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Medtronic

# CD HORIZON® SOLERA™ Spinal System

## Pathology Surgical Technique

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## Pathology Surgical Technique

### Index of Pathologies



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.

# Pedicle Screw Placement

## STEP 1 – Pedicle Positioning

### Thoracic Pedicle Screws

Clean the facet joints and perform a partial inferior articular process osteotomy to enhance visualization and fusion. Remove 3mm to 5mm of the interior facet and denude the articular cartilage on the superior facet, except for the lowest vertebra to be instrumented. This will allow for the intraoperative localization of the thoracic pedicle screw starting points.

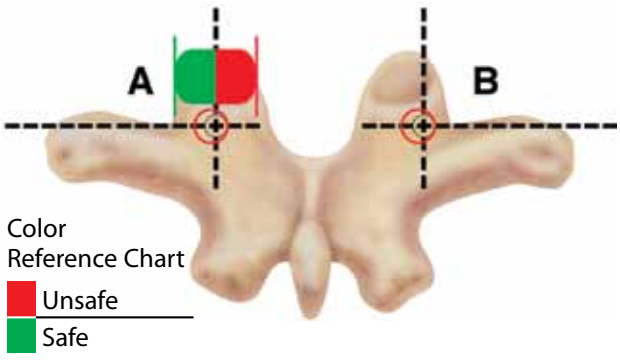
Anatomic starting points vary by the posterior elements that can be observed intraoperatively. These include the transverse process, the lateral portion of the pars interarticularis, and the base of the superior articular process. After a thorough exposure, use as much anatomic information as possible by starting with a neutral, non-rotated vertebra. The lateral and posterior views shown on page XX can be used as a guide for starting points and screw trajectory.

### Lumbar Pedicle Screws

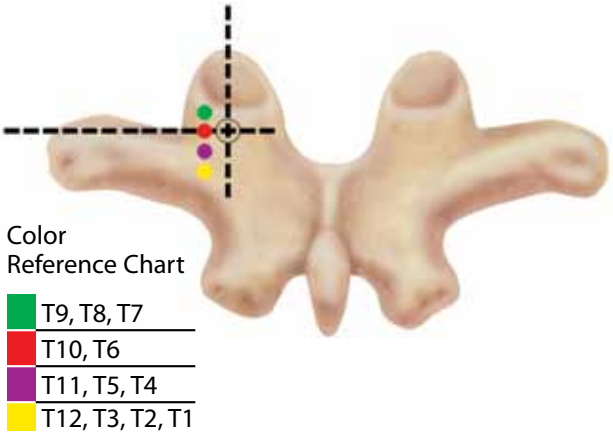
After a thorough exposure, use as much anatomic information as possible by starting with neutral, non-rotated vertebra. The lateral and posterior views of the vertebral segment can be used as a guide for starting points and screw trajectory. Lumbar pedicle screws are placed in the straightforward trajectory and can extend to the anterior cortical wall if desired.

The first and extremely critical step to achieve the desired correction is the safe and secure placement of segmental pedicle screws. Knowledge of the Superior Facet Rule (A) to direct the medial/lateral and the cephalocaudal Starting Points (B) is a helpful reference to accomplish this.

*Superior Facet Rule (A)*




*Cephalocaudal Starting Points (B)*



# Pedicle Screw Placement *continued*

## STEP 1 – Pedicle Positioning *continued*

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

The CD HORIZON® SOLERA™ 5.5/6.0mm Spinal System offers four different screw types, each with specific functionality and each requiring 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.

**Multi-Axial Reduction Screws (MARS):** Like the MAS, these screws can be inserted with the bone screw shaft at the most convenient angle of insertion. The extended tabs on the screw head allow for a larger window to capture and slowly reduce the spinal rod into the implant and are broken off when rod reduction is complete.

*Multi-Axial Screw (MAS)*

*Accepts 5.5mm and 6.0mm rods to accommodate construct demand.*

*Multi-Axial Reduction Screw (MARS)*

# Pedicle Screw Placement *continued*

## STEP 1 – Pedicle Positioning *continued*

**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.

*Fixed Angle Screw (FAS)*

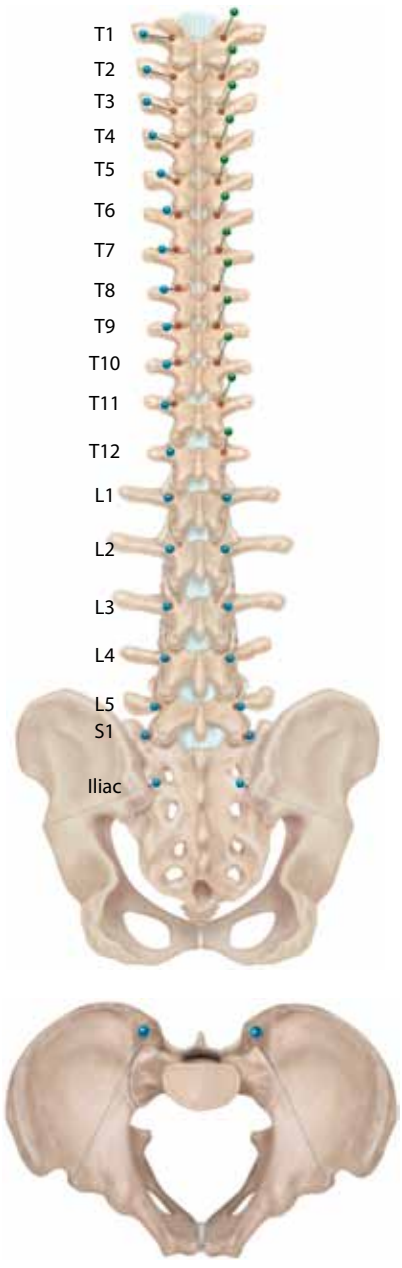
*Sagittal Adjusting Screw (SAS)*

*SAS Implant Accommodates Sagittal Adjustment of Vertebral Bodies.*

# Pedicle Screw Placement *continued*

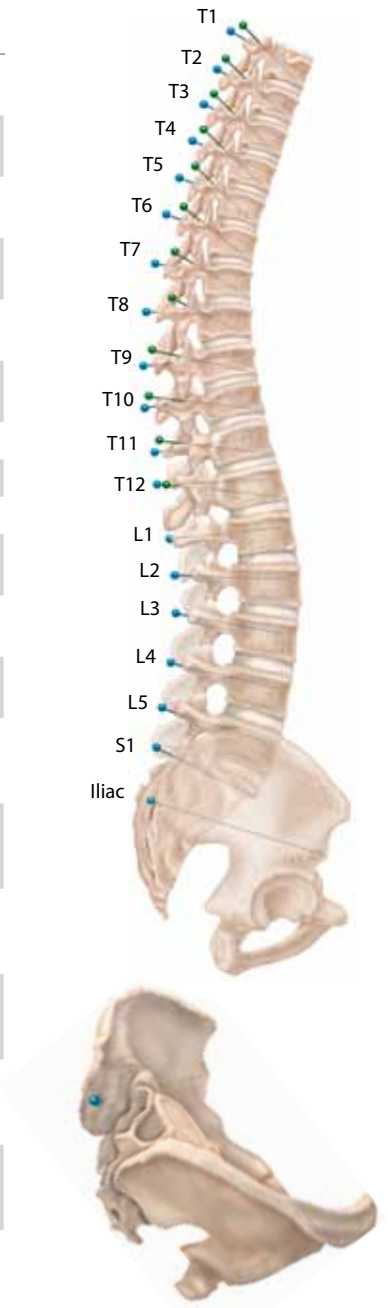
## Starting Point Reference

Sagittal Adjusting, Fixed Angle, or Multi-Axial Screws may be used for the straightforward approach (Blue Pins). Use Sagittal Adjusting or Multi-Axial Screws only for the anatomic approach (Green Pins). The anatomic approach is dependant upon the screw's ability to accommodate to the sagittal position of the spinal rod and not introduce unintended shear force on the vertebra. Typically when using the SAS in an anatomic approach there will be less correction of the hypokyphosis which is usually seen in AIS patients.




*Axial View*

| Level | Cephalad-Caudad Starting Point | Medial-Lateral Starting Point |
|---|---|---|
| T1 | Midpoint Transverse Process (TP) | Junction: TP-Lamina |
| T2 | Midpoint TP | Junction: TP-Lamina |
| T3 | Midpoint TP | Junction: TP-Lamina |
| T4 | Junction: Proximal Third-Midpoint TP | Junction: TP-Lamina |
| T5 | Proximal Third TP | Junction: TP-Lamina |
| T6 | Junction: Proximal Edge-Proximal Third TP | Junction: TP-Lamina-Facet |
| T7 | Proximal TP | Midpoint Facet |
| T8 | Proximal TP | Midpoint Facet |
| T9 | Proximal TP | Midpoint Facet |
| T10 | Junction: Proximal Edge-Proximal Third TP | Junction: TP-Lamina-Facet |
| T11 | Proximal Third TP | Just medial to lateral pars |
| T12 | Midpoint TP | At the level of lateral pars |
| L1 | Midpoint TP | Junction: Lateral pars and superior facet |
| L2 | Midpoint TP | Junction: Lateral pars and superior facet |
| L3 | Midpoint TP | Junction: Lateral pars and superior facet |
| L4 | Midpoint TP | Junction: Lateral pars and superior facet |
| L5 | Midpoint TP | Junction: Lateral pars and superior facet |
| S1 | Midpoint Sacral Ala | Junction: Sacral ala and superior facet |
| Iliac | 1cm Cephalad to Distal Posterior Superior Iliac Spine (PSIS) | 1cm inferior to the superior PSIS on the medial slope |




*Oblique View*

# Pedicle Screw Placement *continued*

### Step 2 – Pedicle Preparation

Create a 3mm-deep posterior cortical breach with an awl or high speed-burr exposing cancellous bone at the base of the pedicle. In the thoracic spine, when preparing small pedicles that are located at the apex of the curve, visualization of intrapedicular cancellous bone will not be evident. In this case, use the Thoracic Probe to search in the cortical breach for soft, funnel-shaped cancellous bone, which indicates the entrance to the pedicle. The tip of the Thoracic or Lumbar probe should be pointed laterally to avoid perforation of the medial cortex **(Figure XX)**. Grip the side of the handle to avoid applying too much ventral pressure. Insert the tip approximately 20mm to 25mm **(Figure XX)**, and then remove to the probe to reorient it so that the tip points medially. Carefully place the probe into the base of the prior hole and use the instrument markings to advance the probe to the desired depth **(Figure XX)**. Rotate the probe 180° to ensure adequate room for the screw.

Alternatively, a NIM® Thoracic or Lumbar Probe can be used to create the hole **(Figure XX)**. Triggered EMG monitoring can be performed during the advancement of the probe into the pedicle. Prior to insertion into the pedicle, the NIM® Probe should be electrified to 8-10 mA. In addition, the O-ARM® Imaging System coupled with the STEALTHSTATION® Image Guidance System can be used to position screws in the often small, narrow apical pedicles.

*Figure XX*

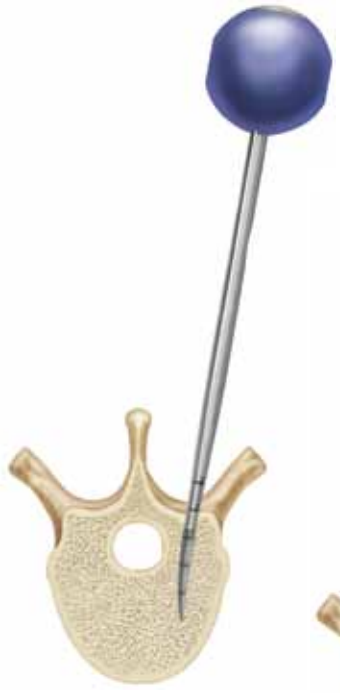


*Figure XX*

*Figure XX*

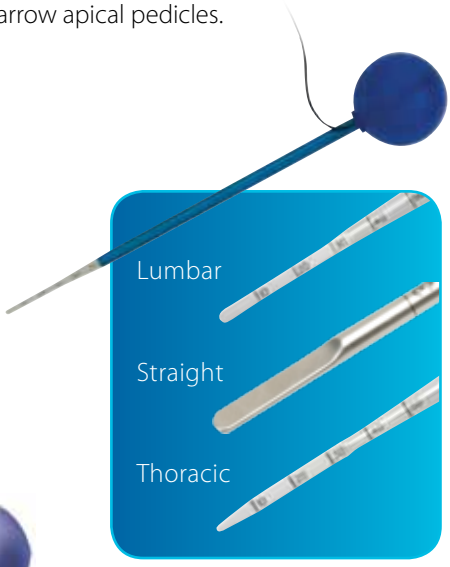



*Figure XX*

# Pedicle Screw Placement *continued*

## Step 2 – Pedicle Preparation *continued*

Check to ensure that only blood is coming out of the pedicle and that bleeding is not excessive. Using a flexible ball-tipped Feeler Probe, locate the base (floor) of the hole and confirm five distinct bony borders: a floor and four walls (medial, lateral, superior, and inferior) **(Figure XX)**. Give special care to the first 10mm to 15mm of the tract. Cortically breached pedicles may be salvageable. When necessary, place bone wax in the pedicle to limit bleeding, then reposition the probe with a more appropriate trajectory.

Next, undertap the pedicle by 0.5mm to 1.0mm of the selected screw diameter **(Figure XX)**. Palpate the tapped pedicle tract with a flexible Feeler Probe to ensure there are no pedicle breaches. Select the appropriate screw diameter and length by confirming the preoperative measurement with an intraoperative observation.

During pedicle preparation there are several enabling options that can be used to assist and confirm the pedicle trajectory. Triggered intraoperative EMG monitoring with the NIM-ECLIPSE® Spinal System may be used to verify the trajectory within the pedicle. The O-ARM® Imaging System coupled with the STEALTHSTATION® Image Guidance System can be used to navigate pedicle preparation and screw placement. And finally, the POWEREASE™ System may be used to drill, tap, and place screws with powered instrumentation while utilizing image guidance and neuromonitoring capabilities.

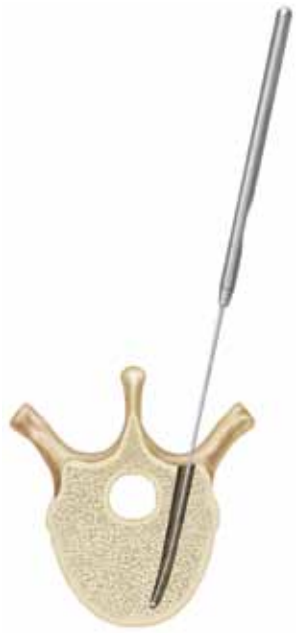


*Figure XX*


*Figure XX*

**Note**

*Although the OSTEOGRIP® thread design on the CD HORIZON® SOLERA™ Spinal System is different than previous CD HORIZON® System thread design, a tapping strategy based upon personal preference can still be used. Using the single lead taps provided in the set, the second thread lead of the OSTEOGRIP® thread will cut new bone as it is inserted. Alternatively, dual lead taps can be ordered as an extra instrument to prepare the pedicle for the second thread. In most instances under tapping by 1mm is recommended. If a pedicle seems sclerotic or brittle, then sized-matched diameter taps may be used for line-to-line tapping.*

# Pedicle Screw Placement *continued*

## Step 3 – Screw Placement

Attach the Quick Connect Handle to either the Multi-Axial Screw or Fixed Angle/Sagittal Adjusting Lock Sleeve Driver by snapping it into place. A slight rotation of the Quick Connect Handle may be required to fully engage with the driver. Ensure the blue locking cap is not engaged with the screwdriver shaft and then thread the driver shaft into the selected screw in the screw caddy **(Figure XX)**. After the driver shaft is fully engaged with the screw, slide the blue locking cap toward the screw to engage the driver shaft **(Figure XX)**. An audible "click" will confirm engagement.

The ring on the Quick Connect Handle determines the direction the screw will be driven by the Lock Sleeve Driver. Turn the ring clockwise to drive the screw into the pedicle **(Figure XX)**. Turning the ring counterclockwise will allow the driver to remove the screw from the pedicle **(Figure XX)**.


*Figure XX*

*Figure XX*

*Figure XX*

*Figure XX*

# Pedicle Screw Placement *continued*

## Step 3 – Screw Placement *continued*

Prior to insertion, break-off the VERIFYI™ Implant Tracking Tag as shown **(Figure XX)** and place the tag in the Tag Sorter. Slowly advance the screw down the pedicle to ensure proper tracking while allowing for viscoelastic expansion **(Figure XX)**. Once the screw is inserted, push the button on the blue locking cap and slide it back toward the handle to disengage the driver **(Figure XX)**. Finally, unthread the Lock Sleeve Driver from the screw. To remove the Quick Connect Handle from the driver, press the cap on the handle to disengage **(Figure XX)**.

*Figure XX*


*Figure XX*

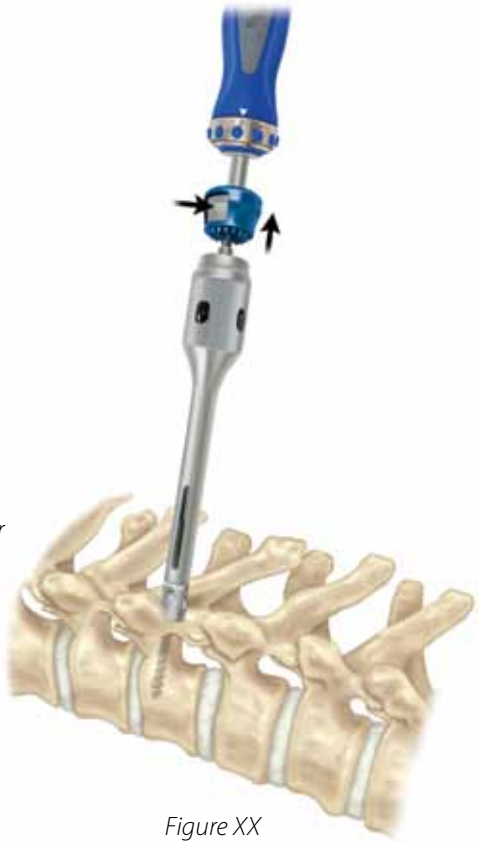


*Figure XX*


*Figure XX*

# Pedicle Screw Placement *continued*

## Step 3 – Screw Placement *continued*

### Alternative Powered Option

Alternatively, the POWEREASE™ System may be used to prepare and insert a pedicle screw **(Figure XX)**. Similar to the quick connect handle, insert the desired drill bit, tap, or screw driver into the POWEREASE™ handle. An audible "click" will confirm engagement. Confirm the driver is in the intended direction of use by rotating the collet on the handle and looking at the IPC™ monitor for drive direction and speed settings. Gradually pressing the trigger will slowly advance the screw down the pedicle **(Figure XX)**. EMG triggering may be conducted during pedicle preparation and screw placement to ensure the proper trajectory is followed. Once the screw is inserted, unthread the sleeve driver from the screw.

*Figure XX*

*Figure XX*

# Pedicle Screw Placement *continued*

## Step 4 - Spinal Rod Selection and Reduction Options

The CD HORIZON® SOLERA™ Spinal System offers a full spectrum of rods with different material types to facilitate intraoperative construct tailoring. The available rod options allow for a full range of pathologies to be addressed with a reduction in hospital inventory due to the accommodation of multiple materials and rod sizes as compared to previous implant systems.

| Rod Options | 4.75mm | 5.5mm | 6.0mm |
|---|---|---|---|
| Pre-bent CHROMALOY™ | • | • | |
| Pre-bent Commercially Pure Titanium | | • | |
| Straight Titanium Alloy | • | • | • |
| Straight Commercially Pure Titanium | | • | • |
| Straight CHROMALOY™ | • | • | • |
| Straight CHROMALOY™ Plus | • | • | • |

### Reduction Options

The CD HORIZON® SOLERA™ 5.5/6.0mm Spinal System can be used with several instruments and recommended techniques to facilitate rod insertion/reduction into the selected implant.

### Beale Rod Reducer

The Beale Rod Reducer can be used when the rod is positioned at the opening of the head of the screw. In this case, where the required reduction distance is less than 15mm and when the rod is positioned inline to the opening of the screw head, then the Beale Rod Reducer may be used to completely reduce the rod into the implant **(Figures XX and XX)**.

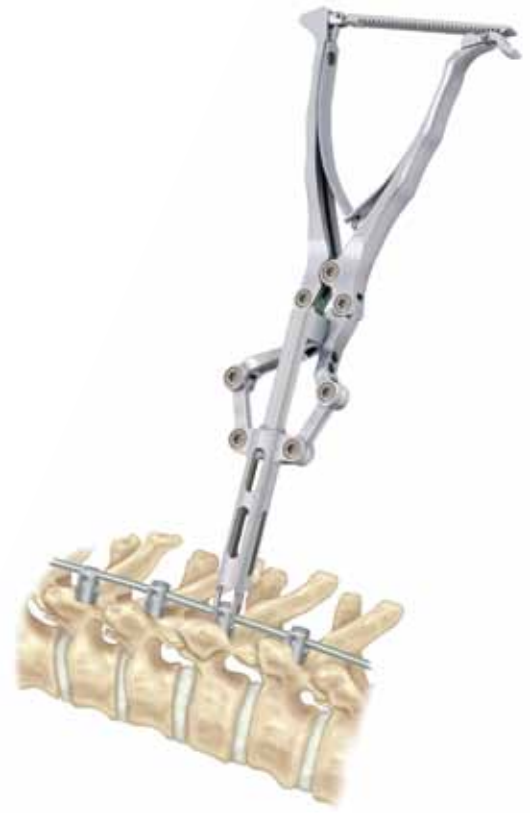


*Figure XX*

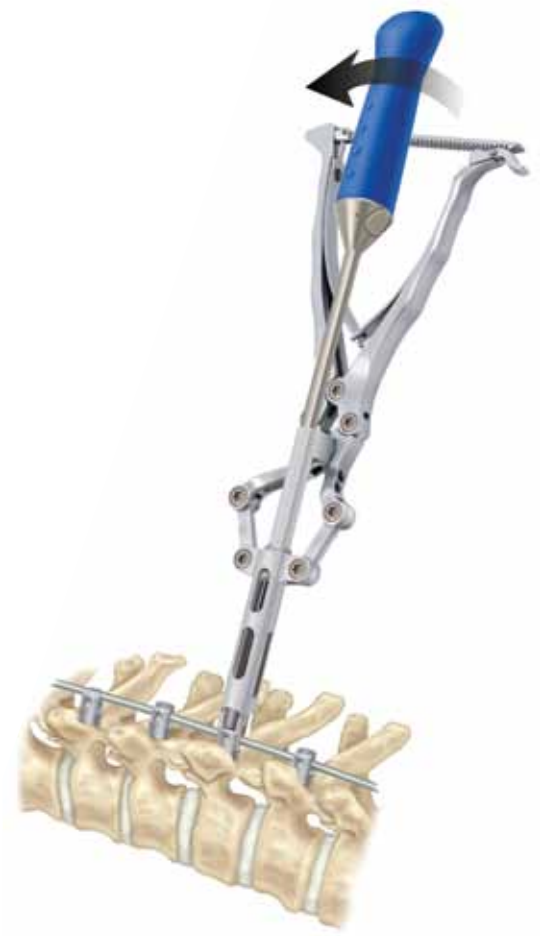


*Figure XX*

# Pedicle Screw Placement *continued*

## Step 4 - Spinal Rod Selection and Reduction Options *continued*

### Advanced Deformity Instruments (ADI)

The ADI may be used to reduce a rod that is positioned up to 60mm away from the open head of the screw. The ADI offers both a closed extender and open extender options allowing for multiple reduction strategies. Utilizing the ADI closed extender the spinal rod can be captured and leveraged during vertebral column rotational maneuvers. The ADI open extender enables the surgeon to rotate or translate the vertebral column to the spinal rod.

To use the ADI, position the open or closed extender over the slots on the caudal/cephalad sides of the screw and lock the extenders onto the screw by sliding the blue locking sleeve down **(Figures XX and XX)**. With the rod captured in the open or closed extender sleeves, insert the reducer into the extender and rotate clockwise **(Figures XX and XX)**.

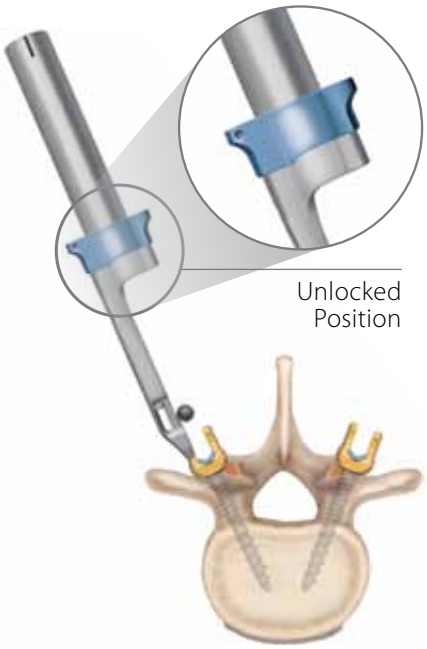



*Figure XX*

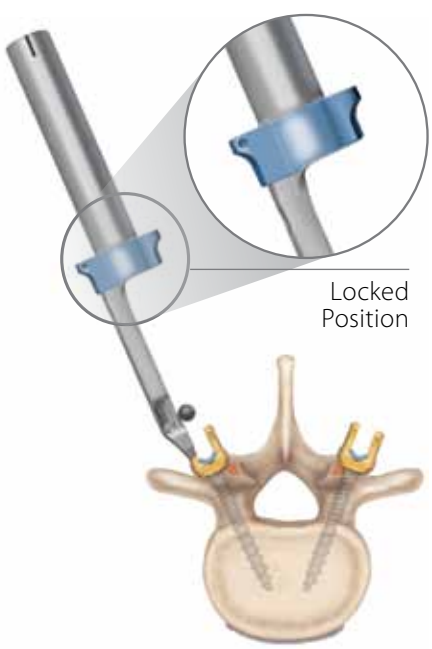



*Figure XX*

*Figure XX*

*Figure XX*

# Pedicle Screw Placement *continued*

## Step 4 - Spinal Rod Selection and Reduction Options *continued*

### Advanced Deformity Instruments (ADI) *continued*

Once the reducers are in place, use the ADI Driver Handle to sequentially reduce the rod **(Figure XX).** In this seated position, remove the ADI Driver Handle and insert a set screw to secure the rod to the bone screw. Introduction of the set screw is accomplished using the Dual Ended Set Screw Starter or the Provisional Driver. Attach the set screw to either instrument and insert it through the cannula of the ADI and provisionally tighten **(Figure XX)**. To remove the ADI from the implant, pull up on the blue sleeve to disengage from the implant **(Figure XX)**. Manually turning the reducer counterclockwise will allow the reducer to be disassembled from the extender.

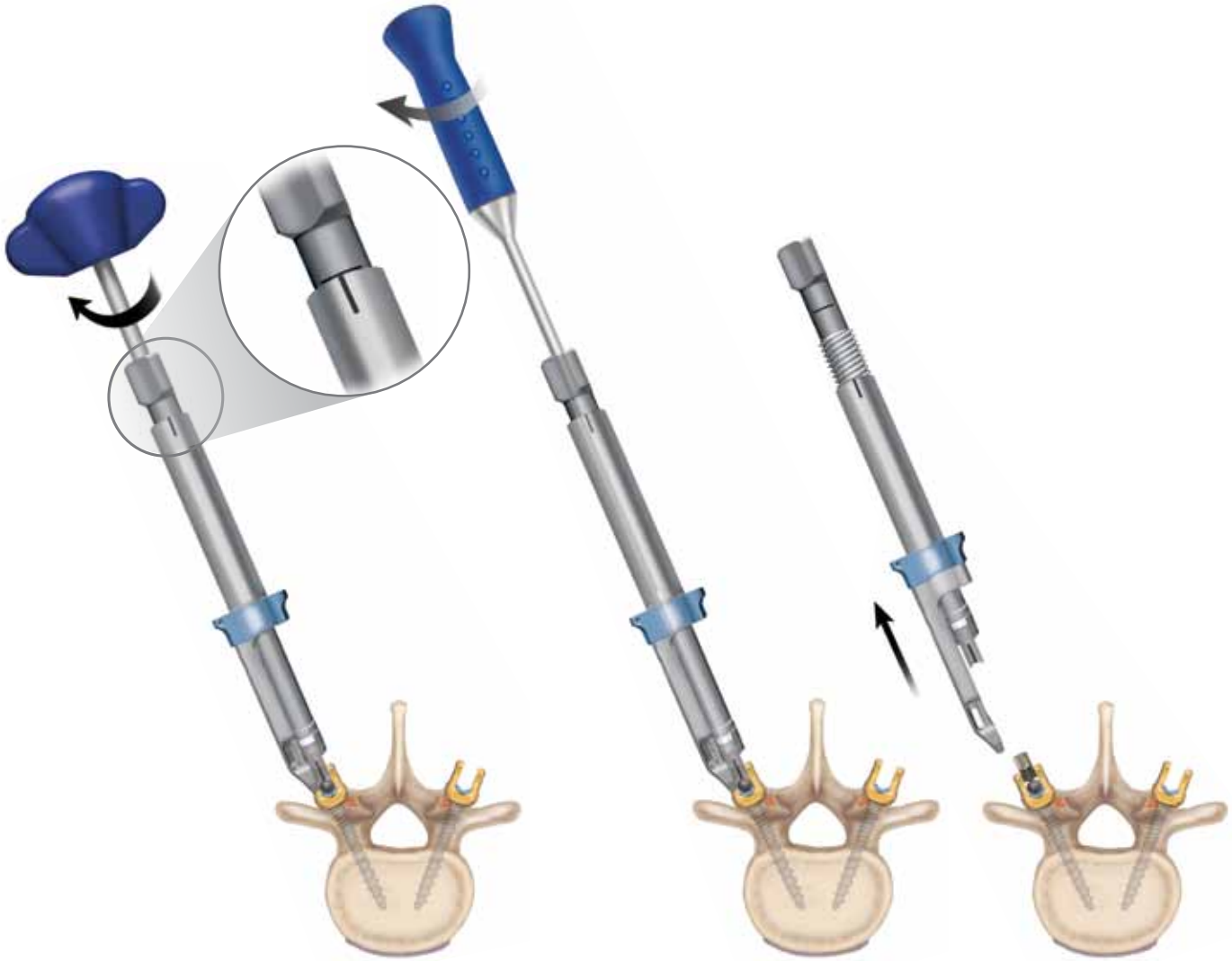


*Figure XX* *Figure XX* *Figure XX*

# Deformity

# Thoracic Idiopathic Scoliosis Correction

The following technique describes the correction of a typical right thoracic idiopathic scoliosis utilizing Sagittal Adjusting Screws (SAS) and Multi-Axial Screws (MAS). The CD HORIZON® SOLERA™ Spinal System can be utilized in the thoracic and lumbar spine to correct three-dimensional deformities and offer greater postoperative maintenance of the correction. For maximum correction and intraoperative flexibility, the SAS may be used in the thoracic aspect of the construct to allow for optimal coronal plane, sagittal plane, and axial plane correction **(Figures XX, XX, and XX)**. The SAS facilitates rod seating due to accommodation of the rod curvature in the sagittal plane while allowing for active derotation at the apex of the curve and active adjustment of kyphosis (at the cephalad end) and lordosis (at the caudal end).

Multi-axial screws may be utilized at the caudal levels of the scoliosis construct since the pedicles tend to be wider and more laterally placed in the lower thoracic and upper lumbar spine. The lateral tilting of the MAS screws tends to facilitate rod reduction into screws at these more caudal levels. The use of MAS screws at these levels does not permit the same active adjustment of the sagittal alignment of the most caudal fused levels as that of the SAS.

*Coronal Correction*

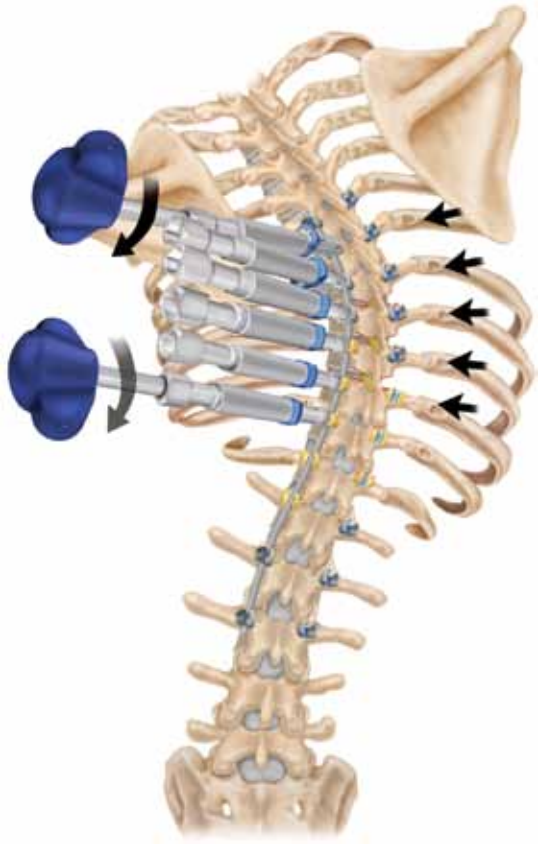


*Figure XX*

*Sagittal Correction*

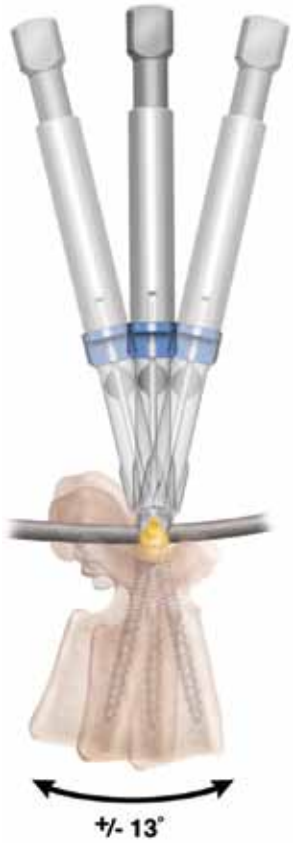



*Figure XX*

*Axial Correction*

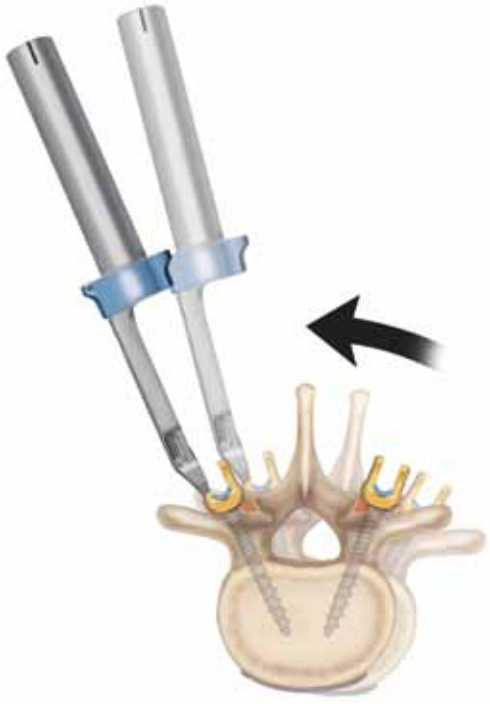


*Figure XX*

# Thoracic Idiopathic Scoliosis Correction *continued*

## Step 1 – Screw Placement

Screws should be placed at strategic positions to achieve the desired correction. For a typical right thoracic idiopathic scoliosis, screws should be placed at every level of the left-sided correcting rod. On the contralateral side, a stabilizing rod with a minimum of two screws should be placed at the cephalad and caudad ends with four convex periapical screws **(Figure XX)**. A combination of SAS and MAS implants may be utilized, however to maximize applied derotational and sagittal correction forces we will describe a construct using primarily SAS screws due to their design features that assist in active vertebral body control. Utilizing the SAS will allow for direct derotation at the apex of the curve as well as fine-tuning of sagittal alignment through compression, distraction, and direct sagittal correction. For derotation maneuvers on the concave side, the bone screw shaft is best positioned against the medial cortex of the pedicle. This will buttress the corrective forces on the screw. On the convex side, positioning the screw along the lateral cortex is desirable. Multi-axial screws may typically be used at the ends of the construct to provide accommodation to the final rod position.

*Figure XX*

# Thoracic Idiopathic Scoliosis Correction *continued*

## Step 2 – Derotation Force Assessment

To determine the amount of force required to perform a derotation, attach the ADI instrumentation to the screw heads at the apex of the convex curve. Note, that if there is a multi-axial reduction screw at the apex, derotation instrumentation does not need to be attached to the implant as the rod will be positioned in the multi-axial reduction screw saddle during rotation. Ventral and medially directed spinal implant forces are applied using the vertical end of the ADI; a periapical derotational maneuver is assessed to quantify the degree of derotational corrective forces to be applied and to assess the stiffness of the curve **(Figure XX)**. Further posterior release by means of transverse, Smith-Peterson, or Ponte type osteotomies may be necessary through the stiff segments of the curve to facilitate correction at this stage.

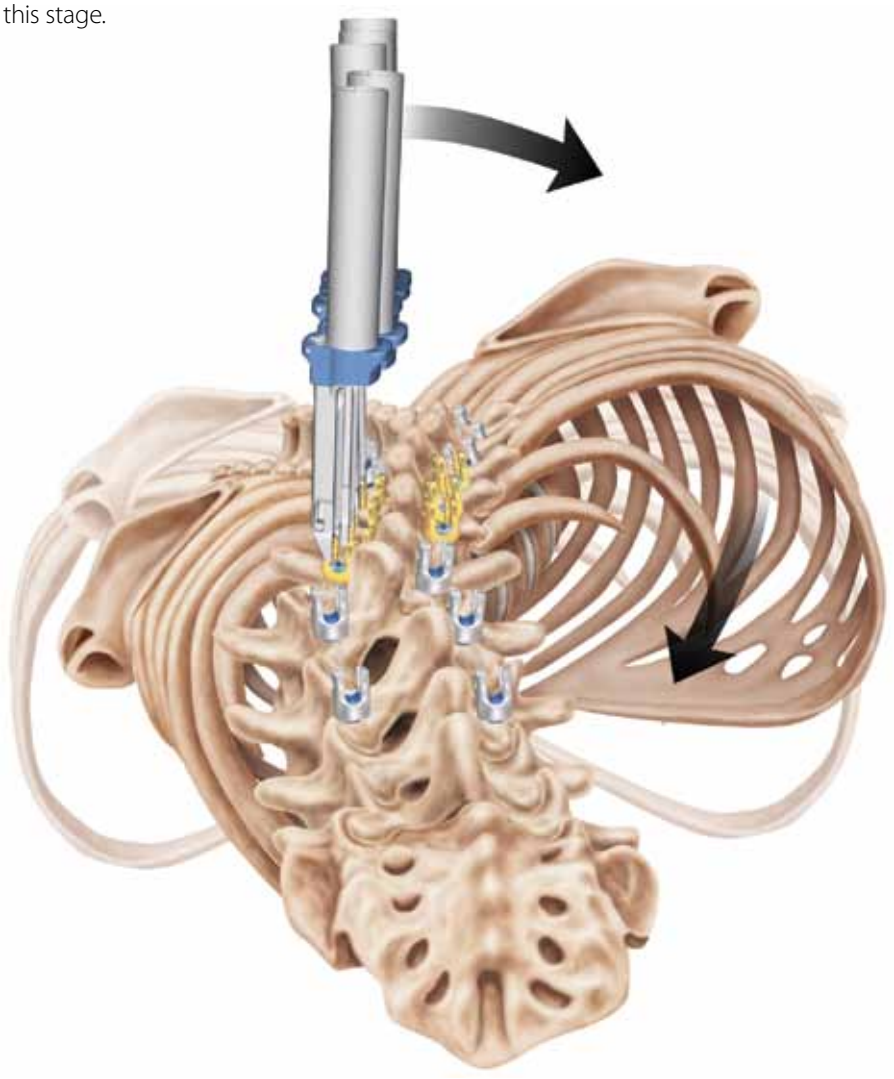


*Figure XX*

# Thoracic Idiopathic Scoliosis Correction *continued*

## Step 3 – Correction Rod Placement

Large curves requiring significant correction are high construct demand situations and therefore may require stronger rods to account for the construct demand, such as the 6.0 mm CHROMALOY™ Plus rod. Specifically, stiffer rods can help to prevent the flattening that can occur with smaller diameter rods which can lead to loss of correction principally in kyphosis and the typical hypo-kyphotic thoracic sagittal alignment of idiopathic scoliosis. Ultimately, the choice of spinal rod used lies with the surgeon based on his/her assessment of the individual patient need. Once the appropriate rod has been selected, either a derotation or translation technique can be used to achieve the desired correction.

### Derotation Technique

With the ADI extenders placed at the apical vertebrae, the contoured rod is placed on the concave side so that the anticipated kyphotic curve of the rod aligns with the concave side of the scoliotic curve **(Figure XX)**. The open ADI extenders can then be used to pull the rod into all of the screws on the concave side.

Using two rod holders, the concave rod can now be rotated 90° as per the classic Cotrel Dubousset (CD®) technique **(Figure XX)**. At this point a convex rod may be contoured, inserted and provisionally captured.

Utilizing four open ADI reducers on the concave side and four additional open ADI reducers of the convex side of the apex, apical axial derotation can be performed and the set screws tightened. Further correction may be obtained with In Situ Benders used to further correct the coronal plane alignment. Sagittal contour restoration can then be optimized by inter-segmental distraction on the concave side beginning at the apical segment and progressing caudal and cephalad. Final adjustment may be achieved at the most cephalad and caudal vertebrae by actively adjusting the SAS degree of kyphosis using the open ADI as a lever to actively kyphose the end vertebrae.

*Figure XX*

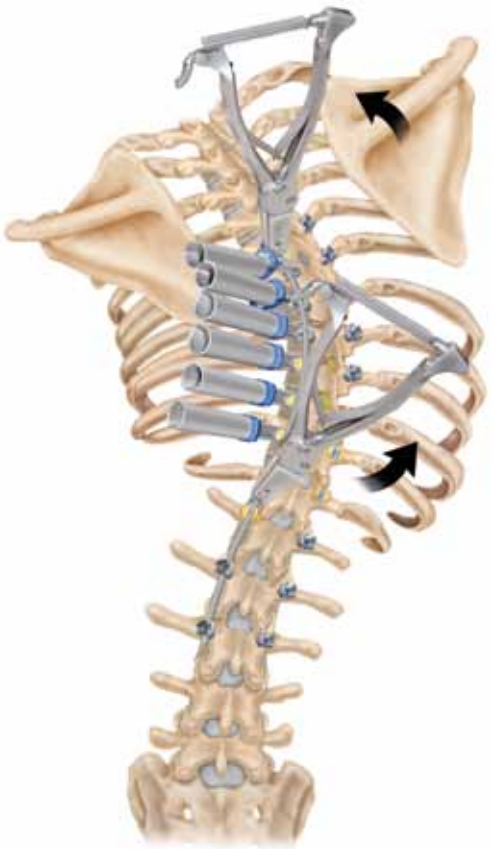


*Figure XX*

# Thoracic Idiopathic Scoliosis Correction *continued*

## Step 3 – Correction Rod Placement *continued*

### Translation Technique

Open ADI extenders are placed on all screws of the concave side. With the ADI open extender, the rod channel remains open for placement of the concave rod, which is inserted into the heads of the uppermost and lowest screws. The rod is provisionally captured in the uppermost screw and is locked into the head of the most caudal screw in what will be anticipated to be its final position once the scoliosis is fully corrected **(Figure XX)**. Beginning at the next most caudal segment and using the open ADI, the concave rod is sequentially reduced into each screw **(Figure XX)**. This reduction maneuver may be performed while the apical vertebral derotation maneuver is simultaneously performed. If the ADI closed extender sleeve is used, the correction rod is captured in the window of the extender allowing for simultaneous rod reduction and apical vertebral derotation.

*Figure XX*

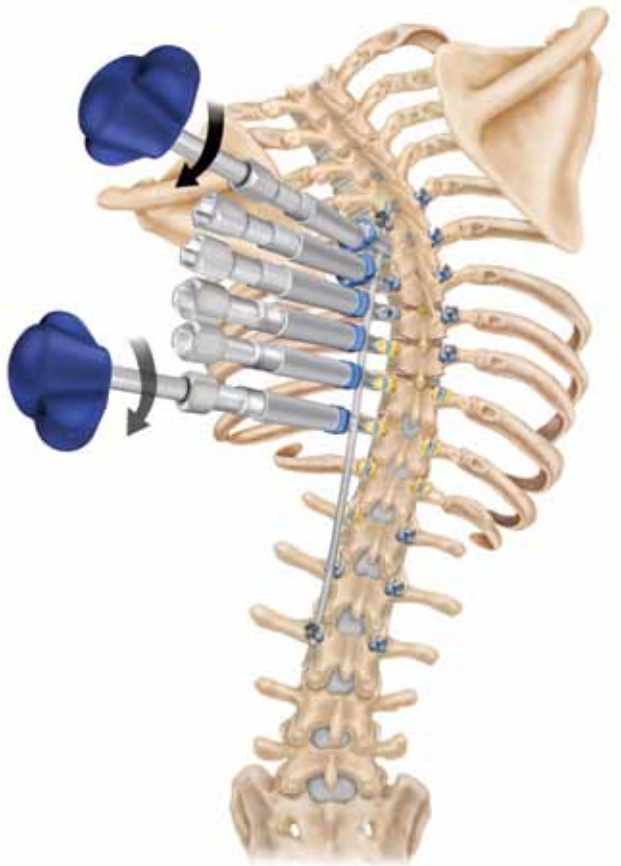


*Figure XX*

# Thoracic Idiopathic Scoliosis Correction *continued*

## Step 4 – Securing Rod Placement

Once the concave rod is fully seated with the set screws tightened, the convex holding rod is attached to the corresponding screws. The ADI instrumentation used to apply the derotation forces on the convex side can still be used to support the derotated corrected position. Once the convex rod has been inserted and secured, set screws can be provisionally tightened at the periapical region. Set screws at the proximal and distal ends of the construct may be broken off.

If the SAS implants were used anywhere within the curve, the sagittal alignment may be adjusted. Typically in AIS patients increased kyphosis is generally desired. Kyphosis is achieved at each segmental level that has an SAS by placing an ADI extender on each of the two screws (i.e., two screws at T8), loosening the set screw and placing a kyphosing force on the ADI **(Figure XX)**. This will actively correct the vertebral body into kyphosis. Once the maximum or desired kyphosis is achieved the set screws can be tightened. The identical technique is then repeated at each level with an SAS to achieve the desired global sagittal alignment **(Figure XX)**. When the desired sagittal balance has been achieved the set screws may be broken off at the apical region.

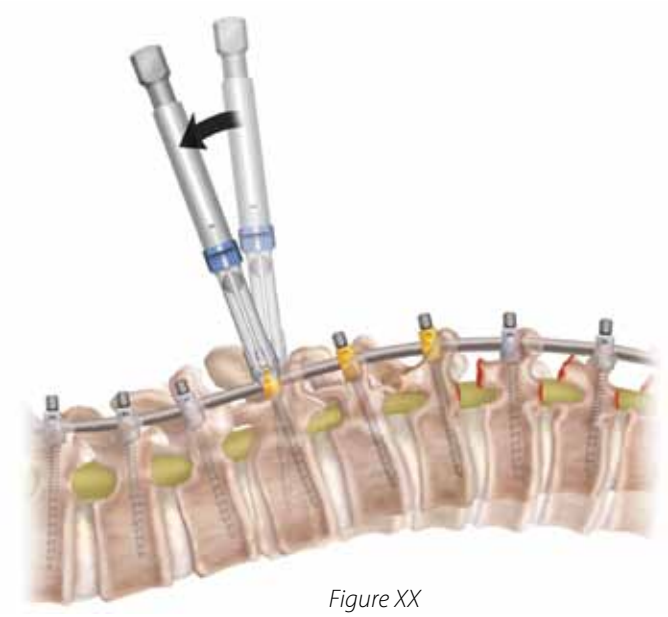


*Figure XX*

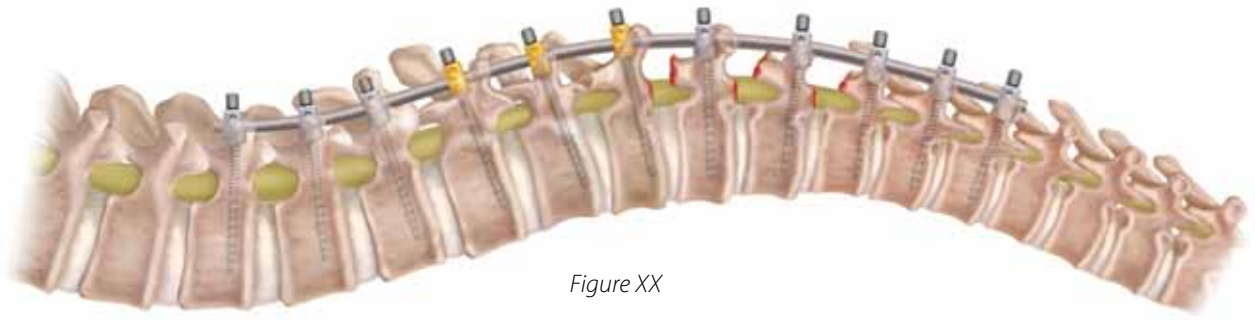


*Figure XX*

To see a video of this sagittal alignment technique, download a QR Code Reader app to your smartphone or mobile device and scan this code.

# Thoracic Idiopathic Scoliosis Correction *continued*

## Step 5 – Final Tightening

When all implants are securely in place, final tightening of the set screws may be accomplished with the Counter Torque handle and Set Screw Break-Off Driver. Slide the assembly over the implant head and provisionally tighten the set screw. Rotate the Set Screw Break-off Driver clockwise until the break-off set screw breaks. An audible "click" is heard when the optimum torque is reached.

Alternatively the POWEREASE™ System with Set Screw Break-Off instrument maybe used for final tightening **(Figure XX)**. Biomechanical testing has shown that using the POWEREASE™ compatible Set Screw Break-Off instrument and compared to manual instruments there is a 22% reduction in energy transferred to the construct during final tightening.

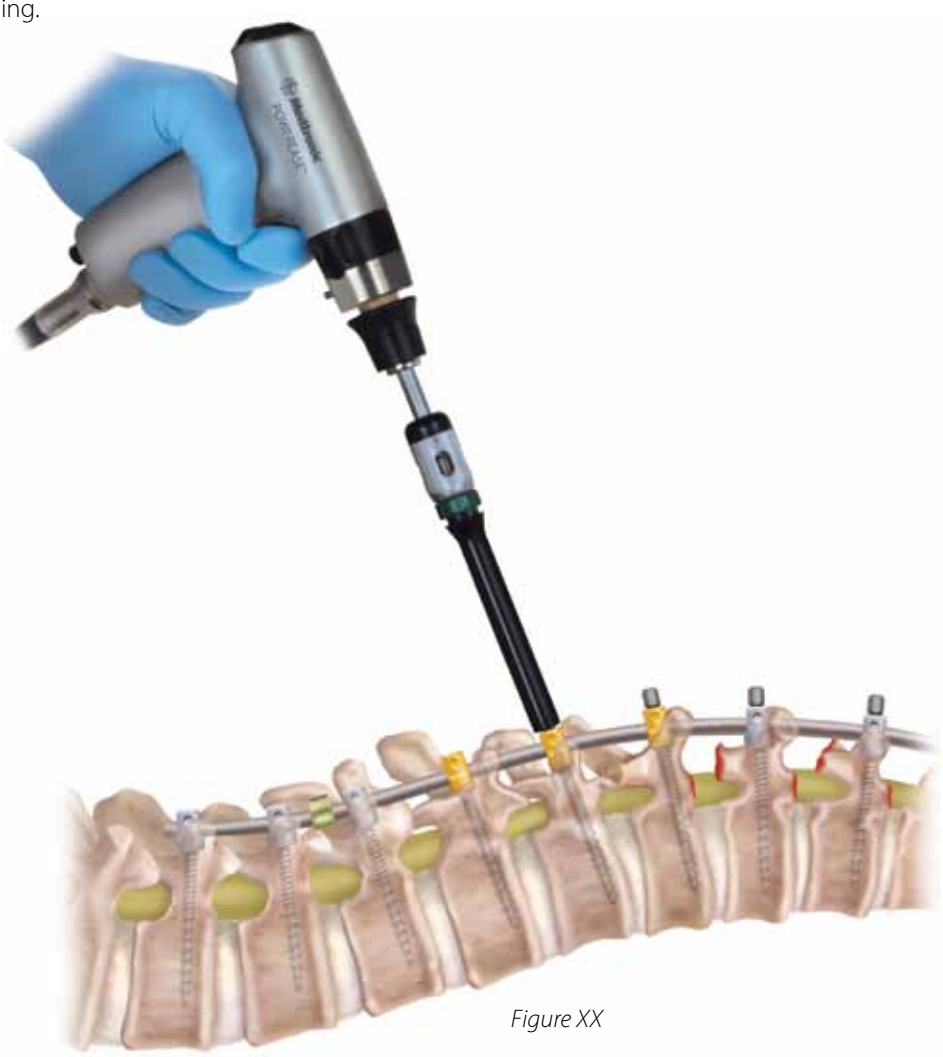


*Figure XX*

# Thoracic Idiopathic Scoliosis Correction *continued*

## Step 5 – Final Tightening *continued*

A CD HORIZON® X10 CROSSLINK® Plate may be attached to the construct for increased torsional stability. The correct size plate is determined by using the Measuring Caliper to measure the span between spinal rods. Once the CD HORIZON® X10 CROSSLINK® Plate has been placed on the rods and is in its final position, the set screws can be advanced and tightened, and bone grafting material placed. The final construct should be verified by x-ray or fluoroscopy prior to closing **(Figures XXa and XXb)**.

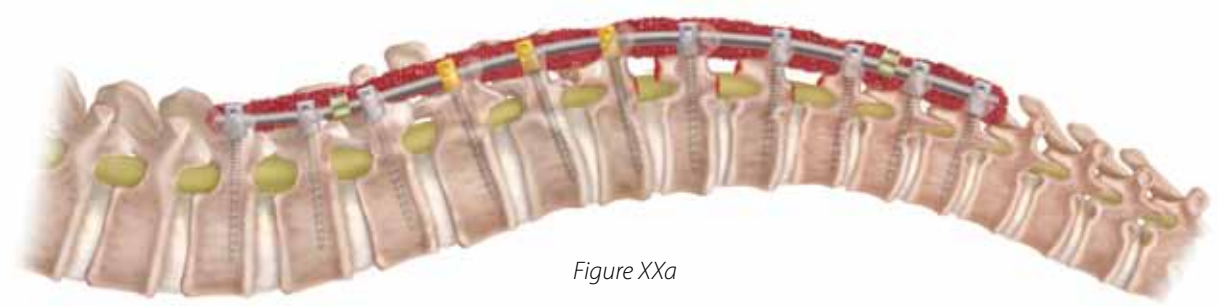


*Figure XXa*

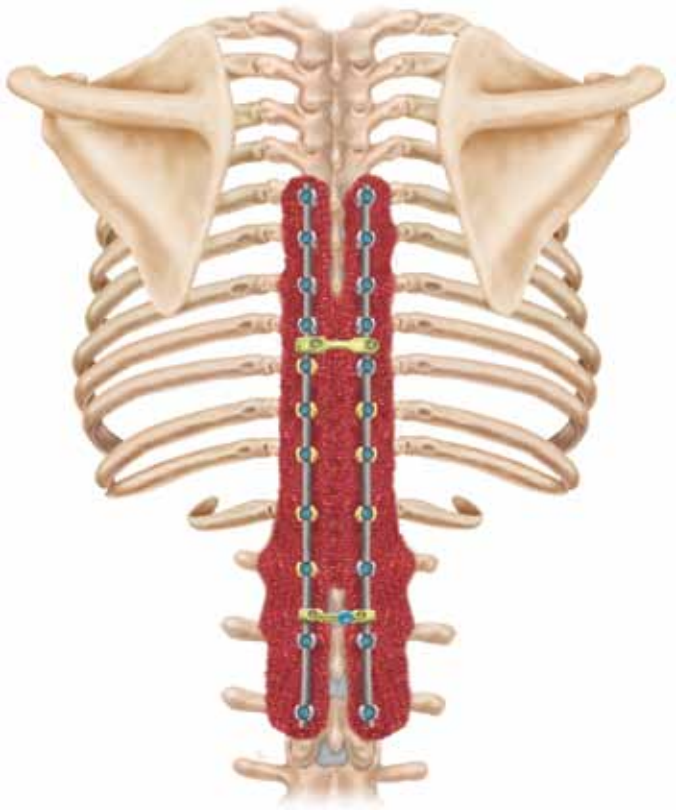


*Figure XXb*

# Left Lumbar Degenerative Scoliosis

The following technique describes correction of an adult left lumbar degenerative scoliosis with instrumentation from T10-S1. There can be tremendous variability in the pattern and severity of adult lumbar degenerative deformity. As such, this technique makes several generalizations. The primary goal of the correction in this technique is to achieve an overall sagittal balance from the sacrum through the thoracolumbar transition.

## Step 1 - Screw Selection

In the transition between low lumbar and pelvic fixation there is an ever increasing distance between the right and left screws as the interpedicular distance widens. Even more laterally positioned are the iliac fixation screws if these are utilized. The ability of the MAS to tilt laterally and accommodate this transition in alignment is helpful at the L5, S1 levels. The SAS implant may be inserted at L4 and more proximally up to T12 to facilitate derotation and sagittal vertebral realignment. In the most cephalad part of the construct, from T12 to T10, MAS may again be used to ease the transition across the thoraco-lumbar junction **(Figure XX)**.

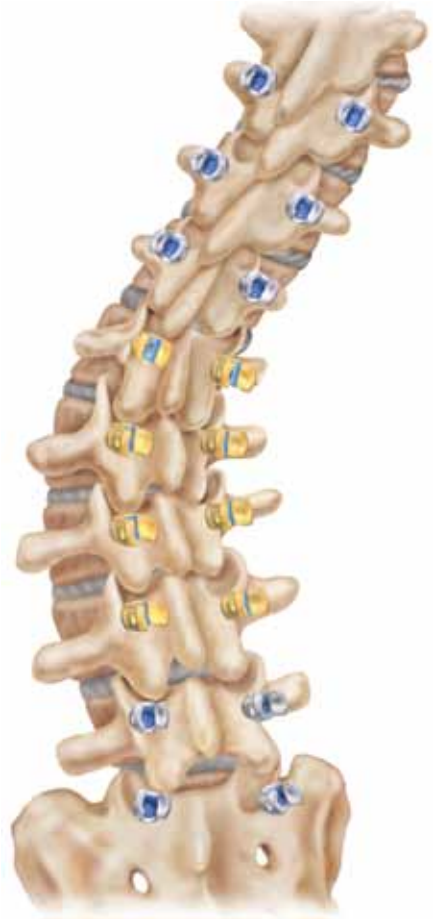


*Figure XX*

# Left Lumbar Degenerative Scoliosis *continued*

## Step 2 – Rod Insertion and Correction Technique

With the screws in position, contour the rod into what will be its final lordotic position. In the lumbar spine, the main goal is to create lordosis, thus the convex rod is first inserted and rotated to facilitate the realignment of this lordosis while simultaneously derotating.

Because the caudal most fixation points are the most complex and technically demanding, the rod is first inserted into the S1 and L5 screws on the convex side **(Figure XX)**. The rod can then be held into what will be its near final position while the ADI reducers are attached and tightened to sequentially reduce the rod into each screw from L4 more proximally **(Figure XX)**. It may be preferable to leave the caudal most fixation points provisionally captured and not fully tightened and use a combination of derotation and segmental translation as the rod is slowly and sequentially reduced into each of the convex screws. Optimal lordosis may require the use of *in situ* benders and ultimately inter-segmental compression on the convex side.

The concave rod is contoured and inserted and then sequentially tightened. The Beale Rod Reducer can be used to fully seat the rod in each of the screws. Care and attention must be paid to not put excessive cantilever correction forces on the screws in the cephalad end vertebra.

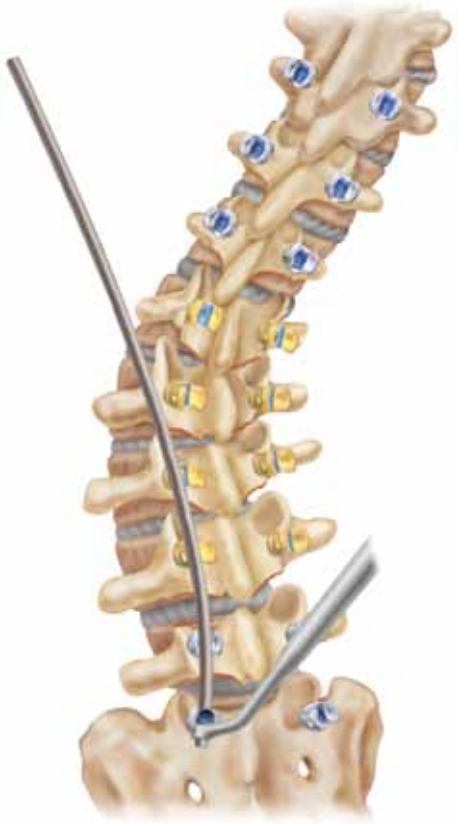


*Figure XX*

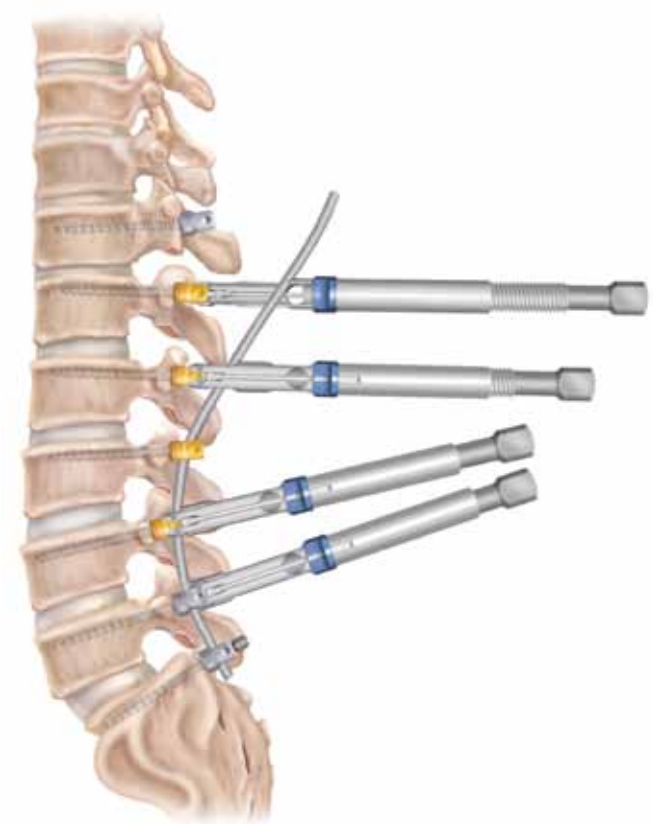


*Figure XX*

To see this procedure, download a QR Code Reader app to your smartphone or mobile device and scan this code.

# Left Lumbar Degenerative Scoliosis *continued*

### Step 3 – Final Tightening

When all implants are securely in place, final tightening of the set screws may be accomplished with the Counter Torque handle and Set Screw Break-Off Driver. Slide the assembly over the implant head and provisionally tighten the set screw. Rotate the Set Screw Break-off Driver clockwise until the break-off set screw breaks. An audible "click" is heard when the optimum torque is reached.

Alternatively the POWEREASE™ System with Set Screw Break-Off instrument maybe used for final tightening. Biomechanical testing has shown that using the POWEREASE™ compatible Set Screw Break-Off instrument and compared to manual instruments there is a 22% reduction in energy transferred to the construct during final tightening.

A CD HORIZON® X10 CROSSLINK® Plate may be attached to the construct to increase torsional stability. The correct size plate is determined by using the Measuring Caliper to measure the span between spinal rods. Once the CD HORIZON® X10 CROSSLINK® Plate has been placed on the rods and is in its final position, the set screws can be advanced and tightened, and bone grafting material placed. The final construct should be verified by x-ray or fluoroscopy prior to closing **(Figures XXa and XXb)**.

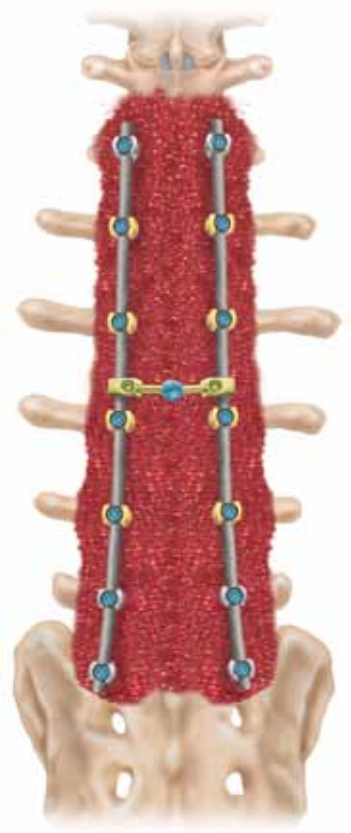


*Figure XXa*

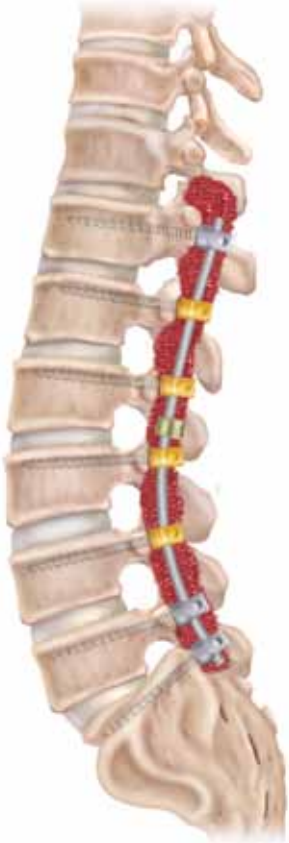


*Figure XXb*

# Kyphosis

The following technique describes thoracic kyphosis correction from T2 to L3 **(Figure XX)**. Kyphosis correction takes advantage of the unique capabilities of the screws available with the CD HORIZON® SOLERA™ Spinal System, particularly the SAS implant. Sagittal adjusting screws are particularly versatile in correcting the sort of uni-planar sagittal plane deformity encountered with a kyphotic curve. The SAS permits a total of 26° of sagittal angulation. Sequential rod reduction and segmental correction can also be achieved with instruments such as the ADI instrumentation.

The exact technique will depend on both the severity and etiology of the deformity. An individual case (particularly with severe or rigid sagittal deformity) may require an anterior release with or without structural grafting or more aggressive osteotomies at the most apically deformed vertebra. Posterior osteotomy techniques could include Smith-Petersen, Ponte, transverse, or chevron-type osteotomies, pedicle subtraction osteotomies (PSO), or vertebral column resections (VCR) **(Figure XX)**. The particular technique or combination of techniques chosen depends primarily on the magnitude of the correction needed to obtain neutral sagittal balance, and the stiffness of the deformity. Each of these cases will require a multi-segmental posterior instrumentation fixation procedure. The levels chosen generally span the entire extent of the kyphotic deformity, and extend caudal to the onset of the lumbar lordosis.

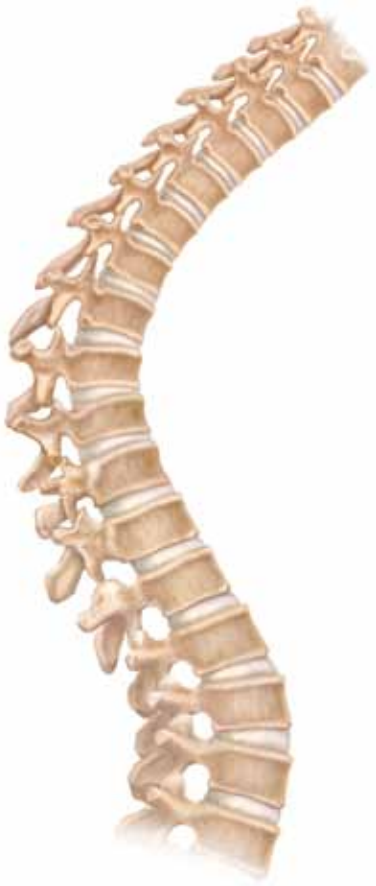


*Figure XX*

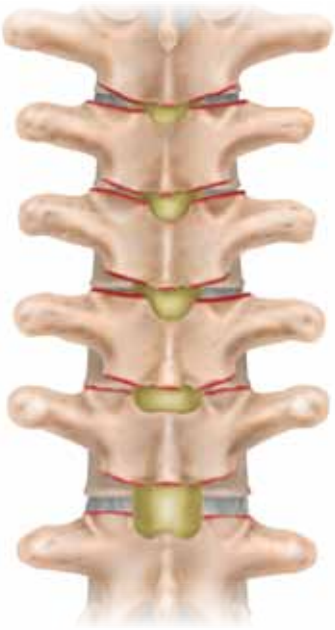


*Figure XX*

# Kyphosis *continued*

## Step 1 – Screw Placement and Rod Selection

In this case the SAS may best be utilized in the thoracic spine, and the MAS, with their ability to accommodate increasing inter-pedicular width, may be better used across the thoraco-lumbar segments. Screws maybe inserted manually or with the POWEREASE™ System. Once the screw is inserted, the screw insertion driver is disengaged from the screw and is removed. After all the screws are inserted and their position verified, then the selected osteotomy type may be performed at each level **(Figures XX and XX)**.

The rod template may be used to determine the length and contour of the spinal rod. If significant kyphosis correction and compression will be performed, the rod will eventually be shorter than initially anticipated. Typically a high stiffness rod would be selected to maintain the desired sagittal curve. The rods can be measured and contoured to the final desired sagittal contour. In most cases of kyphosis no contouring or correction is required in the coronal plane but should still be assessed. Clamping the rod with Rod Grippers at both ends will help prevent the rod from rotating during contouring.

*Figure XX*

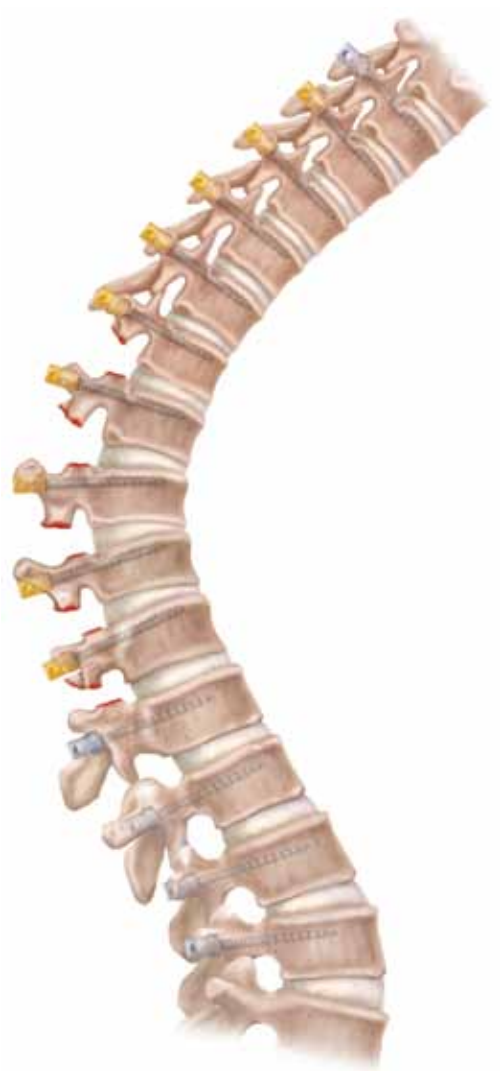


*Figure XX*

# Kyphosis

### Step 3 – Rod Placement, Reduction, and Final Tightening

Position both of the contoured rods into either the distal or proximal most screw with the Rod Inserter and provisionally tighten a set screw to secure the rod to the implant. Sequentially reduce the rod into the screw heads approaching the apex of the kyphosis with a sequential instrument, such as the ADI. Most commonly, the rods will both be secured within the most cephalad one or two screws and the set screws tightened.

Several Open ADI Extenders can be attached to the screws into which the rod is to be sequentially reduced **(Figure XX)**. Using multiple ADI extenders will help to distribute the forces associated with rod reduction and curve correction over a number of pedicle screws instead of individually. Bilateral reduction should also be performed, to again distribute the corrective forces over several segments. As the cantilever correction progresses at each level, a combination of segmental compression and active tilting in a cephalic direction can be used to maximally reduce the segmental kyphosis **(Figure xx)**. Alternating between the right and left rods sequentially reduces the rods. Alternatively, the ADI extenders and reducers can be used to simultaneously reduce both rods over several levels. As each segment is reduced and each set screw tightened, the ADI is removed and placed on the next free screw.

This form of segmental and sequential cantilever correction is continued down to the final most caudal vertebra. Final adjustment may be performed through segmental compression or possibly *in situ* bending. Extreme care must be taken during the reduction to ensure that there is no excessive stress at a single screw which might lead to loosening at the screw bone interface.

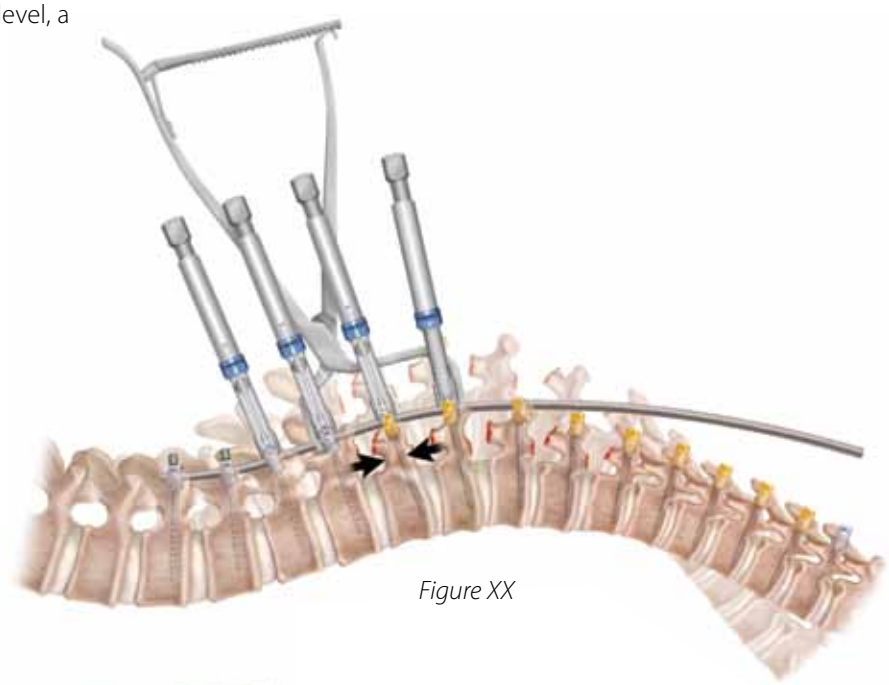


*Figure XX*

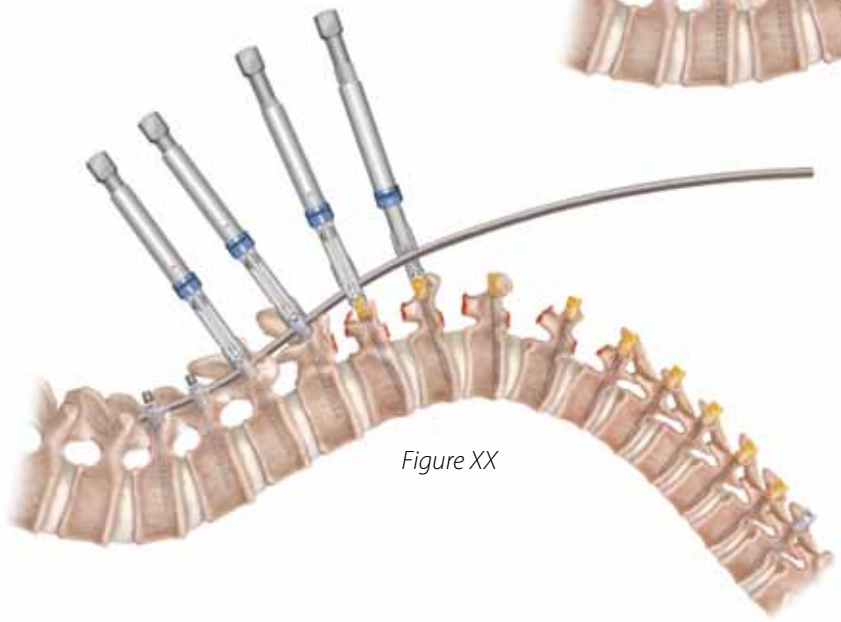


*Figure XX*

# Kyphosis *continued*

## Step 3 – Reduction and Final Tightening *continued*

When all implants are securely in place, final tightening of the set screws may be accomplished with the Counter Torque handle and Set Screw Break-Off Driver. Slide the assembly over the implant head and provisionally tighten the set screw. Rotate the Set Screw Break-off Driver clockwise until the break-off set screw breaks. An audible "click" is heard when the optimum torque is reached.

Alternatively the POWEREASE™ System with Set Screw Break-Off instrument maybe used for final tightening. Biomechanical testing has shown that using the POWEREASE™ compatible Set Screw Break-Off instrument and compared to manual instruments there is a 22% reduction in energy transferred to the construct during final tightening.

A CD HORIZON® X10 CROSSLINK® Plate may be attached to the construct to increase torsional stability. The correct size plate is determined by using the Measuring Caliper to measure the span between spinal rods. Once the CD HORIZON® X10 CROSSLINK® Plate has been placed on the rods and is in its final position, the set screws can be advanced and tightened, and bone grafting material placed. The final construct should be verified by x-ray or fluoroscopy prior to closing **(Figures XXa and XXb)**.

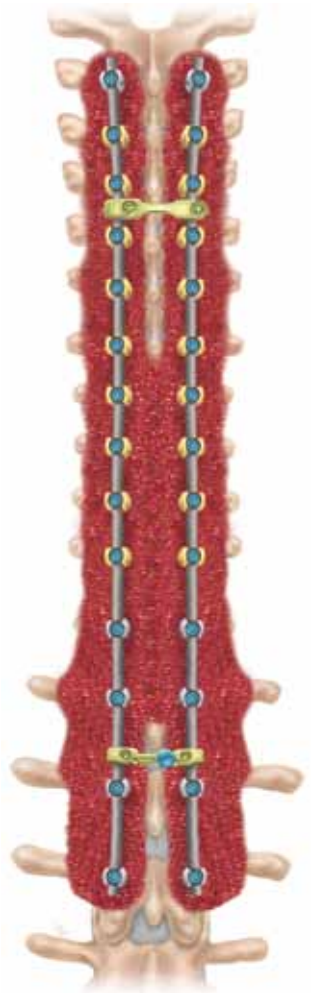


*Figure XXa*

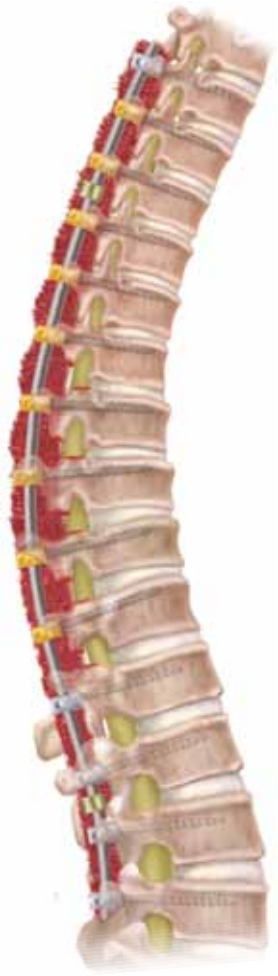


*Figure XXb*

# Trauma

## T10-L2 Burst Fracture

The following technique describes reduction and fixation of an unstable thoracolumbar (T10-L2, inclusive) burst fracture **(Figure XX)**. This technique can be done with an open or minimal access muscle splitting approach. The number of levels instrumented depends on several factors: the level of the fracture, the magnitude of instability, bone quality, whether the fracture level can be instrumented, and the demand a particular patient may place on the final construct.

Traditionally one level above and below the fracture can been instrumented, but to minimize the risk of late failure and to encourage early mobilization, two levels above and one below can be instrumented. Depending on the assessment of the fracture, the fractured vertebra may also be instrumented. In this specific case the technique described will instrument two levels above and two levels below the fracture.

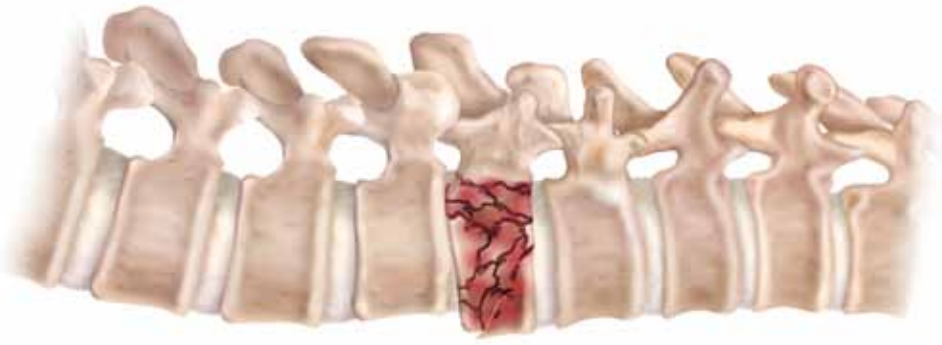


*Figure XX*

To see a video of this procedure, download a QR Code Reader app to your smartphone or mobile device and scan this code.

# T10-L2 Burst Fracture *continued*

## Step 1 – Screw Selection and Placement

Due to its multiple axis accommodation, it is recommended that the MAS be used at the most rostral level if the coronal alignment of the screws is difficult to assist in rod capture. The SAS can be used in the level immediately above and below the fracture **(Figure XX)**. If the fractured level is also to be instrumented, the SAS can be used to elevate the fractured endplate. The SAS allows for active kyphosis correction, a critical component of burst fracture reduction. With the ability of the SAS to accommodate to the sagittal spinal rod position, rod to saddle alignment is not as critical when compared to a Fixed Angle Screw implant.

Pedicle screws may be placed with the assistance of navigation. Alternatively, intraoperative radiographs of fluoroscopy may be used to assist in the verification of appropriate screw position. Screws may be inserted with the POWEREASE™ System and EMG monitoring utilizing the NIM-ECLIPSE® Spinal System to ensure the proper trajectory is followed.

*Figure XX*

# T10-L2 Burst Fracture *continued*

## Step 2 – Rod Selection and Placement

To determine the correct length and curvature of spinal rod, the Rod Template may be utilized. The rods can then be cut and contoured in the sagittal and coronal planes to the normal and desired contour of the spine, which is relatively straight or neutral across the thoracolumbar junction. If the upper lumbar spine is involved, then the bottom of the rod will have slight lordosis and similarly the further up into the thoracic spine some kyphosis may be appropriate. The rod spectrum available with the CD HORIZON® SOLERA™ Spinal System incorporates multiple rod materials and diameters to facilitate selection of a custom intraoperative construct **(Figure XX)**. Generally the construct demand of a fracture will be high, therefore a higher strength, higher stiffness rod such as the CHROMALOY™ Plus rod may be used. Ultimately the choice of spinal rod used lies with the surgeon and is based on his/her assessment of the individual patient need.

Once the appropriate rod has been selected, the Rod Grippers can be used to clamp the rod to help prevent the rod from rotating during contouring. Using the rod inserter, place both rods into the screws and secure loosely with set screws. If there is significant kyphosis sometimes the rods will be slightly dorsal to the rostral screws **(Figure XX)**. This is often seen in a fracture dislocation compared to a burst fracture.

| Rod Options | 4.75mm | 5.5mm | 6.0mm |
|---|---|---|---|
| Pre-bent CHROMALOY™ | • | • | |
| Pre-bent Commercially Pure Titanium | | • | |
| Straight Titanium Alloy | • | • | |
| Straight Commercially Pure Titanium | | • | |
| Straight CHROMALOY™ | • | • | |
| Straight CHROMALOY™ Plus | • | • | • |

*Figure XX*

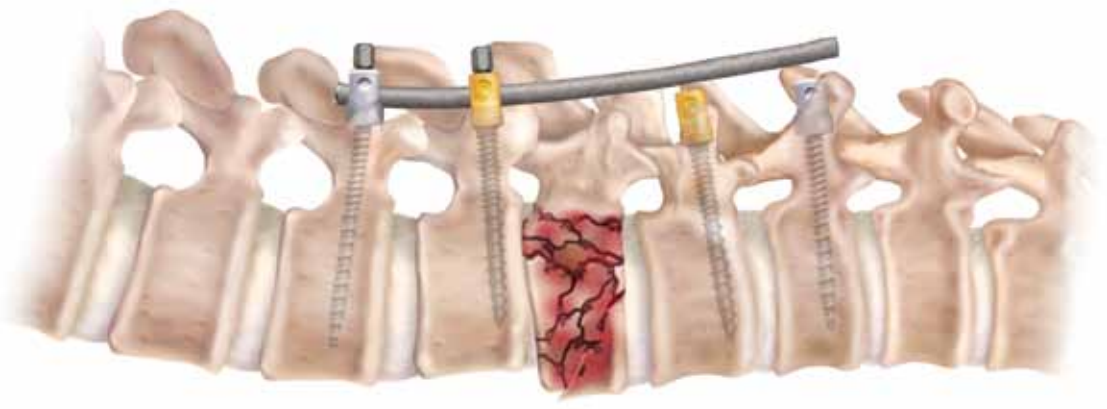


*Figure XX*

# T10-L2 Burst Fracture *continued*

## Step 2 – Rod Selection and Placement *continued*

### ADI Rod Reduction Technique

To fully seat the spinal rod into the implant, either the open or closed ADI extender may be used. The ADI will allow for sequential reduction of the rod into the implant. When used in conjunction with the SAS, rod reduction and sagittal alignment may be adjusted to the desired contour. To use the ADI, position the open or closed extender over the slots on the caudal/cephalad sides of the screw and lock the extenders onto the screw by sliding the blue locking sleeve down **(Figure XX)**. With the rod captured in the open or closed extender sleeves, rotate the reduction sleeve clockwise to seat the rod into the implant **(Figure XX)**. The Provisional driver or Dual Ended set screw starter is used to advance and tighten the set screw through the set screw cannula of the ADI.

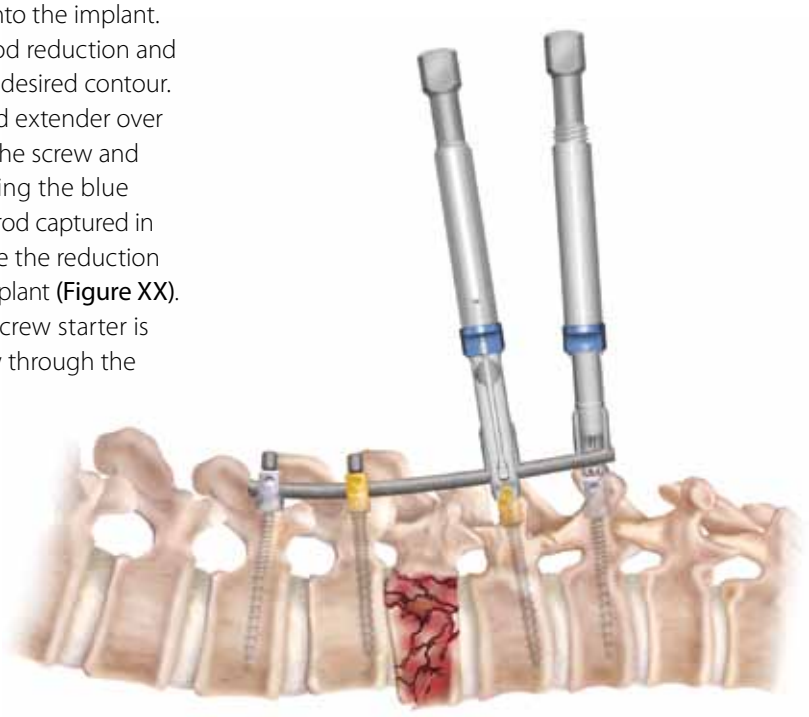


*Figure XX*

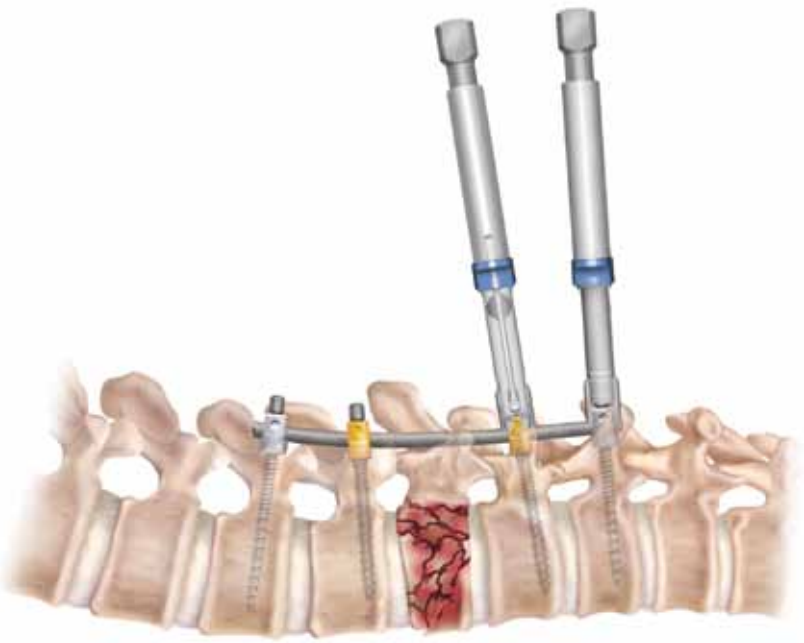


*Figure XX*

# T10-L2 Burst Fracture *continued*

## Step 2 – Rod Selection and Placement *continued*

### ADI Sagittal Plane Reduction

The ADI extenders are placed on the cephalad and rostral screws adjacent to the fracture. If the rod is dorsal to the screw the ADI can be used to reduce the rod into the screw and correct some of the deformity, as described in the previous section. Once the rod is in the screws sagittal plane reduction can occur.

With the rod in place, the caudal set screw is tightened and a distractor is placed between the T11 and L1 screws. The ADI extender on T11 is held by the surgeon in a neutral position as distraction occurs and then with distraction complete applies a lordosing or caudad force to the ADI. The distractor is left in place while conducting this maneuver to prevent shortening. This will actively correct the T11 vertebra into neutral or slight lordosis. The set screw is then tightened. The identical procedure is then carried out on the second side.

If more kyphotic correction is needed, the identical procedure is repeated but this time the rostral screw is locked and the lower caudad screw is distracted and then lordosed with the ADI. Another option is to loosen both set screws and distract both SAS implants at the same time while lordosing or pulling the ADI extenders together. This allows for the simultaneous correction of both vertebra (T11 and L1) by manipulation of their respective screws **(Figures XX and XX)**.

If the pedicles of the fractured vertebra are competent and will accept a pedicle screw, a SAS can be used to elevate the endplate fracture, restoring height and alignment. The same rostral screw maneuver as described above can be used to achieve this. There is not usually any correction maneuver needed for the most rostral screw (T10 in the above example) but this should still be assessed.

Occasionally, the thoracic interpedicular distance is narrower than the lumbar interpedicular distance or the degree of "toe in" of the T12 and L1 pedicles is considerably less than the adjacent ones. This can be managed by utilizing a MAS above and below the fracture due to its ability to accommodate to the coronal position of the spinal rod.

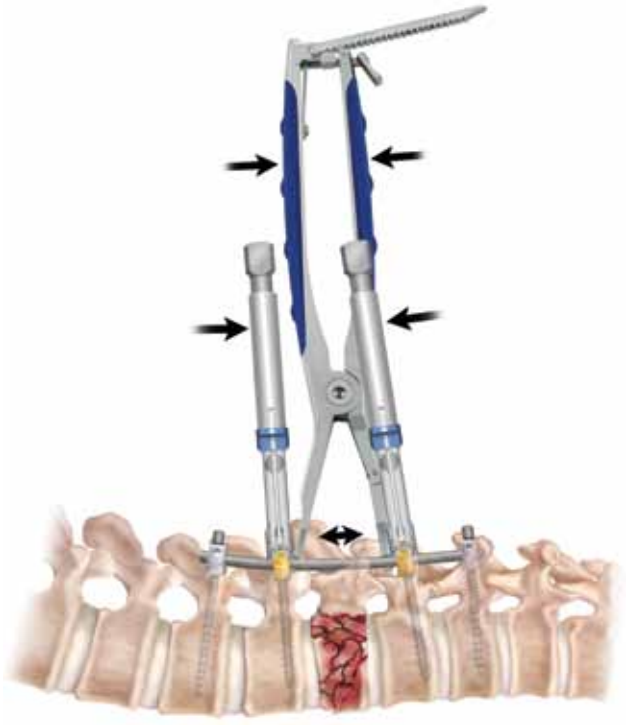


*Figure XX*

*Figure XX*

# T10-L2 Burst Fracture *continued*

## Step 3 – Final Tightening

When all implants are securely in place, final tightening of the set screws may be accomplished with the Counter Torque handle and Set Screw Break-Off Driver. Slide the assembly over the implant head and provisionally tighten the set screw. Rotate the Set Screw Break-off Driver clockwise until the break-off set screw breaks. An audible "click" is heard when the optimum torque is reached.

Alternatively the POWEREASE™ System with Set Screw Break-Off instrument maybe used for final tightening. Biomechanical testing has shown that using the POWEREASE™ compatible Set Screw Break-Off instrument and compared to manual instruments there is a 22% reduction in energy transferred to the construct during final tightening.

A CD HORIZON® X10 CROSSLINK® Plate may be attached to the construct to increase torsional stability. The correct size plate is determined by using the Measuring Caliper to measure the span between spinal rods. Once the CD HORIZON® X10 CROSSLINK® Plate has been placed on the rods and is in its final position, the set screws can be advanced and tightened, and bone grafting material placed. The final construct should be verified by x-ray or fluoroscopy prior to closing **(Figure XX)**.

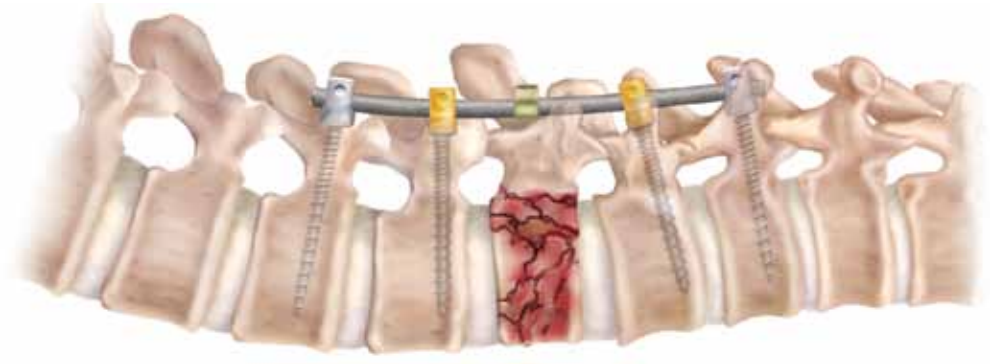


*Figure XX*

# T12 Fracture Dislocation

The following technique describes reduction and fixation of a T12 fracture dislocation. For these very unstable fracture dislocations, the implant is anticipated to support the entire load of the spinal column due to the complete lack of any bony load sharing through either the anterior or posterior columns of the spine. In these situations, posterior pedicle screw fixation is recommended at a minimum of two motion segments above and two motion segments below the fractured vertebra (Figure XX).

## Step 1 – Screw Selection and Placement

This technique describes fixation with an SAS being used above and below the fractured vertebra. The fixed relationship between the SAS head and bone screw help the screw construct to correct the sagittal alignment and allows for small kyphosis correction.

Pedicle screws may be placed with the assistance of Navigation. Alternatively, intraoperative radiographs or fluoroscopy may be used to assist in the verification of the appropriate screw position. Screws may be inserted with the POWEREASE™ System and EMG monitoring utilizing the NIM-ECLIPSE® Spinal System to ensure the proper trajectory is followed.

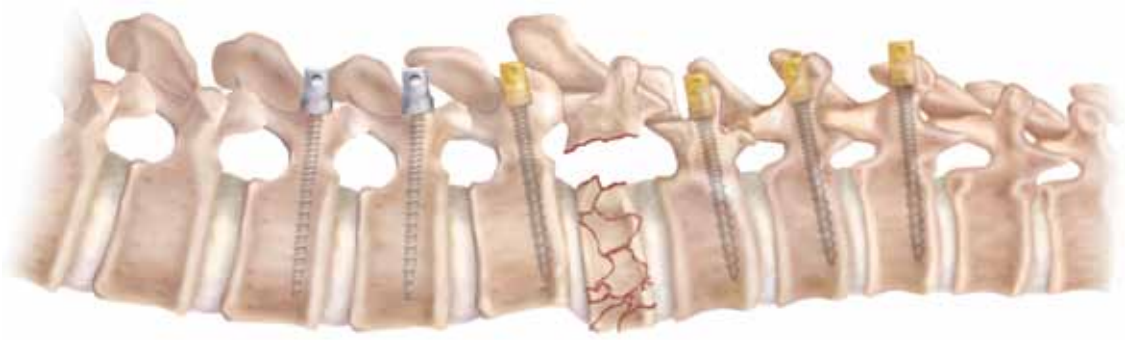


*Figure XX*

# T12 Fracture Dislocation *continued*

## Step 2 – Rod Selection and Placement

To determine the correct length and curvature of rod, the Rod Template may be utilized. The rods can then be cut and contoured in the sagittal and coronal planes to the normal and desired contour of the spine, which is relatively straight in the thoracolumbar spine. The rod spectrum available with the CD HORIZON® SOLERA™ Spinal System incorporates multiple rod materials and diameters to facilitate intraoperative construct tailoring based on the patient demand and bone quality.

In this very unstable trauma construct where the biomechanical demands on the rods are extremely high as there is no effective load sharing through the comminuted and disrupted spinal elements, a high strength and high stiffness rod may be used, such as the 6.0mm CHROMALOY™ Plus. Ultimately the choice of spinal rod used lies with the surgeon and is based on his/her assessment of the individual patient need. Once the appropriate rod has been selected, the spinal rods can be measured and contoured in the sagittal plane to the normal and desired contour of the spine. Clamping the rod with Rod Grippers at both ends will help prevent the rod from rotating during contouring.

Using the rod inserter, insert the contoured rod first into the caudal end of the construct and secure the set screw. In a typical fracture dislocation, the rod will be captured and secured into the caudal screws and will be a fair distance dorsal to the ventrally displaced cephalad fixation points (Figure XX).

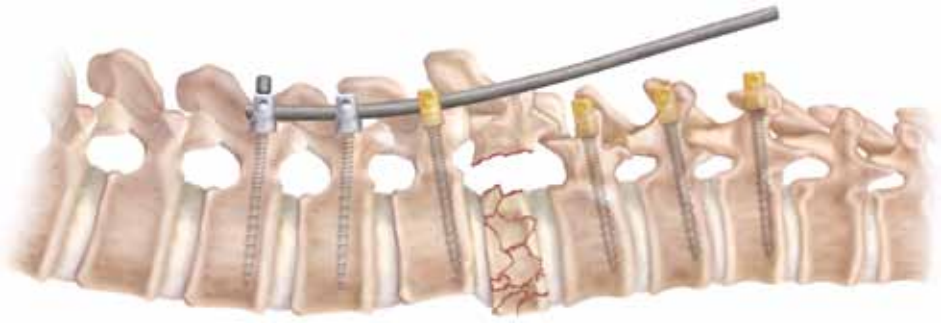


*Figure XX*

# T12 Fracture Dislocation *continued*

### Step 3 – Securing Rod Placement

To reduce the fracture dislocation, the cephalad segment of the spine has to be distracted slightly to disimpact the fractured segments, it then has to be translated dorsally to realign with the more caudal segments, and then some angular correction needs to be applied to correct any residual kyphosis between the proximal and distal segments.

The open ADI extender can be used for this reduction as it allows for controlled sequential reduction of the dislocated cephalad vertebrae to the more caudal segments. When used in conjunction with the SAS, rod reduction and sagittal alignment may be adjusted to desired contour. To use the ADI after both rods have been secured to the caudal vertebral segments, position the open ADI extender over the slots on the sides of the cephalad screws on each side and lock onto the screw by sliding the blue locking sleeve down (**Figure XX**). With the rod provisionally captured in the open or closed extender sleeves, by placing a rod holder adjacent to the ADI reducer, a distractor can be used to disimpact the fracture fragments by gently distracting between the rod holder and the ADI. After gentle distraction and disimpaction of the fracture dislocation, rotation of the reduction sleeve clockwise will seat the rod into the implant (**Figure XX**). The Provisional Driver or Dual Ended set screw starter is used to advance and tighten the set screw. This maneuver may be performed on both the right and left sides simultaneously to help spread the forces out over several segments. In the case of a thoraco-lumbar facet dislocation, the degree of distraction has to be enough to facilitate disimpaction of the dislocated facets which can often be achieved with a combination of distraction and gentle leverage on the ADI extender.

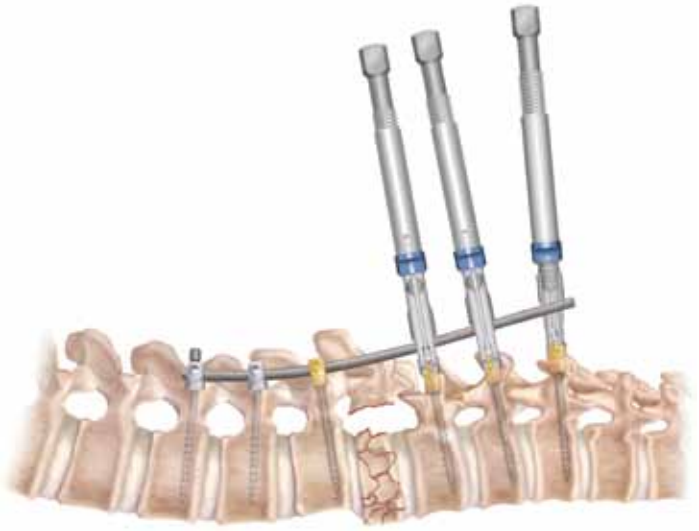


*Figure XX*

*Figure XX*

# T12 Fracture Dislocation *continued*

## Step 4 – Sagittal Adjustment

Once the correcting and stabilizing rod have been placed, the sagittal alignment of the anterior column may be adjusted by actively manipulating the SAS. Attach the ADI and loosen the set screws at the segment to be adjusted. Manipulation of the ADI will translate to direct control of the vertebral body **(Figure XX)**. Once the desired kyphosis correction and anterior column alignment are achieved, tighten the set screws.

Occasionally, the thoracic interpedicular distance is narrower than the lumbar interpedicular distance requiring some in situ coronal-plane rod bending. This can be performed with the Coronal Plane Benders. Once the major reduction has been accomplished, fine adjustments may be made by applying either compression or distraction and kyphosis correction as needed. In either maneuver, the set screws on one side of the fracture dislocation should be provisionally tightened, with the set screws loose in the segments to be compressed or distracted. Utilizing the Hinged Translator for compression or distraction will allow for manipulation of the motion segment without interfering with adjacent implants as it attaches to the rod **(Figure XX)**. Alternatively, the Compressor or Distractor may be used to facilitate correction. Compression or distraction will occur against the provisionally tightened implant and the adjacent implant. If necessary, the Rod Gripper may also be utilized as a point of fixation against which to compress or distract.

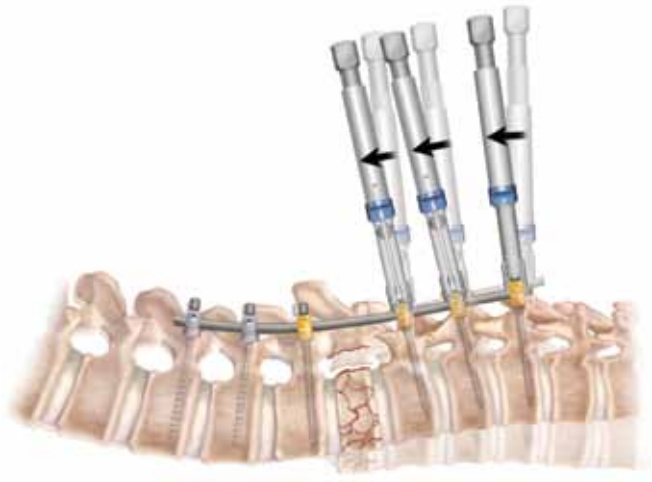


*Figure XX*

*Figure XX*

# T12 Fracture Dislocation *continued*

## Step 5 – Final Tightening

When all implants are securely in place, final tightening of the set screws may be accomplished with the Counter Torque handle and Set Screw Break-Off Driver. Slide the assembly over the implant head and provisionally tighten the set screw. Rotate the Set Screw Break-off Driver clockwise until the break-off set screw breaks. An audible "click" is heard when the optimum torque is reached.

Alternatively the POWEREASE™ System with Set Screw Break-Off instrument maybe used for final tightening. Biomechanical testing has shown that using the POWEREASE™ compatible Set Screw Break-Off instrument and compared to manual instruments there is a 22% reduction in energy transferred to the construct during final tightening.

A CD HORIZON® X10 CROSSLINK® Plate may be attached to the construct to increase torsional stability. The correct size plate is determined by using the Measuring Caliper to measure the span between spinal rods. Once the CD HORIZON® X10 CROSSLINK® Plate has been placed on the rods and is in its final position, the set screws can be advanced and tightened, and bone grafting material placed. The final construct should be verified by x-ray or fluoroscopy prior to closing **(Figure XX)**.

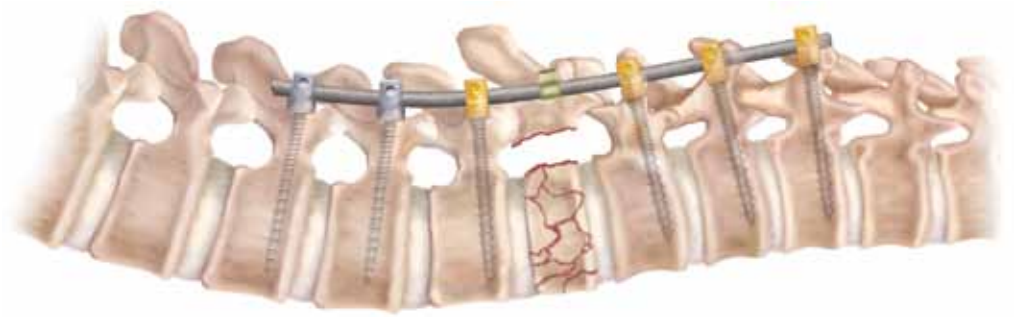


*Figure XX*

# Degenerative

# Degenerative Disc with a Grade 1 Spondylolisthesis at L4-L5 and a Transforaminal Lumbar Interbody Fusion (TLIF)

The following technique describes single level fixation of a degenerative L4-L5 spondylolisthesis utilizing an SAS.

## Step 1 – Screw Selection and Placement

The selection of screws is based on anatomy and surgical goals. In the majority of degenerative cases a reduction and/or realignment is not necessary and therefore a MAS is recommended. In degenerative spondylolisthesis or isthmic spondylolisthesis where realignment is critical using translation, compression, or lordosing maneuvers, a SAS is recommended. The SAS has the advantage of accommodating for misalignment in the sagittal plane.

Either by free hand or with the assistance of STEALTHSTATION® Navigation the screw trajectories are determined; each screw is sequentially inserted into the vertebral body using navigation or intraoperative postero-anterior and lateral plane radiographs or fluoroscopy. When fully inserted, the screws should extend 50 – 80% into the vertebral body and be parallel to the superior end plate.

When a single level L4-L5 fixation is utilized, SAS screws alone may be used in both vertebrae **(Figure XX)**. If the construct is to extend to the sacrum, alignment and seating of the rod is simplified by using the MAS in L5 and S1 while active lordosis correction can be facilitated at L4 with a SAS. If bone quality is a concern, bicortical purchase may be necessary at S1. In some cases the point of convergence of the S1 end plate and anterior cortex may be a good target as it provides a "tri-cortical" point of fixation **(Figure XX).** Intraoperative EMG monitoring utilizing the NIM-ECLIPSE® Spinal System may be used to verify proper placement of the screw.

*Figure XX*

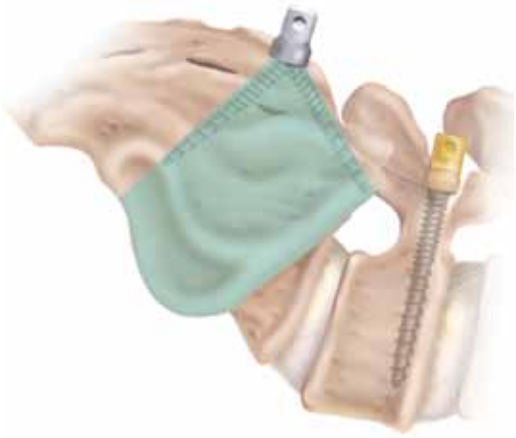


*Figure XX*

# Degenerative Disc with a Grade 1 Spondylolisthesis at L4-L5 and a Transforaminal Lumbar Interbody Fusion (TLIF) *continued*

## Step 2 – Rod Selection and Placement

Selection of a spinal rod should be based on the patient demand and bone quality. A full array of spinal rods is offered with the CD HORIZON® SOLERA™ Spinal System to tailor the construct to the patients needs.

For these lower demand degenerative fixation scenarios, particularly when there is anterior structural graft or interbody device support provided, a less stiff rod may be preferred such as the pre-bent 5.5mm commercially pure titanium spinal rod. Ultimately the choice of spinal rod used lies with the surgeon and is based on his/her assessment of the individual patient need. Once the appropriate spinal rod has been selected, the rod can be placed into the more caudal pedicle screws using the Rod Holder. If the spinal rod sits proud to any of the implants, the Beale Reducer can be used to fully seat the rod into the implant **(Figure XX)**. Once the rod is fully seated into the implant a set screw may be inserted and provisionally tightened **(Figure XX)**.

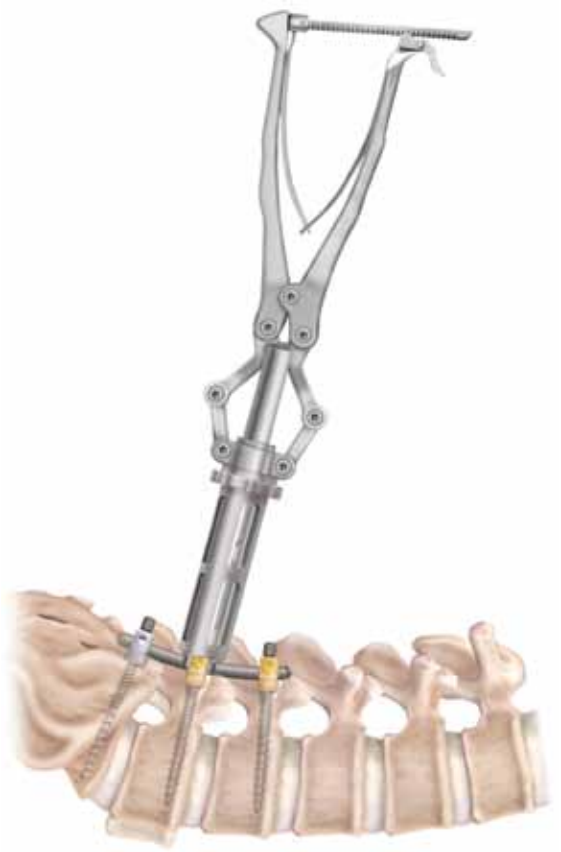


*Figure XX*

*Figure XX*

# Degenerative Disc with a Grade 1 Spondylolisthesis at L4-L5 and a Transforaminal Lumbar Interbody Fusion (TLIF) *continued*

## Step 3 – Construct Adjustment

During the process of disc removal during the TLIF, distraction between the L4 and L5 vertebrae can be used to facilitate access, discectomy, and insertion of structural bone graft or an interbody device into the anterior space. The ability of the SAS to accommodate sagittal angular change facilitates distraction of the disc space during this part of the TLIF. Once the anterior support has been selected and inserted, the surgeon can adjust the segmental lordosis at the L4-5 level through the following maneuvers:

- Ventral placement of the interbody device will optimally position the anterior fulcrum enabling optimal lordosis
- Initial tightening of the caudal screws is followed by attaching the open ADI extender to the cephalad screws
- When the SAS implant is used in the cephalad vertebra, compression may be combined with active lordosing correction applied through the ADI reducer/extender. This maneuver will apply a true lordosing moment to the vertebra and optimizes segmental lordosis at the L4-5 level (**Figure XX**).

When applying compression or distraction, the set screw on the one side of the motion segment should be loosened in the implant to be compressed or distracted. Using the Hinged Translator for compression or distraction will allow for manipulation of the motion segment without interfering with adjacent implants as it attaches to the rod. Alternatively, the Compressor or Distractor may be used to facilitate correction. Compression or distraction will occur against the provisionally tightened implant and the adjacent implant. If necessary, the Rod Gripper may also be utilized as a point of fixation against which to compress or distract.

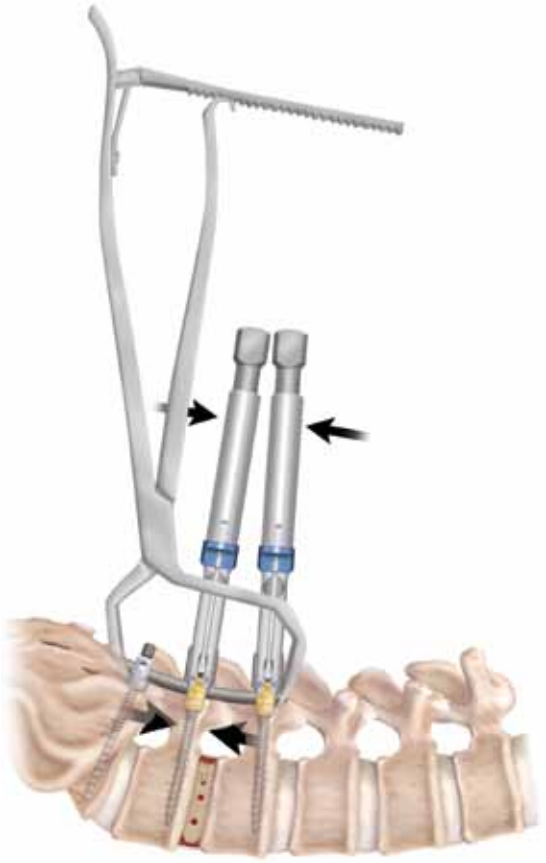


*Figure XX*

# Degenerative Disc with a Grade 1 Spondylolisthesis at L4-L5 and a Transforaminal Lumbar Interbody Fusion (TLIF) *continued*

## Step 4 – Final Tightening

When all implants are securely in place, final tightening of the set screw may be accomplished with the Counter Torque handle and Set Screw Break-Off Driver. Slide the assembly over the implant head and tighten until an audible "click" is heard, indicating the optimum torque has been reached.

Alternatively the POWEREASE™ System with Set Screw Break-Off instrument maybe used for final tightening. Biomechanical testing has shown that using the POWEREASE™ compatible Set Screw Break-Off instrument and compared to manual instruments there is a 22% reduction in energy transferred to the construct during final tightening.

A CD HORIZON® X10 CROSSLINK® Plate may be attached to the construct to increase torsional stability. The correct size plate is determined by using the Measuring Caliper to measure the span between spinal rods. Once the CD HORIZON® X10 CROSSLINK® Plate has been placed on the rods and is in its final position, the set screws can be advanced and tightened, and bone grafting material placed. The final construct should be verified by x-ray or fluoroscopy prior to closing (**Figure XX**).

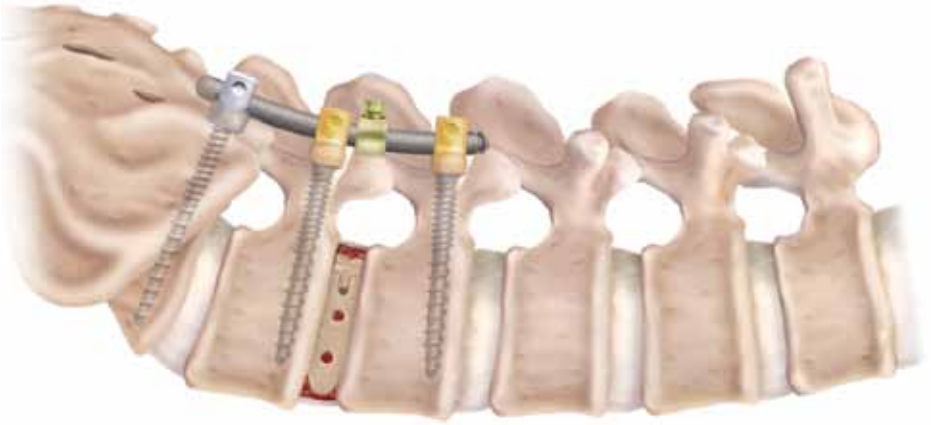


*Figure XX*

# High Grade L4-L5 Isthmic Spondylolisthesis Reduction

This technique will focus on degenerative spondylolisthesis at the L4-L5 level. Degenerative spondylolisthesis is generally treated with decompression and fusion. Degenerative spondylolisthesis represents a spectrum of pathology; degree of slip, slip angle or sagittal alignment, and degree of instability. Stability and realignment are extremely important for the surgeon to consider as they will determine the demand on the construct that is used to achieve these surgical goals. If it is a highly unstable degenerative spondylolisthesis, for example, a lot of movement on flexion-extension x-rays, then a stronger construct will be needed. Similarly, if kyphotic correction needs to be achieved, plus or minus reduction, this may be a high demand situation and require a stronger construct. Usually in both cases, a structural bone graft is utilized along with the posterior rod-screw construct.

### Step 1 – Screw Selection and Placement

If the realignment is not necessary and a posterior-lateral instrumented fusion is to be performed, then a MAS or FAS screw can be utilized. If the surgical plan requires sagittal plane alignment through active lordosing and/or reducing the lithesis by translating L4 backwards on L5, then a SAS may be the preferred option due to its fixed screw head to bone screw orientation. If the surgical plan requires compression or distraction to realign or allow for disc removal for a TLIF, than again a SAS can be used.

If realignment is necessary, then MAS or SAS screws should be placed adjacent to the slip. The extended tab feature of the Multi-Axial Reduction Screw (MARS) provides a benefit at the level of the slip by facilitating reduction of that segment.

Either by freehand or with the assistance of STEALTHSTATION® Navigation, the screw trajectories are determined and prepared. Pedicle screws are sequentially inserted into the vertebral body using navigation or intraoperative posterior-anterior and lateral plane radiographs of fluoroscopy. When fully inserted, the screws should extend 50-80% into the vertebral body and be parallel to the superior end plate. The L4 screws should especially be placed just under the cortical bone of the end plate so if a distraction or lordosing force is applied through the L4 screw, it will be buttressed by the end plate reducing movement (**Figure XX**).

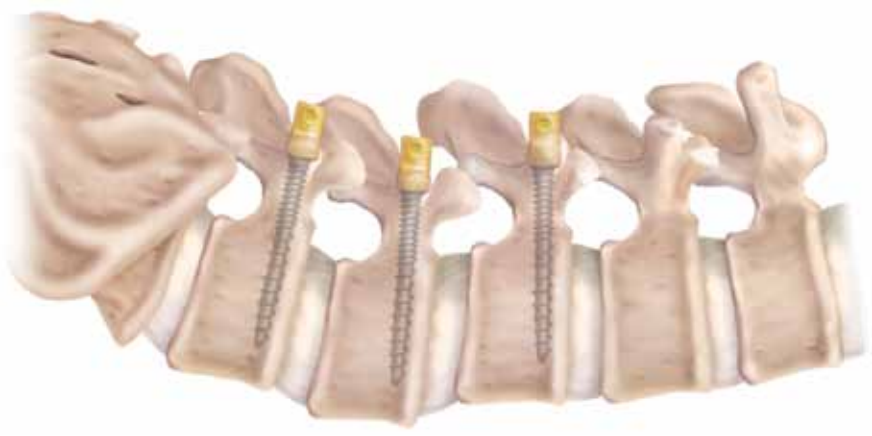


*Figure XX*

# High Grade L4-L5 Isthmic Spondylolisthesis Reduction *continued*

## Step 2- Rod Selection and Placement

Generally, a high stiffness rod, such as the CHROMALOY™ or CHROMALOY™ Plus rod, would be preferred where reduction and realignment need to occur. Ultimately the choice of spinal rod used lies with the surgeon and is based on his/her assessment of the individual patient need. Once the appropriate spinal rod has been selected, the spinal rod is usually contoured into slight lordosis. The rod is placed in the L5 SAS and provisionally secured. The angle of the rod can be adjusted using the saddle of the SAS. If reduction of the L4-L5 spondylolisthesis is desired, the spinal rod can be positioned dorsally over the L4 screw by the magnitude of reduction desired. Alternately, if a MARS is used at L4, the rod can be reduced into the implant with the Extended Rocker Reducer. These maneuvers should not be attempted if screw fixation is poor and the degenerative spondylolisthesis is stable, as these conditions can compromise the bone-screw interface during reduction maneuvers. If a translation maneuver is not planned, then the rod can be positioned into the L4 screw and provisionally secured with a set screw.

### Reduction/Translation Technique

If reduction is to occur, an interbody fusion such as a TLIF or PLIF is recommended. Prior to placement of the spinal rod the TLIF distractor is placed on the L4 and L5 screws and the disc space entered, removing the disc material. Once the discectomy is complete, the spinal rod is placed in the L5 SAS and provisionally secured. The angle of the rod can be adjusted using the saddle of the SAS. Position the spinal rod dorsally over the L4 screw by the desired reduction magnitude. The open ADI extender is then attached to the L4 screw and the dorsally placed rod is captured (**Figure XX**). The spinal rod is then sequentially reduced into the implant. Simultaneous bilateral reduction can be done to reduce the force on the screws. Reduction is carried out prior to placement of a structural bone graft. Once the reduction is complete, the set screws are placed in the SAS and the rod provisionally held. Distraction can now be carried out by placing a structural bone graft and compression between the L4 and L5 screws to facilitate lordosis. In contrast to a MAS, compression and distraction of the SAS results in a direct relationship of movement to applied force due to the fixed position of the implant head to the bone screw shaft.

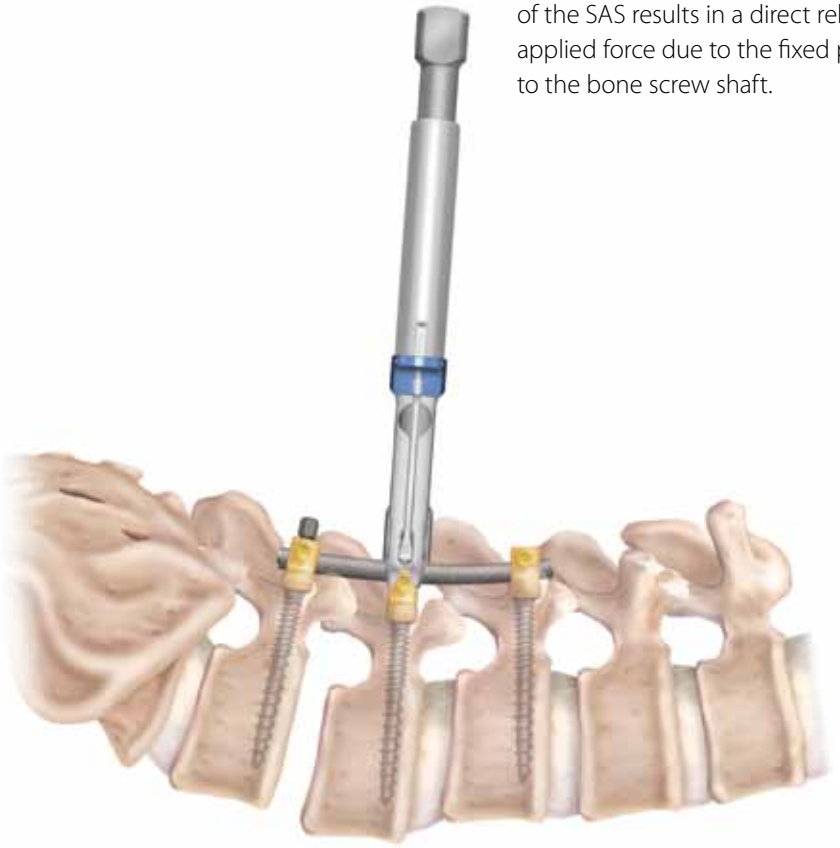


*Figure XX*

# High Grade L4-L5 Isthmic Spondylolisthesis Reduction *continued*

## Step 2- Rod Selection and Placement *continued*

### Sagittal Realignment Technique

Generally once compression of the SAS has occurred, some lordosis will have been achieved. This is influenced by the size and location of the structural bone graft placed for a TLIF or PLIF and the stiffness and bone contours of the degenerative spondylolisthesis level. Due to the saddle technology of the SAS, further lordosis can be achieved through active manipulation of the vertebra. To accomplish this, an ADI extender can be attached first to the L4 screws and the set screw slightly loosened. The ADI is then angled in the caudad direction which applies a lordosing or extending force to the L4 vertebral body. The position of the SAS saddle allows for up to 13° of lordosis to be dialed in (**Figure XX**). Further lordosis can be achieved by repeating the same procedure using the ADI on the L5 screws and applying an extension or lordosing force through the ADI.

*Figure XX*

# High Grade L4-L5 Isthmic Spondylolisthesis Reduction *continued*

## Step 3 – Final Tightening

When all implants are securely in place, final tightening of the set screw may be accomplished with the Counter Torque handle and Set Screw Break-Off Driver. Slide the assembly over the implant head and tighten until an audible "click" is heard, indicating the optimum torque has been reached (**Figure XX**).

Alternatively the POWEREASE™ System with Set Screw Break-Off instrument maybe used for final tightening. Biomechanical testing has shown that using the POWEREASE™ compatible Set Screw Break-Off instrument and compared to manual instruments there is a 22% reduction in energy transferred to the construct during final tightening.

A CD HORIZON® X10 CROSSLINK® Plate may be attached to the construct to increase torsional stability. The correct size plate is determined by using the Measuring Caliper to measure the span between spinal rods. Once the CD HORIZON® X10 CROSSLINK® Plate has been placed on the rods and is in its final position, the set screws can be advanced and tightened, and bone grafting material placed. The final construct should be verified by x-ray or fluoroscopy prior to closing.

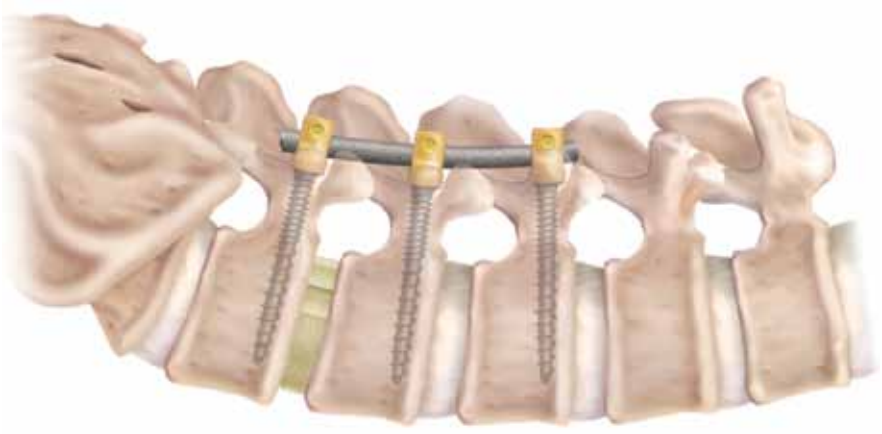


*Figure XX*

# L3 Pedicle Subtraction Osteotomy

The following technique describes a Pedicle Subtraction Osteotomy at the L3 level with the goal of achieving 30 degrees of focal lordosis using MAS and SAS implants. The pedicle subtraction osteotomy can help achieve substantial lordosis in the presence of lumbar flat-back deformity.

## Step 1 – Screw Placement

Either by free hand or with the assistance of STEALTHSTATION® Navigation the screw trajectories are determined; the pedicle screws are sequentially inserted into the vertebral body using navigation or intraoperative posterior-anterior and lateral plane radiographs or fluoroscopy. When fully inserted, the screws should extend 50 – 80% into the vertebral body and be parallel to the superior end plate. To facilitate sagittal alignment at the osteotomy site, SAS screws can be used at the L1, L2, and L4 levels. A MAS implant is preferred at L5, S1, and in the more cephalad levels to facilitate accommodation of the rod in these regions.

In the vertebrae adjacent to the L3 PSO, use of the SAS facilitates control of the adjacent vertebrae in the sagittal plane, ensuring uniform bone surface contact and control of sagittal alignment and seating of the rod (**Figure XX**).

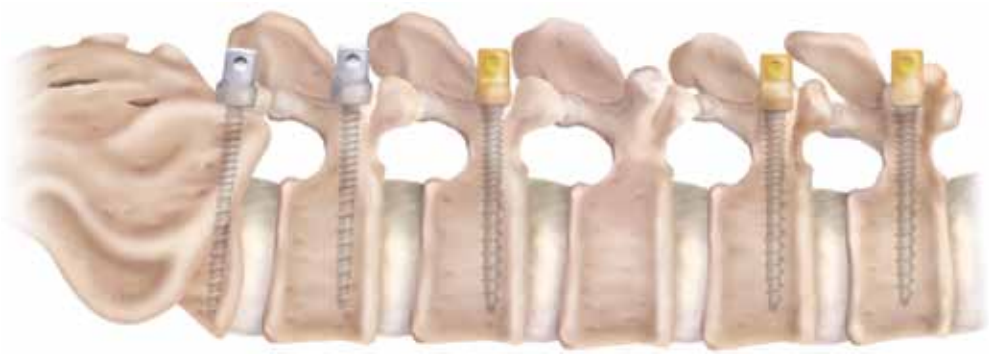


*Figure XX*

# L3 Pedicle Subtraction Osteotomy *continued*

## Step 2 – Rod Selection and Placement

Since the rod in a PSO is functioning primarily in a tension band mechanism for fusion, a low stiffness rod is preferred such as a 5.5mm titanium alloy spinal rod. Ultimately the choice of spinal rod used lies with the surgeon and is based on his/her assessment of the individual patient need. The patient demand on this construct and the patient's bone quality are also important variables to consider. To accommodate these needs a full array of spinal rods is offered with the CD HORIZON® SOLERA™ Spinal System to tailor the construct to the patient's needs.

# L3 Pedicle Subtraction Osteotomy *continued*

### Step 3 – Construct Adjustment

During the process of performing the PSO, the resection of the entire vertical height of the pedicle with a fulcrum at the anterior longitudinal ligament can result in approximately 30° of focal lordotic correction (**Figure XX**). In this case, a 30° acute bend may be put in the rod and positioned at the level of the PSO. Caudal to this acute 30° angulation, the rod will have to be contoured into the caudal spinal contour (characteristically the lordosis of the lumbo-sacral spine) and similarly, above the focal 30° bend, the rod will be contoured to accommodate the thoracolumbar junction contours (**Figure XX**).

*Figure XX*

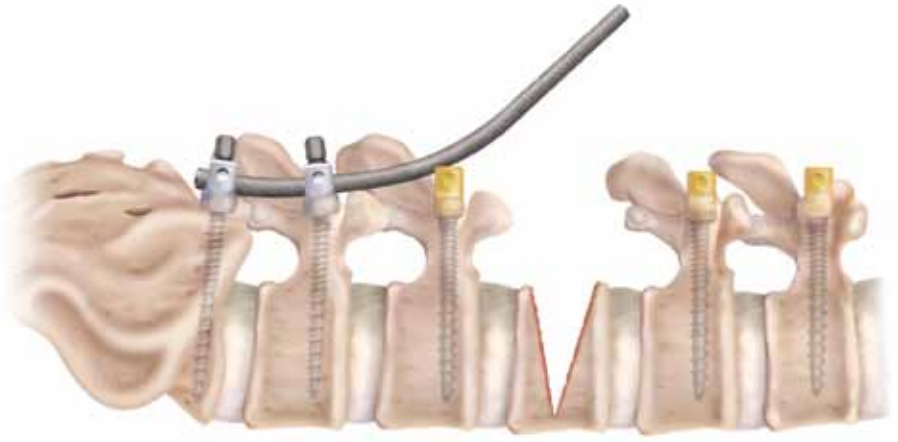


*Figure XX*

# L3 Pedicle Subtraction Osteotomy *continued*

**Step 3 – Construct Adjustment** *continued*

The ability of the SAS to accommodate sagittal angular change facilitates correction at the site of the pedicle subtraction osteotomy. This closure of the osteotomy can be accomplished through the following maneuvers:

Creation of the bone cuts ensuring that the base of the osteotomy includes the complete cephalo-caudal height of the pedicles ensuring that the apex or fulcrum of the osteotomy is at the anterior longitudinal ligament.

Initial insertion of the rod into the caudal screws with the acute 30 degree rod bend located precisely at the level of the osteotomy is followed by applying a number of open ADI instruments to the cephalad screws on both the right and left sides.

Correction through the PSO may be accomplished with a combination of cantilever correction and segmental compression. This is facilitated by the use of multiple ADI reducers to spread the force over multiple screws on both the right and left sides.

*Figure XX*

Use of an SAS also allows for initial tightening of the rod into the caudal screws followed by ADI-facilitated reduction of the rod into the cephalad screws (**Figure XX**). Once the rod is provisionally captured in the cephalad screw heads, active sagittal correction may be achieved by actively angling the ADI extender caudally to position the more cephalad side of the osteotomy.

When applying compression or distraction, the set screw on the one side of the motion segment should be loosened in the implant to be compressed or distracted. Using the Hinged Translator for compression or distraction will allow for manipulation of the motion segment without interfering with adjacent implants as it attaches to the rod (**Figure XX**). Alternatively, the Compressor or Distractor may be used to facilitate correction. Compression or distraction will occur against the provisionally tightened implant and the adjacent implant. If necessary, the Rod Gripper may also be utilized as a point of fixation against which to compress or distract.

If further correction is required beyond the focal correction through the PSO, then additional osteotomies such as Smith Peterson Osteotomies (SPOs) may be performed at the more cephalad levels.

*Figure XX*

# L3 Pedicle Subtraction Osteotomy *continued*

### Step 4 – Final Tightening

When all implants are securely in place, final tightening of the set screw may be accomplished with the Counter Torque handle and Set Screw Break-Off Driver. Slide the assembly over the implant head and tighten until an audible "click" is heard, indicating the optimum torque has been reached.

Alternatively the POWEREASE™ System with Set Screw Break Off instrument maybe used for final tightening. Biomechanical testing has shown that using the POWEREASE™ compatible Set Screw Break-Off instrument and compared to manual instruments there is a 22% reduction in energy transferred to the construct during final tightening.

A CD HORIZON® X10 CROSSLINK™ Plate may be attached to the construct to increase torsional stability. The correct size plate is determined by using the Measuring Caliper to measure the span between spinal rods. Once the CD HORIZON® X10 CROSSLINK™ Plate has been placed on the rods and is in its final position, the set screws can be advanced and tightened, and bone grafting material placed. The final construct should be verified by x-ray or fluoroscopy prior to closing (**Figure XX**).

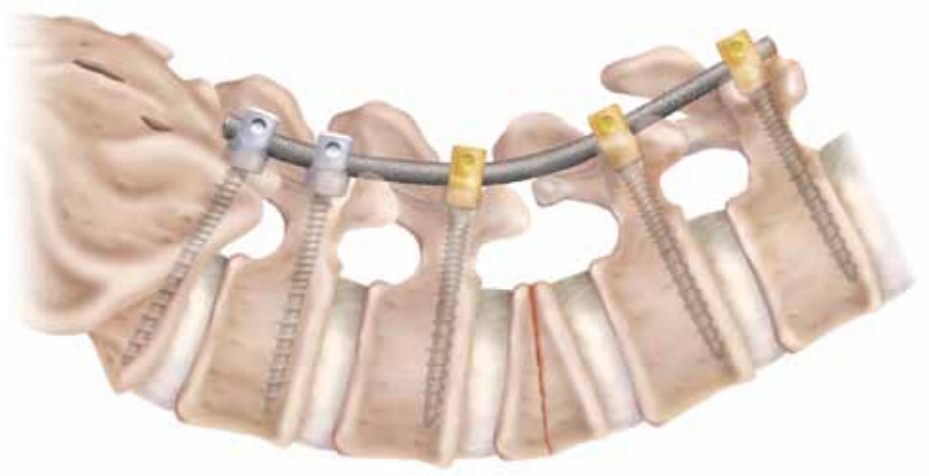


*Figure XX*

# 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 intended 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 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 Neurosurgical (Cranial, Craniofacial), OrthopediArthroscopic, Spinal, Sternotomy, and General surgical procedures.

Do not cut rods in situ.

# 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.