Medtronic
SOFAMOR DANEK

CD HORIZON® LEGACY™ 5.5

Spinal System–Degenerative Surgical Technique

as described by:

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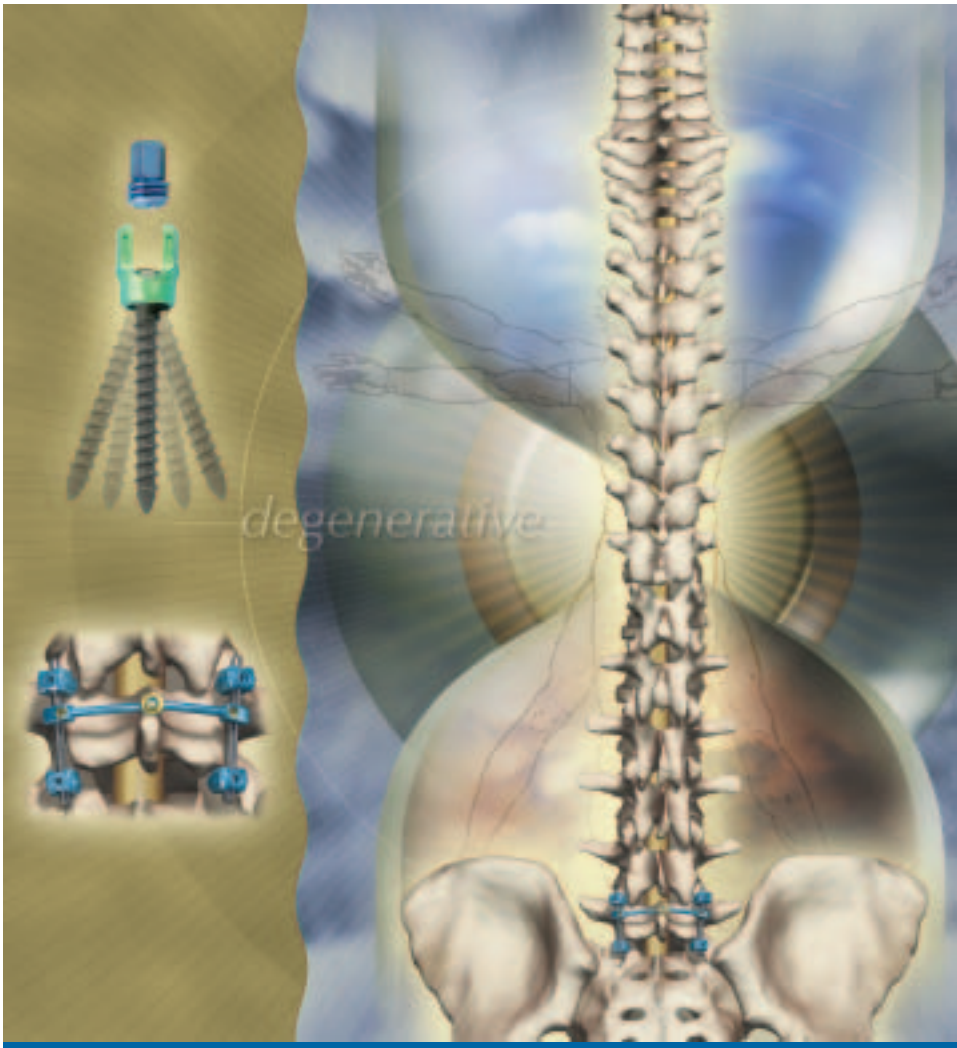

A Masterpiece In Medical Device Design

C4 TECHNOLOGY
REVERSE-ANGLE THREAD FORM

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Preface

Over the past 10 years there has been a continuous evolution in the surgical application of pedicle screw fixation. Meeting the needs of advancing surgical techniques has required systems that are adaptable, reliable, and user-friendly. The CD HORIZON® Multi Axial Screw Spinal System has become the world's most popular pedicle screw instrumentation by continuing to evolve and address these developmental goals. Building on this success, Medtronic Sofamor Danek introduces the next generation in the CD HORIZON® Spinal System lineage, the CD HORIZON® LEGACY™ 5.5 Spinal System.

The CD HORIZON LEGACY 5.5 Spinal System is a familiar top-loading multi axial screw system with an enhanced locking mechanism, a lower functional profile, and an ergonomically designed instrument set. The system has also been designed for treatment of degenerative disease, deformity, and trauma indications.

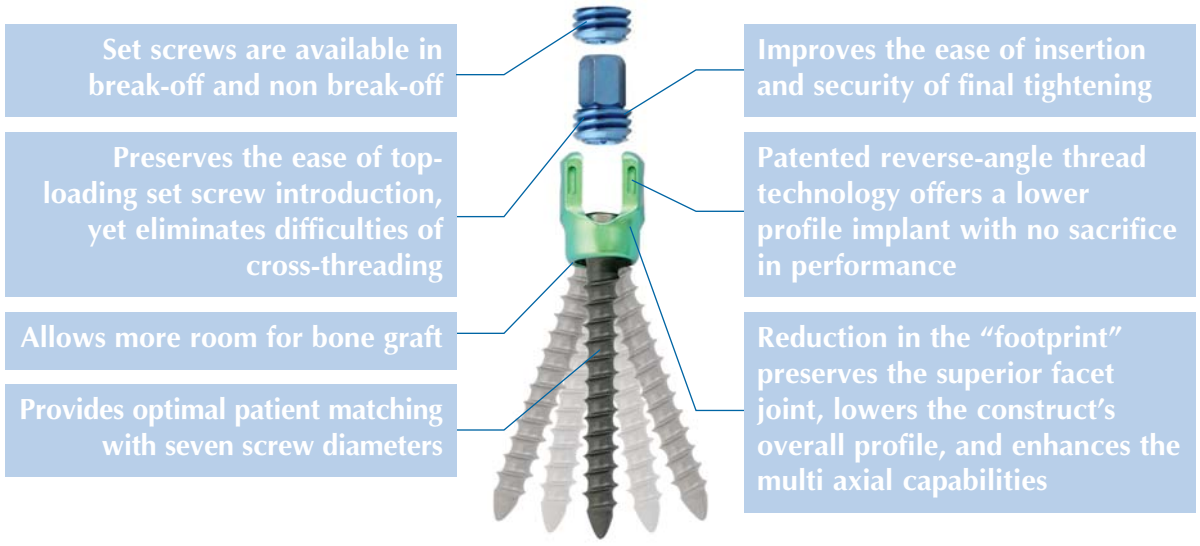
A primary enhancement of the CD HORIZON LEGACY 5.5 Spinal System is a unique reverse-angle thread locking mechanism. This locking mechanism preserves the ease of top-loading set screw introduction, while virtually eliminating the difficulties of cross-threading. This patented design, known as G4 Technology, also improves the ease and security of final tightening. An additional improvement is a reduction in the multi axial screw "footprint." This modification diminishes the functional profile of the screw and limits the problems of facet impingement. Beyond these advances in implant design, the instrument set has been significantly re-engineered and improved.

In addition to the substantial technical advances, an important design focus of the CD HORIZON LEGACY 5.5 Spinal System was to accommodate the specialized needs of the hospital and OR staff. Important factors include a broad range of surgical capabilities within a single system and the availability of modules for treatment of deformity and other specialty needs. Other alterations, such as color-coding by screw size, serve to limit the complexity of the system for the OR technician. Overall, the CD HORIZON LEGACY 5.5 Spinal System represents a significant advancement in the development and refinement of pedicle screw instrumentation.

Implants

Multi Axial Screws/Rods

G4 Technology is the fourth generation closure technology for CD HORIZON instrumentation. The set screw has been designed to thread easier and hold stronger. The reverse-angle thread locking mechanism reverses the force vectors a set screw normally exerts on the side walls of implants during final tightening.



Titanium screw heads are color-coded by screw diameter.

LEGACY 5.5mm
Multi Axial Screw

Color-Coding Reference
NOTE: Color-coding available in titanium only.

4.0mm 4.5mm 5.0mm 5.5mm 6.5mm 7.5mm 8.5mm

5.5mm Rod

CD HORIZON Precut Contoured Rod
NOTE: Available in titanium only.

Instruments

Pedicle Preparation

In-Line Round Awl
(7480104)

Dual Ended Feeler Probe
(7480100)

Sounding/Feeler Probe
(8572102)

Thoracic Ball Handle Probe
(7480112)

Lumbar Ball Handle Probe
(7480110)

Straight Lumbar Probe
(803-290)

Quick Connect Ratcheting Handle
(9339082)

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

Screw Insertion

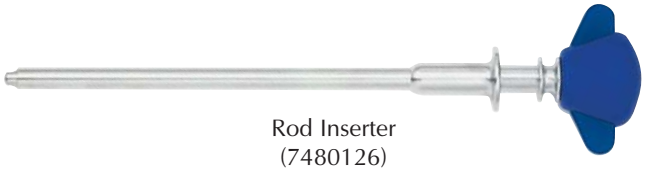
Multi Axial Screwdriver
(7480113)

Self-Retaining Screwdriver
(7480114)

Instruments

Rod Insertion

Rod Template
(808-575)



Rod Inserter
(7480126)

Rod Gripper
(7480175)

French Bender
(7480162)

Dual Ended Plug Starter
(7480122)

Provisional Driver
(7480131)

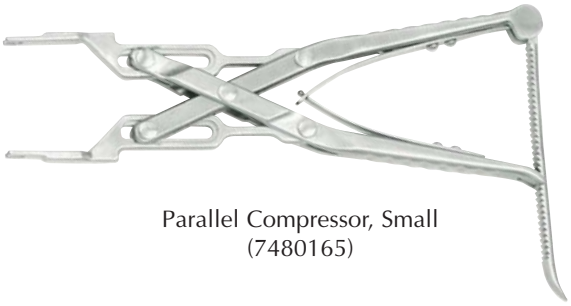
Rod Reduction

Beale Rod Reducer
(7480134)

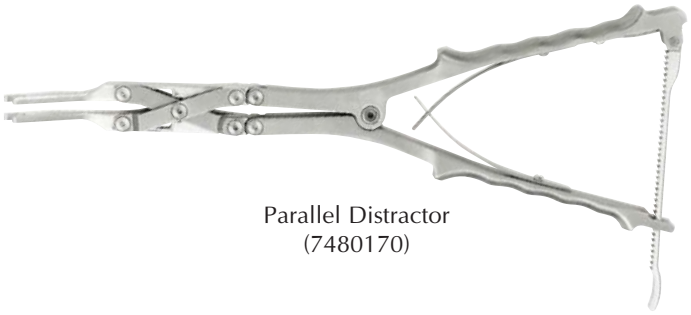
Forceps Rocker
(7480142)

Instruments

Compression and Distraction



Parallel Compressor, Small
(7480165)



Parallel Distractor
(7480170)

Final Tightening

Self-Retaining Break-Off Driver
(7480144)

Counter Torque
(7480150)

T27 Obturator
(7480154)

Additional Instruments

Non Break-Off Plug Starter
(7480156)

Torque-Limiting Driver
(7480146)

T27 - Quick Connect
(7480147)

Instruments

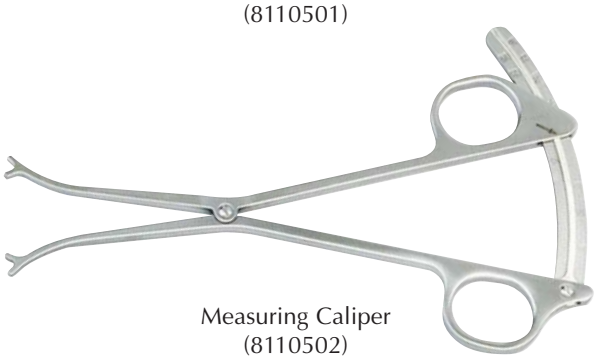
X10 CROSSLINK® Plate Implants and Instruments

X10 CROSSLINK Multi-Span™ Plate

X10 CROSSLINK Fixed Plate

Measuring Credit Card
(8110501)

Implant Positioners
(808-545) (optional)



Measuring Caliper
(8110502)

7/32" Torque-Limiting Set Screwdriver
(8110535)

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**).

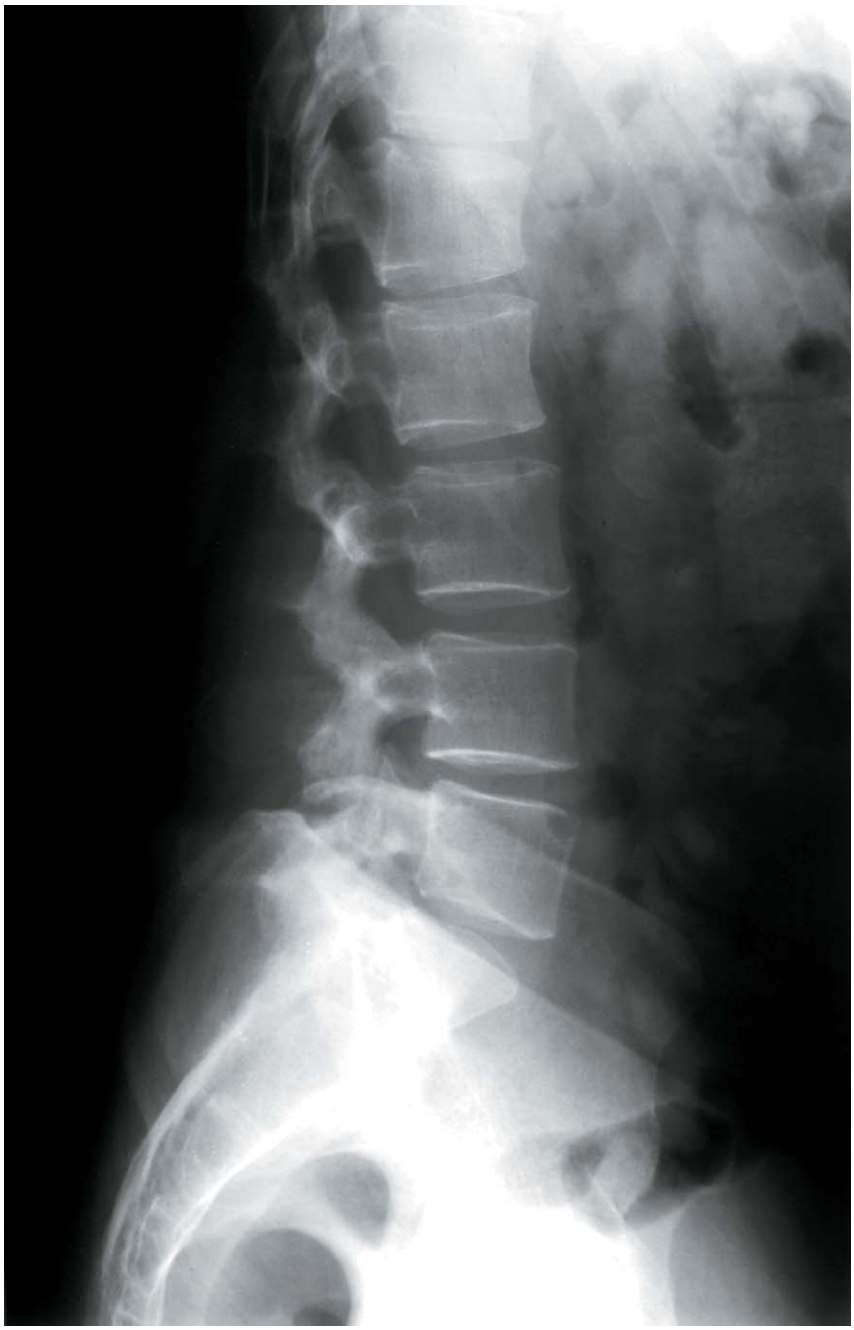


Figure 1

Pedicle Preparation (cont.)

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

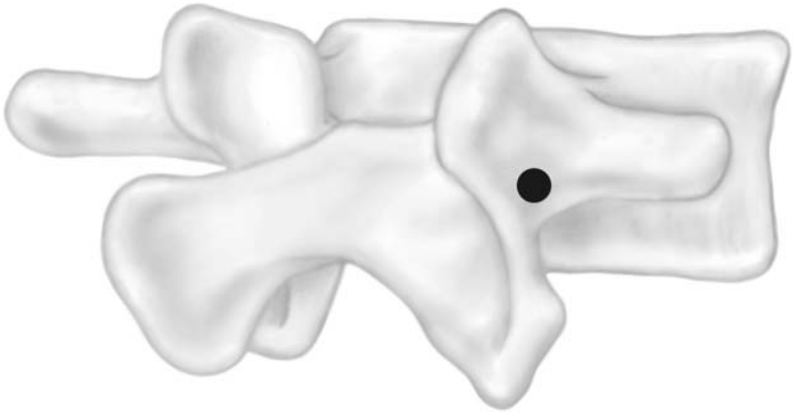


Figure 2a

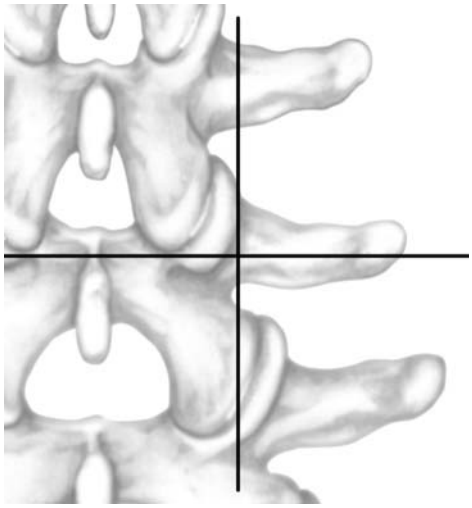


Figure 2b

Pedicle Preparation (cont.)

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

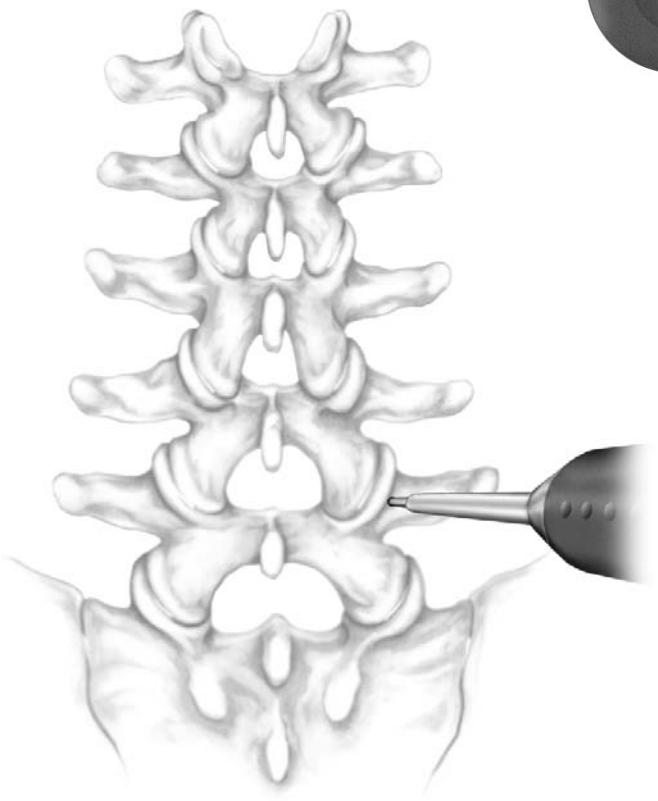


Figure 3

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

Figure 4

Pedicle Preparation (cont.)

The CD HORIZON LEGACY 5.5mm Multi Axial Screws have a self-tapping flute to obviate the tapping step. 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 taps ranging from 4.5mm to 7.5mm, which correspond to the pedicle screw diameters (3.75mm, 4.0mm, and 5.0mm 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**).

"For increased bone purchase, use the tap to prepare the cortical bone of the pedicle and allow the self-tapping bone screw to penetrate the cancellous bone of the vertebral body."

Figure 5

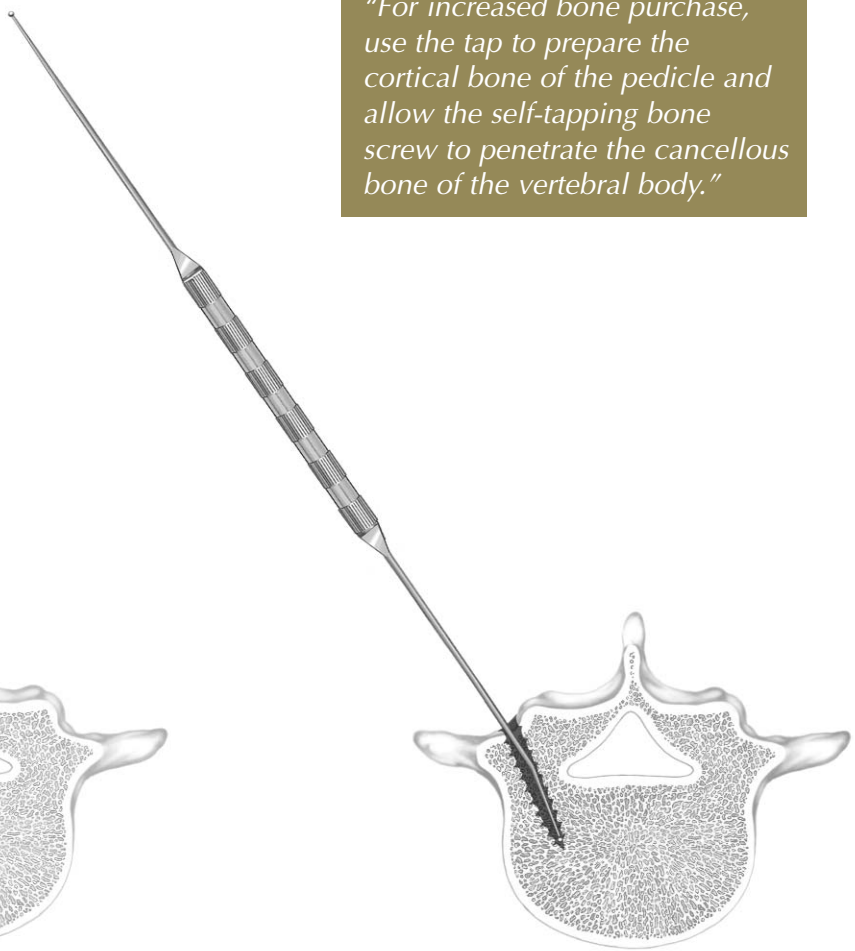


Figure 6

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 hex head and the threaded sleeve provide a stable insertion instrument for inserting the Multi Axial Screws bilaterally (**Figure 9**). Alternatively, the Self-Retaining Screwdriver may be used by fully inserting the hex end of the screwdriver into the screw head.

"The hex must be fully engaged into the bone screw, with the 'T' portion fully seated into the saddle of the screw."

Figure 7

Figure 8

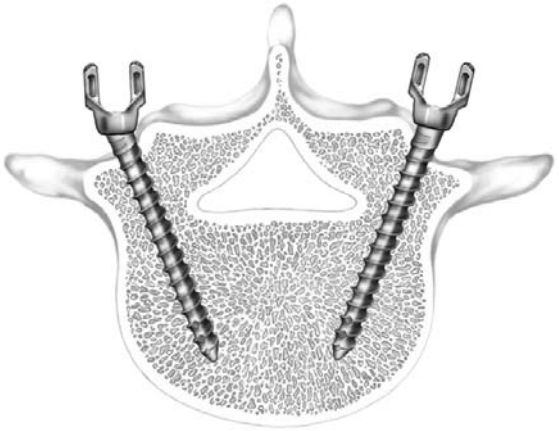


Figure 9

Multi Axial Screw Insertion (cont.)

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 endplate. 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 endplate to the anterior cortex), which provides the best fixation for the S1 pedicle screw. Once the screw is inserted, the instrument sleeve is unscrewed and disengaged from the screw.

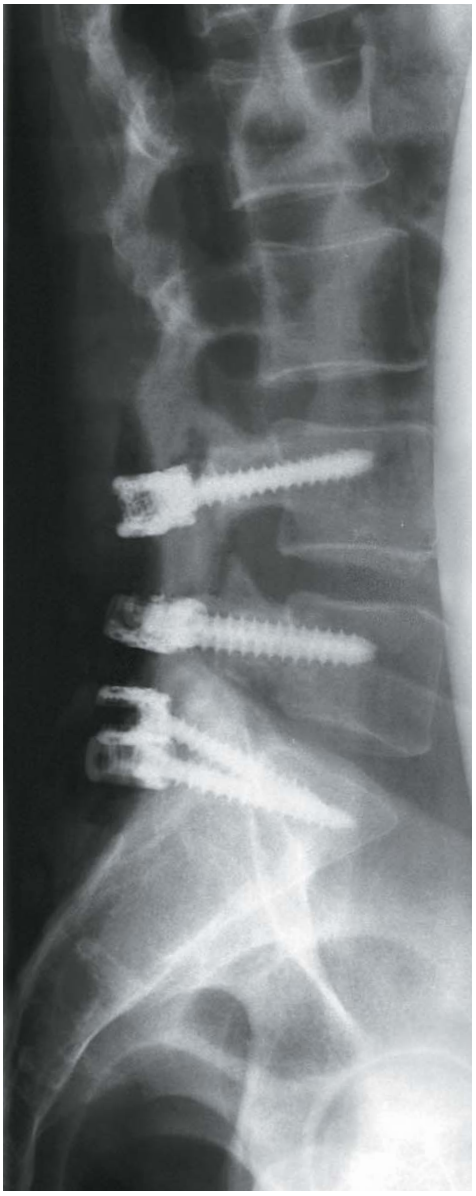


Figure 10a

"The reduced screw head footprint has four immediately noticeable benefits: enhanced multi axial capability, lower overall construct profile, the ability to preserve the superior facet, and better access for bone graft placement."

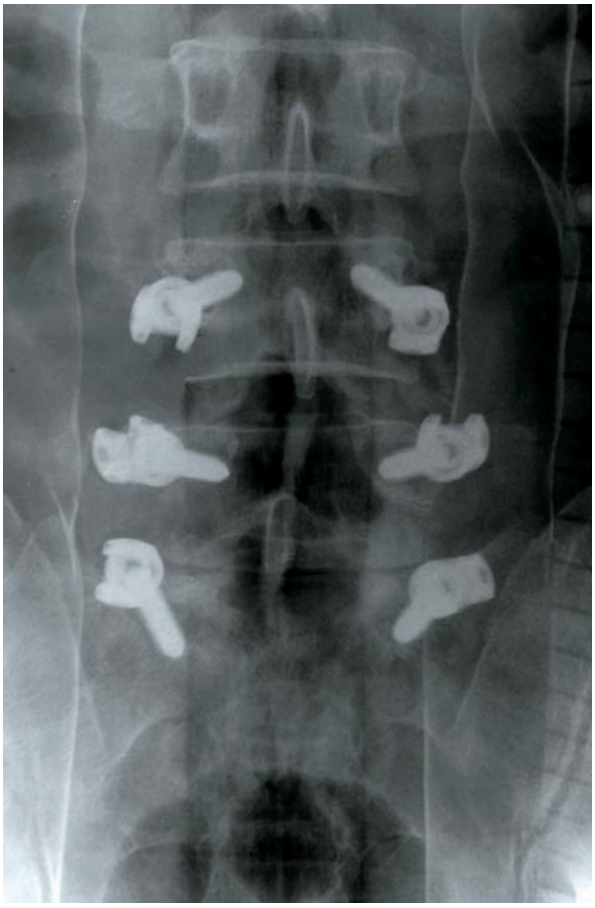


Figure 10b

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**).

"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."

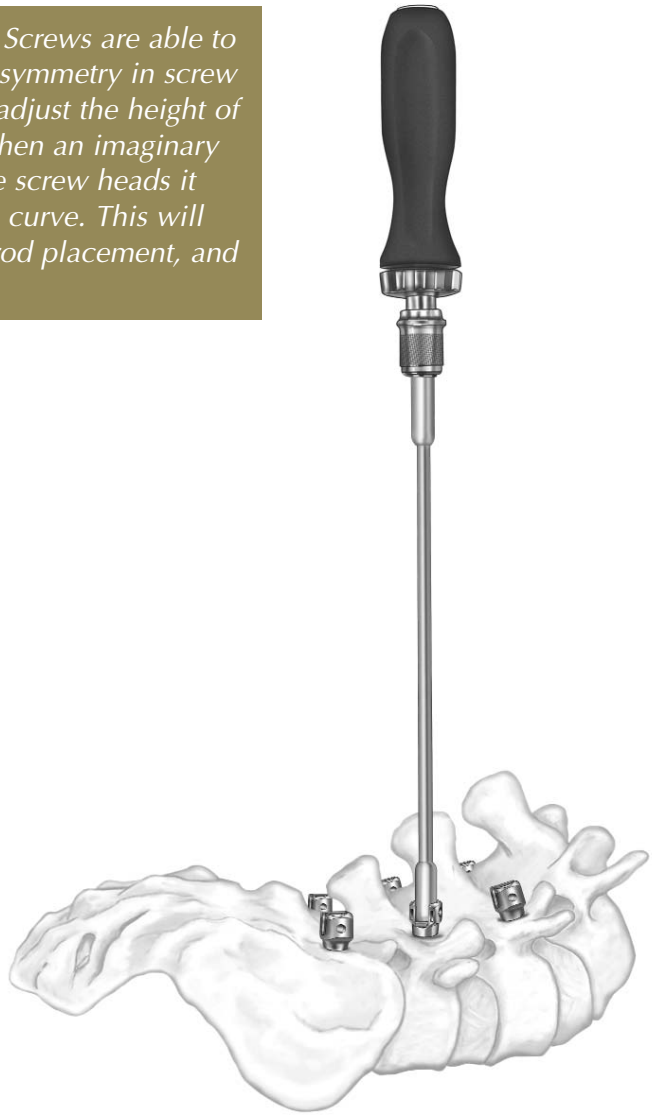


Figure 11

Rod Insertion (cont.)

Next, the rod is placed into the top-loading screws beginning from either the cephalad or caudad direction using either the Rod Inserter (**Figure 12**) or the Rod Gripper (**Figure 13**). With the rod lying in the bottom of the screw heads, the Break-Off Set Screws (hereafter referred to as "plugs") may be inserted into the implants using the plug starter (**Figure 14**).

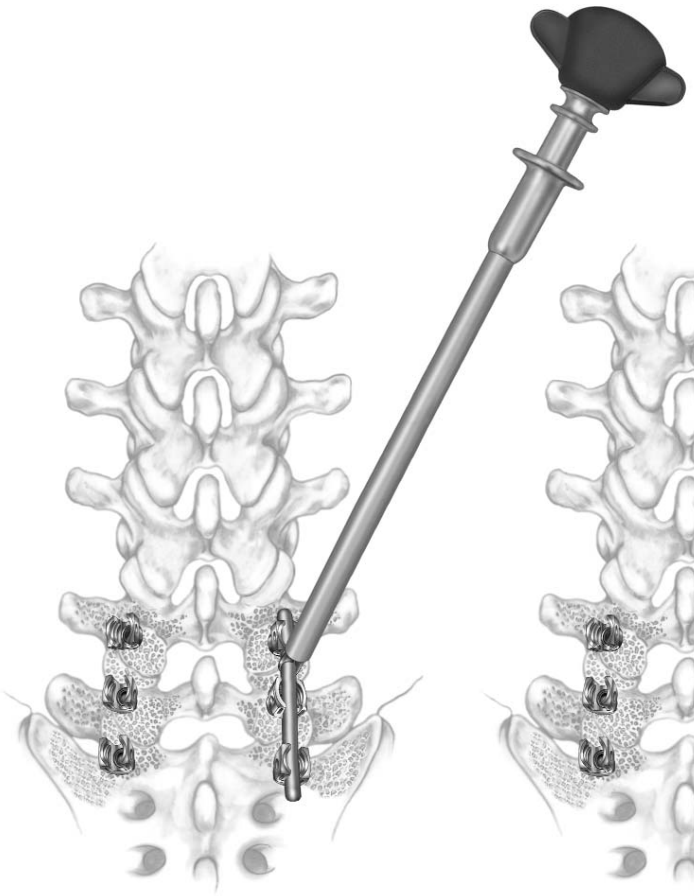


Figure 12

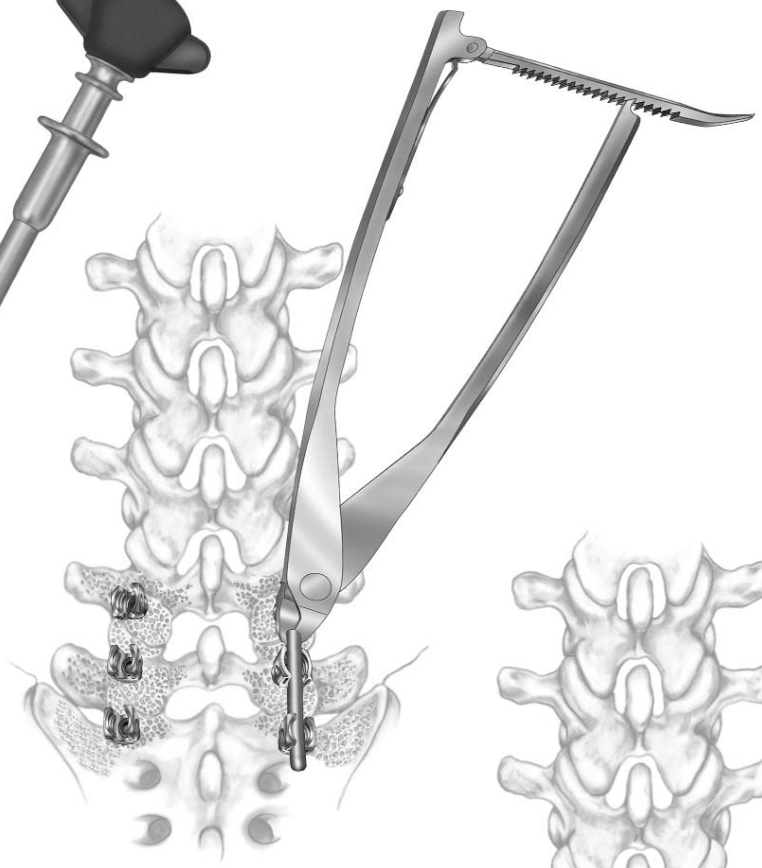


Figure 13

"Multiple plugs can be loaded into the plug starter for intraoperative efficiency."

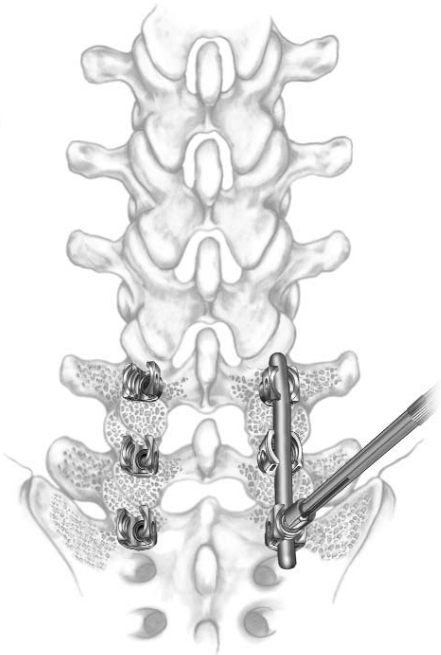


Figure 14

Rod Reduction Options

If the rod is not fully seated into the bottom of the screw head, the Beale Rod Reducer or the Forceps Rocker can be used to fully seat the rod and simplify the plug insertion process. *NOTE:* Care should be taken with any rod reduction maneuver. Improper instrument use may dislodge the implants or damage the bony anatomy.

The Beale Rod Reducer is the preferred method for reduction when the rod is lying even to 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 15**). The plug starter or Provisional Driver is then inserted through the rod reducer plug tube to insert the plug into the head of the pedicle screw (**Figure 16**).

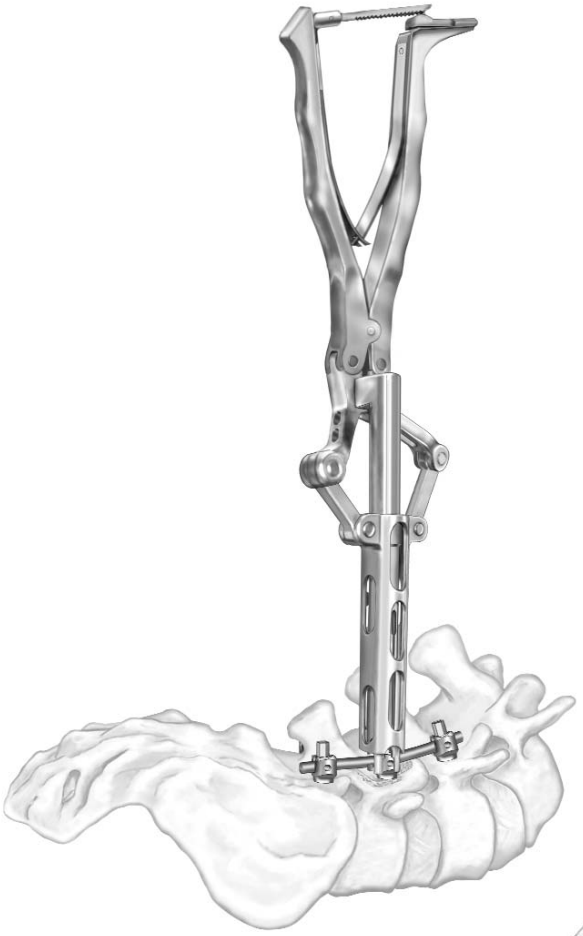


Figure 15

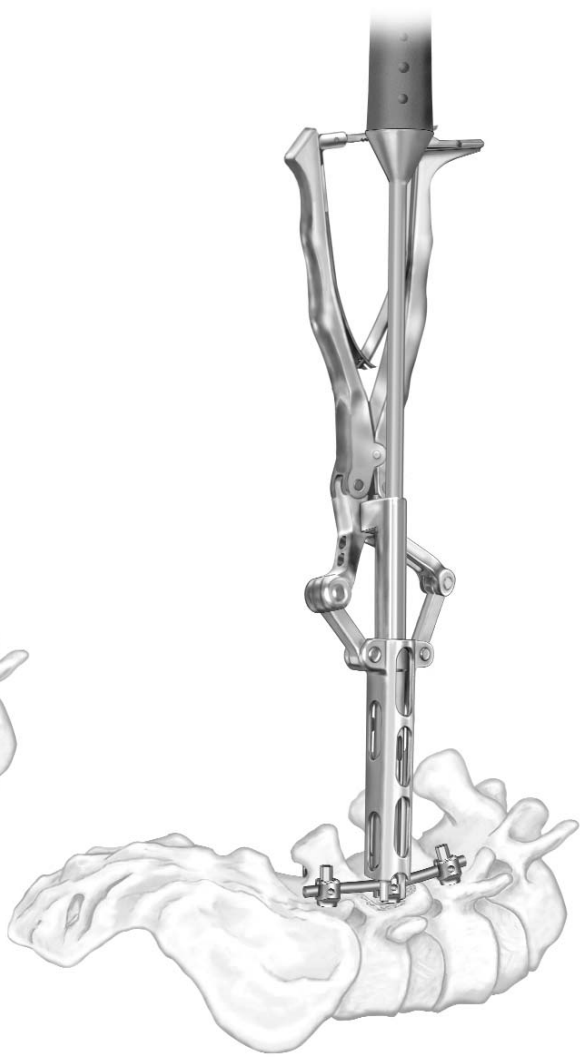


Figure 16

Rod Reduction Options (cont.)

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 17**). The rocker is then pushed backward toward the rod, levering the rod into the screw head. The plug starter or Provisional Driver is then used to start the plug (**Figure 18**).

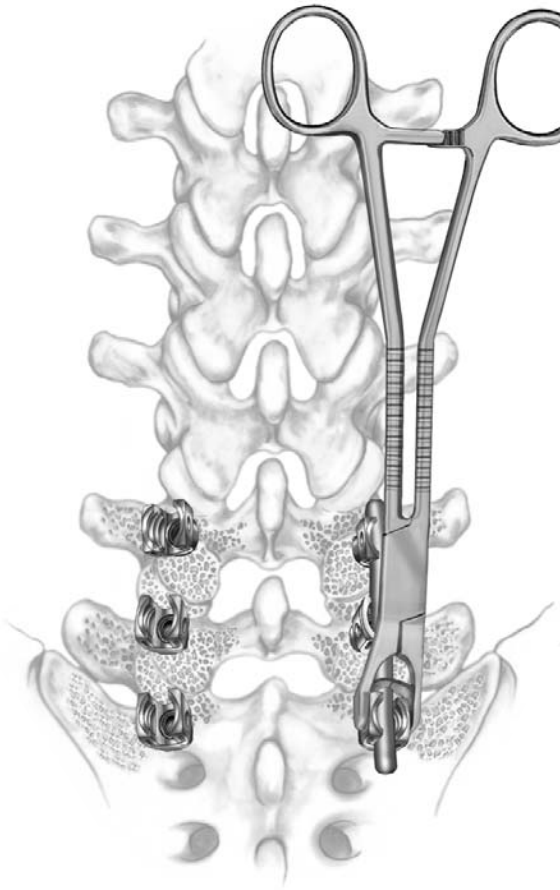


Figure 17

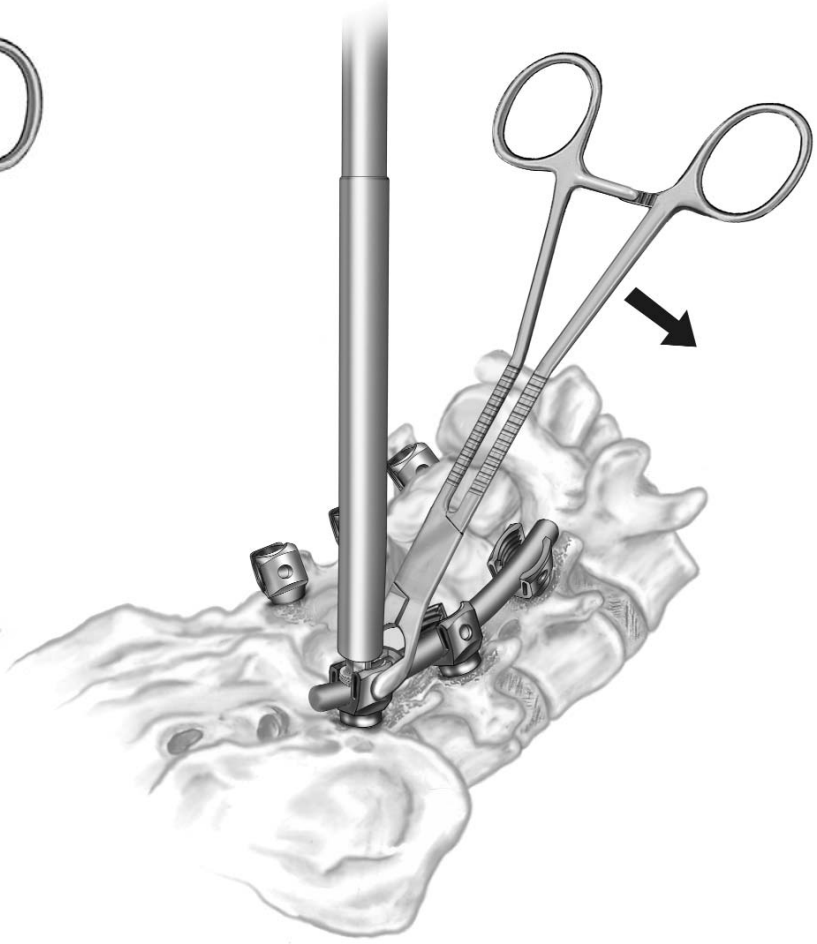


Figure 18

Compression and Distraction

If either compression or distraction is needed, it should be performed at this time. In either maneuver, the plug on one side of the motion segment should be provisionally tightened, with the plug 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 plug or the implant threads. However, if the plug has been cross-threaded, it must be replaced.

Care should be taken with all plugs to ensure that the feet of either the compressor or the distractor are placed securely against the implant body and not against the plug (**Figure 19**). Failure to do this may result in slippage of the implant or premature breaking of the plug. Once satisfactory compression or distraction has been achieved, final tightening may be performed.

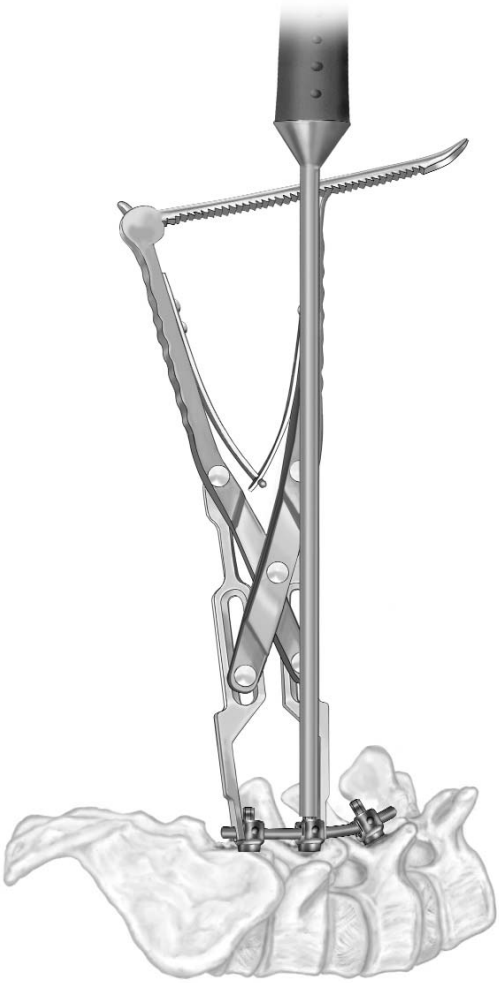


Figure 19

Final Tightening

When all implants are securely in place, final tightening and breakoff of the plug head is done. Insert the Self-Retaining 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 plug head (between 88–106 in-lbs). The handle of the Counter Torque device should be held firmly to prevent torquing of the construct while the plug is secured and sheared off (**Figure 20**).

"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 breakoff."

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

Figure 20

Final Tightening (cont.)

After the plug head has been sheared off, it will be retained within the cannulated shaft of the Self-Retaining Break-Off Driver. Each additional plug can then be sequentially secured and sheared off, while the sheared pieces are retained (**Figure 21**). At any time following set screw breakoff, the T27 Obturator may be inserted into the cannulated shaft of the Self-Retaining Break-Off Driver to release the broken-off sections of the plug's heads which have been retained in the driver (**Figure 22**).

Figure 21

Figure 22

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 due to poor visualization. The preservation of the facet capsules of the unfused adjacent levels should be facilitated due to the implant's reduced bone/screw interface (**Figure 23**).

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 instrumentation is complete and the graft material is placed, the construct should be checked radiographically (**Figures 24a and 24b**).

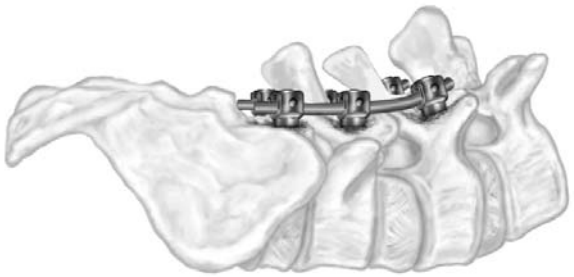


Figure 23

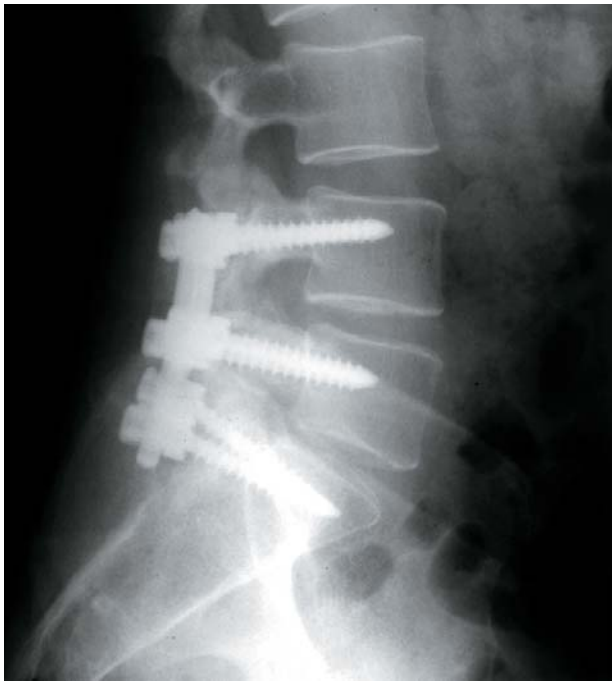


Figure 24a

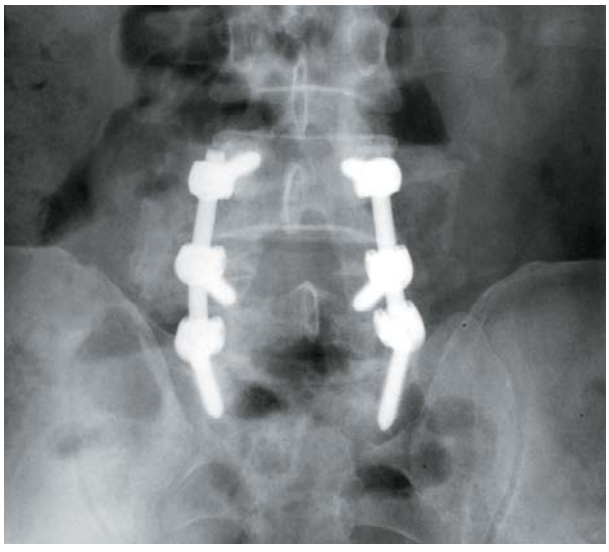


Figure 24b

X10 CROSSLINK® Plate Placement

X10 CROSSLINK Plates should be used to significantly increase the torsional stability of a construct. Longer constructs may necessitate placement of an X10 CROSSLINK Plate at each end to increase construct rigidity. Two measuring devices are available to determine the proper length X10 CROSSLINK Plate to use: the Measuring Credit Card (**Figure 25**) and the Measuring Caliper (**Figure 26**).

Prior to plate placement, ensure that the 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 25

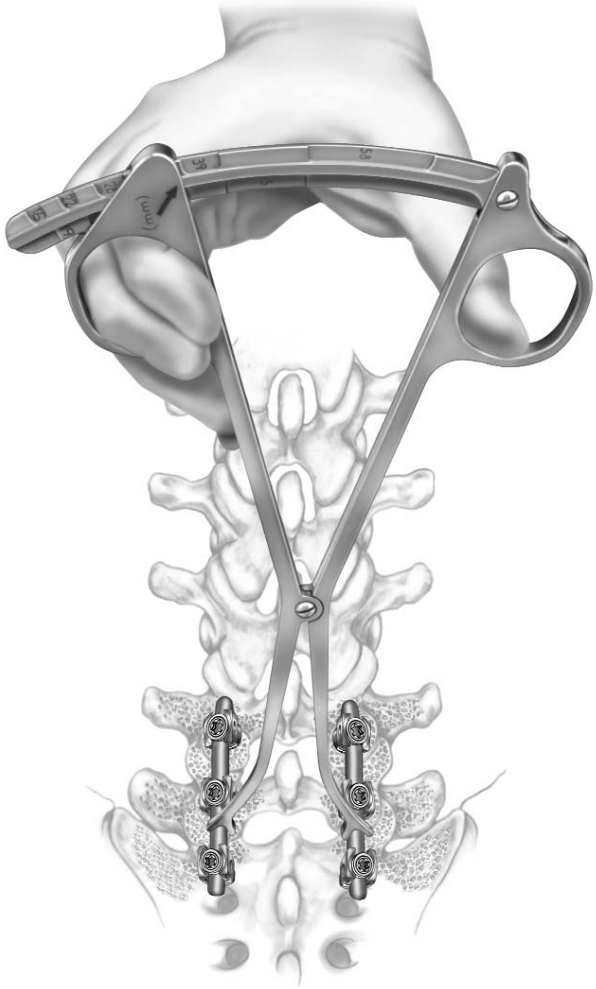


Figure 26

X10 CROSSLINK® Plate Placement (cont.)

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

In Line Plate Holder Method

The midline nut is provisionally tightened to gain control of the multi-span device 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 27**). 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 28**).

Figure 27

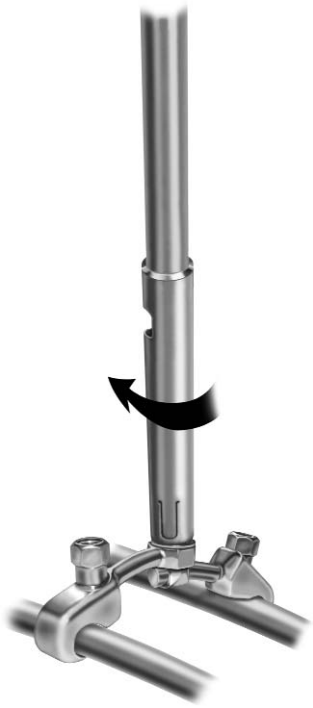


Figure 28

X10 CROSSLINK® Plate Placement (cont.)

Implant Positioner Method

With the use of the Implant Positioners, the appropriate X10 CROSSLINK Multi-Span Plate is selected and gripped (**Figure 29**). Ensure that both Implant Positioners fit securely onto both rod set screws.

The Implant Positioners can be used to sequentially articulate the X10 CROSSLINK Plate around the rod (**Figure 29**). 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 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 30**).

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 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 X10 CROSSLINK Multi-Span Plate is **NOT** a Break-Off Set Screw; the driver will “click” when the appropriate torque is obtained.

Figure 29

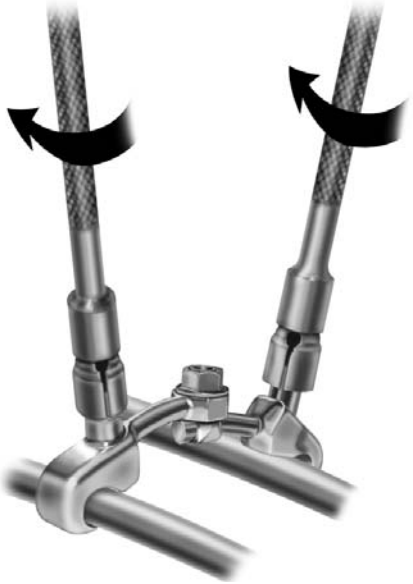


Figure 30

X10 CROSSLINK® Plate Placement (cont.)

Forceps Plate Holder Method

With the use of the Forceps Plate Holder, the appropriate X10 CROSSLINK Multi-Span Plate is selected and gripped (**Figure 31**). The forceps have a notched tip to securely hold both crossbars (**Figure 31a**).

Ensure that both crossbars on the 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 32**). 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 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 X10 CROSSLINK Multi-Span Plate is **NOT** a Break-Off Set Screw, the driver will "click" when the appropriate torque is obtained.

Figure 31

Figure 31a

Figure 32

Postoperative Care and Mobilization

Prior to closure do a final check to ensure that the plugs 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 plug heads is correct (**Figure 33**).

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.

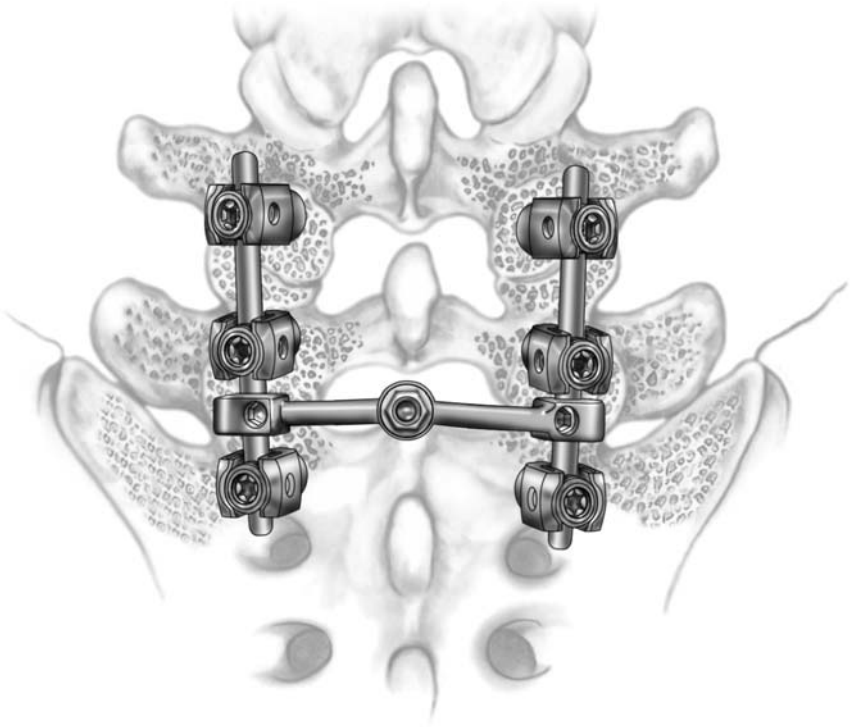


Figure 33

Implant Explantation

The CD HORIZON LEGACY 5.5 Set Screws (plugs) may be removed using the T27 Obturator and the Self-Retaining Break-Off Driver. The T27 Obturator is inserted into the working end of the Self-Retaining 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 plug, turning counter-clockwise until the plug has been removed. The pedicle screws may be removed using either the Multi Axial Screwdriver or the Self-Retaining 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, if utilizing the Multi Axial Screwdriver, thread the instrument sleeve into the screw head. Turn counter-clockwise until the pedicle screws have been removed.

If removal of an X10 CROSSLINK Multi-Span™ Plate is necessary, place the 7/32" Torque-Limiting Set Screwdriver over the midline nut and turn counter-clockwise to loosen. Place the 3.0mm Hex Head Shaft Removal Driver into a standard Medtronic Sofamor Danek 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 counter-clockwise to loosen the set screw from the rod.

Product Ordering Information

RODS		
Catalog Number		Description
Titanium	Stainless Steel	
8690030	N/A	5.5mm x 30mm Prebent Rod, Ti CP
8690040	N/A	5.5mm x 40mm Prebent Rod, Ti CP
8690050	N/A	5.5mm x 50mm Prebent Rod, Ti CP
8690060	N/A	5.5mm x 60mm Prebent Rod, Ti CP
8690070	N/A	5.5mm x 70mm Prebent Rod, Ti CP
8690080	N/A	5.5mm x 80mm Prebent Rod, Ti CP
8690090	N/A	5.5mm x 90mm Prebent Rod, Ti CP
8690100	N/A	5.5mm x 100mm Prebent Rod, Ti CP
8690110	N/A	5.5mm x 110mm Prebent Rod, Ti CP*
8690120	N/A	5.5mm x 120mm Prebent Rod, Ti CP*
869-013	N/A	5.5mm x 50cm Hex End CP Grade IV Rod, Titanium
869-022	N/A	5.5mm x 50cm Hex End Lined CP Grade IV Rod, Titanium*
N/A	868-021	5.5mm x 50cm Lined Hex End Rod, Stainless Steel
		*Available upon request
SET SCREWS		
7540000	7560000	Break-Off Set Screw
7540100	7560100	Non Break-Off Set Screw*
		*Available upon request
MULTI AXIAL SCREWS		
7545525	7565525	5.5mm x 25mm
7545530	7565530	5.5mm x 30mm
7545535	7565535	5.5mm x 35mm
7545540	7565540	5.5mm x 40mm
7545545	7565545	5.5mm x 45mm
7545550	7565550	5.5mm x 50mm
7545555	7565555	5.5mm x 55mm
7546530	7566530	6.5mm x 30mm
7546535	7566535	6.5mm x 35mm
7546540	7566540	6.5mm x 40mm
7546545	7566545	6.5mm x 45mm
7546550	7566550	6.5mm x 50mm
7546555	7566555	6.5mm x 55mm
7547530	7567530	7.5mm x 30mm
7547535	7567535	7.5mm x 35mm
7547540	7567540	7.5mm x 40mm
7547545	7567545	7.5mm x 45mm
7547550	7567550	7.5mm x 50mm
7547555	7567555	7.5mm x 55mm
7547560	7567560	7.5mm x 60mm

Product Ordering Information

MULTI AXIAL SCREWS (Available Upon Request)		
Catalog Number		Description
Titanium	Stainless Steel	
7544020	7564020	4.0mm x 20mm
7544025	7564025	4.0mm x 25mm
7544030	7564030	4.0mm x 30mm
7544035	7564035	4.0mm x 35mm
7544040	7564040	4.0mm x 40mm
7544045	7564045	4.0mm x 45mm
7544520	7564520	4.5mm x 20mm
7544525	7564525	4.5mm x 25mm
7544530	7564530	4.5mm x 30mm
7544535	7564535	4.5mm x 35mm
7544540	7564540	4.5mm x 40mm
7544545	7564545	4.5mm x 45mm
7545025	7565025	5.0mm x 25mm
7545030	7565030	5.0mm x 30mm
7545035	7565035	5.0mm x 35mm
7545040	7565040	5.0mm x 40mm
7545045	7565045	5.0mm x 45mm
7545050	7565050	5.0mm x 50mm
7546520	7566520	6.5mm x 20mm
7546525	7566525	6.5mm x 25mm
7546560	7566560	6.5mm x 60mm
7547525	7567525	7.5mm x 25mm
7547565	7567565	7.5mm x 65mm
7548525	7568525	8.5mm x 25mm
7548530	7568530	8.5mm x 30mm
7548535	7568535	8.5mm x 35mm
7548540	7568540	8.5mm x 40mm
7548545	7568545	8.5mm x 45mm
7548550	7568550	8.5mm x 50mm
7548555	7568555	8.5mm x 55mm
7548560	7568560	8.5mm x 60mm
7548565	7568565	8.5mm x 65mm

Product Ordering Information

INSTRUMENTS	
Catalog Number	**Description**
7480100	Dual Ended Feeler Probe
7480104	In-line Round Awl
7480110	Lumbar Ball Handle Probe
7480112	Thoracic Ball Handle Probe
7480113	Multi Axial Screwdriver, Quick Connect (Fluoronav Compatible)
7480114	Self-Retaining Screwdriver, Quick Connect
7480122	Dual Ended Plug Starter
7480126	Rod Inserter
7480131	Provisional Driver, Short
7480134	Beale Rod Reducer, Short
7480142	Forceps Rocker
7480144	Self-Retaining Break-Off Driver, 6.35mm Hex
7480150	Counter Torque
7480154	T27 Obturator
7480162	French Bender
7480165	Parallel Compressor, Small
7480170	Parallel Distractor
7480175	Rod Gripper
8572102	Sounding/Feeler Probe
9339082	Quick Connect Ratcheting Handle
803-290	Straight Lumbar Probe
808-575	Rod Template
8684500	4.5mm Solid Tap
836-015	5.5mm Solid Tap
836-016	6.5mm Solid Tap
836-018	7.5mm Solid Tap

ADDITIONAL INSTRUMENTS	
Catalog Number	**Description**
7480146	Torque-Limiting Driver
7480147	T27 - Quick Connect
7480156	Non Break-Off Plug Starter

Product Ordering Information

CASES AND TRAYS		
Catalog Number		Description
Titanium	Stainless Steel	
7059313	7058313	Degenerative Multi Axial Screws, Case #1, Implants
7050010L	7050010L	Outer Case Lid
7059325	7058325	Degenerative Multi Axial Screw Implant Tray, (1 of 2)
7059326	7058326	Degenerative Multi Axial Screw Implant Tray, (2 of 2)
7059325L	7058325L	Degenerative Multi Axial Screw Implant Tray Lid
7050233	7050233	Set Screw Module
7059233L	7058233L	Set Screw Module Lid
7050031	7050031	Screw Gauge
7050331	7050331	Degenerative Multi Axial Screw Instrument Tray #1
7050314	7050314	Degenerative Multi Axial Screw, Case #2, Instruments
7050010L	7050010L	Outer Case Lid
7050336	7050336	Degenerative Multi Axial Screw Instrument Tray #2
7050333	7050333	Degenerative Multi Axial Screw Instrument Tray #3

X10 CROSSLINK® Plate Product Ordering Information

Size/Material				
5.5mm Titanium	5.5mm Titanium	5.5mm Stainless Steel	Description	Quantity
Set Type/Description				
Degenerative	Deformity	Deformity		
Loaner Set Number				
410	412	414		
Catalog Number			Cases/Trays	
8111111	8111111	8111111	Outer Base	1
8111112	8111112	8111112	Outer Base Lid	1
8111113	8111113	8111113	Instrument Tray	1
8115501	8115501	8105501	Implant Module	1
8111114	8111114	8111114	Module Upper Lid with Logo	1
8111115	8111115	8111115	Module Lower Lid	1
			Implants	
N/A	8115516	8105516	16mm X10 CROSSLINK Fixed Plate	1
N/A	8115519	8105519	19mm X10 CROSSLINK Fixed Plate	1
N/A	8115522	8105522	22mm X10 CROSSLINK Fixed Plate	1
N/A	8115525	8105525	25mm X10 CROSSLINK Fixed Plate	1
N/A	8115527	8105527	28mm X10 CROSSLINK Fixed Plate (optional)	0
N/A	8115531	8105531	31mm X10 CROSSLINK Fixed Plate (optional)	0
8115528	8115528	8105528	28-30mm X10 CROSSLINK Multi-Span Plate	1
8115530	8115530	8105530	30-34mm X10 CROSSLINK Multi-Span Plate	1
8115534	8115534	8105534	34-36mm X10 CROSSLINK Multi-Span Plate	1
8115536	8115536	8105536	36-39mm X10 CROSSLINK Multi-Span Plate	1
8115539	8115539	8105539	39-45mm X10 CROSSLINK Multi-Span Plate	1
8115545	8115545	8105545	45-57mm X10 CROSSLINK Multi-Span Plate	1
8115558	8115558	8105558	58-81mm X10 CROSSLINK Multi-Span Plate	1
8110855	8110855	8100855	X10 CROSSLINK Plate Break-Off Set Screw	3
			Instruments	
8110501	8110501	8110501	Measuring Credit Card	1
8110502	8110502	8110502	Measuring Caliper	1
8110510	8110510	8110510	Forceps Plate Holder (optional)	0
8110511	8110511	8110511	45° In Line Plate Holder	1
808-545	808-545	808-545	Implant Positioners (optional)	0
8110525	8110525	8110525	Plate Bender	2
8110530	8110530	8110530	3.0mm Hex Head Shaft, Removal Driver	1
8110535	8110535	8110535	7/32" Torque-Limiting Set Screwdriver	1
8110540	8110540	8110540	Counter Torque	1

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 SOFAMOR DANEK spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other MEDTRONIC SOFAMOR DANEK spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washers, GDLH® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK PLUS™ bolts. Please note that certain components are specifically designed to connect to ø 4.5mm, ø 5.5mm, or ø 6.35mm rods, while other components can connect to both ø 5.5mm rods and ø 6.35mm rods. 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, 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 described by such standards as ASTM F138 or ISO 5832-1 or ISO 5832-9. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2. MEDTRONIC SOFAMOR DANEK expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MEDTRONIC SOFAMOR DANEK Catalog for further information about warranties and limitations of liability. **Never use stainless steel and titanium implant components 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 implants only. **Do not use with stainless steel.**

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 SOFAMOR DANEK document. As with all orthopaedic and neurosurgical implants, none of the CD HORIZON® Spinal System components should ever be reused under any circumstances.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS:

The CD HORIZON® Spinal System is intended for posterior, non-cervical fixation 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.

When used in a percutaneous, non-cervical, posterior approach with the CD HORIZON® SEXTANT™ instrumentation, the CD HORIZON® cannulated screws are intended 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; pseudoarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, CD HORIZON® components such as ECLIPSE® components are intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

The CD HORIZON® SPINOUS PROCESS Plate is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: 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); 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:

1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. 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.
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis. Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
10. Suspected or documented metal allergy or intolerance.
11. Any case not needing a bone graft and fusion.
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
13. Any case that requires the mixing of metals from two different components or systems.
14. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
15. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
16. Any patient unwilling to follow postoperative instructions.
17. Any case not described in the indications.

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:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. 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.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. 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.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. 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.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stresses shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. 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.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING AND PRECAUTIONS:

WARNING: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown.

PRECAUTION: 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.

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.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

Implant Selection:

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Device Fixation:

In cases where a percutaneous posterior approach is used refer to the CD HORIZON® SEXTANT™ surgical technique.

Important Information on the CD HORIZON® Spinal System

MEDTRONIC SOFAMOR DANEK CD HORIZON® Spinal System instrumentation contains 4.5 mm, 5.5mm and/or 6.35mm rods and implants, which are intended to be used with device specific instruments.

For self-breaking plugs, always hold the assembly with the Counter Torque device. Tighten and break-off the head of the plug to leave the assembly at optimum fixation security. After the upper part of the self-breaking plug has been sheared off, further re-tightening is not necessary and not recommended. The head part should not remain in the patient. **AFTER THE UPPER PART OF THE SELF-BREAKING PLUG HAS BEEN SHEARED OFF, RE-ADJUSTMENT IS NOT POSSIBLE UNLESS THE PLUG IS REMOVED AND REPLACED WITH A NEW ONE.**

When using DTT Transverse Links, the M6 plug should be tightened to between 8 and 9 Nm (70 to 80 inch-lbs).

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The CD HORIZON® Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer. Different metal types should never be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap.
   Caution: Be careful that the Guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the Guide-wire does not advance during tapping or screw insertion. Remove the Guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures. Do not overtap or use a screw that is either too long or too large. Overtapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.
6. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
7. To assure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
8. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
9. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed go back and firmly tighten all of the screws and nuts. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE:

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
6. The CD HORIZON® Spinal System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the CD HORIZON® Spinal System components should never be reused under any circumstances.

PACKAGING:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC SOFAMOR DANEK.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic Sofamor Danek. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION:

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes
Steam	Gravity	250° F (121° C)	30 Minutes
Steam*	Gravity*	273° F (134° C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g., temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted CD HORIZON® Spinal System component(s) ever "malfunctions". (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC SOFAMOR DANEK product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

FURTHER INFORMATION:

In case of complaint, or for supplementary information, or further directions for use of this system, please see the address listed below.

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Notes

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