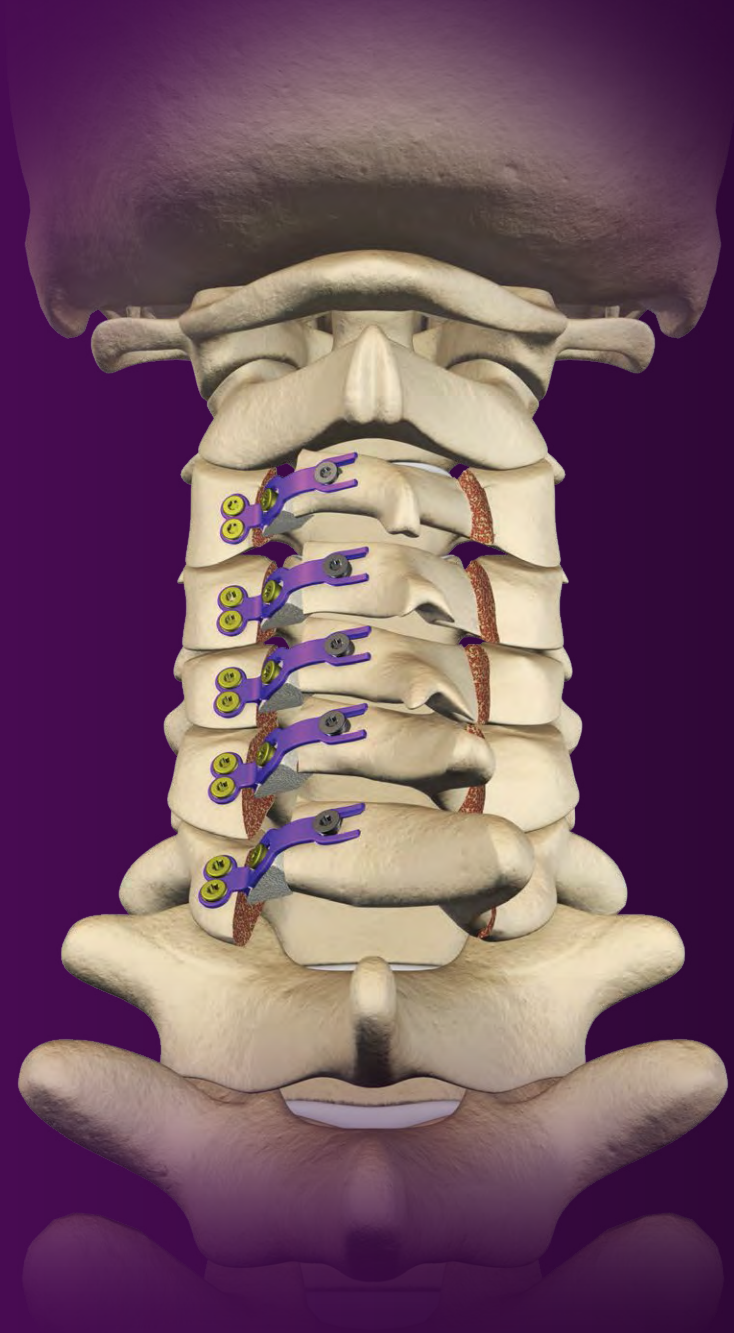
NuVasive®
Speed of Innovation®

LEVERAGE® LFS

Technique Guide



CONTENTS

PREFACE

Fellow Colleagues:

Many different techniques have been applied to treat cervical stenosis; yet, it remains a demanding problem to address. Although decompression can be achieved through posterior laminectomy and fusion, this limits a patient's cervical motion. The development of the open door laminoplasty technique promised to provide an easier solution to expand the canal diameter while preserving anatomical structures and motion.

But despite the many benefits of laminoplasty, the described techniques all share similar drawbacks, requiring care to prevent fracturing the hinge during preparation of the lamina and creating concerns due to the necessity of working over an exposed cord. As a result, we felt that a system was needed that could be safely implanted with minimal risk. This need was answered by the development of the NuVasive® Leverage® Laminoplasty Fixation System (LFS).

Using a novel surgical technique and innovative implant designs, the Leverage LFS allows drilling and placement of the Laminar Screw prior to creation of the hinge, allowing for safer access and more reproducible results. The anatomically appropriate implants and thoughtful instrument designs that have come to define NuVasive products combine to make this system both safe and easy to implant.

The NuVasive Leverage Laminoplasty Fixation System delivers on the once-illusive promise of the laminoplasty technique, to provide an opportunity for patient safety while retaining all the benefits of the laminoplasty procedure.

Best regards,

Christopher R. Brown, M.D.
Assistant Professor, Orthopaedic Surgery
Duke University Medical Center
Durham, North Carolina USA

David G. Schwartz, M.D.
Assistant Clinical Professor, Orthopaedic Surgery
Indiana University School of Medicine
Director, OrthoIndy Spine Fellowship
Indianapolis, Indiana USA

LEVERAGE® LFS OVERVIEW

DESIGN RATIONALE

Our goal is to introduce a system that guarantees the surgeon an easy, safe, and reproducible laminoplasty procedure. Most notably, we wanted to eliminate the most delicate steps of drilling and screwing over an open cord and hinged lamina. This was accomplished with a novel U-Shaped plate design *(Fig. 1)* and Collared Laminar Screw design *(Fig. 2)*.

(Fig. 1)

(Fig. 2)

SURGEON VALUE

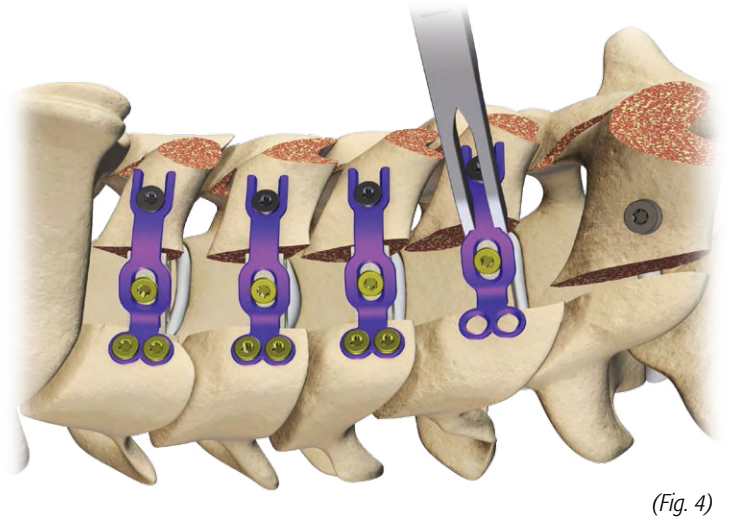
The NuVasive® Leverage® Laminoplasty Fixation System was designed to prevent the occurrence of spinal cord injury and damage to the hinge of the lamina by placing the Laminar Screws prior to creating the trough and hinge cuts on the lamina *(Fig. 3)*. Conversely, in a traditional instrumented laminoplasty procedure, this delicate step is done after the trough and hinge cuts have been made to the lamina, which decreases stability and increases operative risk.

The value of drilling with a fully intact lamina not only decreases the possibility of spinal cord injury, but also provides a sturdy work area, which allows for more stable drilling.

Moreover, the U-Shaped feature of the plate, when coupled with the Collared Laminar Screw design, allows the surgeon to engage onto the stable laminar screw and safely elevate the lamina *(Fig. 4)*.

These novel features are of real value to the surgeon, as they make this procedure less precarious, more reproducible, and safer for their patients.

(Fig. 3)



(Fig. 4)

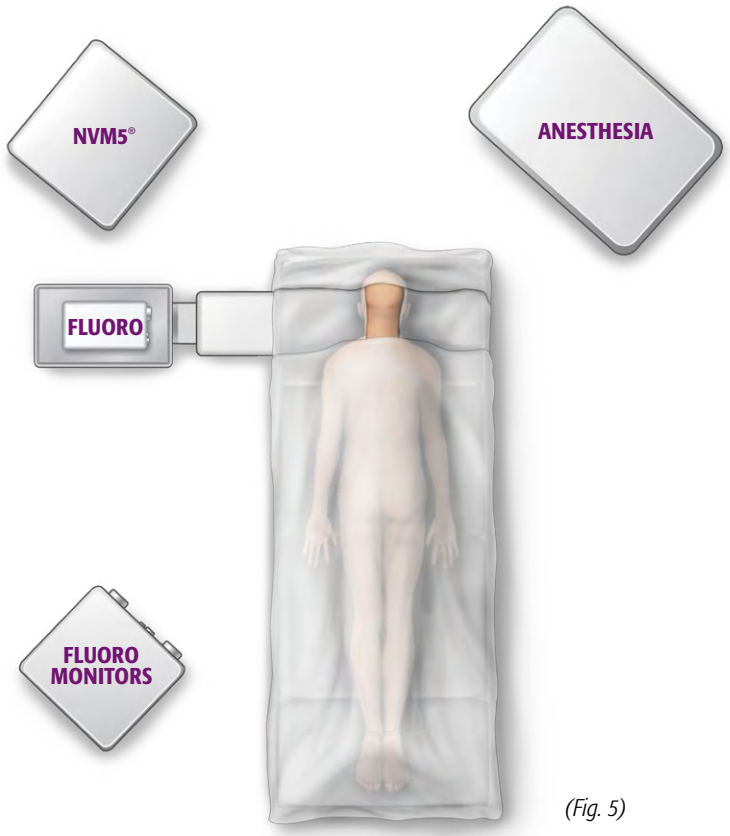
INSTRUMENT REQUIREMENTS:

- Laminar Screw Template Tool
- 5mm Fixed Drill or 5mm Drill Shaft and Universal Handle
- Stab-n-Grab Screwdriver
- Laminar Screws
- Fixed or Adjustable Needle Nose Plate Holder
- Leverage® Traditional or Graft Plates
- Lateral Mass Screws

Optional Instruments:

- Bone Cutter
- 1mm Kerrison
- 2mm Kerrison
- 4-0 Up-Angled Curette
- 3mm, 5mm, 6mm, 7mm, 8mm Drill Shafts
- Large Laminar Plates

For a complete list of intended uses, indications, device description, contraindications, warnings, and precautions, please refer to the Instructions for Use (IFU) in the back of this technique guide.



(Fig. 5)

PRE-OP POSITIONING AND IMAGING

The patient is placed in the prone position with a three-pin or horseshoe head holder. The head is positioned in slight cervical flexion in a chin tuck position. The bed is placed in slight reverse Trendelenburg position *(Fig. 5)* to place the cervical spine in a more horizontal position and to decrease venous bleeding.

NVM5 – MEP AND SSEP

Use NVM5 to monitor spinal cord health and integrity during Leverage® LFS surgery. After the patient is fully anesthetized and positioned, use the Motor Evoked Potentials and Somatosensory Evoked Potentials applications. Subsequent readings should be obtained every 15 minutes at a minimum. Refer to the NVM5 manual for more detailed information on MEP and SSEP functionality.

Tip

"Place patient in slight cervical flexion:

1. *Facilitates both exposure and closure by eliminating posterior skin folds*
2. *Decreases shingling of lamina, allowing for improved identification of adjacent levels*
3. *Allows greater access to C2-C3 interspace during C2 dome osteotomy, allowing for less C2 bone resection."*

- Chris Brown, M.D.

Tip

"Make sure there is no pressure on the chin."

- Dave Schwartz, M.D.

LEVERAGE® LFS TECHNIQUE GUIDE

STEP 1:
SURGICAL EXPOSURE

A posterior longitudinal incision is performed in the usual fashion with a midline approach to the spinous processes *(Fig. 6)*.

Tip

"Care should be taken to limit damage to the facet capsules at any of the exposed levels. Generally, the medial third of the lateral mass will be exposed."

- Dave Schwartz, M.D.

Tip

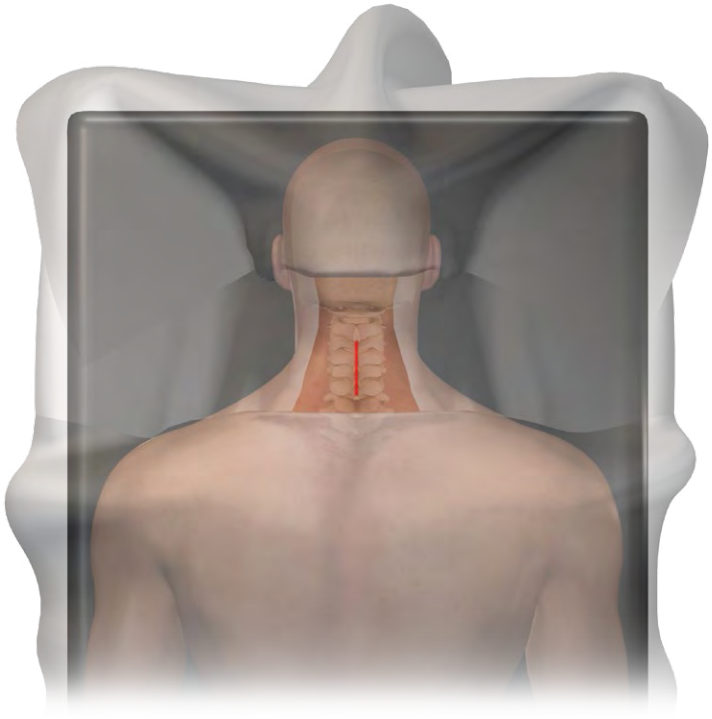
"Exposure in a cephalad to caudal direction will decrease problems with intraoperative bleeding, obscuring visualization."

- Dave Schwartz, M.D.

Tip

"The extensor muscle attachment to the C2 spinous process is carefully preserved. The inferior surface of the C2 lamina is usually broad and should be exposed to aid in visualization of the C3 lateral mass."

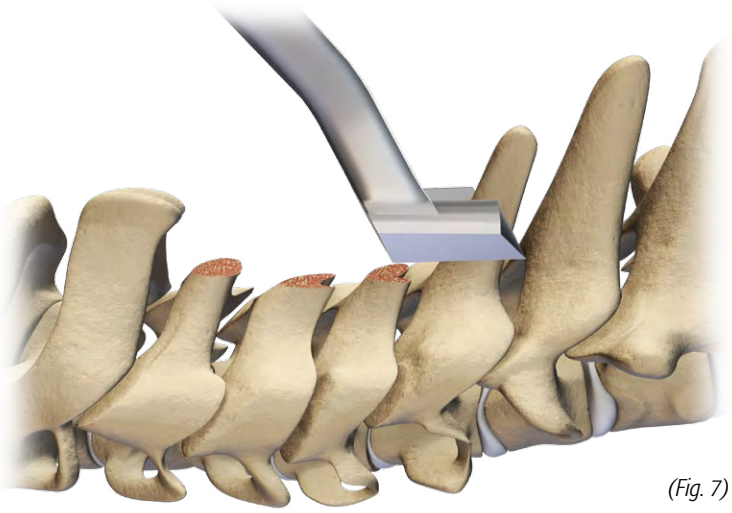
- Chris Brown, M.D.



(Fig. 6)

STEP 2:
REMOVAL OF THE SPINOUS PROCESSES

The spinous processes are removed with the Bone Cutter *(Fig. 7)*. This aids in exposure, reduces the displacement of posterior musculature, and allows greater access for insertion of the Laminar Screw.



(Fig. 7)

LEVERAGE® LFS TECHNIQUE GUIDE

STEP 3:
TROUGH IDENTIFICATION/LAMINAR DRILLING

Identify the trough line and then gently mark it with a bovie or a high-speed burr *(Fig. 8)*.

Place the feet of the Laminar Screw Template Tool over the predetermined trough line *(Fig. 9)*. This will position the U-Shaped template over the lamina. Then bovie the lamina at the center of the U-Shaped design, designated by the laser-etched marking. This bovied marking defines the Laminar Screw entry point. Introduce the 3mm Drill Shaft (black) on the bovied marking, and begin drilling *(Fig. 10)*. Repeat these steps for all Laminar Screw sites. These drilled holes will define the Laminar Screw placement sites. As an alternative, a 5mm Drill Shaft (gold) is available to start a pilot hole.

Tip

"It is desired to drill perpendicular to the laminae. To accomplish this, introduce the 3mm drill at a perpendicular angle to the laminae. I prefer to use a hand drill."

- Dave Schwartz, M.D.

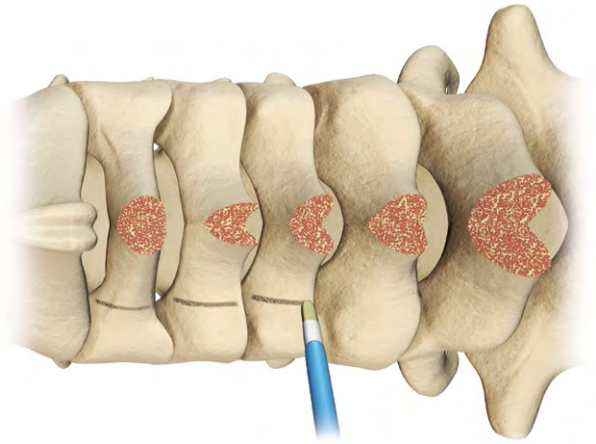
Note

Both hand and power drilling is possible with this system. To hand drill, attach the 3mm Drill Shaft (black) to the Universal Handle.

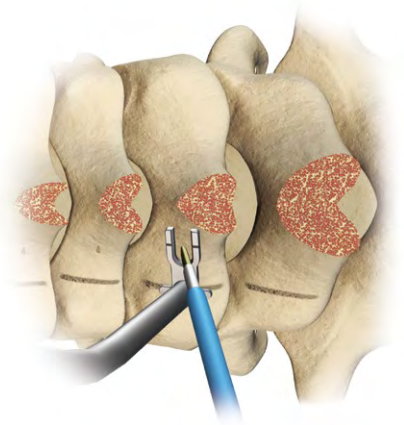
Power drilling may be accomplished by attaching the 3mm Drill Shaft (black) to:

1. *A quick-connect AO power drill, utilizing the AO adaptation segment of the Drill Bit.*
2. *A properly sized 3-jaw chuck, utilizing the full diameter segment of the Drill Bit.*

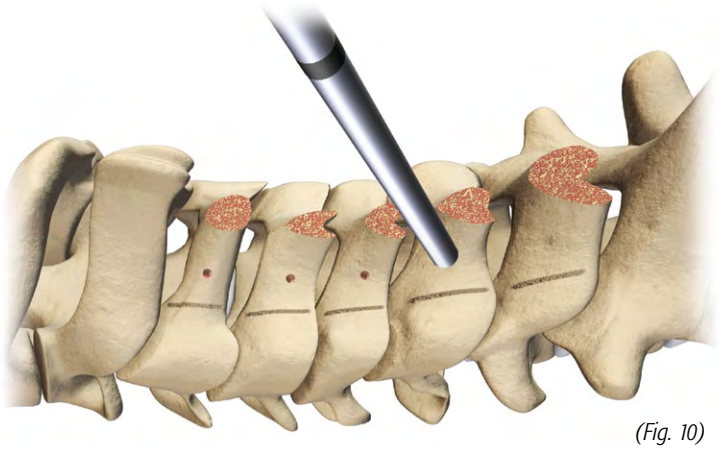
CAUTION:
Drill 3mm to 5mm on the laminae: Use the 3mm Drill Shaft (black), 5mm Fixed Drill (gold), or 5mm Drill Shaft (gold) (Fig. 10). Do not drill deeper than 5mm in the laminae, because the Laminar Screw could countersink, inhibiting the plate engagement.



(Fig. 8)



(Fig. 9)



(Fig. 10)

STEP 4:
LAMINAR SCREW PLACEMENT

Stab-n-Grab Screwdriver

Use the Stab-n-Grab Screwdriver to engage, pick up, and hold a 2.6 x 5mm Laminar Screw *(Fig. 11)*. Insert the 2.6 x 5mm Self-Drilling Screw into the pilot hole and advance until the bottom of the collar is flush with the bone *(Fig. 12)*. Repeat these steps for all Laminar Screw placement sites.

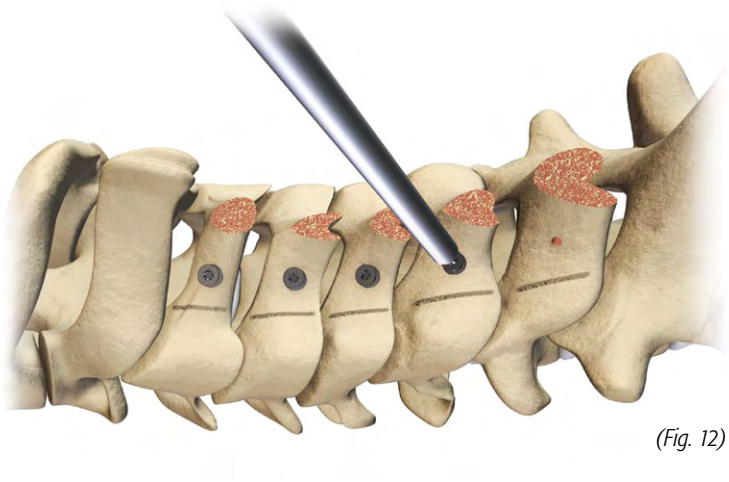
Tip

"Do not countersink or over-penetrate the Laminar Screw collar, as this will hinder plate engagement in a later step."

- Chris Brown, M.D.

Note

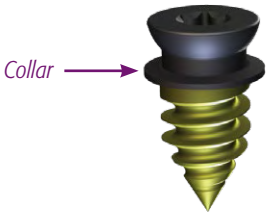
Laminar Screws (Fig. 13) are different than Lateral Mass Screws (Fig. 14); Laminar Screws have a collar for plate engagement. The primary Laminar Screw size is 2.6 x 5mm (gray head, gold shank), and the rescue Laminar Screw size is 3.0 x 5mm (gray).



(Fig. 12)

(Fig. 11)

LAMINAR SCREW



(Fig. 13)

LATERAL MASS SCREW

(Fig. 14)

LEVERAGE® LFS TECHNIQUE GUIDE

STEP 5:
TROUGH PREPARATION

A high-speed drill is used to form the trough *(Fig. 15)*. This entails the removal of three layers of laminar bone: the dorsal cortex, the inner cancellous layer, and the ventral cortex. As the surgeon approaches the ventral cortex of the lamina, bleeding cancellous bone will transition to white cortical bone, confirming that you are approaching the optimal depth to switch instruments and finish the trough. From this point, it is the surgeon's discretion to use a Kerrison or a Curette to complete the trough.

Tip

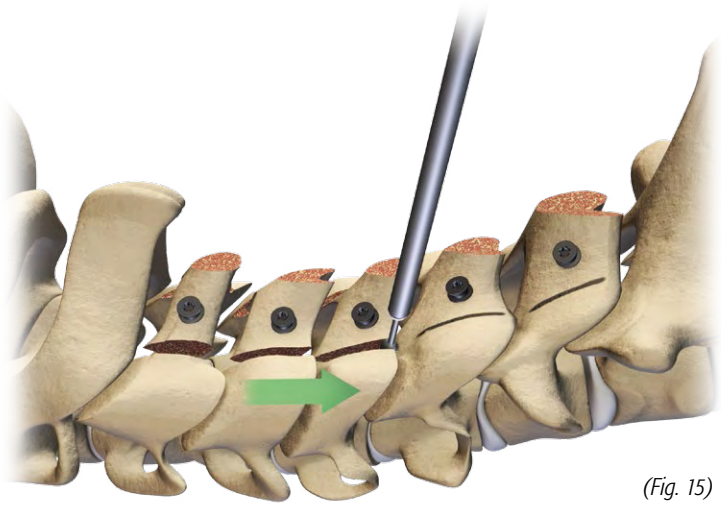
"The trough should be performed in a cephalad to caudal fashion for greater visibility, due to blood running down toward C3. I approach the hinge in the same manner."

- Dave Schwartz, M.D.

Tip

"Choosing which side to open? If foraminotomies are to be performed, the opening is made on the patient's symptomatic side. Otherwise, handedness of the surgeon can determine the opening side."

- Chris Brown, M.D.



(Fig. 15)

STEP 6:
HINGE PREPARATION

This entails removal of the dorsal cortex and inner cancellous layer, leaving the ventral cortex intact *(Fig. 16)*, resulting in a pliable, yet firm, hinge that yields to moderate pressure without breaking the ventral cortex *(Fig. 17)*.

Tip

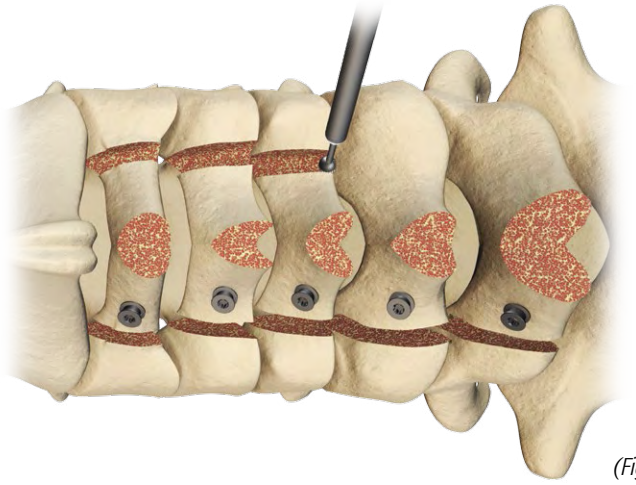
"Oftentimes the most cephalad portion of the laminae is fairly thick and shingled under the adjacent cephalad lamina, which may lead to the lamina not being thinned enough."

- Dave Schwartz, M.D.

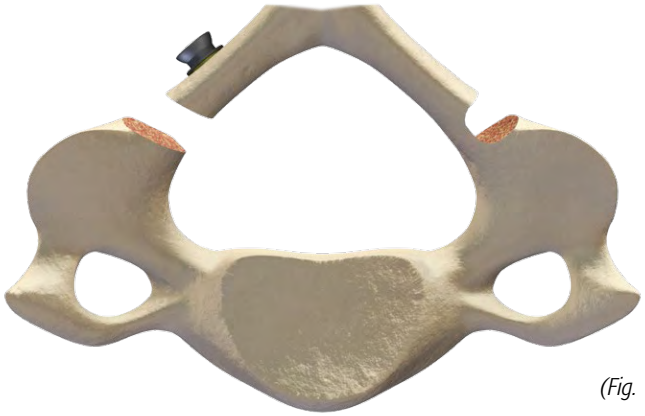
Tip

"Always recheck to make sure the trough side is completely resected if you are having difficulty lifting back the laminae."

- Chris Brown, M.D.



(Fig. 16)



(Fig. 17)

LEVERAGE® LFS TECHNIQUE GUIDE

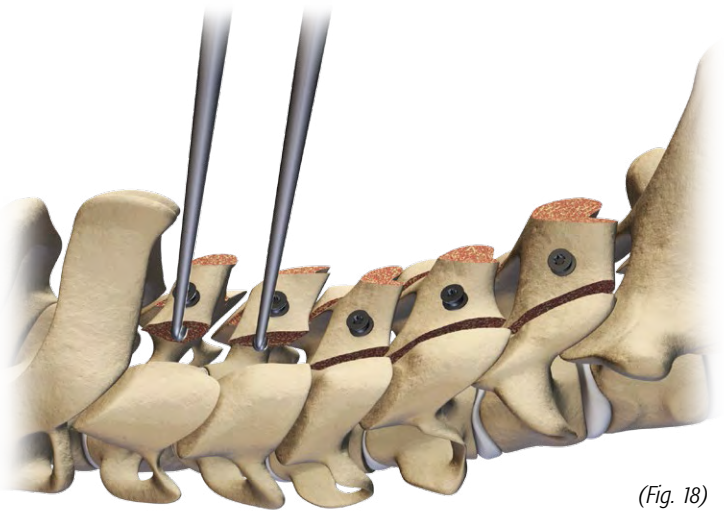
STEP 7:
OPEN THE LAMINOPLASTY DOOR

Gentle lifting of the lamina with a 4-0 Up-Angled Curette can initiate the opening of the laminoplasty *(Fig. 18)*. Additionally, a Curette or nerve hook can be used to free any soft tissue attachments between the dura and the lamina.

Tip

"Bipolar forceps can be used to cauterize epidural veins and remaining ligamentous attachments while maintaining hemostasis. A kerrison punch can be used to divide the remaining facet capsule attachments."

- Chris Brown, M.D.



(Fig. 18)

NVM5® – MEP AND SSEP

Use NVM5 to monitor spinal cord health and integrity during Leverage® LFS surgery. Afterward, subsequent MEP and SSEP readings may be taken to verify there has been no compromise of the spinal cord.

STEP 8:

DETERMINE THE TYPE OF PLATE

Three plate options are available in the set: Graft *(Fig. 19)*, Traditional *(Fig. 20)*, and Large Laminar *(Fig. 21)*.

The Graft Plate offers a screw hole that facilitates attachment of a matching size allograft (e.g., a Medium 9.5mm purple plate is coupled with a Medium allograft). Anchor a 5mm Lateral Mass/Graft Screw (gold) through the Graft Plate and into the allograft *(Fig. 22)*. (The allografts come with a predrilled hole, facilitating screw placement.)

If a Traditional or Large Laminar Plate is utilized, a surgical wire is used to fasten the allograft to the plate.

Note

Both Traditional and Graft Plates are available in two hole orientations, Cranial-Caudal and Medial-Lateral, to accommodate the lateral mass (Figs. 19, 20). The Large Laminar Plate is offered only in a Cranial-Caudal hole orientation.

Tip

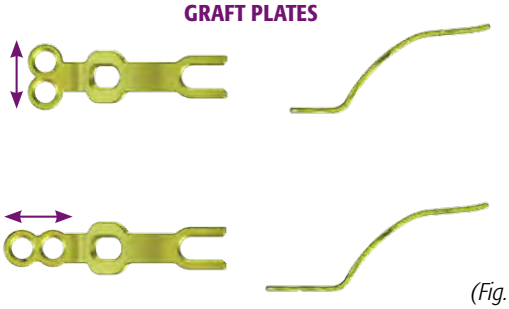
"I routinely use the Cranial-Caudal hole plates. I use the Medial-Lateral hole plates only on patients with small cephalad to caudal lateral masses."

- Dave Schwartz, M.D.

GRAFT PLATES

Cranial-Caudal

Medial-Lateral

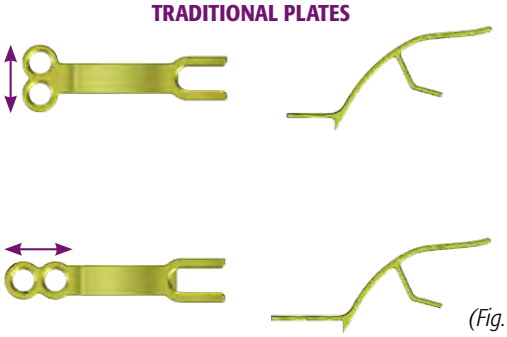


(Fig. 19)

TRADITIONAL PLATES

Cranial-Caudal

Medial-Lateral



(Fig. 20)

LARGE LAMINAR PLATES

Cranial-Caudal

(Fig. 21)

ALLOGRAFT

(Fig. 22)

LEVERAGE® LFS TECHNIQUE GUIDE

STEP 9:
DETERMINE THE GRAFT AND PLATE SIZE

The color-coded Graft Trials can be used to determine the plate and graft size that provides the amount of laminar elevation the surgeon desires.

All three plate styles come in Small (8mm/gold) *(Fig. 23)*, Medium (9.5mm/purple) *(Fig. 24)*, Large (11mm/aqua) *(Fig. 25)*, and Extra-Large (12.5mm/bronze) *(Fig. 26)*.

Tip

The Small plate is consistently appropriate for the C3 lamina, and the Medium plate for the C4-C7 laminae. Often the C7 lamina will necessitate a medium sized Large Laminar Plate to accommodate its thickness."

- Chris Brown, M.D.

SMALL

8mm

(Fig. 23)

MEDIUM

9.5mm

(Fig. 24)

LARGE

11mm

(Fig. 25)

EXTRA-LARGE

12.5mm

(Fig. 26)

STEP 10:
PLATE INSERTION

Use a Plate Holder (Fixed Plate Holder or Adjustable Needle Nose Plate Holder) to engage the plate and approach the lamina at an oblique angle (45°).

Insert the U-Shaped design of the Laminar Plates to engage the collar of the Laminar Screw *(Fig. 27)*.

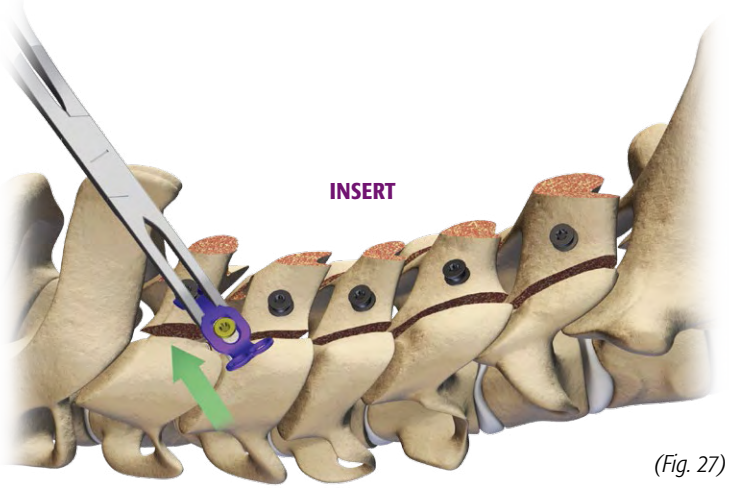
Rotate the plate *(Fig. 28)*.

Elevate the lamina until the plate's lateral mass foot and allograft rest up against the lateral mass *(Fig. 29)*. Repeat these steps for all plate placement sites.

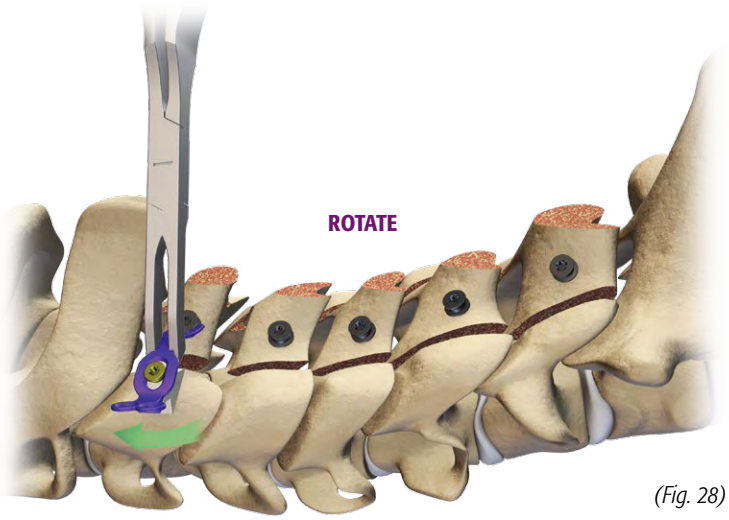
Tip

"Once the plates are positioned, the Needle Nose Plate Holder can be used to move the plates medially so that the lateral mass foot rests nicely on the lateral mass. This is accomplished by placing the distal tips of the needle nose in the lateral holes of the plate to adjust placement medially and further elevate."

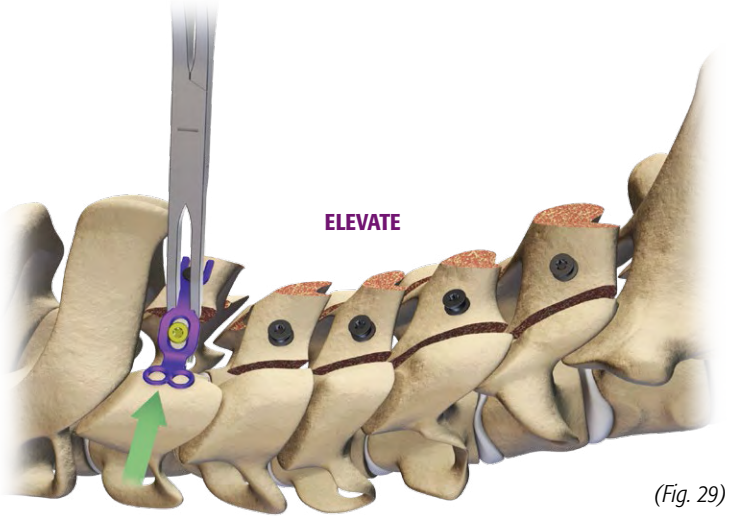
- Dave Schwartz, M.D.



(Fig. 27)



(Fig. 28)



(Fig. 29)

LEVERAGE® LFS TECHNIQUE GUIDE

STEP 11:
LATERAL MASS SCREW PLACEMENT

Drill the lateral mass holes using the appropriate length Drill Bit (e.g., 3mm/black, 5mm/gold, 6mm/purple, 7mm/aqua, 8mm/bronze) *(Fig. 30)*. Once the pilot hole is created, choose the appropriate length Self-Drilling Lateral Mass Screw. Use the Stab-n-Grab Screwdriver to engage, pick up, and insert the screw into the lateral mass pilot hole, which secures the plate to the lateral mass *(Fig. 31)*. Repeat this step for all lateral mass screw holes *(Fig. 32)*.

Tip

"Arthritic changes to the lateral mass may make docking the plate difficult prior to plate placement. Make sure the lateral mass is flat. You can accomplish this by using a high-speed burr."

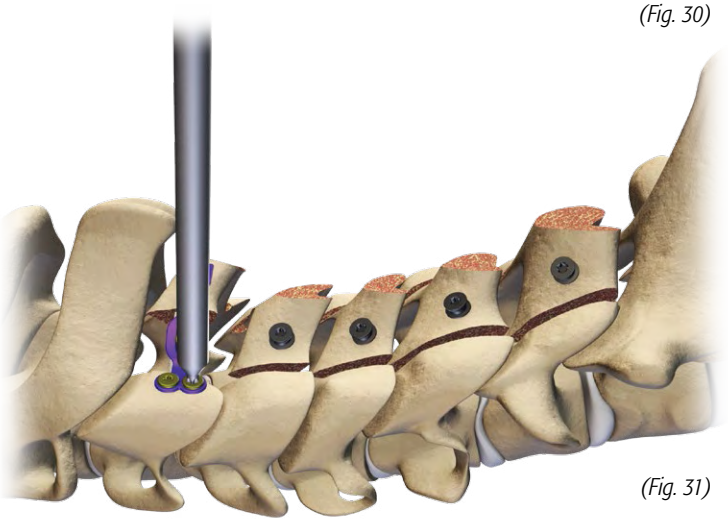
- Chris Brown, M.D.

Tip

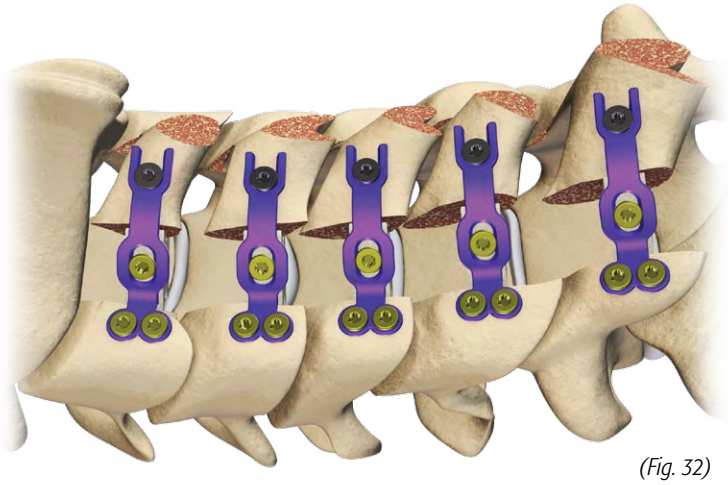
"I tend to use 7mm Lateral Mass Screws. However, when using a Cranial-Caudal Hole plate, a 5mm screw in the caudal hole can be helpful for various patient anatomies."

- Dave Schwartz, M.D.

(Fig. 30)

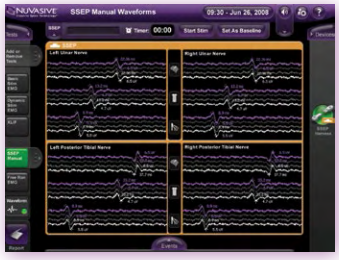


(Fig. 31)



(Fig. 32)

NVM5® – MEP AND SSEP



Use NVM5 to monitor spinal cord health and integrity during Leverage® LFS surgery. Afterward, subsequent MEP and SSEP readings may be taken to verify there has been no compromise of the spinal cord.

IMPLANT REMOVAL

For implant removal, follow this technique guide in the reverse order.

LEVERAGE® LFS INSTRUMENTS

LEVERAGE LFS INSTRUMENTS

3mm DRILL SHAFT DISPOSABLE

5mm DRILL SHAFT DISPOSABLE

6mm DRILL SHAFT DISPOSABLE

7mm DRILL SHAFT DISPOSABLE

8mm DRILL SHAFT DISPOSABLE

4-0 UP-ANGLED CURETTE

LEVERAGE® LFS SYSTEM

LEVERAGE® LFS INSTRUMENTS

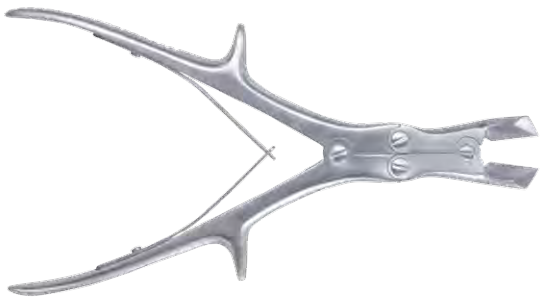
STAB-N-GRAB SCREWDRIVER

5mm FIXED DRILL

FIXED PLATE HOLDER

ADJUSTABLE NEEDLE NOSE PLATE HOLDER

BONE CUTTER



LAMINAR SCREW TEMPLATE TOOL

UNIVERSAL HANDLE

LEVERAGE® LFS INSTRUMENTS

1mm KERRISON

2mm KERRISON

LEVERAGE® LFS SYSTEM

LEVERAGE® LFS IMPLANTS

9.5mm MEDIUM TRADITIONAL PLATE (C-C)

9.5mm MEDIUM TRADITIONAL PLATE (M-L)

9.5mm MEDIUM LAMINAR PLATE (C-C)

2.6 X 5mm LAMINAR SCREW

LEVERAGE® LFS INSTRUMENTS

DESCRIPTION	CATALOG #
Stab-n-Grab Screwdriver	7650710
Fixed Plate Holder	7650715
Adjustable Needle Nose Plate Holder	7650720
Universal Handle	7650725
Bone Cutter	7650730
S-M Graft Trial	7650735
L-XL Graft Trial	7650740
Laminar Screw Template Tool	7650745
5mm Fixed Drill	7650750
1mm Kerrison	7650765
2mm Kerrison	7650770
4-0 Up-Angled Curette	7650775
DISPOSABLE INSTRUMENTS	
3mm Drill Shaft	7650753
5mm Drill Shaft	7650755
6mm Drill Shaft	7650756
7mm Drill Shaft	7650757
8mm Drill Shaft	7650758

LEVERAGE LFS IMPLANTS

DESCRIPTION	CATALOG #
PLATES	
Traditional Plate (Cranial-Caudal Hole)	
8mm Small Traditional Plate (C-C)	7650008
9.5mm Medium Traditional Plate (C-C)	7650009
11mm Large Traditional Plate (C-C)	7650011
12.5mm Extra-Large Traditional Plate (C-C)	7650012
Traditional Plate (Medial-Lateral Hole)	
8mm Small Traditional Plate (M-L)	7650108
9.5mm Medium Traditional Plate (M-L)	7650109
11mm Large Traditional Plate (M-L)	7650111
12.5mm Extra-Large Traditional Plate (M-L)	7650112
Graft Plate (Cranial-Caudal Hole)	
8mm Small Graft Plate (C-C)	7650208
9.5mm Medium Graft Plate (C-C)	7650209
11mm Large Graft Plate (C-C)	7650211
12.5mm Extra-Large Graft Plate (C-C)	7650212
Graft Plate (Medial-Lateral Hole)	
8mm Small Graft Plate (M-L)	7650308
9.5mm Medium Graft Plate (M-L)	7650309
11mm Large Graft Plate (M-L)	7650311
12.5mm Extra-Large Graft Plate (M-L)	7650312
Large Laminar Plate (Cranial-Caudal Hole)	
8mm Large Laminar Plate (C-C)	7650408
9.5mm Large Laminar Plate (C-C)	7650409
11mm Large Laminar Plate (C-C)	7650411
12.5mm Large Laminar Plate (C-C)	7650412

CATALOG

LEVERAGE® LFS IMPLANTS

DESCRIPTION	CATALOG #
LATERAL MASS SCREWS	
2.6mm Lateral Mass Screws	
2.6 x 5mm Lateral Mass/Graft Screw	7650505
2.6 x 6mm Lateral Mass Screw	7650506
2.6 x 7mm Lateral Mass Screw	7650507
2.6 x 8mm Lateral Mass Screw	7650508
3.0mm Lateral Mass Screws	
3.0 x 5mm Lateral Mass/Graft Screw	7650605
3.0 x 6mm Lateral Mass Screw	7650606
3.0 x 7mm Lateral Mass Screw	7650607
3.0 x 8mm Lateral Mass Screw	7650608
LAMINAR SCREWS	
2.6mm Laminar Screws	
2.6 x 5mm Laminar Screw	7650705
3.0mm Laminar Screws	
3.0 x 5mm Laminar Screw	7650805

LEVERAGE LFS ALLOGRAFT

DESCRIPTION	CATALOG #
ALLOGRAFT	
Small Laminoplasty Allograft	7650808
Medium Laminoplasty Allograft	7650809
Large Laminoplasty Allograft	7650811
Extra-Large Laminoplasty Allograft	7650812

DESCRIPTION

LeVerage® LFS consists of plates and screws of various sizes made from titanium alloy (ASTM F136, ISO 5832-3) to provide reinforcement while expanding the spinal canal and preserving the posterior elements. Instruments required to implant the device are also available.

INDICATIONS FOR USE

LeVerage LFS is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. LeVerage LFS is used to hold the allograft material in place in order to prevent the allograft material from expulsion, or impinging the spinal cord.

CONTRAINDICATIONS

LeVerage LFS is not to be used:

- For screw attachment or fixation to the posterior elements of the lumbar spine
- For single or two level spondylosis without developmental spinal canal stenosis
- Under any direct load bearing conditions

LeVerage LFS is not to be used when there is:

- Focal anterior compression
- Isolated Radiculopathy
- Loss of anterior column support resulting from tumor, trauma, or infection

WARNINGS AND PRECAUTIONS

The surgeon should be aware of the following when using metallic implants:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant.
2. The correct handling of the implant is extremely important. Plates should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in surface finish and internal stress concentrations, which may become the focal point for potential failure of the device.
3. Single use only. No metallic surgical implant should be reused. Any metal implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patterns, which may lead to fatigue failure.
4. Non-sterile; the plates, screws and instruments are supplied non-sterile, and therefore, must be sterilized before each use.
5. Postoperative care is important. The patient should be instructed in the limitations of the metallic implant.

WARNING

- The safety and effectiveness of LeVerage LFS has not been established when implanted in the anterior spinal column.
- LeVerage LFS, as with other metallic orthopedic appliances, is contraindicated for use in patients with active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection. The device is also contraindicated for use in patients with known or suspected metal allergies.

POTENTIAL ADVERSE EFFECTS

- Potential adverse effects include, but are not limited to:
  1. Failure of the device to provide adequate mechanical stability
  2. Loss of fixation of the implant
  3. Device component failure
  4. Migration or bending of the device
  5. Immunogenic response to the implant materials
  6. Nerve damage may occur as a result of the surgical trauma

Note: As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, permanent pain and/or deformity.

Care should be taken to insure that all components are ideally fixated prior to closure.

PREOPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. Unless stated otherwise, LeVerage LFS is not to be combined with the components of another system.
5. All parts should be cleaned and sterilized before use.

To order, please contact your NuVasive® Sales Consultant or Customer Service Representative today at:
EC REP **NuVasive, Inc.** 7475 Lusk Blvd., San Diego, CA 92121 USA • phone: 800-475-9131 fax: 800-475-9134
NuVasive UK Ltd. Suite B, Ground Floor, Caspian House, The Waterfront, Elstree, Herts WD6 3BS UK
phone: +44 (0) 208-238-7850 fax: +44 (0) 207-998-7818

www.nuvasive.com

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