

CD HORIZON LONGITUDE™

Multi-Level Percutaneous Fixation System



As described by:

Mark Dekutoski, MD
Associate Professor, Department of
Orthopedics
Mayo Clinic/Mayo Foundation
Rochester, MN

Neel Anand, MD
Director, Orthopedic Spine Surgery
Director, Minimally Invasive Spine
Surgery
Director, Spine Trauma
Institute for Spinal Disorders
Cedars-Sinai Medical Center
Los Angeles, CA

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Dear Colleagues,

We are pleased to introduce the CD HORIZON LONGITUDE™ Multi-Level Percutaneous Fixation System, designed to allow surgeons to place percutaneous screws and rods over multiple levels without the need for significant exposure.

Key elements of the instrument set are a steerable rod inserter and reduction screw extenders. These critical elements allow for tactile, freehand rod passage through the large windows at the base of the screw extenders. Once through the windows, reduction of the rod into the screw occurs through gradual screw extender reduction.

Sincerely,

Mark Dekutoski, MD
Neel Anand, MD

Instrument Set



Dilator (8675422)



5.3mm Dilator (9560420)



9.4mm Dilator (9560421)



*Cannulated Taps
4.0mm (8674000)
4.5mm (8670045)
5.5mm (8670055)
6.5mm (8670065)*



*Tapered Tap, Self-Drilling
4.5mm to 5.5mm (8670085)
5.5mm to 6.5mm (8670087)*



Quick-Connect Ratcheting Handle (9339082)



Quick-Connect Ratcheting T-Handle (7579000)



Ratchet Egg Handle (9098120)



Counter Torque (7570801)



Removable Break-off Handle (7570090)

Instrument Set (Continued)



Suction Trepine (7570802)



Reduction Extender (7570901)



Reduction Inner Sleeve (7570905)



Ball End Driver (7570922)



Non-Retaining Fixed Angle Screwdriver (7570907)



Self-Retaining Set Screwdriver (7650091)



Retaining Multi-Axial Screwdriver (7570923)



T27 Removal Tool (7570988)



Non-Retaining Multi-Axial Screwdriver (7570909)



Tall Reduction Nut Driver (7576309)



Compression/Distractor Rack (7570930)



Compression/Distractor Actuator (7570932)

Instrument Set (Continued)



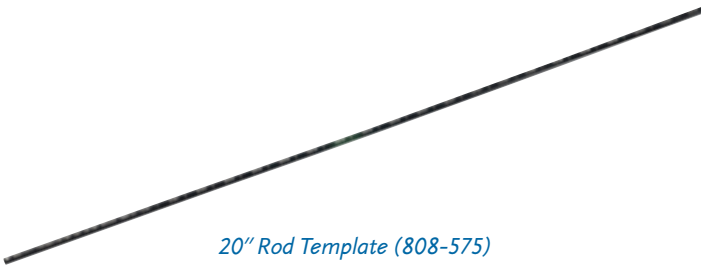
Rod Inserter (7570900)



Rod Entry Point Estimator (7570800)



French Bender (7480162)



20" Rod Template (808-575)



Rod Confirmation Tool (7570011)

Preoperative Planning

Preoperative planning can be useful in determining the proper starting point and screw trajectory. AP/Lateral views demonstrate approximate screw positioning at multiple levels of the thoracolumbar spine (Figures 1 and 2). In addition to the steps detailed in the following pages, a graft must be used when implanting the construct. Graft placement depends upon the medical judgment of the surgeon. For illustrative purposes, graft placement is shown at the end of this procedure (page 44).

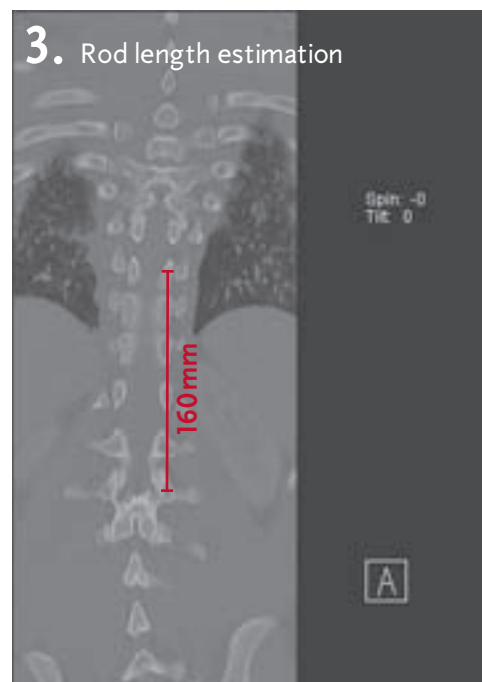
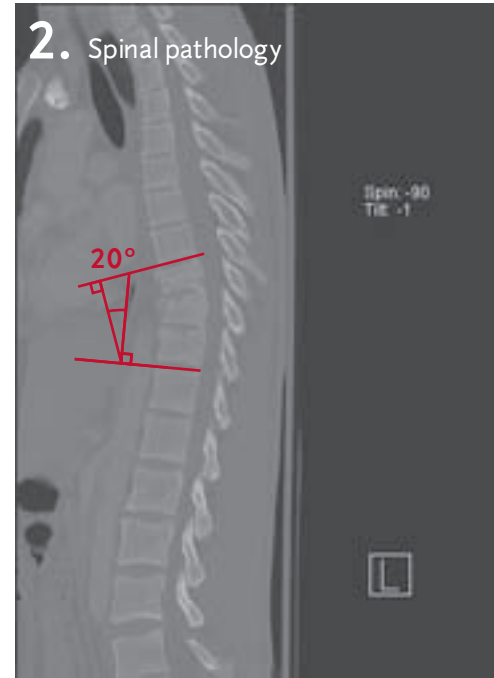
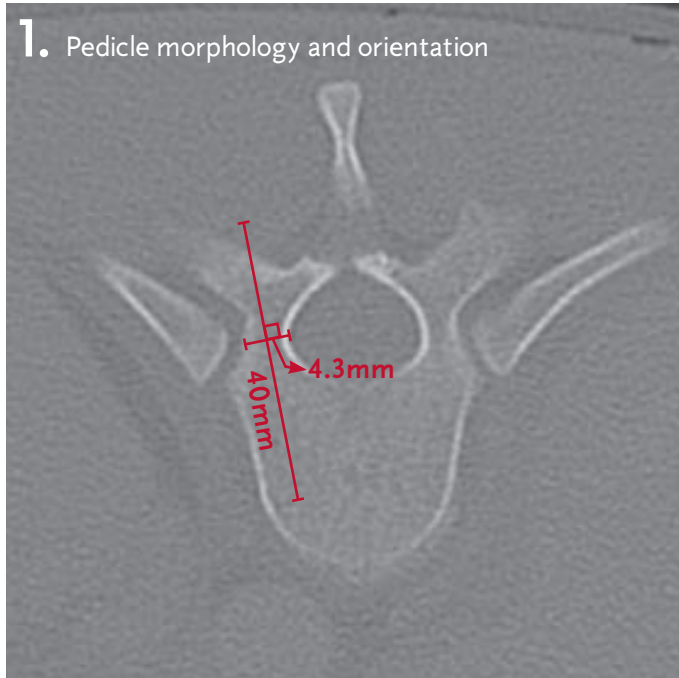


Figure 1



Figure 2

CT imaging can also be useful in the analysis of:



Accessing the Pedicle

STEP 1 | PATIENT POSITIONING

The patient should be positioned prone, lying flat on the table. Either a radiolucent frame or chest rolls may be used, but a knee-to-chest position should be avoided. Verify that adequate fluoroscopic images of the pedicles can be obtained in both the AP and lateral views before proceeding.

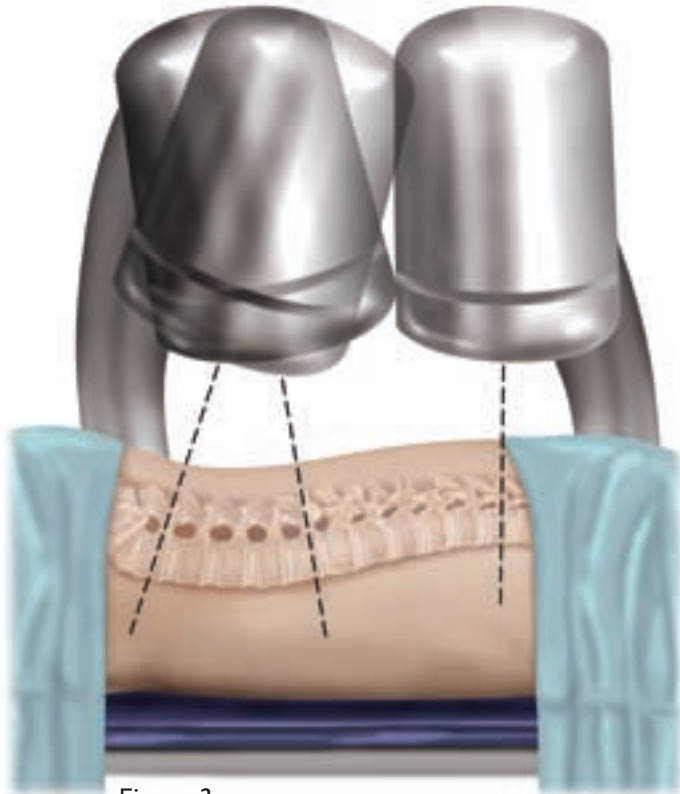


Figure 3

TIP

AP and lateral fluoroscopy projections should be parallel to the end plates nearest the screw to be inserted (Figure 3).

TIP

Some tables have pedestals that make it difficult to get a true AP view of the pedicles. While adjustments in patient positioning can be made, tables that limit good AP fluoroscopy should generally be avoided. A longer prep area is also necessary for intraoperative flexibility.

TIP

On AP fluoroscopy, the spinous processes should lie midway between both pedicles.

TIP

On AP and lateral fluoroscopy, the end plates should be linear and not rounded (Figure 4).



Figure 4

STEP 2 | SKIN INCISION

A 22-gauge spinal needle may be used to verify the appropriate location of the skin incisions (Figure 5). The needle is positioned on the skin directly over the pedicle on an AP image. The needle is then moved laterally 1cm to 2cm and inserted through the skin at the intersection of the facet and transverse process (Figure 6).

Both AP and lateral and (per surgeon preference) pedicle “barrel shot” images confirm the appropriate starting place has been determined with the spinal needle (Figures 7a and 7b). Once the position is confirmed, a skin and fascial incision is then made approximately 18mm in length.

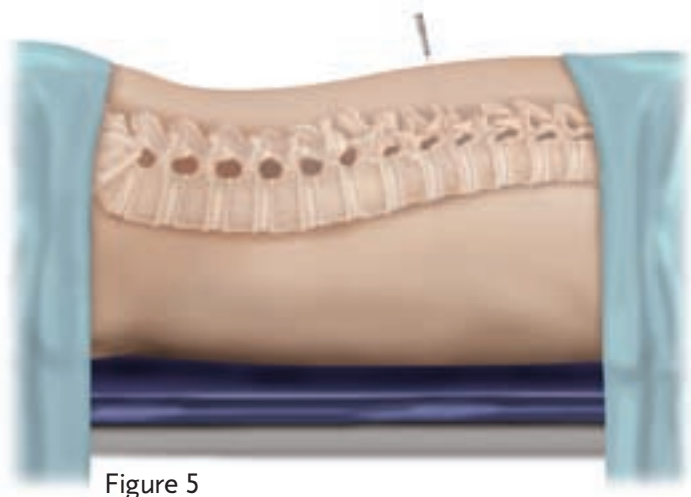


Figure 5

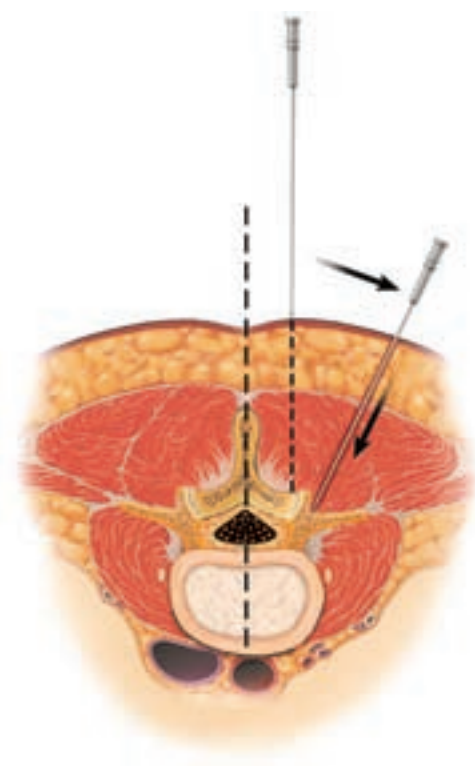


Figure 6

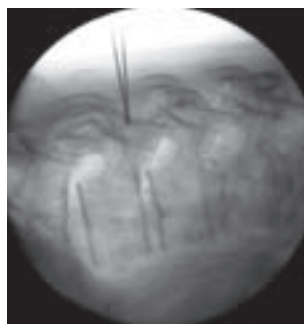


Figure 7a

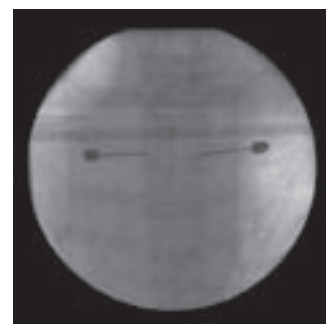


Figure 7b

Accessing the Pedicle

STEP 3 | PEDICLE ACCESS

Using the starting place determined in Steps 2 and 3, a Neural Integrity Monitoring (NIM) PAK (Pedicle Access Kit) Needle is used to gain access to the pedicle (Figure 8). After placing the NIM PAK Needle at the intersection of the facet and the transverse process, and confirming direction on fluoroscopy, the needle is advanced into the pedicle.

AP and lateral fluoroscopy should be used intermittently as needed to confirm direction. An AP image should show the needle tip initially at the lateral margin of the pedicle. As the needle advances toward the base of the pedicle on the lateral image, it should approach the pedicle center on the AP image (Figures 9a, 9b and 9c).



Figure 8

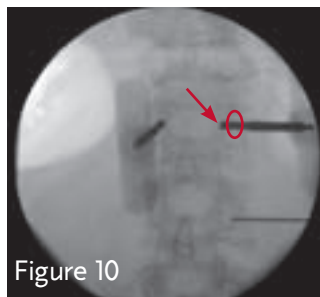


Figure 10

TIP

If the needle within the medial wall of the pedicle at the base and trocar has an oblique trajectory into the body, it may appear medial to the pedicle wall due to the oblique trajectory of the needle (Figure 10).

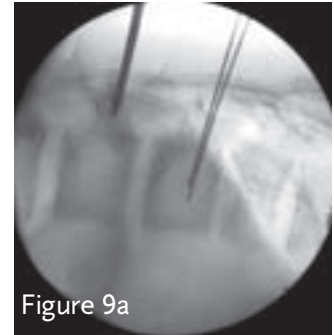


Figure 9a

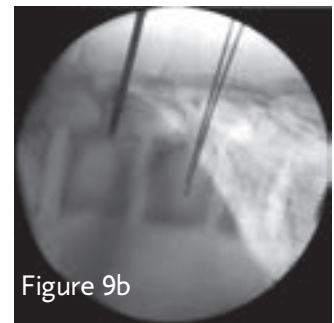


Figure 9b

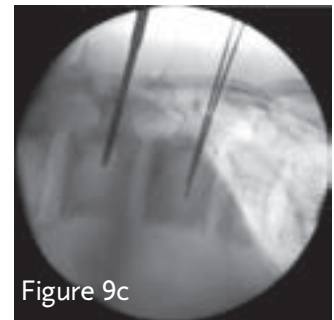


Figure 9c

TIP

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

STEP 4 | NIM INTEGRATION

For neuromonitoring, a NIM PAK Needle may be used to access the pedicle (Figure 11). Triggered EMG monitoring can be performed during advancement of the needle into the pedicle to ensure proper placement. Free-running EMG will monitor any nerve root irritation during this procedure (Figure 12).

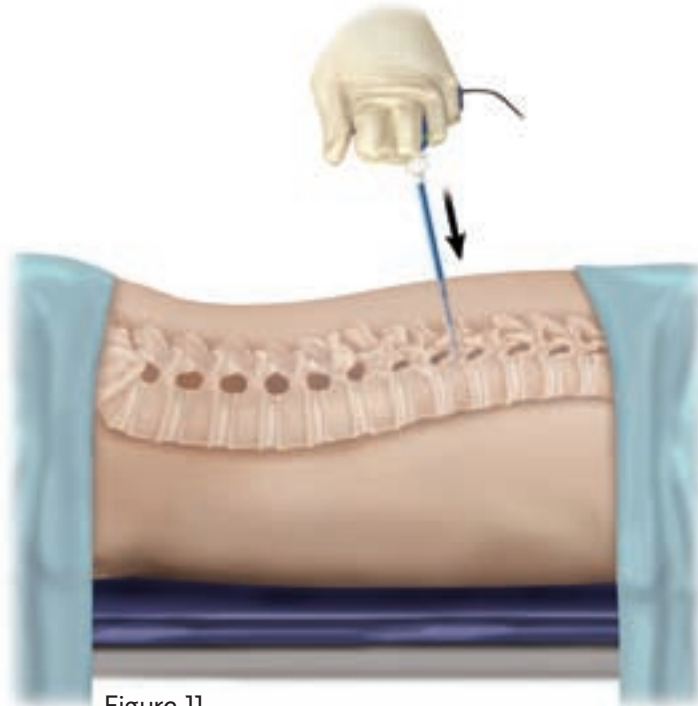


Figure 11



Figure 12

Accessing the Pedicle

STEP 5 | HANDLE AND STYLET REMOVAL

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



Figure 13

STEP 6 | GUIDEWIRE INSERTION

The Guidewire is inserted through the cannula and into the pedicle (Figure 14). The cannula of the NIM PAK Needle is carefully removed using a rotation technique, leaving only the Guidewire in place (Figure 15).

TIP

The Guidewire should be advanced approximately 50%–70% into the vertebral body to allow for proper screw placement.

**TIP**

Care should be taken when removing the cannula to ensure the Guidewire is not removed, as well. A heavy needle holder may be used to assist with removal.



Accessing the Pedicle

STEP 7 | ADDITIONAL GUIDEWIRE PLACEMENT

Steps 2 through 6 should be repeated for each Guidewire to be placed (Figure 16).

NOTE: *Guidewire, Screw Extender placement and Rod passage are shown on one side only for clarity.*



Figure 16

STEP 8 | MUSCLE DILATION

The fascia and muscle must be dilated to allow for screw placement (Figure 17). Three sequential Dilators are used to gently make a path of the appropriate dimension (Figure 18). When using the NIM-ECLIPSE™ Spinal System, the blue Large Disposable Dilator should be used.

TIP

Dilators should be docked on bony anatomy to minimize tissue creepage.

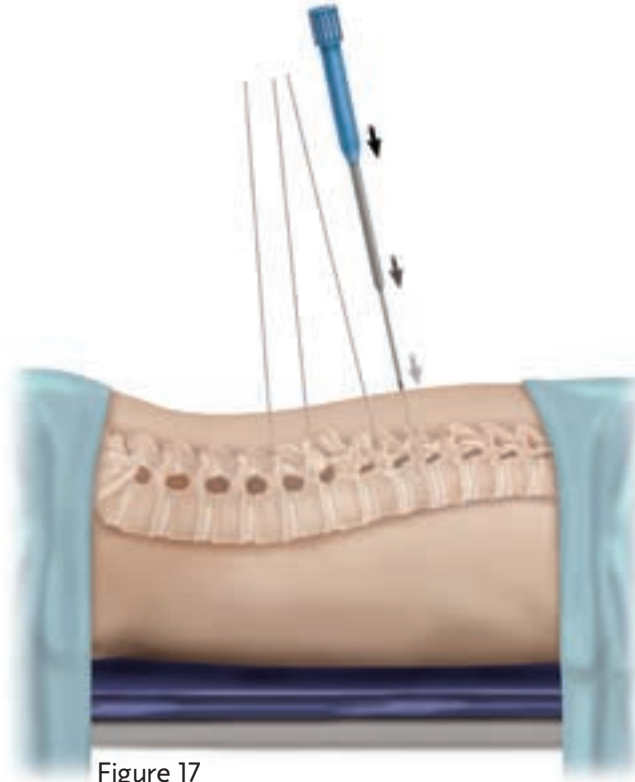


Figure 17



Figure 18

Pedicle Preparation

STEP 9 | INNER DILATOR REMOVAL

The first two Dilators are removed, leaving the Guidewire and the third Dilator to serve as a tissue protection sleeve during tapping (Figure 19).

TIP

Care should be taken when removing the two inner Dilators to ensure the Guidewire is not removed.



Figure 19

STEP 10 | TAP PEDICLE

The pedicle is prepared by placing the Tap over the Guidewire and through the third Dilator (Figure 20). Further evaluation of the tapped pedicle can be performed by using the NIM-ECLIPSE™ Spinal System and the Surgeon-directed Ball-tip Probe to stimulate the Tap (Figure 21).

NOTE: *It is important to keep the Tap along the same axis as the Guidewire. If a change in trajectory is required, the PAK Needle should be reinserted over the Guidewire, the Guidewire removed, and the inner stylet replaced.*

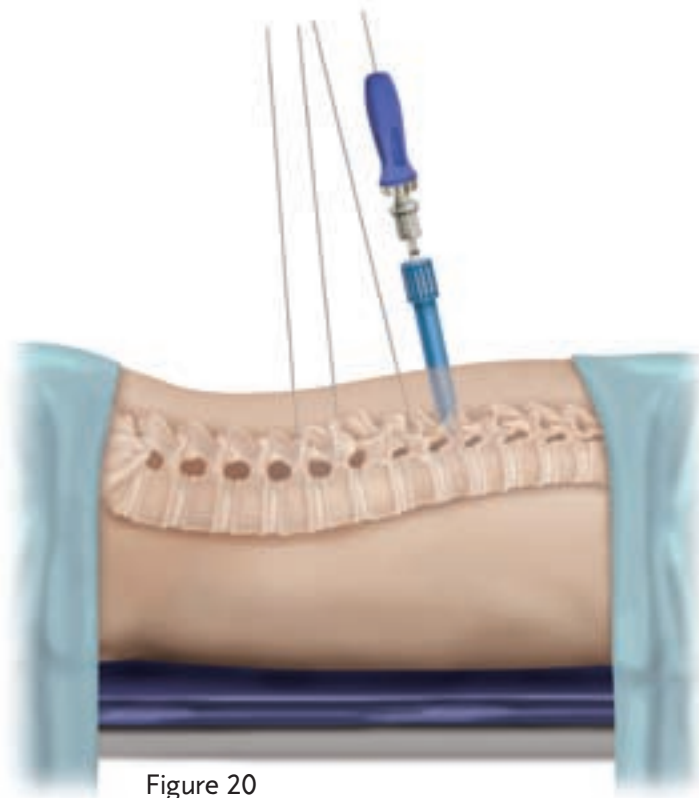


Figure 20



Figure 21



Figure 22

TIP

Screw length can be estimated by referencing the depth marks on the Tap with the rim of the Large Dilator (Figure 22). To ensure accuracy, the Dilator must be docked on bone.

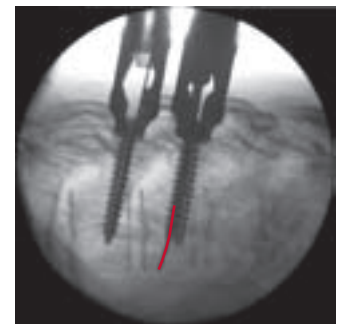


Figure 23

TIP

Unintentional advancement of the Guidewire should be monitored in this step. To avoid this, ensure the direction of Tap is in same plane as the Guidewire (Figure 23). Cleaning the Guidewires prior to tapping and careful attention to other wire lengths can help, as well.

Pedicle Preparation

STEP 11 | TAP REMOVAL

Remove the Tap exercising great care to not remove the Guidewire (Figure 24).

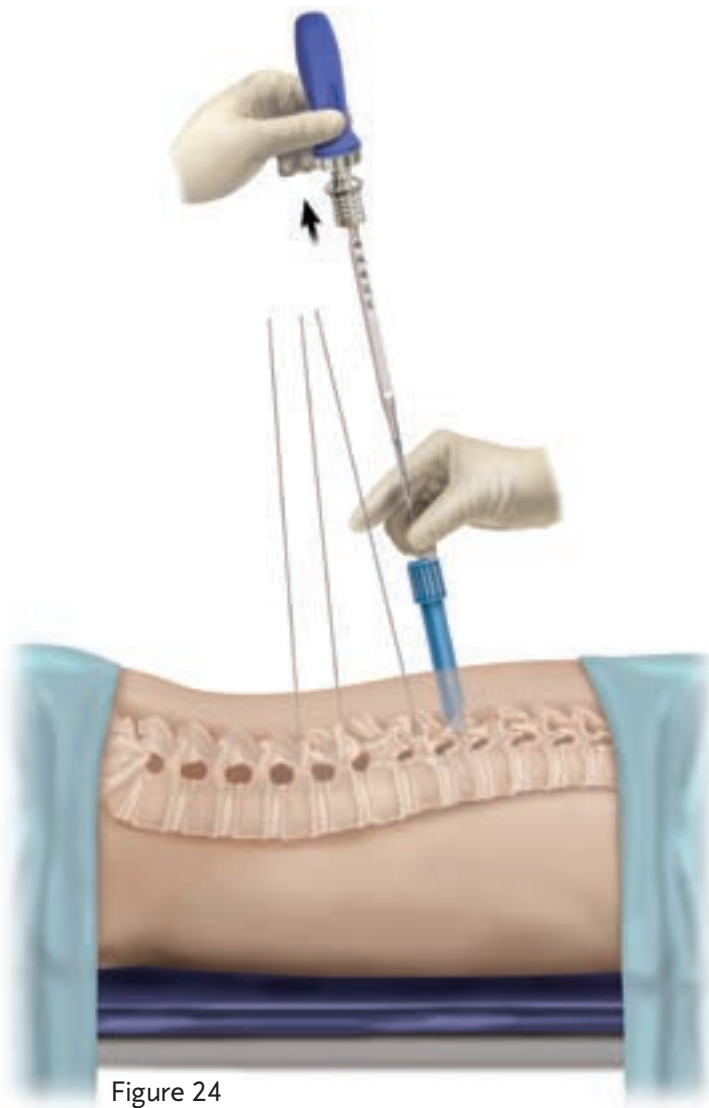


Figure 24

TIP

If you tap beyond the tip of the Guidewire, bone within the end of the Tap may cause the Guidewire to pull out as you remove the Tap. To avoid this, advance the Guidewire through the Tap before you remove the Tap from the vertebral body.

TIP

In order to ensure the Guidewire is not removed, the handle may be removed first, then the Tap.

STEP 12 | FINAL DILATOR REMOVAL

Remove the final Dilator, leaving only the Guidewire in place (Figure 25). Repeat Steps 8 through 12 for additional levels.

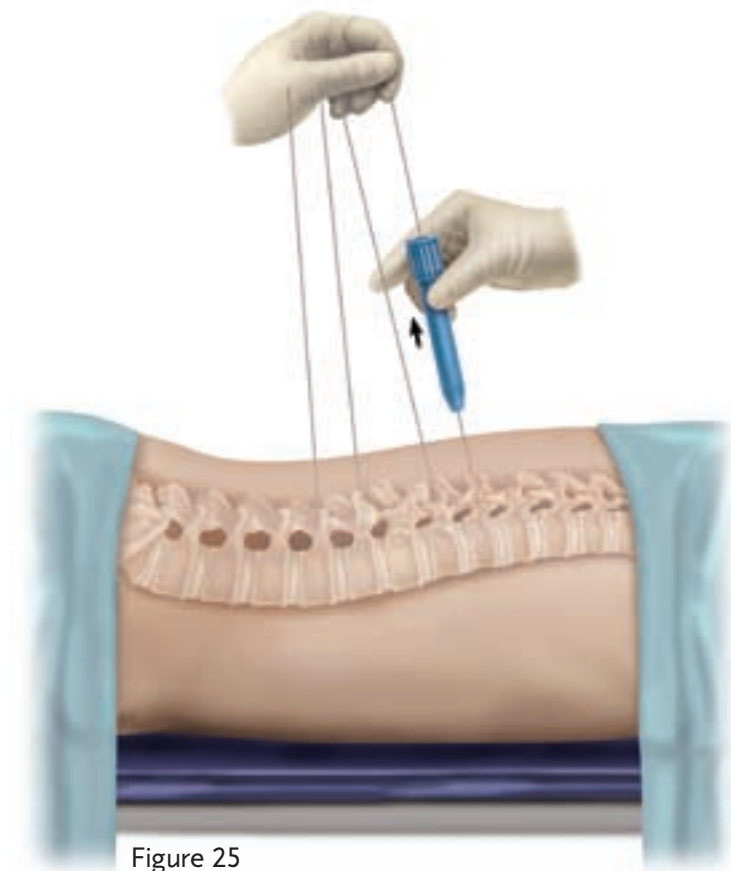


Figure 25

Extender Assembly

STEP 13 | INSERT INNER SLEEVE

Before a Screw can be inserted into the pedicle, the Screw Extenders must be assembled with the appropriate Screws. To assemble the Screw Extender, insert the Inner Sleeve into the Extender, ensuring the etching is visible through the windows on the Outer Extender (Figure 26). **Advance the Inner Sleeve until the head of the arrow is no longer visible** (Figure 27).



Figure 26



Figure 27

STEP 14 | ADVANCE INNER SLEEVE TO “LD”

Rotate the hex on top of the Inner Sleeve PAST the first click at “EJ” (Eject) until the marking in the window aligns with “LD” (Load) (Figures 28a and 28b). There will not be a click to stop the Inner Sleeve at “LD.”

TIP

Initially, if the hex spins freely with no advancement of the Inner Sleeve, apply slight upward pressure on the Inner Sleeve to engage the internal threads.

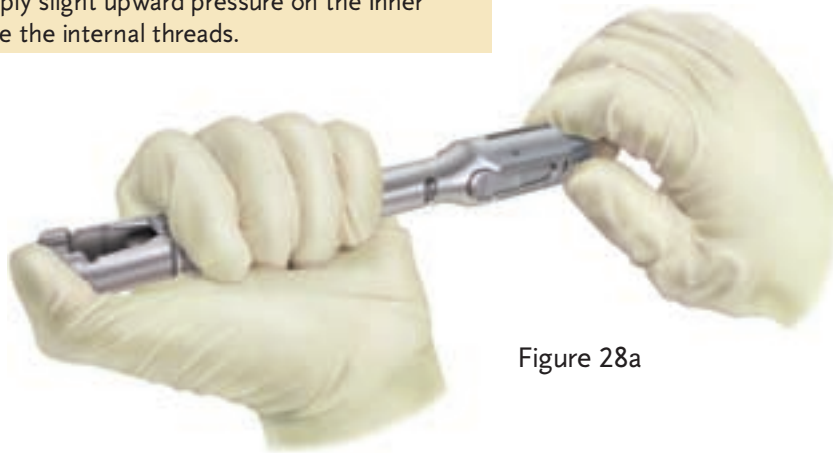


Figure 28a



Figure 28b

TIP

If it is difficult to rotate the hex with fingers, use the blue T-Handle with the hex connection to give more leverage (Figure 29).



Figure 29

Extender Assembly

STEP 15 | LOAD SCREW AND LOCK IN PLACE

With LD showing in the Exterior window, insert the appropriate Screw into the distal tip of the Inner Sleeve, ensuring the Screw head is aligned flush with the Inner Sleeve (Figure 30a). Rotate the hex on top of the Outer Extender until the Inner Sleeve clicks with "ST" (Start) aligned both through the window and visible on top of the hex (Figures 30b and 30c).

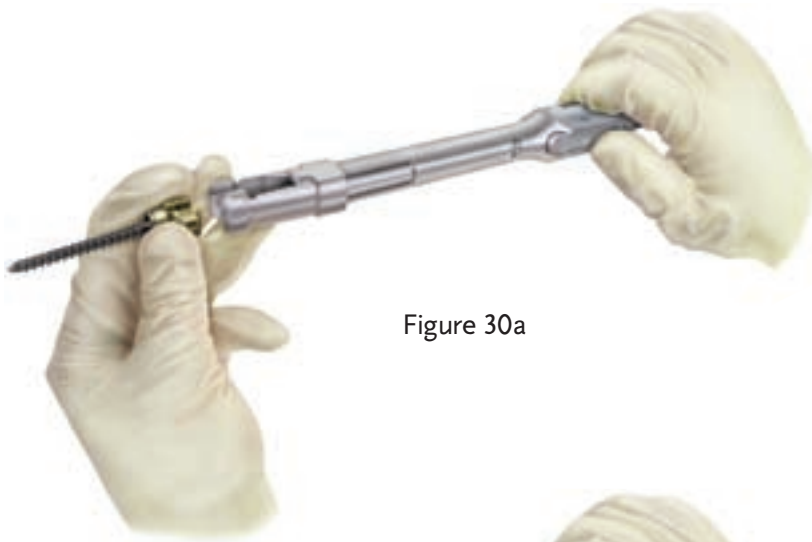


Figure 30a



Figure 30b



Figure 30c

TIP

If it is difficult to rotate the hex, check the Screw alignment to ensure the Screw is not slightly rotated.

STEP 16 | INSERT BONESCREW DRIVER

Insert the Retaining Bonescrew Driver into the Screw Extender assembly. Pass the tip of the driver into the head of the Multi-Axial Screw until the driver fully engages the Screw. Thread the Sleeve of the Retaining Driver into the head of the Screw until tight (Figure 31).

**TIP**

The Cannulated Non-Retaining Bonescrew Driver may also be used for Screw insertion.

Figure 31

Screw Insertion

STEP 17 | INSERT SCREW EXTENDER ASSEMBLY INTO PEDICLE

The entire Screw Extender assembly is inserted over the Guidewire and into the pedicle (Figures 32 and 33). Be certain the Screw assembly is not inserted too far. If the multi-axial head of the CD HORIZON® LEGACY™ Cannulated Screw is inserted flush with the bone, it will lose its multi-axial capabilities.

TIP

After gaining initial purchase of the pedicle with the Screw assembly, remove the Guidewire to prevent it from being advanced too far.

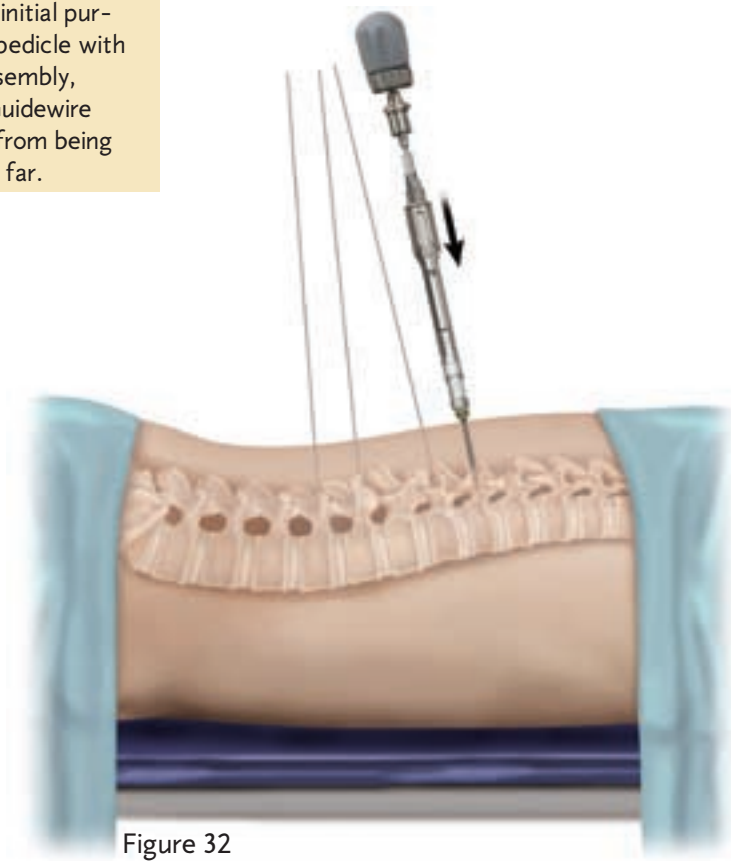


Figure 32

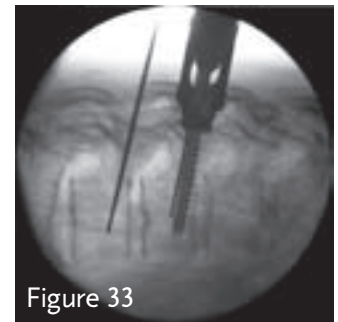


Figure 33

TIP

Care should be used to avoid inadvertent Guidewire removal and unguided Screw placement.

TIP

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

STEP 18 | ADDITIONAL SCREW EXTENDER PLACEMENT

Repeat Steps 7 through 18 for each Screw Extender to be placed (Figures 34 and 35).

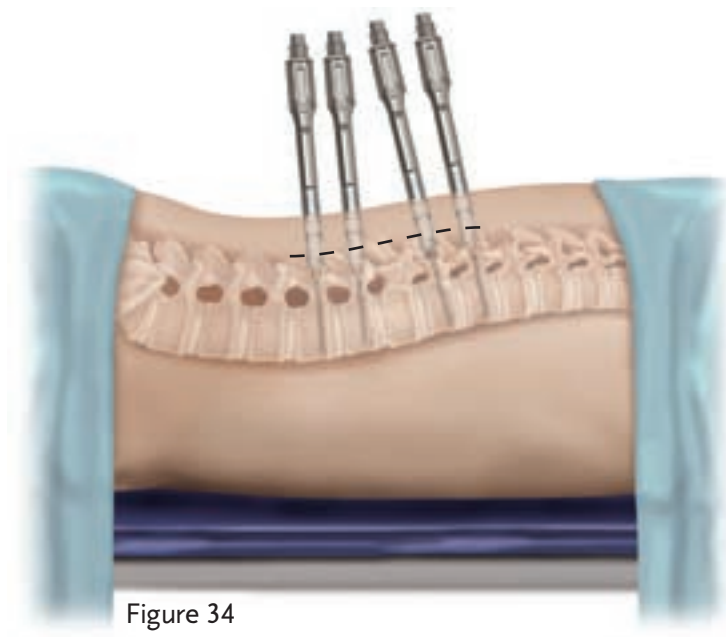


Figure 34

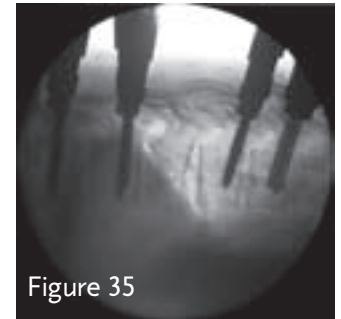


Figure 35

TIP

Under fluoroscopy, visualize screws to ensure they line up coronally as much as possible.

STEP 19 | ALIGN EXTENDERS FOR ROD PASSAGE

Once all Extenders are in place, rotate the Extenders as needed to ensure buttons and markings in windows face medial/lateral (Figure 36). This will align the windows at the distal tip of the Extenders in a position that will allow the Rod to be passed.

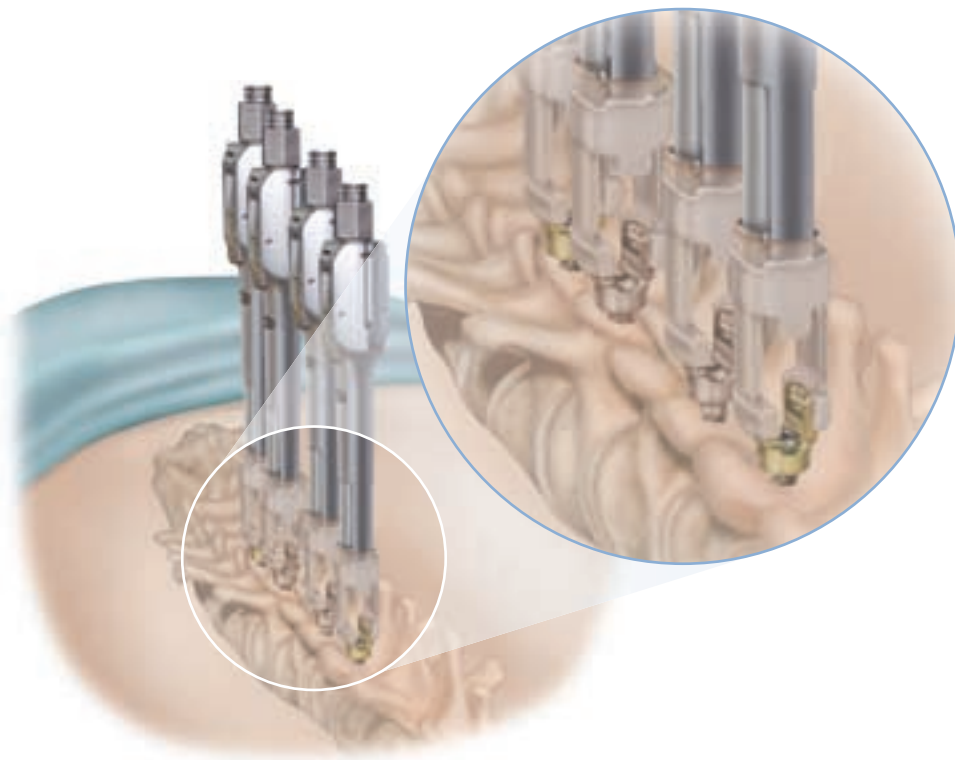


Figure 36

STEP 20 | MEASURE FOR ROD LENGTH

Lay the Rod Measurement Tool on the skin next to the Extenders. Bend the Tool accordingly to ensure all portions of the rod measurement device are in contact with the skin (Figure 37). Read the Rod length off the Rod Measurement Tool to estimate length.

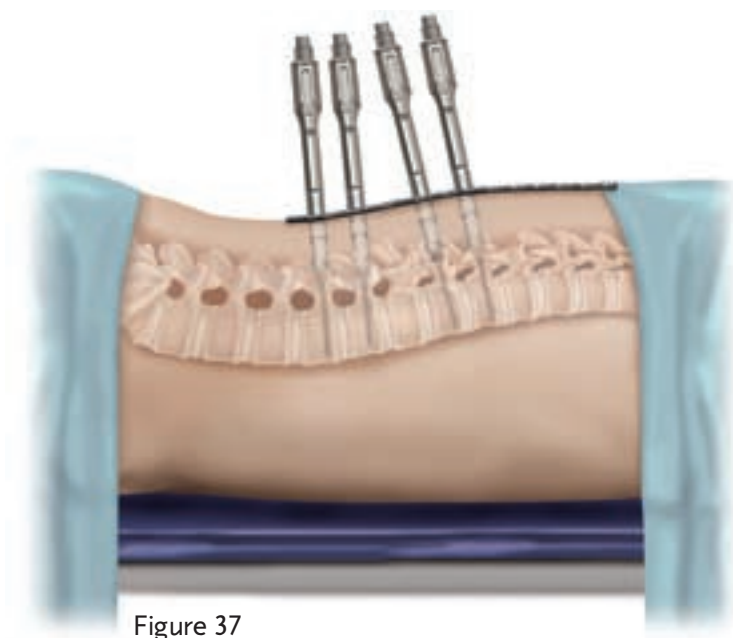


Figure 37

Rod Preparation

STEP 21 | ATTACH ROD TO INSERTER

Open the top clasp on the Inserter by pulling back on the button behind the clasp and lifting the clasp. Insert the appropriate-length Rod, and close the top clasp until it clicks to lock the Rod in place (Figures 38a and 38b). If needed, use the Rod Bender to bend the Rod according to patient anatomy (Figure 38c).



Figure 38a



Figure 38b



Figure 38c

TIP

Do not bend the Rod prior to placing it in the Rod Inserter.

TIP

To estimate any bend for the Rod, place the Rod Inserter lateral to the patient and take a lateral fluoroscopy. Then compare bend in the rod-to-screw trajectory and alter as needed.

STEP 22 | ESTIMATE ROD ENTRY POINT

Attach the Rod Entry Point Estimator to the most cephalad Extender and move the Extender to ensure that it is either perpendicular to skin or pointing slightly toward the caudal Extenders (Figure 39). Allow the Rod Entry Point Estimator to fall freely to the skin and make a vertical incision approximately 1cm (Figure 40).



Figure 39

IMPORTANT

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

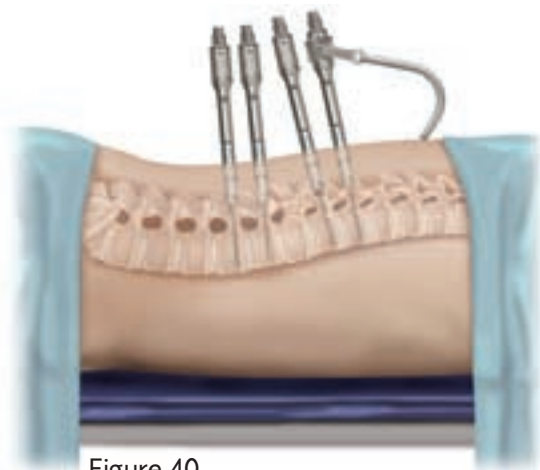
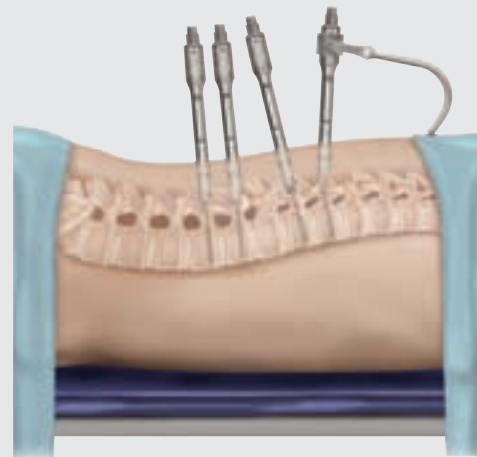


Figure 40

Rod Passage

STEP 23 | PASS ROD THROUGH FIRST EXTENDER – CEPHALAD TO CAUDAL

Pass the Rod through the incision and below the fascia to the opening of the first Extender (Figure 41). Use AP and lateral fluoroscopy as necessary in combination with tactile and visual feedback to find the path through the window in the first Extender (Figure 42).

IMPORTANT

It is very important to pass the Rod cephalad to caudal to allow laminar shingling to serve as an additional safety measure for protecting the spinal canal.



Figure 41

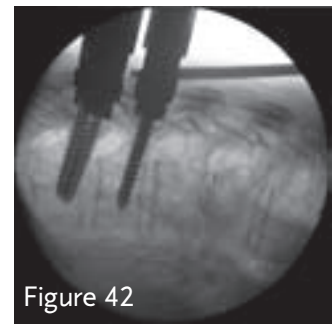


Figure 42

STEP 24 | CONFIRM ROD PASSAGE

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

1. Dropping the Rod Confirmation Tool down the shaft of the Extender. If the line is visible, the Rod is through the Extender (Figure 43). If the line is not visible, the Rod is not through the Extender.
2. If using Multi-Axial Screws, rotate an Extender by hand (Figure 44). If the Extender rotates freely, then the Rod has not passed through the Extender.

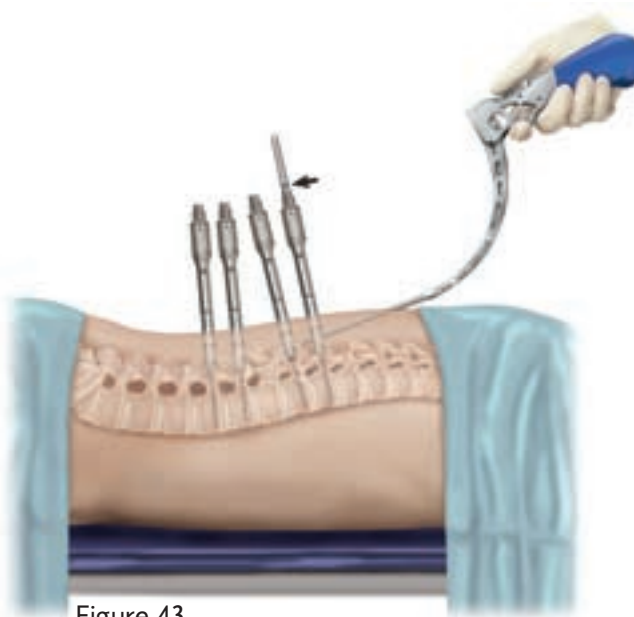


Figure 43

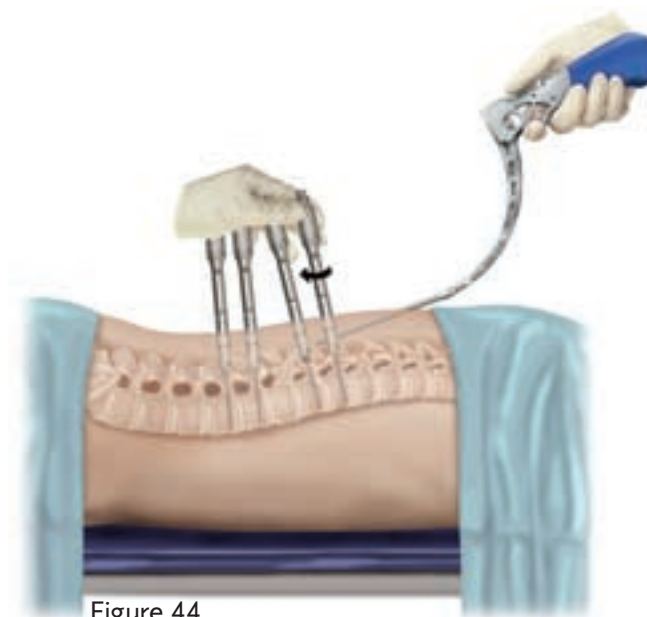


Figure 44

Rod Passage

STEP 25 | PASS ROD THROUGH SUBSEQUENT EXTENDERS

After the Rod is through the first Extender, guide it via the steering handle through the remaining Extenders using tactile feel, AP and lateral fluoroscopy images, the Rod Confirmation Tool and the Extender rotation technique as necessary (Figures 45a, 45b and 45c).

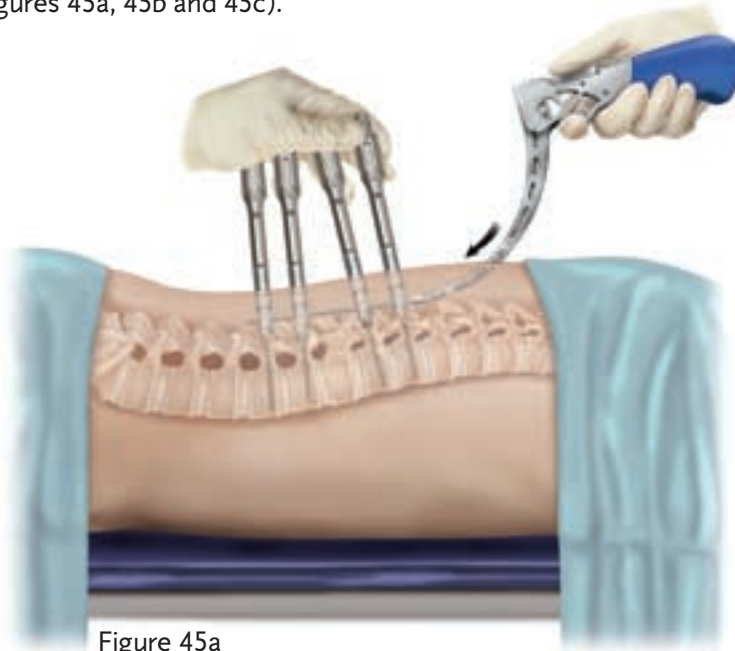


Figure 45a

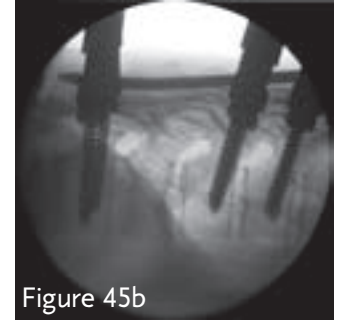


Figure 45b

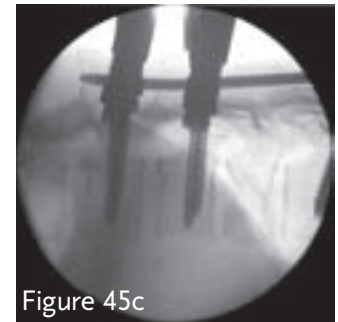


Figure 45c

TIP

To pass a kyphotic Rod, the handle may be used to rotate the Rod in the patient. For example, a coronal bend may initially be placed in the Rod. The Rod may then be passed in a lordotic manner through the first two Extenders with the handle on its side. Once through the first two Extenders, the handle may be rotated 180° to pass a now kyphotic Rod through the final two Extenders (Figure 46).

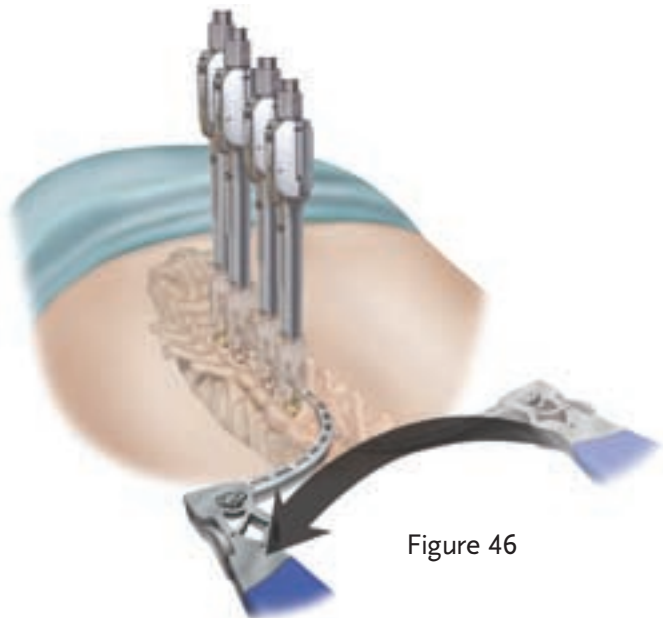


Figure 46

STEP 26 | CONFIRM ROD OVERHANG

With the Rod confirmed through all of the Extenders, take a lateral fluoroscopy to ensure that the Inserter has not passed through the first Extender and that the overhang on the cephalad and caudal Extenders is acceptable (Figures 47a and 47b).

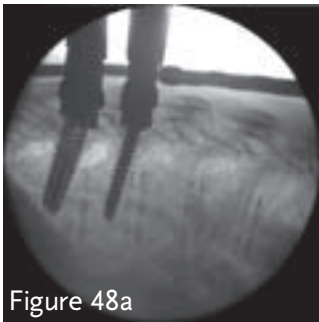


Figure 48a

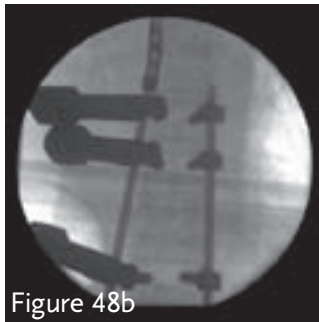


Figure 48b

TIP

The Inserter can pass through the first Extender. It is important to confirm with fluoroscopy that only the Rod passed through the Extender. A sliver of rod should be visible on fluoroscopy between the Extender and the bulbous tip of the Inserter (Figures 48a, 48b, 48c and 48d).

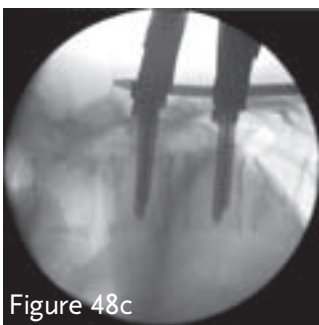


Figure 48c

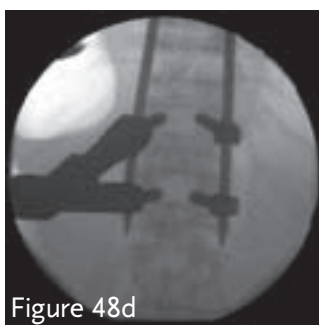


Figure 48d

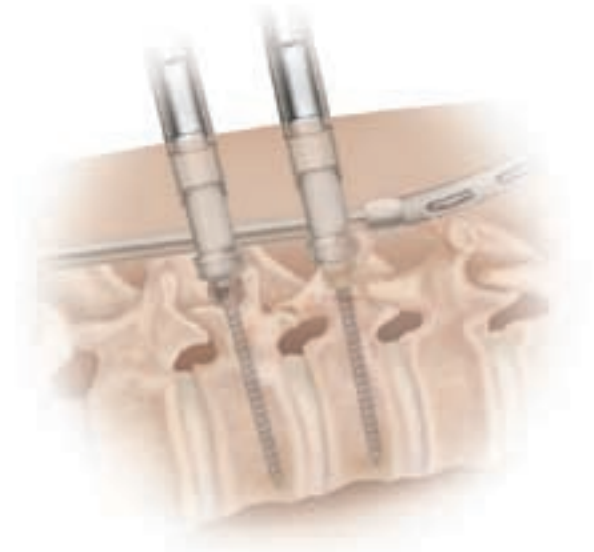


Figure 47a

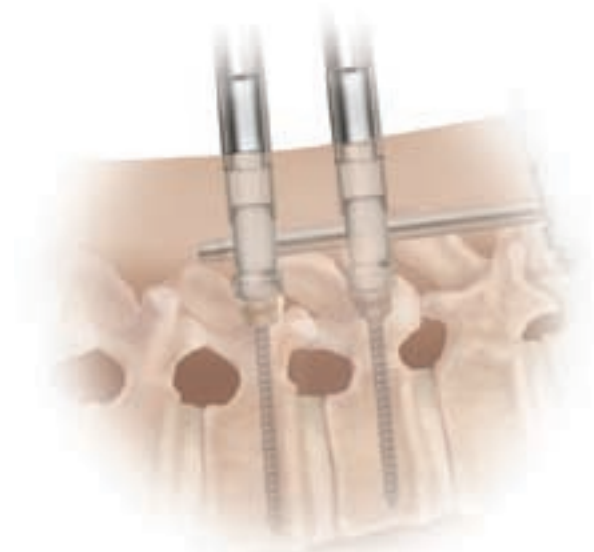


Figure 47b

Rod Reduction

STEP 27 | REDUCE EXTENDERS IN STAGES

While holding the Inserter in place, use the Reduction Nut and Ratchet Handle to reduce each Extender in stages until all of the Extenders read RD (Reduced) in the window (Figure 49).

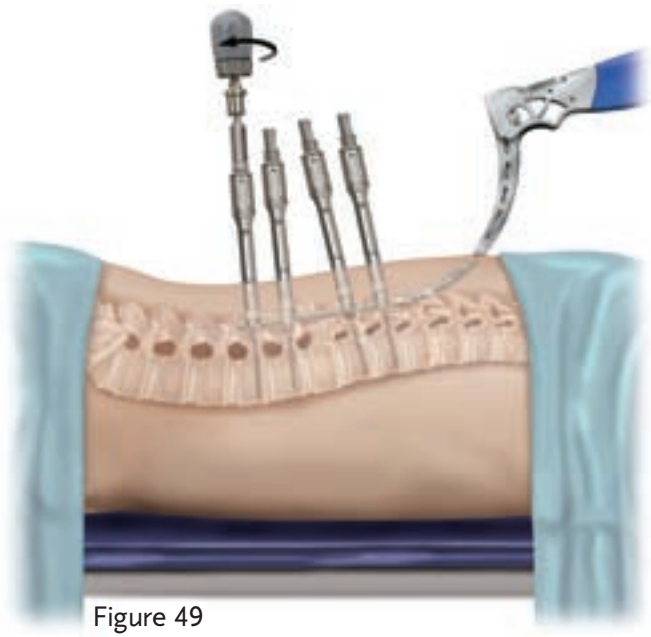


Figure 49

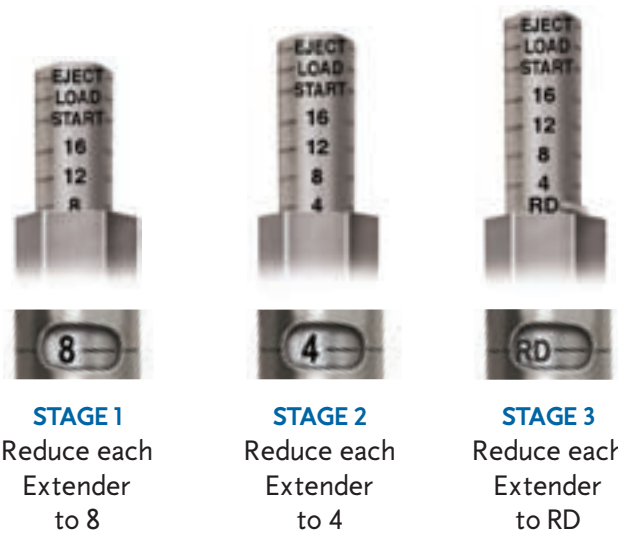


Figure 50

TIP

It is important to reduce the Extenders in stages (Figure 50). The complete reduction of one Extender without reducing the others will cause the Rod to put a strong force on the other Extenders, which can cause difficulties when reducing the others.

IMPORTANT

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

STEP 28 | PASS ROD AND REDUCE EXTENDERS ON OPPOSITE SIDE

Repeat Steps 19 through 27 to pass the Rod on the opposite side (Figure 51).

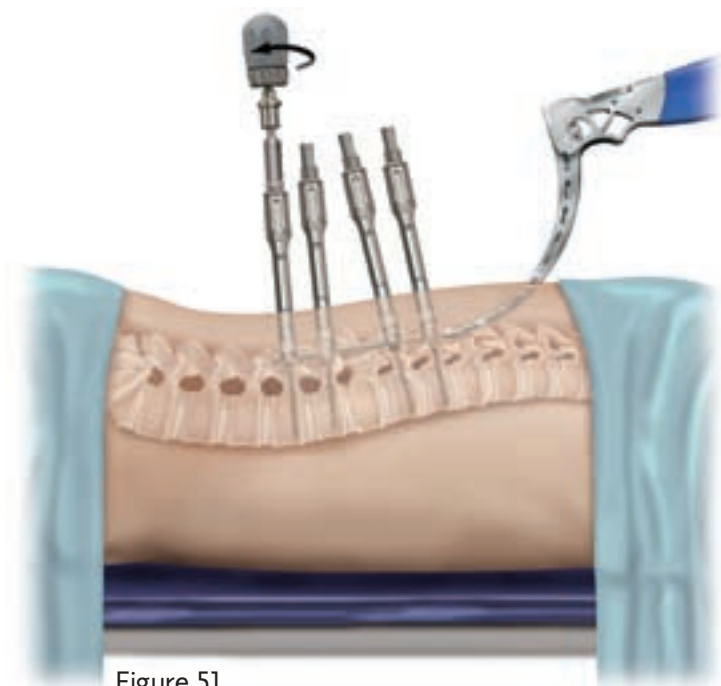


Figure 51

Set Screw Insertion and Break-Off

STEP 29 | LOAD SET SCREW

Load the Set Screw onto the Set Screw Retaining Driver by pulling up on the T-Handle on the shaft and placing the Set Screw onto the distal tip of the Driver (Figure 52).

TIP

Before the first Set Screw is broken off, it is recommended to confirm the Rod overhang with fluoroscopy one more time.



Figure 52

STEP 30 | PLACE COUNTER TORQUE AND BREAK-OFF

Place the Counter Torque over the shaft of first Extender to hold the Extender in place (Figure 53). With the Set Screw loaded on Set Screw Retaining Driver, place the Driver down the shaft of the Extender and — while holding the Counter Torque — rotate the Driver until the Set Screw breaks off (Figure 54). Remove the Counter Torque and Set Screw Retaining Driver, and remove the sheared-off portion of the Set Screw from the Driver by pulling up on the T-Handle on the shaft.



Figure 53



Figure 54

IMPORTANT

If any bend is placed in the Rod, ensure the Inserter is held in the appropriate position, not leaning to one side, to prevent the Rod from rotating in the patient before Set Screw break-off.

TIP

If it is difficult to get the Set Screw to start threading, try the following:

1. Assemble Break-off Handle to Suction Trepine and connect suction. Place Suction Trepine down the shaft and rotate to remove blood and tissue that could be impeding the start of the Set Screw (Figure 55).
2. Unreduce the Extender one-half turn to relieve any possible pressure placed on the tulip of the Screw.



Figure 55

Set Screw Insertion and Break-Off

STEP 31 | COMPRESSION/DISTRACTION

Provisionally tighten one Set Screw in place in the desired Extender to use as leverage to compress or distract. Remove Retaining Driver from Extender without breaking off by pulling up on the T-Handle on the shaft leaving the Set Screw in place (Figure 56). Unreduce other extender by one-half turn to allow it to slide along Rod.

Place the Compressor or Distractor on Extenders by rotating in place in a top-down trajectory (Figure 57). Move the Compressor or Distractor as close to the skin as possible on both Extenders and rotate the clasp on the Compressor or Distractor to compress or distract accordingly.

Once compression/distraction is complete, put the Counter Torque in place on the Extender without the Set Screw, insert the Retaining Driver with Set Screw in place and break off (Figure 58). Re-engage the Set Screw on the provisionally tightened Screw by pulling up on the T-Handle on the shaft of the Retaining Driver and dropping down the shaft of the Extender until the Set Screw engages. Break-off Set Screw accordingly.

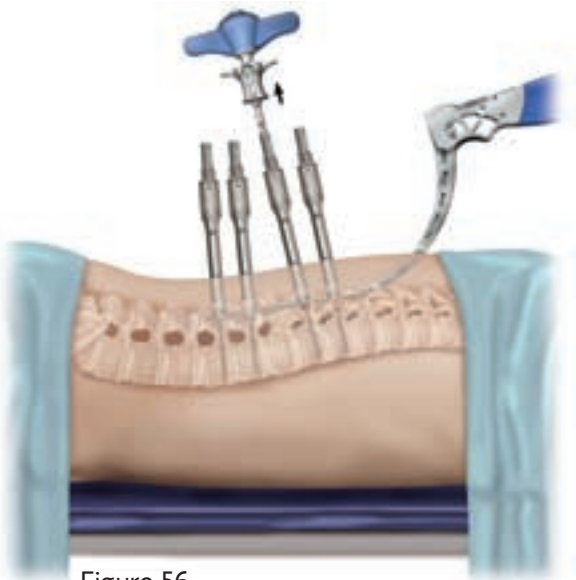


Figure 56

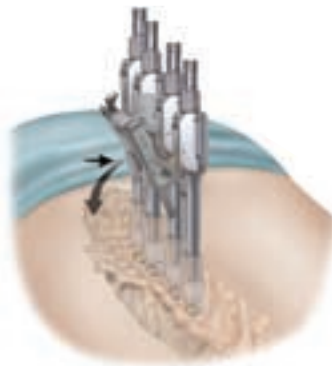


Figure 57



Figure 58

TIP

To assemble as a Compressor, depress the latch on the Actuator (7570932) and slide the Actuator onto the Rack (7570930) with etching "THIS SIDE UP TO COMPRESS" facing up on the Rack.

TIP

To assemble as a Distractor, depress the latch on the Actuator (7570932) and slide the Actuator onto the Rack (7570930) with etching "THIS SIDE UP TO DISTRACT" facing up on the Rack.

STEP 32 | ADDITIONAL COMPRESSION/DISTRACTION, BREAK-OFF

Repeat Steps 29 through 31 as needed for all of the Extenders (Figure 59).



Figure 59

STEP 33 | REMOVE INSERTER

Pull back on the small latch behind the clasp and open the clasp on the Inserter to release the Rod and remove the Inserter from the body (Figure 60).

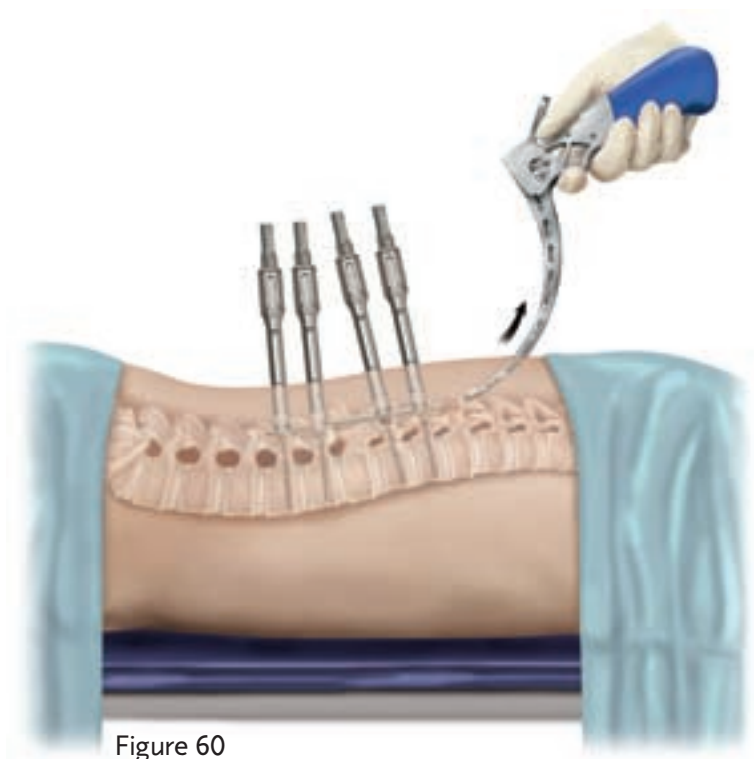


Figure 60

STEP 34 | REMOVE EXTENDERS

Once all Set Screws have been broken off, use the Reduction Nut to unreduce first Extender back to the ST position, at which point reduction will stop and an audible click may be heard (Figure 61). Push both buttons and begin to unreduce again. Immediately let go of the buttons once reduction restarts and unreduce until the Extender stops at EJ (Figures 62a and 62b). Once at EJ another click will be heard. Remove the Extender from the body and Screw by rocking the Extender in a medial/lateral direction and pulling upward (Figure 63).



Figure 61



Figure 62a



Figure 62b

TIP

If you cannot depress the buttons in the ST position, reduce the Extender slightly forward while holding buttons, and then start unreducing again.

TIP

If buttons are held until unreduce past EJ, the Outer Extender will pull off entirely. If this happens, simply remove the Inner Sleeve from the Screw and let go of the buttons sooner on the next attempt.

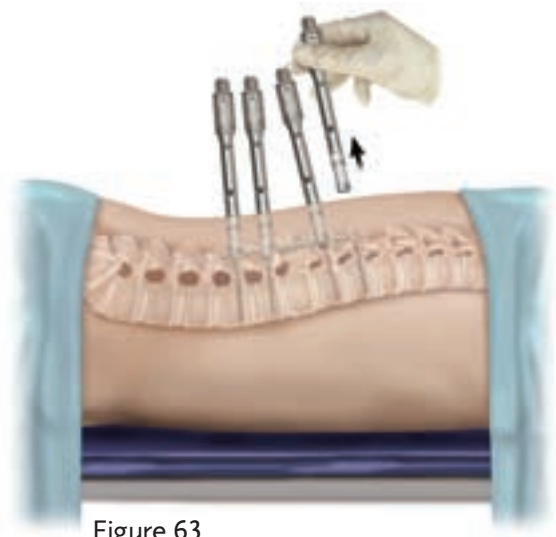


Figure 63

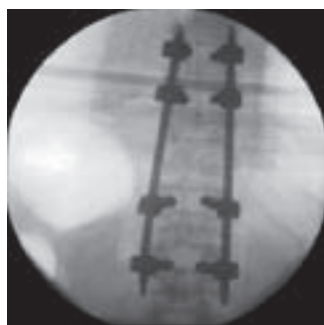
STEP 35 | SUBSEQUENT EXTENDER REMOVAL AND CLOSURE

Repeat Step 34 until all the Extenders are removed.

Closure is accomplished with a few interrupted stitches in the fascia, a subcuticular skin suture, and Steri-Strips™ (Figure 64).



Figure 64



STEP 36 | SCREW EXTENDER DISASSEMBLY

To disassemble the Extenders, with Extender in the EJ position, push both buttons and unreduce by turning the Reduction Nut counterclockwise (Figure 65). Continue to unreduce until the Reduction Nut spins freely (Figure 66). Grab the Inner Sleeve and pull it straight out of the Extender without squeezing the Extender tips together.



Figure 65



Figure 66



Figure 67

TIP

Some force may be required to pull the Inner Sleeve out after Reduction Nut spins freely (Figure 67).

Graft Placement

EXAMPLE OF GRAFT PLACEMENT

Graft must be used when implanting the construct. In this example it is inside the corpectomy device (Figure 68).



Figure 68

EXAMPLE OF IMPLANT REMOVAL

If needed, the CD HORIZON® LEGACY™ Cannulated Multi-Axial Screws, Set Screws and CD HORIZON LONGITUDE™ Rods may be removed from the patient. To attain exposure, use a dissection or preferably a dilation technique to visualize the head of each Screw (Figure 69). Use the T27 Removal Driver to engage the Set Screw and remove each. Grab the tip of the Rod with a Cochler from the head of the first Screw and remove through the most cephalad screw incision (Figure 70). Remove each Screw with either the Retaining or Non-Retaining Bonescrew Driver from the instrument set.



Figure 69

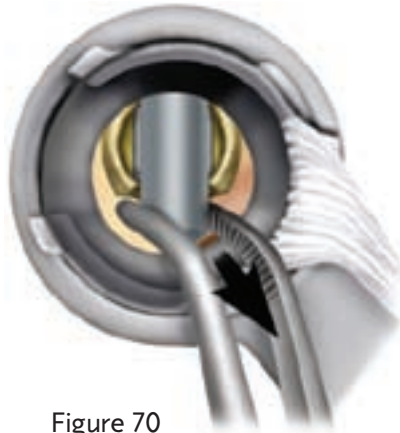


Figure 70

TIP

If difficulties arise seating the Screwdriver, use the Ball End Screwdriver (7570922) in the set to align the Screw head to the shaft and remove.

TIP

Use the Counter Torque to hold the Screw in place and loosen the Set Screw.

TIP

It may be easier to remove the Tubular Retractor prior to removing the Rod.

Important Product Information

PURPOSE

The CD HORIZON® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION

The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washer, 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 ϕ 3.5mm, ϕ 4.5mm, ϕ 5.5mm rods or ϕ 6.35mm rods, while other components can connect to both ϕ 5.5mm rods and ϕ 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, 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 express, 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.

The CD HORIZON® AGILE™ Dynamic Stabilization device is comprised of four components and are comprised by a combination of materials. The proximal and distal rod components are manufactured from commercially pure titanium. The cable is fabricated from a 7x7 filament yarn made from titanium alloy, with a cylinder rotary-swaged to the end, made from the same material. The spacer portion of the device is manufactured from Polycarbonate-Urethane.

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.**

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 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.

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.

The CD HORIZON SPIRE™ 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 processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis, trauma; and/or tumor.

When used as a pedicle screw fixation system in skeletally mature patients, the CD HORIZON® AGILE™ Dynamic Stabilization device is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the degenerative spondylolisthesis with objective evidence of neurologic impairment and/or failed previous fusion in the thoracic, lumbar and/or sacral spine. Additionally, when used as a pedicle screw fixation system, the CD HORIZON® AGILE™ Dynamic Stabilization device is indicated for use in patients who are receiving fusions with autogenous graft only; who are having the device fixed or attached to the lumbar or sacral spine; and/or are having the device removed after the development of a solid fusion mass.

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. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
14. Any patient unwilling to follow postoperative instructions.
15. 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:

1. Severe bone resorption.
2. Osteomalacia.
3. 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:

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, neurosis, 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

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.

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.

Important Product Information (Continued)

USA For US Audiences Only

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.

MEDTRONIC CD HORIZON® Spinal System instrumentation contains 3.5mm, 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).

CD HORIZON® PEEK Rods are not to be used with CROSSLINK® Plates.

When using the CD HORIZON® AGILE™ Dynamic Stabilization device, refer to the surgical technique for the appropriate directions for use.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre dispositions 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.
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. Utilize an imaging system 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.
6. **Caution:** Do not overlap or use a screw/bolt that is either too long or too large. Overtapping, using an incorrectly sized screw/bolt, or accidentally advancing the guidewire during tap or screw/bolt insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a screw/ bolt diameter as will fit into each pedicle.
7. 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.
8. To assure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
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.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened Medtronic 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. 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. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the 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)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 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.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic. Further, if any of the implanted 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 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 and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

For further information:

	
Medtronic B.V Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands Tel: + 31 45 566 80 00	1800 Pyramid Place. Memphis, TN 38132 Telephone: 800 876 3133 (In U.S.A.) 901 396 3133 (Outside U.S.A.) FAX: 901 396 0356

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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 medical information.

MEDTRONIC
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

www.sofamordanek.com
For more information go to www.myspinetools.com

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