



# CD HORIZON<sup>®</sup> LONGITUDE<sup>®</sup> II

Multi-level Percutaneous Fixation System

Surgical Technique







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Multi-level Percutaneous Fixation System

## Surgical Technique

The surgical techniques shown are for illustrative purposes only and are representative of some types of pathologies that can be treated with this system. The techniques 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 of each patient. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.

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## Overview

### Pedicle Screw Type and Influences on Placement and Positioning

The CD HORIZON® SOLERA™ Spinal System offers different screw types for use with the CD HORIZON® LONGITUDE® II System. Each screw type offers specific functionality and require specific adjustment of the orientation of the screw in the vertebra to maximize the functionality of the screw.

**Multi-Axial Screws (MAS):** These screws can be inserted with the bone screw shaft at the most convenient angle of insertion. The freely mobile head will accommodate a variety of entry points and screw trajectories within the limits of the head's ability to tilt and accommodate to the position of the spinal rod.

**Fixed Angle Screw (FAS):** This screw must be inserted perpendicular to the anticipated position of the rod to facilitate set screw engagement. There is no accommodation to the position of the spinal rod, thus attention to the position of the implant saddle and spinal rod sagittal profile prior to final tightening is essential. In the thoracic spine this necessitates positioning the screw in the straightforward approach as opposed to the anatomic approach within the pedicle.

**Sagittal Adjusting Screw (SAS):** Use of the Sagittal Adjusting Screw is similar to the Fixed Angle Screw in that the pedicle screw head position is fixed in relation to the bone screw shaft allowing for medial/lateral or derotation control/correction. In addition, the SAS allows for placement of thoracic screws in either the anatomic or straightforward orientation as the saddle within the screw head can accommodate the sagittal profile of the spinal rod with up to +/-13° of variation. Furthermore, the SAS allows for sagittal balance adjustment due to the fixed relation between the pedicle screw head and bone screw shaft and the accommodation of the spinal rod position.



*CD HORIZON® SOLERA™ System  
5.5/6.0mm Screws accept 5.5mm  
and 6.0mm rods to accommodate  
construct demand.*



Multi-Axial Screw (MAS)

Fixed Angle Screw (FAS)

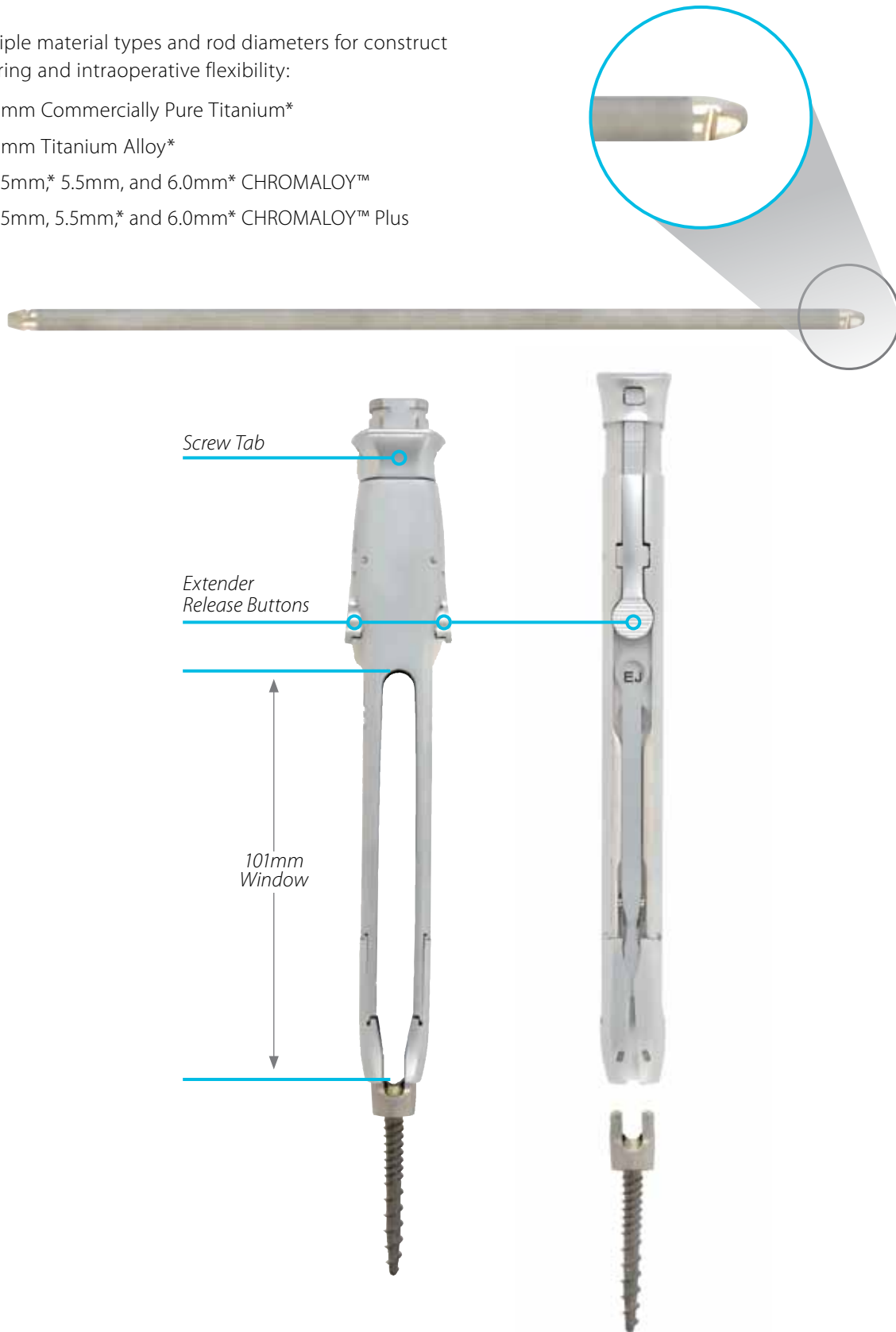
Sagittal Adjusting Screw (SAS)

CD HORIZON® LONGITUDE® II System is compatible with CD HORIZON® SOLERA™ 4.75mm and 5.5/6.0mm cannulated screws as well as CD HORIZON® LEGACY™ 5.5mm cannulated screws.

## Overview *continued*

Multiple material types and rod diameters for construct tailoring and intraoperative flexibility:

- » 5.5mm Commercially Pure Titanium\*
- » 5.5mm Titanium Alloy\*
- » 4.75mm,\* 5.5mm, and 6.0mm\* CHROMALOY™
- » 4.75mm, 5.5mm,\* and 6.0mm\* CHROMALOY™ Plus



Screw Extender  
 (Screw Extenders are available for 4.75mm and 5.5/6.0mm screws.)

\*May be ordered as an extra.

## Instrument Set



**Dilator**  
8675422



**Quick-Connect Ratchet Handle**  
G900000



**Ratcheting T-Handle**  
G900100



**5.3mm Dilator**  
9560420



**9.4mm Dilator**  
9560421



**Cannulated Taps**  
4.5mm 5484845  
5.5mm 5484855  
6.5mm 5484865  
7.5mm 5484875  
8.5mm 5484840  
9.5mm 5484841



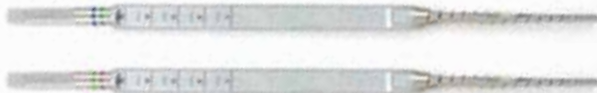
**Cannulated Ratchet Egg Handle**  
9098120



**T-Handle**  
7570090



**Self-Drilling Taps**  
4.5mm to 5.5mm 5484885  
5.5mm to 6.5mm 5484887



**POWEEASE® System Taps**  
4.5mm to 5.5mm 2342425  
5.5mm to 6.5mm 2342426



**Counter Torque**  
7578801

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**Blunt Guidewire**  
8670001

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**610mm Blunt Guidewire**  
2345050

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**Sharp Guidewire**  
8670002

Instrument Set *continued*



**Extender Body**  
7578301 (4.75mm)  
7578302 (5.5/6.0mm)



**Long Fixed Angle Screwdriver**  
5584928



**Sequential Reducer**  
5484902



**Long Retaining Driver**  
5484901 (4.75mm)  
5584099 (5.5/6.0mm)



**POWEREASE® System Screwdriver**  
2342306-L (4.75mm)  
2342305-L (5.5/6.0mm)



**T25 Ball End Driver**  
5584922



**Reduction Nut Driver**  
7578309



**Set Screw Retaining Driver**  
7578900



**POWEREASE® Reduction Nut Driver\***  
2342403



**Rod Confirmation Tool**  
7578911



**Long Multi-Axial Screwdriver**  
5584999



**T27 Removal Driver**  
7570988

\*May be ordered as an extra instrument.

## Instrument Set *continued*



**Rod Inserter**  
7570900



**Rod Entry Estimator Tool\***  
5484900



**French Bender**  
7480162



**Rod Measurement Tool**  
5484510



**Compressor (90mm)**  
7578003



**Distractor**  
5484907



**5.5mm Sagittal  
In Situ Bender**  
7578945 (Left)  
7578930 (Right)

**6.0mm Sagittal  
In Situ Bender\***  
5484255 (Left)  
5484260 (Right)

\*May be ordered as an extra instrument.



## Accessing the Pedicle

### Preoperative Planning and Patient Positioning

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. The starting point is rarely directly over the pedicle.

The patient should be positioned prone, lying flat on the table. Either a radiolucent frame or chest rolls may be used, but a knee-to-chest position should be avoided. Verify that adequate fluoroscopic images of the pedicles can be obtained in both the AP and lateral views before proceeding. On AP fluoroscopy, the spinous processes should lie midway between both pedicles. AP and lateral fluoroscopy projections should be parallel to the end plates nearest the screw to be inserted (**Figure 1**). On AP and lateral fluoroscopy, the end plates should be linear and not rounded (**Figure 2**).

#### ✓ Helpful Tip

*Some tables have pedestals that make it difficult to get a true AP view of the pedicles. 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.*

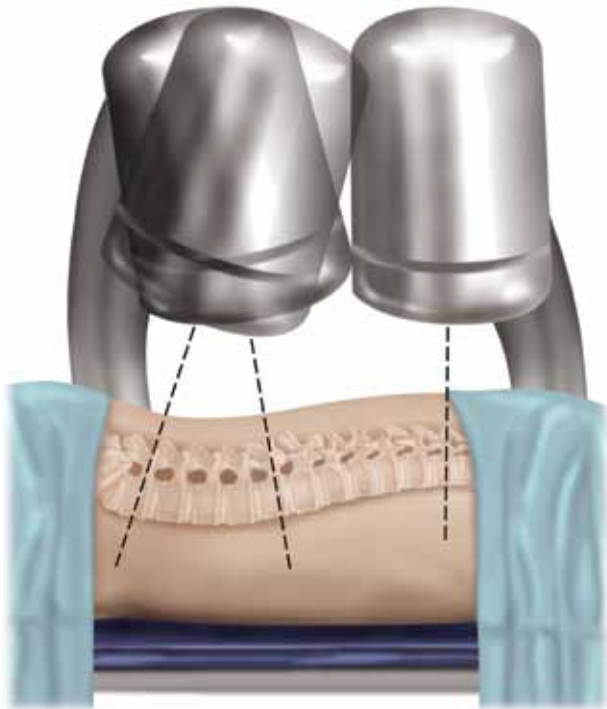


Figure 1

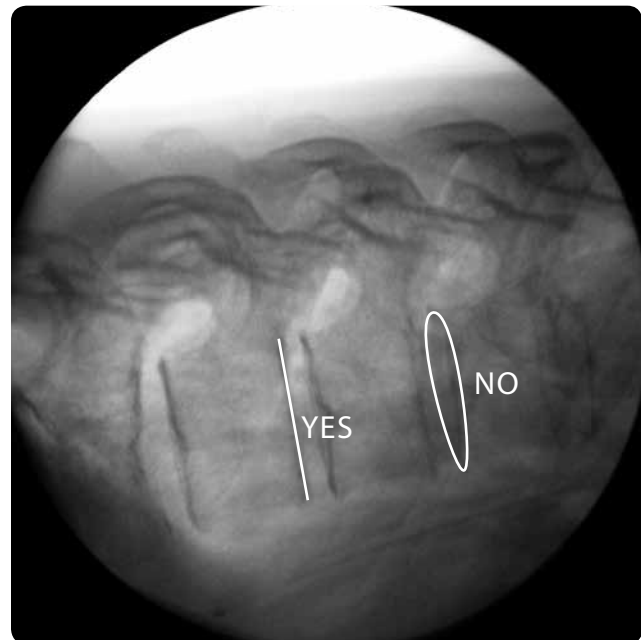
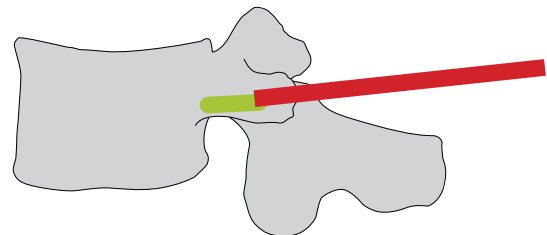
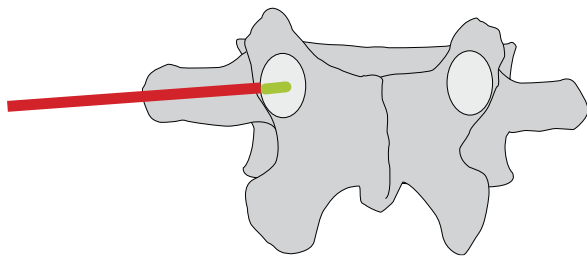
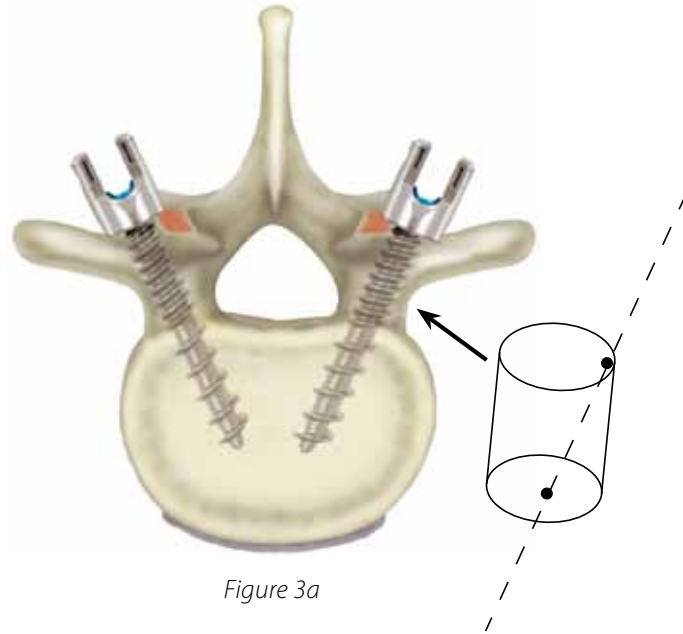


Figure 2

## 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. The ideal starting point is at the intersection of the facet and the transverse process (the lateral edge of the cylinder) (Figures 3a, 3b, and 3c).



## Skin Incision Options

Based upon the number of levels to be instrumented, different incision techniques may be considered. Skin incision options include a midline incision (**Figure 4a**) where one incision is made at the midline and then elevating the plane between the thorocadorsal fascia and the paraspinal fascia. This allows a fascial plane for screw placement. The other option uses separate skin incisions over the intersection of the facet and the transverse process where each screw will be inserted (**Figure 4b**). Both options preserve the muscle and tissue layers and the option selected should be based on surgeon preference.

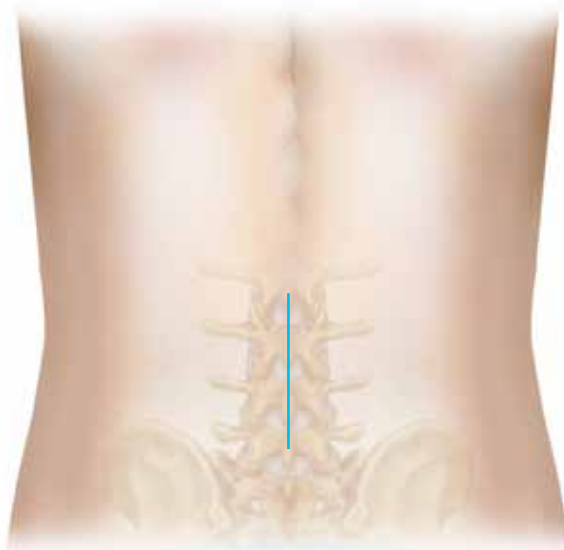


Figure 4a



Figure 4b

✓ Note

*A running lock stitch suture along both sides of the incision will secure the drape to the wound edge and keep the skin from separating from the fascia.*

## Skin Incision Options *continued*

### Pedicle Targeting

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A radiopaque marker may be used to verify the appropriate location of the skin incisions. The marker is positioned on the skin directly over the pedicle on an AP image (**Figure 5a**). A marker is then positioned on the skin at the intersection of the facet and transverse process (**Figure 5b**).

Both AP and lateral and (per surgeon preference) pedicle “barrel shot” images confirm the appropriate starting place has been determined. Once the position is confirmed, a skin and fascial incision is then made approximately 18mm in length.



Figure 5a



Figure 5b

## Skin Incision Options *continued*

### Pedicle Targeting *continued*

A 22-gauge spinal needle may be used to verify the appropriate location of the incisions. The needle is positioned on the paraspinal fascia directly over the pedicle on an AP image. The needle is then moved laterally 1cm to 2cm and inserted to the intersection of the facet and transverse process (**Figures 6a and 6b**).

The fascial 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 6c and 6d**).

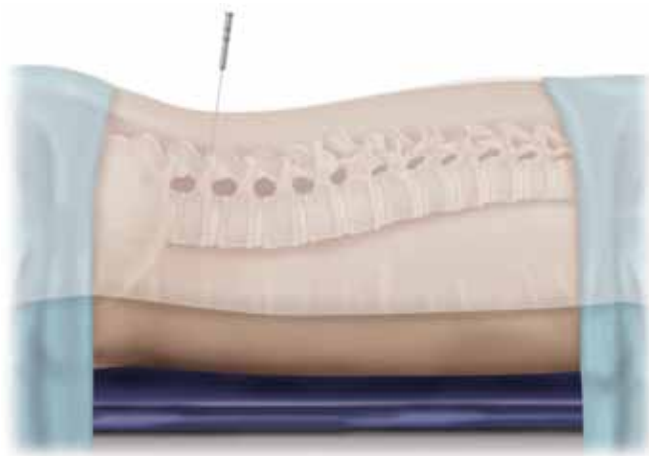


Figure 6a

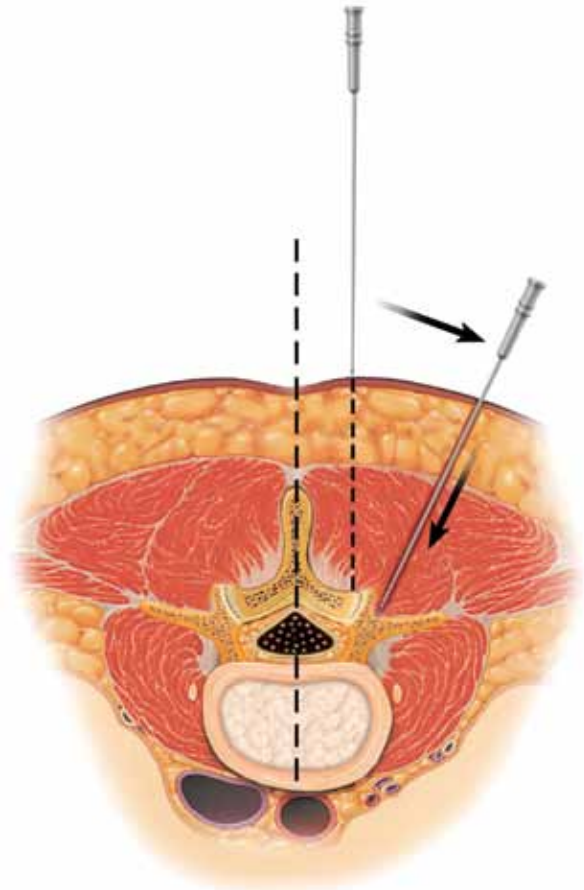


Figure 6b

#### ✓ Note

*When using a midline incision, the starting points through the presented fascia will be the same.*



Figure 6c



Figure 6d

## Considering Navigation Options

The STEALTHSTATION® S7® Navigation System can provide assistance with instrument and implant navigation in a minimally invasive spinal fusion procedure (Figures 7a and 7b). The CD HORIZON® Instrumentation, PAK Needle, and first dilator are designed to work seamlessly with the system. In order to navigate a minimally invasive procedure, an additional module containing all of the necessary attachments is required. The STEALTHSTATION® S7® Navigation System provides the ability to use multiple views, including an axial view.

CD HORIZON® LEGACY™ cannulated screws are compatible with the navigation system, and are designed to work with CD HORIZON® LONGITUDE® and CD HORIZON® LONGITUDE® II Instrumentation.



Figure 7a

Image represents the CD HORIZON® LEGACY™ System



Figure 7b

## Accessing the Pedicle

### NIM® 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 8**).

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

For neuromonitoring, a NIM PAK Needle may be used to access the pedicle. Triggered EMG monitoring, such as the NIM-ECLIPSE® Spinal System,\* can be performed during advancement of the needle into the pedicle to ensure proper placement (**Figure 9**).

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 8



Figure 9

## Accessing the Pedicle *continued*

### Pedicle Access

After placing the NIM® PAK Needle at the intersection of the facet and the transverse process, and confirming direction on fluoroscopy, the needle is advanced into the pedicle (**Figure 10**).

AP and lateral fluoroscopy should be used intermittently as needed to confirm direction. An AP image should show the needle tip initially at the lateral margin of the pedicle. As the needle advances toward the base of the pedicle on the lateral image, it should approach the pedicle center on the AP image (**Figures 11a, 11b, and 11c**).

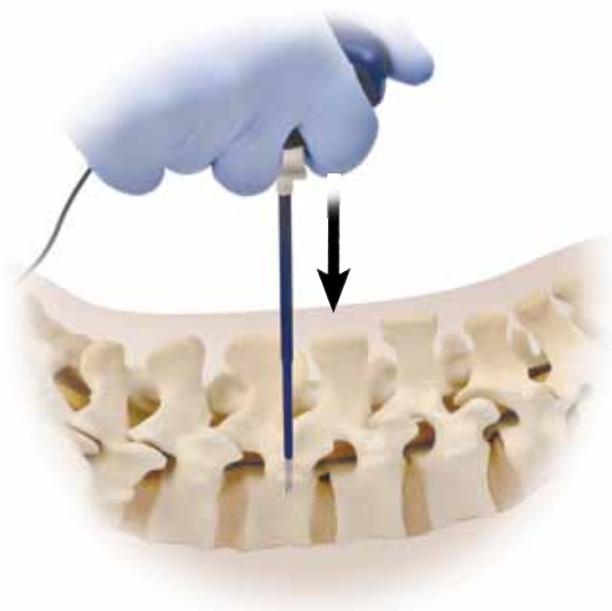


Figure 10

#### ✓ Helpful Tip

*If the needle within the medial wall of the pedicle at the base and trocar has an oblique trajectory into the body, it may appear medial to the pedicle wall due to the oblique trajectory of the needle (**Figure 12**).*

#### ✓ Note

*The NIM® PAK Needle should be advanced across the junction of the pedicle and the vertebral body to allow easier placement of the Guidewire. AP and lateral fluoroscopy should be used to confirm the needle is within pedicle confines when the NIM® PAK Needle is at the base of the pedicle on lateral fluoroscopy.*



Figure 11a



Figure 11b



Figure 11c

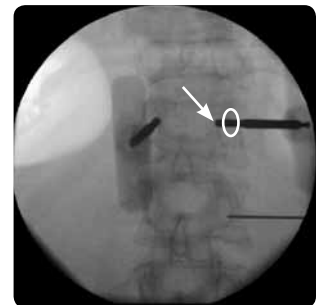


Figure 12



## Accessing the Pedicle *continued*

### Handle and Stylet Removal

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The handle of the NIM® PAK Needle is removed by rotating the locking mechanism to the UNLOCK position and gently pulling the handle upward, ensuring the cannula is not removed from the pedicle (**Figure 13**). If using a NIM® PAK Needle, the inner stylet of the needle is then removed.

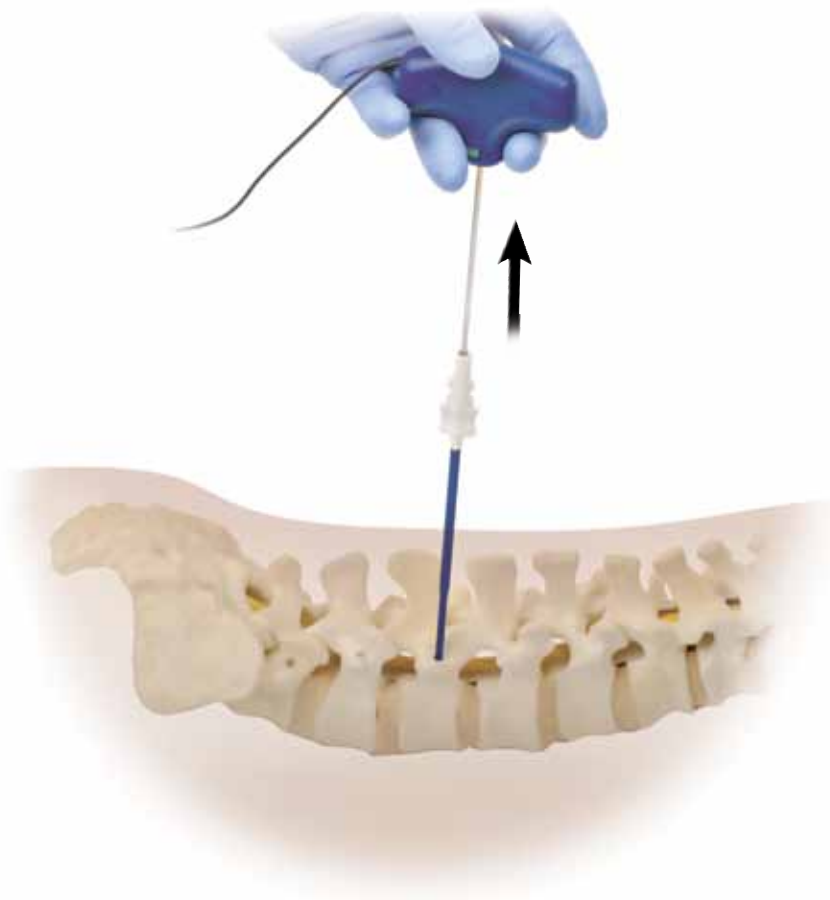


Figure 13

## Guidewire Insertion

The Guidewire is inserted through the cannula and into the pedicle (**Figures 14a and 14b**). 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 (**Figure 15**). The Guidewire insertion steps should be repeated for each Guidewire to be placed.

### ✓ Helpful Tip

*The Guidewire should be advanced approximately 60%–70% into the vertebral body to allow for proper screw placement. This tactic allows for space if the Guidewire advances inadvertently.*

### ✓ Helpful Tip

*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 cannula removal.*

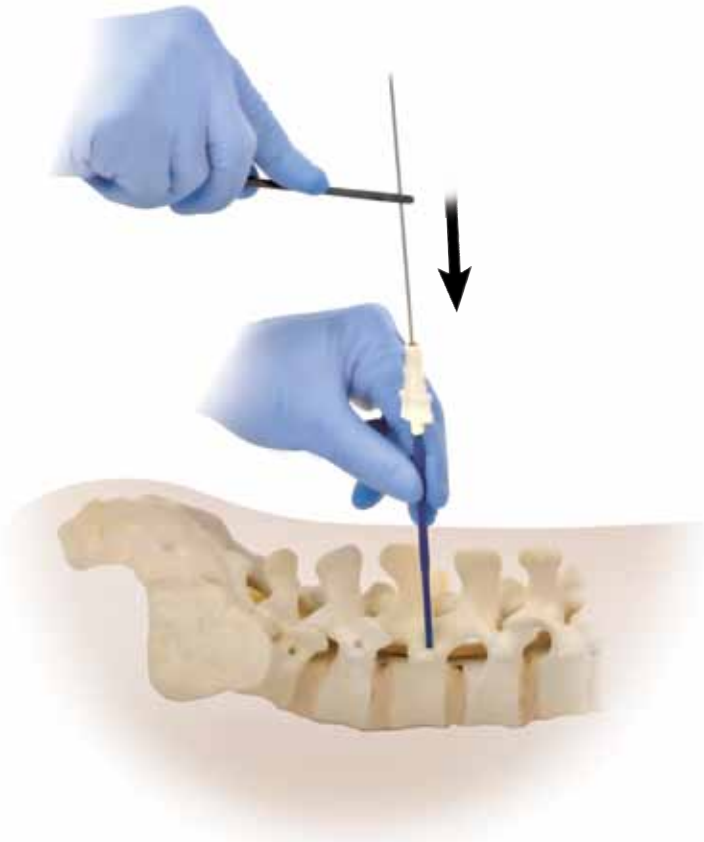


Figure 14a



Figure 14b

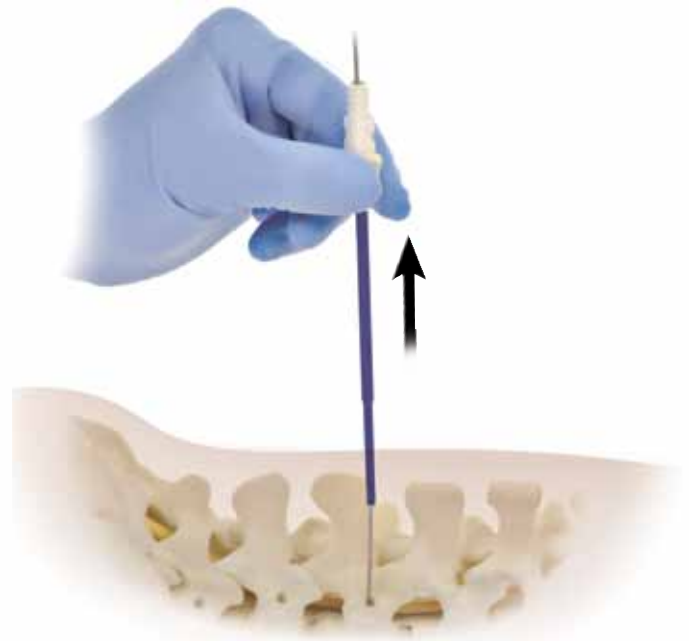


Figure 15

### ✓ Note

*Guidewire, screw extender placement, and rod passage steps are shown on one side only for clarity.*

## Dilation

The fascia and muscle must be dilated to allow for screw placement. Incise the fascia to allow for dilation of the large dilator — approximately 15mm. Three dilators are used to gently make a path of the appropriate dimension (**Figure 16**). Dilators should dock on bony anatomy to minimize tissue creepage (**Figure 17**). The first two dilators are removed, leaving the third dilator to serve as a tissue protection sleeve during the tapping step.

When using the NIM-ECLIPSE® System, a blue Large Disposable Dilator should be used for dilating and tapping purposes. After dilating, the Large Disposable Dilator remains in place and serves as an insulator during the tapping step.



Figure 16

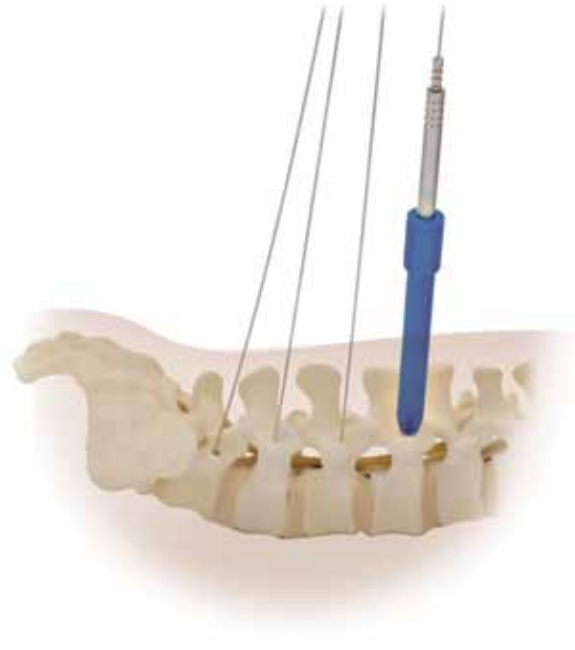


Figure 17

## Pedicle Preparation

The pedicle is prepared by placing the Tap over the Guidewire and through the third dilation sleeve (**Figure 18a**). 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. 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. If using the NIM-ECLIPSE® System\* during this procedure, the Large Disposable Dilator (8675424) must be used.

Alternatively, the IPC® POWEREASE® System\* may be used for tapping (**Figure 18b**). 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. The integrated design allows the POWEREASE® Driver to connect directly to the NIM-ECLIPSE® System.

Further evaluation of the tapped pedicle can be performed by using the NIM-ECLIPSE® System Surgeon-directed Ball-tip Probe to stimulate the Tap (9450097) (**Figure 18c**). Free-running EMG will monitor any nerve root irritation during this procedure (**Figure 18d**).



Figure 18a



Figure 18b



Figure 18c



Figure 18d

### ✓ Helpful Tip

*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 Guidewires prior to tapping and careful attention to other wire lengths can also help.*

\*The POWEREASE® System and the NIM-ECLIPSE® System are manufactured by Medtronic Xomed, Inc. Distributed by Medtronic Sofamor Danek USA, Inc.

## Pedicle Preparation *continued*

### Tap Removal

Hold the Guidewire firmly when removing the Tap and exercise great care to not remove the Guidewire (**Figure 19**). In order to ensure the Guidewire is not removed, the handle may be removed first, then the Tap. 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.

#### ✓ Helpful Tip

*Screw length can be estimated by referencing the depth marks on the Tap with the rim of the Large Dilator. To ensure accuracy, the Dilator must be docked on bone.*

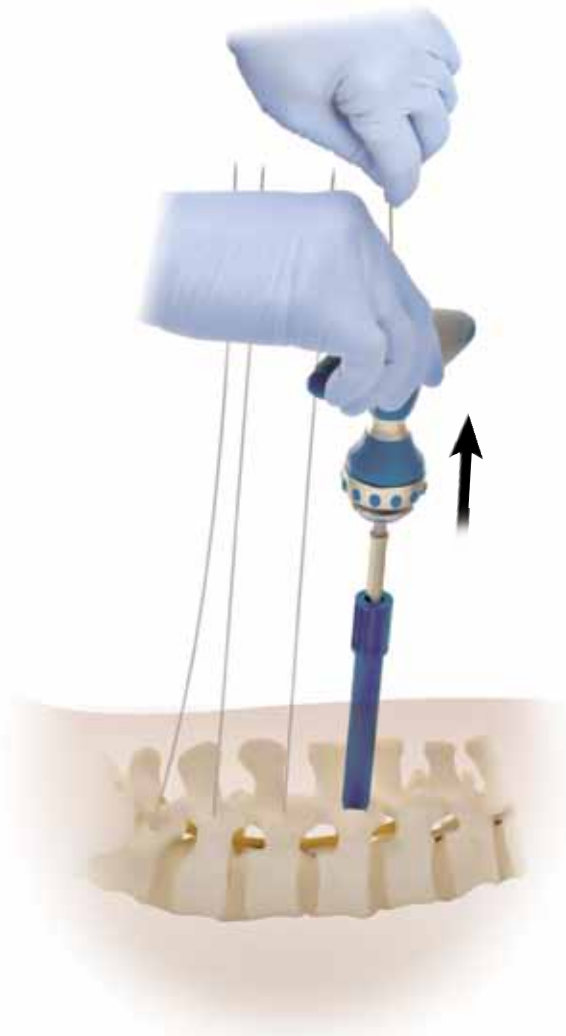


Figure 19

## Pedicle Preparation *continued*

### Final Dilator Removal

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Remove the final Dilator, leaving only the Guidewire in place (**Figure 20**).

✓ Helpful Tip

*Care should be taken when removing the Dilator to ensure the Guidewire is not removed.*

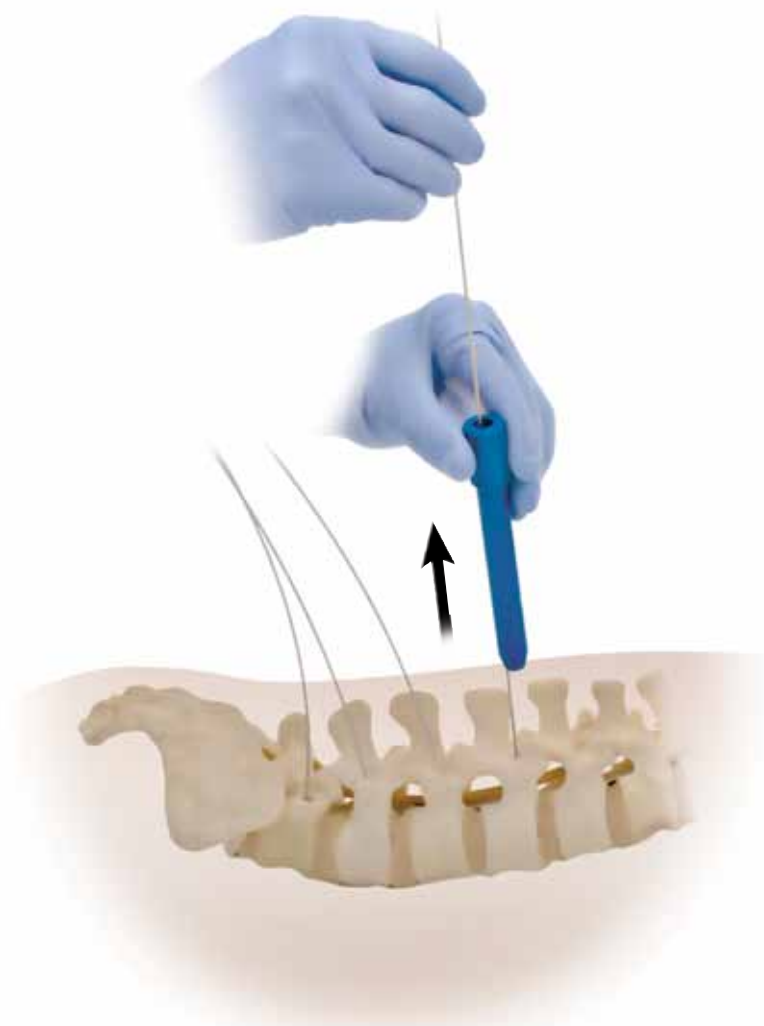


Figure 20

## Screw Extender Assembly

To attach the implant to the Screw Extender, press the extender release buttons and pull up evenly on the screw tab until it is even with the top of the extender. Align the slots and dock the extender to the top of the screw head, aligning the implant slots to the instrument (**Figure 21**). Once aligned, lock the Extender to the implant by pressing the screw tab down (**Figure 22**).

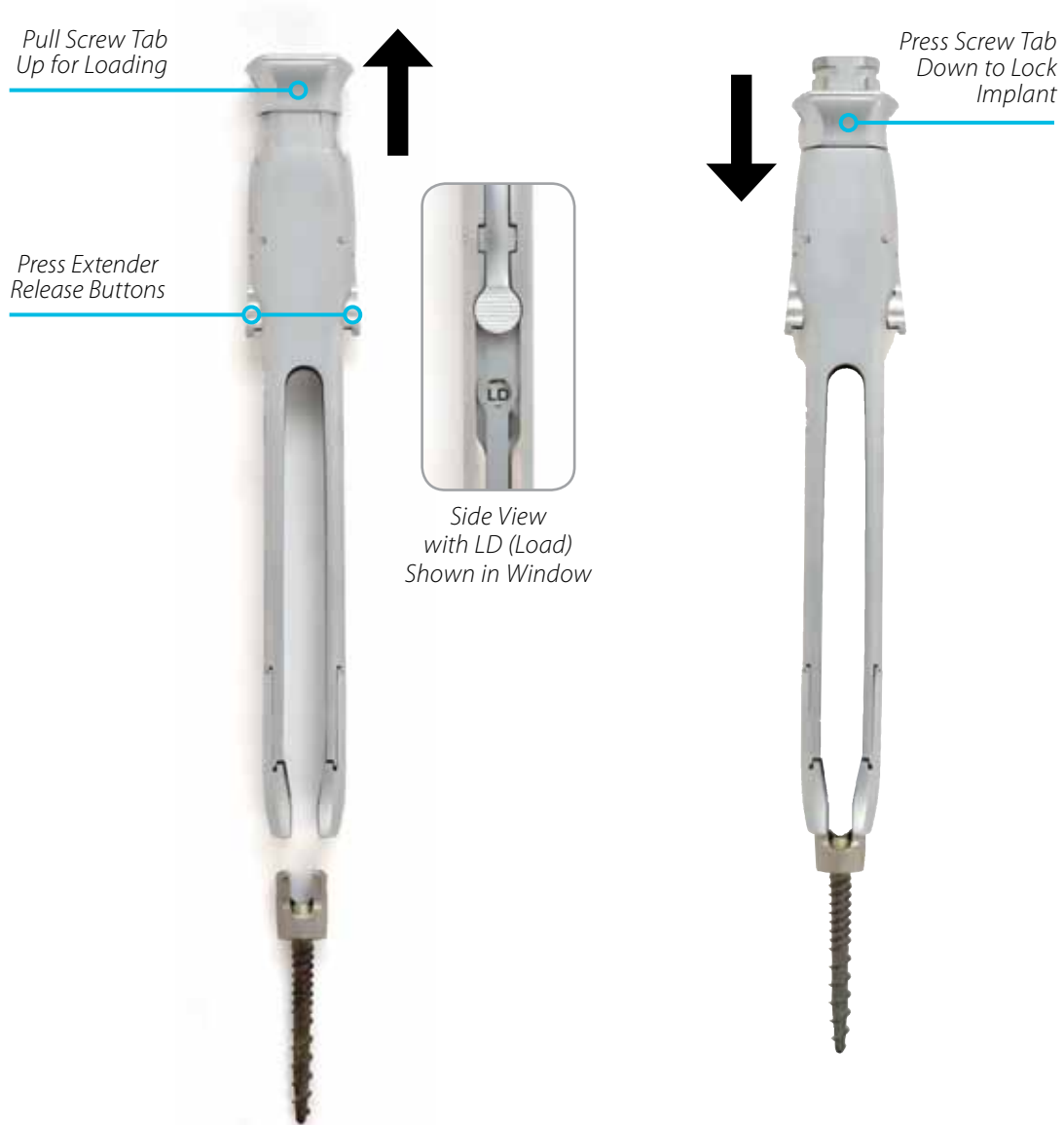


Figure 21

Figure 22

## Screw Extender Assembly *continued*

Insert the driver into the Screw Extender assembly and pass the tip of the driver into the head of the screw until the driver fully engages with the screw. Thread the sleeve of the driver into the head of the screw until tight (**Figure 23**).



Figure 23



## Screw Insertion

Care should be used to avoid inadvertent Guidewire removal prior to screw placement. The entire Screw Extender Assembly is inserted over the Guidewire and into the pedicle (**Figures 24a and 24b**). Be certain the Screw Assembly is not inserted too far. If a multi-axial screw head is inserted flush with the bone, it will lose its multi-axial capabilities. After gaining initial purchase of the pedicle with the screw assembly, remove the Guidewire to prevent it from being advanced too far.

The IPC® POWEREASE® System may be used for insertion of CD HORIZON® SOLERA™ System screws (**Figure 24c**). 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. For comprehensive instructions refer to the POWEREASE® User Manual.

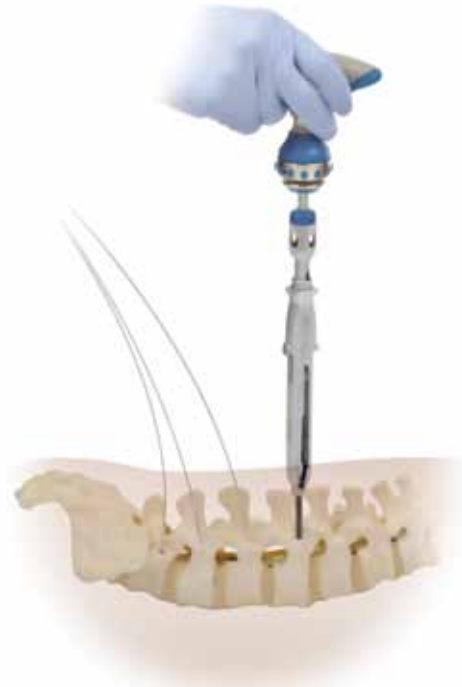


Figure 24a



Figure 24b



4.75mm Screwdriver (2342306-L)  
5.5/6.0mm Screwdriver (2342305-L)

Figure 24c

### ✓ Helpful Hints

*The nerve hook may be used to pull fascial and skin edges around the Screw Extender once the Screw is in place.*

## Screw Insertion *continued*

Repeat steps for each Screw Extender to be placed (**Figure 25**). Under fluoroscopy, visualize screws to ensure they line up coronally as much as possible.



*Figure 25*

## Rod Preparation

### Align Extenders for Rod Passage

---

Once all of the Extenders are in place, rotate the Extenders as needed to ensure the buttons and markings in the windows face medial/lateral (**Figure 26**). This will align the windows at the distal tip of the Extenders in a position that will allow the Rod to be passed.



*Figure 26*

## Rod Preparation *continued*

### Measure for Rod Length

---

Lay the Rod Template on the skin next to the Extenders. Bend the Template accordingly to ensure all portions of the rod measurement device are in contact with the skin (**Figure 27**). Read the measurement off the Template to estimate the length of the rod to be inserted.



Figure 27

## Rod Preparation *continued*

### Attach Rod to Inserter

Open the top clasp on the Inserter by pulling back on the button behind the clasp and lifting the clasp. Insert the appropriate-length rod, and close the top clasp until it clicks to lock the rod in place (**Figures 28a and 28b**). If needed, use the Rod Bender to bend the Rod according to patient anatomy (**Figure 29**). Do not bend the Rod prior to placing it in the Rod Inserter. To estimate any bend for the Rod, place the Rod Inserter lateral to the patient and take a lateral fluoroscopy. Then compare the bend in the rod-to-screw trajectory and alter as needed.



Figure 28a



Figure 28b

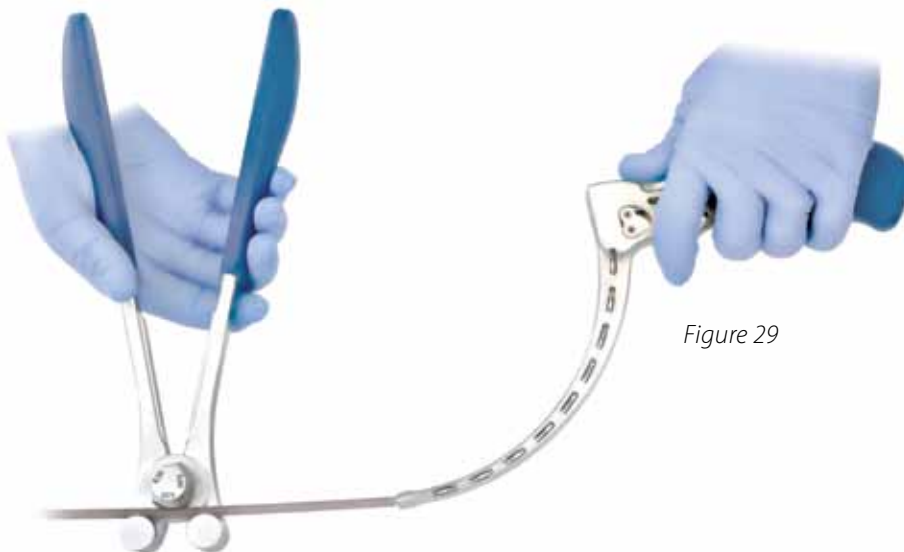


Figure 29

## Rod Preparation *continued*

### Rod Entry Point

Using a measurement device, measure 2.5cm to 5cm from the most cephalad Extender and make an incision approximately 1cm in length (**Figure 30**).



Figure 30

#### ! Important

The Rod Entry Point Estimator can also be used by attaching it to the most cephalad Extender and moving the Extender to ensure that it is either perpendicular to the skin or pointing slightly toward the caudal Extenders (**Figure 31a**). Allow the Rod Entry Point Estimator to fall freely to the skin and make a 1cm vertical incision (**Figure 31b**).

*NOT* moving the most cephalad Extender either perpendicular to the skin or slightly angled toward the caudal Extender will estimate the rod entry point too far cephalad.



Figure 31a



Figure 31b

## Rod Passage

### Pass Rod Through First Extender — Cephalad to Caudal

Pass the Rod through the incision and below the fascia to the opening of the first Extender (**Figures 32a and 32b**). Use AP and lateral fluoroscopy as necessary in combination with tactile and visual feedback to find the path through the window in the first Extender (**Figure 33**).



Figure 32a

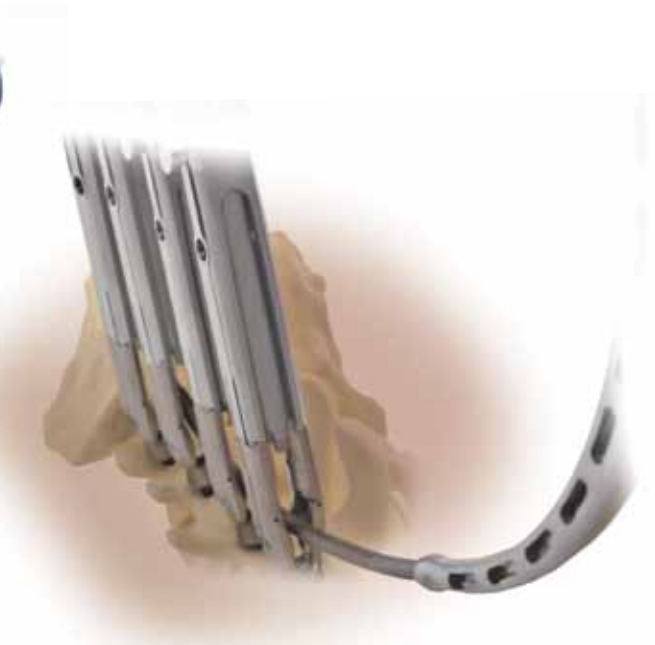


Figure 32b

#### ! 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.*

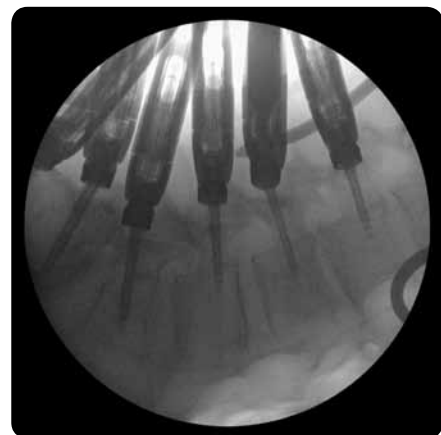


Figure 33

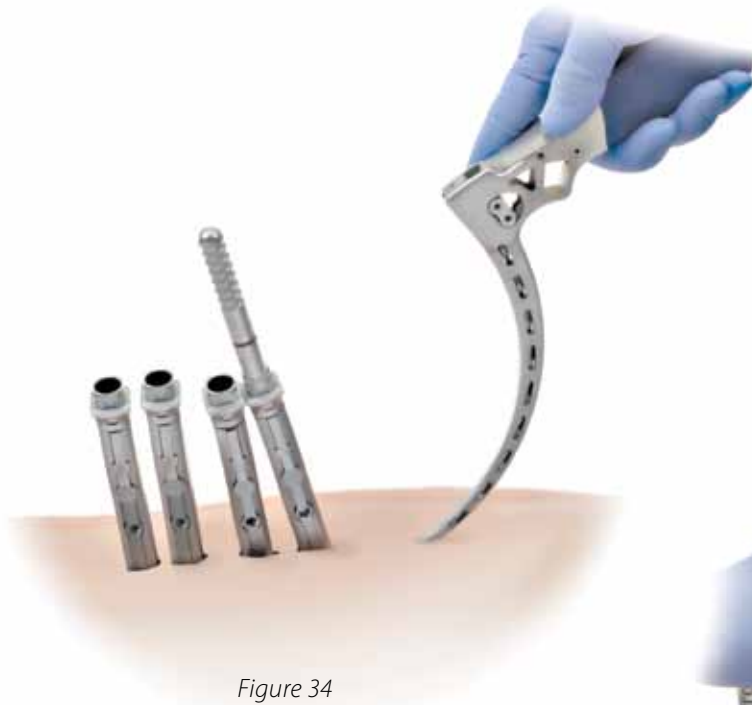
## Rod Passage *continued*

### Confirm Rod Passage

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Once you believe the rod is through the window of the first (or any) Extender, you can use additional methods to test rod passage by either:

1. Dropping the Rod Confirmation Tool down the shaft of the Extender. If the line is visible, the rod is through the Extender (**Figure 34**). If the line is not visible, the rod is not through the Extender.
2. If using Multi-Axial Screws, rotate the Extender by hand (**Figure 35**). If the Extender rotates freely, then the rod has not passed through the Extender.





## Rod Passage *continued*

### Pass Rod Through Subsequent Extenders

After the rod is through the first Extender, guide it via the steering handle through the remaining Extenders using tactile feel, AP and lateral fluoroscopy images, the Rod Confirmation Tool, and the Extender rotation technique as necessary (**Figures 36a and 36b**).



Figure 36a

To pass a kyphotic Rod, the handle may be used to rotate the Rod in the patient. For example, a coronal bend may initially be placed in the Rod. The Rod may then be passed in a lordotic manner through the first two Extenders with the handle on its side. Once through the first two Extenders, the handle may be rotated 180° to pass a now kyphotic Rod through the Extenders (**Figure 36c**).

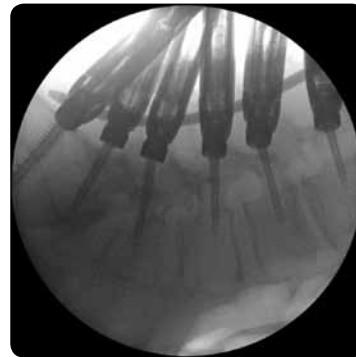


Figure 36b

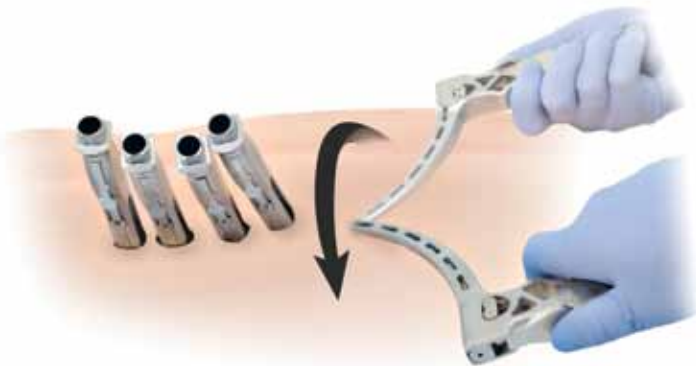


Figure 36c



Figure 37

#### ✓ Helpful Tip

*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 37**).*

## Rod Passage *continued*

### Confirm Rod Overhang

With the rod confirmed through all of the Extenders, use lateral fluoroscopy to ensure that the Inserter has not passed through the first Extender and that the overhang on the cephalad and caudal Extenders is acceptable (**Figures 38a and 38b**).



Figure 38a



Figure 38b

#### ! Important

*The Inserter can pass through the first Extender. It is important to confirm with fluoroscopy that only the Rod passed through the Extender. A sliver of rod should be visible on fluoroscopy between the Extender and the tip of the Inserter and also from the most caudal screw of the construct (**Figure 39**).*

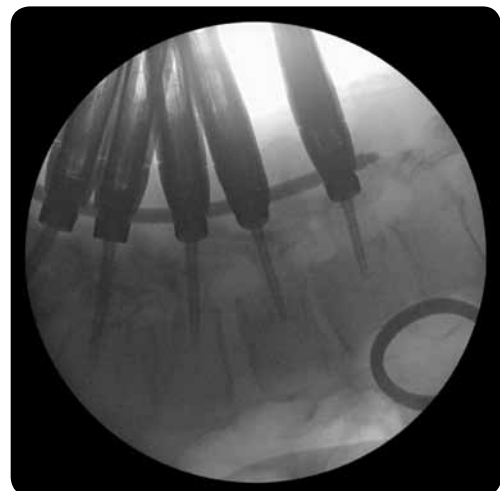


Figure 39

## Rod Reduction

### Reducing the Rod in Stages

To attach the Rod Reducer to the Screw Extender, slide the reducer into the extender and press the Rod Reducer release buttons on both sides to lock it into place (**Figure 40a**). While holding the Inserter in place, use the Reduction Nut and Ratchet Egg Handle to reduce the Rod in stages until all of the Extenders read RD (Reduced) in the window and the Rod is fully seated. It is important to reduce the Rod in stages (**Figure 40b**). The complete reduction of one Extender without reducing the others will cause the Rod to put a strong force on the other Extenders, which can cause difficulties when reducing the others.

Once the Extender window reads RD to show the rod has been seated in the screw heads, repeat the steps on the contralateral side.

As an alternative to manually sequentially reducing the rods, the IPC® POWEREASE® System can also be used to reduce the rod into the screw heads. Attach the POWEREASE® System Reduction Nut Driver (2342403) to the POWEREASE® System Driver and place it over the reduction nut to begin staged reduction (**Figure 40c**). It is recommended that the Integrated Power Console (IPC® System) be set between 40-80 RPMs in the “forward” speed and adjusted to 100-120 RPMs in the “reverse” speed.

#### ! Important

*Do not over-reduce the Extenders. Once the Extender is in the RD position, advancing further will place unneeded pressure on the tulip portion of the Screw.*

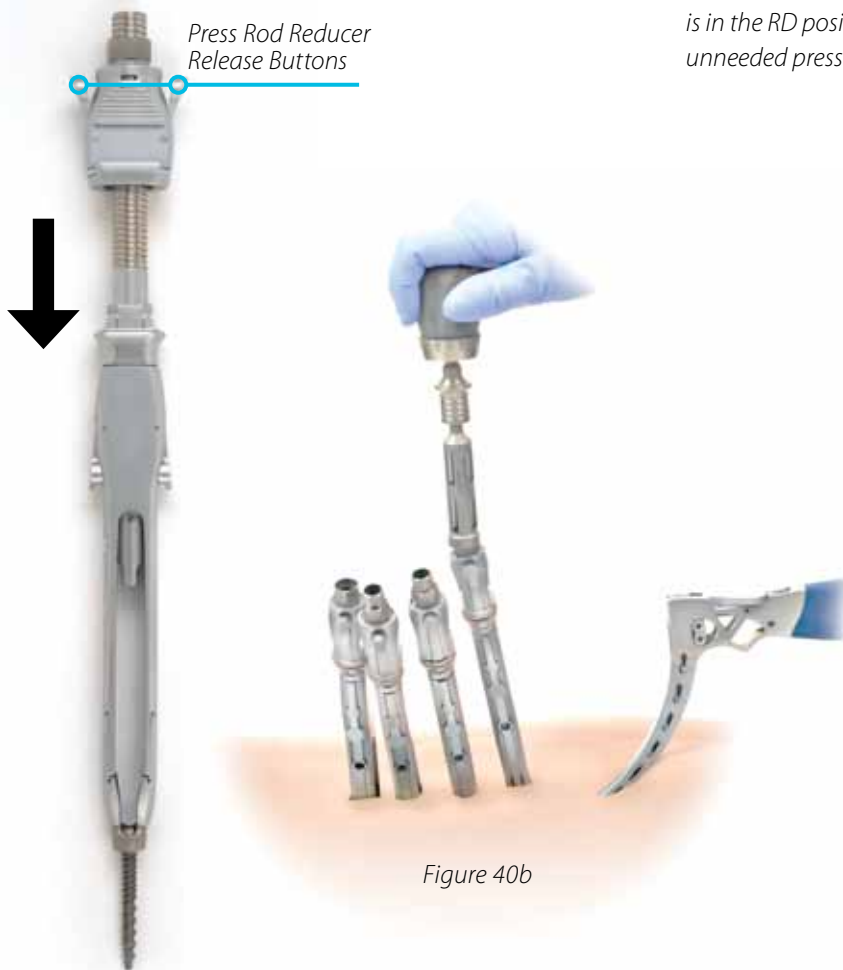


Figure 40a



Figure 40b



Figure 40c

## Derotation Options

Derotation of the vertebral bodies can be accomplished using the screw extenders. After rod is passed and situated in the sagittal plane, begin reducing the rod, starting at the apex of the curve and sequentially reducing adjacent levels starting proximally and then distally. If it is a Thoracic Curve, reduce the concave rod side first and if it is a Lumbar Curve, reduce the convex rod side first. Once the rod is completely reduced/seated in most apical screws, hold extenders and cantilever/push them which will further rotate the vertebral bodies over a fixed rod held in the sagittal plane. It is important to have someone hold the Rod inserter in place, while performing this maneuver (**Figure 41**). After the derotation is complete insert the set screws as described on the following page.



Figure 41

## 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 (7578900).

Begin by loading the set screw on the tip of the driver. Push the button on the driver handle (**Figure 42a**). While pushing the button, insert the set screw on the distal tip of the driver (**Figures 42b and 42c**). Release the button and tug on the set screw to ensure a secure connection.

Provisionally tighten the set screws to secure the rod. Once the rod is secure the Rod Inserter can be detached from the rod.

### ✓ Helpful Hint

*The button on the Set Screw Retaining Driver handle should be proud once the set screw is loaded.*



Figure 42a

Figure 42b

Figure 42c

## Compression/Distraktion

To compress, loosen the set screw from the screw in the vertebral body to be compressed to allow the implant to move along the rod. The Rod Reducer will also need to be turned counterclockwise from the RD position to allow for movement along the rod. Slide the Compressor instrument along the outside of the extenders down to the rod of the screws to be compressed (**Figures 43a and 43b**). Perform the compression and then tighten the set screw to maintain the compressed position.



Figure 43a

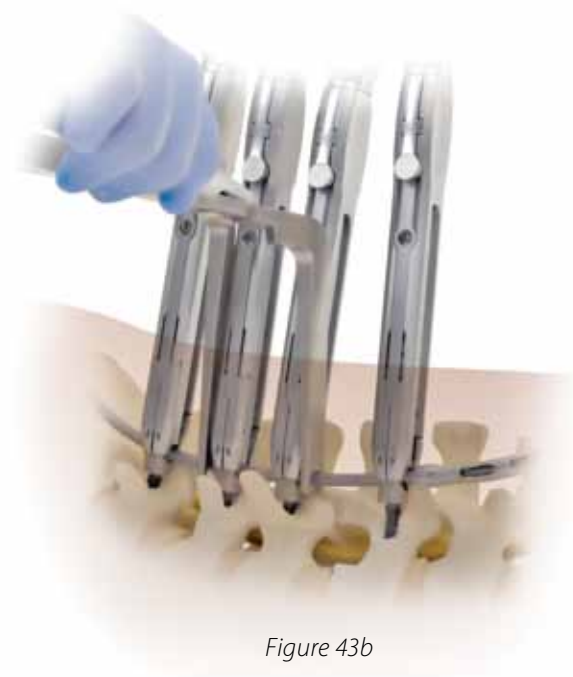


Figure 43b

## Compression/Distraction *continued*

To distract, loosen the set screw from the screw in the vertebral body to be distracted to allow the implant to move along the rod. The Rod Reducer will also need to be turned counterclockwise from the RD position to allow for movement along the rod. Slide the Distractor instrument along the inside of the extenders down to the rod of the screws to be distracted (**Figures 44a, 44b, and 44c**). Perform the distraction maneuver and then tighten the set screw to maintain the distracted position.



Figure 44a

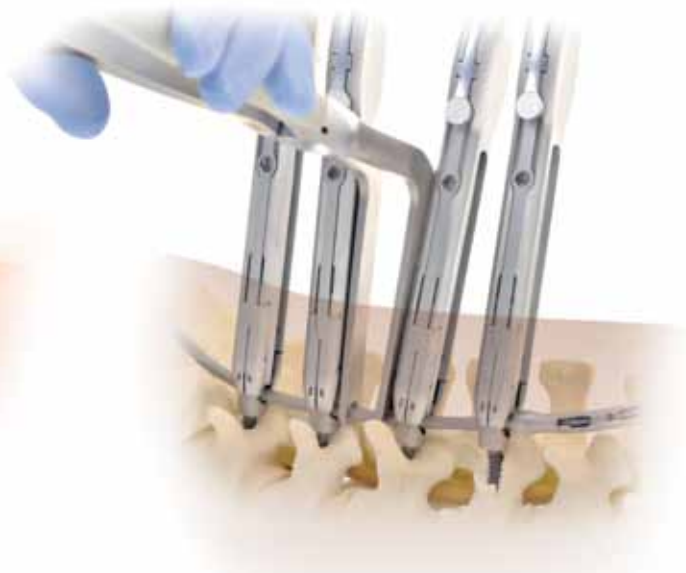
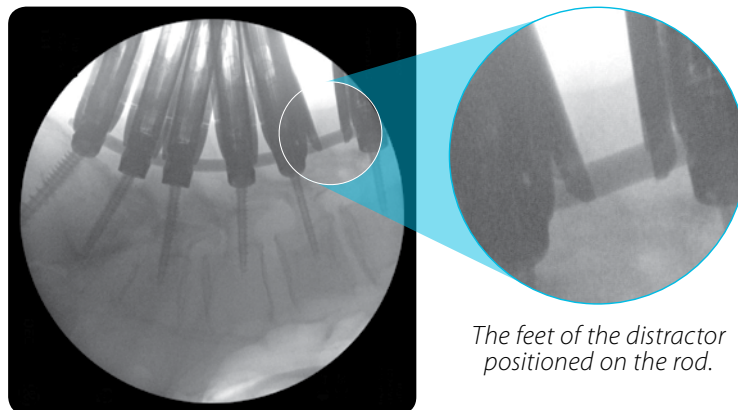


Figure 44b



*The feet of the distractor positioned on the rod.*

Figure 44c

## Set Screw Break-off

Once compression/distraction is complete, use the Counter Torque on the Extender and insert the Self-retaining Set Screw Driver into the Set Screw and break off (**Figure 45**).



Figure 45

✓ Note

*In situ Benders are available if additional rod contouring is required prior to final tightening.*



## Instrument Removal

Once all Set Screws have been broken off, press the Rod Reducer release buttons on both sides to release it from the Screw Extenders (Figure 46a). Next, detach the Screw Extenders from the rod/screw construct by pressing the extender release buttons and pulling up firmly on the screw tab (Figures 46b, 46c, and 46d).

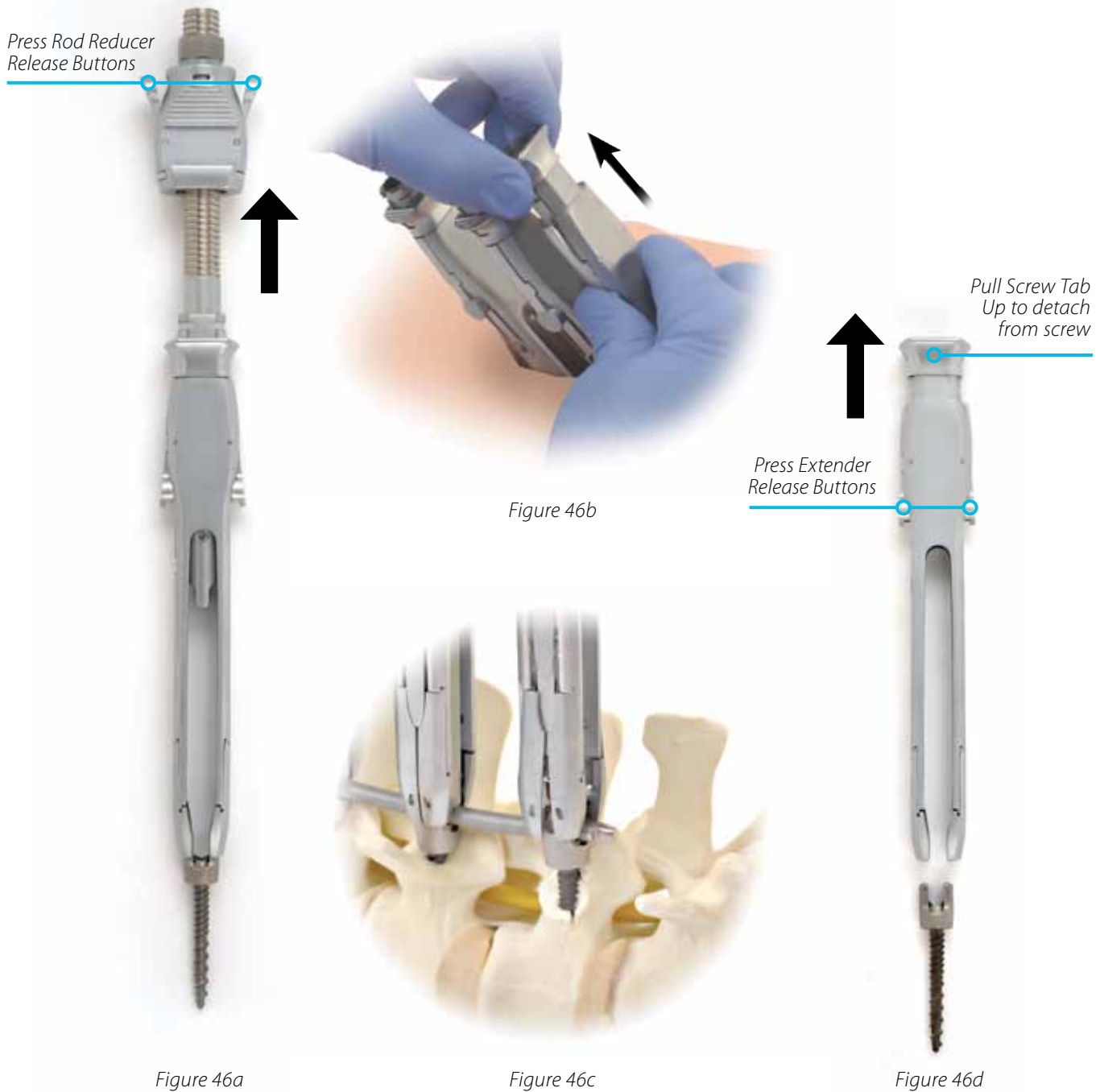


Figure 46a

Figure 46c

Figure 46d

## Closure

Prior to closure, do a final check to ensure that the set screws are symmetrically seated in the screw heads and sheared off, that the bone graft has not become dislodged during manipulation, and that a proper count of all sheared-off set screw heads is correct (Figures 47a and 47b).



*Figure 47a*



*Figure 47b*

## Facet Fusion

### Dilation and Retractor Insertion

Once the screws have been placed and the screw extenders have been removed a facet fusion may be performed. Repeat the tube dilation steps through the screw extender portal to access the facet joint (**Figure 48**). Insert the MAST QUADRANT® Retractor over the dilators and onto the bony anatomy then remove the dilators. Adjust the retraction to visualize the facet joint (**Figure 49**). For comprehensive retractor instructions refer to the MAST QUADRANT® Retractor System Surgical Technique.



Figure 48

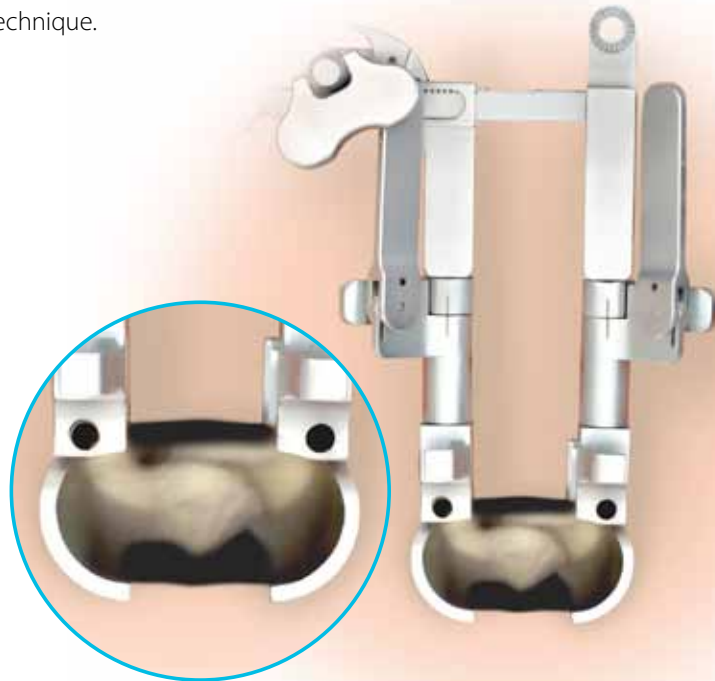


Figure 49

## Facet Fusion

### Decortication and Bone Graft Placement

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Use cautery to expose the articulation between the superior and inferior facets. Alternatively, you may insert and rotate a Freer elevator between the joints. Use a high-speed burr or similar instrument to decorticate the bone (**Figure 50**). Precise placement of bone graft (autograft or allograft bone) is essential to facilitate fusion. A number of Medtronic bone graft options are available to use as fillers for bony voids or gaps of the skeletal system that are not intrinsic to the stability of bony structure. Repeat the facet fusion technique on all of the levels for intended fusion.



Figure 50

## Pelvic Fixation Options

### Inside Out Sacral Fixation Technique

There are many iliac and sacral screw options available today for pelvic fixation. The technique used is always dependent upon surgeon preferences and patient anatomy. The following describes the Inside Out method which is one of many fixation techniques that can be used.

The trajectory starting point for this technique uses direct or enhanced fluoroscopic, 2D/3D-based navigation to locate the starting point which is on inside crest of the iliac spine, medial to the PSIS. The location can be palpated and is typically approximately 15 to 20mm higher than the S1 pedicle entry point (**Figure 51**).

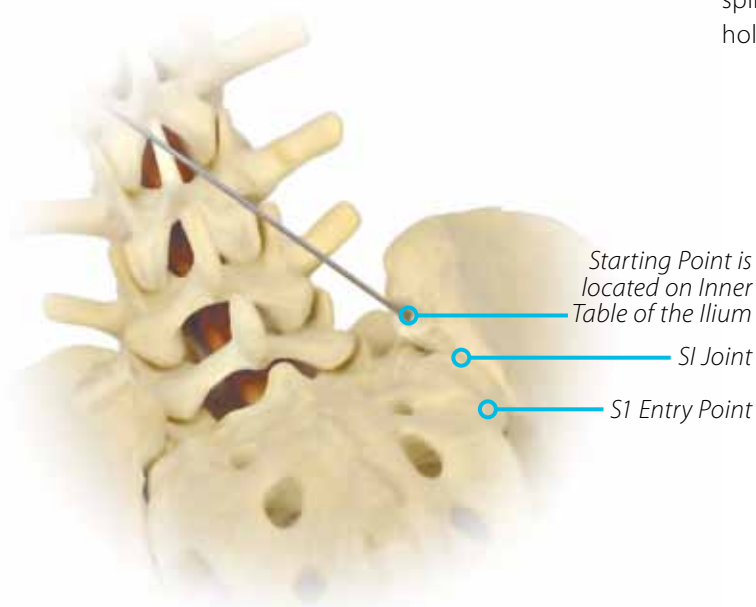


Figure 51

After the starting point is located, the trajectory should be established by aiming lateral and paralleling the sacroiliac (SI) joint toward the greater trochanter of the femur (**Figure 52**). Enhanced visualization, to include an oblique Ferguson view of the iliac crest, can be used to confirm the trajectory (**Figure 53**). This view will confirm for the surgeon that they are lateral to the SI joint and medial to the lateral border of the iliac crest.

Following confirmation of the starting point and the trajectory, a probe or PAK needle can be used to create the pilot hole. Care should be taken using fluoroscopy, spinal navigation, and tactile feel to confirm the pilot hole is entirely within the iliac crest (**Figure 54**).



Figure 52

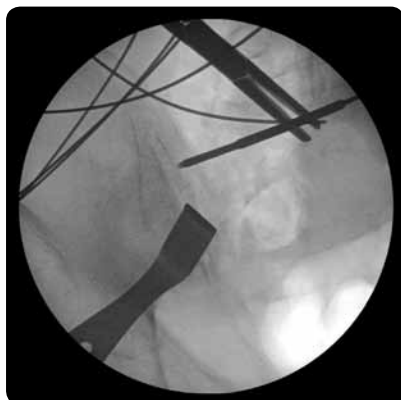


Figure 53



Figure 54

## Pelvic Fixation Options *continued*

### Inside Out Sacral Fixation Technique *continued*

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Once the pilot hole is established an optional guidewire can be used to localize the hole and serve as a switching stick for the dilators, tap, and screw. If a guidewire is used, optional dilators can be used to create a path through the muscle to the starting point of the screw.

Next, the tap is inserted and the pilot hole is tapped in preparation for the screw. The tap should travel at least through the cortical shell of the iliac crest. If dilators are used, the tap is inserted over the guidewire and through the dilator. If dilators are not used, the tap is just inserted

over the guidewire. Fluoroscopy and/or spinal navigation can be used to confirm the tap is following the pilot hole and that it is not advancing the guidewire.

Once the tap has been removed a screw is inserted over the optional guidewire or directly into the pilot hole. The screw should be advanced such that the tulip head is in close proximity, but proud, to the iliac crest. Again, fluoroscopy and/or spinal navigation can be used to confirm the screw trajectory. After the screw is inserted, a rod is used to connect to the proximal portion of the construct (**Figures 55a and 55b**).



Figure 55a

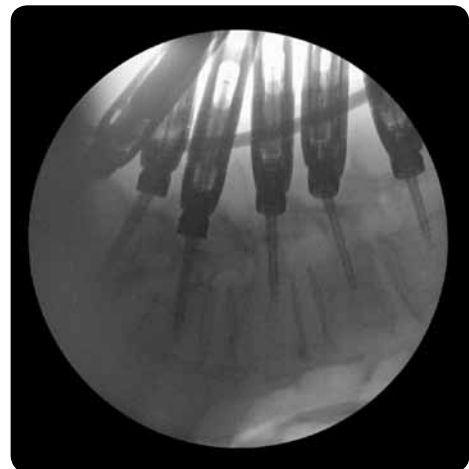


Figure 55b

## Product Ordering Information *continued*

### CD HORIZON® LONGITUDE® II 5.5mm Percutaneous Rods



Catalog Number	Description
1555006070	70mm Straight Cobalt Chrome
1555006080	80mm Straight Cobalt Chrome
1555006090	90mm Straight Cobalt Chrome
1555006100	100mm Straight Cobalt Chrome
1555006110	110mm Straight Cobalt Chrome
1555006120	120mm Straight Cobalt Chrome
1555006130	130mm Straight Cobalt Chrome
1555006140	140mm Straight Cobalt Chrome
1555006150	150mm Straight Cobalt Chrome
1555006160	160mm Straight Cobalt Chrome
1555006170	170mm Straight Cobalt Chrome
1555006180	180mm Straight Cobalt Chrome
1555006190	190mm Straight Cobalt Chrome
1555006200	200mm Straight Cobalt Chrome
1555006210	210mm Straight Cobalt Chrome
1555006220	220mm Straight Cobalt Chrome
1555006230	230mm Straight Cobalt Chrome
1555006240	240mm Straight Cobalt Chrome
1555006250	250mm Straight Cobalt Chrome
1555006260	260mm Straight Cobalt Chrome

### CD HORIZON® LONGITUDE® II 4.75mm Percutaneous Rods



Catalog Number	Description
1476006070	70mm Straight Cobalt Chrome Plus
1476006080	80mm Straight Cobalt Chrome Plus
1476006090	90mm Straight Cobalt Chrome Plus
1476006100	100mm Straight Cobalt Chrome Plus
1476006110	110mm Straight Cobalt Chrome Plus
1476006120	120mm Straight Cobalt Chrome Plus
1476006130	130mm Straight Cobalt Chrome Plus
1476006140	140mm Straight Cobalt Chrome Plus
1476006150	150mm Straight Cobalt Chrome Plus
1476006160	160mm Straight Cobalt Chrome Plus
1476006170	170mm Straight Cobalt Chrome Plus
1476006180	180mm Straight Cobalt Chrome Plus
1476006190	190mm Straight Cobalt Chrome Plus
1476006200	200mm Straight Cobalt Chrome Plus
1476006210	210mm Straight Cobalt Chrome Plus
1476006220	220mm Straight Cobalt Chrome Plus

## Product Ordering Information *continued*

### Cannulated Multi-Axial Screws



4.75mm	5.5/6.0mm	Description
54840014530	55840014530	4.5mm x 30mm
54840014535	55840014535	4.5mm x 35mm
54840014540	55840014540	4.5mm x 40mm
	55840015530	5.5mm x 30mm
54840015535	55840015535	5.5mm x 35mm
54840015540	55840015540	5.5mm x 40mm
54840015545	55840015545	5.5mm x 45mm
54840015550	55840015550	5.5mm x 50mm
54840016535	55840016535	6.5mm x 35mm
54840016540	55840016540	6.5mm x 40mm
54840016545	55840016545	6.5mm x 45mm
54840016550	55840016550	6.5mm x 50mm
54840016555	55840016555	6.5mm x 55mm
54840017530		7.5mm x 30mm
54840017535	55840017535	7.5mm x 35mm
54840017540	55840017540	7.5mm x 40mm
54840017545	55840017545	7.5mm x 45mm
	55840017550	7.5mm x 50mm
	55840017555	7.5mm x 55mm
	55840018590	8.5mm x 90mm
	55840018500	8.5mm x 100mm
	55840018511	8.5mm x 110mm
	55840019590	9.5mm x 90mm
	55840019500	9.5mm x 100mm
	55840019511	9.5mm x 110mm
	55840011590	10.5mm x 90mm
	55840011500	10.5mm x 100mm
	55840011511	10.5mm x 110mm

### CD HORIZON® SOLERA™ SEXTANT® Set Screws



Catalog Number	Description
5440430	4.75mm Titanium Non-sterile Break Off SEXTANT Set Screws
5540430	5.5/6.0mm Titanium Non-sterile Break Off SEXTANT Set Screws



## Important Product Information

### SUMMARY OF IMPORTANT PRODUCT INFORMATION FOR THE CD HORIZON® SPINAL SYSTEM

#### 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 and/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 adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, and fracture caused by tumor and/or trauma. 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

## Important Product Information *continued*

- 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, and/or 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 and/or distorted anatomy)
- Pedicle screw malpositioning, with or without neurological or vascular injury
- Proximal or distal junctional kyphosis
- Pancreatitis

### WARNINGS

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.

## Important Product Information *continued*

### **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.**

## Summary of Important Product Information for the POWEREASE® System

### INDICATIONS FOR USE

The IPC® POWEREASE® System is indicated for drilling, tapping, and driving screws and working end attachments during spinal surgery, including open and minimally invasive procedures. It is also used in the placement of screws or cutting of screws, posts, and rods.

The IPC® POWEREASE® System is indicated for the incision/cutting, removal, drilling, and sawing of soft and hard tissue and bone, and biomaterials in Neurological (Cranial, Craniofacial), Orthopedic Arthroscopic, Spinal, Sternotomy, and General surgical procedures.

Do not cut rods *in situ*.

Refer to the Reprocessing Instructions for the POWEREASE® System Working Ends package insert (M708348B184) for the cleaning instructions and sterilization parameters and requirements.

## Notes

## 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.

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

