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

O-arm™
O2 Imaging System

CD Horizon™ Solera™
Voyager™ 5.5 System

SURGICAL TECHNIQUE

Medtronic

MICHELSON TECHNOLOGY AT WORK

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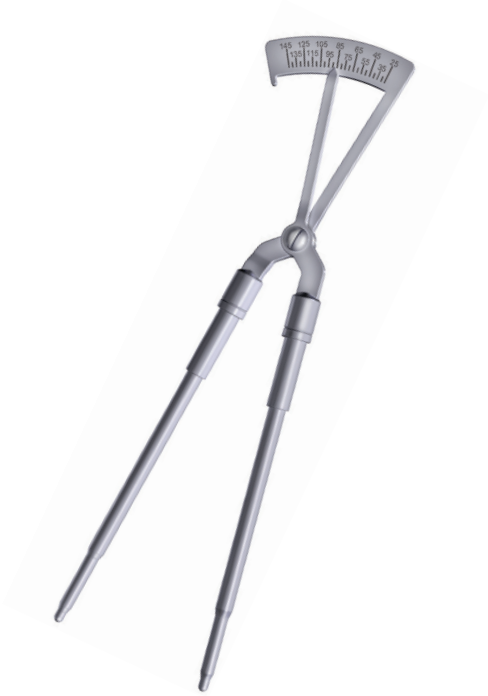
INSTRUMENTS

Set Screw Driver
(6550006)

Multi-Axial Screw Driver
(6550002)

Rod Holder
(8350312)



MAS Rod Template
(6550013)

Plier Compressor
(6550009)

INSTRUMENTS

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

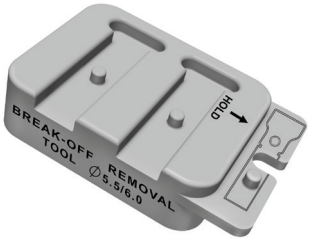
(7480147)

Tab Breaker

(6550019)

Tab Extender

(6550017)



Tab Removal Tool

(6550020)

Quick Connect Ratcheting Egg Handle

(9098120)

Extender Cap

(6550016)

*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 Threaded Rod Reducer
(6550027)

5.5/6.0mm Nut Driver
(6550031)

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)

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

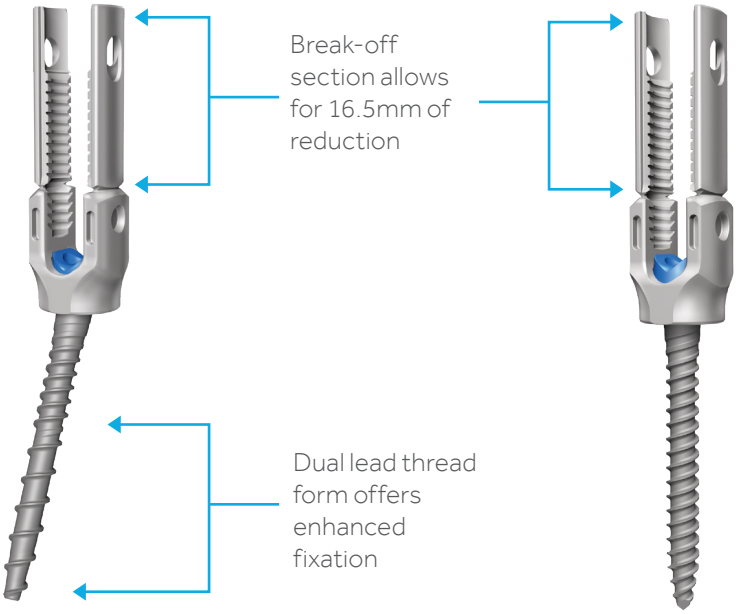
IMPLANT ASSEMBLY
AND SCREW OVERVIEW

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

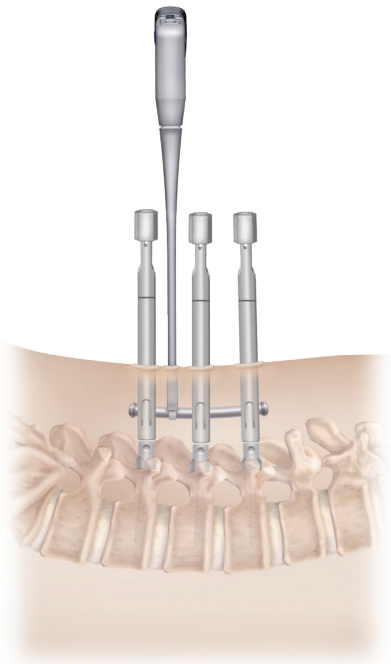
Dual lead thread form offers enhanced fixation

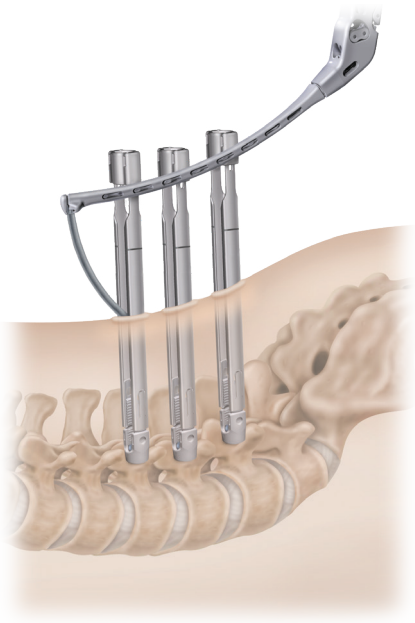
5.5/6.0mm CD Horizon™ Solera™ Voyager™ Extended Tab Cannulated Multi-Axial Screw

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

Two Rod Insertion Methods:

- Mini-Open
- Percutaneous





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.

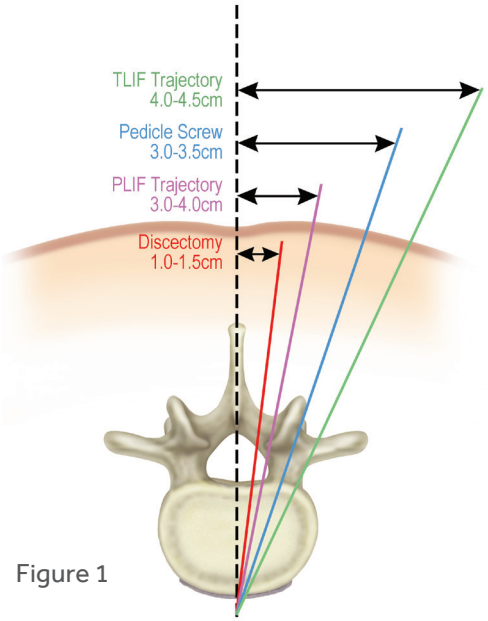


Figure 1

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 maximise 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.

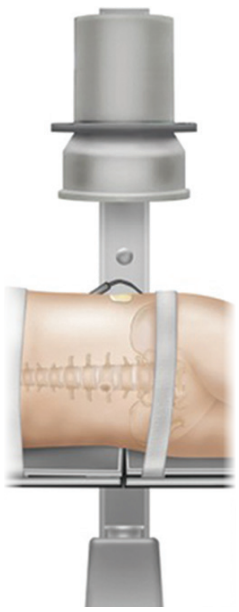


Figure 2a

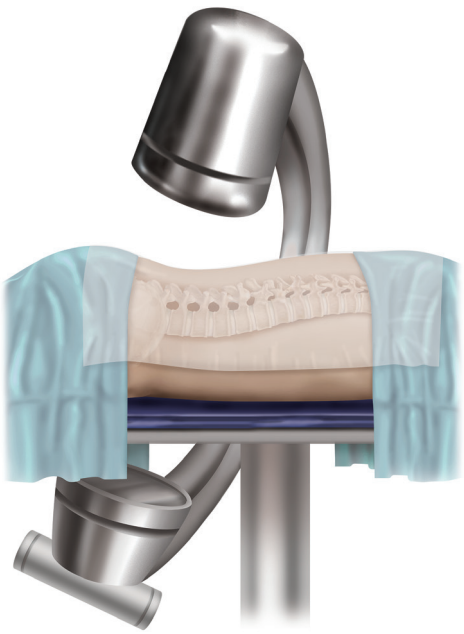
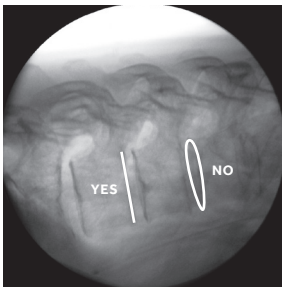


Figure 2b



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.

Figure 2c

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 visualisation of the pedicles is required **(Figure 5b)**.

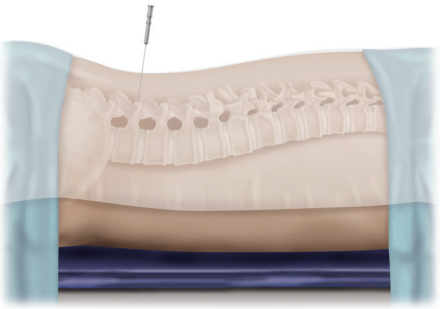


Figure 3a

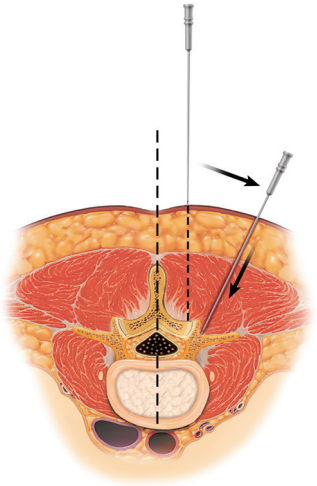


Figure 3b

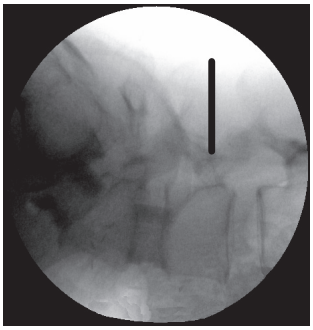


Figure 4a

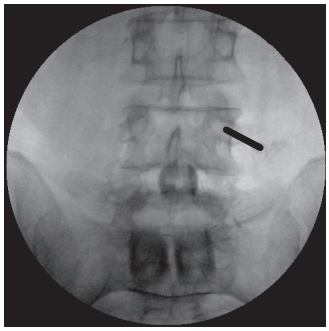


Figure 4b

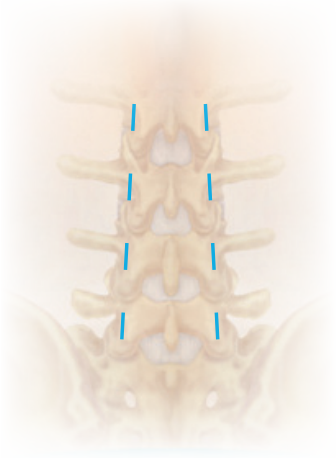


Figure 5a

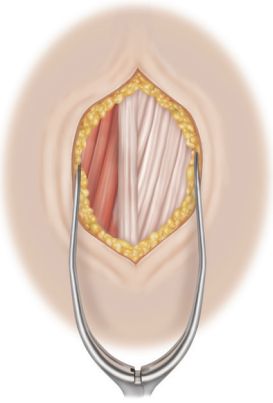


Figure 5b

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)**.

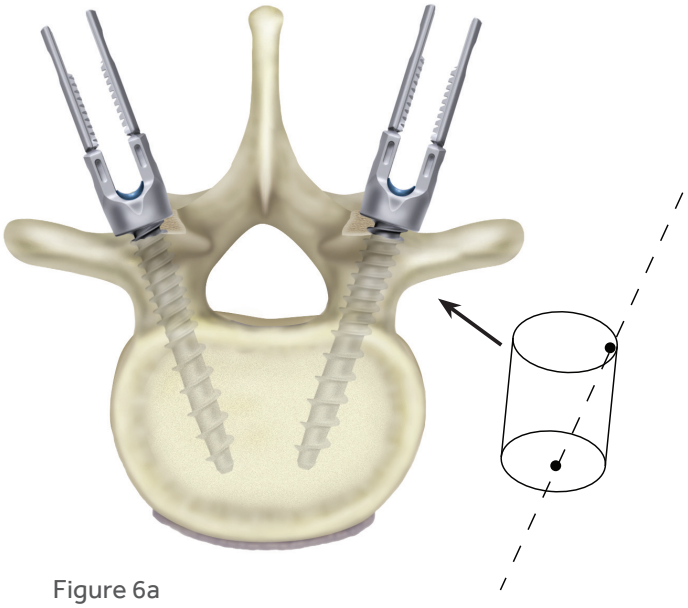


Figure 6a

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)**.

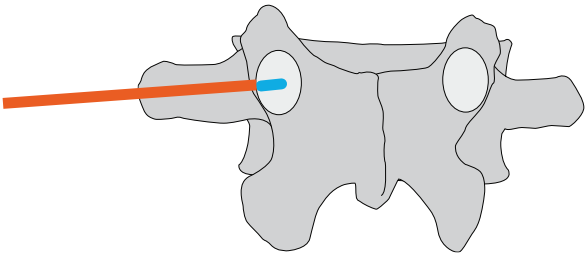


Figure 6b

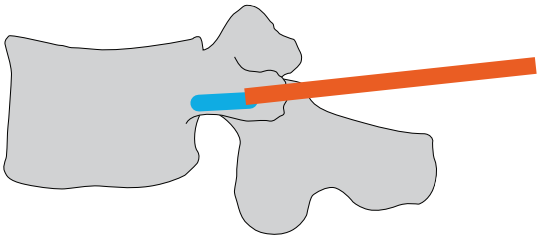


Figure 6c

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 centre 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.

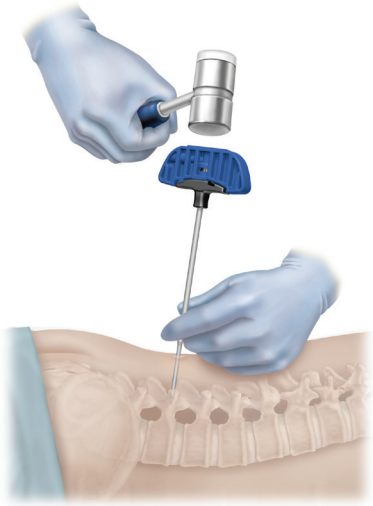


Figure 7

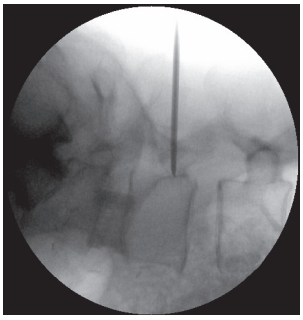


Figure 8a

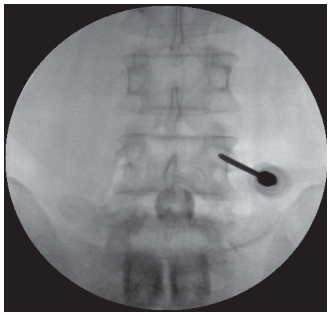


Figure 8b

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 localisation 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.

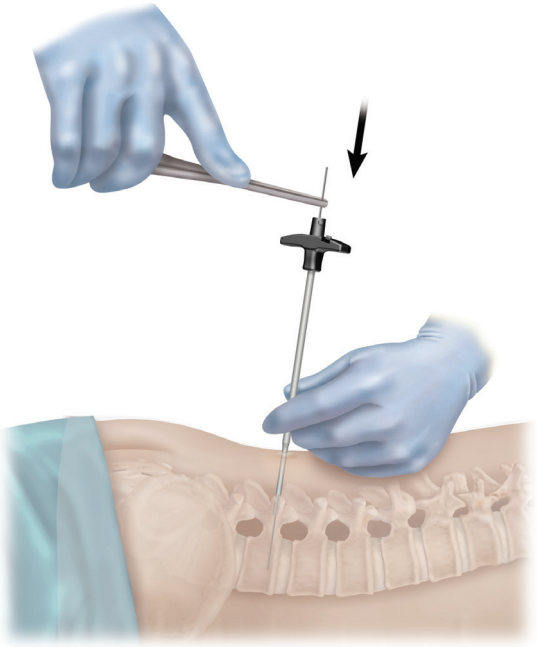


Figure 9a

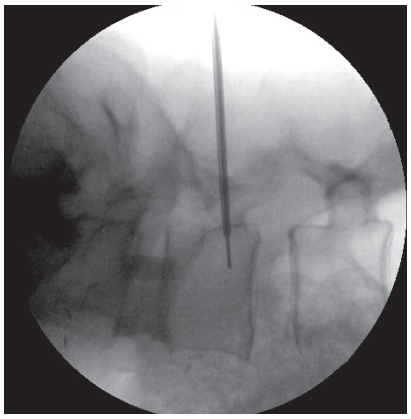


Figure 9b

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 minimise tissue creep **(Figure 11)**.

Figure 10

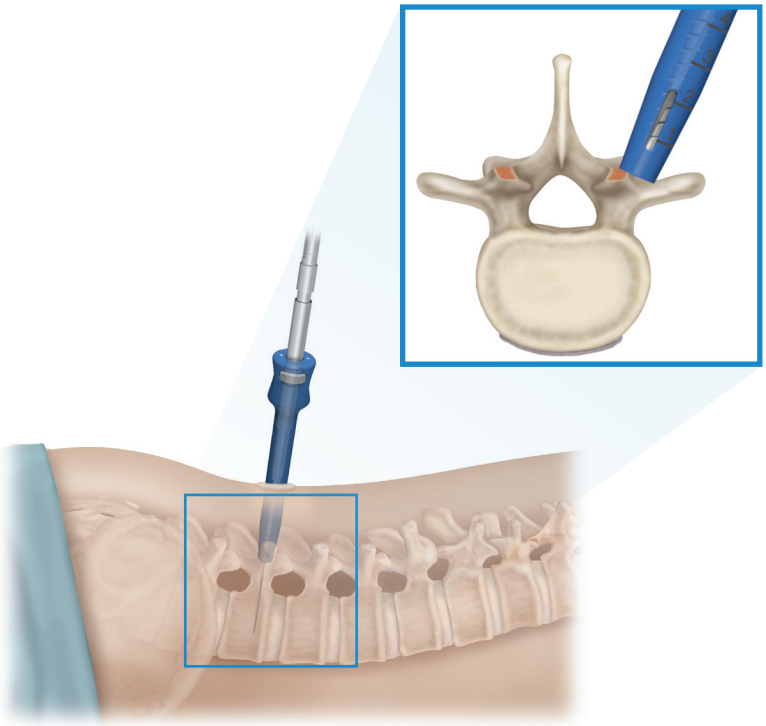


Figure 11

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)**.

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.

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)**.

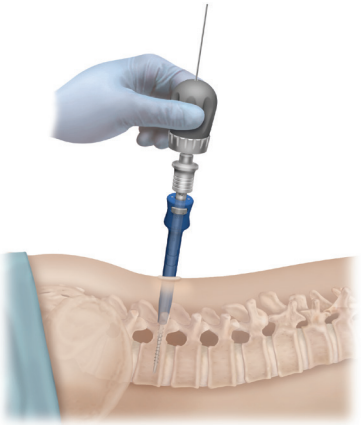


Figure 13

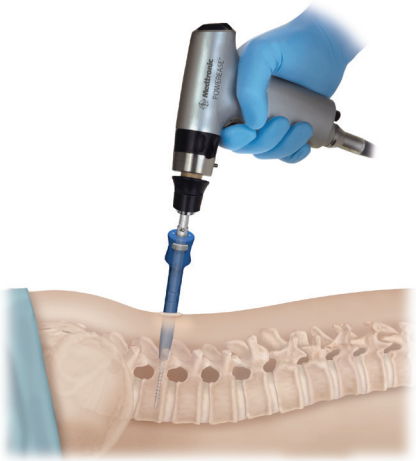


Figure 14

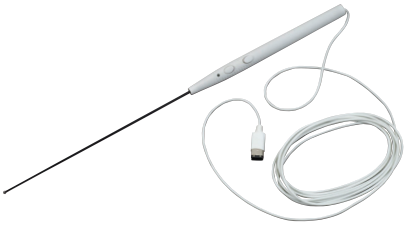


Figure 15

Figure 16

Figure 17a

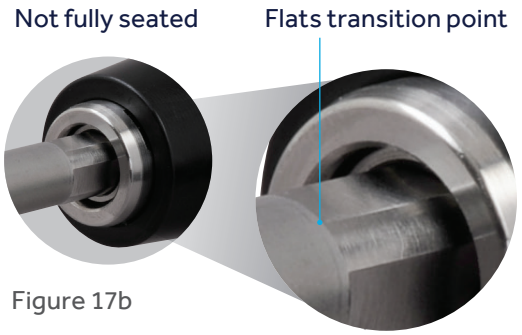


Figure 17b

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 19b

Figure 19a

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

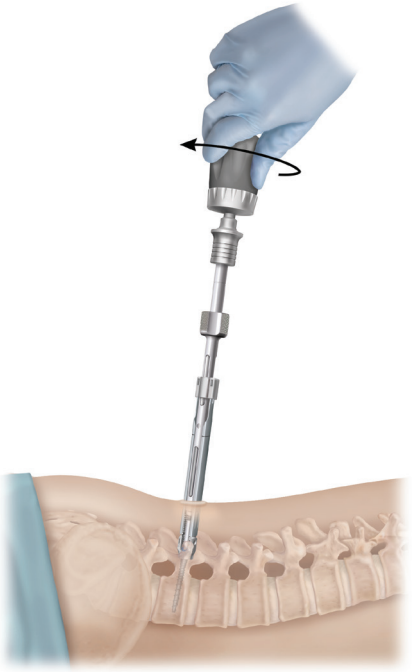


Figure 21

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.

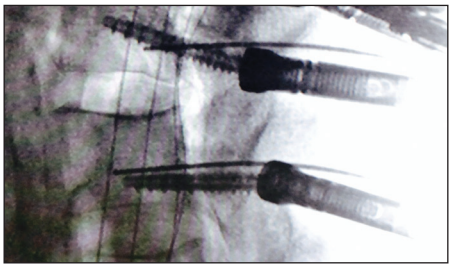


Figure 22

NAVIGATION

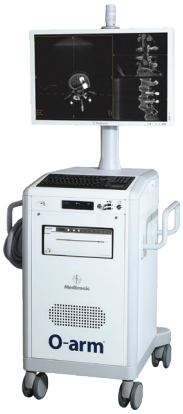
- Cannulated CD Horizon™ Solera™ Voyager™ 5.5/6.0mm Extended Tab Multi-Axial Screws
- CD Horizon™ Solera™ Voyager™ 5.5/6.0mm Extended Tab ATS Multi-Axial Screws

TECHNOLOGY
OVERVIEW

O-arm™ Image Acquisition System

O-arm Imaging System

Mobile Viewing Station



Main Cart

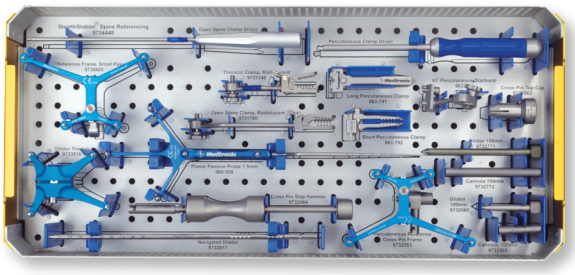
Camera Cart

StealthStation™ S8 Surgical Navigation

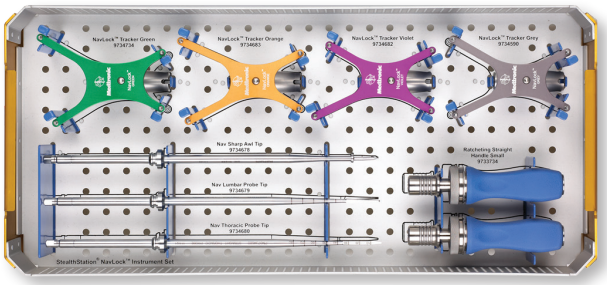
Navigated Stealth-Midas™ Powered Drilling System

CD Horizon Solera Voyager 5.5 System

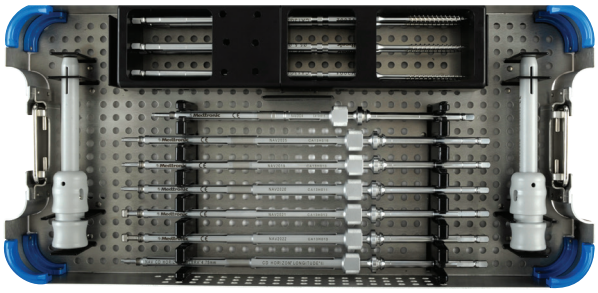
INSTRUMENTS AND EQUIPMENT



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.

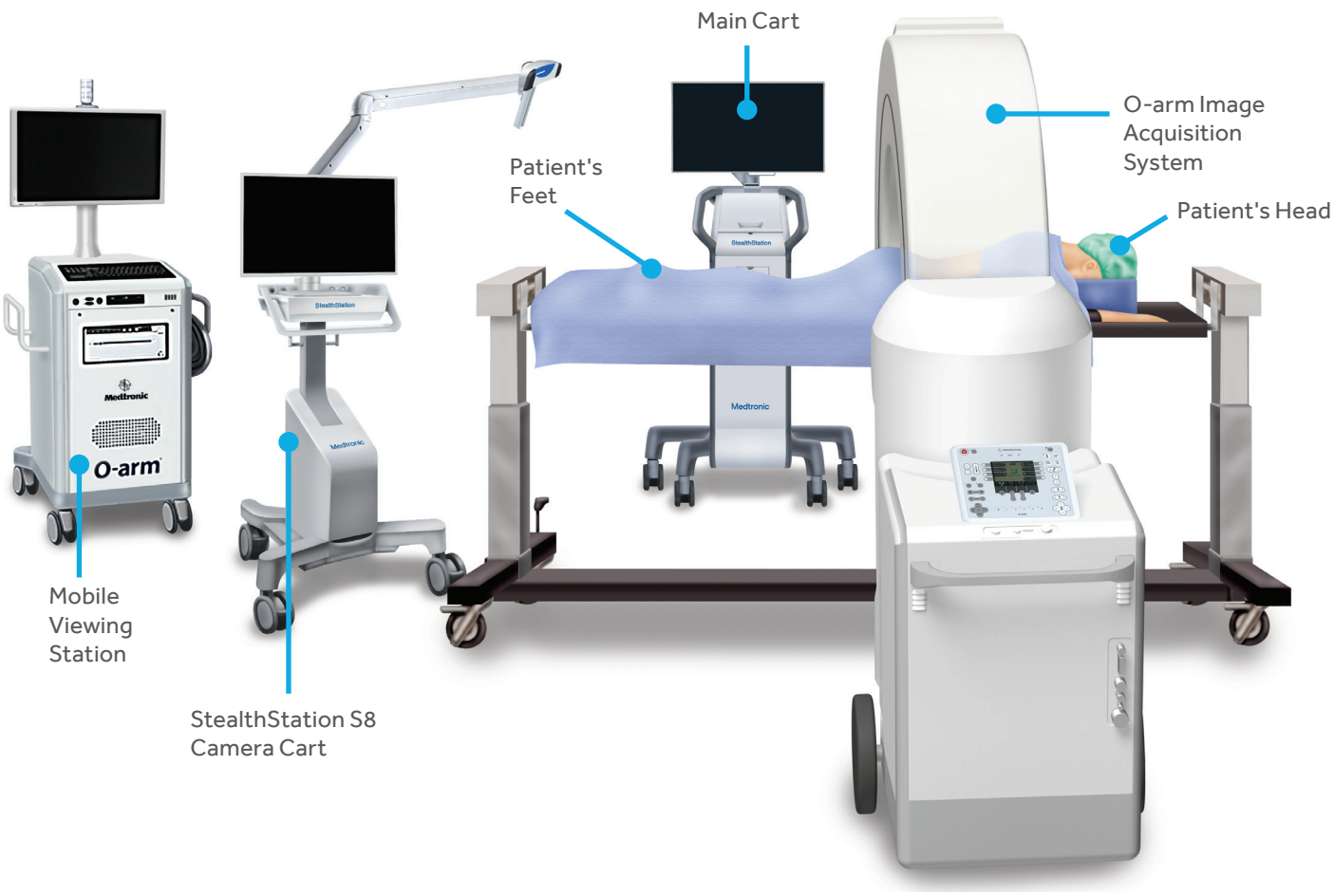


Figure 29

EQUIPMENT AND ROOM SETUP

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.

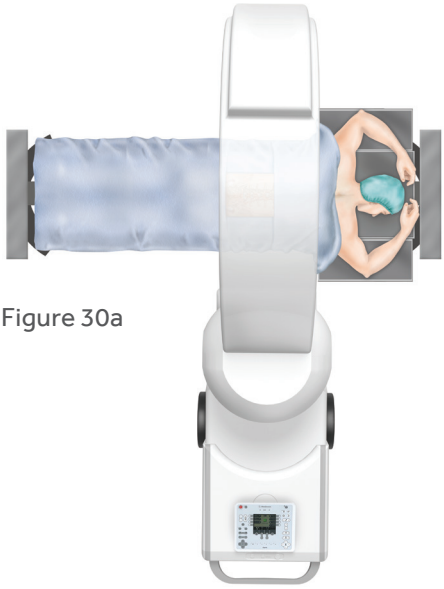


Figure 30a

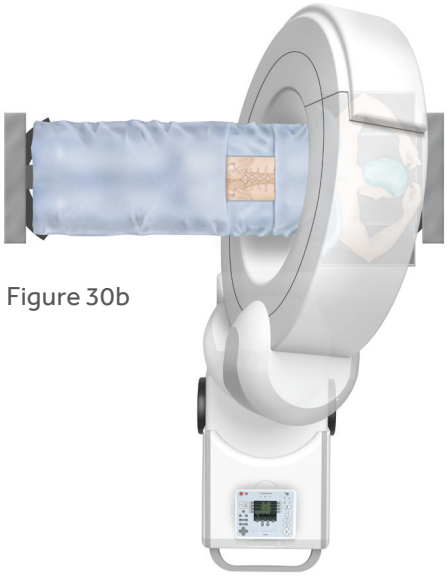
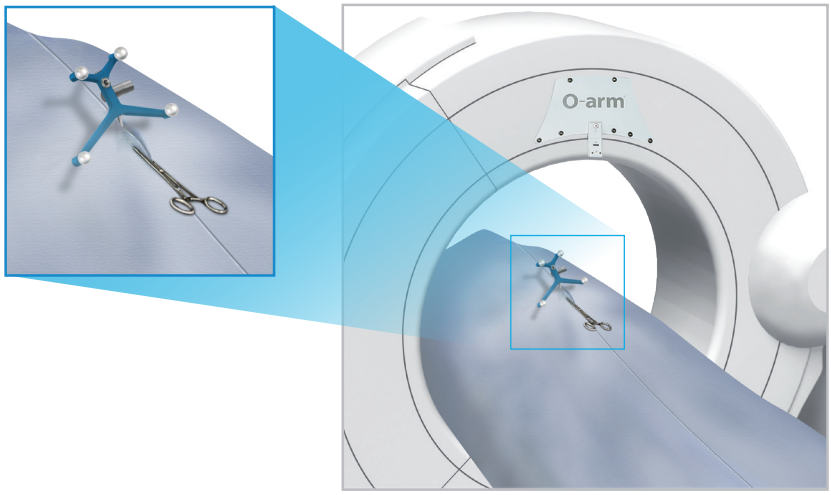


Figure 30b

Helpful Information

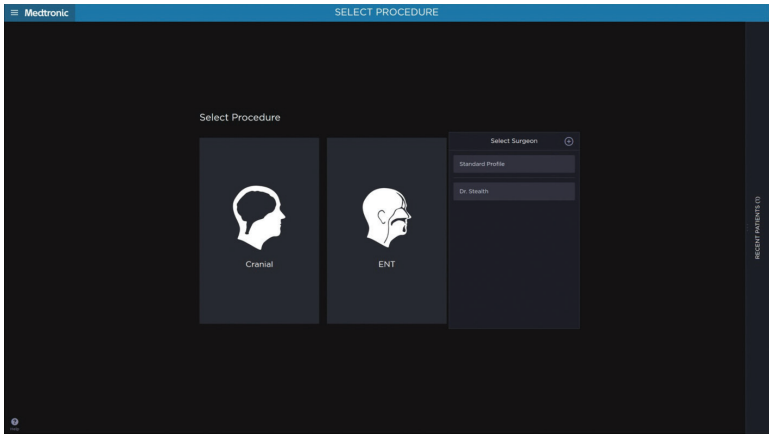
If the O-arm™ System will remain in the sterile field during the procedure, drape the O-arm™ System gantry using the O-arm™ IAS Sterile Tube Drape during the positioning of the system. If the O-arm™ System will be removed from the sterile field, place and clamp two half-drapes over the sides of the patient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



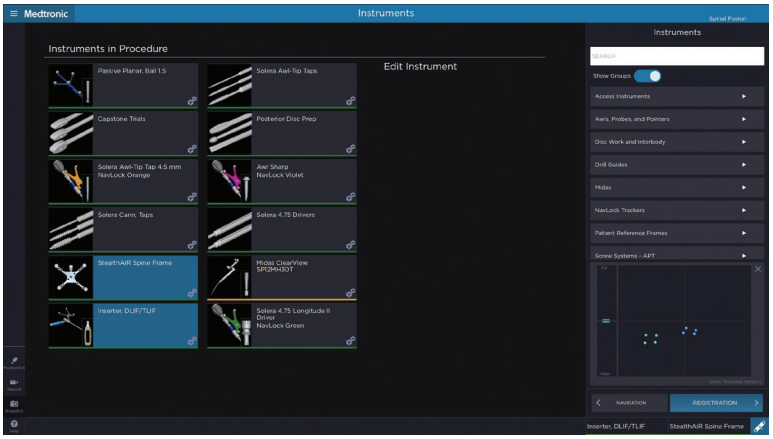
In the StealthStation™ S8 Spine Software, complete the "Select Surgeon" and then "Select Procedure" tasks. Continue through the software by completing the "Set-Up Equipment" and "Verify Instruments" tasks to reach the "Acquire Scan" screen.

StealthStation™ S8 Spine Software Workflow



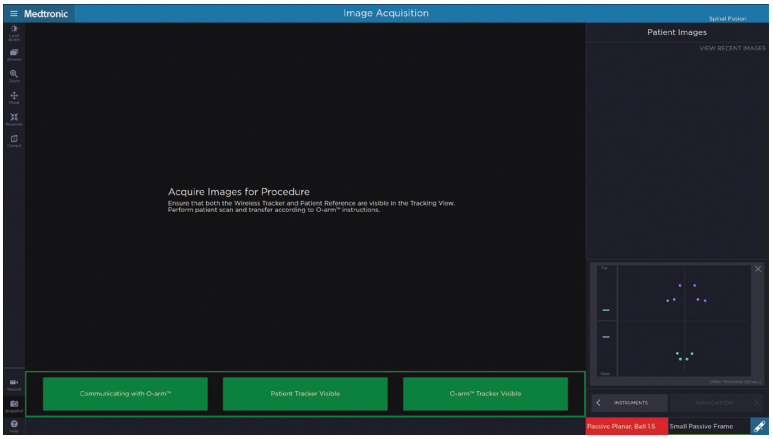
1. Select Procedure

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 colour 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 coloured 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.

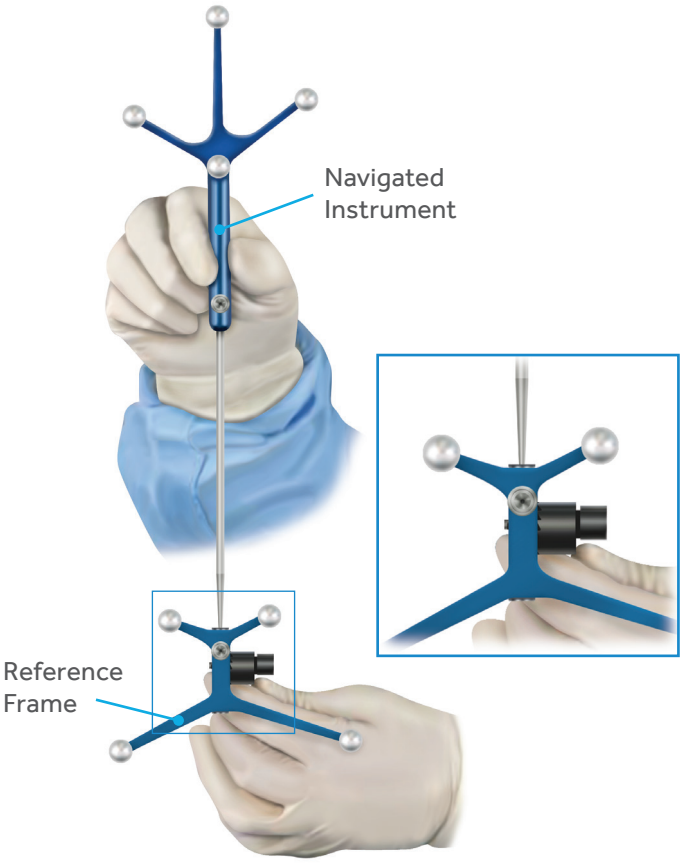


Figure 31a

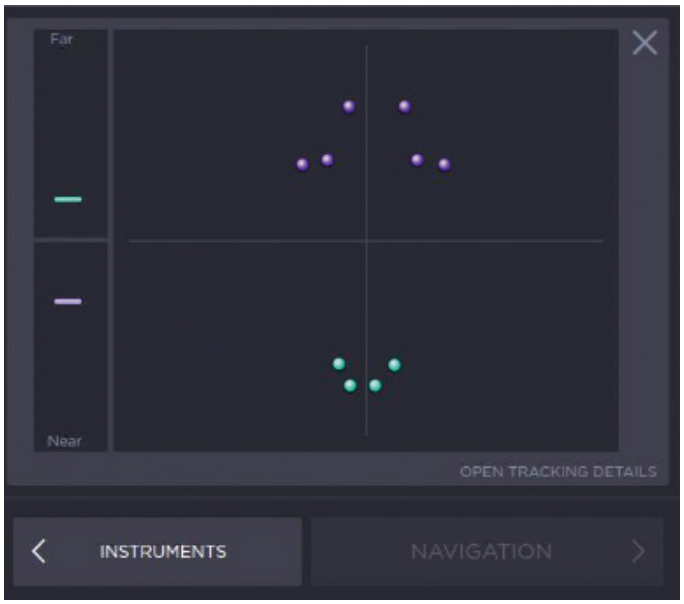


Figure 31b

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 medialising 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.

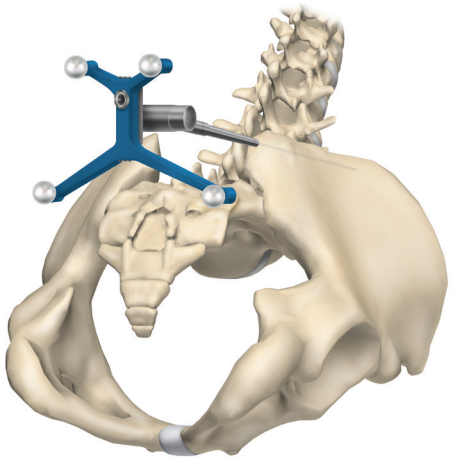


Figure 32a

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.

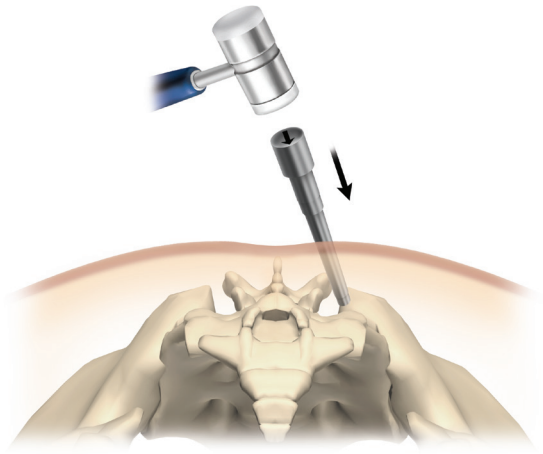


Figure 32b

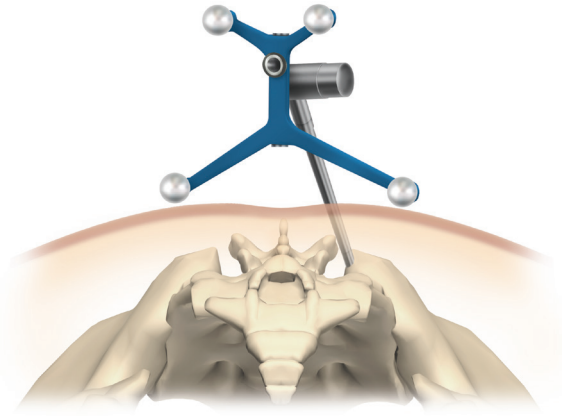


Figure 32c

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

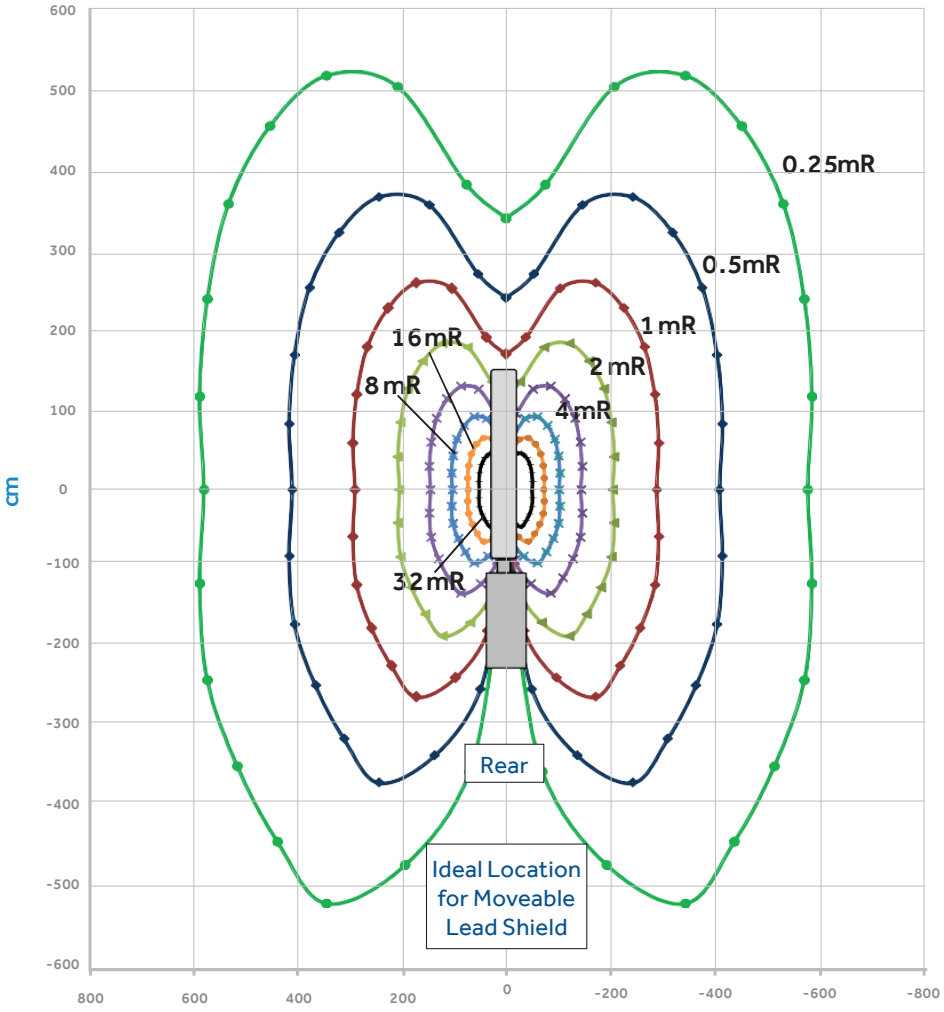


Figure 4

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™.

- 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
- Visualise 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.

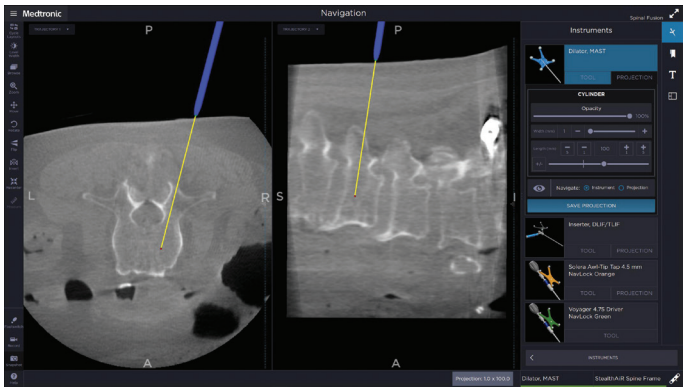


Figure 34a

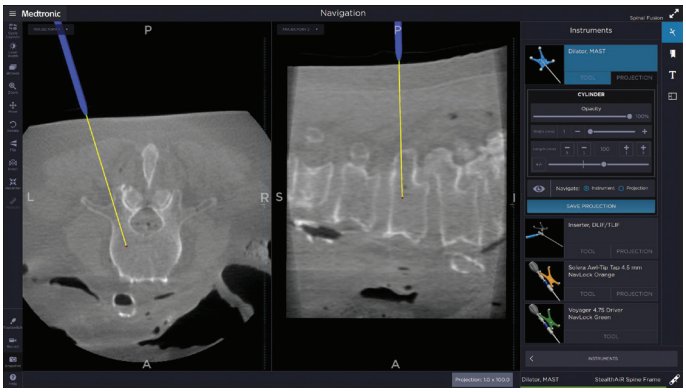


Figure 34b

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)**.

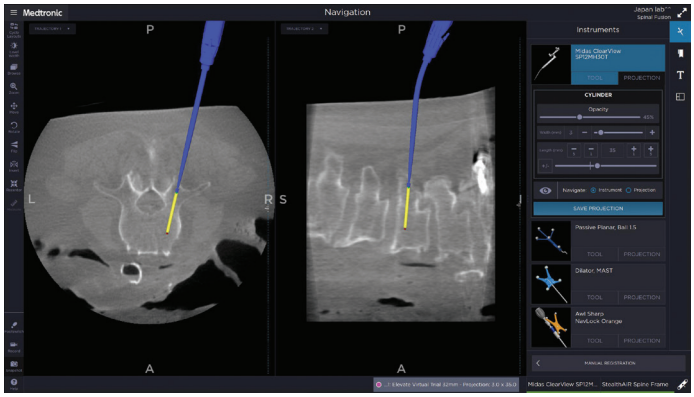


Figure 34d

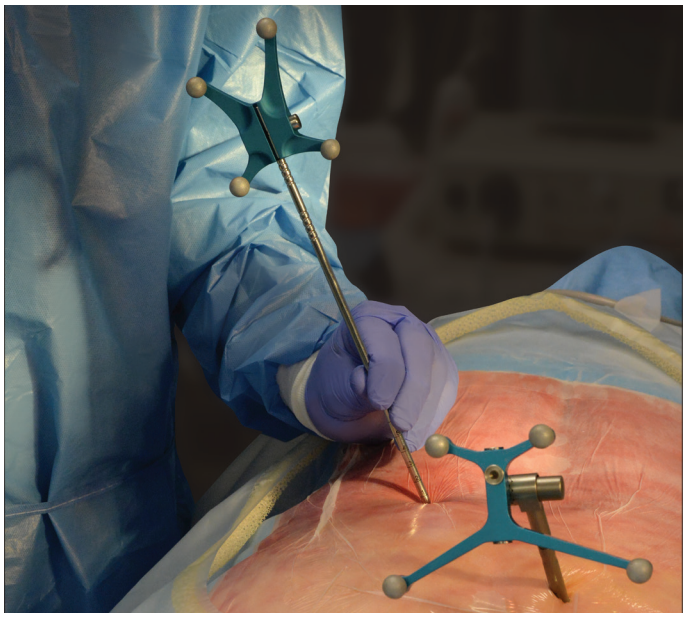


Figure 34c

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 visualisation of the pedicles is required **(Figure 35b)**.

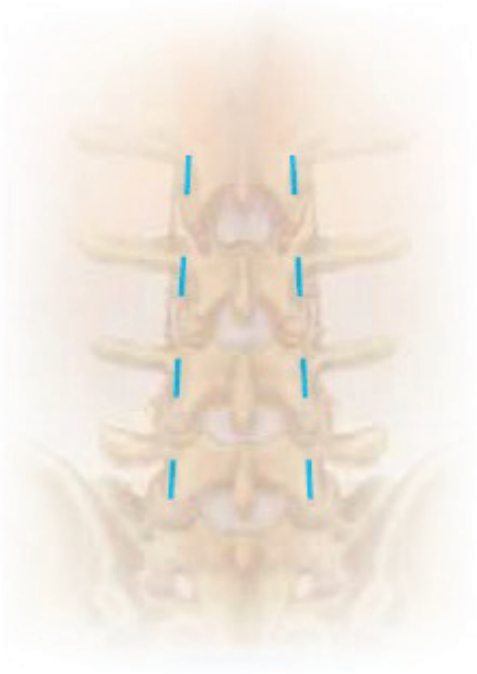


Figure 35a

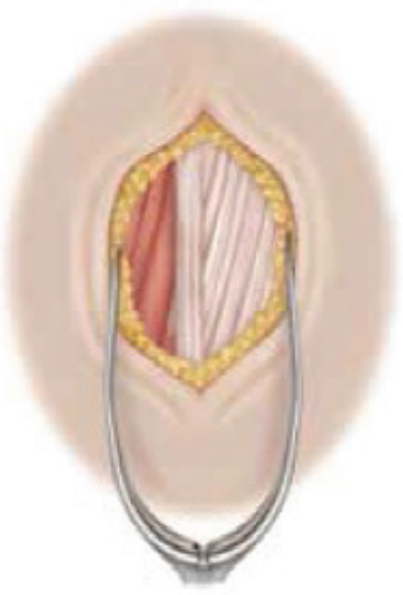


Figure 35b

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.

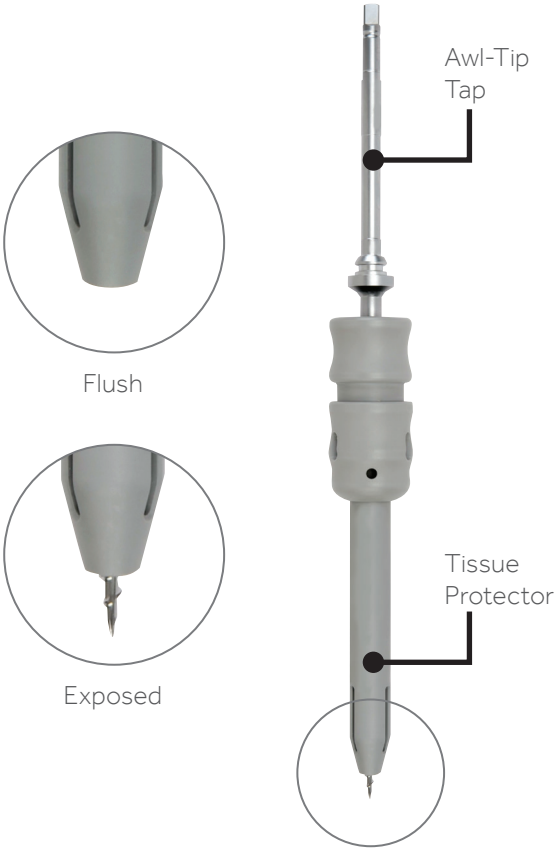


Figure 37a

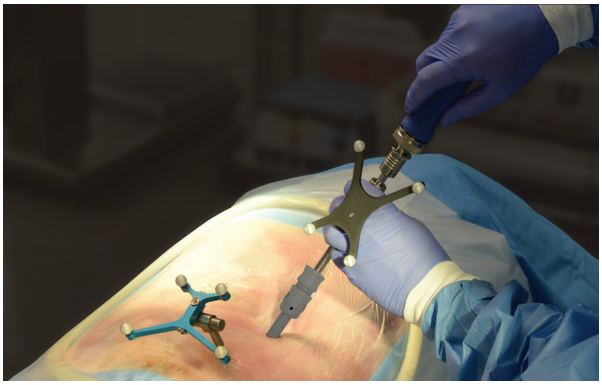


Figure 37b

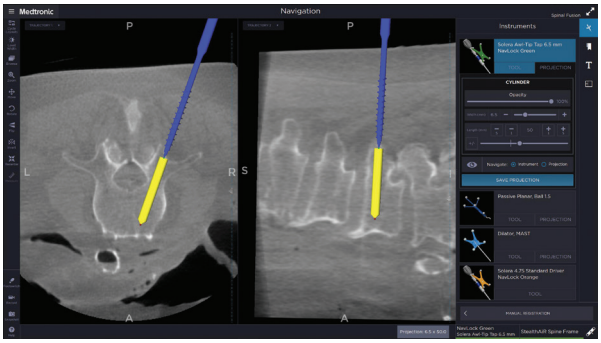


Figure 37c

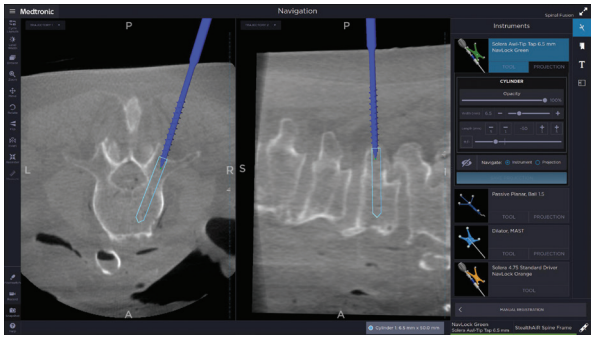


Figure 37d

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.

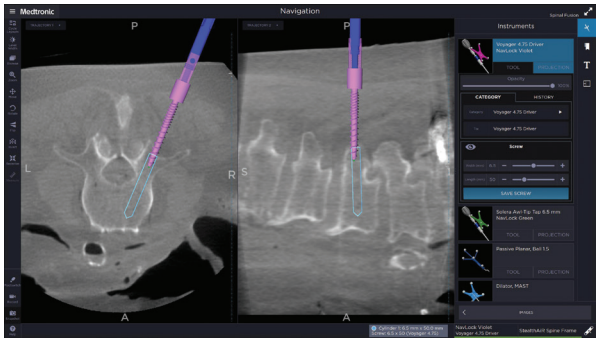


Figure 38a

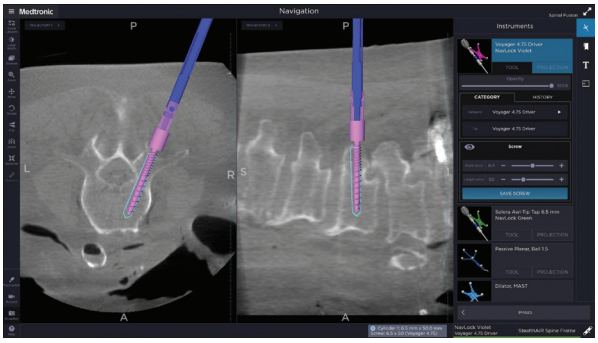


Figure 38b

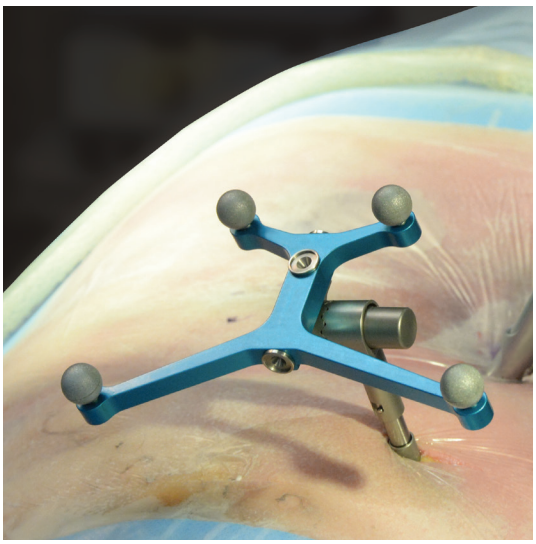


Figure 38c

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)**.

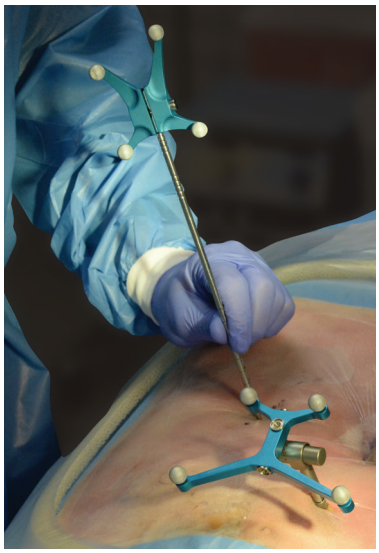


Figure 39a

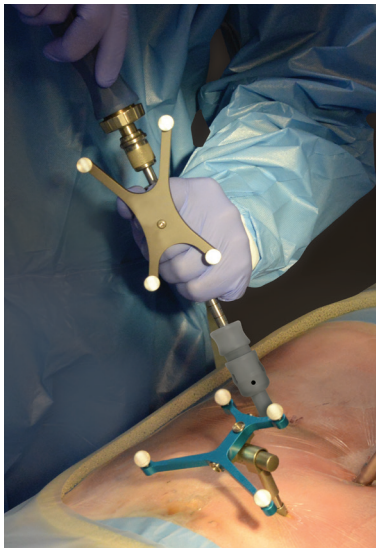


Figure 39b

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".

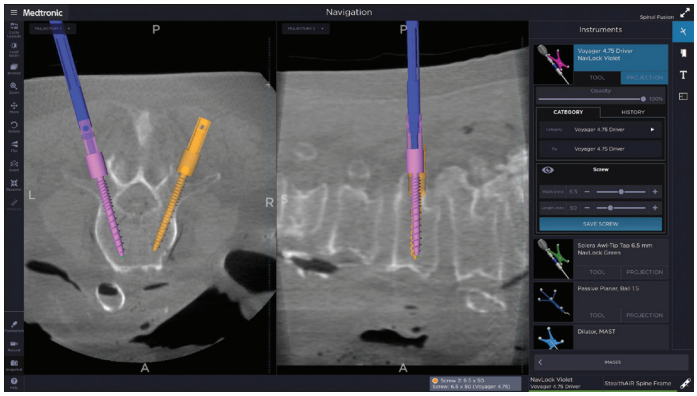


Figure 40a

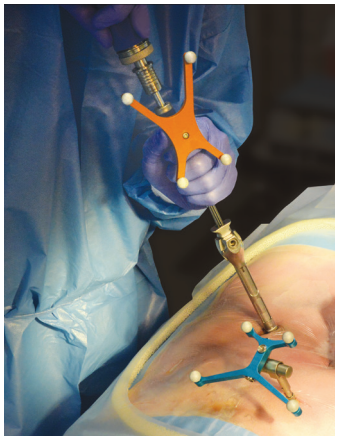


Figure 40b

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 through the use of the virtual guidewire available on the StealthStation™ S8 Navigation System. Due to the sharp tip design, use of intraoperative imaging is recommended. The implant can be used with StealthStation™ 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 StealthStation™ 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 through 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.

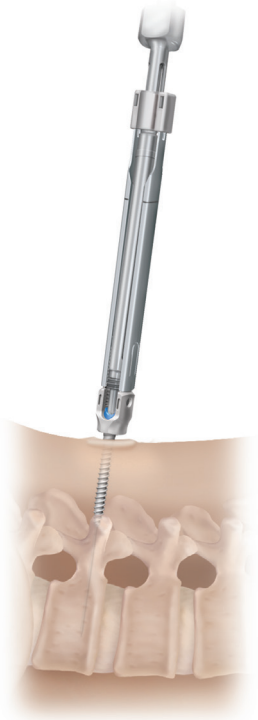


Figure 41a

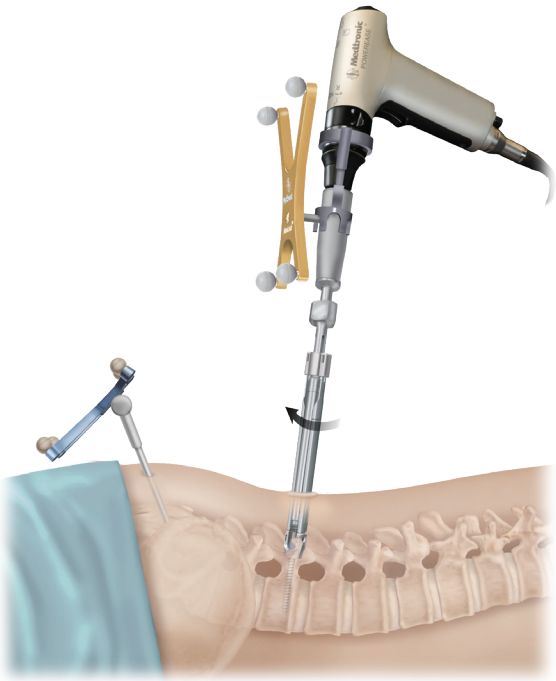


Figure 41b

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.

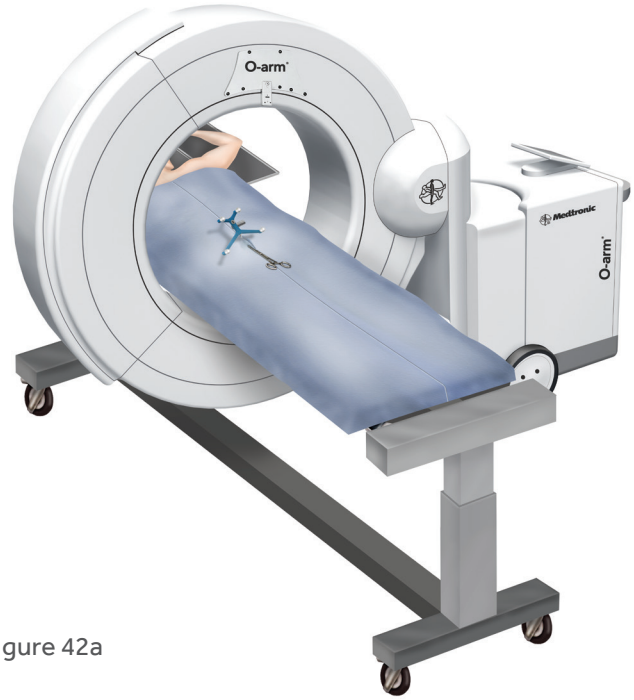


Figure 42a

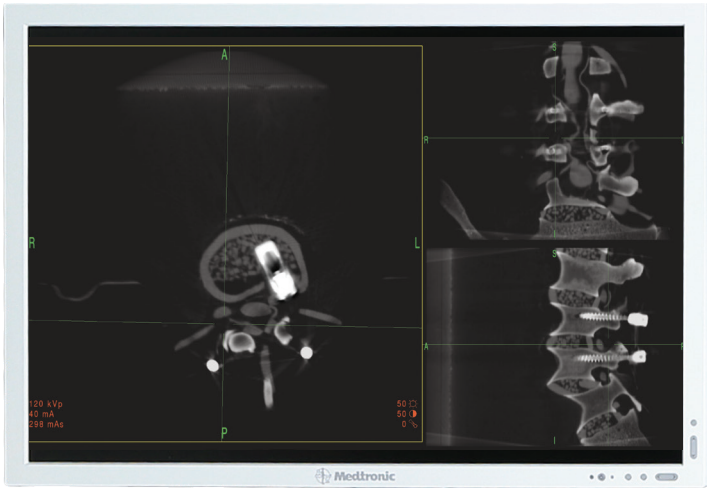


Figure 42b

INTERBODY

MINIMALLY INVASIVE INTERBODY ACCESS **AND PREPARATION**

Combined with the CD Horizon™ Solera™ Voyager™ 5.5/6.0mm, The **Space-D™** and **SpaceView™** systems allow for minimally invasive interbody access and preparation.

The **Space-D™** System connects onto the Voyager™ Extenders to provide controlled screw based in-situ distraction / compression capability for accessing the disc space. The **SpaceView™** System is a low profile retractor that fits in between the Voyager™ Extenders to create an enhanced visualisation and working channel. Refer to the MAST™ Degenerative Fusion Platform Surgical technique for more information on the **Space-D™** and **SpaceView™** systems.

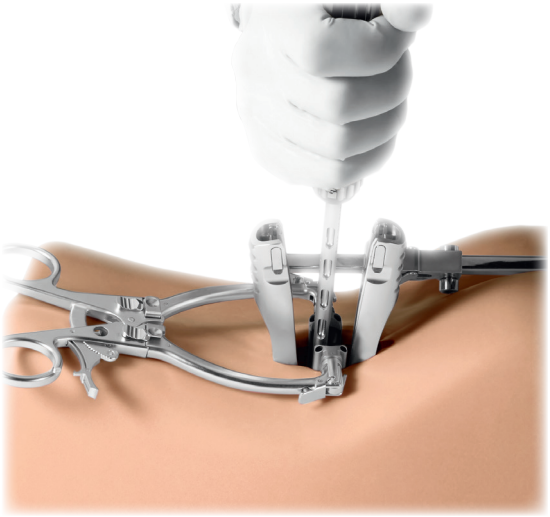


Figure 43

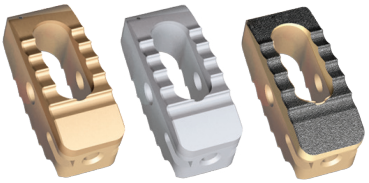
Perform either a unilateral or bilateral facetectomy along with a total discectomy for each operative level. Once the discectomy is performed, placing a distractor in the disc space will allow access for final endplate preparation and, if reducing a spondylolisthesis, will also facilitate its reduction.

Alternatively, 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. Those procedures should be performed before or after the insertion of the CD Horizon™ Solera™ Voyager™ 5.5/6.0mm system. This is dependant on surgeon's choice.

For detailed instructions regarding the use of the mentioned systems and/or procedures, please refer to their respective surgical techniques.

INTERBODY OPTIONS

A LARGE CHOICE OF INTERBODY SYSTEMS IS AVAILABLE



ARTiC-L™ 3D TI Spinal System

- TiONIC™ technology
- Roughened titanium surface
- Internal articulation for inserter attachment
- Lordotic angles = 5°, 10° and 20°

AVILA™ Interbody Fusion Device

- Dual convexity to maximizing cage-endplate contact surface and primary stabilization
- Anti-back out teeth for expulsion resistance
- Large lateral window to assess fusion

Capstone™ Family Spinal Systems

- Capstone PEEK™ has modulus of elasticity similar to bone
- Capstone Ti™ to allow for bony attachment
- Capstone PTC™ with roughened surface for increased surface area and coefficient of friction

GRAFT PLACEMENT

Bone graft must be used when implanting the construct.

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 44)**.

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 44

EXTENDERS ALIGNMENT

Begin the Rod insertion step by rotating the Tab Extenders, as needed, until the Rod slots are aligned for Rod passage **(Figure 45)**.

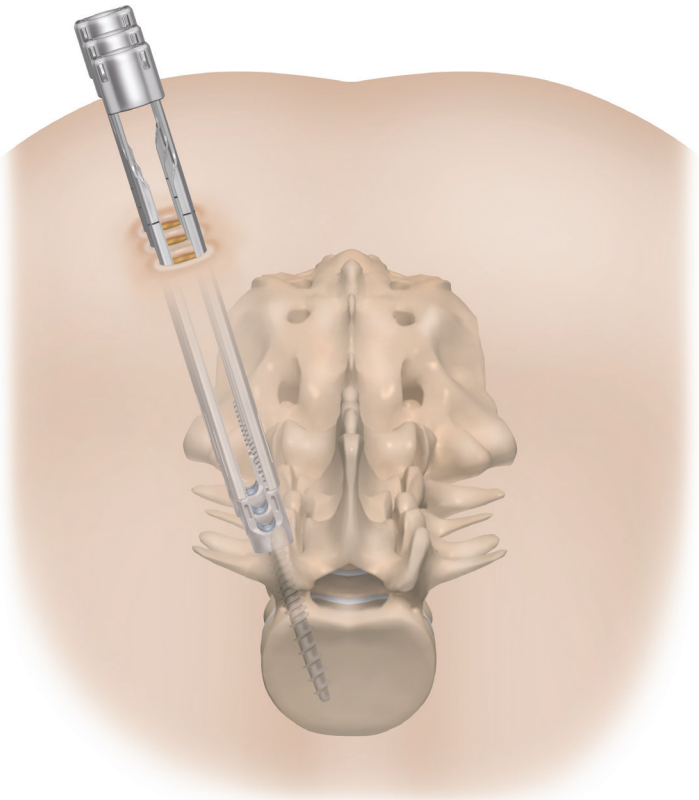


Figure 45

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 46a)**. Next, lift the clasp further to open the primary lock stage **(Figure 46b)**. 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 46c)**. 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.

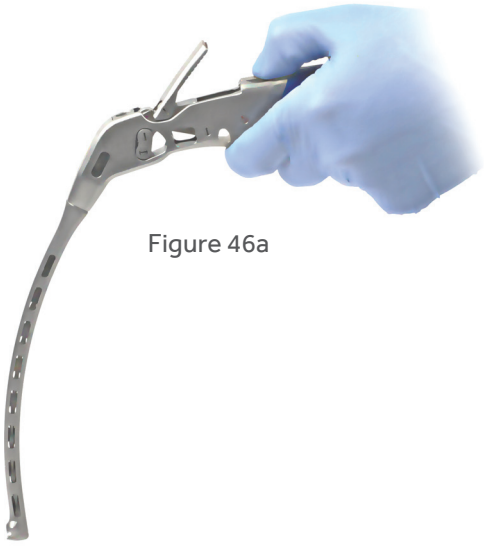


Figure 46a

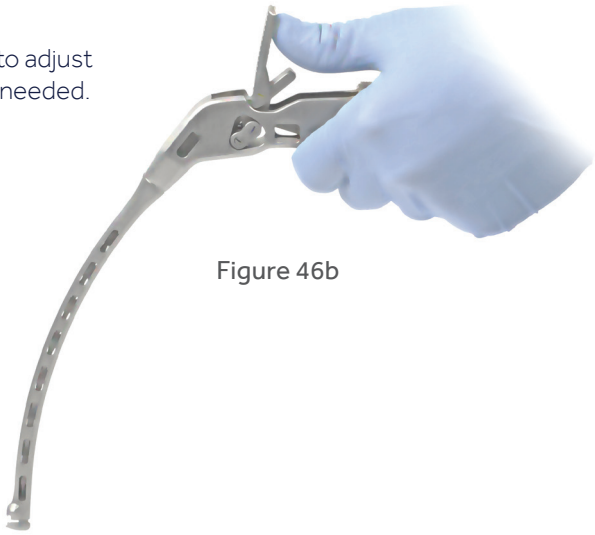


Figure 46b

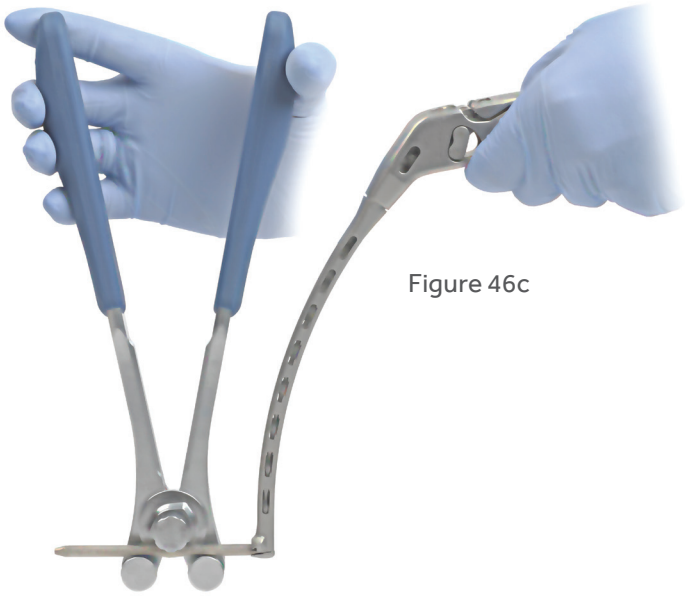


Figure 46c

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 47)**. Use AP and lateral fluoroscopy as necessary in combination with tactile and visual feedback to find the path through the remaining Extenders.

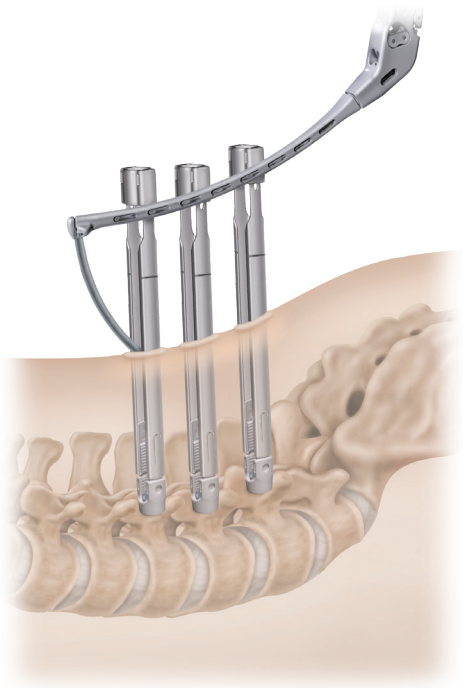


Figure 47

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.

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 48a)**. A sliver of Rod should be visible from the most caudal Screw of the construct on fluoroscopy **(Figure 48b)**.

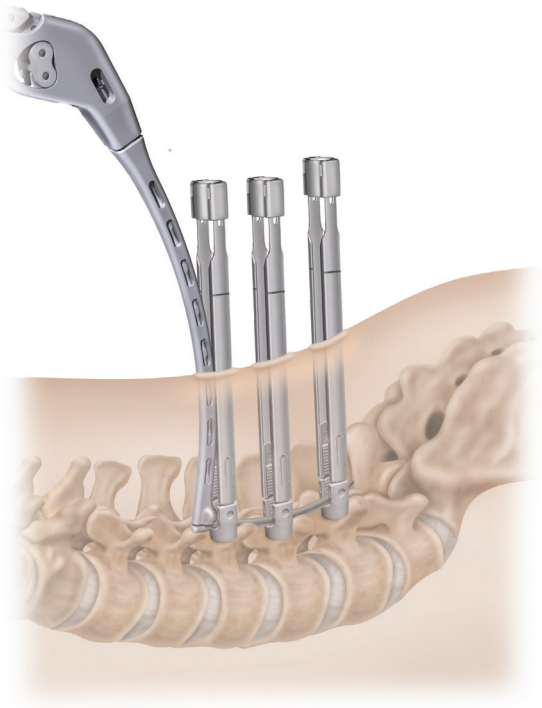


Figure 48a

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 recognised the Rod may not reduce into the Screw.

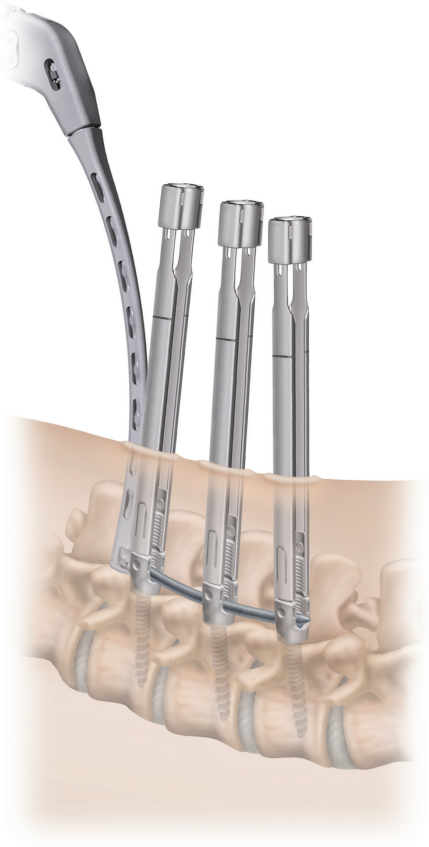


Figure 48b

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 49)**.

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 50)**.

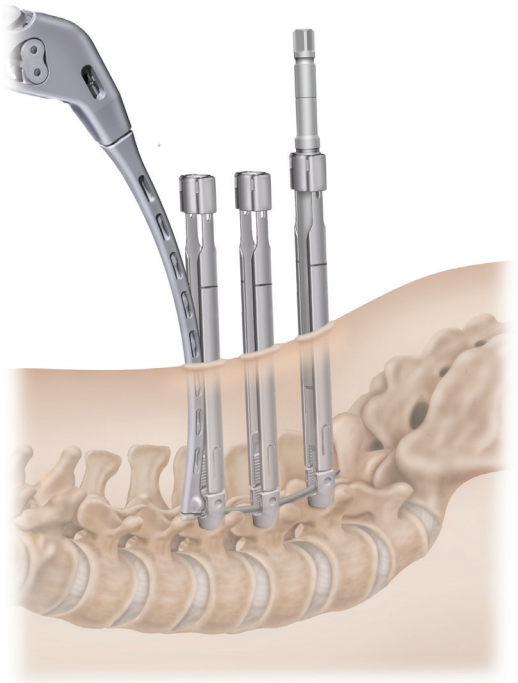


Figure 49

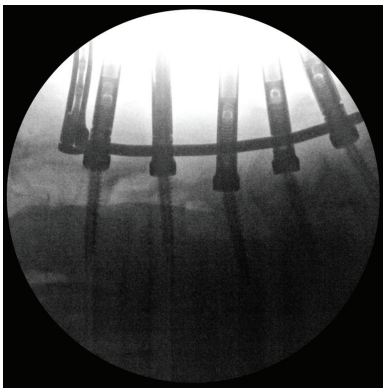


Figure 50

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 51a)**. 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 51b)**

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 51a

Figure 51b

Pass the Rod into the openings on the top of the Tab Extenders **(Figure 52a)**. Align Rod so the End Caps of the Rod extend to both sides of the Tab Extenders **(Figure 52b)**. Push Rod down to fully seat in the Screw Heads **(Figure 52c)**. Rod confirmation can be made using fluoroscopy **(Figure 53)**.

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.

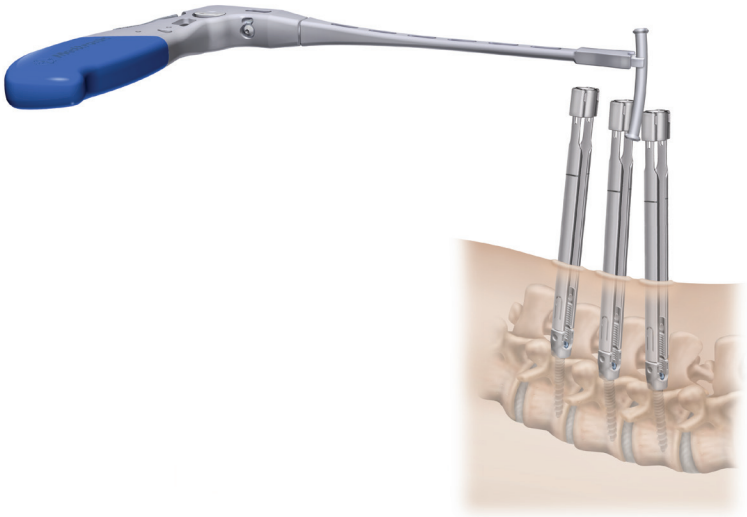


Figure 52a

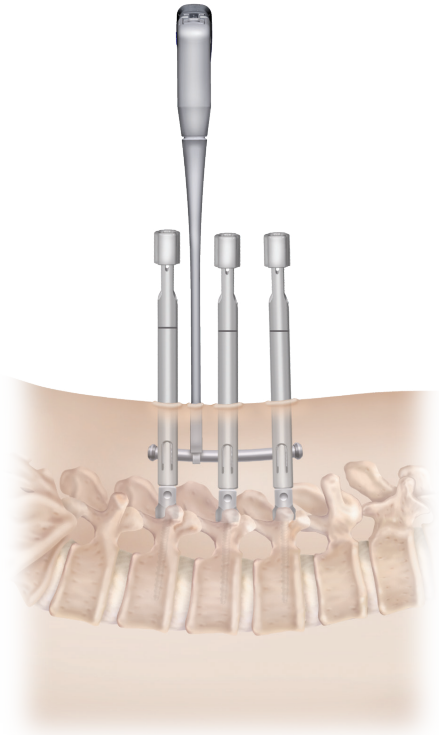


Figure 52b

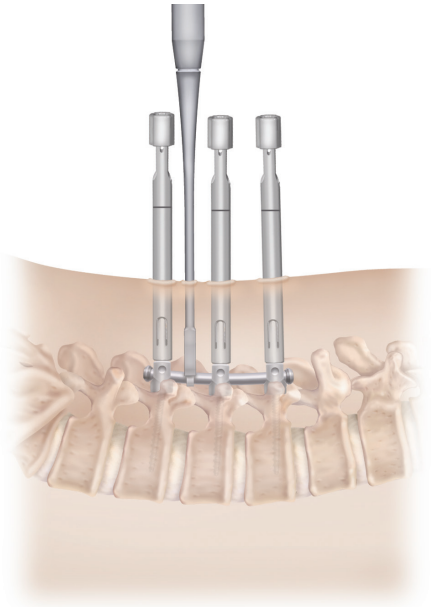


Figure 52c

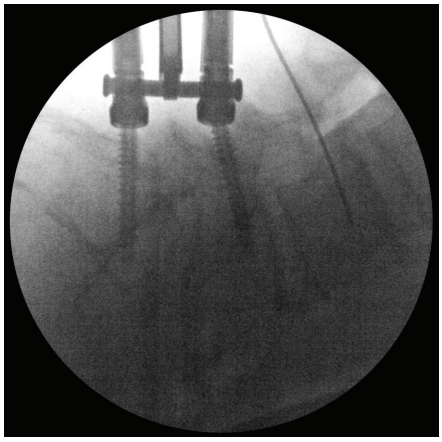


Figure 53

OPTIONAL ROD REDUCTION

If needed the Rod Reducers **(Figure 54)** 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 55a)**.

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 55b)**.

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

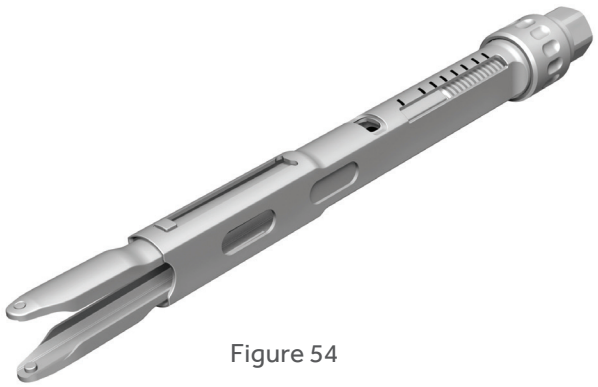


Figure 54

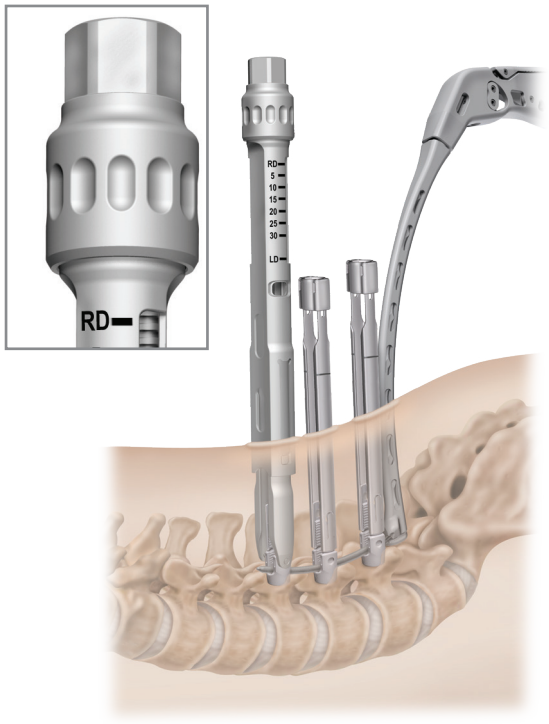


Figure 55a

Figure 55b

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 56)**. While pushing the button, insert the Set Screw on the distal tip of the Set Screw Retaining Driver **(Figure 57)**. 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.

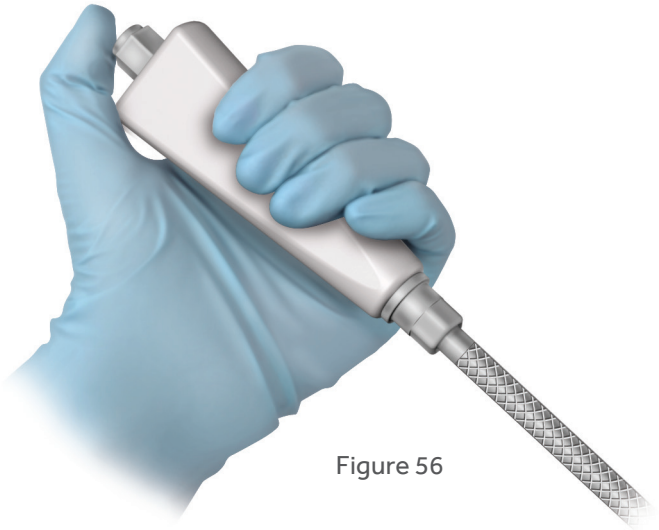


Figure 56

Figure 57

SET SCREW INSERTION

Provisionally tighten the Set Screws by inserting the Set Screw Assembly down the Tab Extenders **(Figure 58)**.
If the black line on the Set Screw Retaining Driver is visible, the Rod is not fully seated **(Figure 59)**.

Provisionally tighten all Set Screws to secure the Rod.

Figure 58

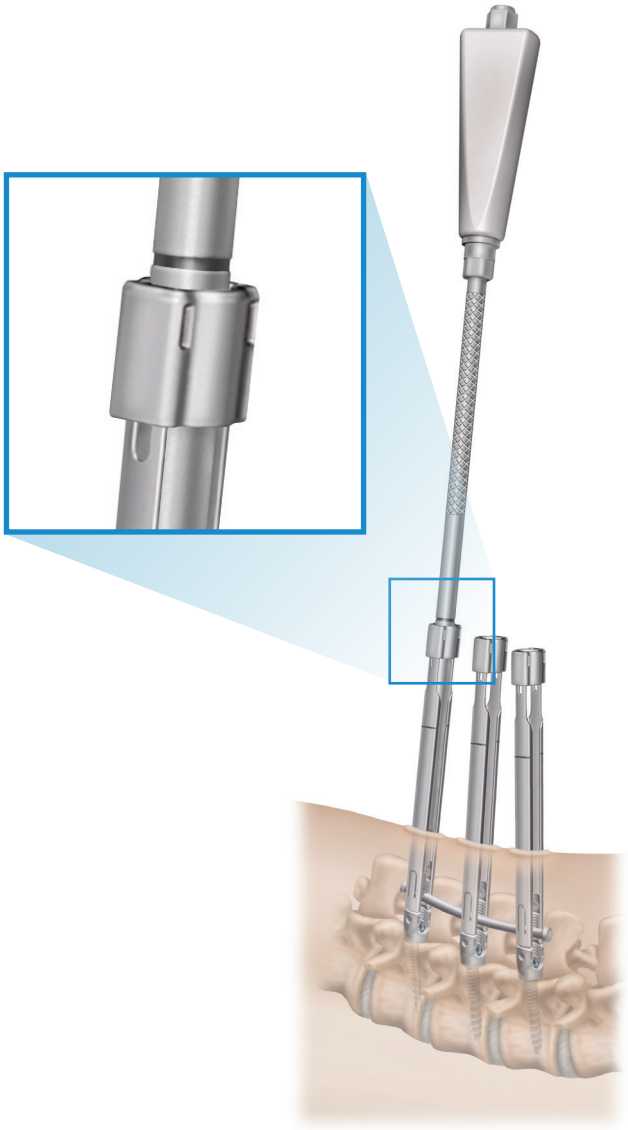


Figure 59

Compression with the Pliers

Another 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 60)**. 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 61)**.

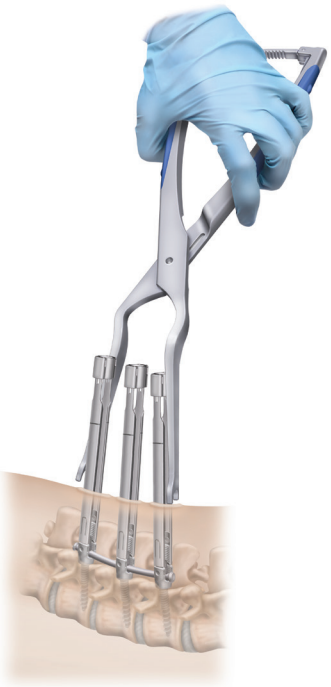


Figure 60

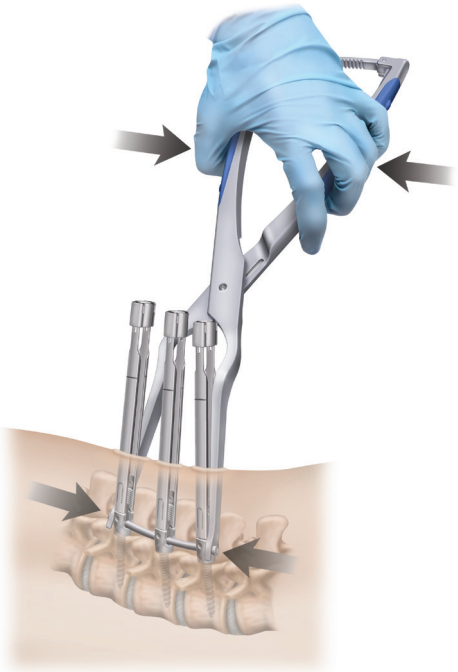
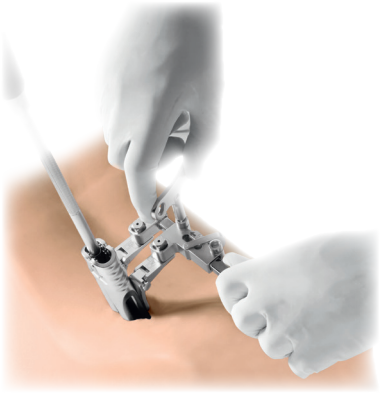


Figure 61

Compression with Space-D™ Distractor / Compressor System

If **Space-D™** system was mounted onto the Voyager™ 5.5 Extenders for interbody access and preparation, it can be used to achieve segmental compression. Refer to the MAST™ Degenerative Fusion Platform surgical technique for guidance regarding this step.



SET SCREW FINAL TIGHTENING
INSERTION AND BREAK-OFF

Once the Rod has been reduced and/or compression or distraction has been achieved and all implants are securely in place, final tightening may be performed. It is preferred that compression be released just prior to the Set Screws being broken off or final tightening. This technique will help ensure that the Implant Head and Rod are normalised to one another and allow for the Rod to be fully seated in the Implant Head during the final tightening step. Once these maneuvers are performed, the Set Screws should be broken off.

If the Rod Reducer is being used, position the Rod Reducer Counter Torque around the Rod Reducer **(Figure 62)**. Insert the Set Screw Driver into the Rod Reducer and ensure it is fully engaged with the Set Screw by gently pulling upward. The Break-Off Handle should be attached to the Set Screw Driver to facilitate the final break-off of the Set Screw. Tighten Set Screw to break-off. Once the Set Screws are broken off the Rod Reducer can be removed from the Extender Assembly by unlocking it.

The Ring Counter Torque is used with the Extenders and Caps for final tightening. Slide the Ring Counter Torque over the Extenders **(Figure 63)** and position the bottom portion around the Screw Head and the top portion around the Cap **(Figure 64)**. The Break-Off Handle should be attached to the Set Screw Driver to facilitate the final break-off of the Set Screw. Tighten Set Screw to break-off. Once the Set Screw is broken off the Ring Counter Torque can be removed.

Note

Do not push the button on the top of the Set Screw Retaining Driver Handle until it is completely removed from the Extender as this will release the Set Screw Retaining Driver Handle while pushing in the button on the top of the handle to reconnect the Set Screw.

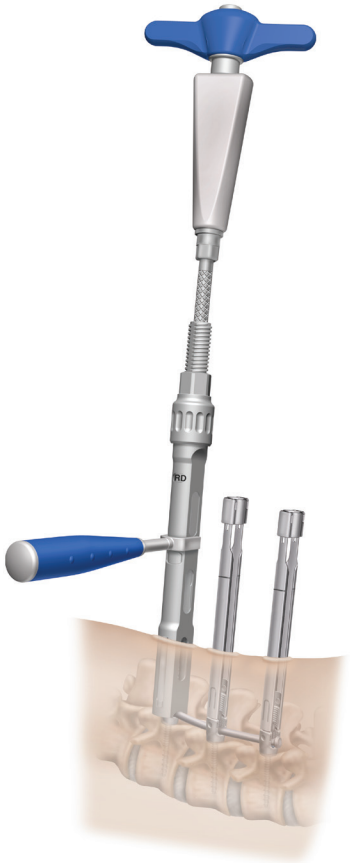


Figure 62

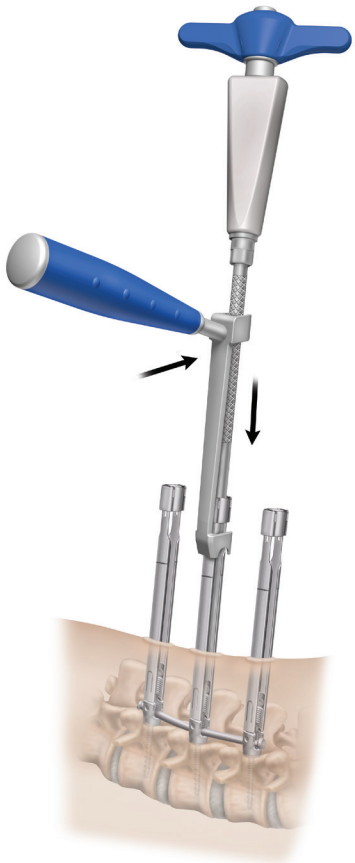


Figure 63

Figure 64

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 65)**. 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 66)**.

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.

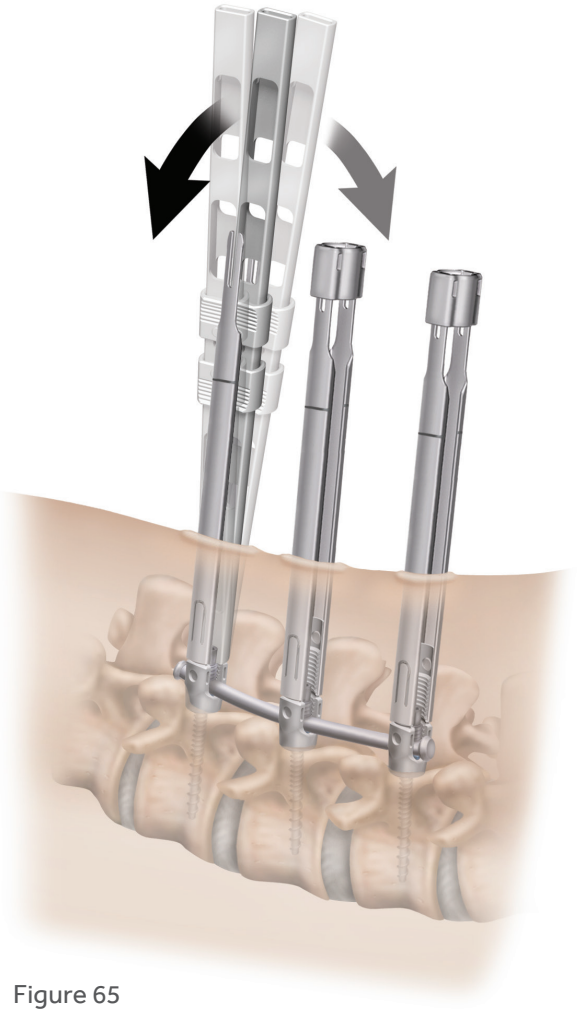


Figure 65

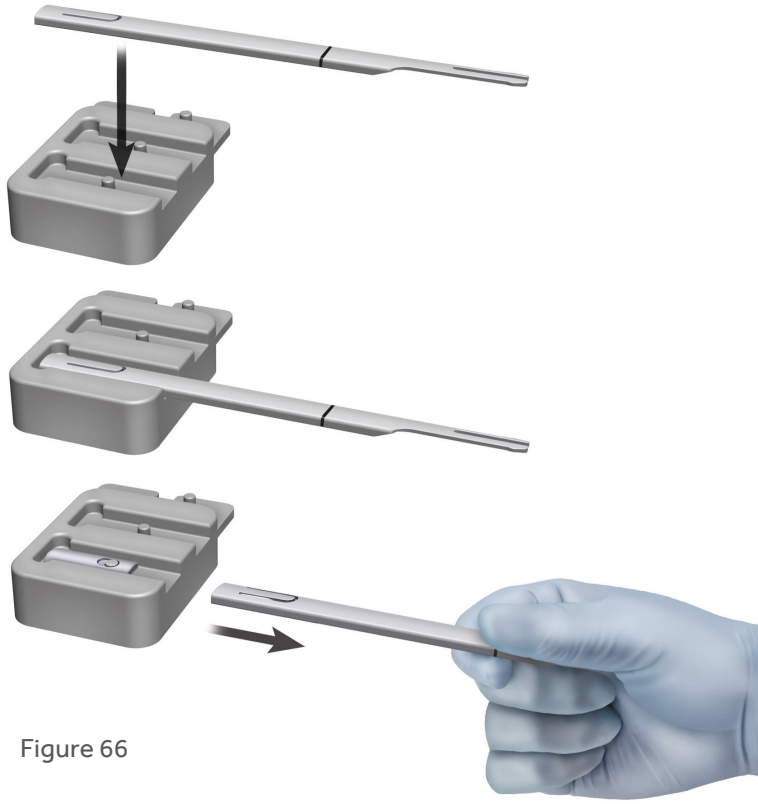


Figure 66

To remove the Tab Extenders from an unused Tab Extender Screw Assembly, use the side portion of the Break-Off Removal Tool **(Figure 67)**.

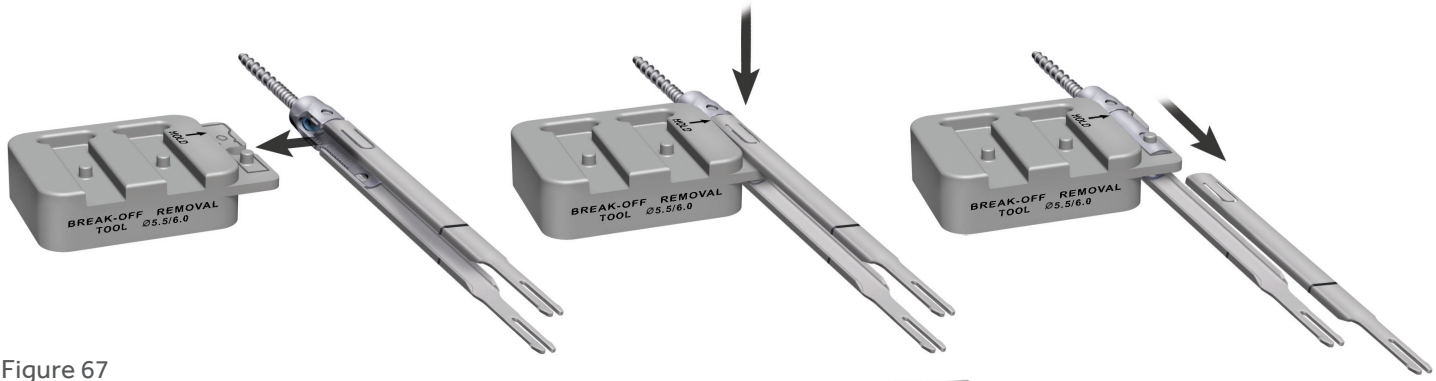


Figure 67

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 68)**.

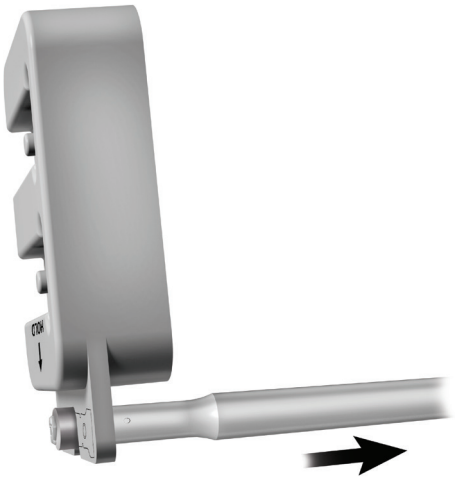


Figure 68

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 69)**.

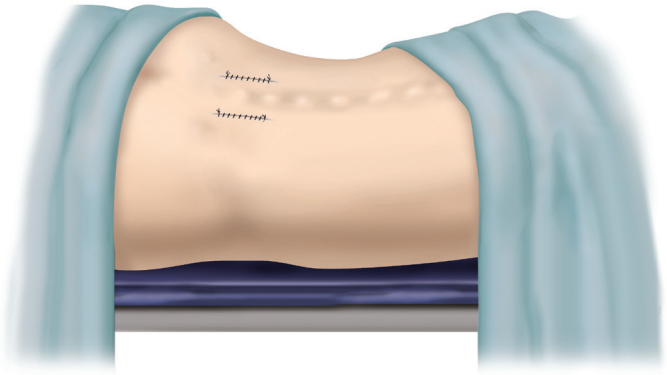


Figure 69

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.

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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.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.com.

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