Medtronic

# OLIF25™
Procedure

# Oblique Lateral Interbody Fusion For L2 to L5 Surgical Technique


**As described by:**

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MICHELSON TECHNOLOGY AT WORK

The **Oblique Lateral Interbody Fusion (OLIF)** Procedure provides spine surgeons with a **complete minimally invasive solution** for the treatment of degenerative lumbar conditions. By utilizing an **oblique lateral approach to the spine**, this procedure enables placement of a large interbody graft into the disc space for anterior column support while avoiding obstacles associated with traditional anterior, posterior and/or direct lateral approaches. The OLIF25™ Procedure allows for **psoas-preserving access to the L2-L5 levels**. This procedure also incorporates a comprehensive set of instruments and implants including fully integrated neuromonitoring and navigation, streamlined access instrumentation, anatomically designed implants and percutaneous fixation systems.

**Interbody**
CLYDESDALE®
Spinal System*

**Access**
MAST QUADRANT™
Lateral Retractor System

**Neuromonitoring**
NIM-ECLIPSE® Spinal System**

**Navigation**
O-ARM® System and
StealthStation® System

**Fixation**
CD HORIZON® SEXTANT® Percutaneous
Rod Insertion Systems and
CD HORIZON® LONGITUDE™ Multi-level
Percutaneous Fixation System

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.

*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 NIM-ECLIPSE® System is manufactured by Medtronic Xomed, Inc. Distributed by Medtronic Sofamor Danek USA, Inc.

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# Oblique Lateral Interbody Fusion

# Ante-Psoas Approach OLIF25™ Surgical Technique


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## Preoperative Planning

Preoperative planning can be useful in determining:

- Location of the iliac crest and lower ribs in relation to disc space of interest
- Position of the psoas, anterior vasculature, posterior nerve structures and the kidneys via axial MRI
- The oblique angle of entry into the disc space
- Curvature of the spine

Although the OLIF25™ Approach, which is lateral to the anterior vasculature is not recommended for use at L5-S1 in certain patients, it may be performed if the patient has a low bifurcation of anterior vasculature and a low iliac crest. Physicians should use preoperative planning to determine the location of anterior vasculature, the iliac crest, and the surgical trajectory to determine the appropriateness of this technique at the L5-S1 disc space.

Standard lateral surgical positioning is right lateral decubitus, or left side up, and is the preferred positioning for an oblique lateral approach based on vasculature positioning. However, the surgeon should consider ease of access, surgeon preference and the preoperative images in determining which side to approach. Correction can be achieved equally from either the convex or concave side of the curve.

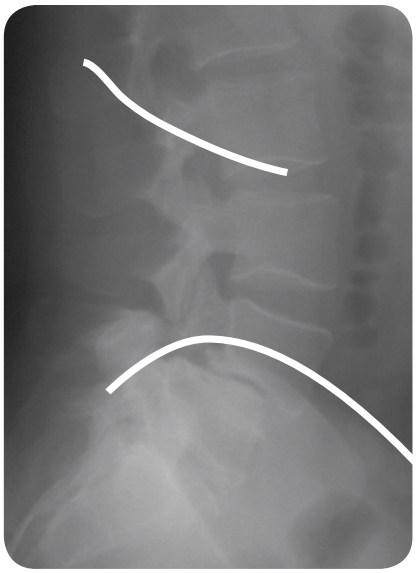


*Figure 1*

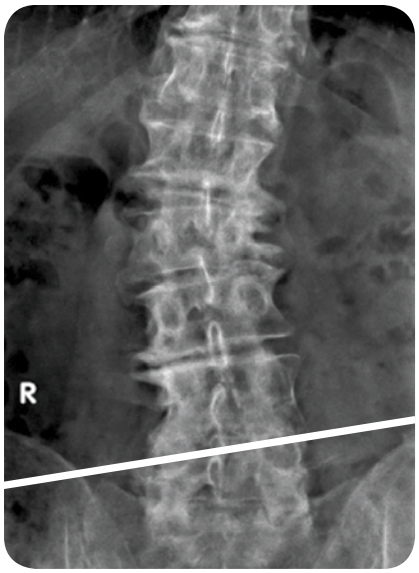



*Figure 2*

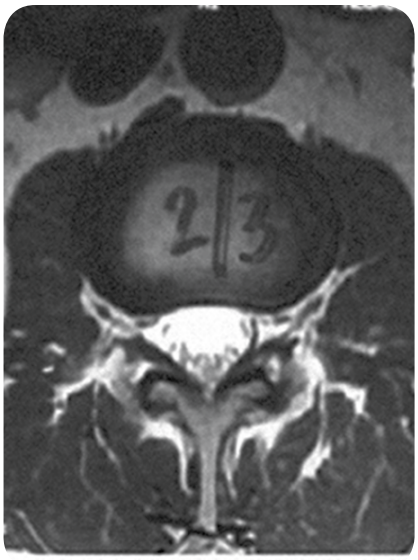



*Figure 3*

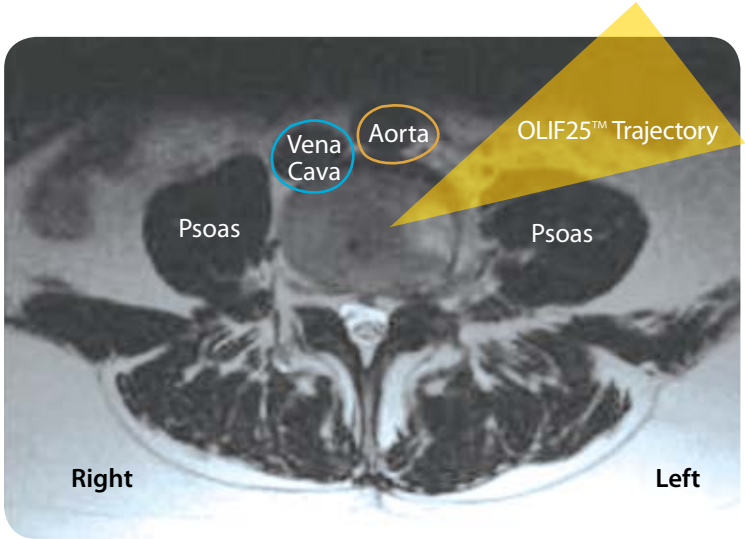



*Figure 4*

# 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 Module. Power on the NIM-ECLIPSE® Spinal System* to begin monitoring.

**Helpful Tip**

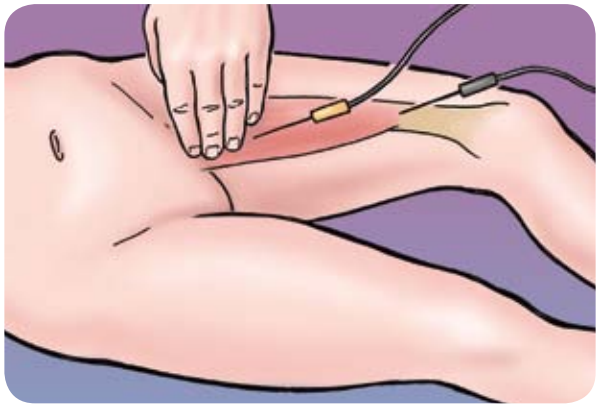
*Let the anesthesiologist know EMG monitoring will be used during the procedure to ensure that no neuromuscular blocking agents are administered during monitoring. During intubation, a fast-acting neuromuscular blocking agent should be used.*

*Sample L2 – L5 Setup*

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 |

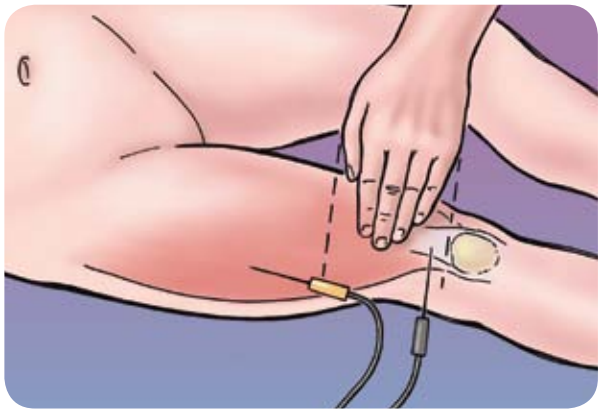


*Adductor Longus (AL)*

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 Sofamor Danek USA, Inc.

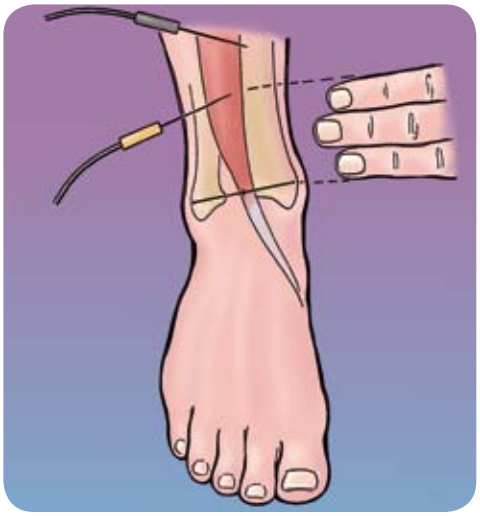
## NIM-ECLIPSE® Spinal System Electrode Placement *continued*

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



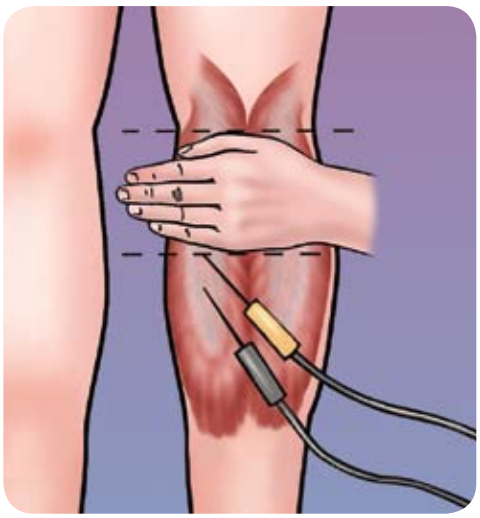
*Extensor Hallucis Longus (EHL)*

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

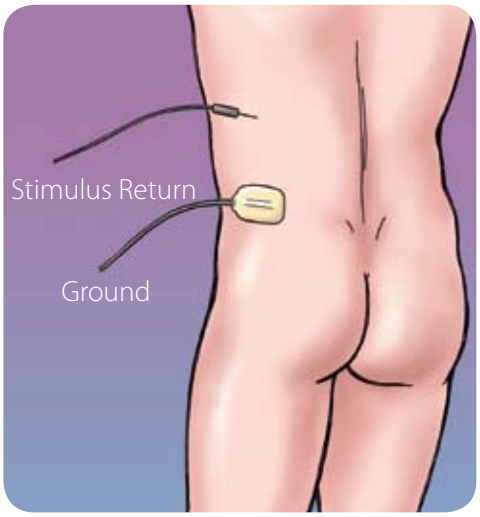
Reference: insert needle subcutaneously 2cm to 3cm away from the active electrode.

Channel 4 Left S1 – S2 GASTROC

Channel 8 Right S1 – S2 GASTROC



*Medial Gastrocnemius (GASTROC)*




*Ground/Stimulus Return*

## Patient Positioning

The patient should be placed in the right lateral decubitus (left side up) position. 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. Padding is also placed beneath and in between the legs from the knees distally **(Figures 5 and 6)**.

The legs of the patient may be slightly flexed in order to prevent the patient from rolling on the bed. However, extreme flexion to relax the psoas is not required because the approach is outside or within the anterior portion of the psoas (ante-psoas).

Breaking of the surgical table is not required, even if the patient has a high iliac crest and deep seated L4-5 disc space, as the oblique lateral approach is anterior to the iliac crest.

The patient is secured to the surgical table with tape at four locations:

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

The surgeon and operating team should be positioned to work on the abdominal side of the patient with the C-Arm positioned posterior to the patient.

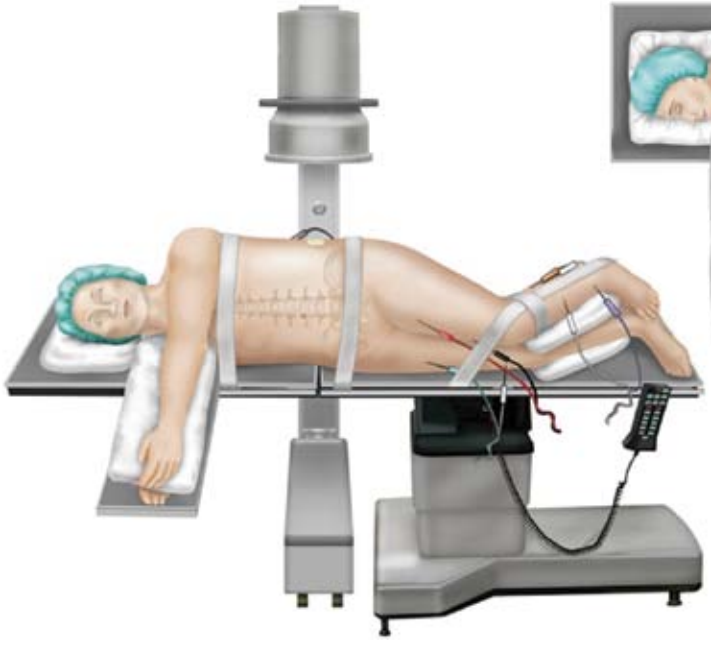


*Figure 5*

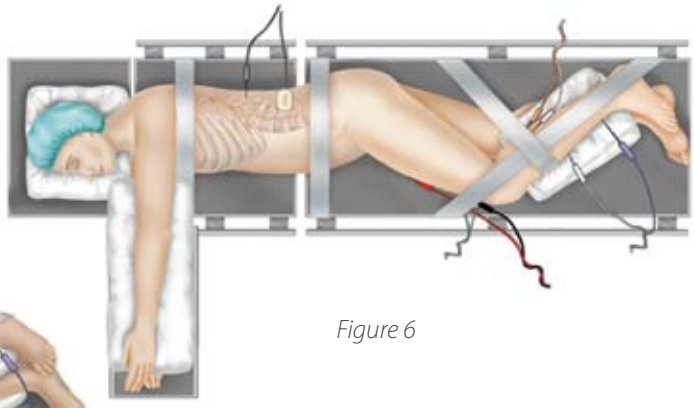


*Figure 6*

## Patient Positioning *continued*

First, an AP image should be obtained to ensure the patient is positioned in a true lateral position **(Figure 7)**. On the AP x-ray clear, distinct pedicles that are equidistant from the spinous process should be visible. Then, a lateral x-ray is obtained and clean, distinct end plates should be seen **(Figure 8)**. Pedicles should overlap as should transverse processes to ensure a true lateral position has been achieved.

**Important**

*It is critical the C-arm remain in the 0° and 90° positions at all times to ensure true lateral positioning and a safe lateral working channel across the disc space. For multilevel cases, rotate the surgical table independent of the C-arm for each level to obtain true images. Each disc space is measured on lateral fluoroscopy and line drawn on the patient to assist the radiology technician with lining up the angle specific to each disc.*

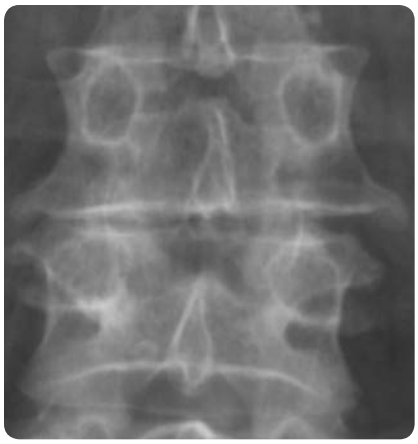


*Figure 7*

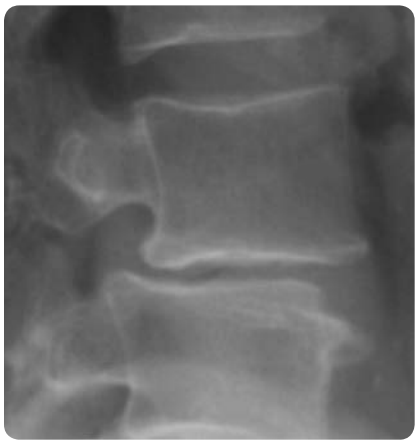


*Figure 8*

## Localization

Fluoroscopy is used to confirm the target segment and mark the location for the initial incision. The disc spaces of interest, lower ribs and iliac crest can be marked on the skin as landmarks. For a single-level case the patient should be marked 4cm-10cm anterior to the midsection of the target disc (or approximately one third of the distance from the top of the iliac crest to the umbilicus).

A 3cm to 6cm vertical, horizontal or oblique incision can be made. For a two-level case, the patient should be marked 4cm-10cm anterior to the midsection of the intervening vertebral body. In addition, the lumbar lordosis of the operative levels can be marked on the skin to determine the angle in line with the disc space **(Figures 9–11)**.

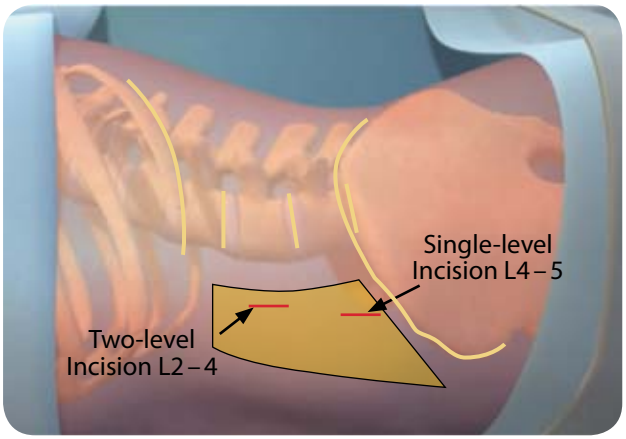



*Figure 9*

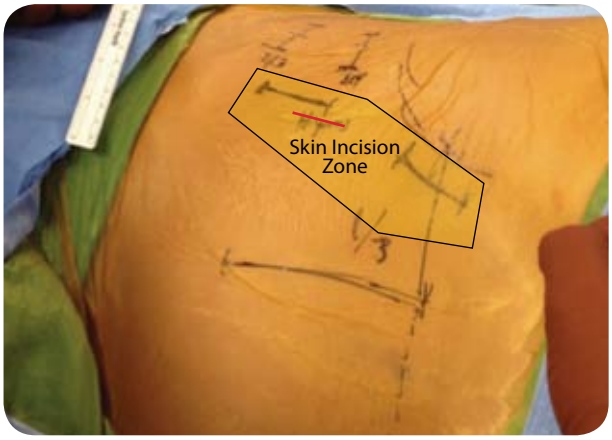



*Figure 10*

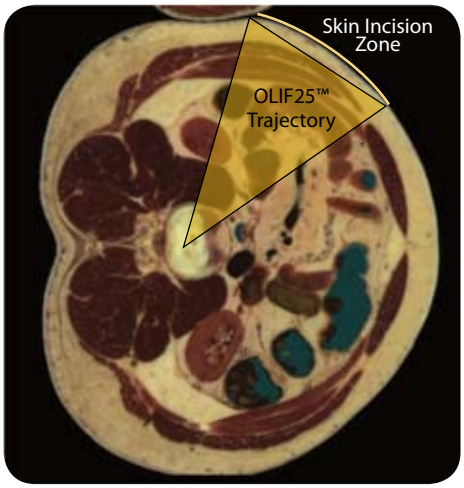



*Figure 11*

## Localization *continued*

If image guidance is being used, a Navigation probe may be used to approximate the location of the initial skin incision based on the system images **(Figures 12 and 13)**.

*Figure 12*

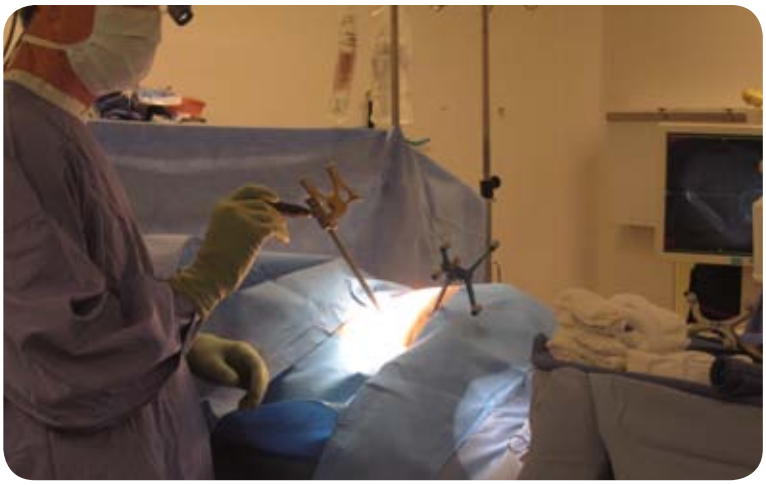
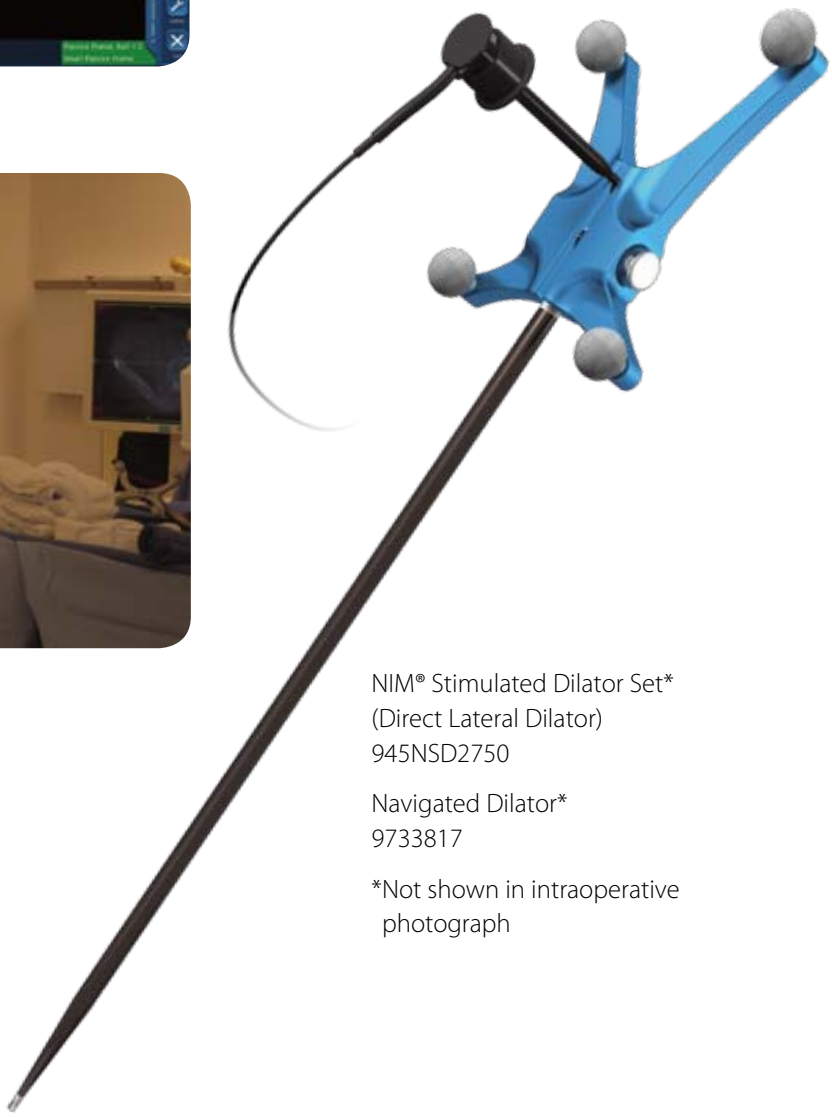


*Figure 13*



NIM® Stimulated Dilator Set*
(Direct Lateral Dilator)
945NSD2750

Navigated Dilator*
9733817

*Not shown in intraoperative photograph

## Dissection

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.

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 muscle layers run in opposite directions. After bluntly penetrating the transversalis fascia, the yellow retroperitoneal fat is exposed.

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.

The finger or a blunt instrument is used to sweep the peritoneal contents, including the ureter, which reflects with the peritoneum, and the retroperitoneal fat anteriorly past the anterior portion of the psoas clearing to the anterior vertebral body **(Figure 14)**.

Direct visualization may be employed in addition to tactile feel to ensure a safe approach to the disc space free from vascular, peritoneal and nerve obstructions. The fat overlying the psoas muscle can be swept in a cephalad and caudal direction as well as dorso-ventral with handheld retractors in order to visualize placement of the NIM® X-PAK Probe or the first Direct Lateral Dilator **(Figure 15)**. Use of hand-held retractors placed between peritoneal contents and the Probe will also minimize risk of injury to ureters and vascular structures anteriorly. A kitner or cloth-based dissector may be used to sweep soft tissue structures anteriorly.

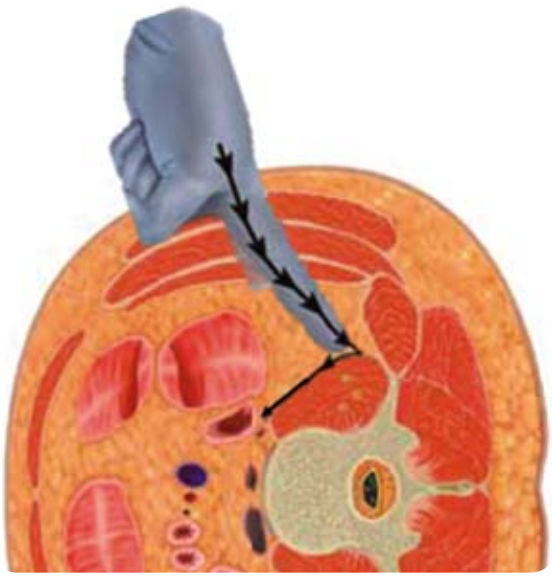


*Figure 14*

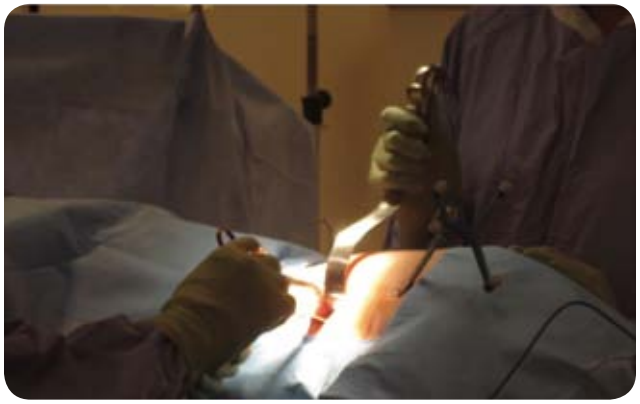


*Figure 15*

**Helpful Tip**

*Entering the transversalis fascia obliquely from anterior in the incision to posterior to the quadratus muscle will prevent inadvertent entry into the peritoneum. Palpating the quadratus muscle, followed by the tip of the transverse process and finally the psoas muscle, will help verify that the correct retroperitoneal plane is being entered and ensures that the peritoneum is not compromised.*

## Placement of Initial Probe

After a safe retroperitoneal pathway to the anterior portion of the psoas has been established under direct visualization, a probe (NIM® X-PAK Probe or the first Direct Lateral Dilator) is guided down to the disc space in front or on the anterior portion of the psoas while using the finger or handheld retractors to protect the peritoneal membrane and retract retroperitoneal fat **(Figures 16 and 17)** (see Helpful Tip on Page 9). The NIM® X-PAK Probe and Direct Lateral Dilator include an insulated shaft that enables controlled electrification at the tip of the devices.

A Needle Driver is used to position the NIM® X-PAK Probe onto the disc space or psoas. The preferred starting position of the probe on the disc space is anterior to the psoas and away from the major vessels, although the probe may start on the anterior portion of the psoas muscle as well. Approaching the spine obliquely as opposed to direct lateral will further ensure the instruments work away from the peritoneum and anterior vascular structures. The oblique angle of the probe may be assessed preoperatively and measured intraoperatively using a mechanical or digital protractor. Probe position should be confirmed using lateral fluoroscopy or image-guided navigation (if using the Direct Lateral Dilator) **(Figure 18)**.

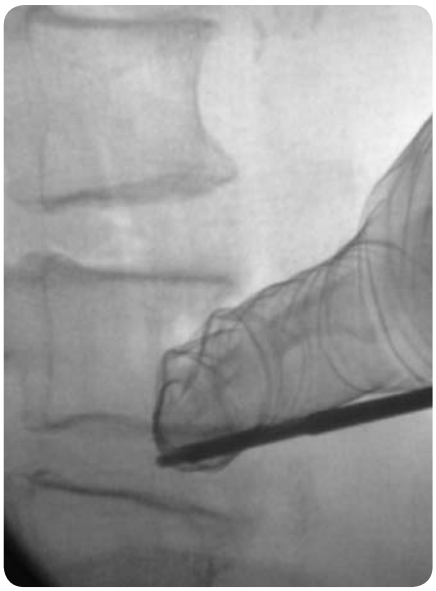


*Figure 16*

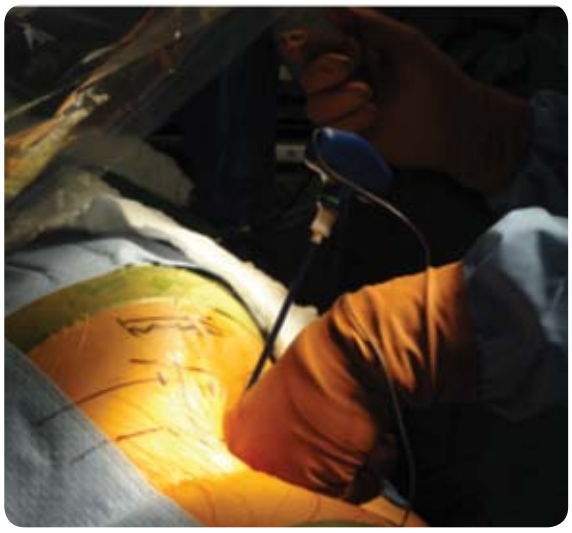


*Figure 17*

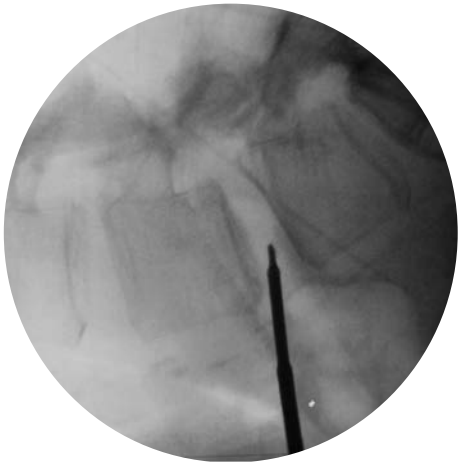


*Figure 18*

## Placement of Initial Probe *continued*

Avoiding the posterior aspect of the psoas muscle or staying out of the psoas muscle completely will minimize the potential risk to the nerves within the psoas and to the psoas muscle itself. Cadaveric studies have shown that the motor nerves typically reside in the posterior one third of the psoas muscle **(Figure 19)**.

Note that the entry point into the disc may be slightly more anterior than the midpoint of the disc **(Figure 20)**. This will minimize the risk of injury to the contralateral foramen due to the oblique trajectory of disc preparation instruments and cage placement.

After the proper position has been established, carefully pass the probe into the disc space. If passing the probe through the anterior portion of the psoas, current is delivered to monitor for any neural structures as the fibers of the muscle are being split. The recommended stimulating current setting is between 6 milliamps and 8 milliamps. If an EMG response is generated at this level, the probe should be repositioned until a nerve-free pathway is located.

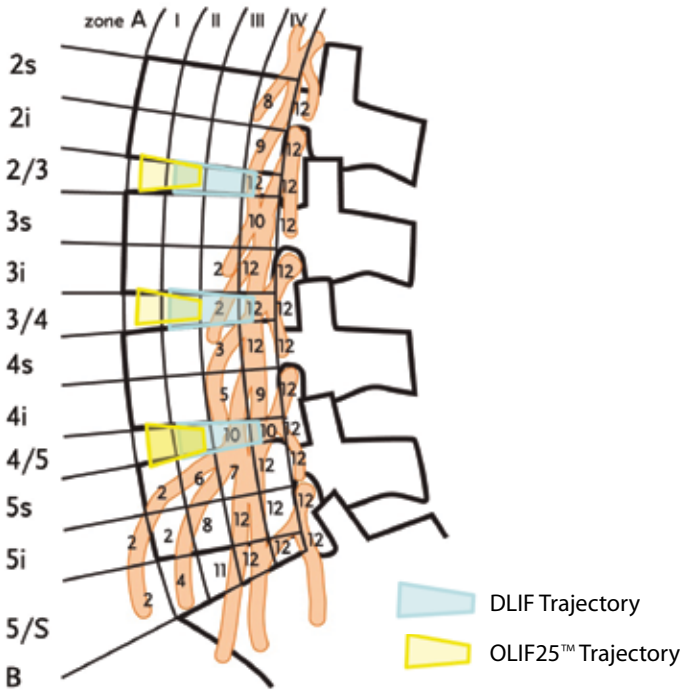



*Figure 19*

**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 21)**.*

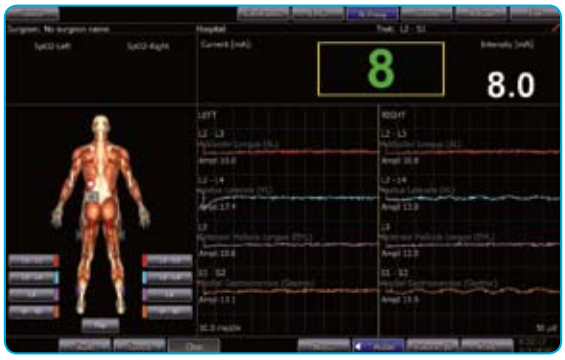



*Figure 21*

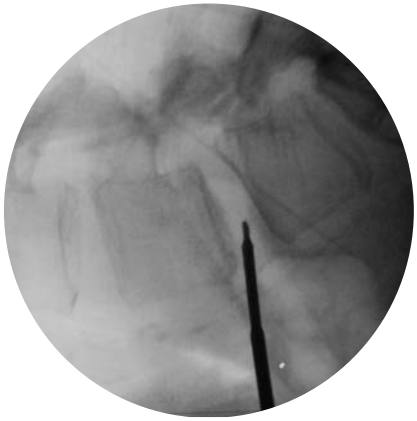


*Figure 20*

**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 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.*

## Placement of Initial Probe *continued*

After the probe has safely passed in front of or through the anterior portion of the psoas, the tip of the probe should be passed into the disc space to secure its location. The oblique angle and lordotic angle of the probe as it enters the disc space may be assessed preoperatively and measured intraoperatively using image guidance or using a mechanical or digital protractor.

Fluoroscopy or image guidance (if using the Direct Lateral Dilator) is used to confirm proper probe alignment into the disc space **(Figures 22 and 23)**. If the NIM® X-PAK Probe is used, 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 fluoroscopy.

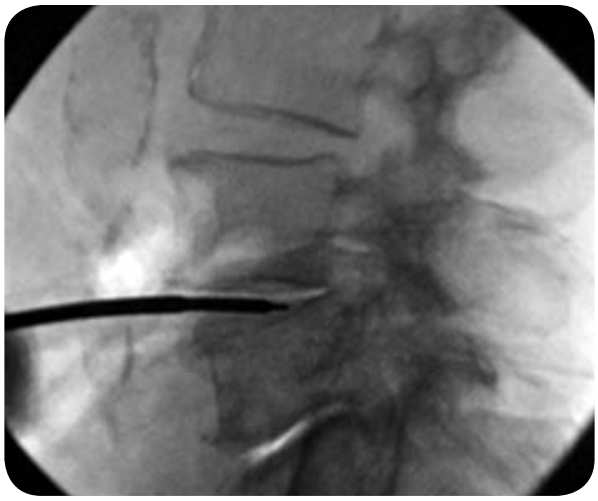


*Figure 22*

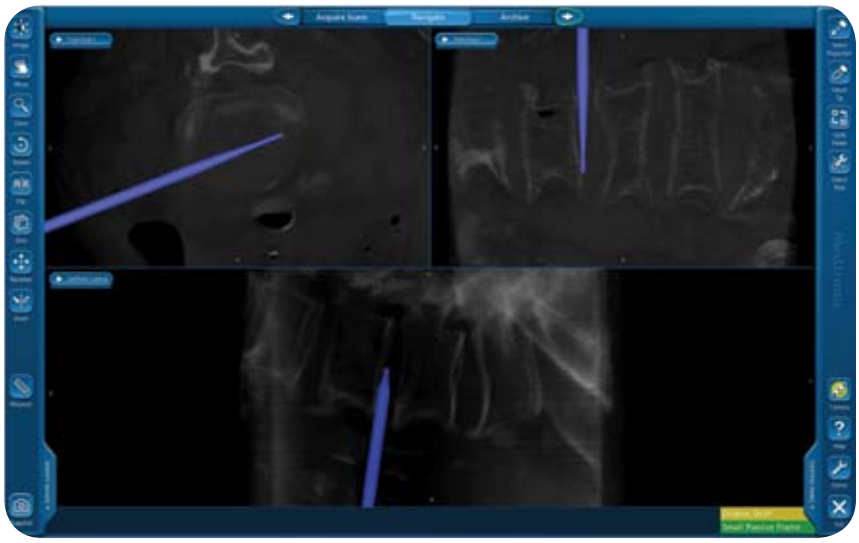


*Figure 23*

## Dilation and Retractor Placement

With the guidewire or first dilator in place and impacted into the annulus for firm fixation, sequential dilation is used to spread the fibers of the abdominal musculature to a diameter of 22mm **(Figure 24)**. If the anterior portion of the psoas muscle is dilated, EMG is active to detect any mechanical and triggered effect to the nerve roots.

Measure the depth from the skin to the disc space using the graduated markings on the dilators and select the appropriate Retractor Blades. Attach the blades to the Lateral Retractor base and place the assembly over the Grooved Dilator **(Figures 25-27)**. 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 fascia 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 AP 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.*

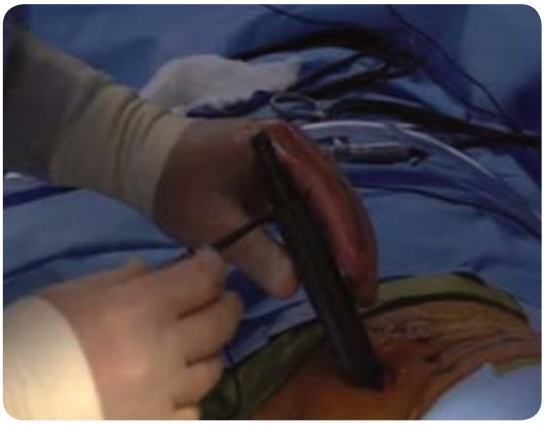


*Figure 24*

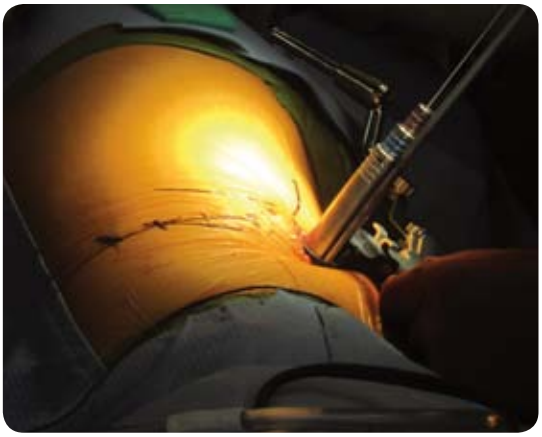


*Figure 26*

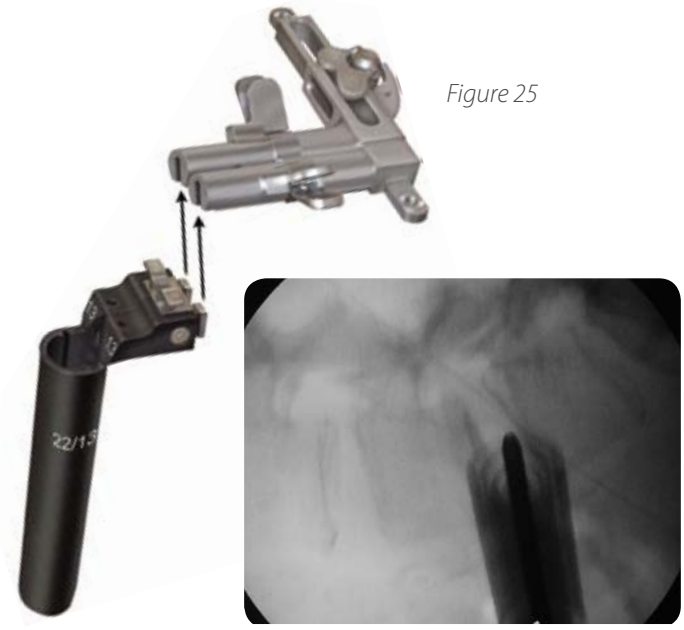


*Figure 25*

*Figure 27*

## Dilation and Retractor Placement *continued*

The Retractor Assembly is then attached to the Flexible Arm using the Rotating Flex Arm Attachment to provisionally maintain retractor position.

It is important to align the retractor blades so that the opening between them is parallel to the disc space. Utilize the skin markings drawn during localization to orient the Retractor Blades. This will facilitate orthogonal disc preparation and final implant placement.

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.

Insert a Stability Pin through one of the Retractor Blades to help prevent retractor migration during the procedure. Use the Stability Pin Driver to thread the pin in the channel of whichever blade is closest to the end plate **(Figure 28)**.

Fluoroscopy is recommended for placement of the Stability Pin to ensure it is not placed too far anteriorly risking injury to vascular structures.

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

A final lateral fluoroscopic image is taken to confirm proper retractor placement over the spine.

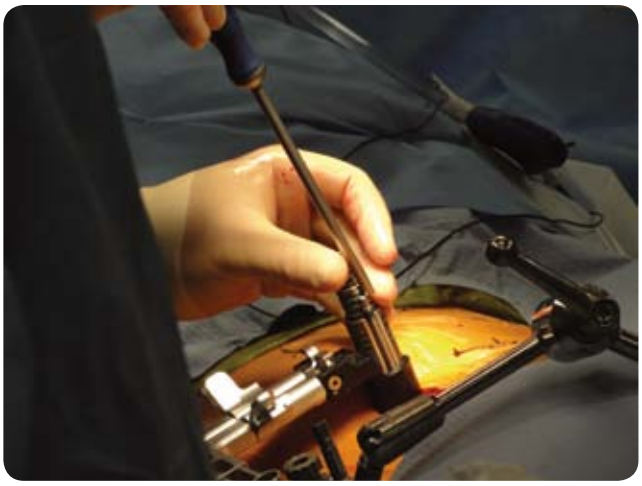


*Figure 28*

# Disc Preparation

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.

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.

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

The annulus is then incised and an annulotomy at least 18mm in length is created using the Bayoneted Knife **(Figure 29)**. Undercut, beneath the psoas, more annulus as needed with Kerrison rongeur which facilitates implant position and implantation and permits easy rotation of implant into orthogonal position.

A thorough discectomy is then performed using pituitaries and other disc preparation instruments **(Figure 30)**.

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

A Paddle Style Shaver is placed into the disc space and rotated several times (clockwise and counterclockwise) to clean the end plates **(Figure 31)**. AP fluoroscopy should be used to center the shaver in the disc before turning **(Figure 32)**. The appropriately-sized shavers should be carefully selected to ensure the end plates are not compromised.

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.

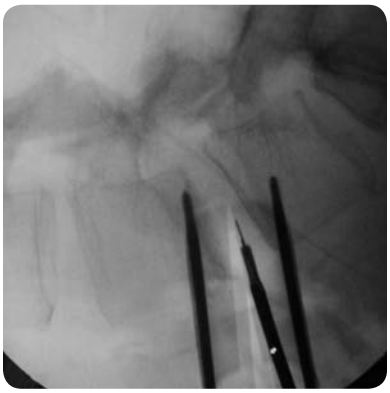


*Figure 29*

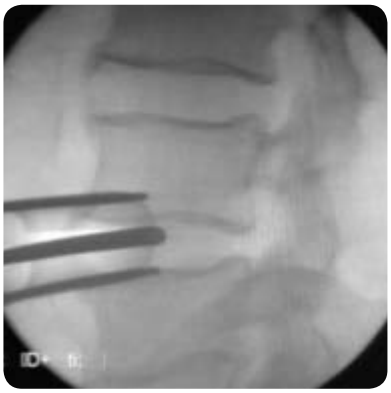


*Figure 30*

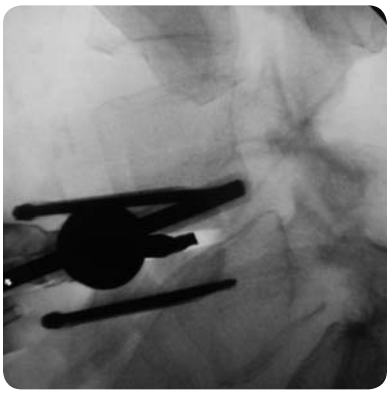


*Figure 31*

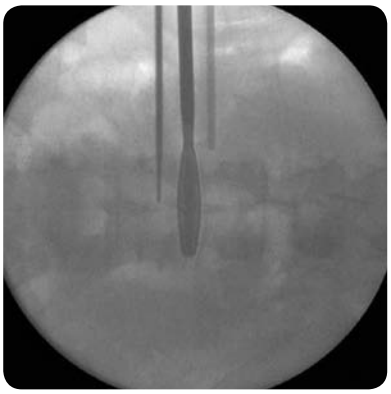


*Figure 32*

**Important**

*All disc preparation instruments, including the Cobb and Shavers, can enter obliquely through the retractor and then be turned orthogonally to allow the surgeon to work orthogonally across the disc space and release the contralateral annulus. The retractor should be slightly opened to allow for the instruments to turn orthogonally. A mechanical or digital protractor may be used to assess the oblique and lordotic angles of entry into the disc space, but the location of the instruments is confirmed using fluoroscopy.*

# Trialing

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

The Trials are passed through the retractors obliquely and then are turned to allow the surgeon to place them orthogonally across the disc space. A mechanical or digital protractor may be used to further assess the oblique and lordotic angles of entry into the disc space, but the location of the trials is confirmed using fluoroscopy or image guidance **(Figures 33 – 35)**.

The Trial is impacted into the disc space. A properly-sized Trial should be centered with the spinous process and should span the entire ring apophysis in order to reach fully across the vertebral body end plate.

**Helpful Tip**

*When using 22mm Trials, it may be necessary to open the Retractor Blades more to allow the passing of the larger Trial.*

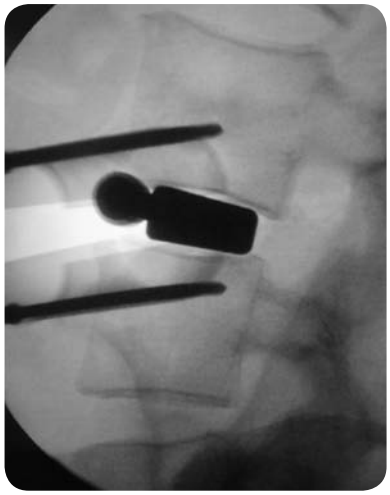


*Figure 33*

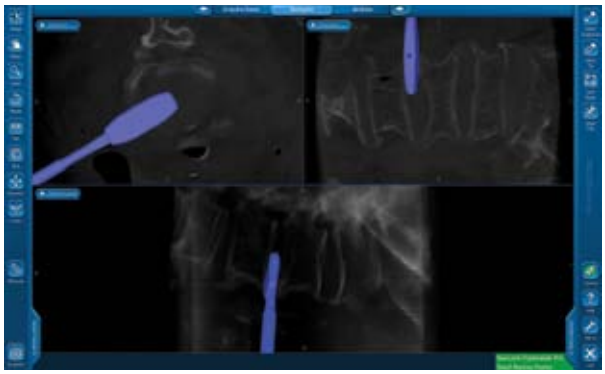


*Figure 34*

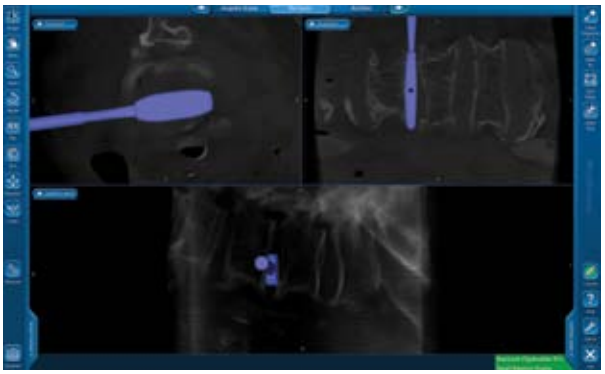


*Figure 35*

# Implant Placement

Once trialing is complete, the corresponding CLYDESDALE® Spinal System implant is attached to the Inserter **(Figure 36)** 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**.

Before inserting the CLYDESDALE® Spinal System implant, place autograft in the implant's central cavity.

If using the DL Inserter, slightly extend the sleeves to cover the implant's graft chamber or fully extend the sleeves to cover the entire implant by unthreading the nut from the outer sleeve **(Figures 37 and 38)**.

*Figure 36*

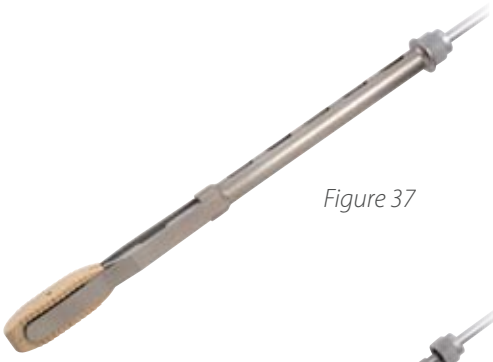


*Figure 37*

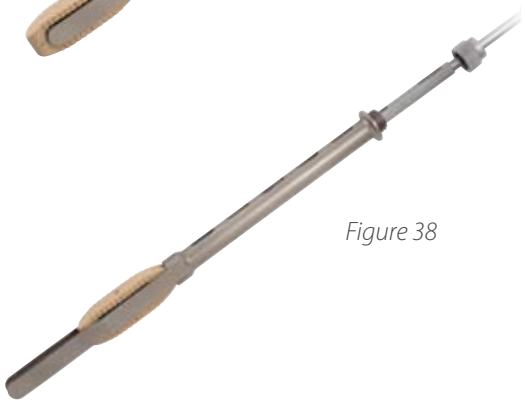


*Figure 38*

**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 27 of this surgical technique.*

## Implant Placement *continued*

A mallet is then used to gently insert the implant while monitoring placement under AP fluoroscopy. The inserter enters obliquely and can then be turned orthogonally to allow the surgeon to place it orthogonally across the disc space. A mechanical or digital protractor may be used to further assess the oblique and lordotic angles of entry into the disc space, but the location of the implant is confirmed using fluoroscopy or image guidance. Near complete rotation and alignment of the implant should be complete by the time approximately 50 – 75% of the implant is inserted into the disc space while fluoroscopy is in lateral position. The implant is easily viewed during this insertion due to the oblique view portal through the retractors. Then, the final positioning of implant should be completed under AP fluoroscopy. Care should be taken to ensure the CLYDESDALE® Spinal System implant is aligned properly.

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 39 – 44)**.

*Figure 39*

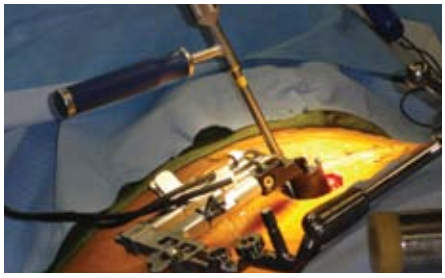


*Figure 40*

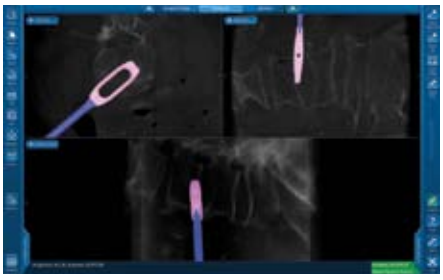


*Figure 41*

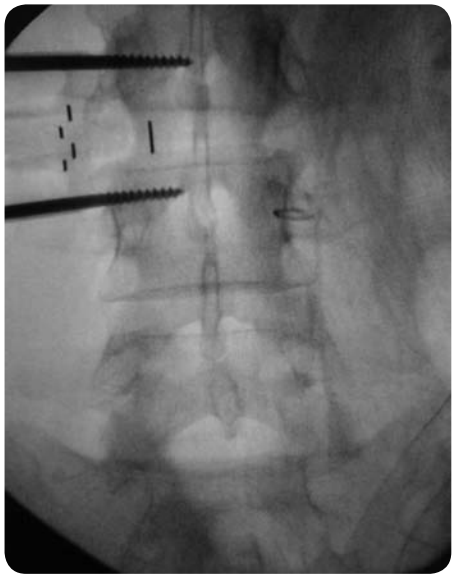


*Figure 42*

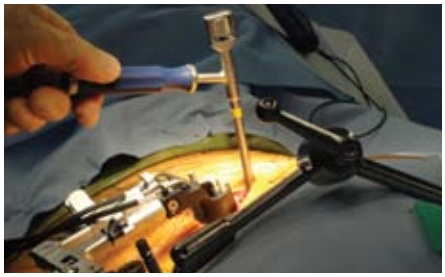


*Figure 43*

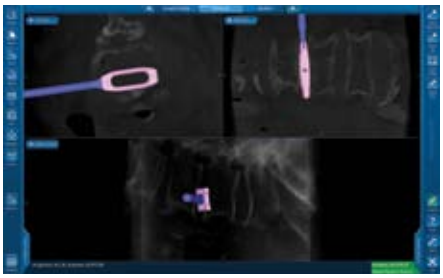
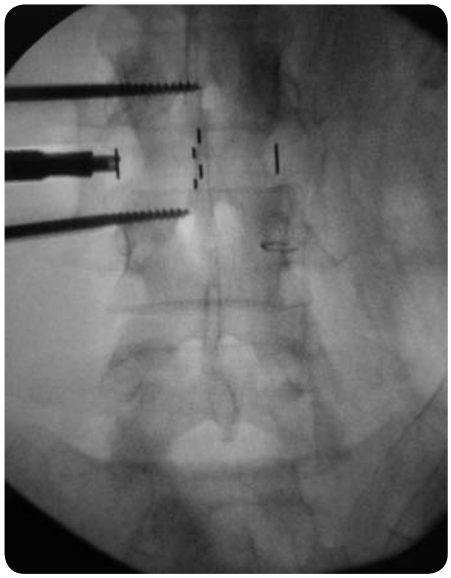


*Figure 44*



(For navigation use the Navigation Interbody inserter, Part Number 97344556. Instrument not shown in intraoperative photographs.)

## Closure

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

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.

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

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)**.

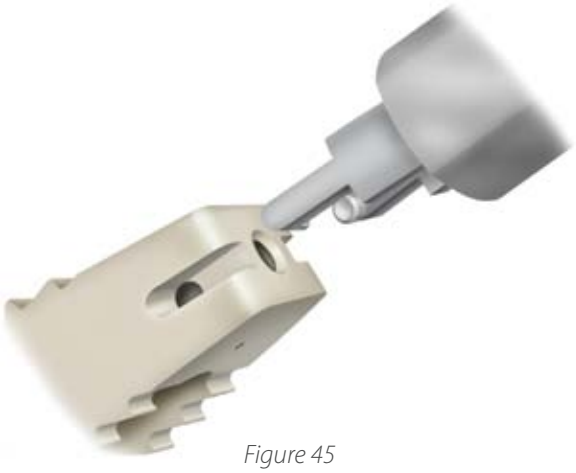


*Figure 45*

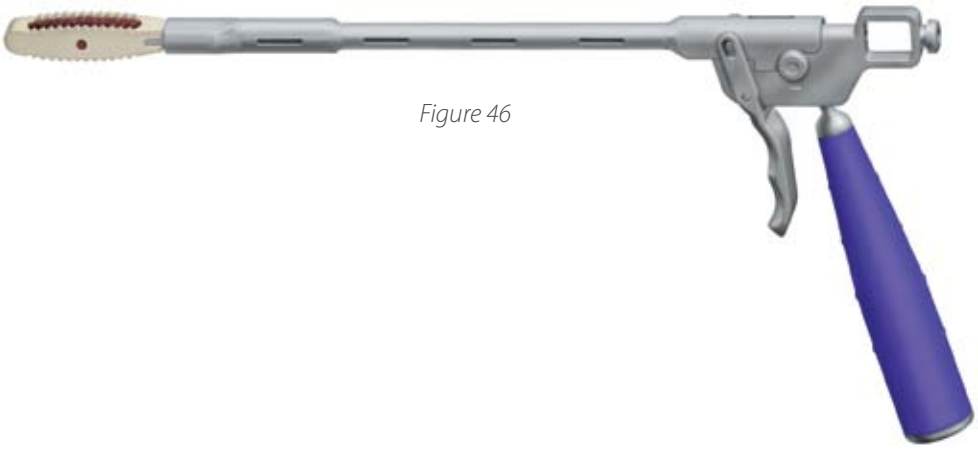
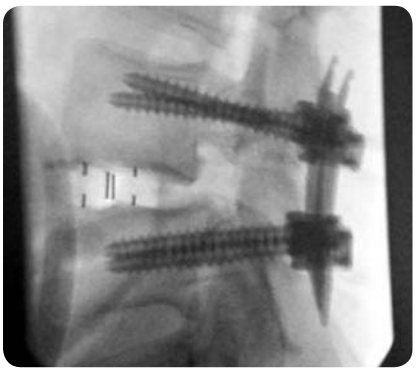


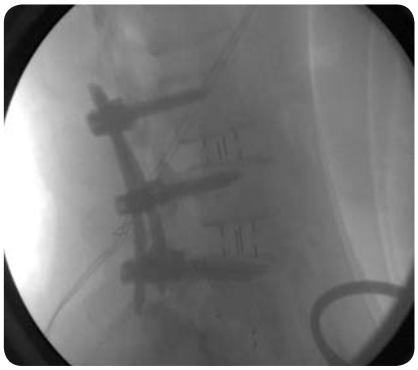
*Figure 46*

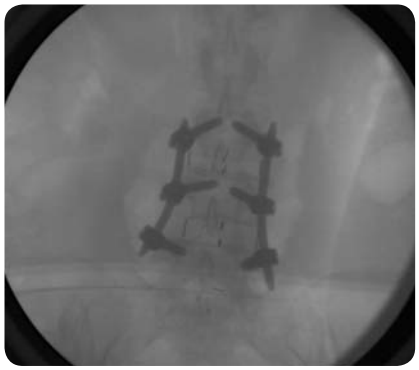
# Fixation

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

**INDICATIONS FOR THE CD HORIZON® Spinal System**

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CD HORIZON® Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, the CD HORIZON® Spinal System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis and fracture caused by tumor and/or trauma. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD HORIZON® SPIRE™ Plate is a posterior, single level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis; trauma; and/or tumor.

In order to achieve additional levels of fixation, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

**Warning:** The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

# 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 |
| 2922060 | 10mm × 60mm |
| 2922240 | 12mm × 40mm |
| 2922245 | 12mm × 45mm |
| 2922250 | 12mm × 50mm |
| 2922255 | 12mm × 55mm |
| 2922260 | 12mm × 60mm |
| 2922440 | 14mm × 40mm |
| 2922445 | 14mm × 45mm |
| 2922450 | 14mm × 50mm |
| 2922455 | 14mm × 55mm |
| 2922460 | 14mm × 60mm |
| 2922640 | 16mm × 40mm |
| 2922645 | 16mm × 45mm |
| 2922650 | 16mm × 50mm |
| 2922655 | 16mm × 55mm |
| 2922660 | 16mm × 60mm |

# 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 pene¬tration 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 be¬low 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 con¬sortium, and sexual dysfunction.
- Development of respira¬tory problems, e.g. pul¬monary embolism, atelectasis, bron¬chitis, pneumonia, etc.
- Change in mental status.
- Cessation of any poten¬tial growth of the operated por¬tion 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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**EXPLANATION OF SYMBOLS**

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

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

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