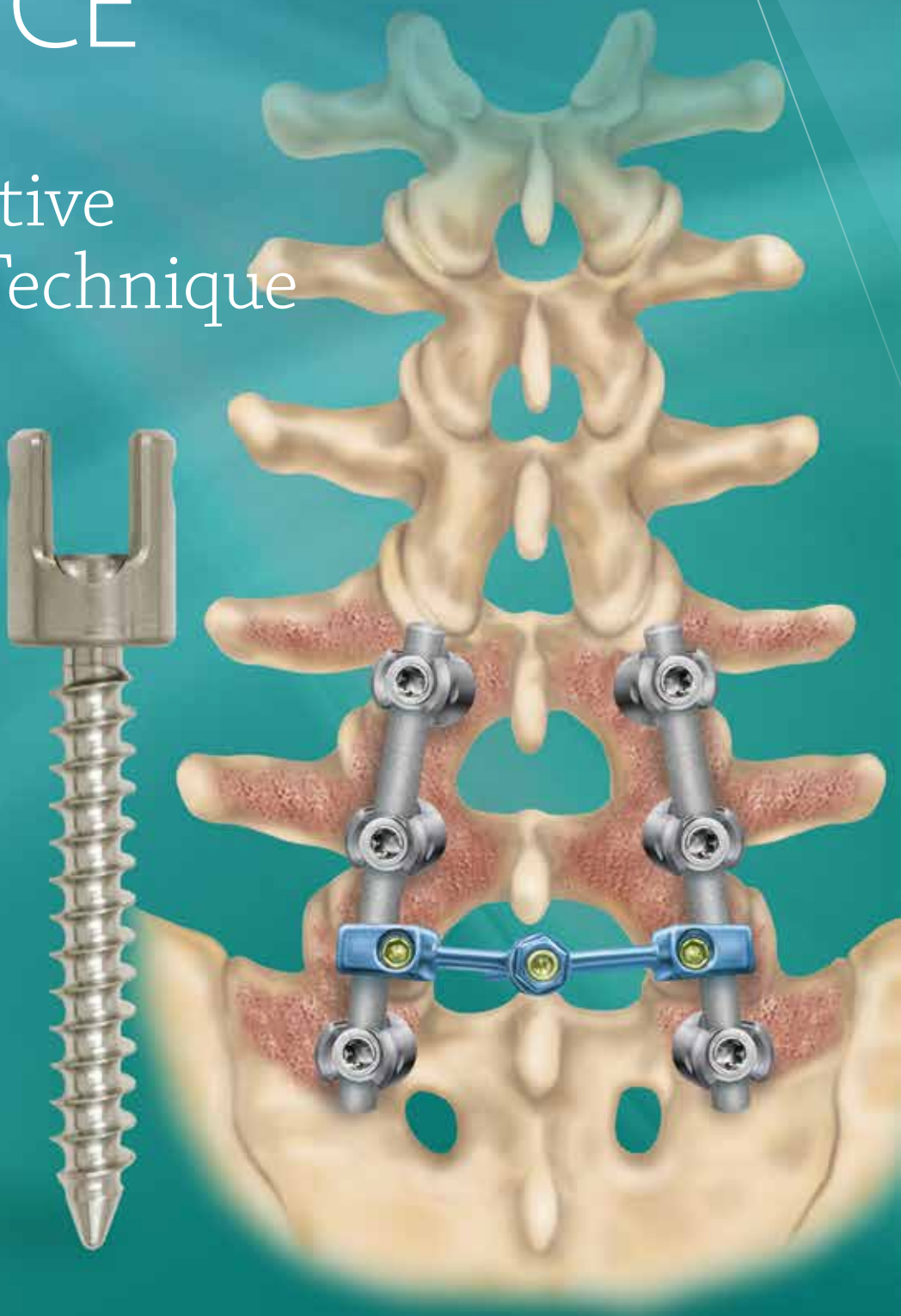
Medtronic

CD HORIZON® ESSENCE™

Spinal System

Degenerative Surgical Technique



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System Overview

The CD HORIZON® ESSENCE™ Spinal System is backed by more than 30 years and over 500,000 cases of CD HORIZON® clinical experience and Medtronic expertise. Meeting the needs of advancing surgical technique has required systems that are adaptable, reliable, and user friendly. Designed with the degenerative spine pathologies in mind, the CD HORIZON® ESSENCE™ Spinal System is a familiar top-loading screw system with instruments designed to accommodate the specialized needs of the hospital and OR staff.

Multi-Axial Screw

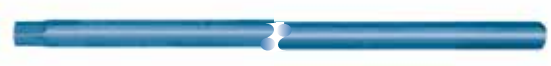
- 5.5mm Titanium Multi-Axial Screw is offered in four diameters to match varying patient anatomies
- Low profile design allows room for bone graft

Fixed Angle Screw

- 5.5mm Titanium Fixed Angle Screw is offered in two diameters to match varying patient anatomies
- Low profile design allows room for bone graft

Break-Off Set Screw

- Titanium Break-off Set Screw preserves the ease of top-loading set screw introduction



5.5mm Rod

Titanium Rod

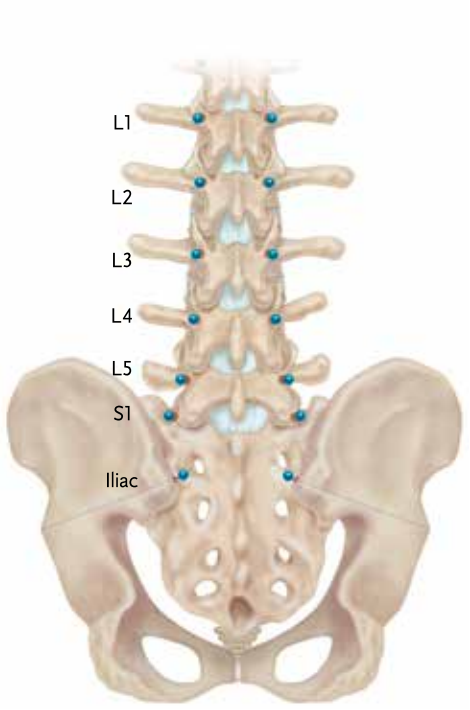
- Commercially Pure Titanium Rod

CD HORIZON® X10 CROSSLINK® Plates

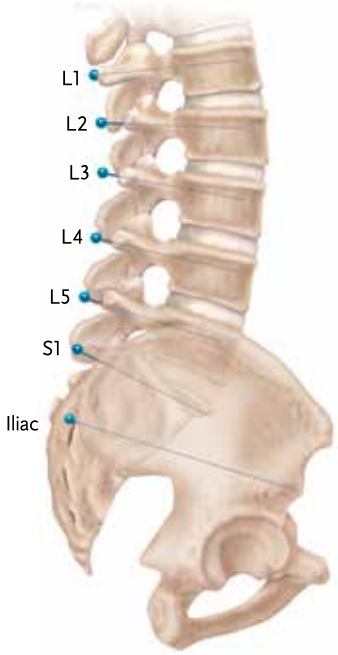
- Compatible with Titanium Rods
- Adjustable or fixed length options
- Adjustable plate attaches to the rod in the coronal, sagittal, or transverse planes in any orientation

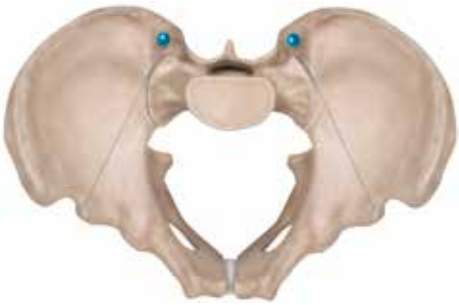
Screw Starting Points

Use Fixed-Angle or Multi-Axial Screws for the straight-forward approach (Blue Pins).

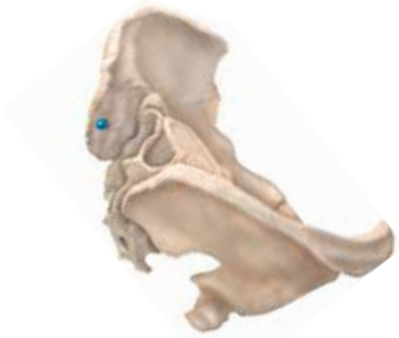


Level	Cephalad-Caudad Starting Point	Medial-Lateral Starting Point
L1	Midpoint TP	Junction: Lateral pars and superior facet
L2	Midpoint TP	Junction: Lateral pars and superior facet
L3	Midpoint TP	Junction: Lateral pars and superior facet
L4	Midpoint TP	Junction: Lateral pars and superior facet
L5	Midpoint TP	Junction: Lateral pars and superior facet
S1	Midpoint Sacral Ala	Junction: Sacral ala and superior facet
Iliac	1cm Cephalad to Distal PSIS	1cm inferior to the superior PSIS on the medial slope





Axial View



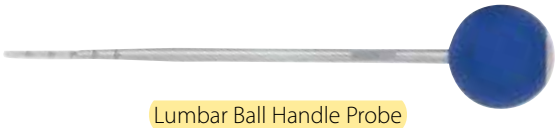
Oblique View

Instrument Set

Dual Ended Feeler Probe
7480100

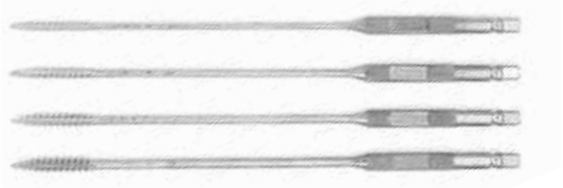
Round Holt Probe
803-291

Straight Holt Probe
803-292



Lumbar Ball Handle Probe
7480110/823-366

Quick Connect Ratcheting Handle
9339082/836-011



Tap
8684500 (4.5mm)
836-015 (5.5mm)
836-016 (6.5mm)
836-018 (7.5mm)

Screw Gauge
7220031

Screw Insertion

Fixed Angle Screwdriver
7480280

Multi-Axial Screwdriver
4591000

Instrument Set *continued*

Rod Insertion

Rod Measurement Tool
5484510

Rod Gripper
7480175 / 815-905 / 85603

French Bender
7480162 / 808-530

Set Screw Starter
7480122

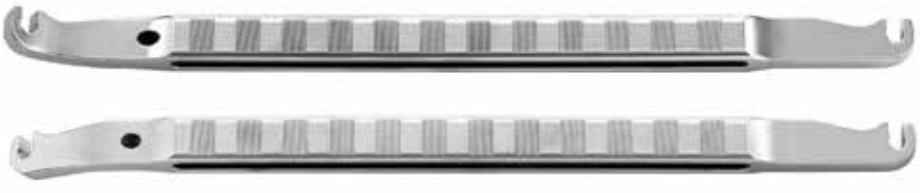
Provisional Driver
7480131

Rod Correction

Coronal Benders
Left, 7480265
Right, 7480270

Instrument Set *continued*

Rod Correction *continued*

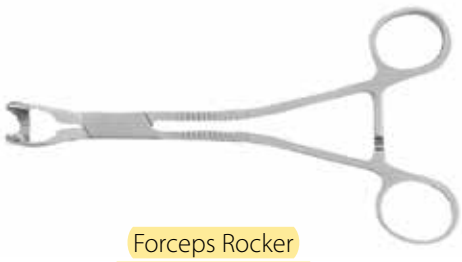


In Situ Benders
Left, 7480255
Right, 7480260

Apical Derotators
7480290

Rod Reduction

MAST® Beale Rod Reducer
7480136



Forceps Rocker
7480142/815-500

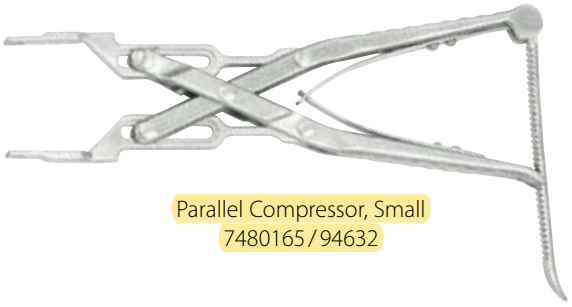
Sequential Reducer Inner Sleeve
5485008V

Sequential Reducer Outer Sleeve
5484328

Sequential Reducer
(Assembled)

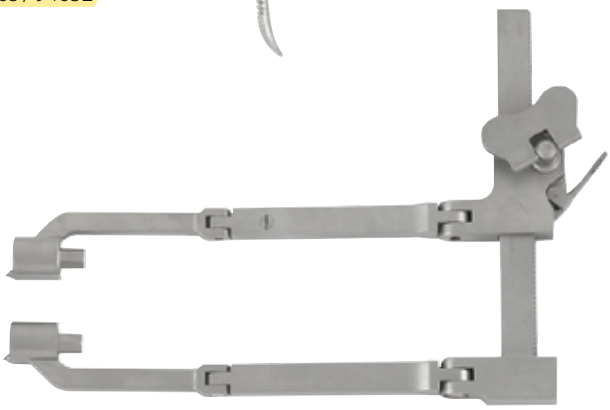
Instrument Set *continued*

Compression and Distraction



Parallel Compressor, Small
7480165 / 94632

Distractor
94633



TLIF Distractor
7480172

Final Tightening

Break-off Driver
8350316

T27 Obturator
7480154

Counter Torque
7480150

Instrument Set *continued*

CD HORIZON® X10 CROSSLINK® Plate Implants and Instruments

CD HORIZON® X10 CROSSLINK® Multi-Span Plate

CD HORIZON® X10 CROSSLINK® Fixed Plate

Measuring Credit Card
8110501 (5.5mm)
7486175 (6.35mm)

Implant Positioners
808-545 (optional)

7/32" Torque Limiting Set Screwdriver
8110535

Measuring Caliper
8110502

Counter Torque
8110540

45° In-line Plate Holder
8110511

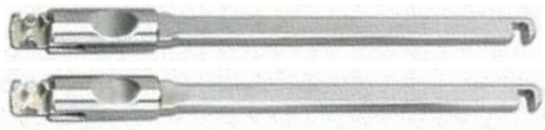


Plate Benders
8110525

Forceps Plate Holder
8110510 (optional)

3.0mm Hex Head Shaft, Removal Driver
8110530

Pedicle Preparation

In preparation for the screw insertion process, it is important to determine the sagittal orientation of the pedicles for the vertebrae to be instrumented. A plain intraoperative lateral radiograph is sufficient for this purpose (**Figure 1**).

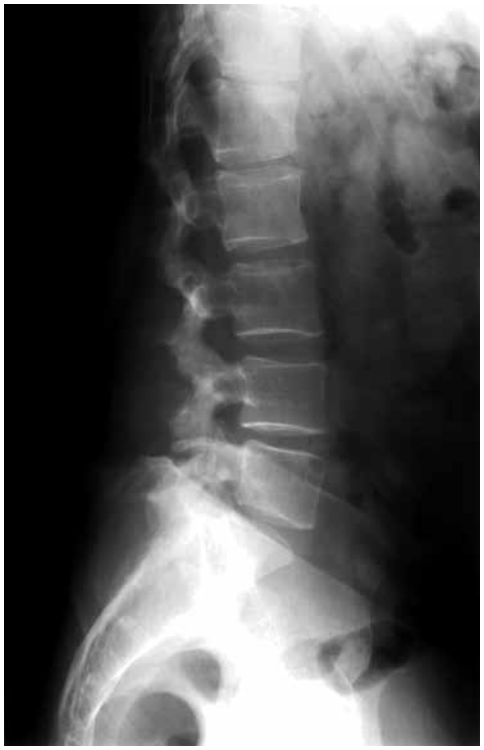


Figure 1

Pedicle Preparation *continued*

Identify the appropriate anatomical landmarks for creating the entry points of the pilot holes for screw insertion (**Figures 2a and 2b**).

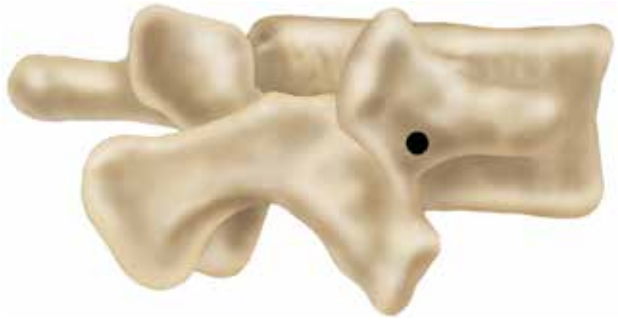


Figure 2a

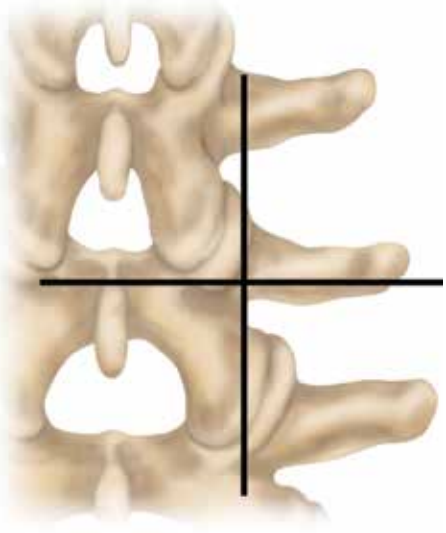


Figure 2b

Pedicle Preparation *continued*

Pilot holes are created with a sharp awl or burr, depending on surgeon preference (**Figure 3**), and then followed by a Lumbar Ball Handle Probe (**Figure 4**).

Helpful Tip

At this time, a feeler probe may be used to follow the pilot holes and palpate for any perforations in the pedicle walls.

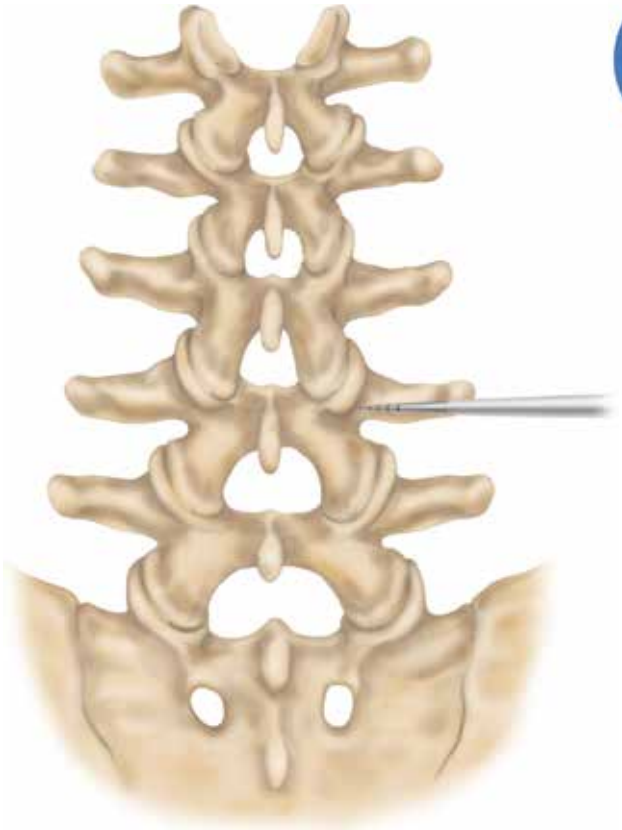


Figure 3

Figure 4

Pedicle Preparation *continued*

The CD HORIZON® ESSENCE™ Multi-Axial Screws have a tapered minor at the tip which provides ease in introduction of the screw. The screws may be inserted immediately following the preparation and probing of the pedicle. However, in cases of dense, sclerotic, or osteoporotic bone, tapping is recommended. Some surgeons may prefer to under tap by 0.5mm to 1mm for enhanced screw purchase. The instrument set contains 4.5mm and 5.5mm taps, which correspond to the pedicle screw diameters (6.5mm and 7.5mm taps are available upon request). The appropriate diameter tap is inserted through the pedicle into the vertebral body **(Figure 5)**. Following this final preparation of the pedicle, a feeler probe can again be used to follow the tap threads through the cancellous bone and palpate for any perforations in the pedicle walls (**Figure 6**).

Helpful Tip

For increased bone purchase, use the tap to prepare the cortical bone of the pedicle.

Note

Although not absolute contraindications, conditions to be considered as potential factors for not using this device include severe bone resorption, osteomalacia, and severe osteoporosis.

Figure 5

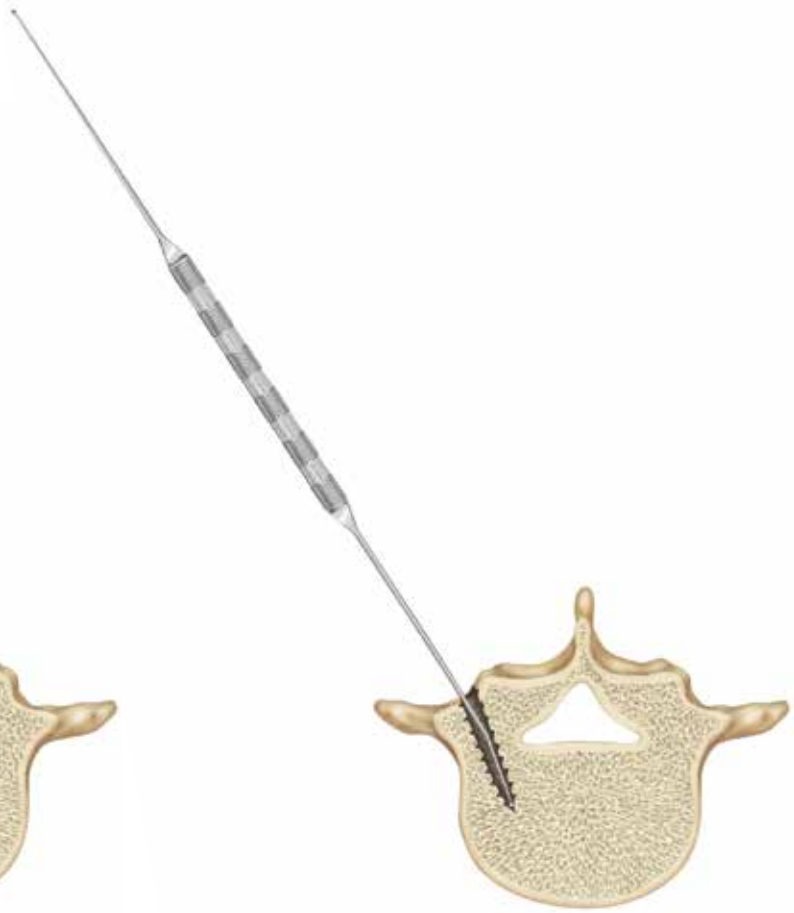


Figure 6

Multi-Axial Screw Insertion

With the pedicles prepared and the proper screw lengths determined, fully insert the hex end of the Multi-Axial Screwdriver into the screw head (**Figure 7**). Next, thread the screwdriver sleeve into the screw head (**Figure 8**). The combination of the hexalobe and the threaded sleeve provide a stable insertion instrument for inserting the Multi-Axial Screws bilaterally (**Figure 9**).

Figure 7

Figure 8

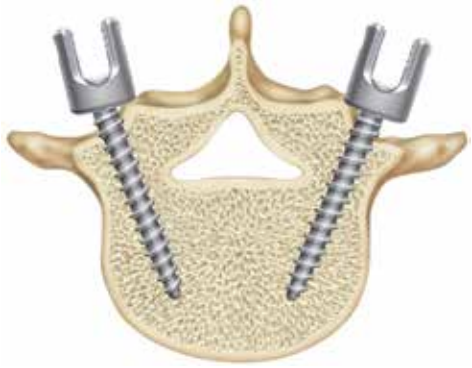


Figure 9

Multi-Axial Screw Insertion *continued*

Intraoperative posteroanterior and lateral plain radiographs are taken to evaluate the position of the screws in two planes (**Figures 10a and 10b**). Intraoperative EMG monitoring can be used if available. When fully inserted, the screws should extend 50% to 80% into the vertebral body and be parallel to the superior end plate. For sacral fixation, especially when the bone is osteopenic, bicortical purchase may be utilized. Some surgeons also suggest targeting screws toward the "tri-cortical point" (the convergence of the S1 end plate to the anterior cortex), which provides fixation for the S1 pedicle screw. Once the screw is inserted, the instrument sleeve is unscrewed and the screwdriver is disengaged from the screw.

Note

Although not absolute contraindications, conditions to be considered as potential factors for not using this device include severe bone resorption, osteomalacia, and severe osteoporosis.

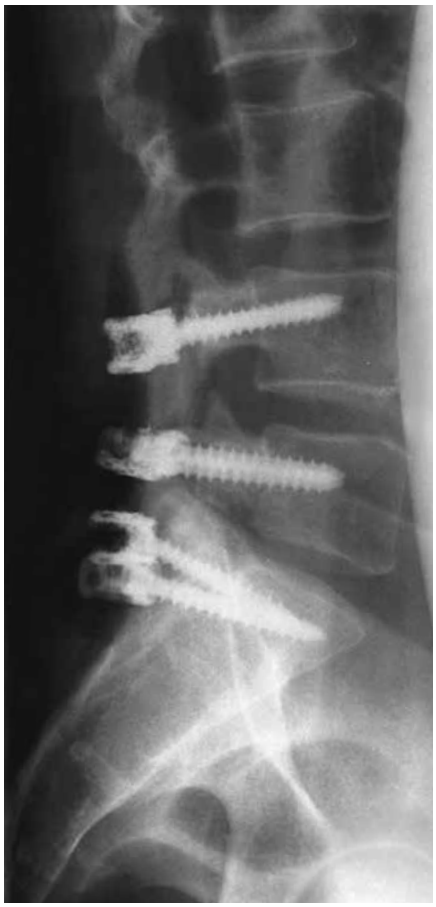


Figure 10a

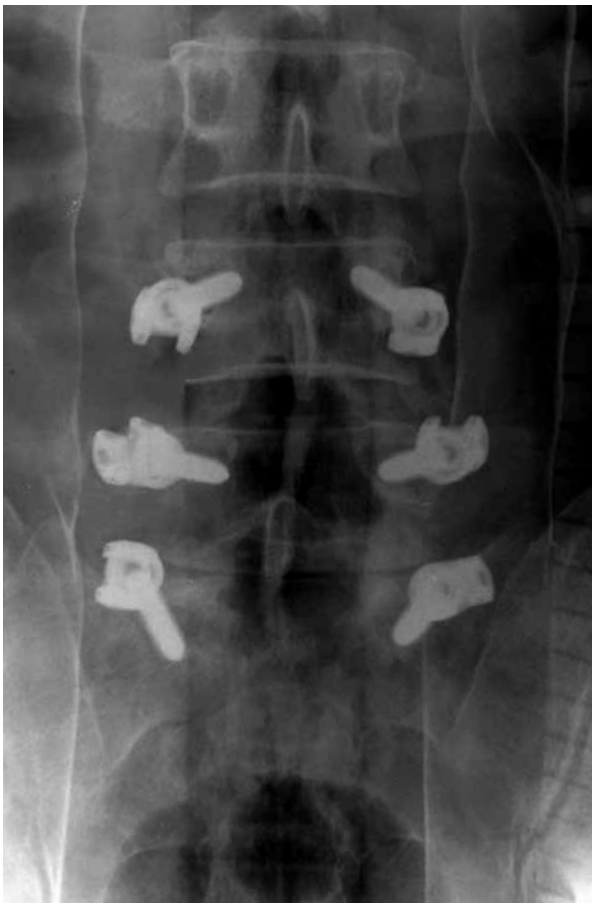


Figure 10b

Rod Insertion

Prior to the rod placement step, the patient's frame or operating table should be adjusted to increase lumbar lordosis. If additional dorsal screw adjustment is needed, the Self-retaining Screwdriver can be used (**Figure 11**).

Helpful Tip

Although the Multi-Axial Screws are able to accommodate moderate asymmetry in screw alignment, it is helpful to adjust the height of the screw heads so that when an imaginary line is drawn on top of the screw heads, it will form a gentle lordotic curve. This will facilitate rod contouring, rod placement, and set screw insertion.

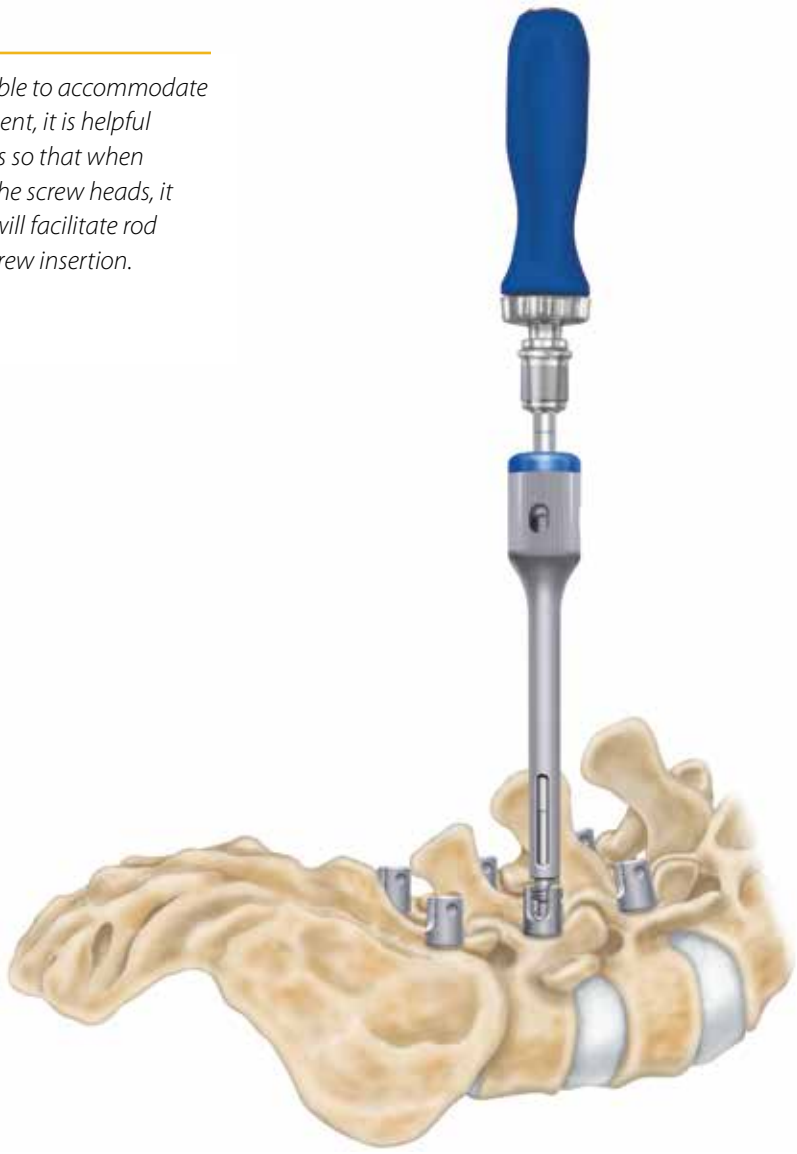


Figure 11

Rod Insertion *continued*

Next, the rod is placed into the top-loading screws beginning from either the cephalad or caudad direction using either the Rod Gripper (**Figure 12**). With the rod lying in the bottom of the screw heads, the Break-off Set Screws may be inserted into the implants using the Dual Ended Plug Starter (**Figure 13**).

Helpful Tip

Multiple set screws can be loaded into the Dual Ended Plug Starter for intraoperative efficiency.

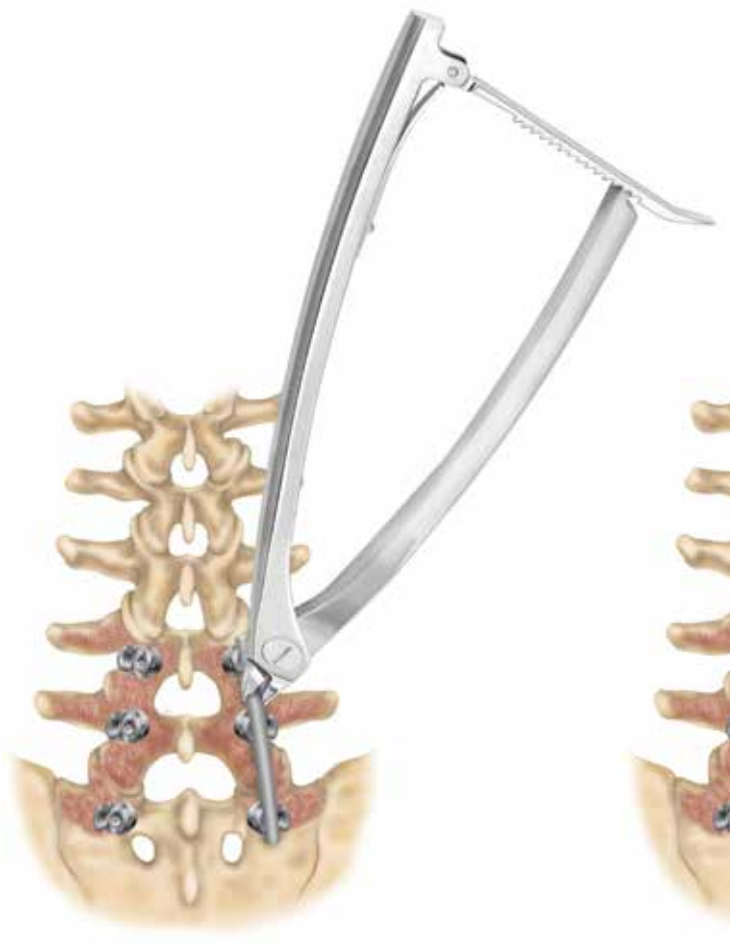


Figure 12

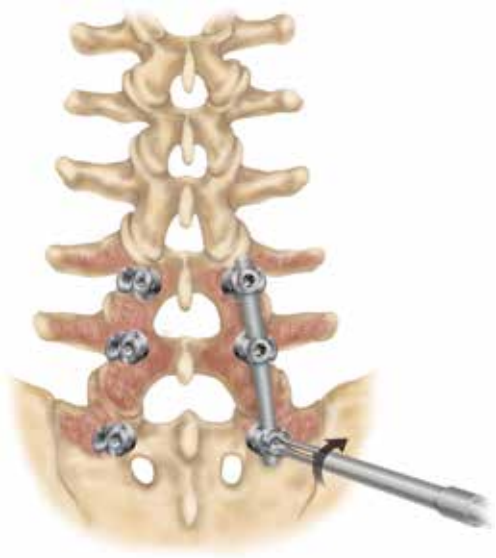


Figure 13

Rod Reduction Options

If the rod is not fully seated into the bottom of the screw head, the MAST® Beale Rod Reducer or the Forceps Rocker can be used to fully seat the rod and simplify the set screw insertion process.

The MAST® Beale Rod Reducer is the preferred method for reduction when the rod is lying even with the top of the implant head. To use the rod reducer, position the reducer so that the handles are parallel to the rod and grasp the screw head from above. The reducer handles are slowly compressed allowing the sleeve to slide down and seat the rod (**Figure 14**). The Dual Ended Plug Starter or Provisional Driver is then inserted through the rod reducer tube to insert the set screw into the head of the pedicle screw (**Figure 15**).

Note

Care should be taken with any rod reduction maneuver. Improper instrument use may dislodge the implants or damage the bony anatomy.

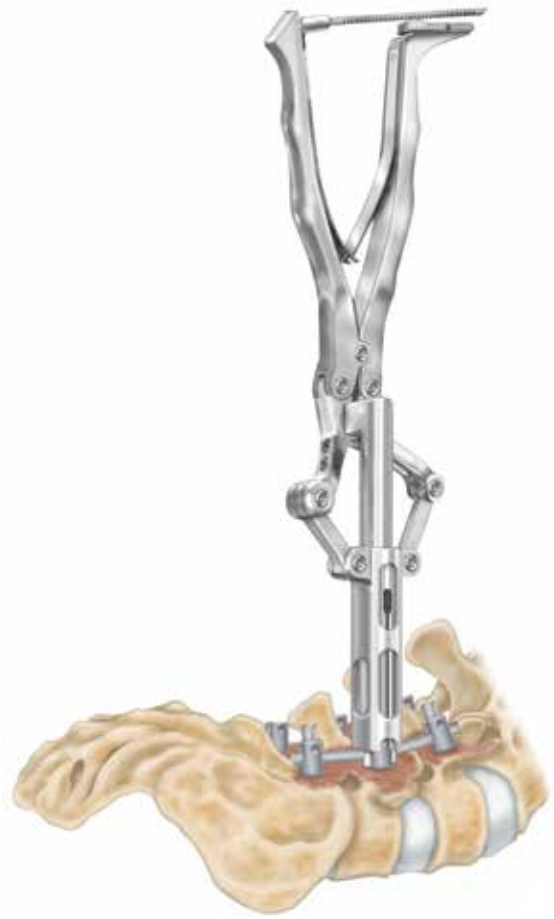


Figure 14

Figure 15

Rod Reduction Options *continued*

When a minimal amount of reduction is required, the Forceps Rocker can be used to reduce the rod into the head of the pedicle screw. Grasp the screw head from either side with the rocker, ensuring that the rocker cam is positioned above the rod (**Figure 16**). The rocker is then pushed backward toward the rod, levering the rod into the screw head. The Dual Ended Set Screw Starter or Provisional Driver is then used to start the set screw (**Figure 17**).

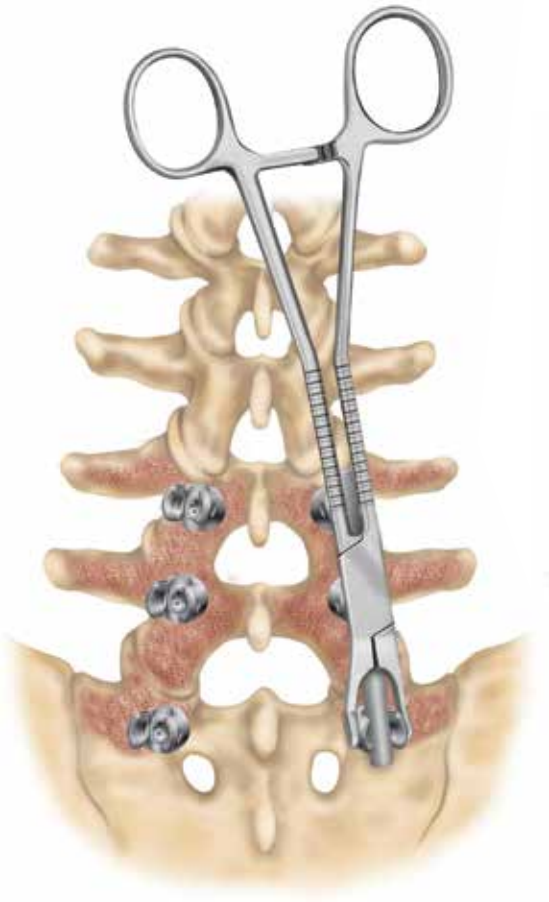


Figure 16

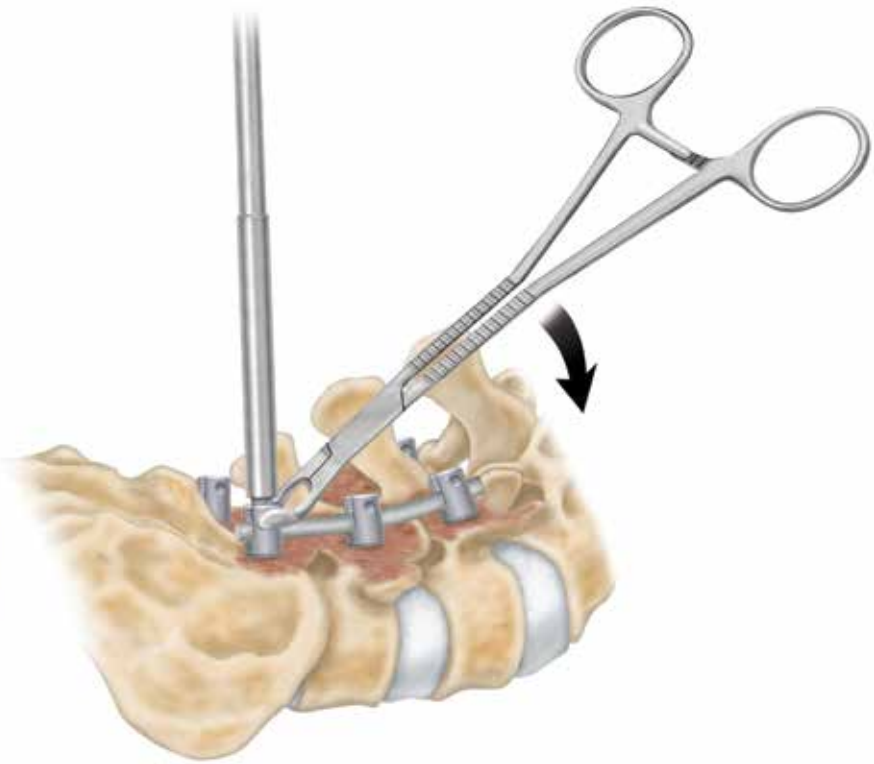


Figure 17

Compression and Distraction

If either compression or distraction is needed, it should be performed at this time. In either maneuver, the set screw on one side of the motion segment should be provisionally tightened, with the set screw loose in the implant to be compressed or distracted. Compression or distraction will occur against the provisionally tightened implant.

The Provisional Driver may be used to temporarily lock and secure the rod and implant construct. Usually, temporary fixation of the implant may be performed numerous times without damage to either the set screw or the implant threads; however, if the set screw has been cross threaded, it must be replaced.

Care should be taken with all set screws to ensure that the feet of either the compressor or the distractor are placed securely against the implant body and not against the set screw (**Figure 18**). Failure to do this may result in slippage of the implant or premature breaking of the set screw. It is preferred that compression be released just prior to the set screw being broken off or final tightened. This technique will help ensure that the implant head and rod are normalized to one another and, thus, allow for the rod to be fully seated in the implant head during the final tightening step. Once satisfactory compression or distraction has been achieved, final tightening may be performed.

Note

It is highly recommended that the set screw not be broken off or final tightened under compression.

Figure 18

Final Tightening

When all implants are securely in place, final tightening and break-off of the set screw head is done. Insert the Break-off Driver into the cannulated portion of the Counter Torque, which should be positioned over the implant and rod. The T-handle on the driver provides adequate leverage for the break off of the set screw head. The handle of the Counter Torque device should be held firmly to prevent torquing of the construct while the set screw is secured and sheared off (**Figure 19**).

Note

A slight rostral/caudal movement of the Counter Torque during set screw tightening will adjust the Multi-Axial Screw saddle squarely to the rod and should simplify final tightening and break-off.

Note

Prior to final tightening, ensure that the distance between the screw heads is adequate to place a CD HORIZON® X10 CROSSLINK® Plate in the upper and lower one-third of the construct to increase construct rigidity.

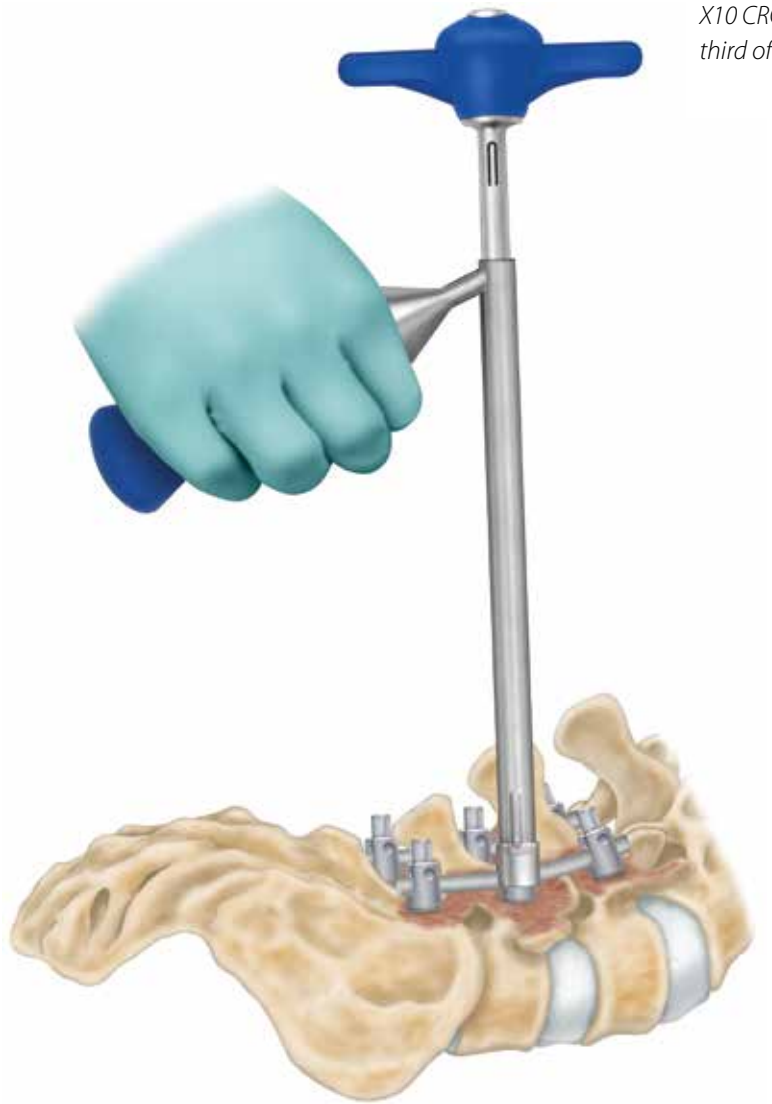


Figure 19

Final Tightening *continued*

After the set screw head has been sheared off, it will be retained within the cannulated shaft of the Self-retaining Break-off Driver. Each additional set screw can then be sequentially secured and sheared off, while the sheared pieces are retained (**Figure 20**). At any time following set screw break-off, the T27 Obturator may be inserted into the cannulated shaft of the Break-off Driver to release the broken off sections of the set screws which have been retained in the driver (**Figure 21**).

Figure 20

Figure 21

Graft Placement

Meticulous attention to bony fusion remains critical to the success of the surgical outcome, despite the use of instrumentation. Careful decortication of the transverse processes, the facet joints, and the pars interarticularis using manual instruments or a high speed burr should be accomplished. The surgeon may choose in certain instances to perform the decortication prior to the instrumentation if the decortication would prove difficult because of poor visualization. The preservation of the facet capsules of the unfused adjacent levels should be facilitated because of the implant's reduced bone-screw interface (**Figure 22**).

Whether the procedure utilizes autograft or allograft bone, precise placement of the graft material onto the decorticated bone is essential. This can only be done with excellent visualization of the decorticated bone surfaces. Keep in mind that fusion commonly occurs from transverse process to transverse process and that interposing muscle tissue may result in the development of a pseudarthrosis. If the facet architecture is sufficiently maintained, graft material should be impacted into the facet to obtain a facet fusion. Once the instrumentation is complete and the graft material is placed, the construct should be checked radiographically (**Figures 23a and 23b**).

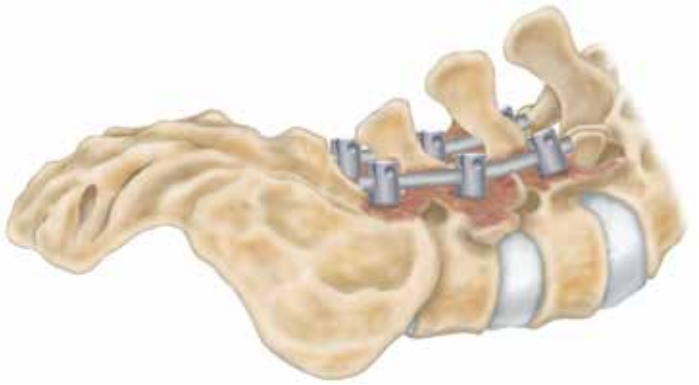


Figure 22

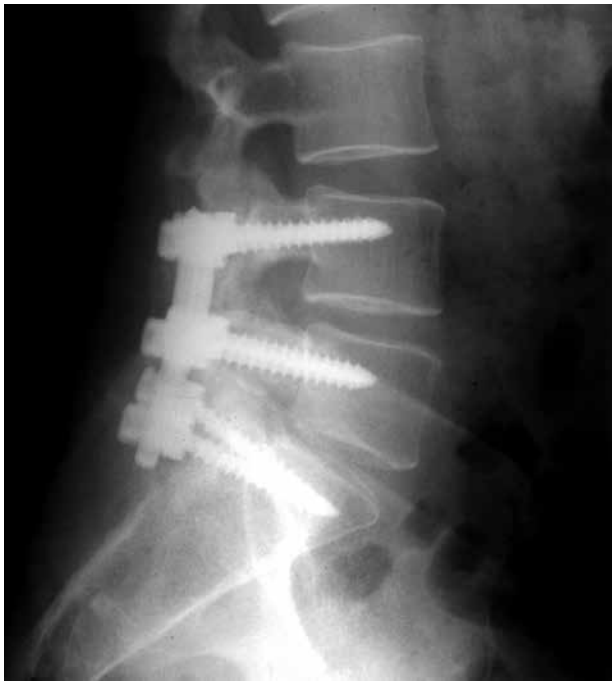


Figure 23a

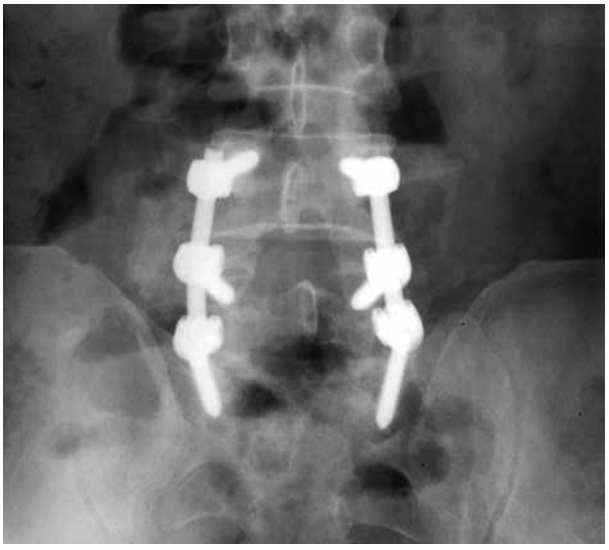


Figure 23b

CD HORIZON® X10 CROSSLINK® Plate Placement

CD HORIZON® X10 CROSSLINK® Plates should be used to increase the torsional stability of a construct. Longer constructs may necessitate placement of a CD HORIZON® X10 CROSSLINK® Plate at each end to increase construct rigidity. Two measuring devices are available to determine the proper length CD HORIZON® X10 CROSSLINK® Plate: the Measuring Credit Card (**Figure 24**) and the Measuring Caliper (**Figure 25**).

Prior to plate placement, ensure that the CD HORIZON® X10 CROSSLINK® Plate set screws are backed out to prevent binding during placement onto the rods of the construct. If the set screw is backed out too far, it will disengage from the plate, but it can easily be reinserted.

Figure 24

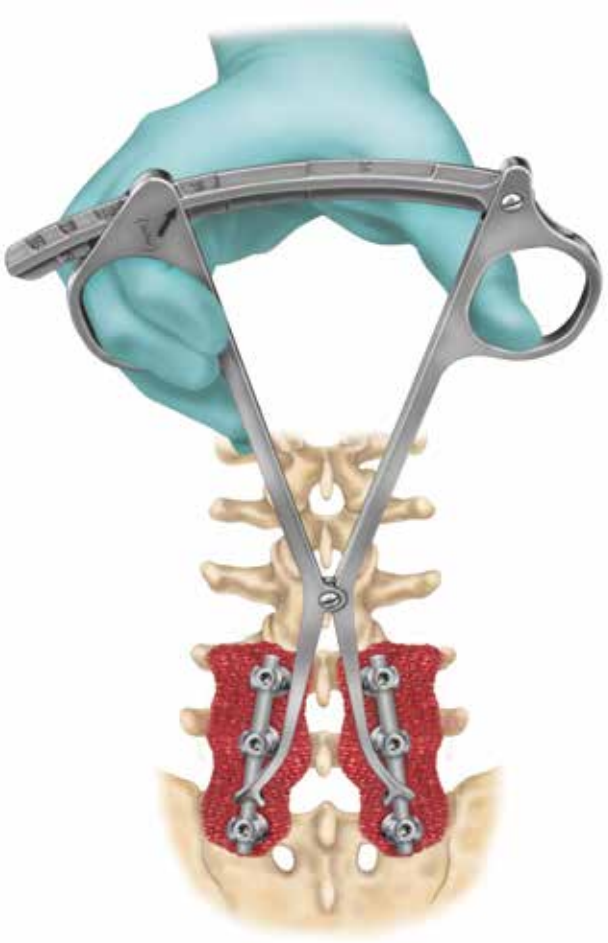


Figure 25

CD HORIZON® X10 CROSSLINK® Plate Placement *continued*

The surgeon may choose one of several CD HORIZON® X10 CROSSLINK® Plate placement options.

In-line Plate Holder Method

The midline nut is provisionally tightened to gain control of the CD HORIZON® X10 CROSSLINK® MULTI-SPAN Plate during placement. With the use of the In-line Plate Holder, the plate is selected, gripped, and positioned to capture the far rod. Following placement of the plate onto one rod, tighten the set screw using the 7/32" Torque Limiting Set Screwdriver until it is firmly attached to the rod (**Figure 26**). Next, loosen the midline nut to appreciate the multi-axial flexibility of the plate and seat the opposite end onto the other rod, followed by final tightening of the break-off set screws to 60 in-lbs. Finally, tighten the midline nut to 80 in-lbs, remembering that the midline nut is not a break-off set screw (**Figure 27**).

Figure 26

Figure 27

CD HORIZON® X10 CROSSLINK® Plate Placement *continued*

Implant Positioner Method

With the use of the Implant Positioners, the appropriate CD HORIZON® X10 CROSSLINK® MULTI-SPAN Plate is selected and gripped (**Figure 28**). Ensure that both Implant Positioners fit securely onto both rod set screws.

The Implant Positioners can be used to sequentially articulate the CD HORIZON® X10 CROSSLINK® Plate around the rod (**Figure 28**). If the plate cannot be precisely seated against the rod, the set screw is still too prominently extended into the ventral opening. Keep the plate in the wound and abutting against the rod. By rotating the Implant Positioners, the set screw can be manipulated and slightly backed out, allowing the rod to fully seat in the ventral opening. Once precise contact has been achieved between the plate and the rod, the Implant Positioners can be used to provisionally tighten the CD HORIZON® X10 CROSSLINK® Plate to the rod. The same process is carried out for the other side of the plate. Both halves of the plate should precisely articulate with the rod before final tightening and set screw breakoff (**Figure 29**).

Remove the Implant Positioners and provisionally tighten the midline nut using the 7/32" Torque Limiting Set Screwdriver. A Counter Torque may be placed on the CD HORIZON® X10 CROSSLINK® MULTI-SPAN Plate to minimize torque transfer to the construct during final tightening. The screwdriver shaft is introduced through the Counter Torque. The set screws are sheared off using the screwdriver. The midline nut then undergoes final tightening with the same screwdriver. The midline nut on the CD HORIZON® X10 CROSSLINK® MULTI-SPAN Plate is not a break-off set screw; the driver will "click" when the appropriate torque is obtained.

Figure 28

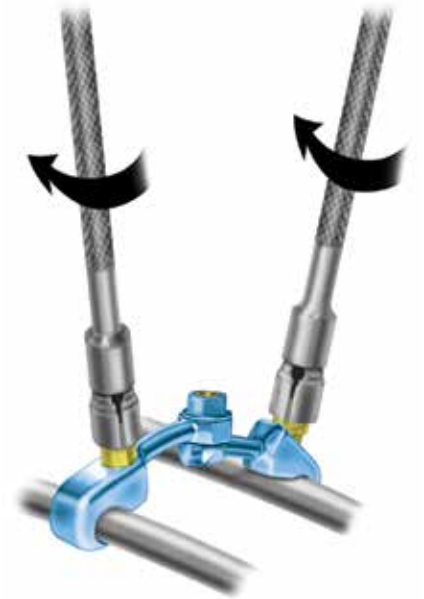


Figure 29

CD HORIZON® X10 CROSSLINK® Plate Placement *continued*

Forceps Plate Holder Method

With the use of the Forceps Plate Holder, the appropriate CD HORIZON® X10 CROSSLINK® MULTI-SPAN Plate is selected and gripped (**Figure 30**). The forceps have a notched tip to securely hold both crossbars (**Figure 30a**).

Ensure that both crossbars on the CD HORIZON® X10 CROSSLINK® Plate are gripped. The plate is then placed to capture the far rod (in relation to the surgeon) of the two rods to be stabilized. Using the 7/32" Torque Limiting Set Screwdriver, the far rod's set screw is provisionally tightened to anchor the device to this rod.

Remove the Forceps Plate Holder from both crossbars. Place the Forceps Plate Holder on the crossbar that is able to move (**Figure 31**). Anchor the second side of the plate to the rod and provisionally tighten the set screw. Remove the Forceps Plate Holder and provisionally tighten the midline nut.

A Counter Torque may be placed on the CD HORIZON® X10 CROSSLINK® MULTI-SPAN Plate to minimize torque transfer to the construct during final tightening. The screwdriver shaft is introduced through the Counter Torque. The set screws are sheared off using the 7/32" Torque Limiting Set Screwdriver. The midline nut then undergoes final tightening with the same screwdriver. The midline nut on the CD HORIZON® X10 CROSSLINK® MULTI-SPAN Plate is not a break-off set screw; the driver will "click" when the appropriate torque is obtained.

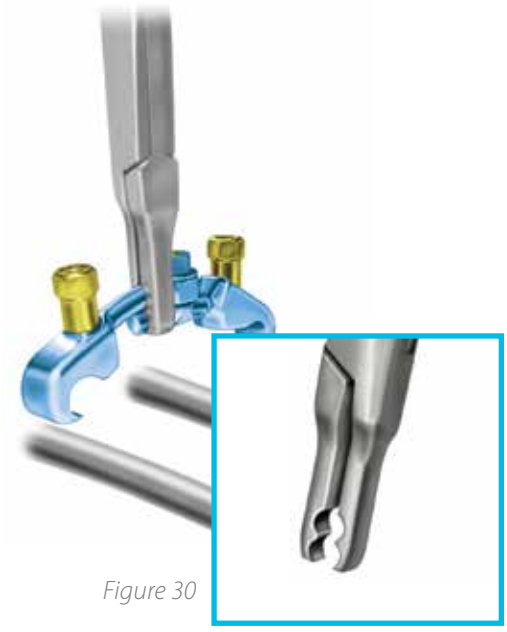


Figure 30

Figure 30a

Figure 31

Postoperative Care and Mobilization

Prior to closure do a final check to ensure that the set screws are symmetrically seated in the screw heads and sheared off, that the bone graft has not become dislodged during manipulation, and that a proper count of all sheared-off set screws is correct (**Figure 32**).

Appropriate postoperative monitoring following evaluation of the extent of the surgical procedure and the patient's overall medical status is essential. Deep vein anti-embolic treatment should be considered for all patients, along with active pulmonary toilet, fluid balance, nutritional status, and monitoring of neurologic function. Prophylactic antibiotics may be continued for a brief duration following surgery until the wound seals. Finally, postoperative bracing may be considered for longer fusions or situations where significant instability following instrumentation exists.

A structured, progressive physical therapy program is essential to mobilize the patient in order to diminish postoperative complications and to rehabilitate the patient sufficiently for discharge. During the inpatient rehabilitation period, patients should be carefully instructed in the appropriate methods of getting in and out of bed, stair climbing, and brace application, as well as how long to sit and various other activities of daily living. Patients that lag behind a normal recovery period proportional to the extent of their surgery should be expediently considered for transfer to a rehabilitation inpatient facility.

Finally, postoperative follow-up for a minimum of two years is crucial to assess the progression of fusion and, equally important, the patient's clinical improvement.

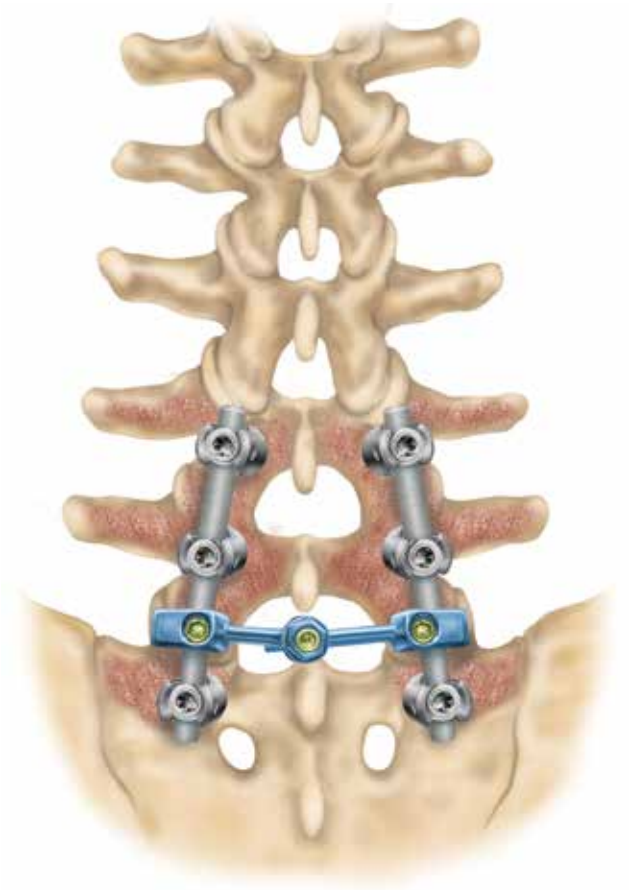


Figure 32

Implant Expantation

The CD HORIZON® ESSENCE™ set screws may be removed using the T27 Obturator and the Break-off Driver. The T27 Obturator is inserted into the working end of the Break-off Driver, so that the knurled portion of the T27 Obturator is flush with the driver. Insert the obturator tip through the Counter Torque, which should be seated on the screw and into the set screw, turning counterclockwise until the set screw has been removed. The pedicle screws may be removed using the Multi-Axial Screwdriver in connection with the Ratcheting Handle. First, attach the Ratcheting Handle to the modular end of the driver. Next, fully engage the hex end of the screwdriver into the screw head, then thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.

If removal of a CD HORIZON® X10 CROSSLINK® MULTI-SPAN Plate is necessary, place the 7/32" Torque Limiting Set Screwdriver over the midline nut and turn counterclockwise to loosen. Place the 3.0mm Hex Head Shaft Removal Driver into a standard Medtronic Quick Connect Handle. Place the tip of the 3.0mm internal hex screwdriver into the set screw and confirm that the 3.0mm tip is completely inserted and seated in the set screw so that the tip does not strip the hex. Turn the screwdriver counterclockwise to loosen the set screw from the rod.

Product Ordering Information

Implants

CFN	Description
Multi-Axial Screws	
45440005535	5.5mm × 35mm Multi-Axial Screw
45440005540	5.5mm × 40mm Multi-Axial Screw
45440005545	5.5mm × 45mm Multi-Axial Screw
45440006535	6.5mm × 35mm Multi-Axial Screw
45440006540	6.5mm × 40mm Multi-Axial Screw
45440006545	6.5mm × 45mm Multi-Axial Screw
45440006550	6.5mm × 50mm Multi-Axial Screw
45440007540	7.5mm × 40mm Multi-Axial Screw
45440007545	7.5mm × 45mm Multi-Axial Screw
45440007550	7.5mm × 50mm Multi-Axial Screw
45440004535	4.5mm × 35mm Multi-Axial Screw
45440004540	4.5mm × 40mm Multi-Axial Screw
45440004545	4.5mm × 45mm Multi-Axial Screw
45440005530	5.5mm × 30mm Multi-Axial Screw
45440005550	5.5mm × 50mm Multi-Axial Screw
45440006530	6.5mm × 30mm Multi-Axial Screw
45440006555	6.5mm × 55mm Multi-Axial Screw
45440007535	7.5mm × 35mm Multi-Axial Screw
Fixed Angle Screws	
45410005535	5.5mm × 35mm Fixed Angle Screw
45410005540	5.5mm × 40mm Fixed Angle Screw
45410005545	5.5mm × 45mm Fixed Angle Screw
45410005550	5.5mm × 50mm Fixed Angle Screw
45410006535	6.5mm × 35mm Fixed Angle Screw
45410006540	6.5mm × 40mm Fixed Angle Screw
45410006545	6.5mm × 50mm Fixed Angle Screw
45410006550	5.5mm × 35mm Fixed Angle Screw

Implants *(continued)*

CFN	Description
Rods	
869-012	5.5mm Commercially Pure Titanium Rod, 350mm
869-013	5.5mm Blue Commercially Pure Titanium Rod, 500mm
869-022	5.5mm Lined Commercially Pure Titanium Rod, 500mm

CFN	Description
Set Screws	
4540020	Set Screw

Important Product Information

IMPORTANT INFORMATION ON 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 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.

Important Product Information *continued*

- 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.

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

EC REP

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

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

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