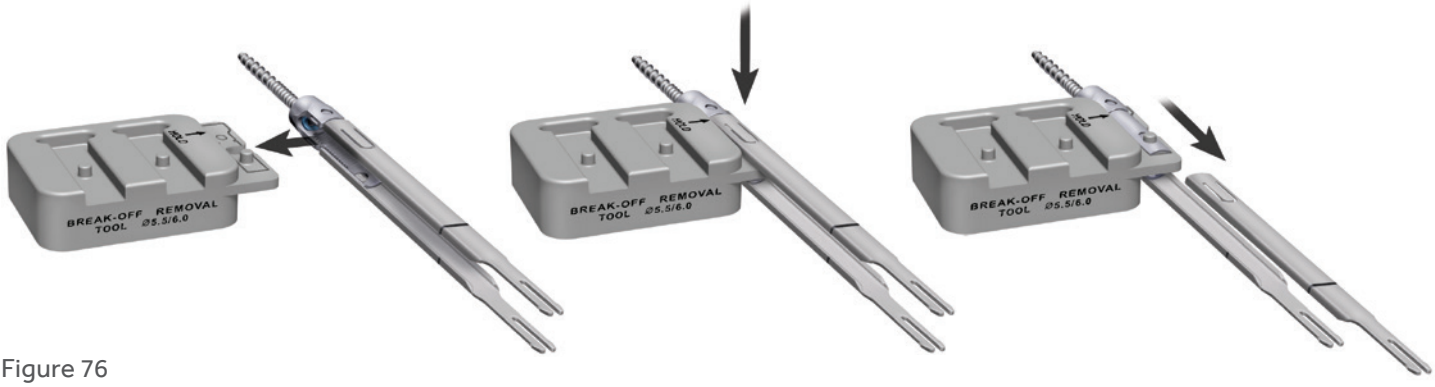


Figure 76

Note
The Tab Removal Tool may also be used to remove the break-off portion of the Set Screw if needed from the Set Screw Driver after final tightening. Place the break-off portion of the Set Screw in the slot as illustrated below and pull up on the Set Screw Driver while pressing on the top handle to release the break-off portion of the Set Screw **(Figure 77)**.

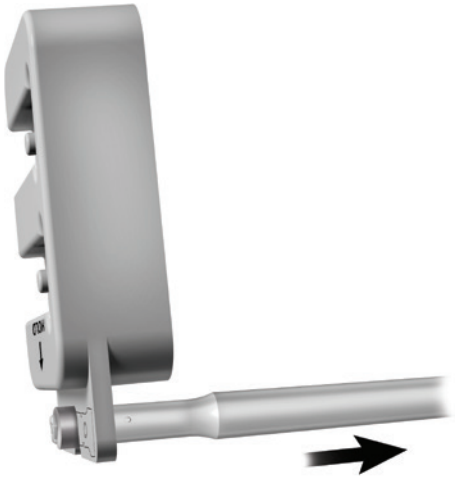


Figure 77

CLOSURE

The entire process is repeated on the contralateral side. Closure is accomplished with a few interrupted stitches in the fascia, a subcuticular skin structure, and Steri-Strips™ **(Figure 78)**.

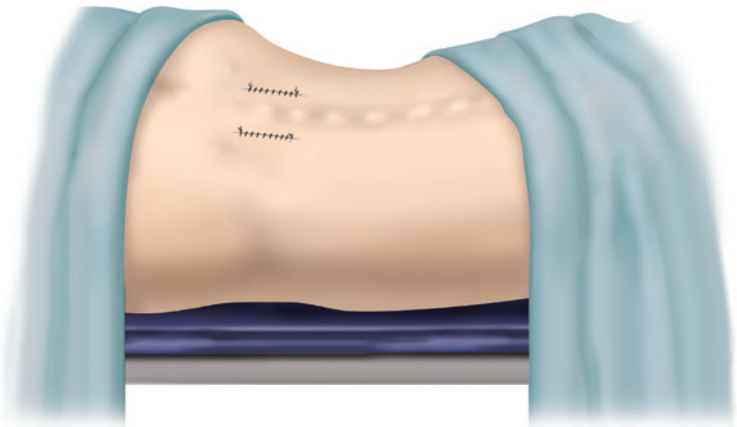


Figure 78

GRAFT PLACEMENT

Bone Graft must be used when implanting the construct **(Figures 79a, 79b, and 79c)**.

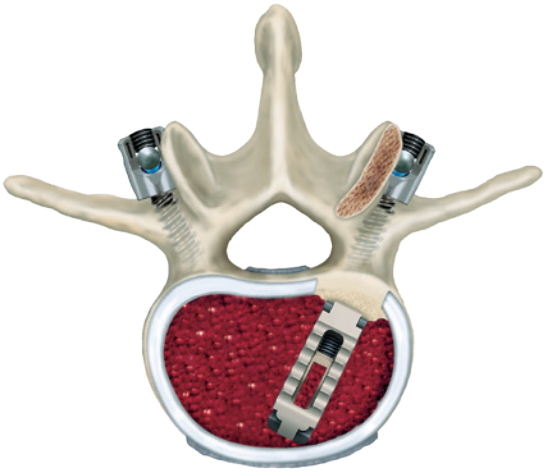


Figure 79a

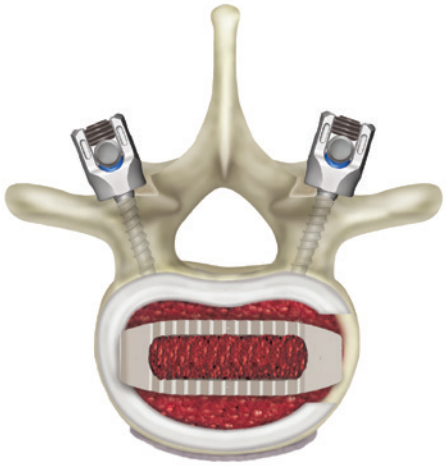


Figure 79b

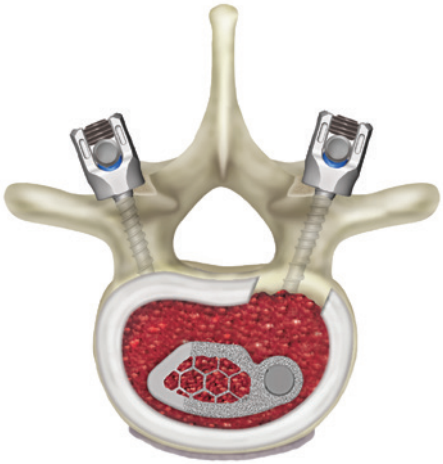


Figure 79c

EXPLANTATION

The CD Horizon Solera Voyager 5.5/6.0mm Cannulated Multi-Axial Screws, Awl Tap Multi-Axial Screws, Set Screws and Rods may be removed by applying a Ball-Ended Driver, or Removal Driver to the Set Screw and turning counterclockwise until the Set Screw is removed. CD Horizon Solera Voyager 5.5/6.0mm Cannulated Multi-Axial Extended Tab Screws and Extended Tab ATS Multi-Axial Screws may be removed by applying the Multi-Axial Screwdriver, Ball-Ended Driver, or Removal Driver from the CD Horizon Solera Voyager 5.5/6.0mm Instrument Set to the Screw and turning counterclockwise until the Screw is removed from the pedicle.

PRODUCT ORDERING INFORMATION

CD Horizon Solera Voyager 5.5/6.0mm Cannulated Multi-Axial Screw and Instrument Set

Part Number	Description	Qty
55850014535	4.5mm × 35mm Cannulated MAS	4
55850014540	4.5mm × 40mm Cannulated MAS	4
55850014545	4.5mm × 45mm Cannulated MAS	4
55850015535	5.5mm × 35mm Cannulated MAS	6
55850015540	5.5mm × 40mm Cannulated MAS	8
55850015545	5.5mm × 45mm Cannulated MAS	8
55850015550	5.5mm × 50mm Cannulated MAS	6
55850016535	6.5mm × 35mm Cannulated MAS	6
55850016540	6.5mm × 40mm Cannulated MAS	8
55850016545	6.5mm × 45mm Cannulated MAS	8
55850016550	6.5mm × 50mm Cannulated MAS	8
55850016555	6.5mm × 55mm Cannulated MAS	6
55850017535	7.5mm × 35mm Cannulated MAS	6
55850017540	7.5mm × 40mm Cannulated MAS	6
55850017545	7.5mm × 45mm Cannulated MAS	6
55850017550	7.5mm × 50mm Cannulated MAS	4
55850017555	7.5mm × 55mm Cannulated MAS	4
5584007	Screw Gauge	1
6551004	4.5mm One-Step Tap	1
6551005	5.5mm One-Step Tap	1
6551006	6.5mm One-Step Tap	1
6551007	7.5mm One-Step Tap	1
6551045	4.5-5.5mm One-Step Drill Tap	1
6551056	5.5-6.5mm One-Step Drill Tap	1
6550000	Tap Sleeve	1

CD Horizon Solera Voyager 5.5mm Voyager ATS

Part Number	Description	Qty
NAV6550005	5.5/6.0 SV Nav Mas Driver	2
55850044530	5.5/6.0 Solera Voyager, ATS 4.5×30	4
55850044535	5.5/6.0 Solera Voyager, ATS 4.5×35	4
55850044540	5.5/6.0 Solera Voyager, ATS 4.5×40	4
55850045530	5.5/6.0 Solera Voyager, ATS 5.5×30	4
55850045535	5.5/6.0 Solera Voyager, ATS 5.5×35	6
55850045540	5.5/6.0 Solera Voyager, ATS 5.5×40	8
55850045545	5.5/6.0 Solera Voyager, ATS 5.5×45	8
55850045550	5.5/6.0 Solera Voyager, ATS 5.5×50	6
55850046530	5.5/6.0 Solera Voyager, ATS 6.5×30	4
55850046535	5.5/6.0 Solera Voyager, ATS 6.5×35	6
55850046540	5.5/6.0 Solera Voyager, ATS 6.5×40	8
55850046545	5.5/6.0 Solera Voyager, ATS 6.5×45	8
55850046550	5.5/6.0 Solera Voyager, ATS 6.5×50	8
55850047535	5.5/6.0 Solera Voyager, ATS 7.5×35	6
55850047540	5.5/6.0 Solera Voyager, ATS 7.5×40	6
55850047545	5.5/6.0 Solera Voyager, ATS 7.5×45	6
55850047550	5.5/6.0 Solera Voyager, ATS 7.5×50	6
55850047555	5.5/6.0 Solera Voyager, ATS 7.5×55	4

CD Horizon Solera Voyager 5.5/6.0mm Large Diameter Screw Kit

Part Number	Description	Qty
55850018580	8.5mm × 80mm Cannulated MAS	3
55850018590	8.5mm × 90mm Cannulated MAS	3
55850018500	8.5mm × 100mm Cannulated MAS	3
55850019580	9.5mm × 80mm Cannulated MAS	3
55850019590	9.5mm × 90mm Cannulated MAS	3
55850019500	9.5mm × 100mm Cannulated MAS	3
55850011580	10.5mm × 80mm Cannulated MAS	3
55850011590	10.5mm × 90mm Cannulated MAS	3
55850011500	10.5mm × 100mm Cannulated MAS	3
5484840	8.5mm Tap	1
5484841	9.5mm Tap	1

CD Horizon Solera Voyager 5.5/6.0mm Capped Rods and Instruments

Part Number	Description	Qty
6550014	Rod Gripper	1
651003030	5.5mm Cobalt Chrome Capped Rod, 30mm	3
651003035	5.5mm Cobalt Chrome Capped Rod, 35mm	3
651003040	5.5mm Cobalt Chrome Capped Rod, 40mm	3
651003045	5.5mm Cobalt Chrome Capped Rod, 45mm	3
651003050	5.5mm Cobalt Chrome Capped Rod, 50mm	3
651003055	5.5mm Cobalt Chrome Capped Rod, 55mm	3
651003060	5.5mm Cobalt Chrome Capped Rod, 60mm	3
651003065	5.5mm Cobalt Chrome Capped Rod, 65mm	3
651003070	5.5mm Cobalt Chrome Capped Rod, 70mm	3
651003075	5.5mm Cobalt Chrome Capped Rod, 75mm	3
651003080	5.5mm Cobalt Chrome Capped Rod, 80mm	3

CD Horizon Solera Voyager 5.5/6.0mm Percutaneous Rods and Instruments and Instrument Set

Part Number	Description	Qty
651000030	5.5mm Cobalt Chrome Percutaneous Rod, 30mm	4
651000035	5.5mm Cobalt Chrome Percutaneous Rod, 35mm	4
651000040	5.5mm Cobalt Chrome Percutaneous Rod, 40mm	4
651000045	5.5mm Cobalt Chrome Percutaneous Rod, 45mm	4
651000050	5.5mm Cobalt Chrome Percutaneous Rod, 50mm	4
651000055	5.5mm Cobalt Chrome Percutaneous Rod, 55mm	4
651000060	5.5mm Cobalt Chrome Percutaneous Rod, 60mm	4
651000065	5.5mm Cobalt Chrome Percutaneous Rod, 65mm	4
651000070	5.5mm Cobalt Chrome Percutaneous Rod, 70mm	4
651000075	5.5mm Cobalt Chrome Percutaneous Rod, 75mm	4
651000080	5.5mm Cobalt Chrome Percutaneous Rod, 80mm	4
651000085	5.5mm Cobalt Chrome Percutaneous Rod, 85mm	4
651000090	5.5mm Cobalt Chrome Percutaneous Rod, 90mm	4

Note
CD Horizon Solera Voyager 5.5/6.0mm Screws will accept either a 5.5mm or a 6.0mm Rod. 6.0mm Rods are not available in the set. They must be ordered separately as a custom item.

CD Horizon Solera Voyager 5.5/6.0mm Longer Percutaneous Rods

Part Number	Description	Qty
654000100	5.5mm Titanium Percutaneous Rod, 100mm	3
654000110	5.5mm Titanium Percutaneous Rod, 110mm	3
654000120	5.5mm Titanium Percutaneous Rod, 120mm	3
654000130	5.5mm Titanium Percutaneous Rod, 130mm	3
654000140	5.5mm Titanium Percutaneous Rod, 140mm	3
654000150	5.5mm Titanium Percutaneous Rod, 150mm	3
654000160	5.5mm Titanium Percutaneous Rod, 160mm	3
654000170	5.5mm Titanium Percutaneous Rod, 170mm	3
654000180	5.5mm Titanium Percutaneous Rod, 180mm	3
654000190	5.5mm Titanium Percutaneous Rod, 190mm	3
654000200	5.5mm Titanium Percutaneous Rod, 200mm	3
6550027	5.5/6.0mm Threaded Rod Reducer	4
6550011	5.5/6.0mm Rack Distractor/ Compressor	2
6550034	5.5/6.0mm Reinforcement Sleeve	2
6550017	5.5/6.0 SV Tab Extender	18
6550016	5.5/6.0 SV CAP	10

CD Horizon Solera Voyager 5.5/6.0mm Universal Instruments

Part Number	Description	Qty
6550027	5.5/6.0mm Threaded Rod Reducer	2
6550031	5.5/6.0mm Nut Driver	2
6550009	5.5/6.0mm Plier Compressor	1
6550034	5.5/6.0mm Reinforcement Sleeve	2
6550035	5.5/6.0mm Fulcrum Pliers	1
6550036	5.5/6.0mm Fulcrum	1
7480162	French Bender	1

CD Horizon Solera Voyager 5.5/6.0mm Universal Instruments

Part Number	Description	Qty
8670001	Guidewire, Blunt	6
8670002	Guidewire, Sharp	6
7579000	Quick Connect Ratcheting T-Handle	1
G170059	Egg Handle	2
6550016	5.5/6.0 SV Cap	10
6550017	5.5/6.0 SV Tab Extender	18
6550002	5.5/6.0 SV MAS Driver	2
6550003	5.5/6.0 SV Non-Retaining Driver	1
7480147	T27 Removal Driver	1
6550004	Ball-Ended Driver	1
6550013	MAS Rod Template	1
9010000849	Perc Inserter	2
6540530	5.5/6.0mm Solera Voyager Set Screw	20
6550006	5.5/6.0mm Solera Voyager Set Screw Driver	2
6550022	5.5/6.0mm Solera Voyager Ring Counter Torque	1
6550021	Counter Torque Threaded	1
6550020	5.5/6.0mm Solera Voyager Tab Removal Tool	1
6550019	5.5/6.0mm Solera Voyager Tab Breaker	2
7570090	Break-Off T-Handle	1
8350312	Rod Holder	1

Navigated CD Horizon Solera Complete Percutaneous Taps/Drivers Set

Part Number	Description
NAV2002	Solera Awl Tip Tap 4.5mm
NAV2004	Solera Awl Tip Tap 5.5mm
NAV2006	Solera Awl Tip Tap 6.5mm
NAV2008	Solera Awl Tip Tap 7.5mm
NAV2015	Solera Awl Tip Tap 4.5-5.5mm
NAV2016	Solera Awl Tip Tap 5.5-6.5mm
NAV2017	Solera Awl Tip Tap Small Dilator
NAV2018	Solera Awl Tip Tap Large Dilator
NAV2020	Solera 5.5/6.0 MAS Lg2 Driver
NAV2022	Solera 5.5/6.0 FAS/SAS Lg2 Driver
NAV2023	Solera 4.75 MAS Lg2 Driver
NAV2024	Solera 4.75 Standard MAS Driver
NAV2025	Solera 4.75 Reduct MAS Driver
NAV6550005	Solera Voyager 5.5/6.0 Nav MAS Driver
NAV6640009	Solera Voyager 4.75 Nav MAS Driver

IMPORTANT
PRODUCT INFORMATION

PURPOSE
The CD HORIZON Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION
The CD HORIZON™ Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK™ Plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

A subset of CD HORIZON™ Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5mm to 6.35mm), hooks, screws, CROSSLINK™ Plates, and connecting components. Similarly to the CD HORIZON™ implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain components within the CD HORIZON™ Spinal System are specifically excluded for use in pediatric patients. These include PEEK rods, Shape Memory Alloy Staples, SPIRE™ Plates and DYNALOK bolts. All screws used in pediatric cases are only cleared for use via a posterior approach. All of the components used in pediatric cases are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, and medical grade cobalt-chromium-molybdenum alloy.

Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON™ Spinal System in non-pediatric cases. These components include TSRH™ rods, hooks, screws, plates, CROSSLINK™ plates, connectors, staples, washers, GDLH rods, hooks, connectors and CROSSLINK™ bar and connectors; LIBERTY rods and screws; DYNALOK PLUS and DYNALOK CLASSIC bolts along with rod/bolt connectors; and Medtronic Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to specific rod diameters, while other components can connect to multiple rod diameters. Care should be taken so that the correct components are used in the spinal construct.

CD HORIZON™ hooks are intended for posterior use only. CD HORIZON™ staples and CD HORIZON™ ECLIPSE™ rods and associated screws are intended for anterior use only. However, for patients of smaller stature and pediatric patients, CD HORIZON™4.5mm rods and associated components may be used posteriorly.

The CD HORIZON™ Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK OPTIMA-LT1. Certain CD HORIZON™ Spinal System components may be coated with hydroxyapatite. No warranties expressed or implied are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog for further information about warranties and limitations of liability.

Never use stainless steel and titanium implant components in the same construct.

Medical grade titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct.

The CD HORIZON™ Spinal System also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt-chromium-molybdenum alloy. Do not use with stainless steel. **These staples are not to be used in pediatric patients.**

PEEK OPTIMA-LT1 implants may be used with stainless steel, titanium, or cobalt-chromium-molybdenum alloy implants. **CD HORIZON™ PEEK Rods are not to be used with CROSSLINK™ Plates or in pediatric patients.**

To achieve best results, do not use any of the CD HORIZON™ Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. As with all orthopaedic and neurosurgical implants, none of the CD HORIZON™ Spinal System components should ever be reused under any circumstances.

INDICATIONS
The CD HORIZON™ Spinal System with or without SEXTANT™ instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON™ Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON™ LEGACY™ 3.5mm rods and the CD HORIZON™ Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON™ Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD HORIZON™ Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON™ SPIRE™ Plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON™ Spinal System rods may be connected to the VERTEX™ Reconstruction System with the VERTEX™ rod connector. Refer to the VERTEX™ Reconstruction System Package Insert for a list of the VERTEX™ indications of use.

CONTRAINDICATIONS
Contraindications include, but are not limited to:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.

- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion.
- 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.
- The CD HORIZON™ SPIRE™ Plate and the CD HORIZON™ PEEK Rods are specifically contraindicated for use in pediatric patients.
- Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- **Severe bone resorption.**
- **Osteomalacia**
- **Severe osteoporosis.**

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is 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 implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain.
- Bursitis.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Ileus, gastritis, bowel obstruction, loss of bowel control, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

ADDITIONAL POTENTIAL ADVERSE EVENTS FOR PEDIATRIC PATIENTS

- Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
- Pedicle screw malpositioning, with or without neurological or vascular injury
- Proximal or distal junctional kyphosis
- Pancreatitis

WARNING

The safety and effectiveness of pedicle screw spinal 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 degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses. In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend, or fracture as a result of exposure to every day mechanical stresses.

A device that has been implanted should never be reused, reprocessed or resterilized under any circumstances. Sterile packaged devices should also never be resterilized. Reuse, reprocessing, or resterilization may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

Warning: The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

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 not skeletally mature that undergo 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.

Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their smaller stature.

ADDITIONAL WARNING FOR THE CD HORIZON™ SPIRE™ SPINOUS PROCESS PLATE

Please consider the extent of decompression, as well as the amount of intact bone remaining on the spinous processes, when using the CD HORIZON™ SPIRE™ Plate as the sole supplemental fixation for an interbody fusion procedure.

PRECAUTIONS

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

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. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device(s) will eventually occur.

Preoperative and operating 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 by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

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.

Preoperative and operating 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.

The selection of the proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

!USA For US Audiences Only

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

EC REP

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

The NIM-ECLIPSE™ E4 System is manufactured by Medtronic Xomed, Inc. Distributed by Medtronic's Spinal and Biologics Business.

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