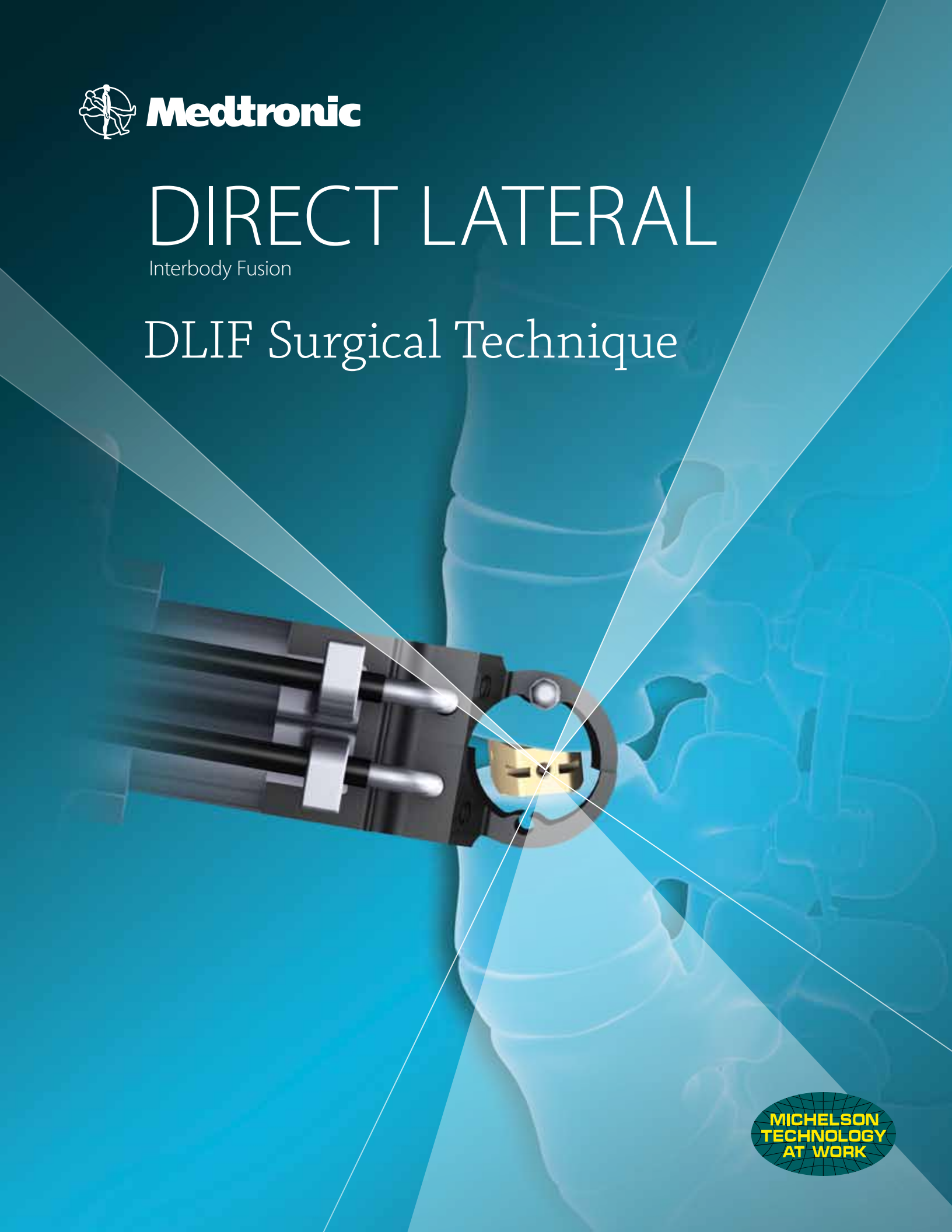
Medtronic

DIRECT LATERAL

Interbody Fusion

DLIF Surgical Technique



MICHELSON TECHNOLOGY AT WORK

Access

MAST QUADRANT® DL Retractor System

- Illuminated surgical access with sequential soft tissue dilation
- Vertebral body stabilization pins to prevent retractor migration

The Direct Lateral Interbody Fusion procedure provides spine surgeons with a complete minimally invasive solution for the treatment of degenerative lumbar conditions. By utilizing a direct lateral approach to the spine, this procedure enables placement of a large interbody graft into the disc space for anterior column support while avoiding the obstacles associated with traditional anterior or posterior approaches. The DLIF procedure incorporates a comprehensive set of instruments and implants including fully integrated neuromonitoring, streamlined access instrumentation, anatomically designed implants and percutaneous fixation systems.

There are some risks associated with minimally invasive spine surgery, including transitioning to a conventional open procedure, neurological damage, damage to the surrounding soft tissue, and, where used, instrument malfunction. Other risks associated with implants used include device migration, non-fusion, loss of spinal curvature, correction, height, and/or reduction. Minimally invasive procedures may be associated with longer operative times.

Interbody

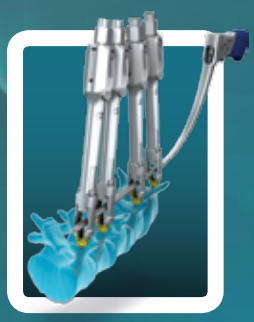
CLYDESDALE® Spinal System*

- Bullet-nosed tip to aid in distraction
- Convex design to contact vertebral body end plates

Neuromonitoring

NIM-ECLIPSE® Spinal System

- Advanced surgeon-directed and neurophysiologist supported neuromonitoring.
- Accurate and immediate warning of potential harm to nerves with real time nerve proximity detection.



Fixation

CD HORIZON® SEXTANT® II Percutaneous Rod Insertion System and CD HORIZON® LONGITUDE® Multi-level Percutaneous Fixation System

- Reproducible percutaneous rod and screw implantation.
- Minimally invasive fixation for spine procedures.

*The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Medtronic

DIRECT LATERAL

Interbody Fusion

Transpsoas Approach DLIF Surgical Technique

Instrument Set

Retractor/Access Instruments

Retractor Blade
9cm Left, Right (9567309, 9567319)
10cm Left, Right (9567300, 9567310)
11cm Left, Right (9567301, 9567311)
12cm Left, Right (9567302, 9567312)
13cm Left, Right (9567303, 9567313)
14cm Left, Right (9567304, 9567314)
15cm Left, Right (9567305, 9567315)
16cm Left, Right (9567306, 9567316)
17cm Left, Right (9567307, 9567317)

Rotating Flex Arm Attachment
(9568010)

Stability Pin Driver
(8970400)

Blade Pins
9cm (9569309)
10cm (9569310)
11cm (9569311)
12cm (9569312)
13cm (9569313)
14cm (9569324)
15cm (9569315)
16cm (9569326)
17cm (9569327)

Pituitary Rongeur
Up (2940076)
Straight (2940075)

Rotate Kerrison Punch
3mm (2940068)
5mm (2940069)

Instrument Set *continued*

Retractor/Access Instruments

Guidewire
Sharp Long (8670002)
Trocar Short (8670005)

5.3mm Dilator
(9560420)

10.6mm Dilator
(9561421)

16.0mm Dilator
(9561422)

20.8mm Grooved Dilator
(9561424)

Retractor Base
(9569000)

Instrument Set *continued*

Retractor/Access Instruments

A/P Blades
90mm (2942002)
100mm (2942003)
110mm (2942004)
120mm (2942005)
130mm (2942006)
140mm (2942007)
150mm (2942008)
160mm (2942009)
170mm (2942010)

Medial Lateral Rack Assembly
(9568008)

Access Handles
Left (2942022)
Right (2942050)

6mm Pituitary Rongeur
(74-619-106)

Dilator Holder
(2942017)

DL Retractor Opener
(2942011)

Instrument Set *continued*

Disposables

NIM® X-PAK Probe
(9450069)

NIM-SPINE® 23cm Ball-tip Probe
(9450015)

MAST QUADRANT® Illumination System (9560658)

Bayoneted Discectomy Knife
(9560659)

Flexible Arm

Flexible Arm
(9561524)

Bed Rail Clamp
(9561523)

Instrument Set *continued*

Disc Preparation Instruments

Combo Tool
(2940050)

Angled Combo Tool
(2940051)

Reverse Angle
Combo Tool
(2940052)

Straight Serrated
Cup Curette
(2940053)

Angled Serrated
Cup Curette
(2940054)

Reverse Angle
Serrated Cup Curette
(2940055)

Straight Ring Curette
(2940056)

10mm Cobb Elevator
(2940057)

18mm Cobb Elevator
(2940059)

Shavers, 45mm Length
8mm (2941608) Green
10mm (2941610) Blue
12mm (2941612) Yellow
14mm (2941614) Brown
16mm (2941616) Purple

Rotate Distractors
8mm (2942026)
10mm (2942028)
12mm (2942030)
14mm (2942032)

Long Suction
(2940200)

Cannulated Reamer T-Handle
(2900165)

Instrument Set *continued*

Disc Preparation Instruments *continued*

Straight Cobb
10mm (2942035)

Wedge Distractor
14mm (2942023)

Osteotome
(2942020)

Straight Cobb
18mm (2942036)

Wedge Distractor
18mm (2942024)

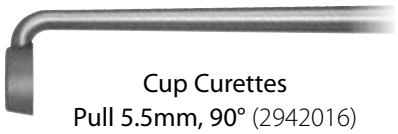
Rasps
Flat (2942018)

Cup Curettes
Push 5.5mm, 90° (2942014)

Uterine Curette
(2942012)

Rasps
Curved (2942019)

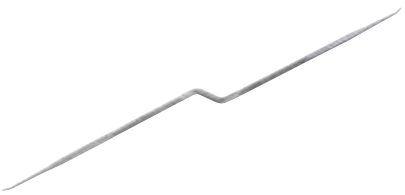
Cup Curettes
Pull 5.5mm, 45° (2942015)



Cup Curettes
Pull 5.5mm, 90° (2942016)

Wide Nerve Root Retractor, Long
(9561554)

6/8mm Distractor
(2940186)



Bayoneted Penfield 4
(9569650)

Instrument Set *continued*

Implant Instruments

18mm Standard Trials 6 degree

8mm Trial/Distractor
45mm (2986845) I
50mm (2986850) II
55mm (2986855) III

10mm Trial/Distractor
45mm (2986045) I
50mm (2986050) II
55mm (2986055) III

12mm Trial/Distractor
45mm (2986245) I
50mm (2986250) II
55mm (2986255) III

14mm Trial/Distractor
45mm (2986445) I
50mm (2986450) II
55mm (2986455) III

16mm Trial/Distractor
45mm (2986645) I
50mm (2986650) II
55mm (2986655) III

22mm DL Trials 6 degree

8mm Trial/Distractor
45mm (2988845)
50mm (2988850)
55mm (2988855)

10mm Trial/Distractor
45mm (2988045)
50mm (2988050)
55mm (2988055)

12mm Trial/Distractor
45mm (2988245)
50mm (2988250)
55mm (2988255)

14mm Trial/Distractor
45mm (2988445)
50mm (2988450)
55mm (2988455)

16mm Trial/Distractor
45mm (2988645)
50mm (2988650)
55mm (2988655)

22mm DL Trials 12 degree

8mm Trial/Distractor
45mm (2989845)
50mm (2989850)
55mm (2989855)

10mm Trial/Distractor
45mm (2989045)
50mm (2989050)
55mm (2989055)

12mm Trial/Distractor
45mm (2989245)
50mm (2989250)
55mm (2989255)

14mm Trial/Distractor
45mm (2989445)
50mm (2989450)
55mm (2989455)

16mm Trial/Distractor
45mm (2989645)
50mm (2989650)
55mm (2989655)

Instrument Set *continued*

Implant Instruments

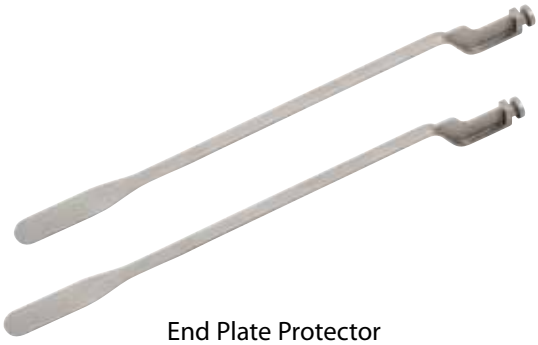
Threaded Inserter
(2982001)

DL Inserter
(2942001)

Removal Tool
(2982002)

Slap Hammer
(9074002)

DL Slap Hammer
(2942049)



End Plate Protector
18mm (2942058)

End Plate Protector
10mm (2942037)

Preoperative Planning

Preoperative planning can be useful in determining:

- Location of the iliac crest and lower ribs in relation to disc space of interest **(Figure 1)**
- Position of the anterior vasculature and posterior nerve structures via axial MRI
- Curvature of the spine **(Figure 2)**

Although infrequent, a few patients may have a deep-seated L4 – L5 disc space that could be difficult to reach via a direct lateral approach, even if table breaking options are employed. Obtaining standing anterior-posterior x-ray images with the patient bending laterally can help determine whether or not a level can be accessed above the iliac crest.

Standard lateral surgical positioning is right lateral decubitus, or left side up; however, the surgeon should consider ease of access and surgeon preference in determining which side to approach. Correction can be achieved equally from either the convex or concave side of the curve. However, approaching from the concave side allows the skin incision to be minimized in some cases.

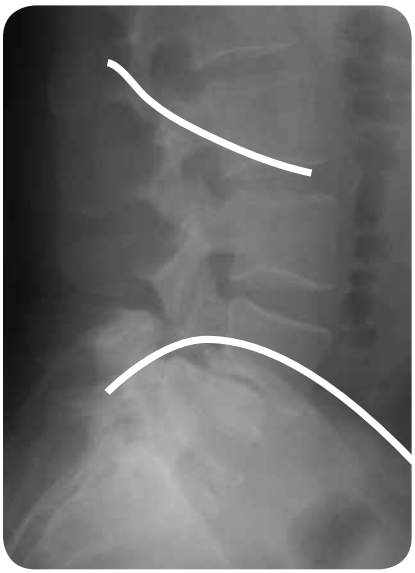


Figure 1

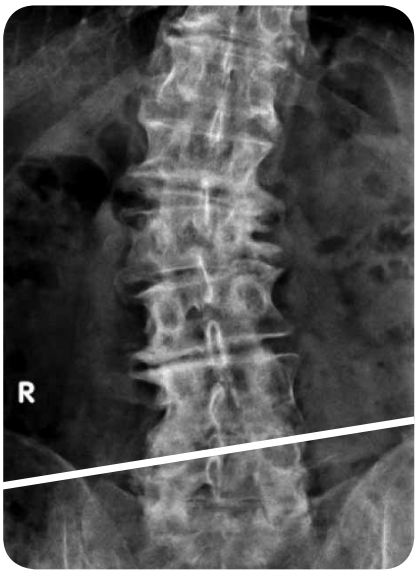


Figure 2

NIM-ECLIPSE® Spinal System Electrode Placement

After the patient is asleep, needle recording electrodes are placed in the innervated muscles in the legs to monitor the affected nerve roots during the procedure. Please follow the instructions below, as well as the accompanying electrode placement guide, to correctly place the electrodes in the appropriate muscles for the desired levels.

1. Electrodes are placed prior to patient draping and the establishment of the sterile field.
2. Clean the areas with alcohol wipes.
3. The green lead ground electrode should be placed between the stimulator and the monitoring electrodes in a location where the bone is close to the skin and the electrode will not contact muscle.
4. The white stimulus return electrode should be placed near the location of stimulation. Connect the Probe lead wire to the instrument jack of the patient interface module.
5. Tape all of the electrodes securely in place and plug the leads into the patient interface box and turn on the NIM-ECLIPSE® Spinal System* to begin monitoring.

Helpful Tip

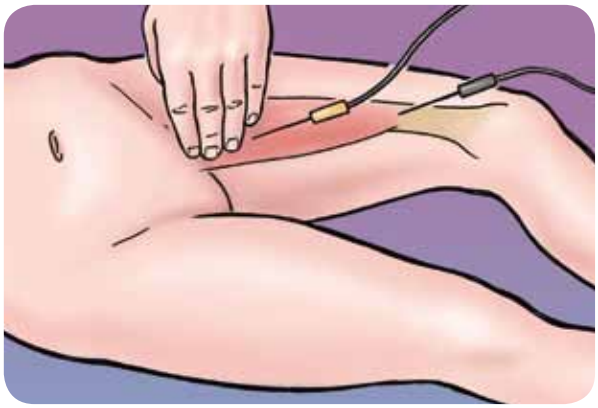
Let the anesthesiologist know EMG monitoring will be used during the procedure to ensure that no neuromuscular blocking agents are administered during monitoring. During intubation, a fast-acting neuromuscular blocking agent should be used.

Active: needle inserted four to five fingerbreadths (fb) below the pubic tubercle and deeply into the palpable muscle belly.

Reference: needle inserted subcutaneously above the active needle.

Channel 1	Left L2 – L3	AL
Channel 5	Right L2 – L3	AL

Sample L2 – L5 Setup

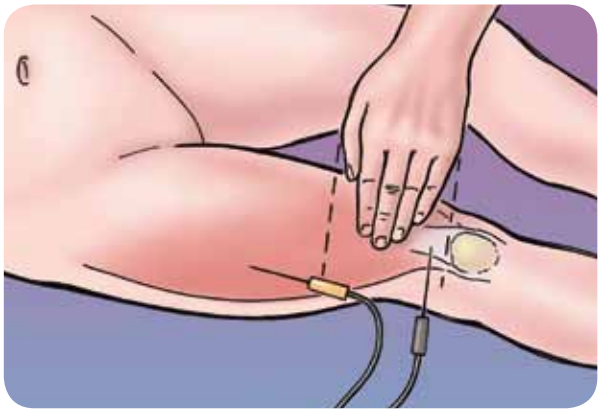


Adductor Longus (AL)

Active: insert needle tangentially but deep into muscle belly one handbreadth above the patella.

Reference: insert needle subcutaneously at patellar tendon.

Channel 2	Left L2 – L4	VL
Channel 6	Right L2 – L4	VL



Vastus Lateralis (VL)

*NIM-ECLIPSE® Spinal System is manufactured by Medtronic Xomed, Inc. Distributed by Medtronic's Spinal and Biologics Business.

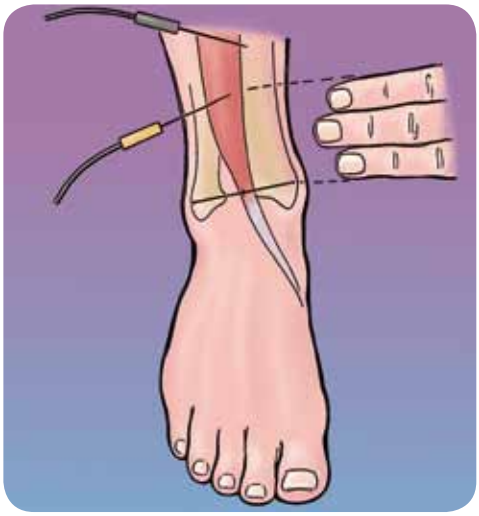
NIM-ECLIPSE® Spinal System Electrode Placement *continued*

Active: insert needle into muscle belly three fb above the midpoint of the bi-malleolar line (lateral to the tibial crest).

Reference: insert needle over the tibial crest (shin).

Channel 3 Left L5 EHL

Channel 7 Right L5 EHL



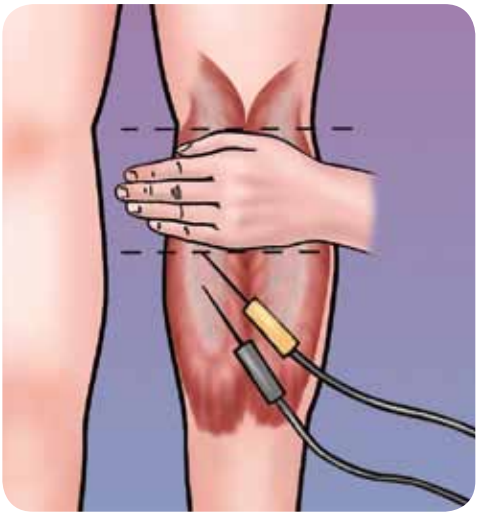
Extensor Hallucis Longus (EHL)

Active: insert needle into the muscle belly one handbreadth below the posterior crease of the knee.

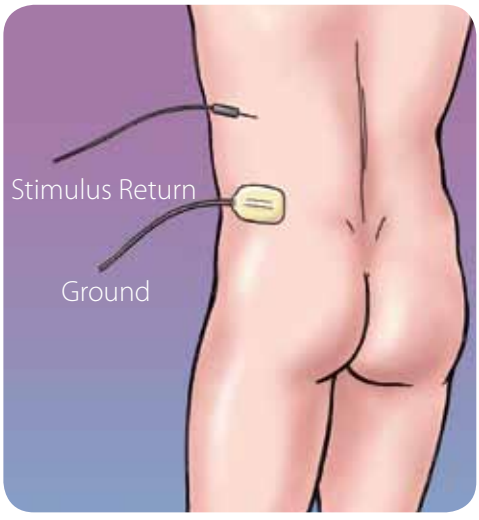
Reference: insert needle subcutaneously 2cm to 3cm away from the active electrode.

Channel 4 Left S1 – S2 GASTROC

Channel 8 Right S1 – S2 GASTROC



Medial Gastrocnemius (GASTROC)



Ground/Stimulus Return

Patient Positioning

The patient is placed in the lateral decubitus position and should be positioned so that the top of the iliac crest is in line with the break of the radiolucent surgical table. An axillary roll is placed to protect the neurovascular structures in the axilla. Padding is placed between the arms to ensure they remain suspended in the neutral position. The top leg of the patient should be flexed in order to relax the psoas muscle and prevent spreading of the nerves across the psoas. Padding is also placed beneath and in between the legs from the knees distally **(Figure 3)**.

The patient is secured to the surgical table with tape at four locations **(Figure 4)**:

1. Just beneath the iliac crest
2. Over the thoracic region, just beneath the shoulder
3. From the back of the table, over the ankle, and past the knee to the front of the table
4. From the shin to the back of the table

Starting in a reverse Trendelenburg position, the head of the table is dropped and a slight flexion is applied to the surgical table. This technique allows for better access to the lumbar spine by increasing the distance between the iliac crest and lower rib as well as by opening up the disc to be entered.

Helpful Tip

For certain tables, the bed must be set up in the reverse position to ensure that the C-arm has adequate room to maneuver under the break of the table.

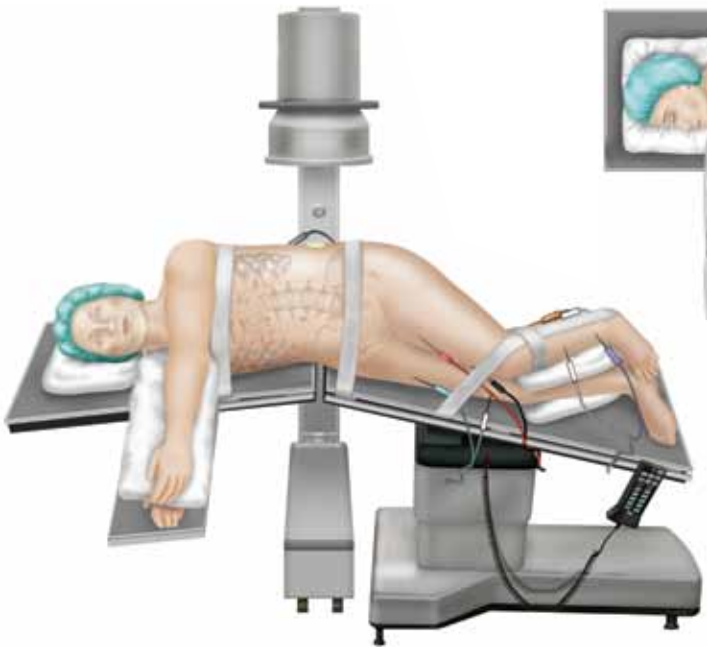


Figure 3

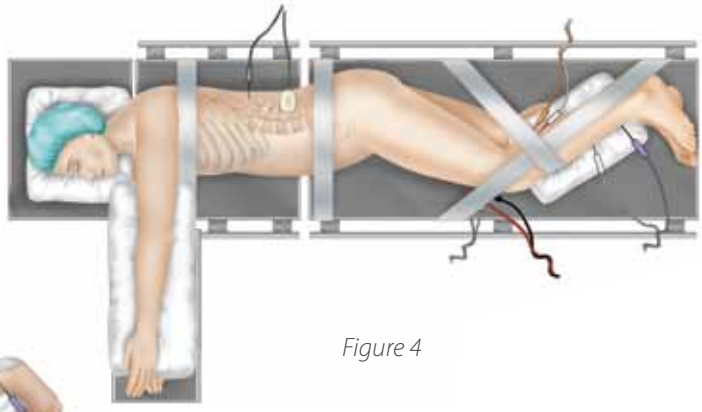


Figure 4

Patient Positioning *continued*

First, a true A/P image should be obtained to ensure the patient is positioned in a true lateral position. On the A/P x-ray, clear, distinct pedicles that are equidistant from the spinous process should be visible **(Figure 5)**. Then a lateral x-ray is obtained and clean, distinct end plates should be seen **(Figure 6)**.

Important

It is critical the C-arm remain in the 0 and 90 degree positions at all times to ensure a safe lateral working channel across the disc space. For multi-level cases, rotate the surgical table independent of the C-arm for each level to re-obtain true images.

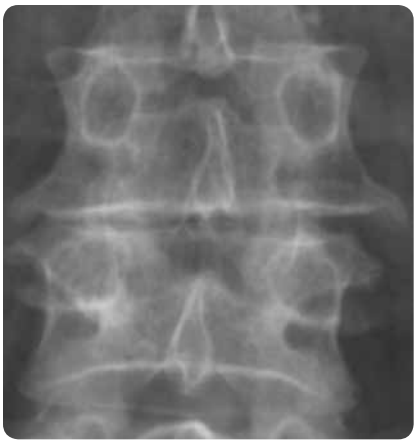


Figure 5

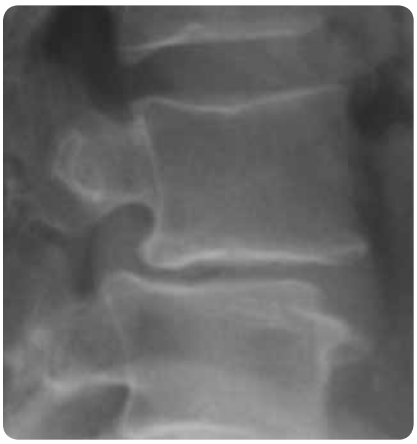


Figure 6

Localization

Fluoroscopy is used to confirm the target segment and mark the location for the initial incision. For a single-level case, the patient should be marked over the midsection of the target disc, and an approximately 3cm horizontal, vertical, or oblique incision can be made **(Figure 7)**. For a two-level case, the patient should be marked over the midsection of the intervening vertebral body **(Figure 8)**.

Helpful Tip

It may be possible to access multiple levels through one vertical skin incision, depending on the anatomy and curvature of the spine. Although a single incision may be used to reach multiple levels, the surgeon must perform separate dilations through the psoas for each operative disc space.

Figure 7

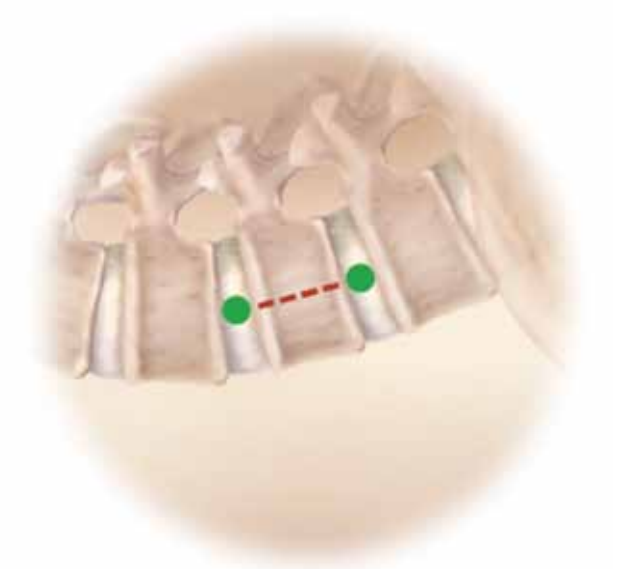


Figure 8

Dissection to the Psoas

Step 1 After making a single skin incision, the subcutaneous fat layers are dissected until the abdominal musculature is reached. A monopolar cautery may be used for hemostasis, and a small self-retaining retractor can be used for initial dissection of the skin and subcutaneous layer.

Step 2 The external oblique fascia will be the first plane encountered and is the only layer that will need to be sharply incised. A Kelly Clamp is then used to bluntly spread through the fibers of the external oblique, internal oblique, and transversalis muscles. All dissection is done in line with the muscle fibers as these muscles layers run in opposite directions. After bluntly penetrating the transversalis fascia, the yellow retroperitoneal fat is exposed **(Figure 9)**.

Step 3 Once inside the retroperitoneal space, the index finger is used to follow the internal abdominal wall posteriorly down to the psoas muscle, which can be visualized. Use of the finger to sweep the peritoneal contents as well as the retroperitoneal fat anteriorly will allow a clear path down to the psoas muscle **(Figure 10)**.

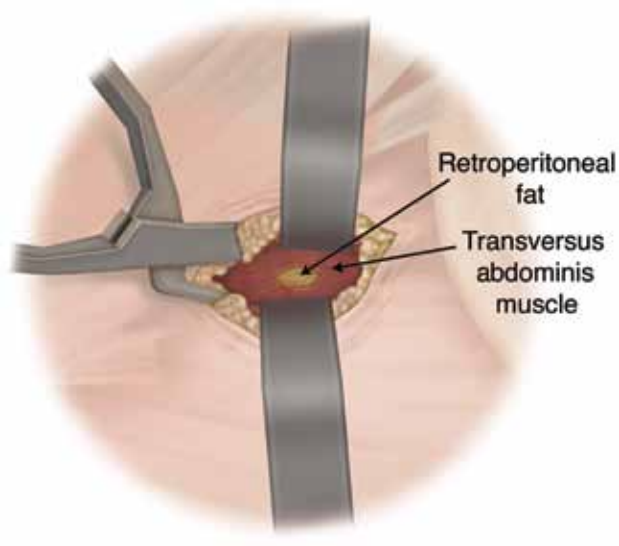


Figure 9

Helpful Tip

Palpating the quadratus muscle, followed by the tip of the transverse process and finally the psoas muscle, will verify that the correct retroperitoneal plane is being entered and ensures that the peritoneum is not compromised.

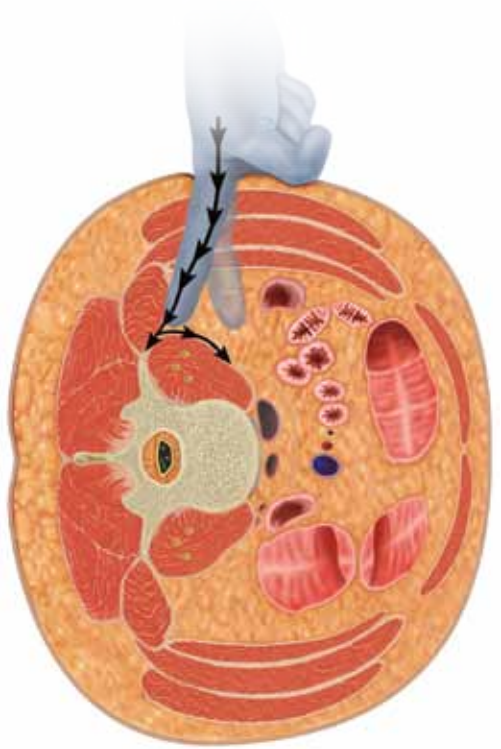


Figure 10

Neuromonitoring through the Psoas

Step 1 After a safe retroperitoneal pathway to the psoas has been established, the NIM® X-PAK Probe is guided down to the psoas while using the finger to protect the peritoneal membrane. The NIM® X-PAK Probe includes an electrified handle stylet assembly and an insulated cannula that enables controlled electrification at the tip of the device **(Figure 11)**.

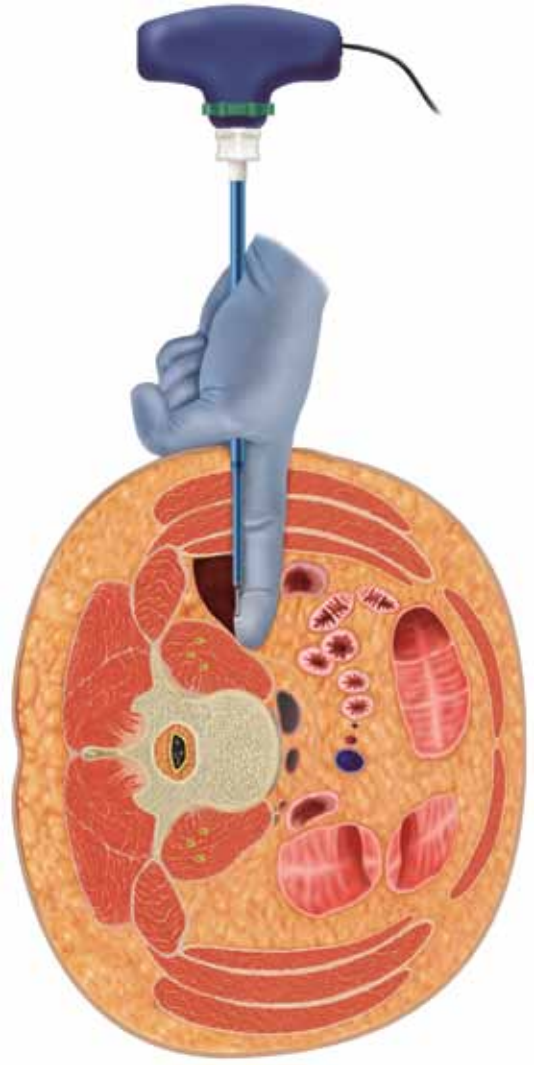


Figure 11

Step 2 A Needle Driver is used to position the NIM® X-PAK Probe onto the top surface of the psoas. The entry point of the NIM® X-PAK Probe into the psoas should be targeted between the anterior half to third of the disc space in order to avoid the nerves of the lumbar plexus and to remain posterior to vascular structures. Cadaver studies have shown that the motor nerves typically reside in the posterior one third of the psoas muscle **(Figure 12)**. Lateral fluoroscopy is used to make adjustments until the NIM® X-PAK Probe is in the proper position **(Figure 13)**.

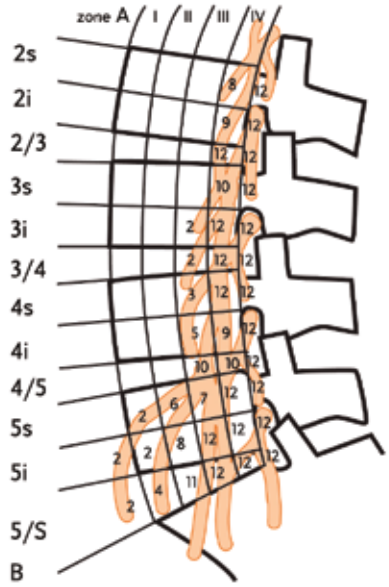


Figure 12

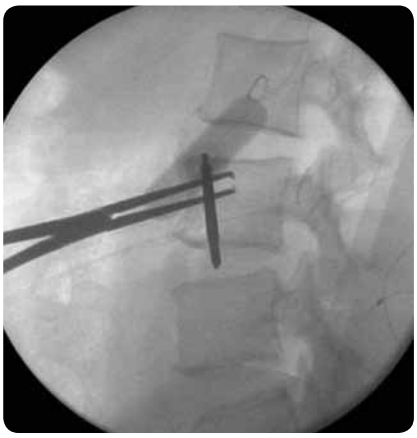


Figure 13

Neuromonitoring through the Psoas *continued*

Step 3 After the proper position has been established, carefully pass the NIM® X-PAK Probe through the psoas muscle. As the fibers of the muscle are being split, current is delivered to monitor for any neural structures. The recommended stimulating current setting is between 6 and 8 milliamps. If an EMG response is generated at this level, the NIM® X-PAK Probe should be repositioned slightly anterior until a nerve-free pathway is located **(Figure 14)**.

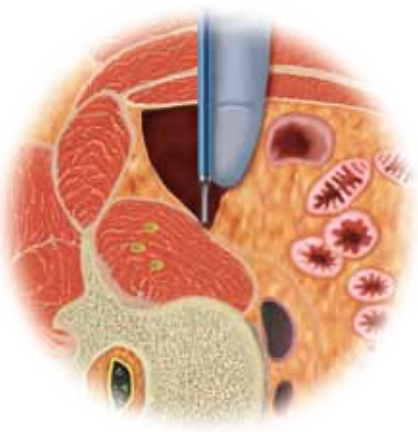


Figure 14

Helpful Tip

*When monitoring with the NIM-ECLIPSE® Spinal System, the surgeon has the additional option of setting the machine to nerve proximity mode. In this mode, the system will send out a cycling current to continuously search for the stimulus threshold required to elicit an EMG response. The displayed current value will decrease as the NIM® X-PAK Probe is moved closer to a nerve. Ensuring threshold values above 8 milliamps is recommended **(Figure 15)**.*

Figure 15

Important

Please see the NIM-ECLIPSE® Spinal System package insert and user's manual for complete instructions and a list of warnings, precautions, and other medical information.

The NIM-ECLIPSE® Spinal System is intended for use to record, monitor, and stimulate/record biopotential signals including electromyograph (EMG), evoked response and nerve/muscle potentials, and for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The system provides feedback to the surgeon and OR team to assist in the localization and assessment of spinal nerves and verification of placement of spinal instrumentation to avoid injury to at-risk nerve roots.

Neuromonitoring through the Psoas *continued*

Step 4 After the NIM® X-PAK Probe has safely dissected through the psoas, the tip of the probe as well as a portion of the insulated cannula should be tapped into the disc space to secure its location **(Figure 16)**.

Step 5 A/P fluoroscopy is used to confirm proper probe alignment into the disc space and the blue stimulating handle is then removed, leaving only the insulated cannula within the disc space. A guidewire is then placed through the cannula into the desired disc space and its position confirmed with A/P fluoroscopy **(Figure 17)**.

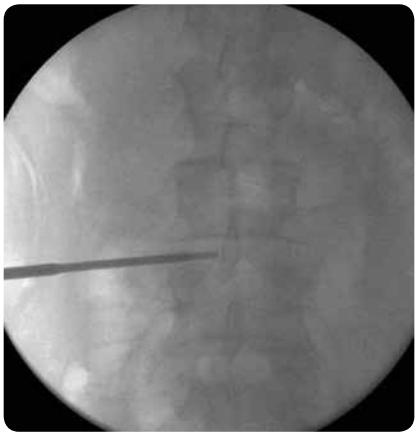


Figure 16

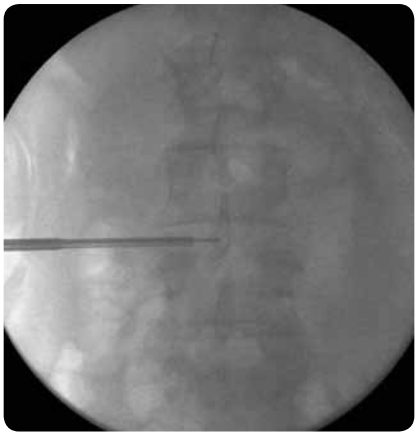


Figure 17

Dilation and Retractor Placement

Step 1 With the Guidewire in place, sequential dilation is used to spread the fibers of the psoas up to a diameter of 22mm, and free-running EMG is active to detect any mechanical effect to the nerve roots **(Figure 18)**.

Step 2 Measure the depth from the skin to the disc space using the graduated markings on the dilators and select the appropriate retractor blades **(Figure 19)**. Attach the blades to the Direct Lateral Retractor base and place the assembly over the Grooved Dilator **(Figure 20)**. The Retractor should be advanced employing a back and forth twisting motion with only gentle downward pressure through the fascia and muscle. This technique helps to ensure the fascial and muscle fibers are not pulled down into the surgical corridor.

Helpful Tip

To minimize the amount of residual muscle, employ a back and forth twisting motion with each dilator and use A/P fluoroscopy to confirm that each dilator has reached the disc space. The first dilator may be extended slightly into the disc space to ensure complete dilation through the psoas muscle.

Important

The grooves on the largest dilator should be aligned cephalad and caudal and must be aligned with the corresponding retractor Stability Pin channels on the blades. Failure to mate the grooves could cause the blades to splay.

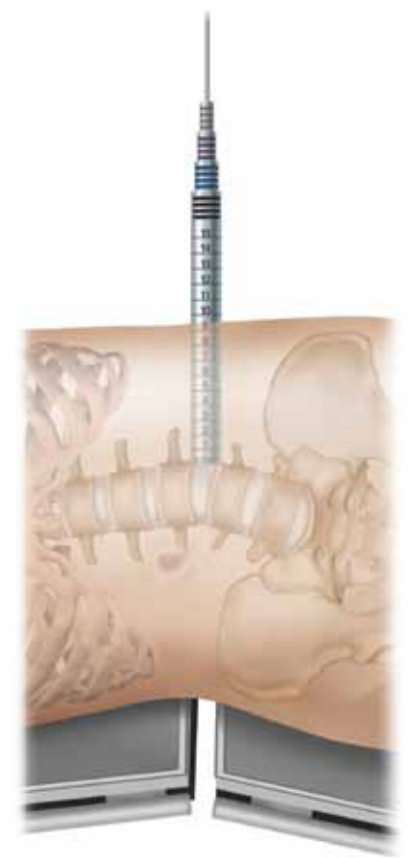


Figure 18

Figure 19

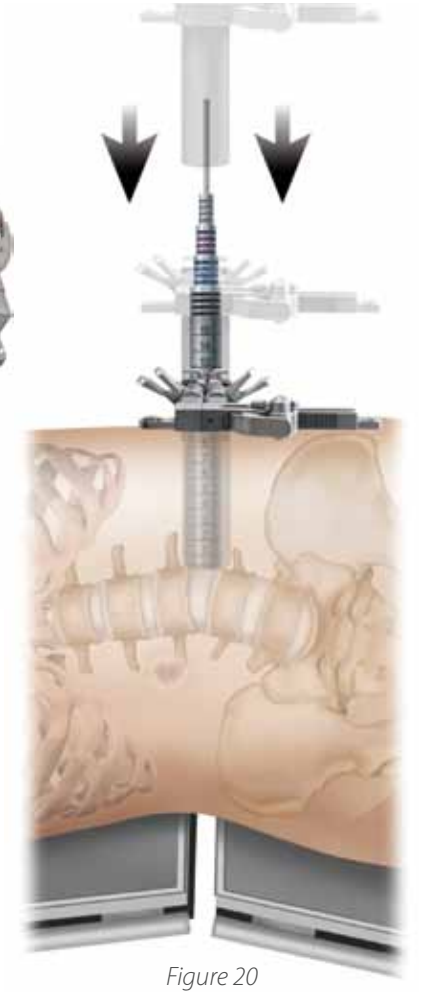


Figure 20

Dilation and Retractor Placement *continued*

Step 3 The Retractor Assembly is then attached to the Flexible Arm using the Rotating Flex Arm Attachment to provisionally maintain retractor position **(Figure 21)**.

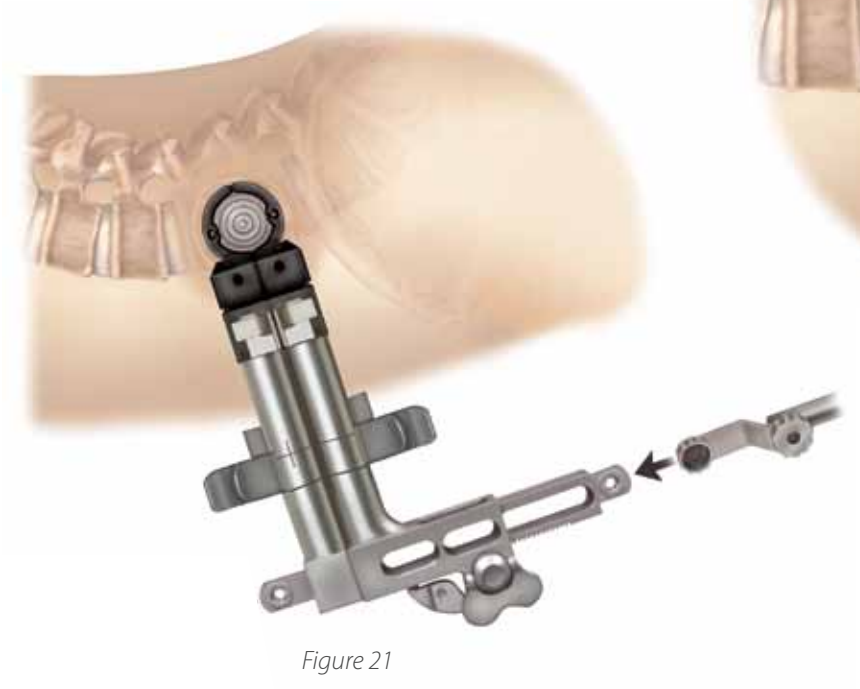


Figure 21

Step 4 Use the NIM-SPINE® Ball-tip Probe to test both Stability Pin channels of the Retractor Blades to ensure a nerve-free pathway before placing a pin **(Figure 22)**.

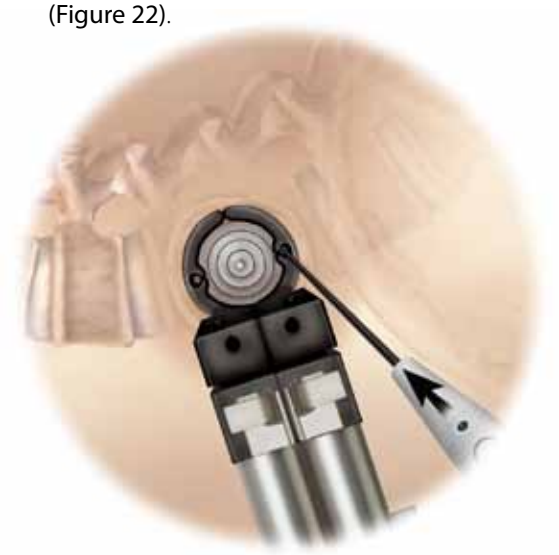


Figure 22

Dilation and Retractor Placement *continued*

Step 5 Insert a Stability Pin through one of the retractor blades to help prevent retractor migration during the procedure **(Figure 23)**. Use the Stability Pin Driver to thread the pin in the channel of whichever blade is closest to the end plate **(Figure 24)**.

Step 6 With the Stability Pin in place, the Dilator Tubes are removed, leaving only the Retractor Assembly and Guidewire. The Guidewire may be left in place as a final reference point to verify position.

Step 7 A final lateral fluoroscopy image is taken to confirm proper retractor placement over the lateral spine **(Figure 25)**.

Important

Placement near the end plate will avoid the middle of the vertebral body where the segmental vessels typically course.

Figure 23

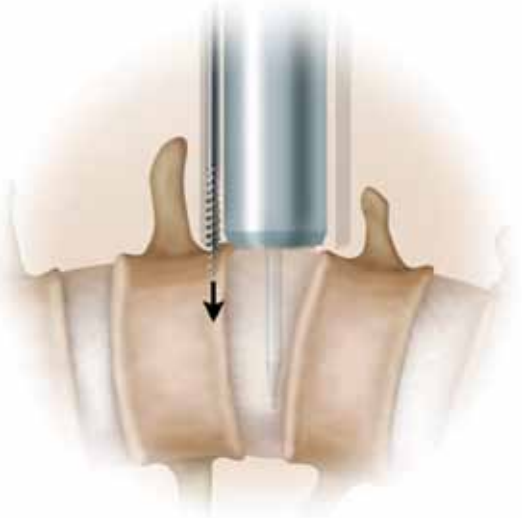


Figure 24

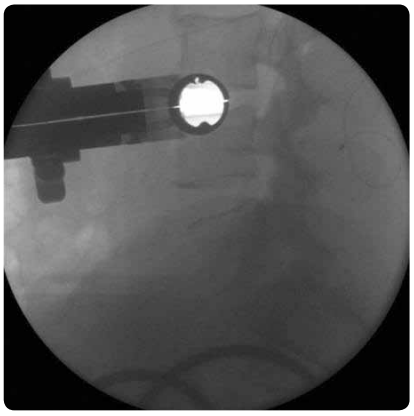


Figure 25

Disc Preparation

Step 1 The MAST QUADRANT® Illumination System is attached to the retractor blades by placing the metal tips of the light source into the holes on the top of the blades and then sliding the tips under the built-in retaining sleeves **(Figure 26)**.

Step 2 Typically, a thin layer of soft tissue will remain at the base of the retractor blades. The NIM-SPINE® Ball-tip Probe is used to stimulate in all four quadrants at the Retractor Base in order to identify any nerve structures that may be present in the residual muscle.

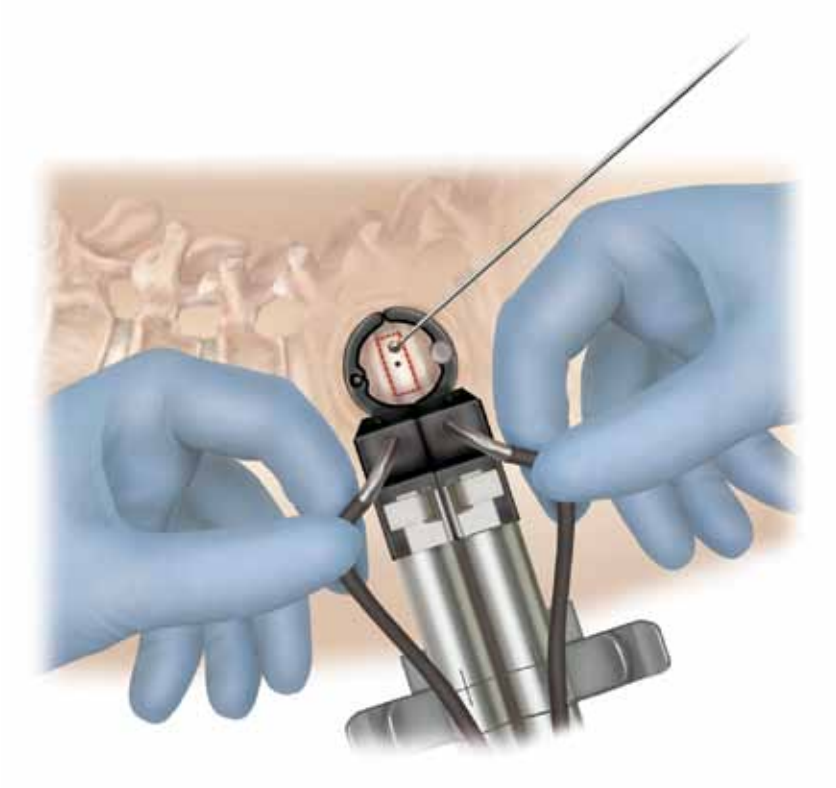


Figure 26

Disc Preparation *continued*

Step 3 A Penfield 4 is then used to sweep the residual muscle off of the disc space until the annulus is visualized.

Step 4 The annulus is then incised and an annulotomy at least 18mm in length is created using the Bayoneted Knife **(Figures 27 and 28)**.

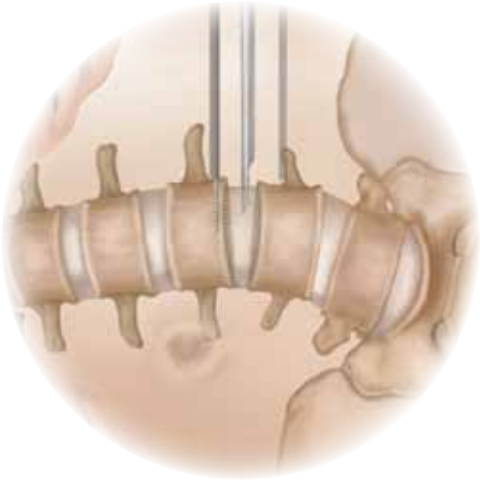


Figure 27

Figure 28

Step 5 A thorough discectomy is then performed using pituitaries and other disc preparation instruments **(Figure 29)**.

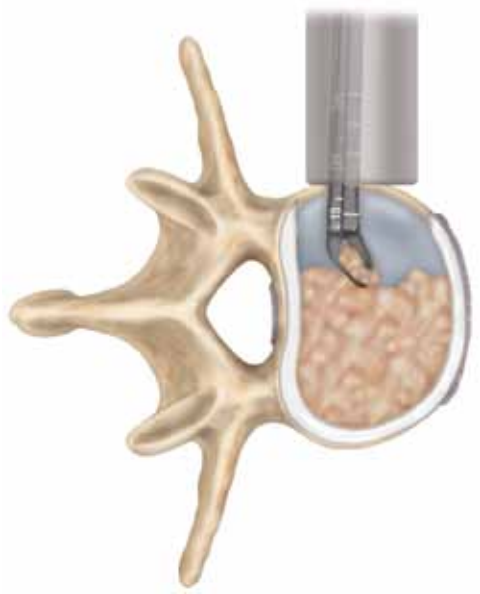


Figure 29

Disc Preparation *continued*

Step 6 A large Cobb is passed along both end plates to the contralateral annulus **(Figure 30)**. A mallet is then used to gently release both the superior and inferior aspects of the contralateral annulus **(Figure 31)**. This step is critical to ensure that appropriate distraction and coronal alignment can be achieved.

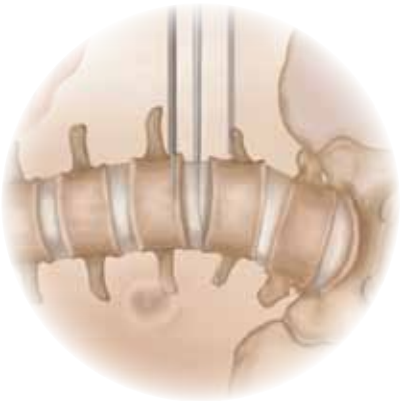


Figure 30

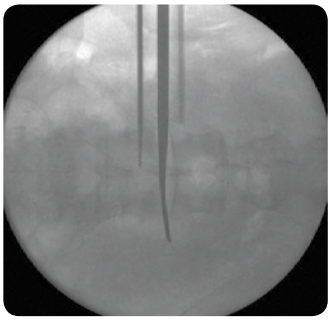


Figure 31

Step 7 A Paddle Style Shaver is placed into the disc space and rotated several times to clean the end plates **(Figures 32 and 33)**. A/P fluoro should be used to center the shaver in the disc before turning. The appropriate sized shavers should be carefully selected to ensure the end plates are not compromised.

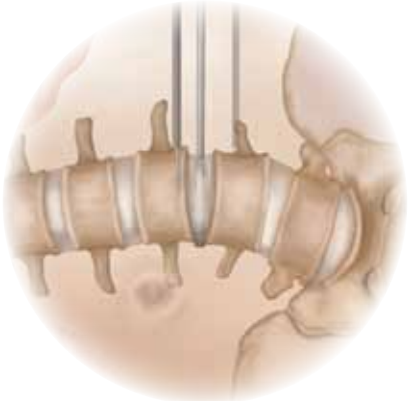


Figure 32

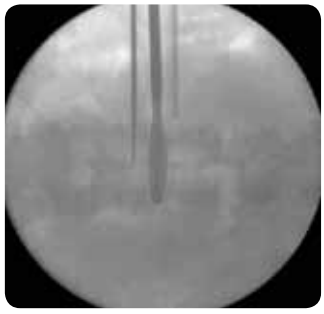


Figure 33

Important

It is important that the working trajectory of the instruments stays perpendicular to the floor in order to avoid injury to vessels or nerve structures.

Disc Preparation *continued*

Step 8 Serrated Curettes, Rasps, a Ring Curette, a Uterine Curette and Combo Tools are used to ensure proper end plate preparation. It is extremely important that the end plates be meticulously prepared for fusion by removing the cartilaginous disc without destroying the cortical end plates (**Figures 34 and 35**).

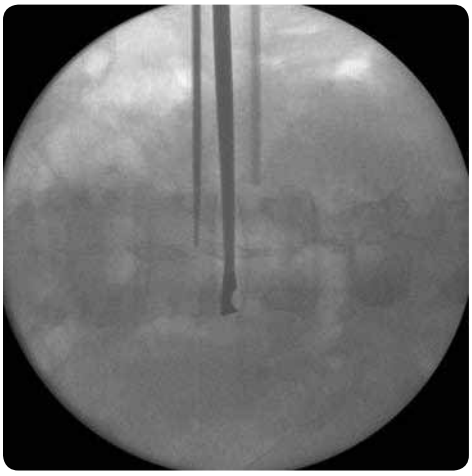


Figure 34

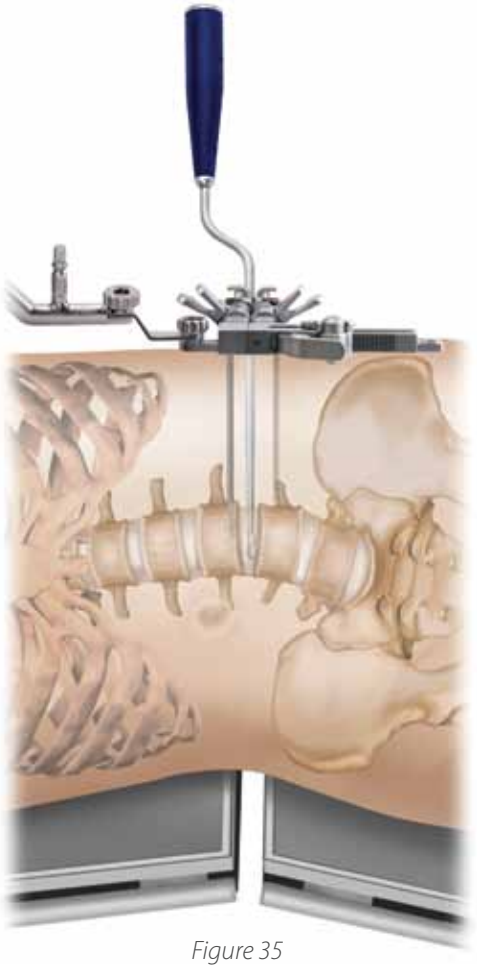


Figure 35

Trialing

Step 1 The disc space is sequentially distracted with Trials until adequate disc space height is obtained and adequate foraminal size is restored.

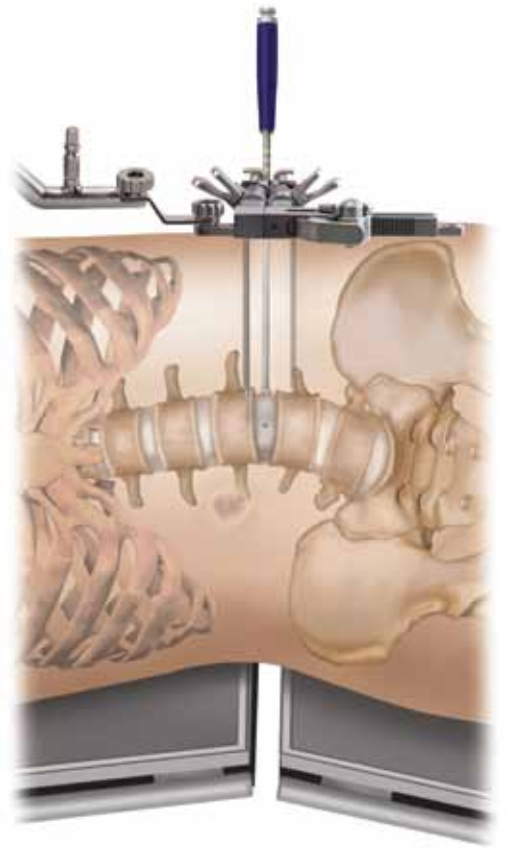


Figure 36

Important

When using 22mm trials, it may be necessary to open the retractor blades to allow the passing of the larger trial. To minimize tissue creep, the medial/lateral rack and associated anterior/posterior blades may be utilized as shown in ***Figures 36A and 36B****.*

Figure 36A

Figure 36B

Step 2 The Trial is passed through the Retractor and impacted into the disc space. A properly sized Trial should be centered with the spinous process and span the ring apophysis in order to reach fully across the vertebral body end plate **(Figures 36 and 37)**.

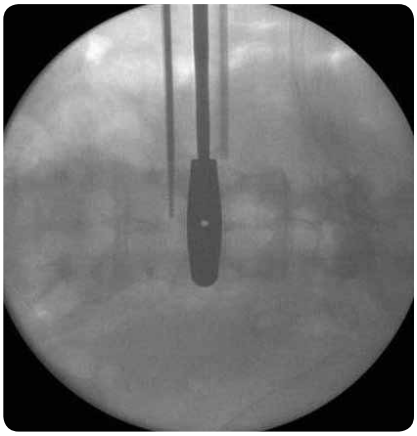


Figure 37

Implant Placement

Step 1 Once trialing is complete, the corresponding CLYDESDALE® Spinal System implant is attached to the Inserter **(Figure 38)** or the optional DL Inserter. The DL Inserter utilizes sleeves for graft containment. The sleeves must be retracted to attach the implant. If using a lordotic implant, take note of the anterior side of the implant, marked "ANTERIOR."

Figure 38

Step 2 Before inserting the CLYDESDALE® Spinal System device, place the autograft in the implant's central cavity. If using the DL Inserter, slightly extend the sleeves to cover the implant's graft chamber **(Figure 39)** or fully extend the sleeves to cover entire implant **(Figure 40)** by unthreading the nut from outer sleeve.

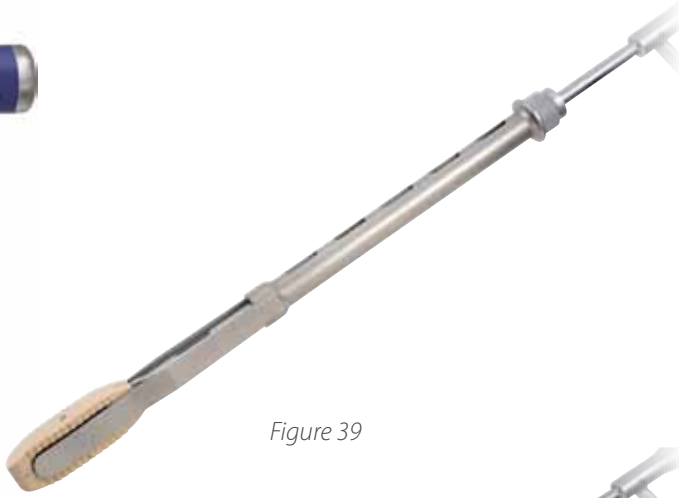


Figure 39

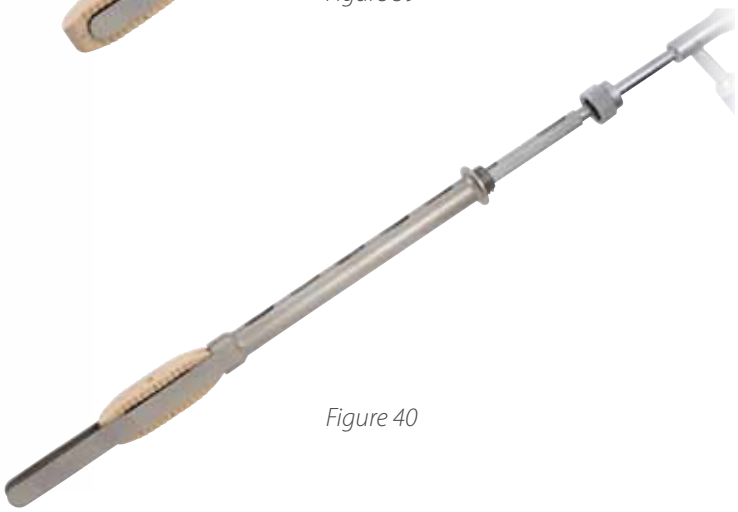


Figure 40

Important

For disassembly/reassembly and cleaning information on the DL Inserter (part number 2942001), refer to the Cleaning section of the CLYDESDALE® Spinal System Important Product Information beginning on page 34 of this surgical technique.

Implant Placement *continued*

Step 3 Carefully insert the sleeves into the disc space if using the DL Inserter. A mallet is then used to gently insert the implant while monitoring placement under A/P fluoroscopy **(Figure 41)**. Care should be taken to ensure the CLYDESDALE® Spinal System implant is aligned properly **(Figure 42)**.

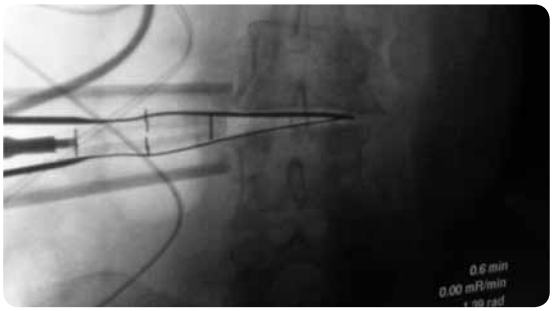


Figure 41

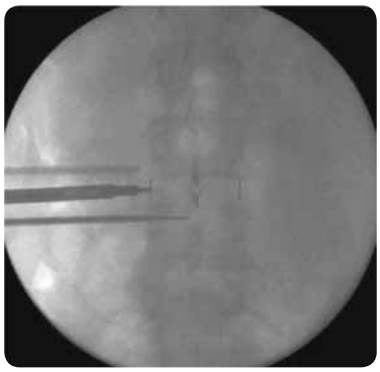


Figure 42

Step 4 After the implant is positioned in the center of the disc space from a medial/lateral perspective, the Inserter is unthreaded from the implant and removed **(Figures 43 and 44)**.

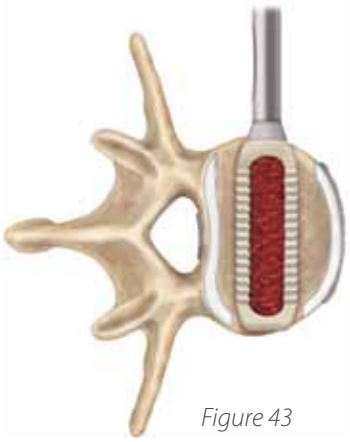


Figure 43

Figure 44

Closure

Step 1 After the autograft material has been inserted into the disc space, the Stability Pin may be unthreaded and removed.

Step 2 The Retractor is then detached from the Flex Arm and the Retractor Blades are carefully withdrawn from the surgical site. As the Retractor is removed, the muscle and fat layers can be visualized closing back into place.

Step 3 The surgical site is irrigated appropriately and the fascia over the external oblique is then closed with interrupted synthetic absorbable suture.

Step 4 Finally, the subcutaneous layers and skin are closed and the skin is sealed with skin adhesive.

Explantation

Should it be necessary to remove or reposition the CLYDESDALE® Spinal System device, the Removal Tool may be used.

To remove the implant, first fit the tips of the Removal Tool with the divots at the end of the implant **(Figure 45)**. Next, depress the trigger to lock onto the implant. Finally, attach the Slap Hammer to the Removal Tool and gently impact the Slap Hammer to facilitate implant removal **(Figure 46)**.

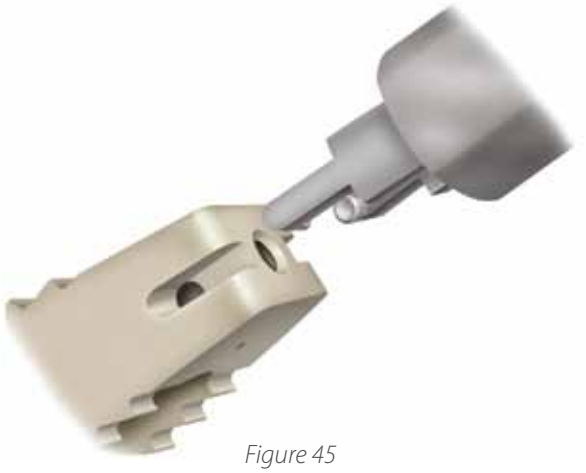


Figure 45

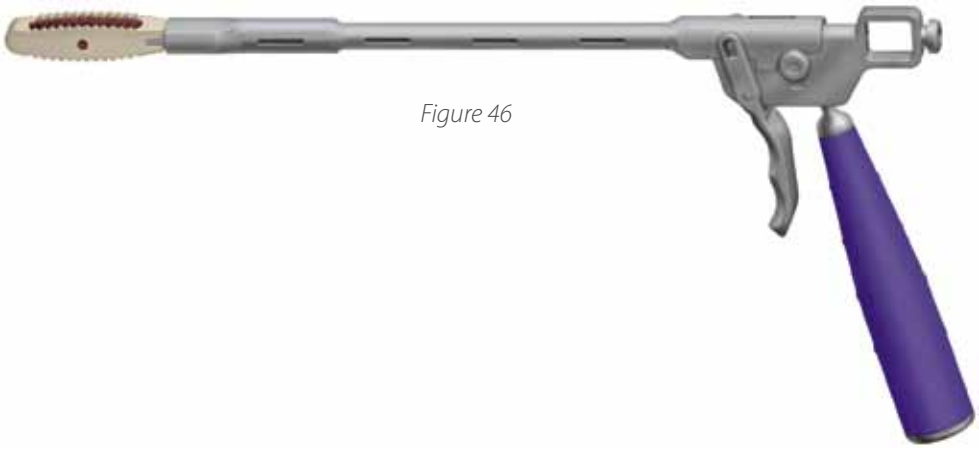
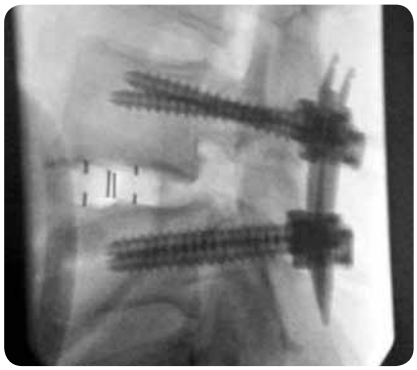


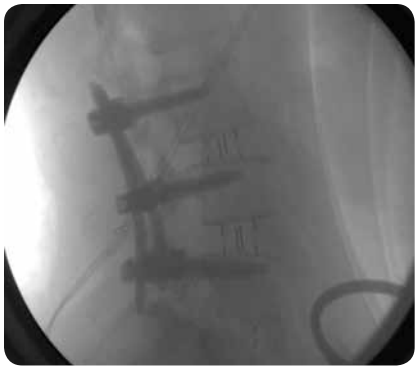
Figure 46

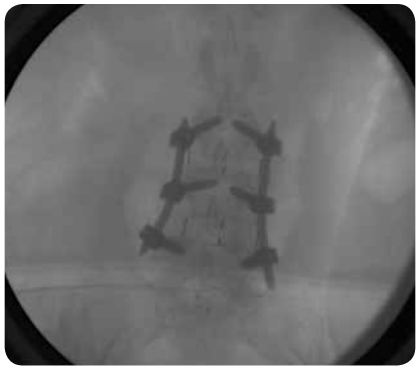
Fixation

Supplemental instrumentation is then placed according to the appropriate surgical technique. The CLYDESDALE® Spinal System can be used with any Medtronic posterior or anterior fixation system.



» CD HORIZON® SEXTANT® II Percutaneous Rod Insertion System





» CD HORIZON® LONGITUDE® Multi-level Percutaneous Fixation System

Product Ordering Information

INSTRUMENT CASE 1

SPS02028 – Retractor and Kerrison Pituitary Trays

Part Number	Description	Set Quantity
Retractor, Blades, Pins, and Driver		
9569000	Retractor Base	1
9568010	Rotating Flex Arm Attachment	1
9567319	9cm Retractor Blade Internal Pin, Right	1
9567309	9cm Retractor Blade Internal Pin, Left	1
9567310	10cm Retractor Blade Internal Pin, Right	1
9567300	10cm Retractor Blade Internal Pin, Left	1
9567311	11cm Retractor Blade Internal Pin, Right	1
9567301	11cm Retractor Blade Internal Pin, Left	1
9567312	12cm Retractor Blade Internal Pin, Right	1
9567302	12cm Retractor Blade Internal Pin, Left	1
9567313	13cm Retractor Blade Internal Pin, Right	1
9567303	13cm Retractor Blade Internal Pin, Left	1
9567315	15cm Retractor Blade Internal Pin, Right	1
9567305	15cm Retractor Blade Internal Pin, Left	1
9569309	9cm Blade Pin	2
9569310	10cm Blade Pin	2
9569311	11cm Blade Pin	2
9569312	12cm Blade Pin	2
9569313	13cm Blade Pin	2
9569315	15cm Blade Pin	2
8970400	Stability Pin Driver	1
Dilators		
9560420	5.3mm Dilator	1
9561421	10.6mm Dilator	1
9561422	16.0mm Dilator	1
9561424	20.8mm Grooved Dilator	1
Guidewires		
8670002	Guidewire Sharp (long)	2
8670005	Guidewire – Trocar Tip 1.6mm, 350mm (short)	2
Kerrisons and Pituitaries		
2940068	3mm Rotate Kerrison Punch	1
2940069	5mm Rotate Kerrison Punch	1
2940075	Pituitary Rongeur, 4mm × 10mm Straight	1
2940076	Pituitary Rongeur, 4mm × 10mm Up	1

INSTRUMENT CASE 2

SPS02027 – CLYDESDALE® Trial and Inserter Removal Trays

Part Number	Description	Set Quantity
Trials		
2986845	8mm × 45mm DL Trial	1
2986850	8mm × 50mm DL Trial	1
2986855	8mm × 55mm DL Trial	1
2986045	10mm × 45mm DL Trial	1
2986050	10mm × 50mm DL Trial	1
2986055	10mm × 55mm DL Trial	1
2986245	12mm × 45mm DL Trial	1
2986250	12mm × 50mm DL Trial	1
2986255	12mm × 55mm DL Trial	1
2986445	14mm × 45mm DL Trial	1
2986450	14mm × 50mm DL Trial	1
2986455	14mm × 55mm DL Trial	1
2986645	16mm × 45mm DL Trial	1
2986650	16mm × 50mm DL Trial	1
2986655	16mm × 55mm DL Trial	1
Instruments		
9074002	Slap Hammer	1
2982002	DL Removal Tool	1
2982001	Threaded Inserter	1

DISPOSABLE CASES

SPS00589 – Disposables

Part Number	Description	Set Quantity
NIM-SPINE® Probes, Dilator, Light Source, and Knife		
9450015	NIM-SPINE® 23cm Ball-tip Probe	1
9450069	NIM® X-PAK Probe	1
9560658	MAST QUADRANT® Illumination System	1
9450070	5.3mm Dilator (Plastic)	1
9560659	Bayoneted Discectomy Knife	1

INSTRUMENT CASE 3

SPS00586 – Flex Arm Tray

Part Number	Description	Set Quantity
Flex Arm and Attachment		
9561523	Bed Rail Clamp	1
9561524	Flexible Arm	1

Product Ordering Information *continued*

INSTRUMENT CASE 4

SPS02029 – Instrument Trays 1 and 2

Part Number	Description	Set Quantity
Disc Preparation Instruments Tray 1		
2940050	Combo Tool	1
2940051	Angled Combo Tool	1
2940052	Reverse Angle Combo Tool	1
2940053	Straight Serrated Cup Curette	1
2940054	Angled Serrated Cup Curette	1
2940055	Reverse Angle Serrated Cup Curette	1
2940056	Straight Ring Curette	1
2940057	10mm Cobb Elevator	1
2940059	18mm Cobb Elevator	1
Disc Preparation Instruments Tray 2		
2940186	6/8mm Distractor	1
9561554	Wide Nerve Root Retractor, Long	1
9569650	Bayoneted Penfield 4 Push/Pull, Long	1
2940200	Long Suction	2
2900165	Cannulated Reamer T-Handle	2
2941608	8mm Shaver, 45mm length	1
2941610	10mm Shaver, 45mm length	1
2941612	12mm Shaver, 45mm length	1
2941614	14mm Shaver, 45mm length	1
2941616	16mm Shaver, 45mm length	1

DL SUPPORT SET - DISC PREPARATION INSTRUMENTS

SPS02408 - Disc Preparation Tray 1

Part Number	Description	Set Quantity
2942001	DL Inserter	1
2942049	DL Slap Hammer	1
2942037	10mm Endplate Protector	2
2942058	18mm Endplate Protector	2
2942026	8mm Rotate Distractor	1
2942028	10mm Rotate Distractor	1
2942030	12mm Rotate Distractor	1
2942032	14mm Rotate Distractor	1
2942020	Osteotome	1
2942017	Dilator Holder	1
74-619-106	6mm Pituitary Rongeur	1

DL SUPPORT SET - DISC PREPARATION INSTRUMENTS

SPS02408 - Disc Preparation Tray 2

Part Number	Description	Set Quantity
2942035	10mm Straight Cobb	1
2942036	18mm Straight Cobb	1
2942014	5.5mm 90 degree Push Curette	1
2942015	5.5mm 45 degree Pull Curette	1
2942016	5.5mm 90 degree Pull Curette	1
2942012	Uterine Curette	1
2942018	Flat Rasp	1
2942019	Curved Rasp	1
2942023	14mm Wedge Distractor	1
2942024	18mm Wedge Distractor	1

DL SUPPORT SET - ACCESS INSTRUMENTS

SPS02409 - Access Instrument Tray 1

Part Number	Description	Set Quantity
9569324	14mm Stability Pin	2
9569326	16mm Stability Pin	2
9569327	17mm Stability Pin	2
9567314	DL Blade Right 14cm	1
9567304	DL Blade Left 14cm	1
9567316	DL Blade Right 16cm	1
9567306	DL Blade Left 16cm	1
9567317	DL Blade Right 17cm	1
9567307	DL Blade Left 17cm	1
2942022	Access Handle Left	1
2942050	Access Handle Right	1
2942011	Retractor Opener	2

DL SUPPORT SET - ACCESS INSTRUMENTS

SPS02409 - Access Instrument Tray 2

Part Number	Description	Set Quantity
9568008	Medial Lateral Rack Assembly	1
2942002	9cm Anterior/Posterior Blade	2
2942003	10cm Anterior/Posterior Blade	2
2942004	11cm Anterior/Posterior Blade	2
2942005	12cm Anterior/Posterior Blade	2
2942006	13cm Anterior/Posterior Blade	2
2942007	14cm Anterior/Posterior Blade	2
2942008	15cm Anterior/Posterior Blade	2
2942009	16cm Anterior/Posterior Blade	2
2942010	17cm Anterior/Posterior Blade	2

Product Ordering Information *continued*

CLYDESDALE® 22mm DL Trials
SPS02418

Part Number	Description
6° CLYDESDALE® 22mm Trial Set	
2988845	8mm × 45mm
2988850	8mm × 50mm
2988855	8mm × 55mm
2988045	10mm × 45mm
2988050	10mm × 50mm
2988055	10mm × 55mm
2988245	12mm × 45mm
2988250	12mm × 50mm
2988255	12mm × 55mm
2988445	14mm × 45mm
2988450	14mm × 50mm
2988455	14mm × 55mm
2988645	16mm × 45mm
2988650	16mm × 50mm
2988655	16mm × 55mm

CLYDESDALE® 22mm DL Trials
SPS02419

Part Number	Description
12° CLYDESDALE® 22mm Trial Set	
2989045	10mm × 45mm
2989050	10mm × 50mm
2989055	10mm × 55mm
2989245	12mm × 45mm
2989250	12mm × 50mm
2989255	12mm × 55mm
2989445	14mm × 45mm
2989450	14mm × 50mm
2989455	14mm × 55mm
2989645	16mm × 45mm
2989650	16mm × 50mm
2989655	16mm × 55mm

Product Ordering Information *continued*

CLYDESDALE® SPINAL SYSTEM IMPLANTS

Part Number	Description
6° CLYDESDALE® Spinal System SPS02156	
2968840	8mm × 40mm
2968845	8mm × 45mm
2968850	8mm × 50mm
2968855	8mm × 55mm
2968860	8mm × 60mm
2968040	10mm × 40mm
2968045	10mm × 45mm
2968050	10mm × 50mm
2968055	10mm × 55mm
2968060	10mm × 60mm
2968240	12mm × 40mm
2968245	12mm × 45mm
2968250	12mm × 50mm
2968255	12mm × 55mm
2968260	12mm × 60mm
2968440	14mm × 40mm
2968445	14mm × 45mm
2968450	14mm × 50mm
2968455	14mm × 55mm
2968460	14mm × 60mm
2968640	16mm × 40mm
2968645	16mm × 45mm
2968650	16mm × 50mm
2968655	16mm × 55mm
2968660	16mm × 60mm

CLYDESDALE® SPINAL SYSTEM IMPLANTS

Part Number	Description
0° CLYDESDALE® Spinal System SPS02157	
2969840	8mm × 40mm
2969845	8mm × 45mm
2969850	8mm × 50mm
2969855	8mm × 55mm
2969040	10mm × 40mm
2969045	10mm × 45mm
2969050	10mm × 50mm
2969055	10mm × 55mm
2969240	12mm × 40mm
2969245	12mm × 45mm
2969250	12mm × 50mm
2969255	12mm × 55mm
2969440	14mm × 40mm
2969445	14mm × 45mm
2969450	14mm × 50mm
2969455	14mm × 55mm
2969640	16mm × 40mm
2969645	16mm × 45mm
2969650	16mm × 50mm
2969655	16mm × 55mm

Product Ordering Information *continued*

CLYDESDALE® SPINAL SYSTEM IMPLANTS

Part Number	Description
6° CLYDESDALE® 22mm Spinal System SPS02416	
2926840	8mm × 40mm
2926845	8mm × 45mm
2926850	8mm × 50mm
2926855	8mm × 55mm
2926860	8mm × 60mm
2926040	10mm × 40mm
2926045	10mm × 45mm
2926050	10mm × 50mm
2926055	10mm × 55mm
2926060	10mm × 60mm
2926240	12mm × 40mm
2926245	12mm × 45mm
2926250	12mm × 50mm
2926255	12mm × 55mm
2926260	12mm × 60mm
2926440	14mm × 40mm
2926445	14mm × 45mm
2926450	14mm × 50mm
2926455	14mm × 55mm
2926460	14mm × 60mm
2926640	16mm × 40mm
2926645	16mm × 45mm
2926650	16mm × 50mm
2926655	16mm × 55mm
2926660	16mm × 60mm

CLYDESDALE® SPINAL SYSTEM IMPLANTS

Part Number	Description
12° CLYDESDALE® 22mm Spinal System SPS02417	
2922040	10mm × 40mm
2922045	10mm × 45mm
2922050	10mm × 50mm
2922055	10mm × 55mm
2922240	12mm × 40mm
2922245	12mm × 45mm
2922250	12mm × 50mm
2922255	12mm × 55mm
2922440	14mm × 40mm
2922445	14mm × 45mm
2922450	14mm × 50mm
2922455	14mm × 55mm
2922640	16mm × 40mm
2922645	16mm × 45mm
2922650	16mm × 50mm
2922655	16mm × 55mm
2922660	16mm × 55mm

Important Product Information

IMPORTANT INFORMATION ON CLYDESDALE® SPINAL SYSTEM

PURPOSE

This device is a PEEK (POLYETHERETHERKETONE) interbody fusion device intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

DESCRIPTION

The CLYDESDALE® Spinal System consists of PEEK cages of various widths and heights, which include Tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability.

INDICATIONS

The CLYDESDALE® Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE® Spinal System is used for patients diagnosed with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. **These implants may be implanted via a minimally invasive lateral approach.**

CONTRAINDICATIONS

This device is not intended for cervical spine use.

Contraindications include, but are not limited to:

- Infection, local to the operative site
- Signs of local inflammation,
- Fever or leukocytosis,
- Morbid obesity,
- Pregnancy,
- Mental illness,
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials,
- Any case not needing a fusion,
- Any case not described in the indications,
- Any patient unwilling to cooperate with postoperative instructions.
- Patients with a known hereditary or acquired bone friability or calcification problem.
- Pediatric cases or where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- **Severe bone resorption.**
- **Osteomalacia**
- **Severe osteoporosis.**

POTENTIAL ADVERSE EVENTS

Adverse effects may occur when the device is used either with or without associated instrumentation.

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

- Implant migration.
- Breakage of the device(s).
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
- Pressure on the surrounding tissues or organs.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis).
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury.
- Cerebral spinal fluid leakage.
- Haemorrhage of blood vessels and/or hematomas.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Bone graft donor site complication.
- Inability to resume activities of normal daily living.
- Early or late loosening or movement of the device(s).
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Loss of or increase in spinal mobility or function.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Cessation of any potential growth of the operated portion of the spine.
- Death.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and / or alcohol / drug abuse patients and those with poor muscle and bone quality and / or nerve paralysis are also poor candidates for spinal fusion.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

A device that has been implanted should never be reused, reprocessed or resterilized under any circumstances. Sterile packaged devices should also never be resterilized. Reuse, reprocessing, or resterilization may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

!USA FOR US AUDIENCES ONLY

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

MRI INFORMATION

The CLYDESDALE® Spinal System has not been evaluated for safety,,compatibility, heating, or migration in the MR environment.

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. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the human anatomy. Unless great care is taken in patient selection, placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage or loosening of the device before the fusion process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by MEDTRONIC. In the interests of patient safety, it is therefore recommended that MEDTRONIC implants are not used with devices from any other source.

Never, under any circumstances, reuse a CLYDESDALE® Spinal System device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and / or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be taken in the handling and storage of the device(s). They should not be scratched or damaged. Devices should be protected during storage especially from corrosive environments.
- Further information about this system will be provided upon request.
- The surgeon should be familiar with the various devices before use and should personally verify that all devices are present before the surgery begins.
- The size of device for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

Important Product Information *continued*

- Unless supplied sterile, all devices should be cleaned and sterilized before use. Additional sterile components should be available in case of any unexpected need.

INTRAOPERATIVE

- The instructions in any available CLYDESDALE® Spinal System surgical technique manual should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
- To assure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
- Bone cement should not be used, because this material may make removal of these components difficult or impossible. The heat generated from the curing process may damage or deform the PEEK devices.

POSTOPERATIVE

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

- Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and / or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity, or sudden jolts or shock to the spine.
- The patient should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
- The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and / or break, the devices should be revised and / or removed immediately before serious injury occurs.
- CLYDESDALE® Spinal System implants are interbody devices and are intended to stabilize the operative area during the fusion process.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING

Devices may be supplied in a sterile or non-sterile form. Packages for each of the components should be intact upon receipt. Once the seal on the sterile package has been broken, the product should not be re-sterilized. 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

Disassembly/reassembly and cleaning instructions can be found at http://manuals.medtronic.com/. Refer to the "Reprocessing Instructions for the Direct Lateral (DL) Inserter– M708348B087" for disassembly and cleaning instructions specific to the DL Inserter instrument (part number 2942001). Refer to the "Reprocessing Instructions for the General Instruments" 0380035 for cleaning instructions for CLYDESDALE® Spinal System trials.

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:

Table 1: Sterilization cycle parameters for the United States and its territories below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	MINIMUM DRY TIME[1]
Steam	Gravity Displacement	250°F (121°C)	30 Minutes	30 Minutes
Steam	Gravity Displacement	270°F (132°C)	15 Minutes	30 Minutes
Steam	Gravity Displacement	275°F (135°C)	10 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	270°F (132°C)	4 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	275°F (135°C)	3 Minutes	16 Minutes

For Medical Facilities Located Outside the United States and its territories: 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.

Table 2: Sterilization cycle parameters for medical facilities outside the United States and its territories

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	MINIMUM DRY TIME[1]
Steam	Gravity Displacement	273°F (134°C)	20 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	273°F (134°C)	4 Minutes	30 Minutes
Steam	Dynamic-Air-Removal	273°F (134°C)	20 Minutes	30 Minutes

[1] The minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, exposure times) used for their equipment.

The sterilization cycles listed in Table 2 above are not considered by the Food and Drug Administration to be standard sterilization cycles. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

Sterilization instructions can be found at http://manuals.medtronic.com/. Refer to the "Reprocessing Instructions for the Direct Lateral (DL) Inserter– M708348B087" for the sterilization instructions specific to the DL Inserter instrument (part number 2942001). Refer to the "Reprocessing Instructions for the General Instruments" 0380035 for sterilization instructions for CLYDESDALE® Spinal System trials.

SERVICING

Inspect all instruments prior to use. Please return the instrument to Medtronic if any of the following are observed: corrosion, discoloring, pitting, or any other signs of wear.

Inspect the threaded shaft of the inserter instrument. Please return the instrument to Medtronic if threads are damaged or distorted or if the shaft appears bent.

Inspect the silicone handle of the inserter instrument. Please return the instrument to Medtronic if the silicone handle is discolored, cut, or damaged in any way.

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 or 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.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact MEDTRONIC.

EC REP

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Covered by one or more of U.S. Pat. Nos. 5,772,661; 5,860,973; 6,991,654; 7,125,425; and other pending patent applications.

EXPLANATION OF SYMBOLS

Symbol	Definition
EC REP	Authorised Representative in the European Community
Rx only	CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.
	Consult Instructions for Use
2	Do Not Reuse
LOT	Batch Code
	Manufacturer
REF	Catalog Number
NON STERILE	Non-sterile
!USA	For US audiences Only
CE 0123	The device complies with European Directive MDD 93/42/EEC
STERILE R	Sterilized by irradiation
	Use by date specified
CE	The device complies with European Directive MDD 93/42/EEC

Notes

Notes

www.medtronic.com

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For more information visit
www.myspinetools.com

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

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