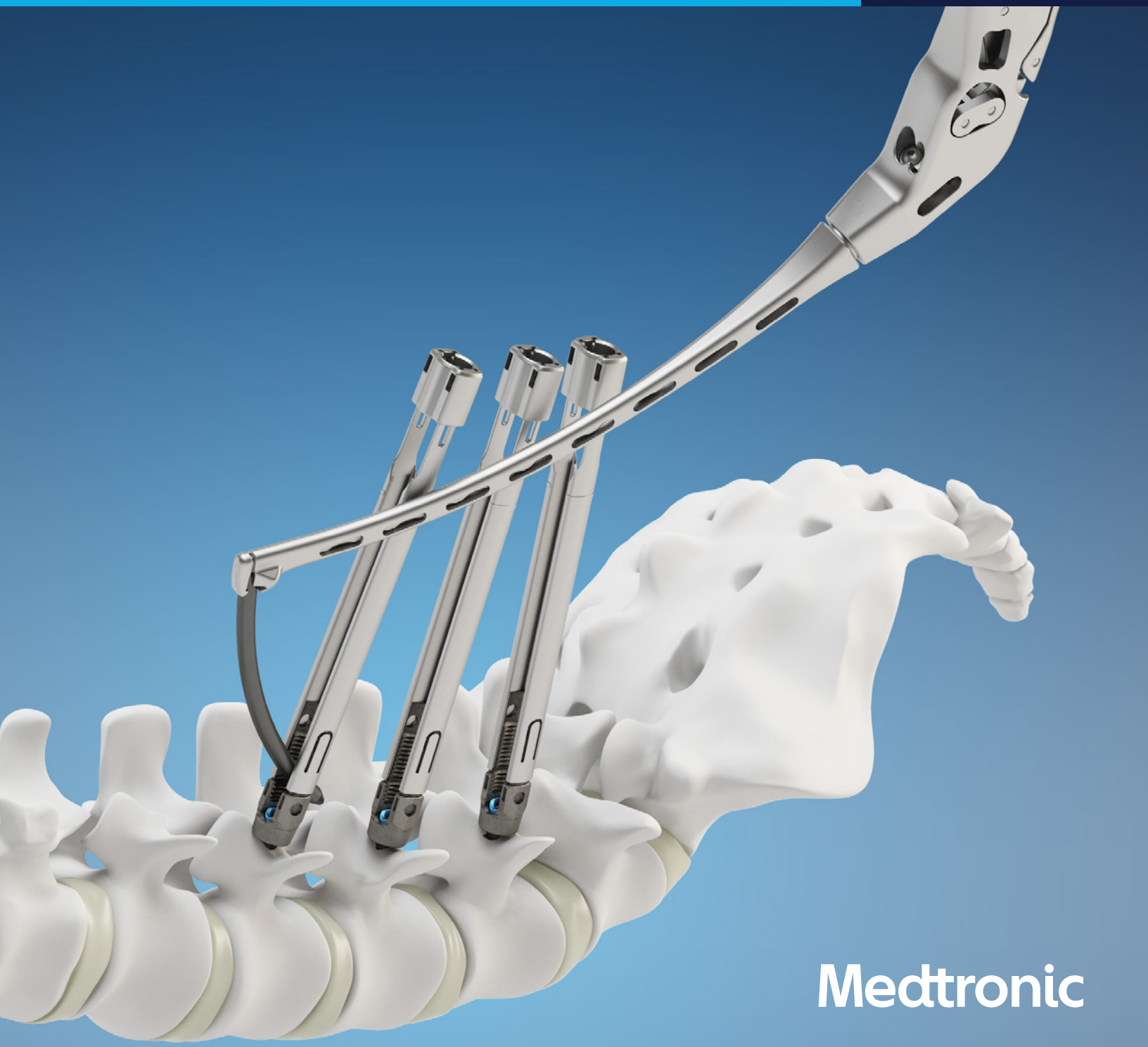
CD HORIZON™ SOLERA™ VOYAGER™ 4.75 SPINAL SYSTEM

SURGICAL TECHNIQUE



Medtronic

MICHELSON TECHNOLOGY AT WORK

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Set Screw Driver

(6642002)

Multi-Axial Screw Retaining Driver

(6640008)

Rod Template

(6642011)

Pliers Compressor

(6642017)

Compressor/Distractor Arm A

(6642000)

Compressor/Distractor Arm B

(6642001)

One-step Inner Dilator

(6642014)

One-step Small Outer Dilator

(6642015)

Cannulated Taps

(4.5mm 5484845)
(5.5mm 5484855)
(6.5mm 5484865)
(7.5mm 5484875)
(8.5mm 5484840)

Break-Off Removal Tool

(6642012)

Self-Drilling Taps

(4.5mm to 5.5mm 5484885)
(5.5mm to 6.5mm 5484887)

Quick-Connect
Ratcheting Egg Handle

(9098120)

T25 Removal Driver

(815-518)

Tab Breaker

(6642013)

Extender Cap

(6642006)

Tab Extender

(6642007)

4.75mm Non-Retaining Screwdriver

(6640005)

4.75mm Ball-Ended Driver

(6640004)

PAK Needle

2 Bevel Tips (PK1001)

2 Trocar Tips (PK1002)

1 Trocar/ 1 Bevel Tip (PK1003)

Rod Confirmation Tool

(6642010)

Reusable Handle

(6640020)

NIM™ Pedicle Access Needle

(9450020)

Guidewires

Sharp (8670002)
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Rod Gripper

(6642009)

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Ratcheting T-Handle

(7579000)

Countertorque

(6642004)

Percutaneous Inserter

(9010000849)

Rod Pusher

(6642008)

T-Handle

(7570090)

Navigated MAS Retaining Driver

(NAV6640009)

IMPLANTS

4.75mm CD Horizon Solera Voyager
Capped Rod

4.75mm CD Horizon Solera Voyager
Perc Rod

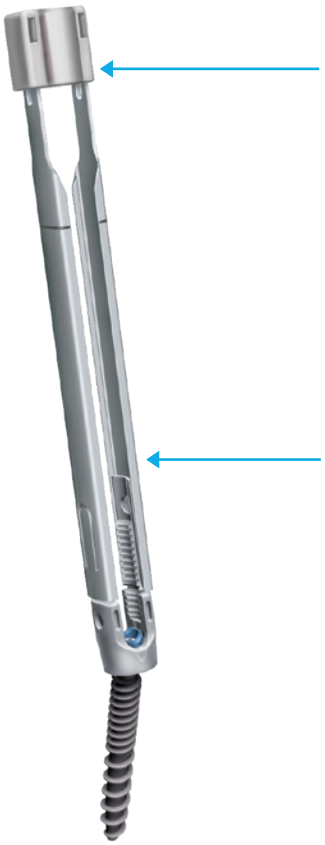
Set Screw

(6440530)

4.75mm CD Horizon
Solera Voyager
Extended Tab
Cannulated
Multi-axial Screw

4.75mm 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

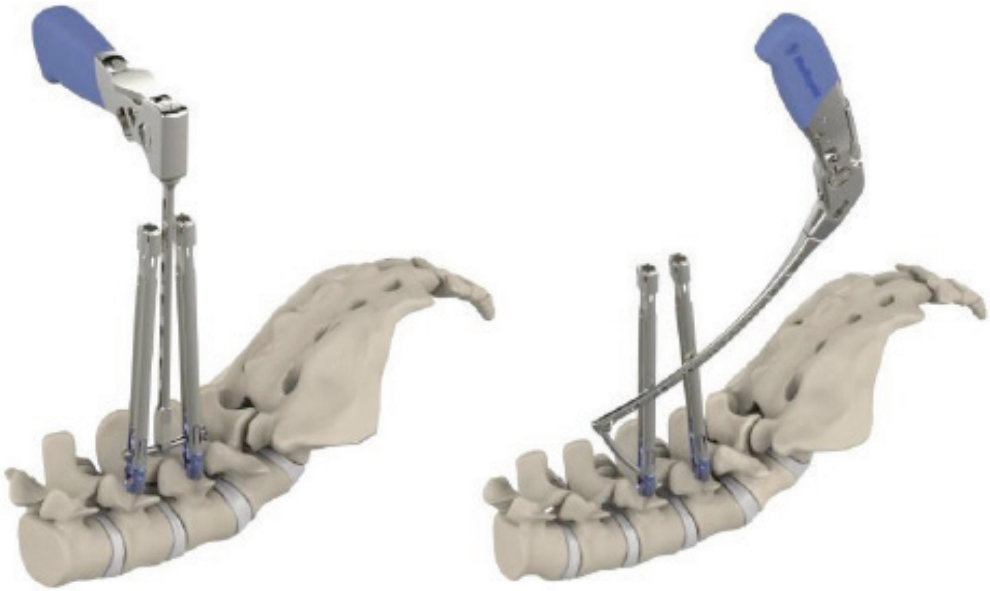
Dual lead thread form offers enhanced fixation

4.75mm CD Horizon Solera Voyager Extended Tab Cannulated Multi-axial Screw

4.75mm CD Horizon Solera Voyager Extended Tab ATS Multi-Axial Screw

Two Rod Insertion Methods:

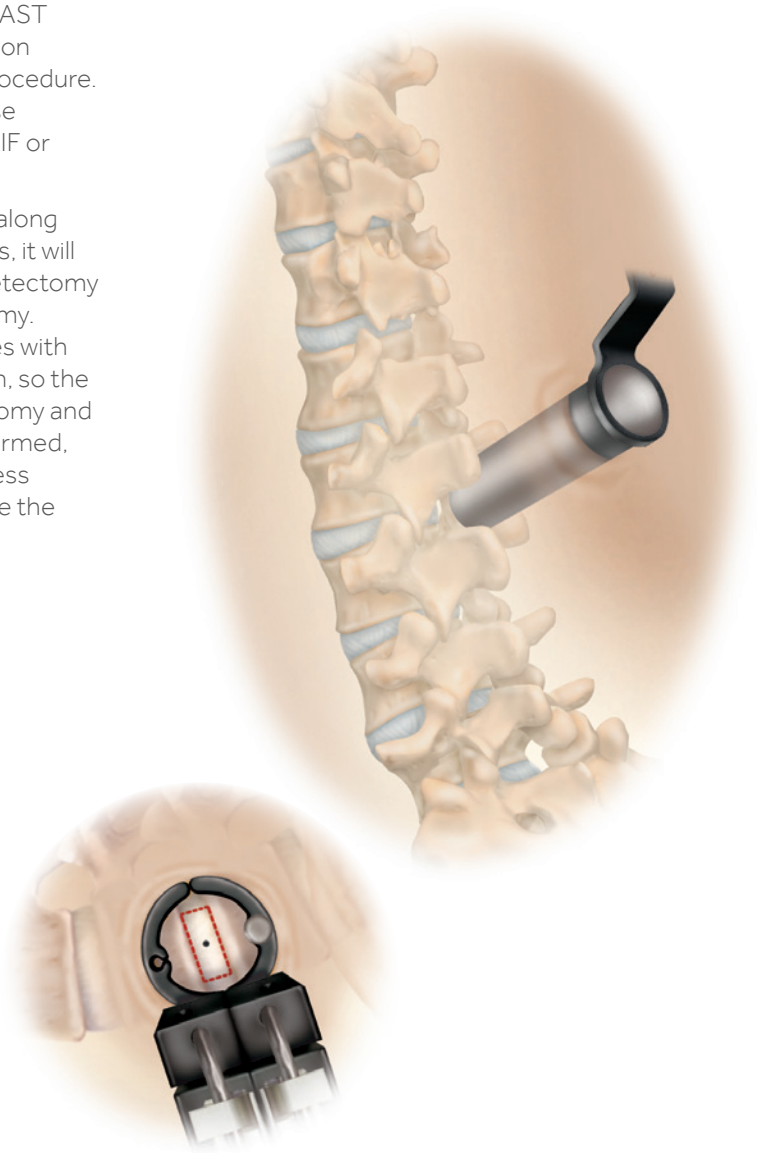
- Mini-Open
- Percutaneous



INTERBODY ACCESS AND PREPARATION

Initial access to the surgical site can be performed with the METRx™ II System, METRx X-Tube™ System, MAST Quadrant™ System, Oblique Lateral Interbody Fusion (OLIF) or Direct Lateral Interbody Fusion (DLIF) Procedure. For detailed instructions regarding the use of these systems, refer to the METRx II System and the OLIF or DLIF surgical techniques.

Perform either unilateral or bilateral facetectomy along with total discectomy. By releasing these elements, it will help to reduce the spondylolisthesis. Bilateral facetectomy will create more mobility than unilateral facetectomy. 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. Once the discectomy has been performed, placing a distractor in the disc space will allow access for final end plate preparation and will also facilitate the reduction of the spondylolisthesis.



PREOPERATIVE PLANNING AND SET UP

Preoperative planning can be useful in determining the proper starting point and screw trajectory. An axial view demonstrates the distance lateral to the pedicle initially taken through the skin **(Figure 1)**.

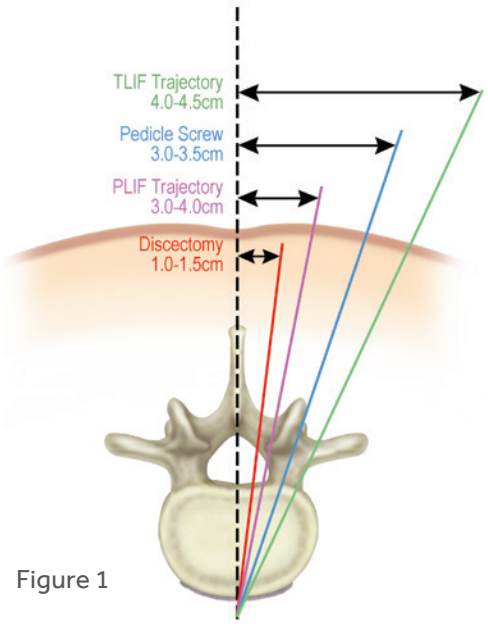


Figure 1

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. A longer prep area is also necessary for intraoperative flexibility.

When using the Cd Horizon Solera Voyager Spinal System, the patient should be positioned prone, lying flat on the table, or in the lateral position **(Figure 2a)**. Either a radiolucent frame or chest rolls may be used, but a knee-to-chest position should be avoided. Verify adequate fluoroscopic images of the pedicles can be obtained in both an AP and lateral view before proceeding **(Figure 2b)**. To adequately view the S1 pedicle, a Ferguson view presents the best image.

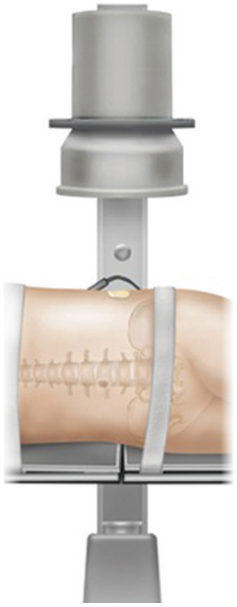


Figure 2a

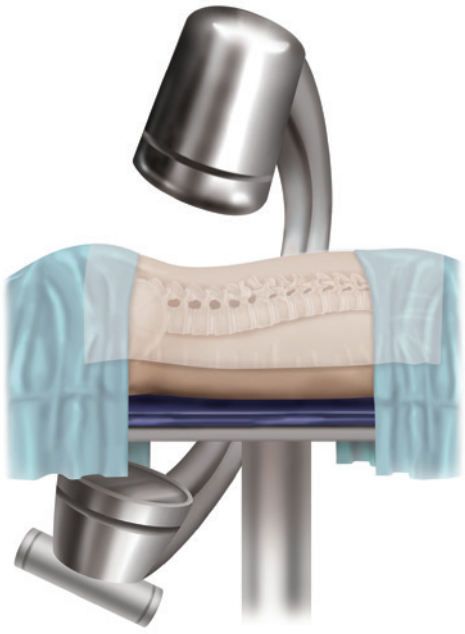
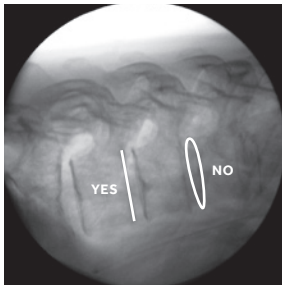


Figure 2b

Important
On lateral 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)**.

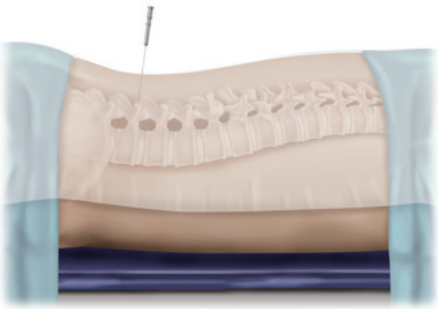


Figure 3a

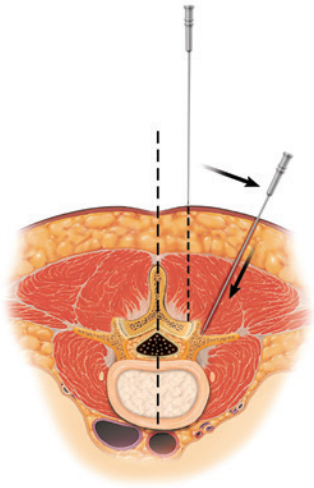


Figure 3b

Important
The skin incision is slightly lateral to the pedicle 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**).

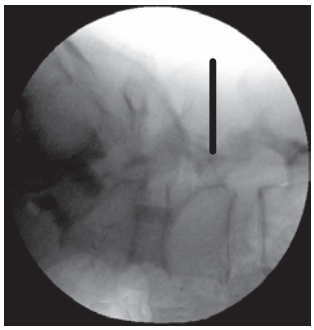


Figure 4a

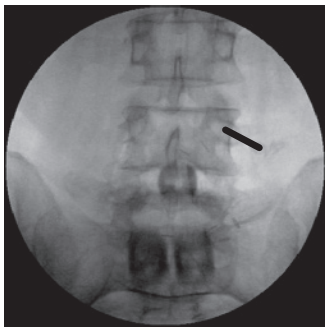


Figure 4b

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 a mini-open rod insertion method, make the stab incision over the pedicle. Once the pedicle has been identified, sweep the PAK Needle to the adjacent pedicle. This step will create a pathway through the muscle plane and allow 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)**.

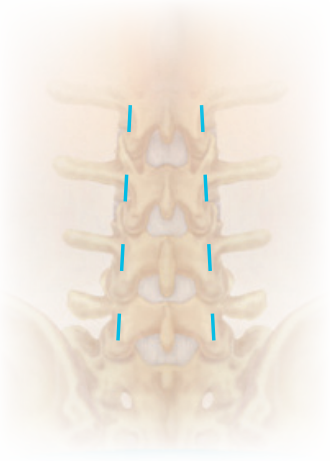


Figure 5a

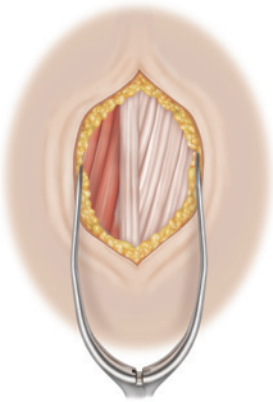


Figure 5b

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 6)**.

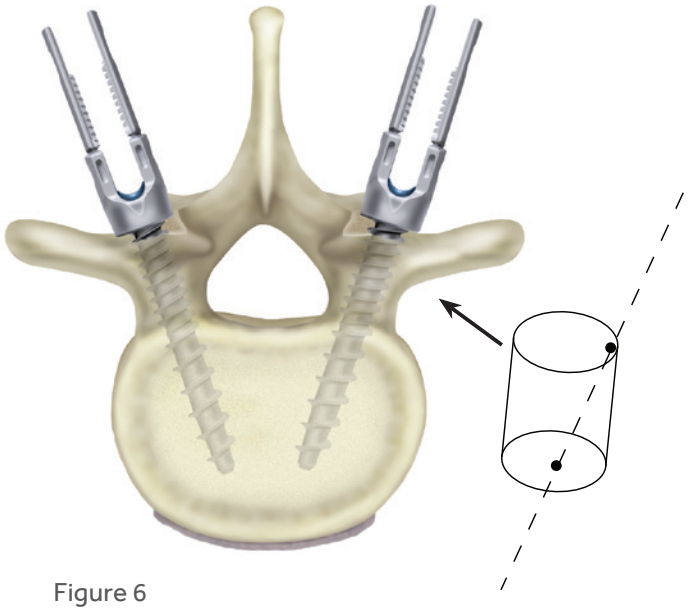


Figure 6

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

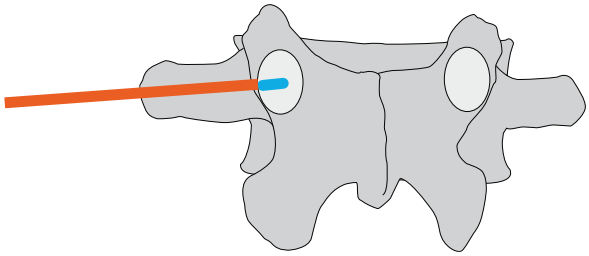


Figure 6a

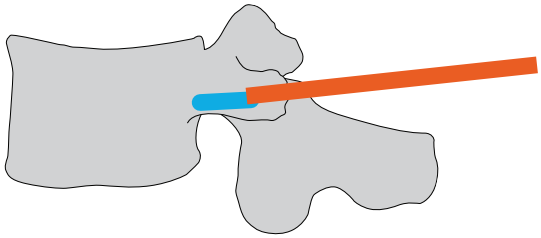


Figure 6b

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 **(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 **(Figure 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.

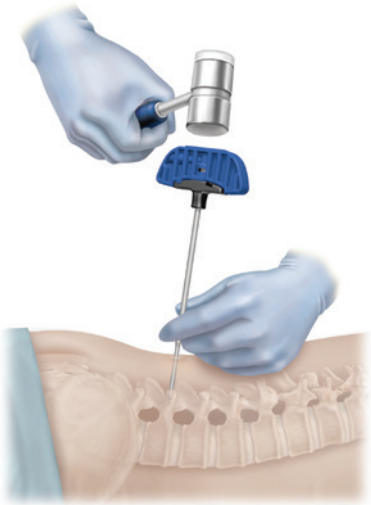


Figure 7

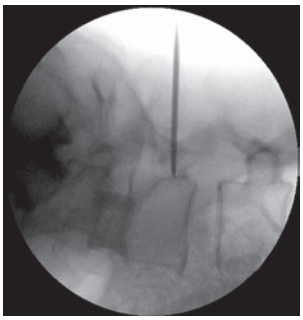


Figure 8a

Figure 8c

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

Care should be taken so the needle is not too medial. This avoids breaching the medial wall when tapping or inserting the Screw.

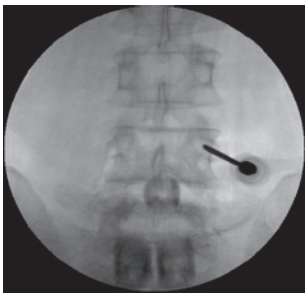


Figure 8b

Figure 8d

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.

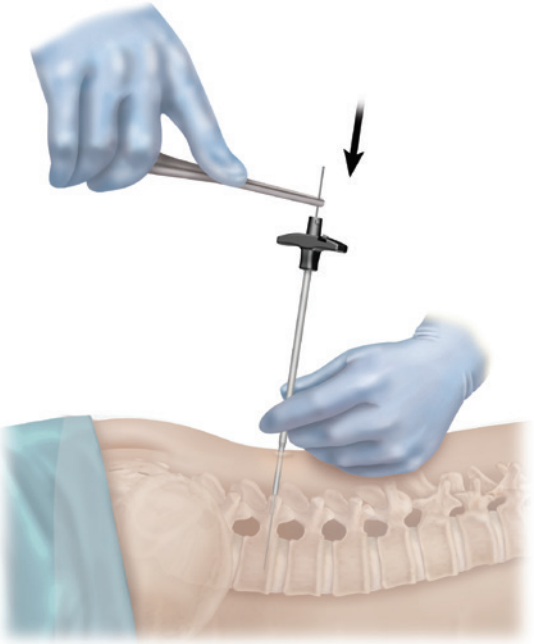


Figure 9a

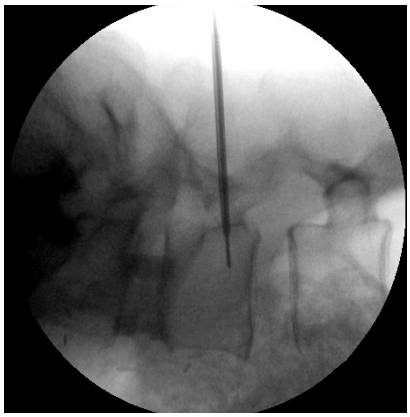


Figure 9b

Dilating the Fascia

The fascia and muscle must be dilated to allow for screw placement.

Assemble the One-Step Dilator by inserting the One-Step Inner Dilator into the One-Step Outer Dilator **(Figure 10)**. Dilate the tissue by inserting the assembled One-Step Dilator. The One-Step Dilator should be docked on bony anatomy to minimize tissue creep **(Figure 11)**.

The inner dilator is then removed leaving the Outer Dilator to serve as a tissue protective sleeve during the tapping step **(Figure 12)**.

Important
Incise the skin to allow for dilation of the One-Step Outer Dilator - approximately 15mm.

Note
The One-Step Dilator is a multi-use instrument.

Figure 10

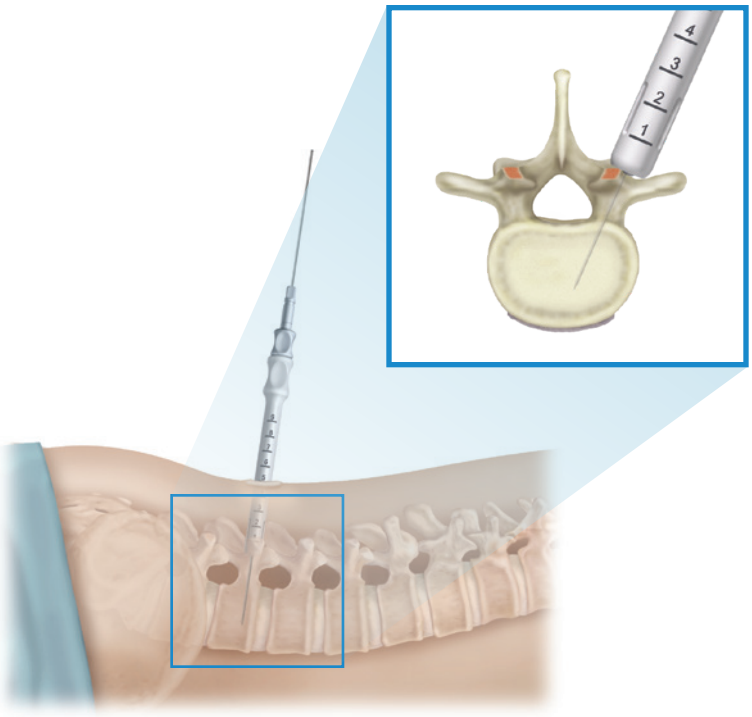


Figure 11

Figure 12

PEDICLE
PREPARATION

The pedicle is prepared by placing the Tap over the Guidewire and through the One- Step Outer Dilator **(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 and can be helpful.

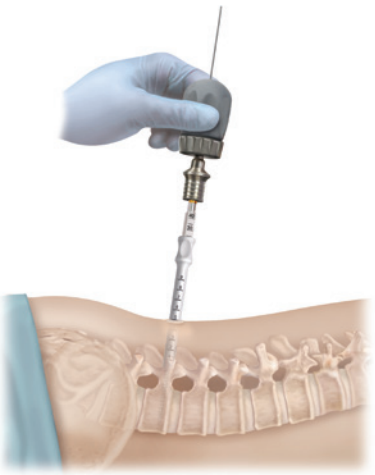


Figure 13

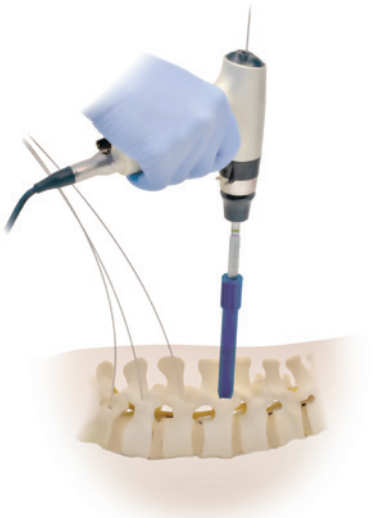


Figure 14

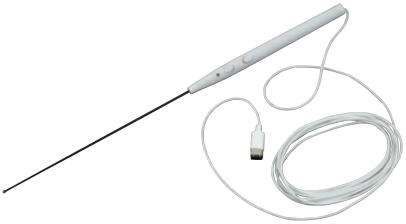


Figure 15

Figure 16

Screw length can be estimated by referencing the depth marks on the Tap with the rim of the One-Step Outer Dilator **(Figure 17)**. To ensure accuracy, the One-Step Outer Dilator 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 (straight) Guidewire.

Important

Care should be taken when removing the One-Step Outer Dilator.

Figure 17

EXTENDER, CAP, AND **SCREW ASSEMBLY**

Before a screw can be inserted into the pedicle, the Tab Extenders (6642007) and Cap (6642006) **(Figures 18a and 18b)** must be assembled with the Multi-Axial Extended Tab Screws. To assemble the Tab Extenders, insert the Multi- Axial Extended Tab Screw Head into the Extenders until locked. With both Tab Extenders locked onto the Multi-Axial Extended Tab Screw Head, insert the Cap into the forked tips of the Tab Extenders.

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

Figure 18a

Figure 18b

SCREW
INSERTION

Insert the Cannulated Retaining Bonescrew Driver (6640008) 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 19)**.

Thread the Sleeve of the Retaining Driver into the head of the Screw before inserting over the Guidewire **(Figure 20)**.

The entire Screw Extender assembly is inserted over the Guidewire and into the pedicle **(Figure 21)**. 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 19

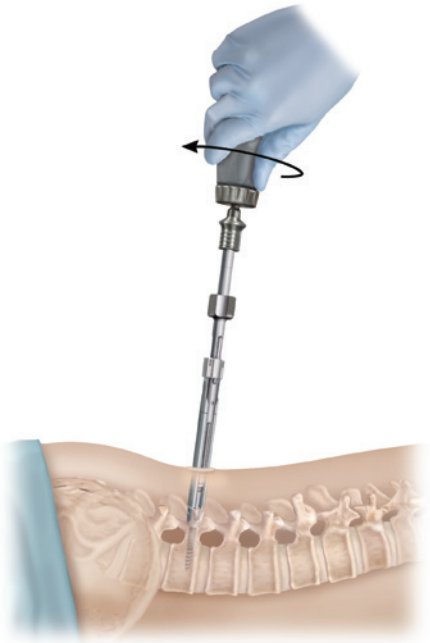


Figure 20

Note
If desired, the Guidewire may be removed from the pedicle once the Screw is in the vertebral body.

Note
The IPC Powerease System may be used for insertion of CD Horizon Solera 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.

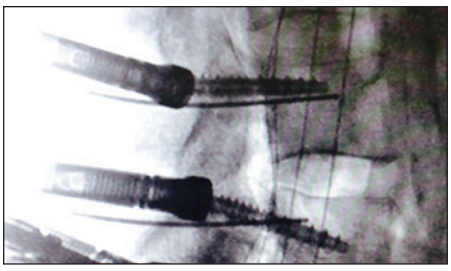


Figure 21

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 **(Figure 22)**. The assemblies should move freely following screw insertion.

If more advanced reduction capabilities are required on certain levels, it is possible to use CD Horizon Longitude II extenders with CD Horizon Solera 4.75mm cannulated screws in the same construct with CD Horizon Solera Voyager Spinal System **(Figure 23).** The CD Horizon Solera Voyager extenders are often ideal for use in the lower lumbar spine where the potential for high lordosis exists.

For detailed instructions on how to assemble and insert CD Horizon Longitude™ II extenders and sequential reducers, refer to CD Horizon Longitude II Spinal System surgical technique.

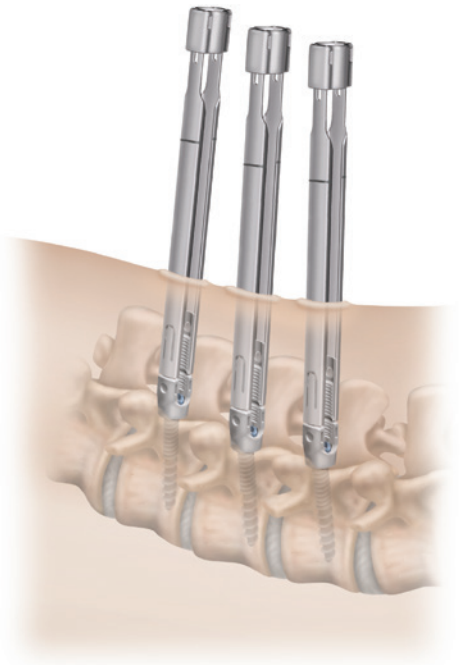


Figure 22

Hybrid Construct

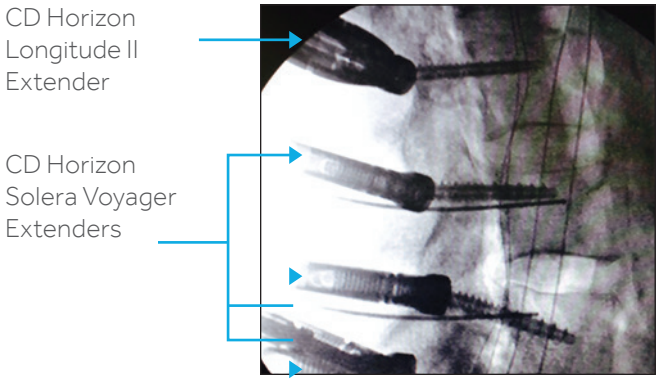


Figure 23

NAVIGATION

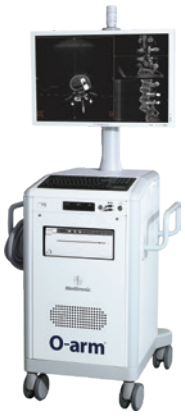
- Cannulated CD Horizon Solera Voyager 4.75 Extended Tab Multi-Axial Screws
- CD Horizon Solera Voyager 4.75 Extended Tab ATS Multi-Axial Screws

TECHNOLOGY
OVERVIEW

O-arm™ Image Acquisition System

O-arm Imaging System

Mobile Viewing Station



Main Cart

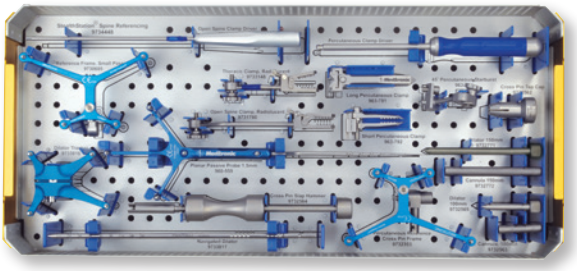
Camera Cart

StealthStation™ S8 Surgical Navigation

Navigated Stealth-Midas™ Powered Drilling System

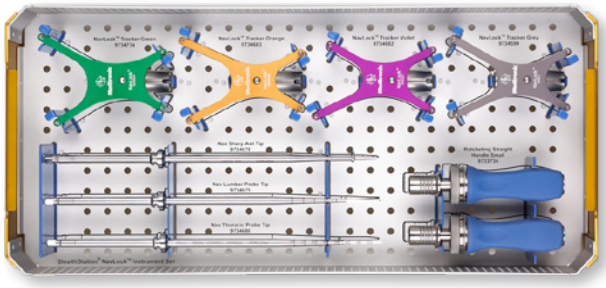
CD Horizon Solera Voyager 4.75 System

INSTRUMENTS
AND EQUIPMENT



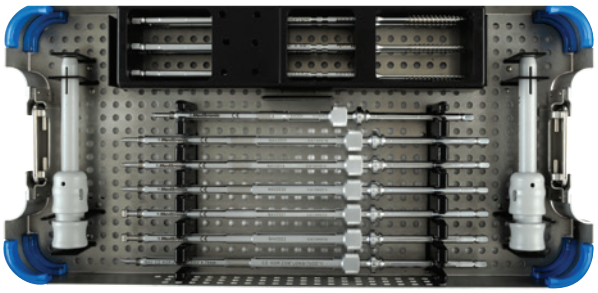
StealthStation™ Spine Referencing Set

(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 24)**. 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.

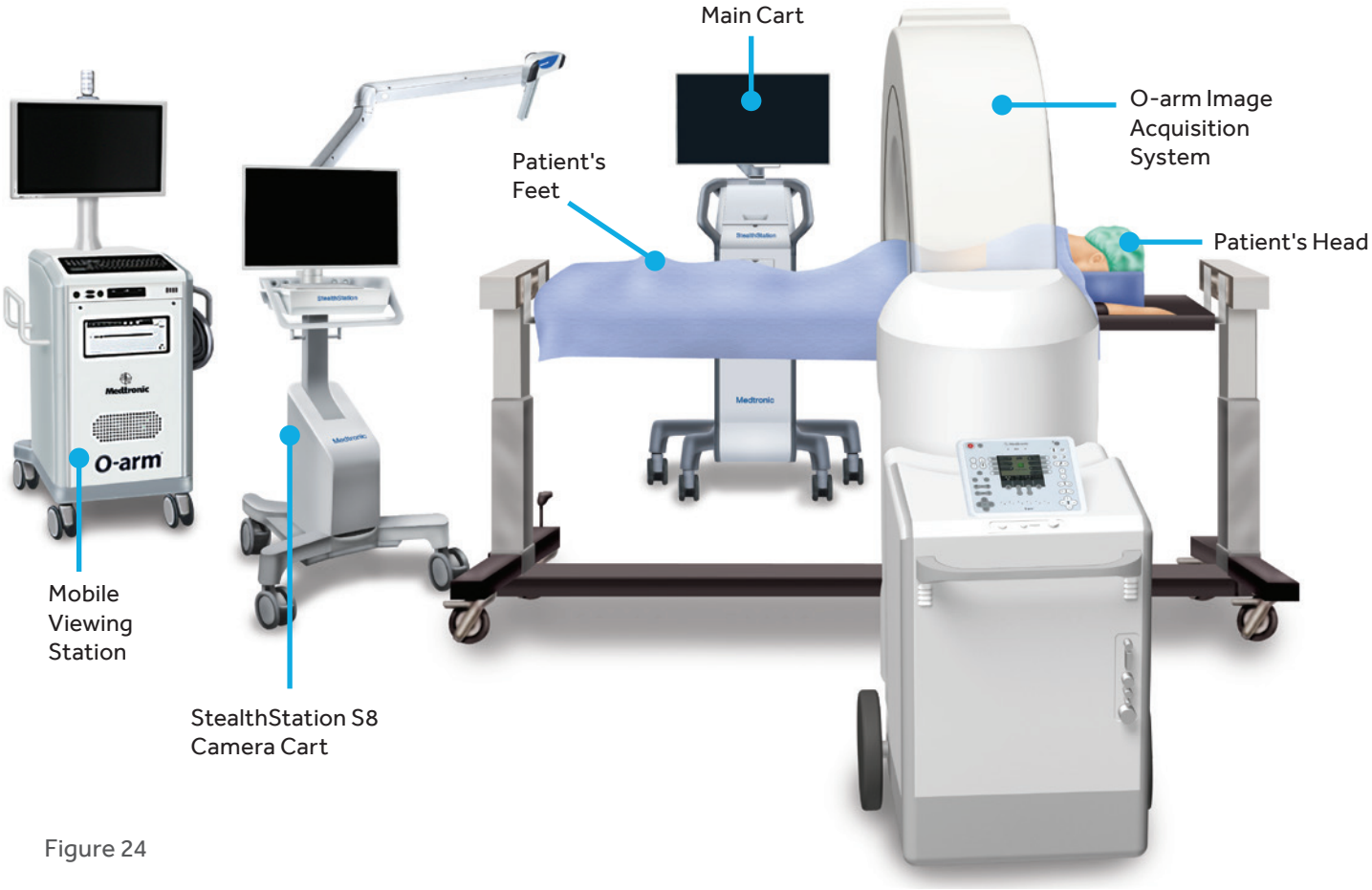


Figure 24

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 25a)**. 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 25b)**.

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.

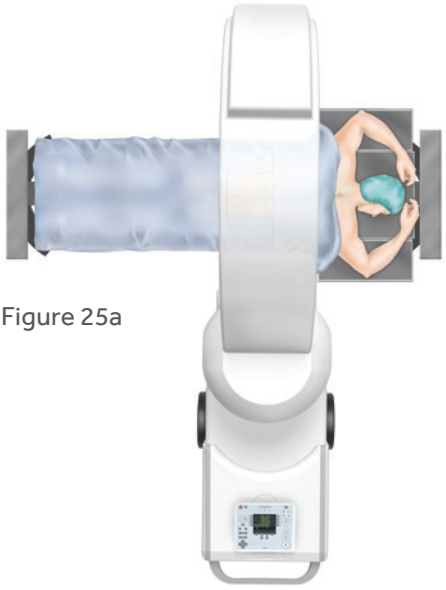


Figure 25a

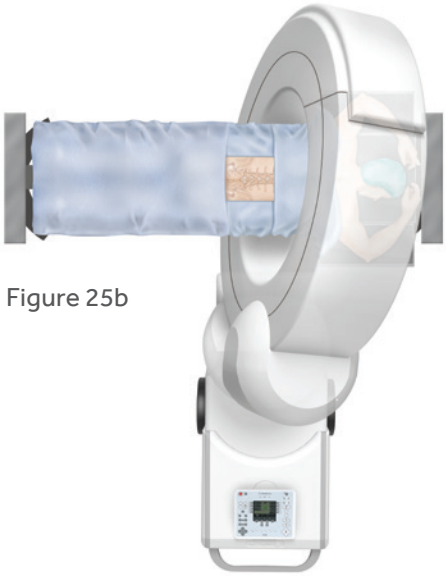
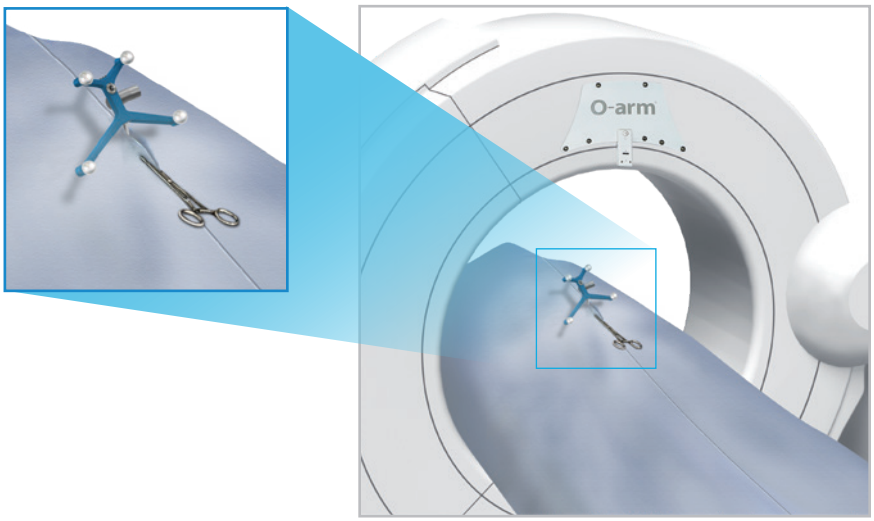


Figure 25b

Helpful Information

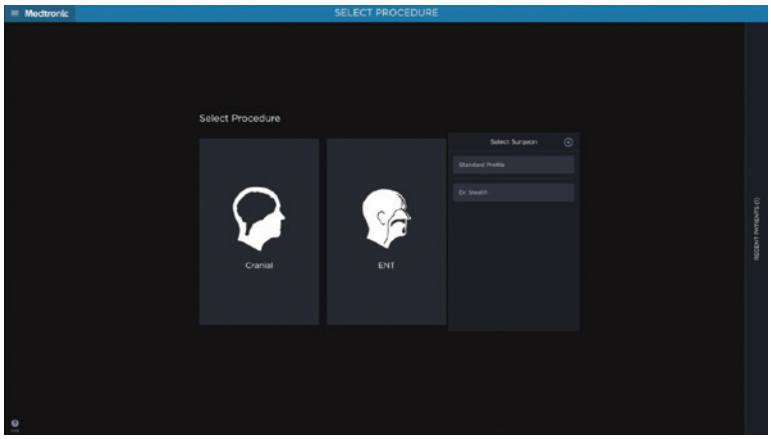
If the O-arm System will remain in the sterile field during the procedure, drape the O-arm System gantry using the O-arm IAS Sterile Tube Drape during the positioning of the system. If the O-arm System will be removed from the sterile field, place and clamp two half-drapes over the sides of the patient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



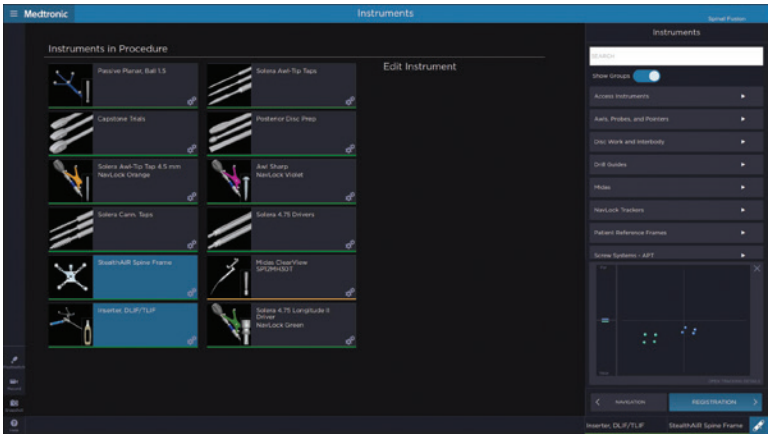
In the StealthStation S8 Spine Software, complete the "Select Surgeon" and then "Select Procedure" tasks. Continue through the software by completing the "Set-Up Equipment" and "Verify Instruments" tasks to reach the "Acquire Scan" screen.

StealthStation S8 Spine Software Workflow



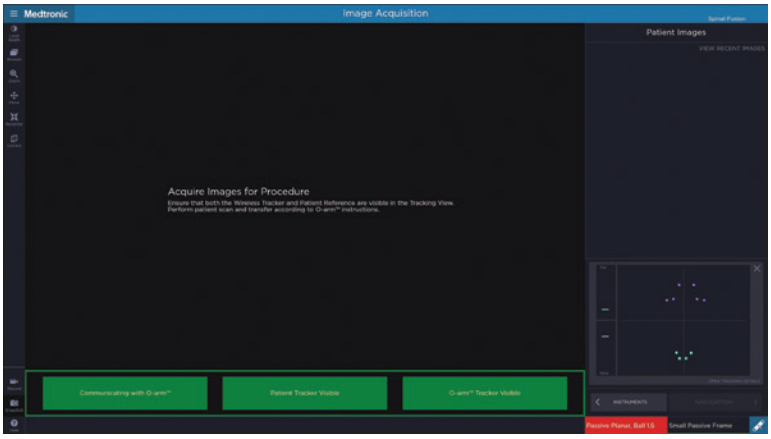
1. Select Procedure

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 26a)** 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 26b)**.

- 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.

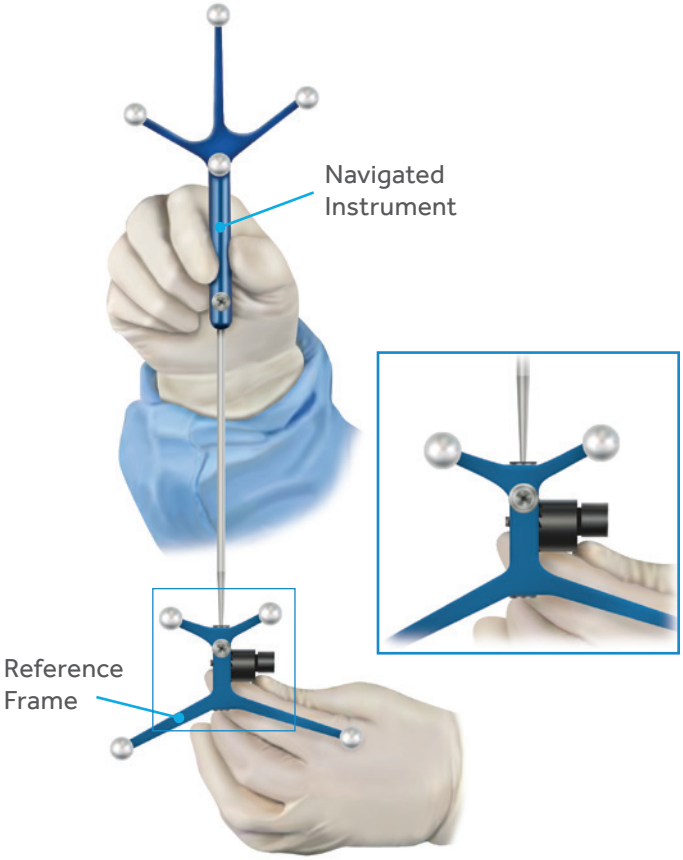


Figure 26a

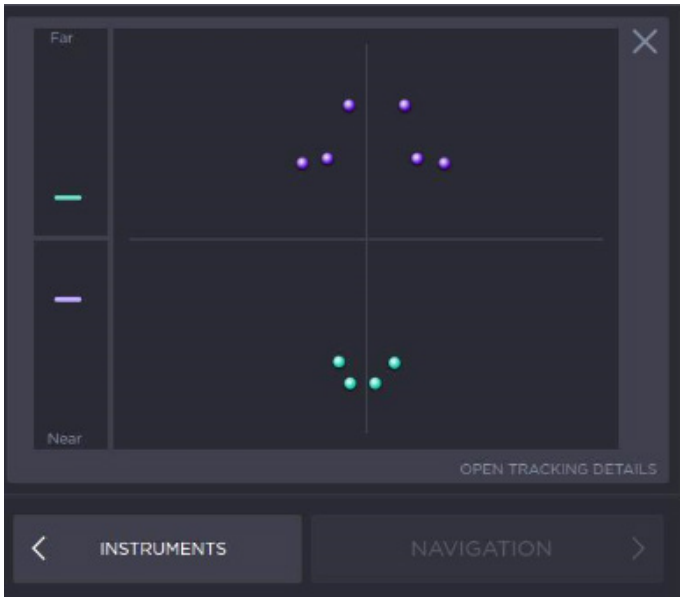


Figure 26b

REFERENCE FRAME PLACEMENT

When performing a Synergy TLIF™ 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 27a)**. 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 27b)**. Remove the Tap Cap from the pin and attach the Percutaneous Reference Frame to the pin **(Figure 27c)**.

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.

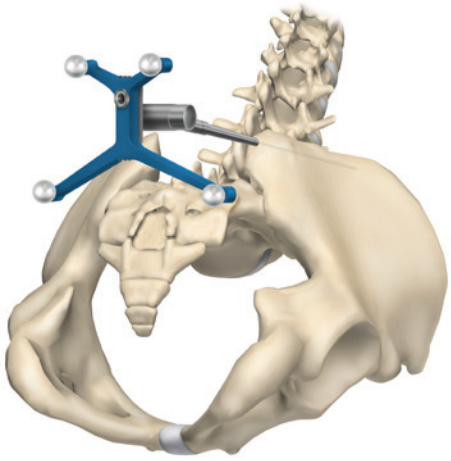


Figure 27a

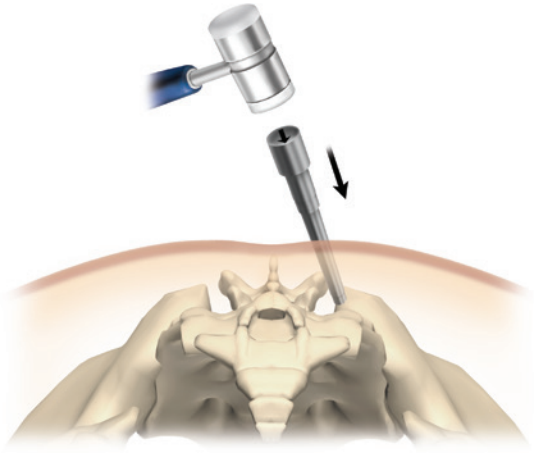


Figure 27b

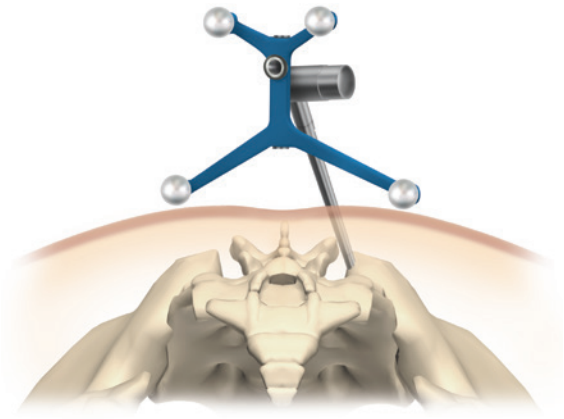


Figure 27c

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 28**).

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

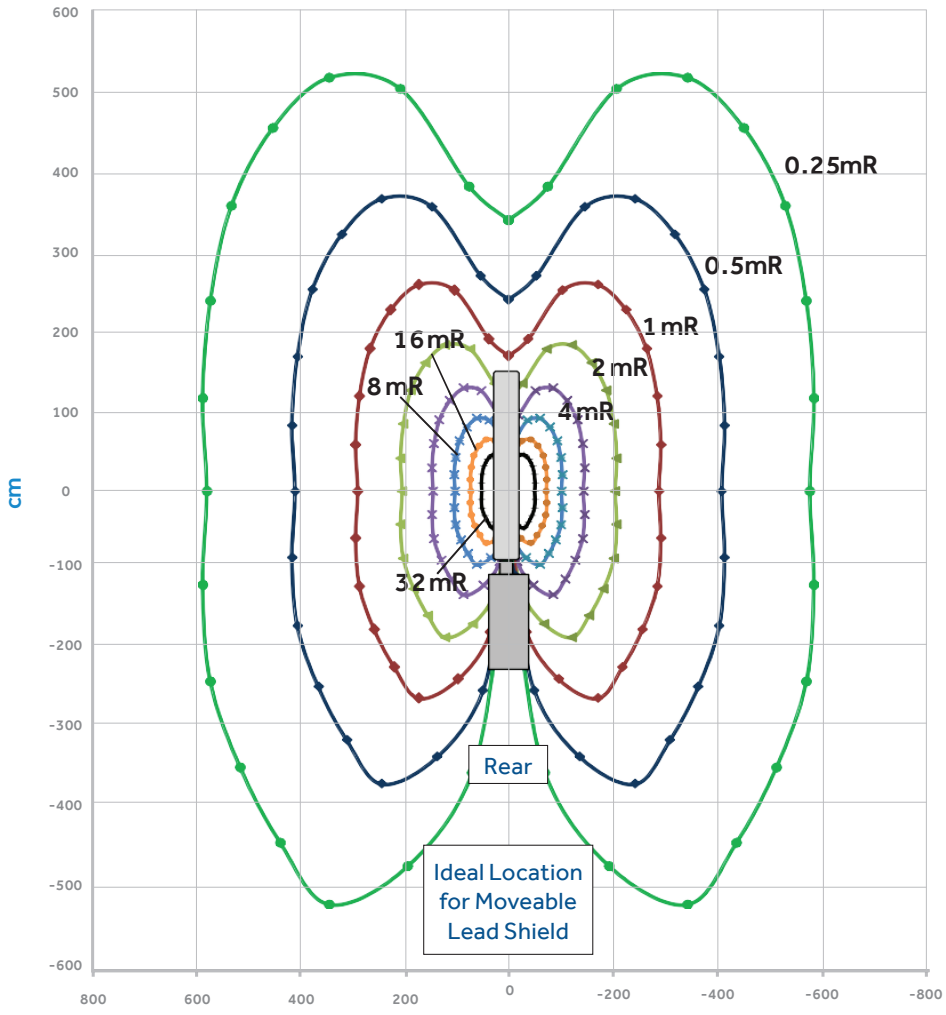


Figure 28

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 29a and 29b)**.

Make the skin incision on the side contralateral to the planned TLIF **(Figure 29c)**. The ipsilateral incision is made in a subsequent step.

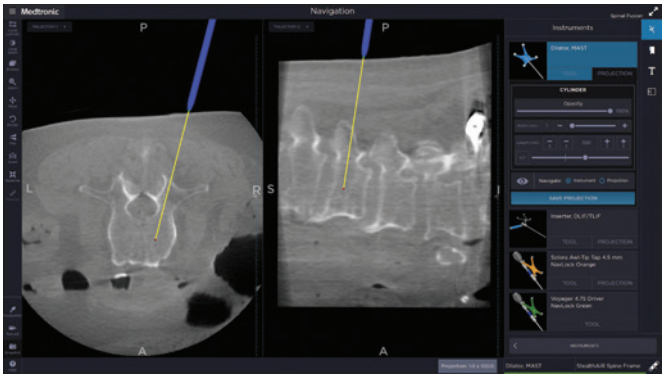


Figure 29a

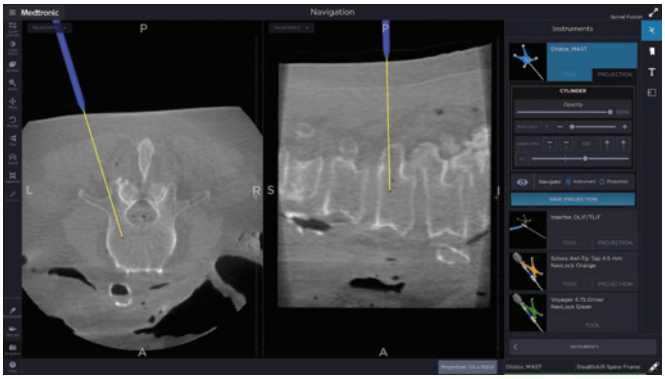


Figure 29b

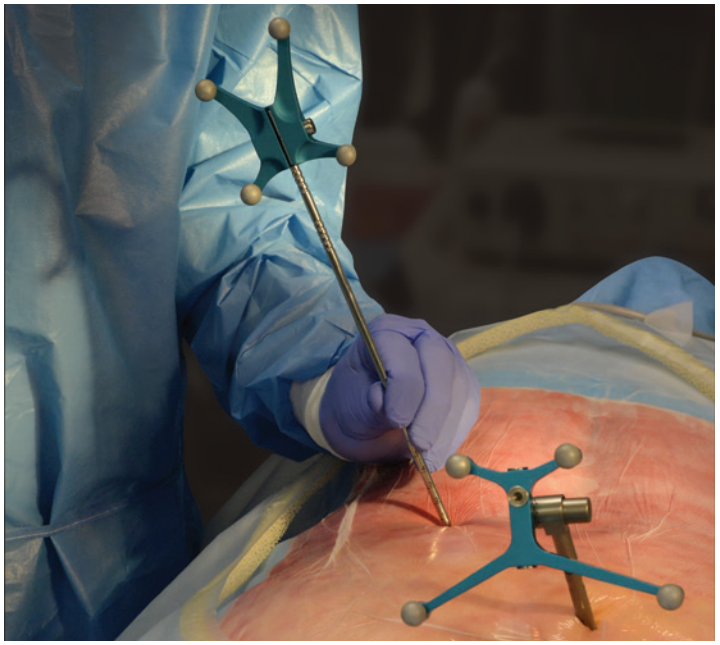


Figure 29c

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 29d)**.

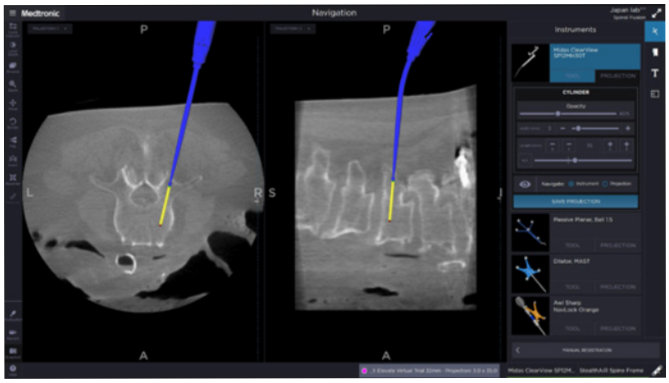


Figure 29d

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 30a)**.

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 30b)**.

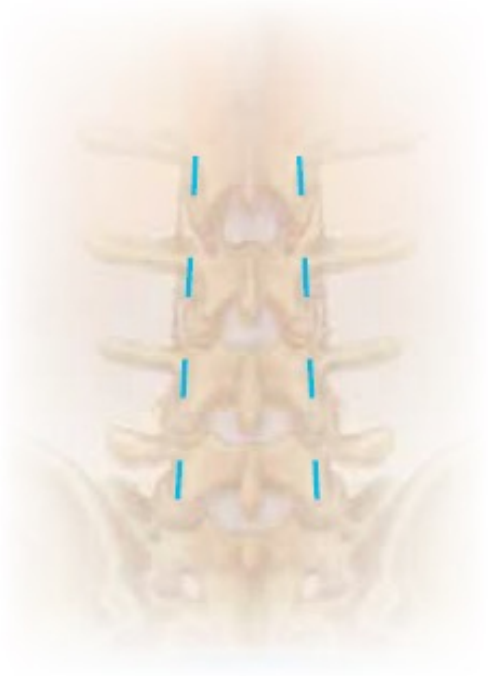


Figure 30a

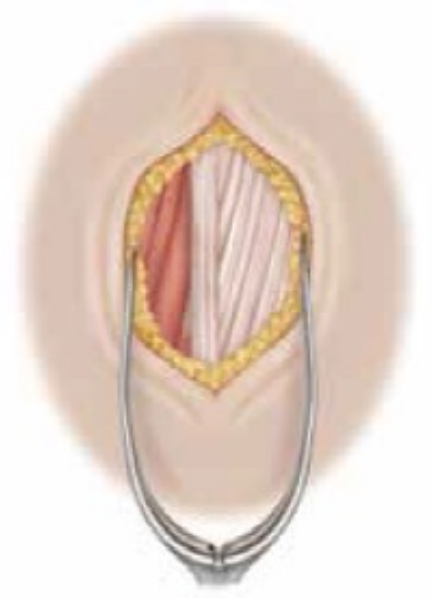


Figure 30b

EXTENDER, CAP, AND **SCREW ASSEMBLY**

Before a Screw can be inserted in to the pedicle, the Tab Extenders (6550017) and Cap (6550016) **(Figure 31a)** must be assembled with either the Extended Tab Multi-Axial Screws or the Extended Tab ATS Screws. To assemble the Screw Extenders, insert the Tab Extenders into either the Extended Tab 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 31b)**.

Note

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

Figure 31a

Figure 31b

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 32a)**.

Insert the assembly into the skin incision and verify the trajectory on the surgeon monitor **(Figure 32b)**. Advance the assembly until it contacts the bone. A virtual tip projection can be selected under the "Projection" button to provide additional guidance **(Figures 32c)**. 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 32d)**. 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.

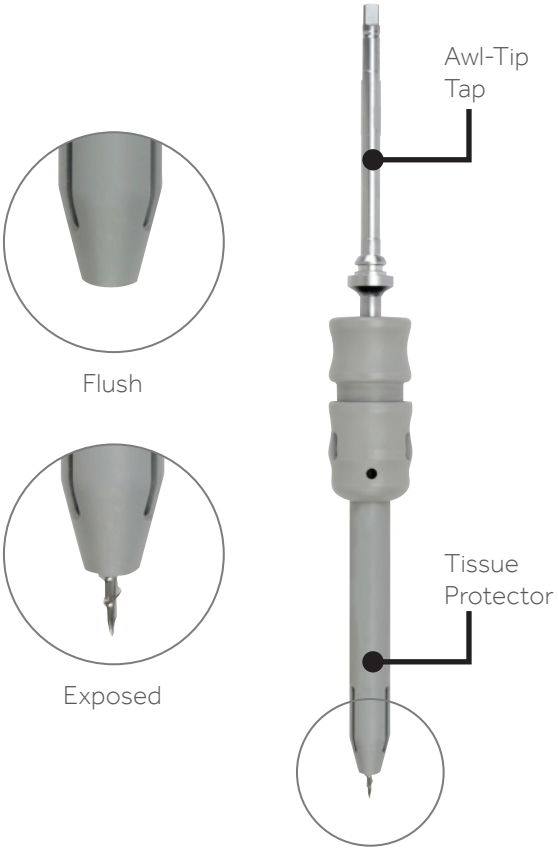


Figure 32a

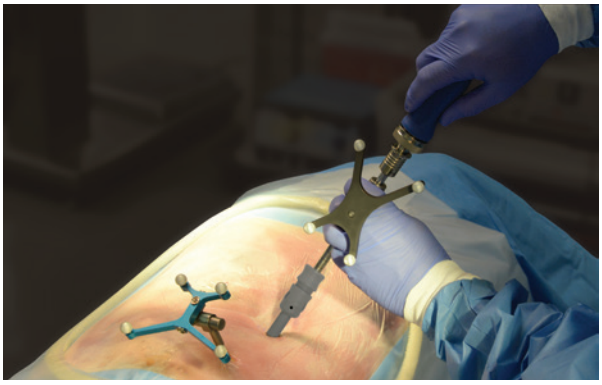


Figure 32b

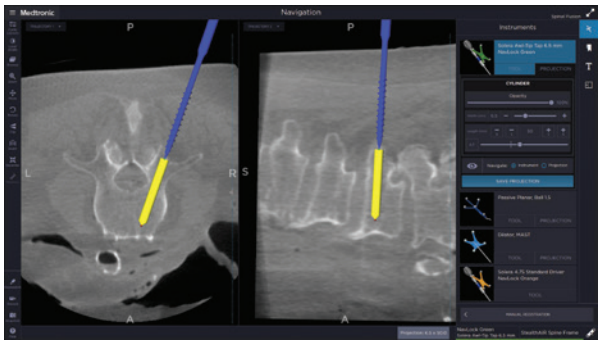


Figure 32c

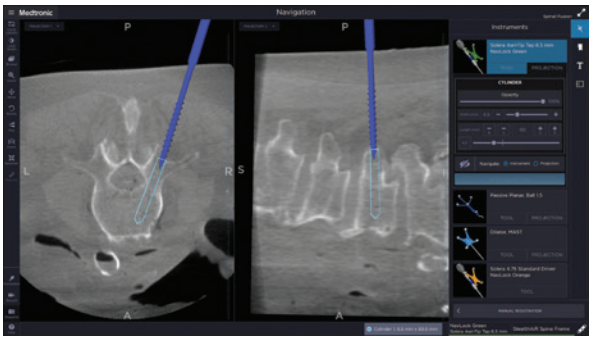


Figure 32d

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 33a)**. 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 33b)**. 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 33c)**. The Assemblies should move freely following Screw insertion.

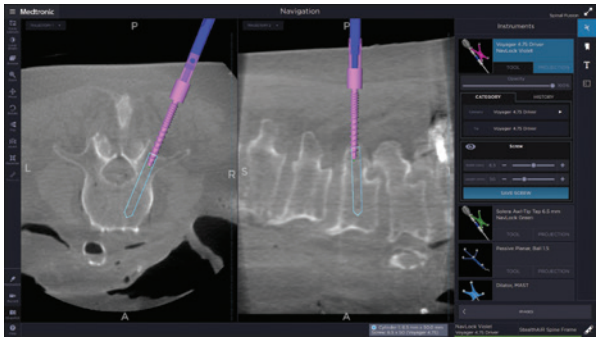


Figure 33a

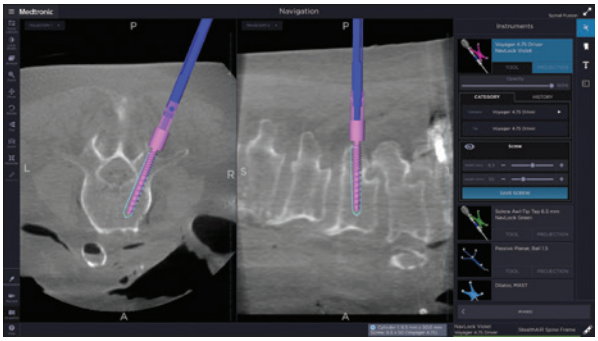


Figure 33b

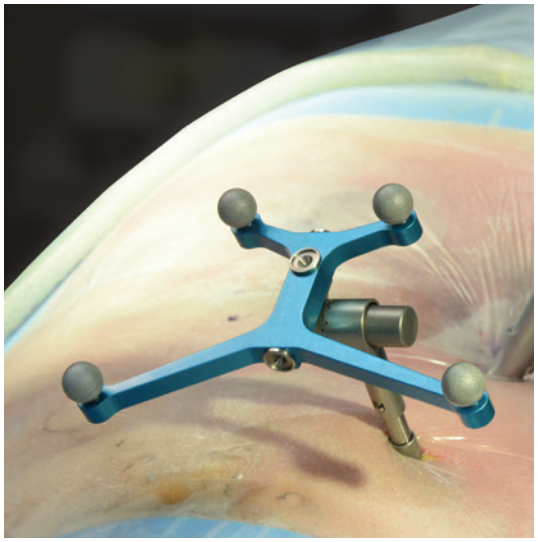


Figure 33c

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 34a and 34b)**.

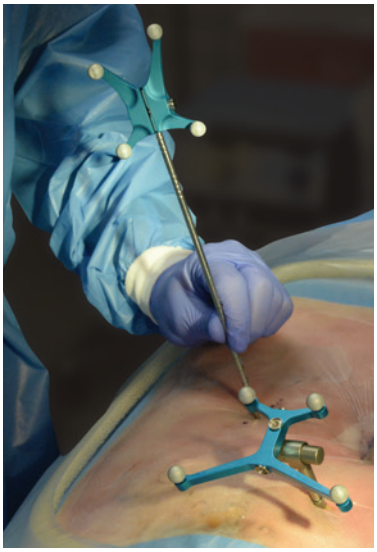


Figure 34a

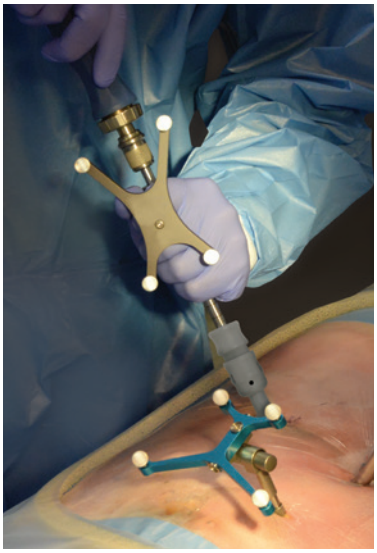


Figure 34b

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 35a and 35b)**.

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".

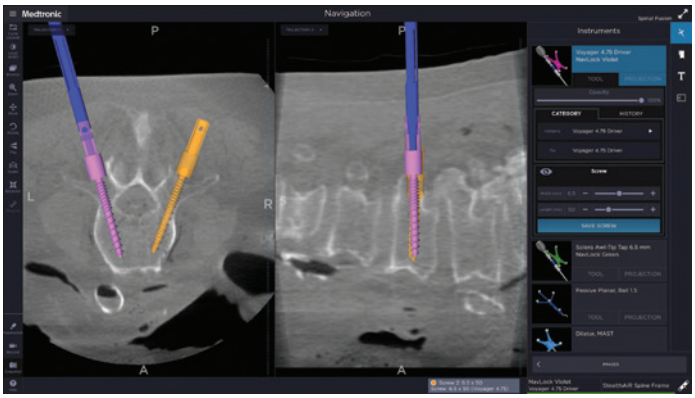


Figure 35a

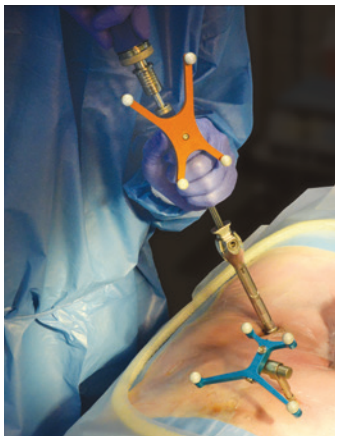


Figure 35b

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.

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 36a and 36b)**. 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.

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.

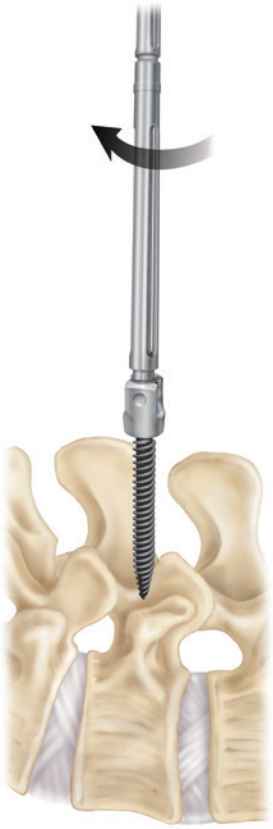


Figure 36a

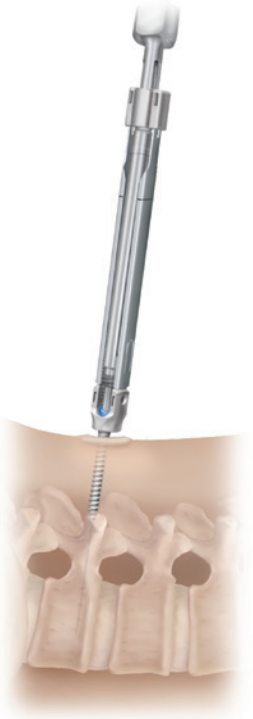


Figure 36b

CONFIRMATION
IMAGE AQUISITION

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 37a)**.
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 37b)**. 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.

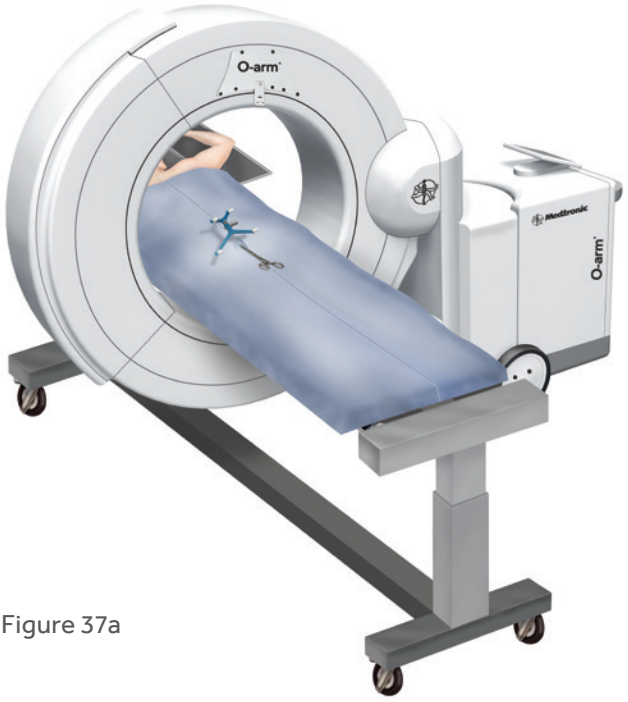


Figure 37a

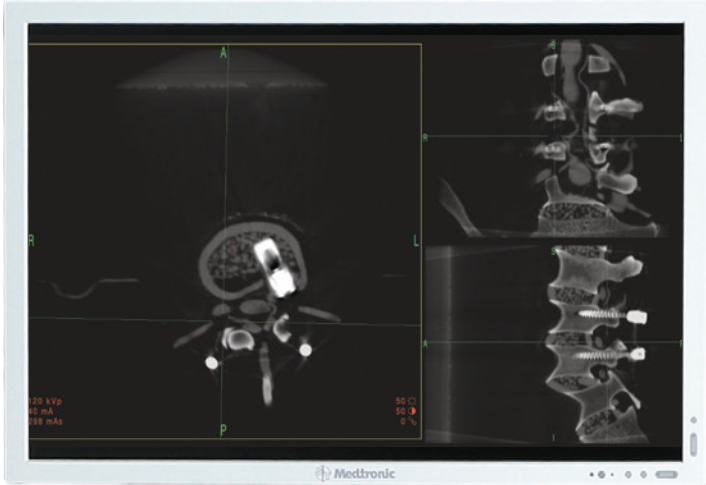


Figure 37b

MEASURING THE ROD

If using a hybrid construct with both CD Horizon Solera Voyager and CD Horizon Longitude II extenders, please note that the Rod Template is compatible with both extender types.

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 **(Figures 38a and 38b)**.

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 38a

Figure 38b

EXTENDERS ALIGNMENT

Begin the rod insertion step by rotating the Tab Extenders, as needed, until the rod slots are aligned for rod passage (**Figure 39**).

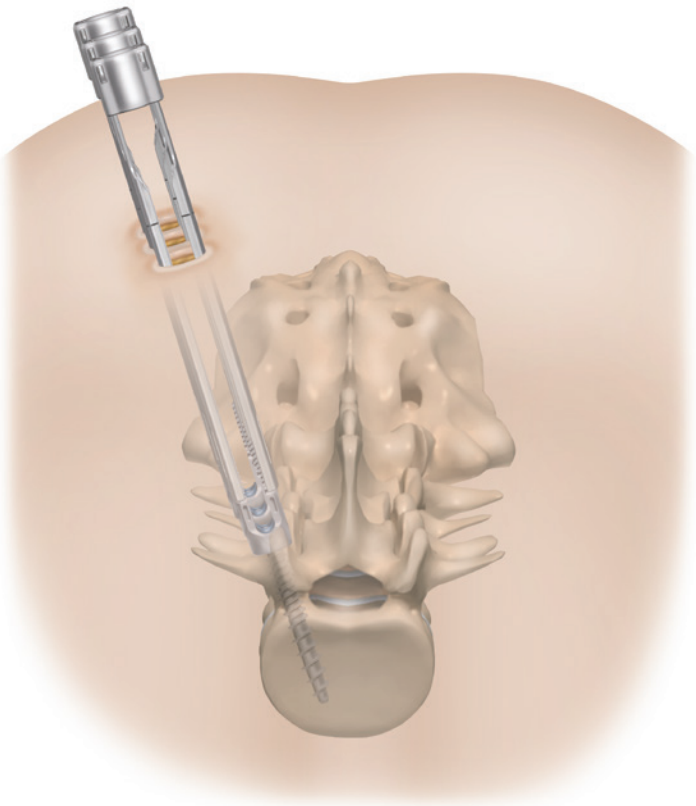


Figure 39

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 40a**). Next, lift the clasp further to open the primary lock stage (**Figure 40b**). 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 40c**). 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, if needed.

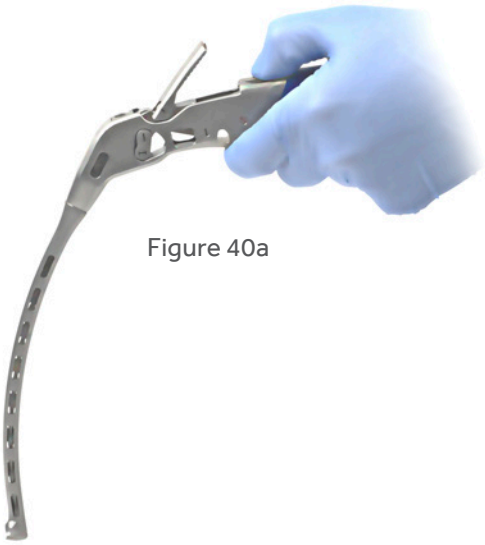


Figure 40a

Figure 40b

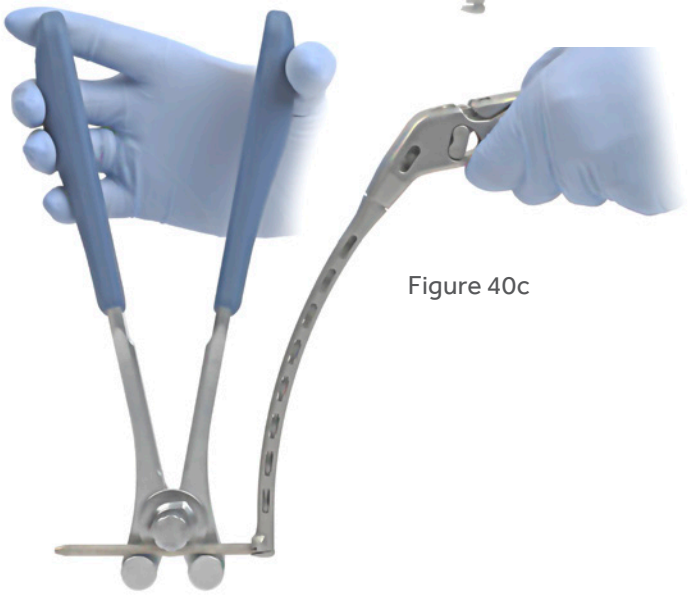


Figure 40c

Rod Passage Through First Extender — Cephalad to Caudal

Using a hybrid construct with both CD Horizon Longitude II extenders and CD Horizon Solera Voyager extenders does not alter the following percutaneous rod insertion steps (**Figure 41a**).

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 41b**). Use AP and lateral fluoroscopy as necessary in combination with tactile and visual feedback to find the path through the remaining Extenders (**Figure 41c**).

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.

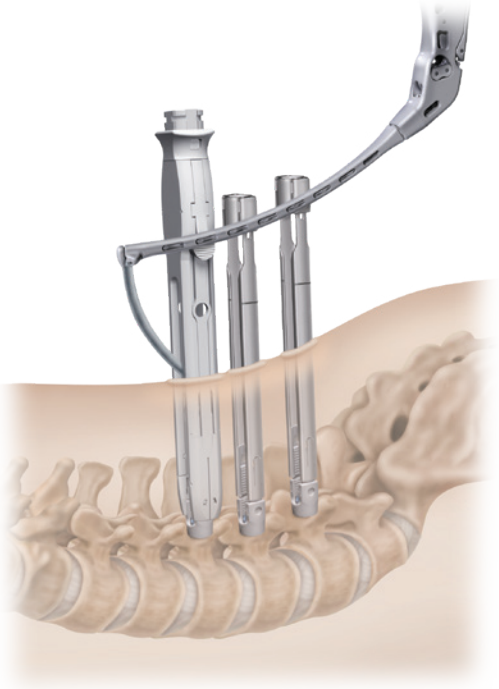


Figure 41a

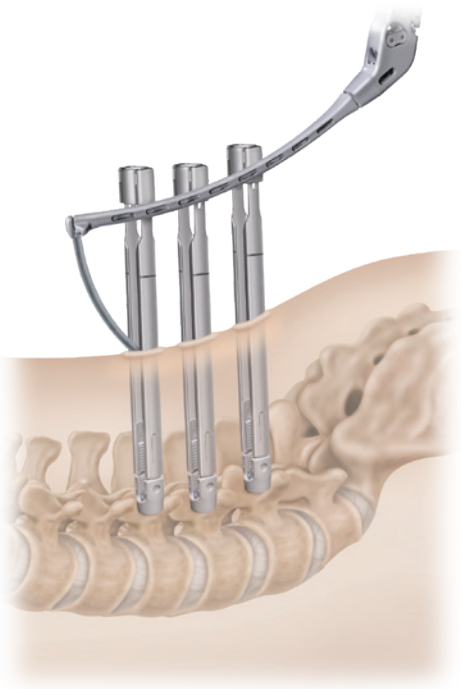


Figure 41b

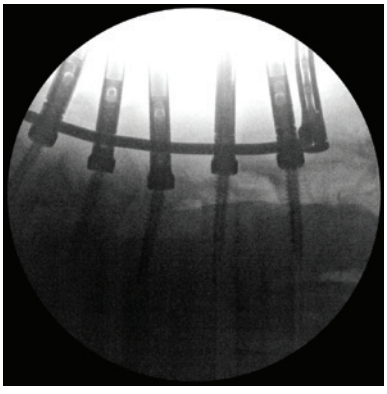


Figure 41c

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 42a**). A sliver of rod should be visible from the most caudal screw of the construct on fluoroscopy (**Figure 42b**).

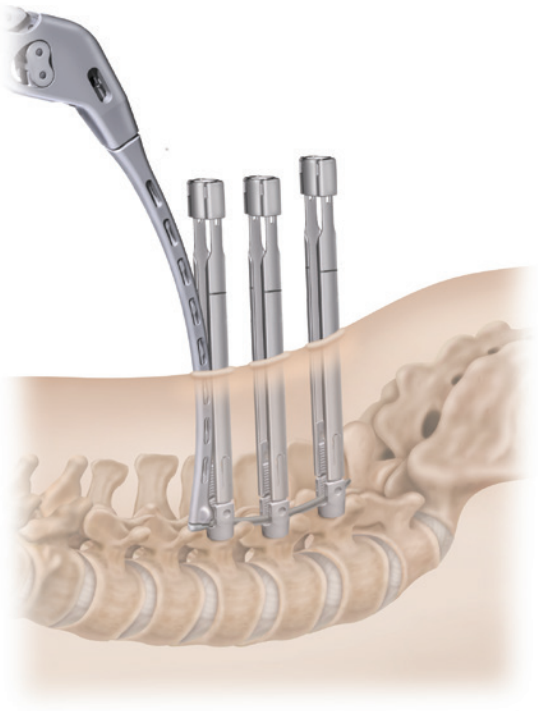


Figure 42a

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.

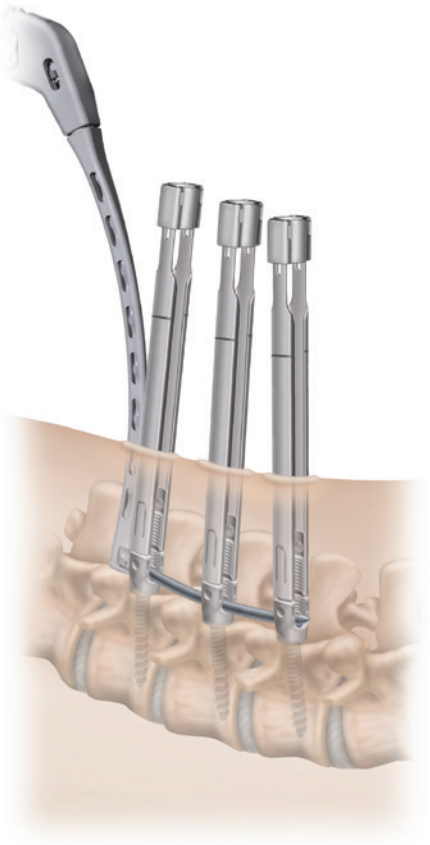


Figure 42b

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 Rod Confirmation Tool may also be used to confirm rod passage by placing the tool into each Extender. If using a hybrid construct, use the Rod Confirmation Tool number 6642011 for the CD Horizon Voyager System extenders and use the Rod Confirmation Tool number 7578911 for the CD Horizon Longitude II System extenders. If the line is visible above the Extender, then the rod has passed correctly into the screw heads (**Figure 43**).

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. When utilizing navigation, rod placement/ overhang should be assessed via a 3D confirmational image at the end of the procedure.

Note
If needed, use Rod Pusher 6642008 to make sure that the rod is fully seated in the screw heads (**Figure 44**).

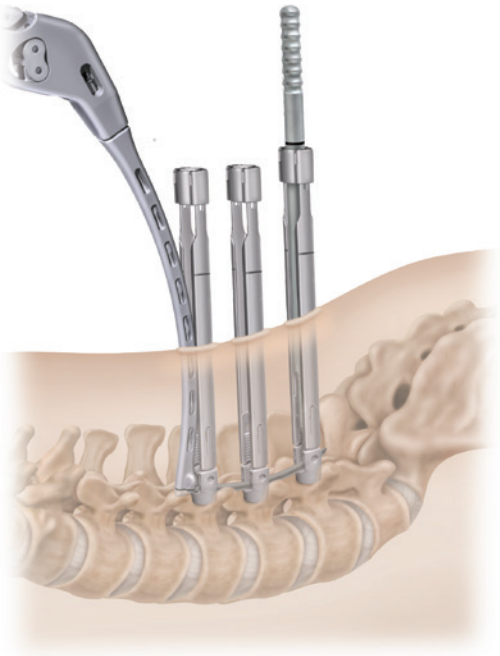


Figure 43

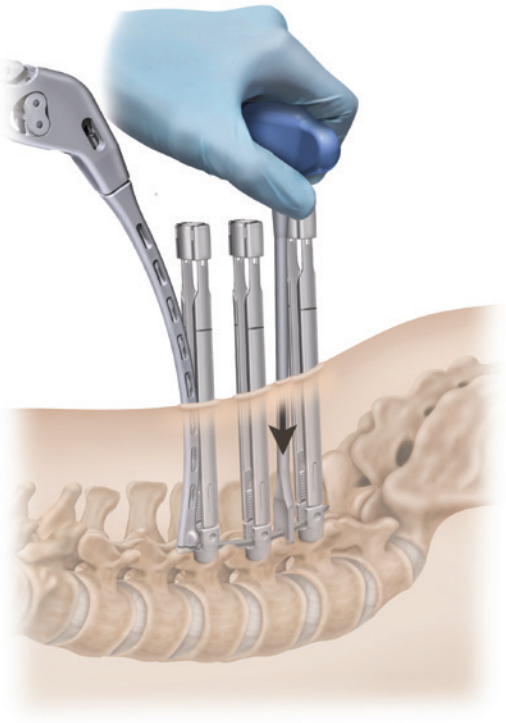


Figure 44

ROD INSERTION:
MINI-OPEN TECHNIQUE

If the mini-open rod insertion technique is preferred, start by dissecting the soft tissue between the Screw Extender Assemblies to create a channel for the placement of the rod. It is recommended that the Capped Rod is used with this insertion method.

Press the button behind the clasp to open the secondary lock stage. Next, lift the clasp further to open the primary lock stage **(Figure 45)**. Load the appropriate size rod as determined by the Rod Template into the Rod Gripper 6642009. Press the clasp closed until it clicks to lock the rod in the Rod Gripper **(Figure 46)**.

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.

Figure 45

Figure 46

Pass the rod into the openings on the top of the Tab Extenders **(Figure 47a)**. Align rod so the End Caps of the Rod extend to both sides of the Tab Extenders **(Figure 47b)**. Push rod down to fully seat in the Screw Heads **(Figure 47c)**. Rod confirmation can be made with fluoroscopy **(Figure 48)**.

Note
If needed, use the Rod Pusher (6642008) to make sure that the rod is fully seated into the screw heads.

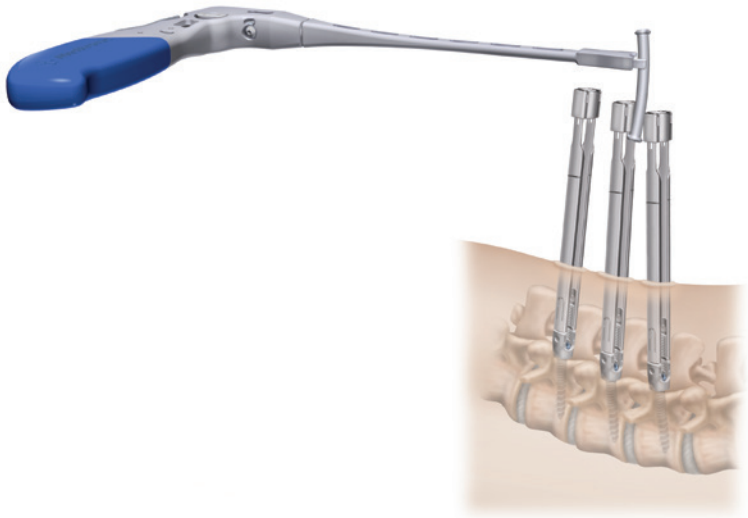


Figure 47a

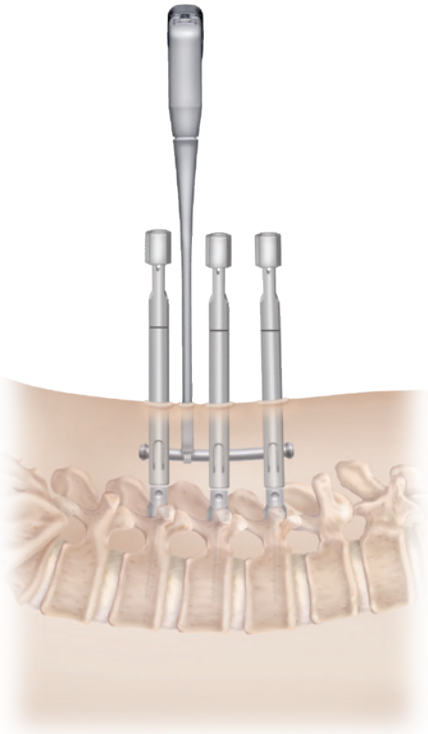


Figure 47b

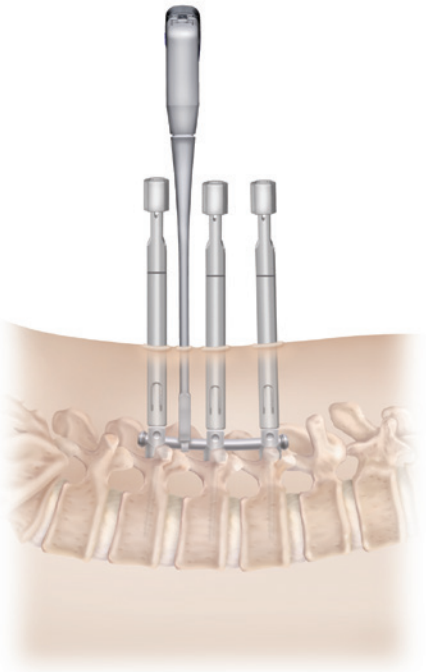


Figure 47c

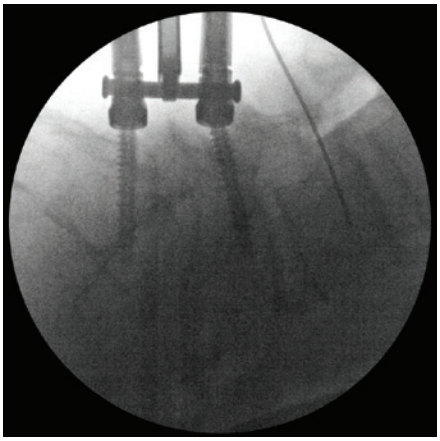


Figure 48

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 49)**. While pushing the button, insert the set screw on the distal tip of the Set Screw Retaining Driver **(Figure 50 and 51)**. 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 49

Figure 50

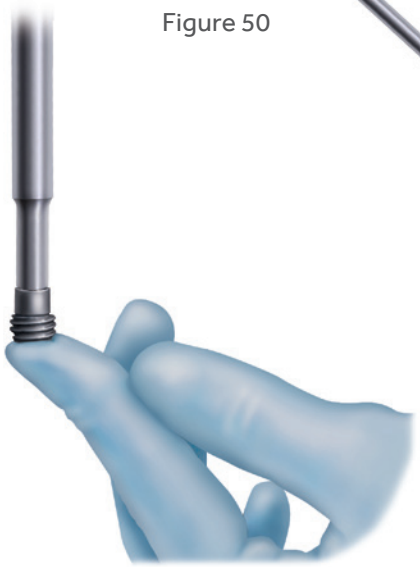


Figure 51

Provisionally tighten the set screws by inserting the Set Screw Assembly down the Tab Extenders **(Figure 52)**. If the black line on the Set Screw Retaining Driver is visible, the rod is not fully seated **(Figure 53)**.

Provisionally tighten all set screws to secure the rod.

Figure 52

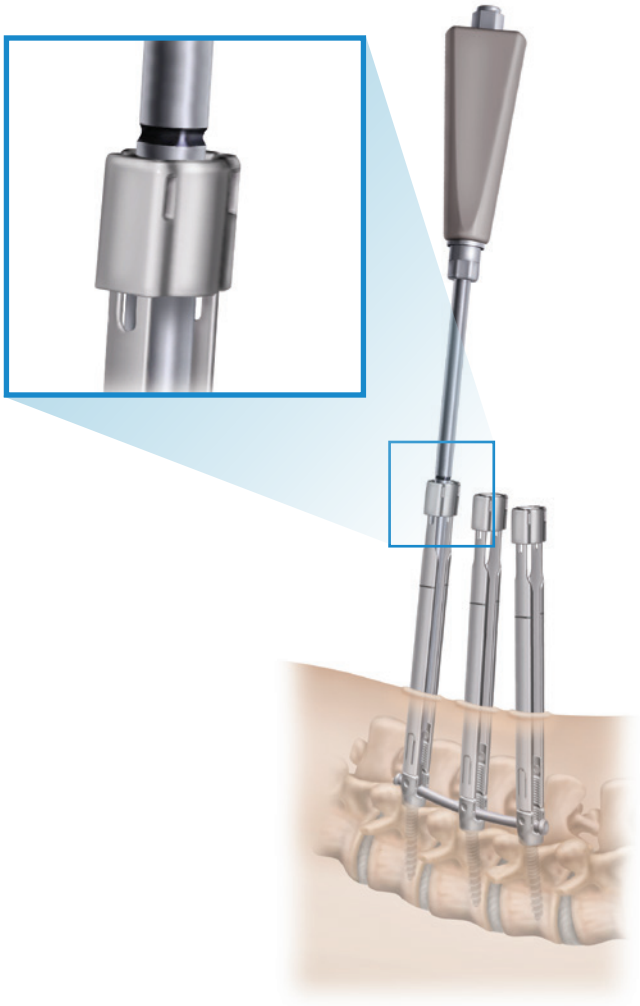


Figure 53

COMPRESSION OR DISTRACTION

If either compression or distraction is needed, it should be performed at this time. Start by loosening the set screw from the screw in the vertebral body that needs to be adjusted.

Remove Caps from the Tab Extenders **(Figure 54)**. 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 55)**. If the black line on the Tab Extender is visible through the Compressor/Distractor Arm window, the Compressor/Distractor Arm is fully seated **(Figure 56)**. 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 57)**. To distract, pull the two arms apart **(Figure 58).**

Lock down the final set screw by inserting the Set Screw Driver through the cannulated portion of the Compressor/Distractor Arms. **(Figure 59)**. Pull the Set Screw Driver to ensure that it is fully engaged with the set screw. After set screw tightening, remove Extender Arms one at time.

Note

For pre-bent rods only: Compressor/Distractor Arms can act as a counter torque during set screw final break off.

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 over).

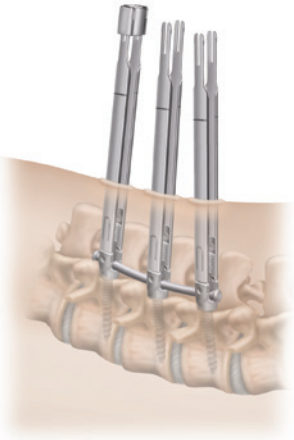


Figure 54

Figure 55

Figure 56

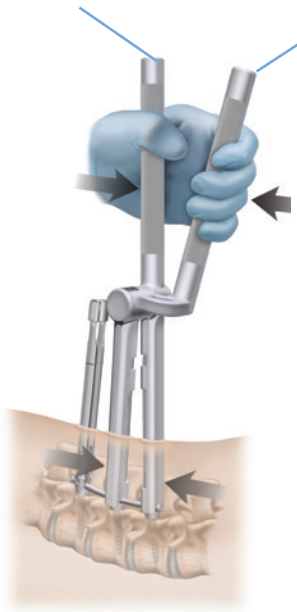


Figure 57

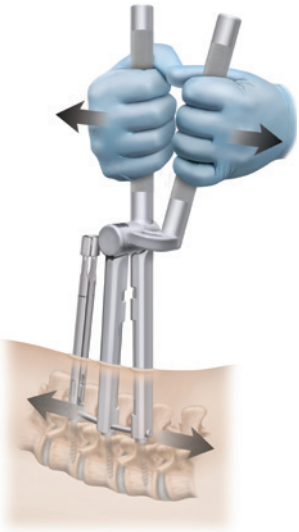


Figure 58

Figure 59

If the Pliers Compressor is used, the Caps do not need to be removed. Slide the Compressor instrument along the outside of the extenders down to the rod of the screws to be compressed **(Figure 60)**. Perform the compression and then tighten the set screw to maintain the compressed position **(Figure 61)**. Lock down the final set screw.

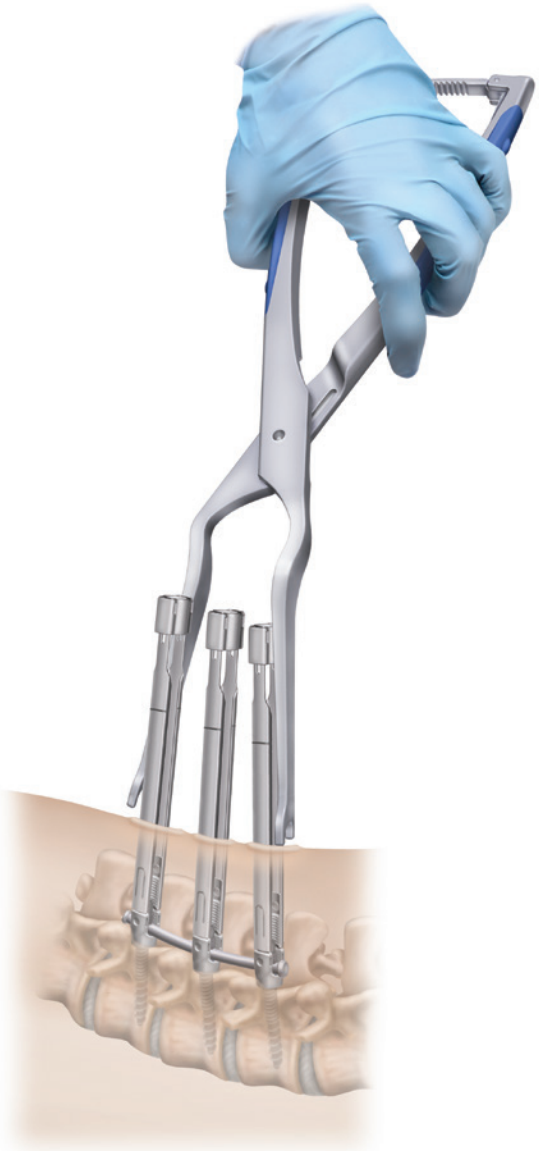


Figure 60

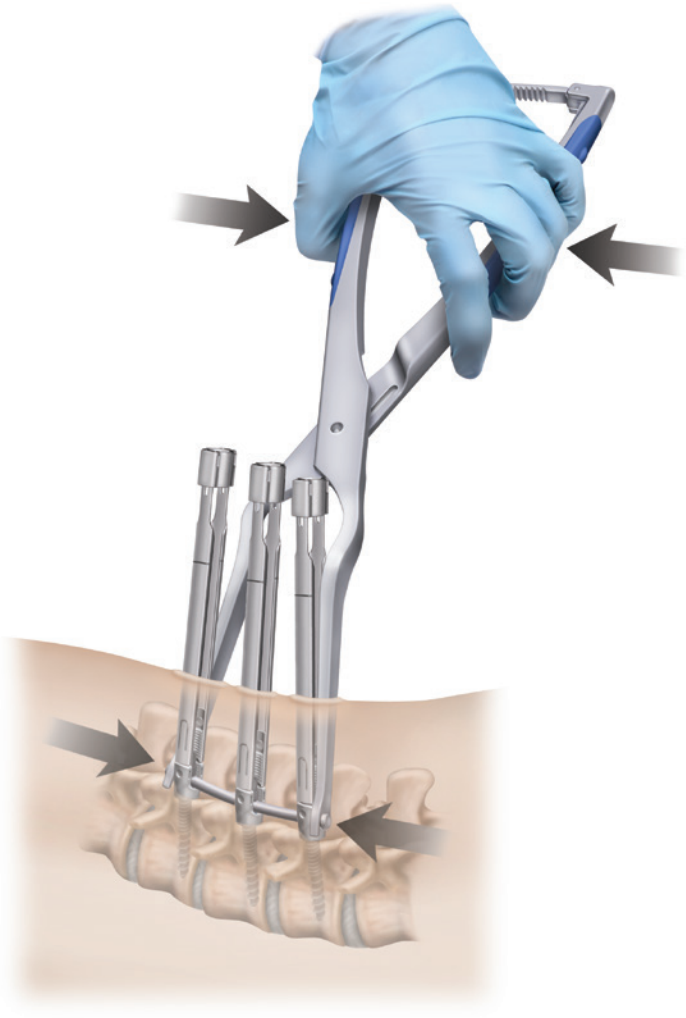


Figure 61

SET SCREW INSERTION AND FINAL BREAK-OFF

Once satisfactory 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 normalized 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.

Remove both Caps from the Tab Extenders (if not already removed during compression/distraction). Insert the Set Screw Driver into the cannulated portion of the Counter Torque, which should be positioned over the implant and seated on the rod **(Figure 62)**. Pull the Set Screw Driver to ensure that it is fully engaged with the set screw.

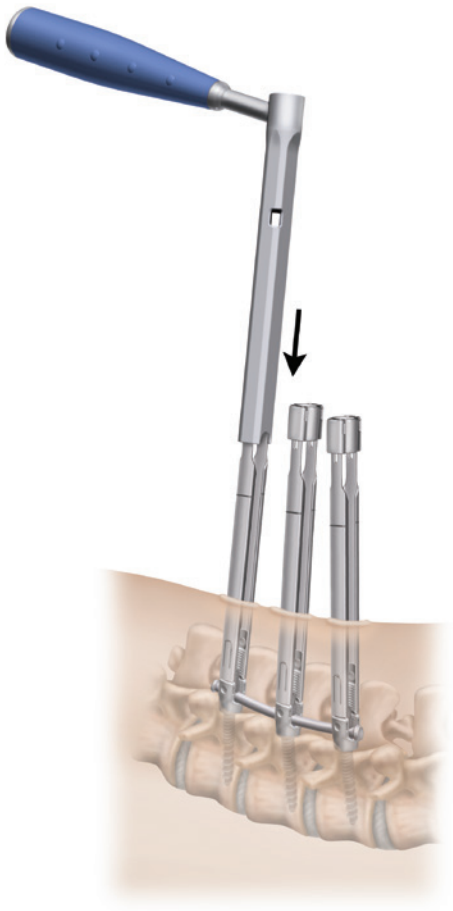


Figure 62

If the black line on the Extender Tab is visible through the side window of the Counter Torque, the Counter Torque is fully seated **(Figure 63).** The break-off handle should be attached to the Set Screw Driver to facilitate the final break-off of the set screw **(Figure 64)**. Tighten set screw to break off. Once the set screws are broken off, the Rod Inserter can be detached from the rod.

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.

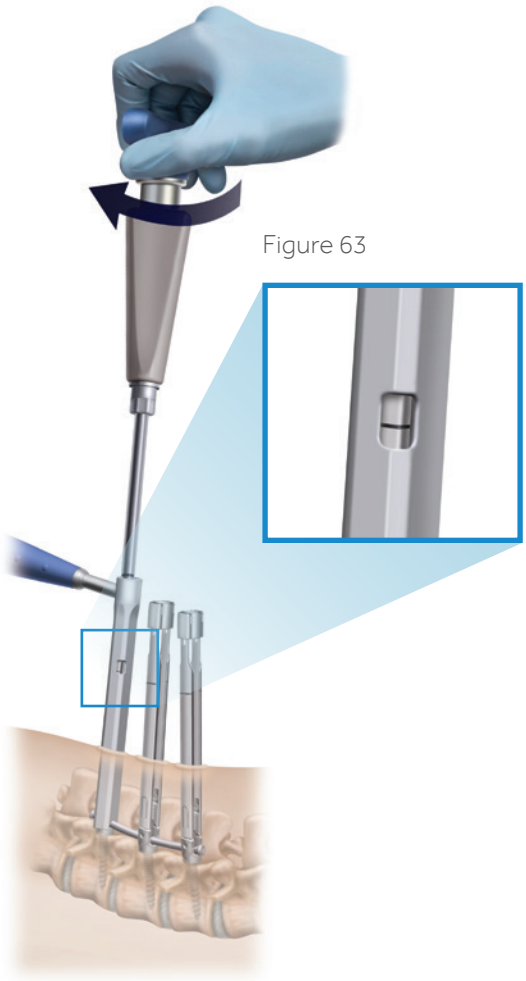


Figure 63

Figure 64

REMOVING ASSEMBLY

To break off the Extended Tabs, slide the Tab Breaker over each of the Tab Extenders. Apply pressure to the Tab Breaker while simultaneously moving it medial to lateral **(Figure 65**).

To remove and dispose of the Break-off Tab from the screw, use the Break-off Removal Tool, 6642012 **(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.

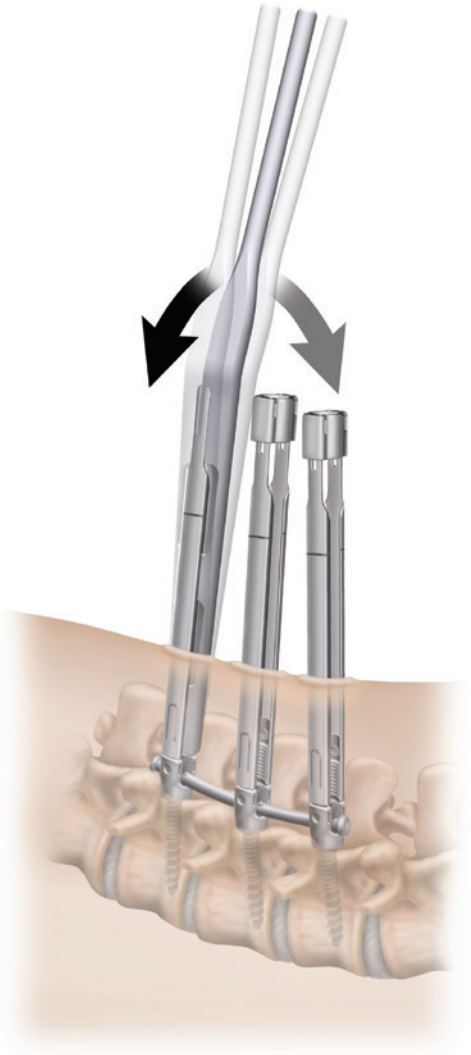


Figure 65

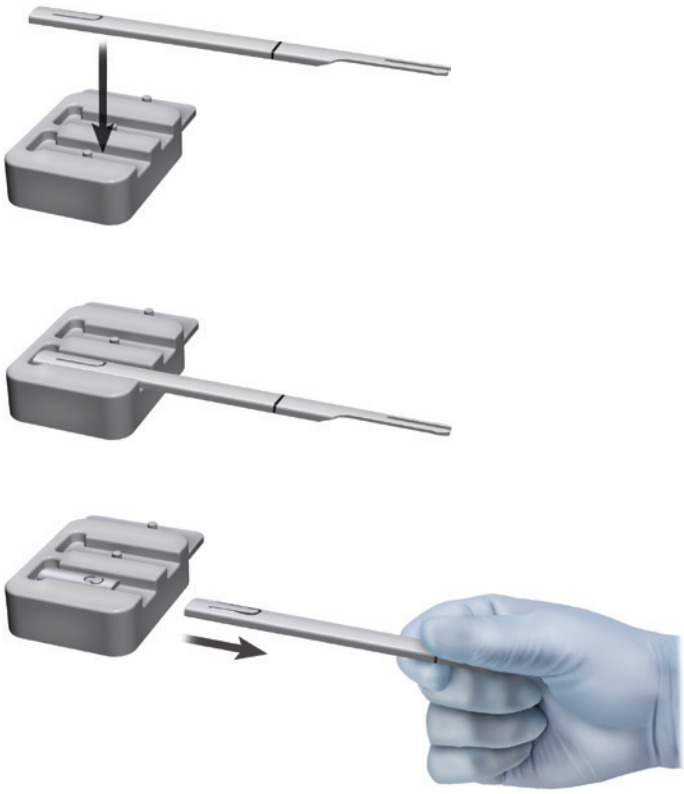


Figure 66

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

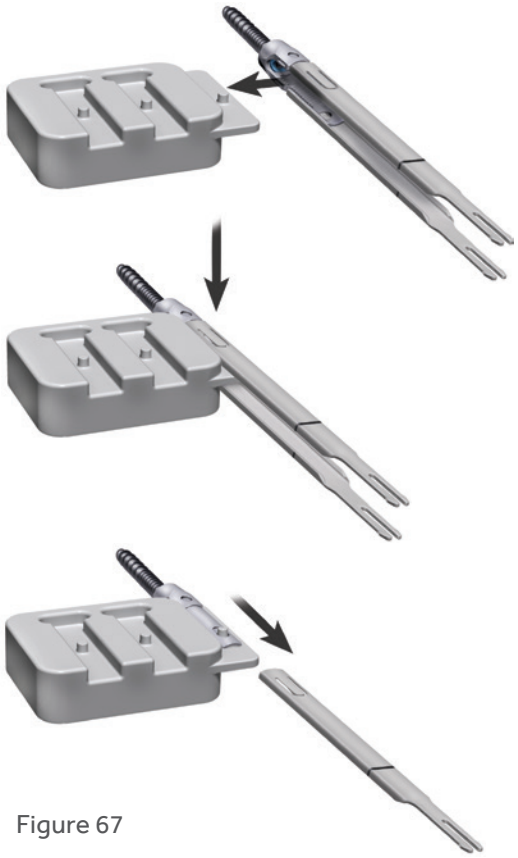


Figure 67

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 68)**.

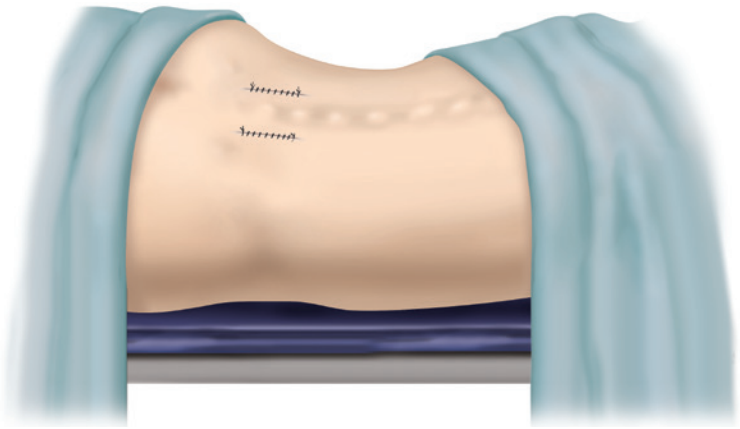


Figure 68

GRAFT
PLACEMENT

Bone Graft must be used when implanting the construct **(Figures 69a and 69b)**.

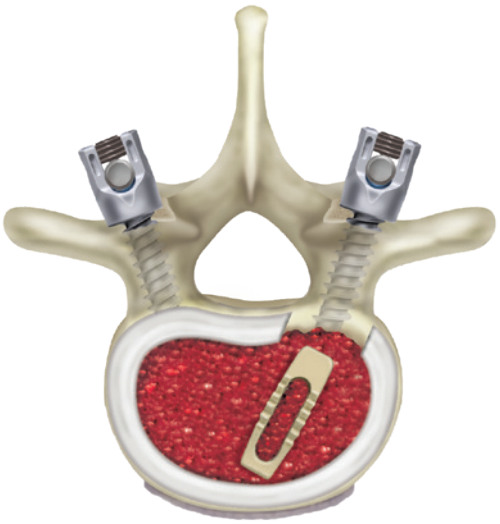


Figure 69a

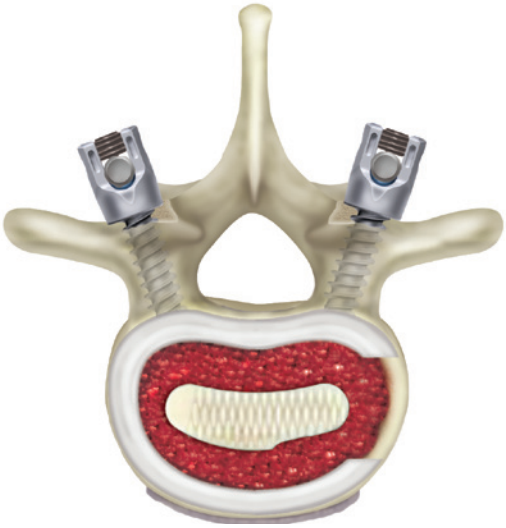


Figure 69b

EXPLANTATION

The CD Horizon Solera Voyager 4.75mm 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 4.75mm 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 4.75mm Instrument Set to the Screw and turning counterclockwise until the Screw is removed from the pedicle.

PRODUCT ORDERING INFORMATION

CD Horizon Solera Voyager Universal Instruments

Part Number	Description	Qty
6640008	4.75 MAS Screwdriver	2
6640005	4.75 Non-Retaining Screwdriver	1
6640004	4.75 Ball-Ended Driver	1
6642014	One-step Inner Dilator	1
6642015	One-step Small Outer Dilator	1
6642010	Rod Confirmation Tool	1
7579000	Q/C Ratcheting T-Handle	1
9098120	Cannulated Ratcheting Egg Handle	2
6642000	Compressor/Distractor A	1
6642001	Compressor/Distractor B	1
6642017	Pliers Compressor	1
6642002	4.75 Set Screw Retaining Driver	2
6642004	Countertorque	1
6642013	Tab Breaker	1
6642008	Rod Pusher	1
6642011	Rod Template	1
8670001	Guidewire, Blunt	6
8670002	Guidewire, Sharp	6
815-518	T25 Removal Driver	1
7570090	T-Handle	1

CD Horizon 4.75 Percutaneous Rods & Instruments

Part Number	Description	Qty
9010000849	Perc Inserter	2
641000030	30mm Perc Rod,4.75mm CCM	4
641000035	35mm Perc Rod,4.75mm CCM	4
641000040	40mm Perc Rod,4.75mm CCM	4
641000045	45mm Perc Rod,4.75mm CCM	4
641000050	50mm Perc Rod,4.75mm CCM	4
641000055	55mm Perc Rod,4.75mm CCM	4
641000060	60mm Perc Rod,4.75mm CCM	4
641000065	65mm Perc Rod,4.75mm CCM	4
641000070	70mm Perc Rod,4.75mm CCM	4
641000075	75mm Perc Rod,4.75mm CCM	4
641000080	80mm Perc Rod,4.75mm CCM	4
641000085	85mm Perc Rod,4.75mm CCM	4
641000090	90mm Perc Rod,4.75mm CCM	4
6440530	4.75 Solera PERC Set Screw Ti	12

CD Horizon Solera Voyager4.75 Screw & Instrument Set

Part Number	Description	Qty
54850014535	4.75 Solera Voyager, MAS 4.5×35cc	4
54850014540	4.75 Solera Voyager, MAS 4.5×40cc	4
54850014545	4.75 Solera Voyager, MAS 4.5×45cc	4
54850015535	4.75 Solera Voyager, MAS 5.5×35cc	6
54850015540	4.75 Solera Voyager, MAS 5.5×40cc	8
54850015545	4.75 Solera Voyager, MAS 5.5×45cc	8
54850015550	4.75 Solera Voyager, MAS 5.5×50cc	6
54850016535	4.75 Solera Voyager, MAS 6.5×35cc	6
54850016540	4.75 Solera Voyager, MAS 6.5×40cc	8
54850016545	4.75 Solera Voyager, MAS 6.5×45cc	8
54850016550	4.75 Solera Voyager, MAS 6.5×50cc	8
54850016555	4.75 Solera Voyager, MAS 6.5×55cc	6
54850017535	4.75 Solera Voyager, MAS 7.5×35cc	6
54850017540	4.75 Solera Voyager, MAS 7.5×40cc	6
54850017545	4.75 Solera Voyager, MAS 7.5×45cc	6
54850017550	4.75 Solera Voyager, MAS 7.5×50cc	4
54850017555	4.75 Solera Voyager, MAS 7.5×55cc	4
5584007	Screw Gauge	1
6642012	Break-off Removal Tool	1
6642006	Tab Extender Cap	10
6642007	Tab Extender	18
5484845	4.5 Cannulated Tap	1
5484855	5.5 Cannulated Tap	1
5484865	6.5 Cannulated Tap	1
5484875	7.5 Cannulated Tap	1
5484885	4.5-5.5mm Self Drilling Tap	1
5484887	5.5-6.5mm Self Drilling Tap	1

Optional Set

CD Horizon4.75 Capped Rod & Instrument Set

Part Number	Description	Qty
6642009	Rod Gripper	1
641003030	30mm Capped Rod,4.75mm CCM	3
641003035	35mm Capped Rod,4.75mm CCM	3
641003040	40mm Capped Rod,4.75mm CCM	3
641003045	45mm Capped Rod,4.75mm CCM	3
641003050	50mm Capped Rod,4.75mm CCM	3
641003055	55mm Capped Rod,4.75mm CCM	3
641003060	60mm Capped Rod,4.75mm CCM	3
641003065	65mm Capped Rod,4.75mm CCM	3
641003070	70mm Capped Rod,4.75mm CCM	3
641003075	75mm Capped Rod,4.75mm CCM	3
641003080	80mm Capped Rod,4.75mm CCM	3
6440530	4.75 Solera™ Perc Set Screw Ti	10

CD Horizon Solera Voyager 4.75 ATS Implants

Part Number	Description	Qty
54850044530	Solera Voyager 4.75 ATS 4.5 × 30	4
54850044535	Solera Voyager 4.75 ATS 4.5 × 35	4
54850044540	Solera Voyager 4.75 ATS 4.5 × 40	4
54850045530	Solera Voyager 4.75 ATS 5.5 × 30	4
54850045535	Solera Voyager 4.75 ATS 5.5 × 35	6
54850045540	Solera Voyager 4.75 ATS 5.5 × 40	8
54850045545	Solera Voyager 4.75 ATS 5.5 × 45	8
54850045550	Solera Voyager 4.75 ATS 5.5 × 50	6
54850046530	Solera Voyager 4.75 ATS 6.5 × 30	4
54850046535	Solera Voyager 4.75 ATS 6.5 × 35	6
54850046540	Solera Voyager 4.75 ATS 6.5 × 40	8
54850046545	Solera Voyager 4.75 ATS 6.5 × 45	8
54850046550	Solera Voyager 4.75 ATS 6.5 × 50	8
54850047535	Solera Voyager 4.75 ATS 7.5 × 35	6
54850047540	Solera Voyager 4.75 ATS 7.5 × 40	6
54850047545	Solera Voyager 4.75 ATS 7.5 × 45	6
54850047550	Solera Voyager 4.75 ATS 7.5 × 50	6
54850047555	Solera Voyager 4.75 ATS 7.5 × 55	4
NAV6640009	Solera Voyager 4.75 NAV DRIVER	2

CD Horizon Solera Voyager 4.75 ATS Streamlined Instruments

Part Number	Description	Qty
6642006	4.75mm Voyager Extender Cap	10
6642007	Tab Extender	18
6642012	Break-off Removal tool 4.75	1
5584007	Screw Gauge	1

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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Please contact your Sales Representative or Customer Service for the most up-to-date version of the package insert.

IMPORTANT INFORMATION FOR MEDTRONIC NAVIGATED REUSABLE INSTRUMENTS

DESCRIPTION

Medtronic Navigated Reusable Instruments are spine preparation instruments made of high grade stainless steel. These instruments are specifically designed for use in procedures where the use of stereotactic surgery may be appropriate. Placing Medtronic single-use sterile spheres on each of the NavLock™ Tracker passive stems allows a Medtronic computer-assisted surgery system such as the StealthStation® Image Guidance System to track the instruments in the surgical field.

Medtronic Navigated Reusable Instruments are compatible with various Medtronic spinal implant systems. These instruments are also compatible with Medtronic's IPC® POWEREASE™ System when connected to the POWEREASE™ Driver.

INTENDED USE

Medtronic Navigated Reusable Instruments are intended to be used during the preparation and placement of Medtronic screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open, or minimally invasive, procedures. Medtronic Navigated Reusable Instruments are specifically designed for use with the StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR-based model, fluoroscopy images, or digitized landmarks of the anatomy. Medtronic Navigated Reusable Instruments are also compatible with the IPC® POWEREASE™ System.

DO NOT IMPLANT THE INSTRUMENTS

If there is any doubt or uncertainty concerning the proper use of these instruments, contact Medtronic. Any available surgical techniques will be provided at no charge.

Medtronic does not and cannot warrant the use of this instrument nor any of the component parts upon which repairs have been made or attempted, except as performed by Medtronic or an authorized Medtronic repair representative. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

WARNINGS

- Breakage, slippage, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient or operative personnel.
- Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose or even dangerous to the patient or surgical staff.
- It is important the surgeon exercise extreme caution when working in close proximity to vital organs, nerves, or vessels and the forces applied while correcting the position of the instrumentation is not excessive, such that it might cause injury to the patient.
- During navigation, it is important to frequently confirm navigational accuracy by touching the tip of the instrument on known anatomical points, including accuracy checkpoints, and comparing the position to the instrument tip in the image with its physical location.

PRECAUTIONS

- Excessive force applied by instruments to implants can dislodge devices, particularly hooks.
- Never expose instruments to temperatures in excess of 135 °C that may modify the physical characteristics.
- Extreme care should be taken to ensure that this instrument remains in good working order. During the procedure, successful utilization of this instrument is extremely important. Instruments should not be bent or damaged in any way. Misuse of instruments resulting in corrosion, "freezing-up", scratching, loosening, bending, or fracture of any or all sections of an instrument may inhibit or prevent proper function.
- These instruments should be carefully placed on trays, cleaned after each use, and stored in a dry environment.
- Do not use this instrument for any action for which it was not intended.
- Regularly review the operational state of all instruments and, if necessary, make use of repair and replacement services.
- To avoid injury or navigation inaccuracy, the instrument should be carefully examined for functionality or damage prior to use. A damaged instrument should not be used. Additional back-up instruments should be available.
- Preoperative and operating procedures, including knowledge of surgical techniques, are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results.
- Proper patient selection and operative care are critical to the success of the surgery and avoidance of injury during surgery. Read and follow all other product information supplied by the manufacturer of the implants or the instruments.
- Special precautions are needed during pediatric use. Care should be taken when using instruments in pediatric patients since these patients can be more susceptible to the stresses involved in their use.
- Some surgeries require the use of instruments which incorporate a measuring function. Ensure these are not worn and any surface engravings are clearly visible.

POSSIBLE ADVERSE EFFECTS

- Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs, or joints.
- Infection if instruments are not properly cleaned and sterilized.
- Pain, discomfort, or abnormal sensations resulting from the presence of the instrument.
- Nerve damage due to surgical trauma.
- Dural leak in cases of excessive load application.
- Impingement of close vessels, nerves, and organs by slippage or misplacement of the instrument.
- Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.
- Cutting of skin or gloves of operating staff.
- Bony fracture in cases of deformed spine or weak bone.
- Tissue damage to the patient, physical injury to operating staff, and/or increased operating time that may result from the disassembly of multi-component instruments occurring during surgery.
- The methods of use of instruments are to be determined by the user's experience and training in surgical procedures. A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results.

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.

This device should be used only by physicians familiar with the device, its intended use, any additional instrumentation, and any available surgical techniques.

NOTES

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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.

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

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