

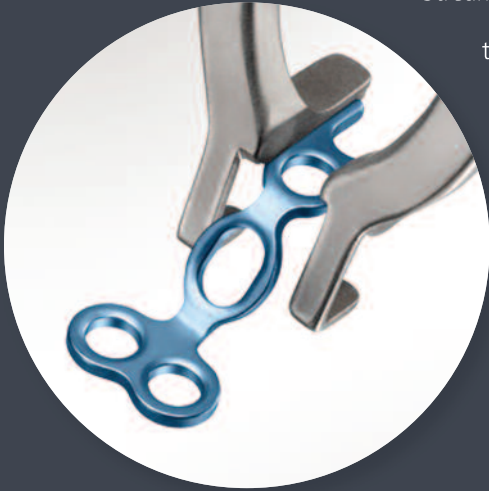
*Surgical
Technique*
Guide and
Product Catalog



INTRODUCTION

The MOUNTAINEER Laminoplasty System is a complete set of implants and instruments designed to allow for a systematic approach to laminoplasty procedures in the cervical spine. The system consists of three plate configurations to better accommodate patient anatomy and anatomical changes due to decompression procedures.

Streamlined instrumentation provides an intuitive means to implantation of the laminoplasty plate.



CONSULTING SURGEONS

Carl Lauryssen, MD

Co-Director of Spine Research and Development
Olympia Medical Center
Los Angeles, CA

Frank Phillips, MD

Professor, Director
Section of Minimally Invasive Spine Surgery
Rush University Medical Center
Chicago, IL



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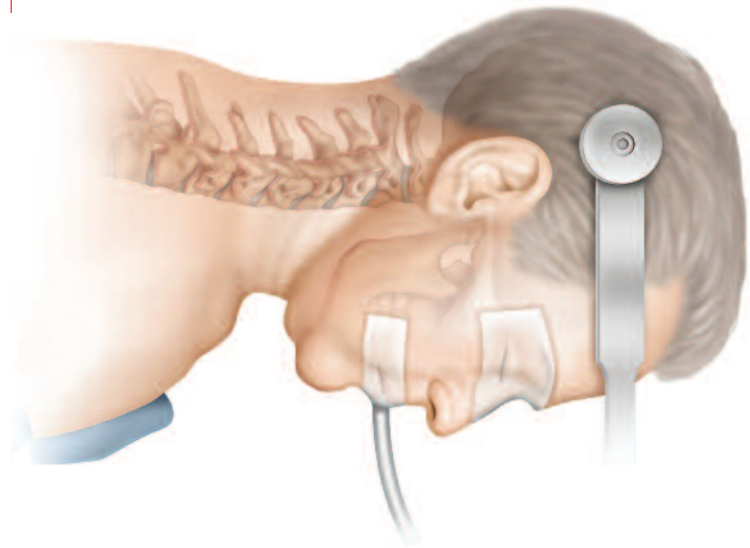
PREOPERATIVE PLANNING

It is a pre-requisite that, due to the anatomic variability of each patient, the surgeon has available the range of necessary images in order to be equipped to plan the operation appropriately.

PATIENT POSITIONING

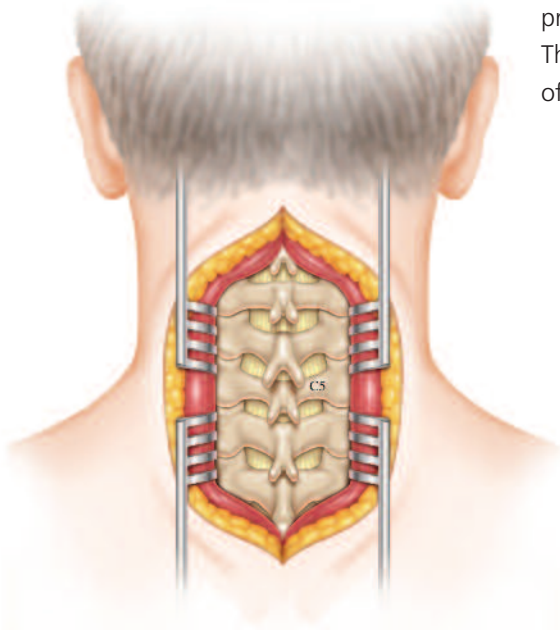
The patient is placed on the operating table in the prone position with head and neck held securely in proper alignment (Figure 1). Confirm proper alignment with an image intensifier, or radiograph as well as direct visualization prior to draping.

FIGURE 1



EXPOSURE

FIGURE 2



A standard midline sub-periosteal exposure of the involved levels is performed, preserving muscular attachments to C2. When possible, preserve the inter and supraspinous ligament between C7 and T1. The lateral dissection follows the subperiosteal plane out to the edge of the lateral mass, but preserves the facet joint capsule (Figure 2).

INTRA-OPERATIVE PLANNING

Once the required exposure is achieved, evaluate the anatomy and assess its ability to accept the pre-operative construct strategy. Identify all system components required for the final construct.

TROUGH PREPARATION

The open side trough is prepared with a burr along the junction of the laminae and the lateral mass (Figure 3/Figure 4). A combination of burrs and Kerrisons may be used to create the trough avoiding intrusion of instruments into the spinal canal. If symptoms are unilateral, the trough should be located on the symptomatic side. When symptoms are bilateral, the location of the trough is left to the discretion of the surgeon. An attempt should be made to release the ligamentum flavum at the rostral and caudal ends of the levels being addressed if possible.

FIGURE 3

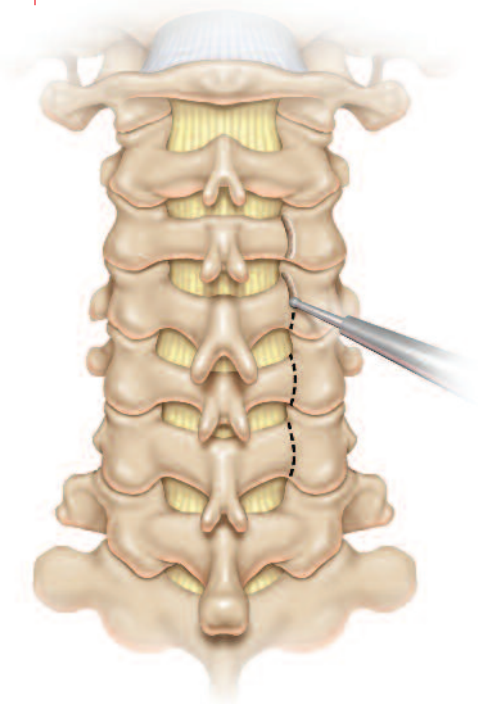
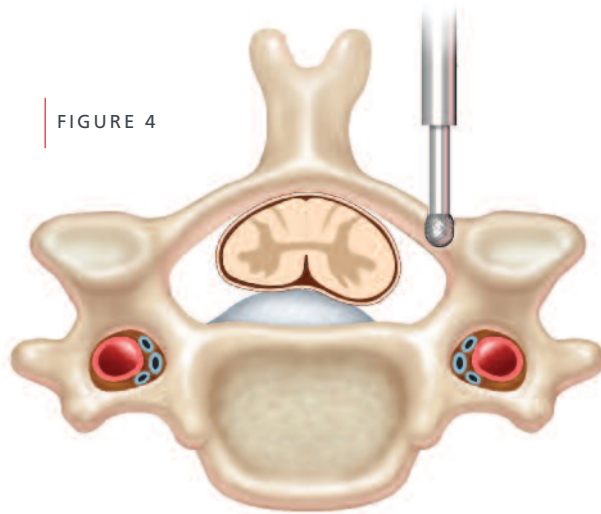


FIGURE 4



ALTERNATIVE TECHNIQUE (Screw-First Technique)

The addition of an open slot on the lamina portion of the plate allows for placement of the lamina screw after the creation of the trough and prior to the creation of the hinge.

After the trough has been created, use the Screw-First Template to identify the proper location of the medial lamina screw. Once the proper positioning is achieved, the fixed-depth drill is then used through the template (Figures 5 – 7).

FIGURE 5

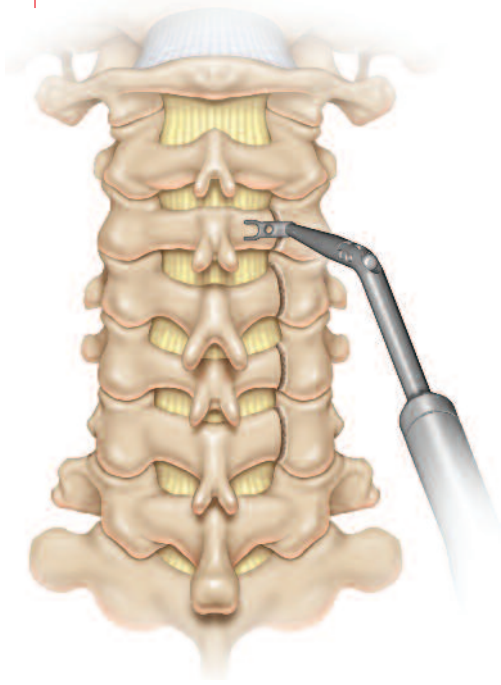


FIGURE 6

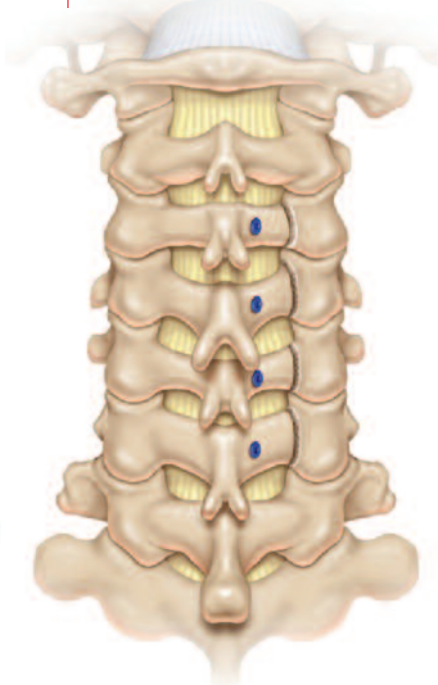
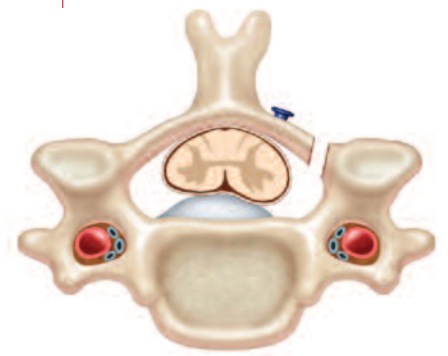


FIGURE 7



The lamina screw may be placed prior to the creation of the hinge only if there is no risk of compressing or injuring the spinal cord and/or dura (Figure 8).

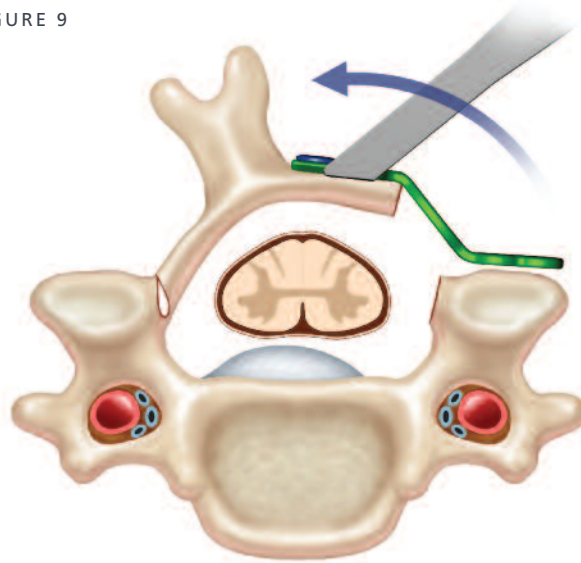
Place lamina screws at all levels to be instrumented.

The laminar screw should be inserted until they are at least 1 mm proud to account for the thickness of the plate. The hinge is then created at all involved levels. The lamina are then hinged open in the normal manner (Figure 9).

FIGURE 8



FIGURE 9

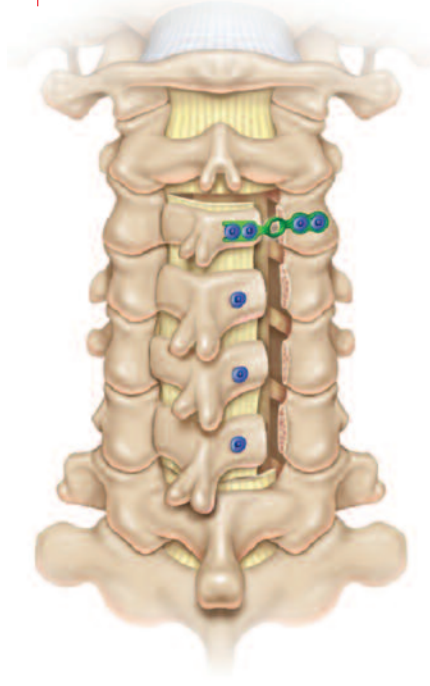


The open end of the plate is then engaged with the lamina screw. Screws are then placed in the lateral mass. The second lamina screw is then inserted in the lamina. Compression may be applied to the allograft prior to inserting the second lamina screw. It is important to re-visit the medial lamina screws to ensure they are properly seated against the plate (Figures 10/figure 11).

FIGURE 10



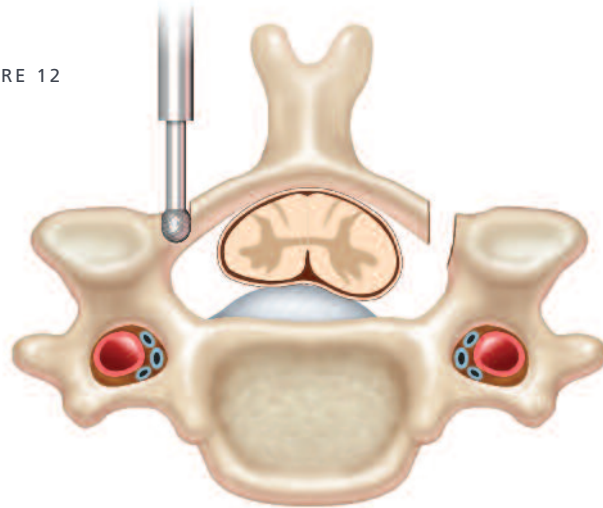
FIGURE 11



HINGE SIDE PREPARATION

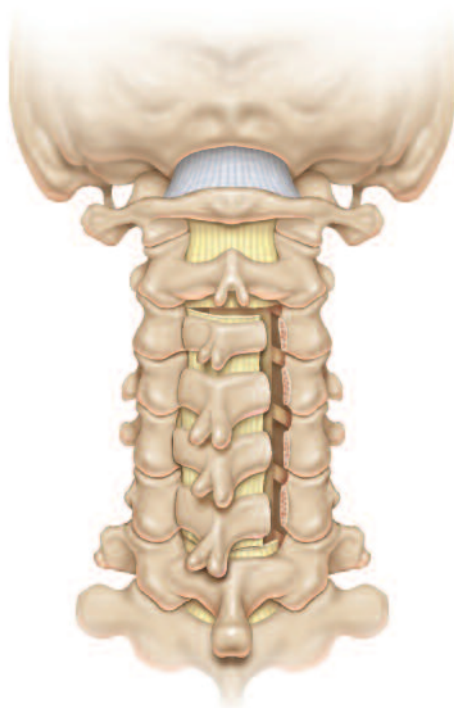
The hinge side should be prepared in the same manner as the creation of the trough with a burr. The location of the hinge is similar to that of the trough on the contralateral side; at the lamino-lateral mass junction. The amount of bone to be removed for the hinge should be sufficient to create a greenstick fracture (Figure 12). The deep cortex should be preserved to prevent complete fracture of the lamino-lateral mass junction. Too much bone removal may result in a fracture requiring additional fixation.

FIGURE 12



LAMINA EXPANSION

FIGURE 13

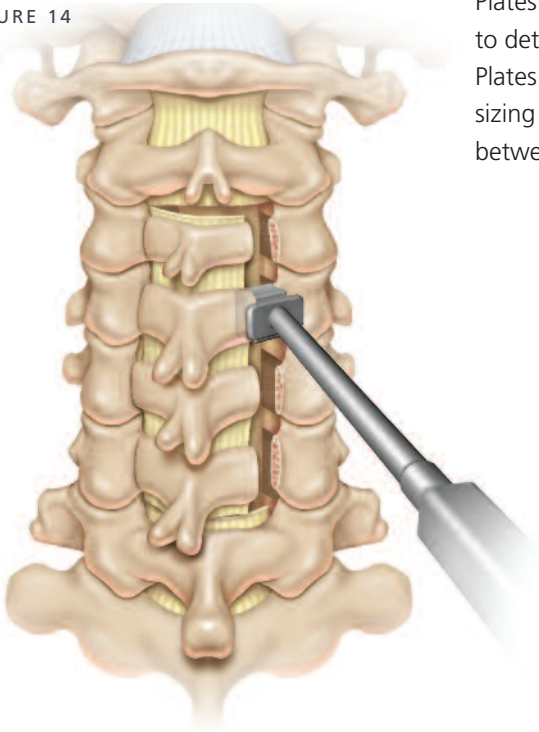


Sequential hinging should occur until all the laminae are hinged open. Gentle pressure against the spinous process will allow for the surgeon to feel how much “give” the hinge is providing. Only after all levels have been hinged or released, should the surgeon attempt to insert the trial for sizing.

Attention should be paid to the Ligamentum Flavum as a structure that may be preventing the hinge from opening (Figure 13).

ALLOGRAFT/PLATE TRIALING

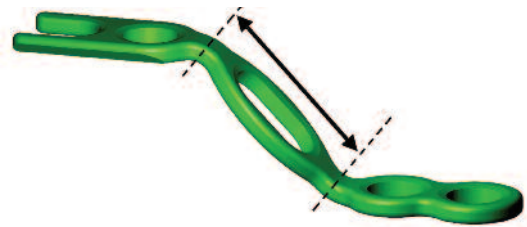
FIGURE 14



Plates may be used with or without allograft spacers. Trials are used to determine both the size of the allograft and the size of the plate. Plates are available in 6mm to 18mm in increments of 2mm. Plate sizing corresponds to the amount of distraction/spacing achieved between the lamina and lateral mass (Figures 14/Figure 14A).

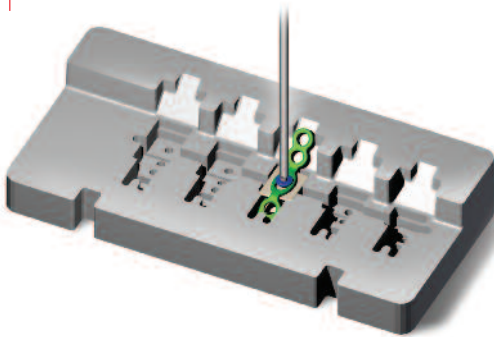
Plate Thickness:	1mm
Plate Offering:	6-18mm (2mm increments)
Screw Offering:	2.3mm+2.6mm (4-12mm lengths)

FIGURE 14A



ALLOGRAFT ATTACHMENT

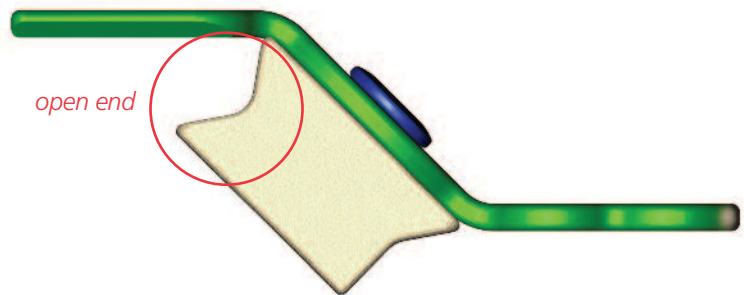
FIGURE 15



After the appropriate allograft size has been determined through the use of the graft/plate trials, use the graft loading block (Figure 15) to secure the allograft to the plate with a 2.3mm x 4.0mm screw through the pre-drilled hole. The graft should fit “loosely” to the plate to allow for compression of the graft after the plate has been secured.

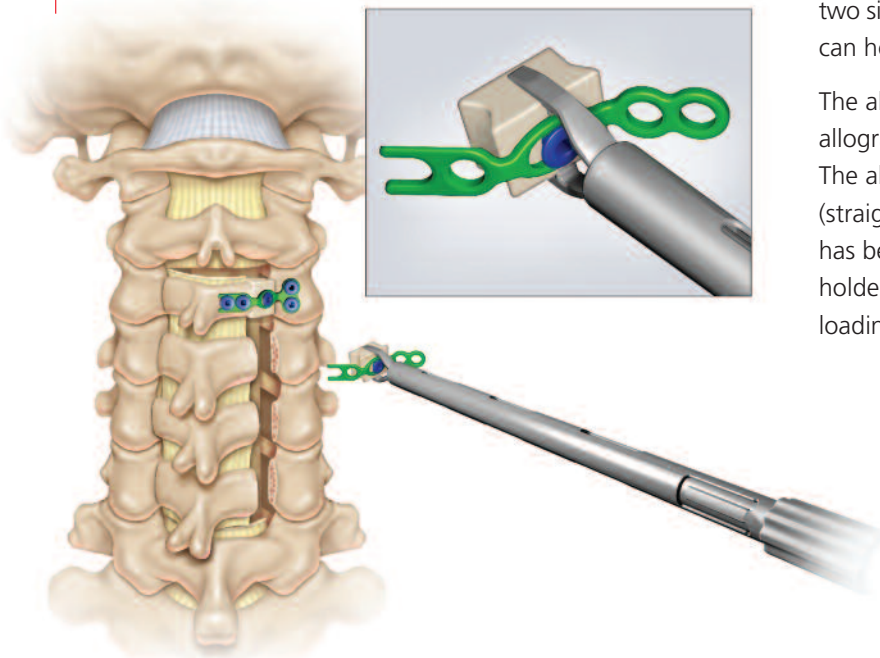
The allograft should be orientated in the graft loading block such that the “v” portion of the allograft (identified in Figure 16) faces the open end of the laminoplasty plate. The graft loading block is designed so that, when placed correctly, the allograft will fit flush within the well. Images on the graft loading block will assist with the correct orientation of the allograft to the plate.

FIGURE 16



- The allograft has been designed to fit the anatomy of the lateral mass and the lamina after the trough has been created (Figure 17).
- Cortical allografts are available from 4mm to 12mm in 2mm

FIGURE 17



increments. Plates are designed to accommodate two sizes of allograft. For example a 6mm plate can house a 4mm or 6mm allograft.

The allograft holder may be used to insert the allograft with or without the plate attached. The allograft holder has two removable tips (straight and angled). The graft loading block has been designed to allow for the allograft holder to engage the allograft directly from the loading block.

PLATE CONTOURING

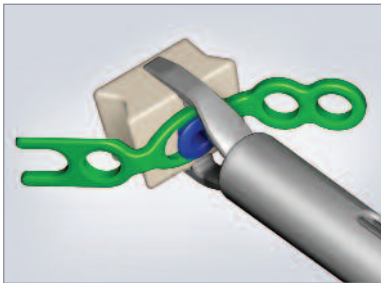
The plates may be sculpted to achieve the best fit for the angles of the lateral mass and lamina in the axial, coronal and sagittal planes. Plates are manufactured of Commercially Pure Ti and can be contoured by hand. A plate cutter is also provided for additional contouring.

PLATE HOLDERS

FIGURE 18A



FIGURE 18B



There are three types of plate holders available with the system.

- Tweezers: ideal for use when utilizing the Screw First Technique (Figure 18A).
- Allograft holder: directly engages the lateral slots of the allograft (Figure 18B).
- Lamina stabilizer: engages the lamina for additional stabilization when inserting screws into the lamina. The screw caddies have been designed to allow the lamina stabilizer to engage the laminoplasty plate while it is housed in the caddy. This will ensure proper positioning of the lamina stabilizer on the plate. The lamina stabilizer is ideal when the Screw First Technique is not being employed or when allograft is not being utilized (Figure 18C).

FIGURE 18C



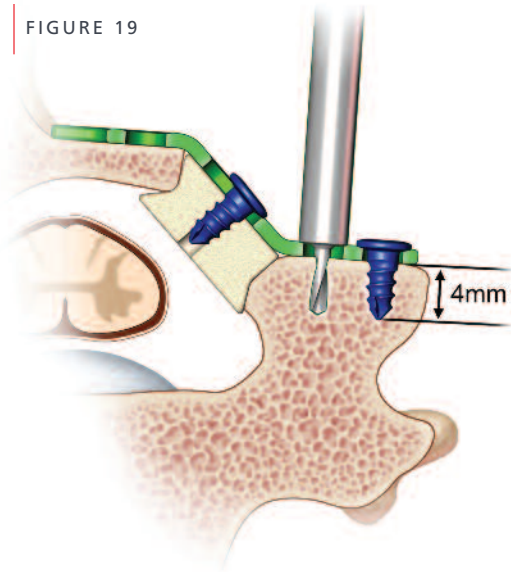
PLATE POSITIONING

The laminoplasty plates should be positioned such that the screw holes allow for screw placement in the center of the lateral mass and the thickest portion of the lamina.

Plates are available in two configurations, inline and inline side-by-side. This refers to the screw placement on the lateral mass portion of the laminoplasty plate.

DRILLING/SCREW INSERTION

FIGURE 19



Drilling is accomplished through the use of the 1.8mm diameter fixed-depth drill (Figure 19). Drills are available in 4, 6, 8, 10 and 12mm lengths. The drill may be attached to the quick connect handle for manual drilling or attached to a power drill.

Attach the self-retaining square tip driver to the quick connect handle for screw insertion. Insert the square tip driver into the square feature of the screw head prior to sliding the outer sleeve over the screw. Insert appropriate length 2.3mm self-tapping screws so that screws are secured to the plate. Do not over tighten screws to the plate. Screws are provided in both 2.3mm and 2.6mm diameters (Figure 20A/ Figure 20B).

FIGURE 20A

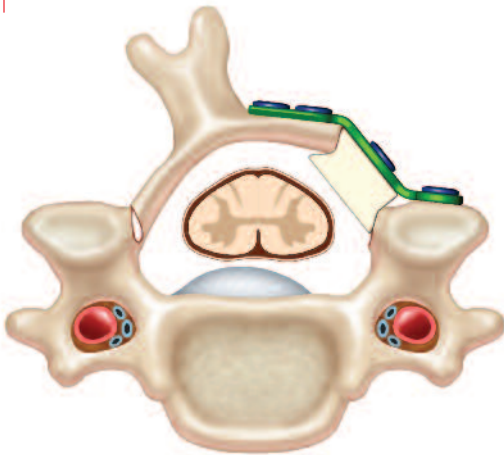
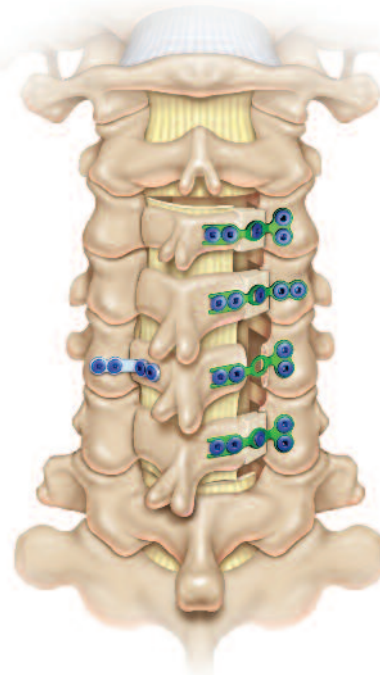


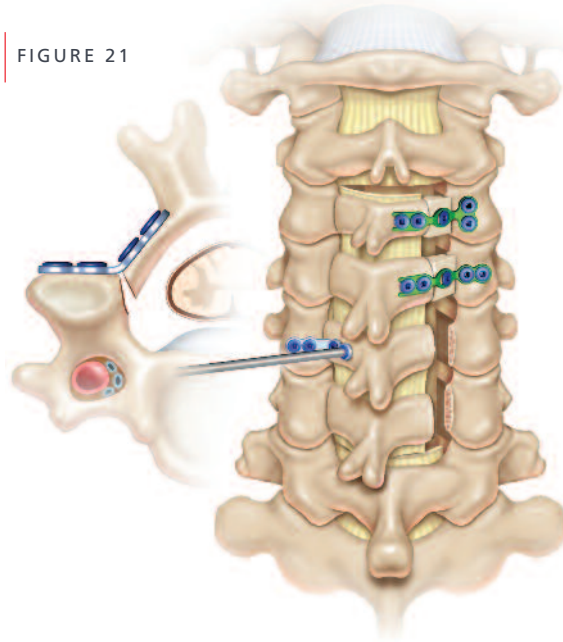
FIGURE 20B



HINGE PLATE

A hinge plate is provided in the event the hinge becomes weakened or displaced. The lamina should be stabilized and held firmly for drilling. The hinge plate is then attached to the lamina with two screws. The lamina can then be opened as usual. Finally, two screws are used to attach the hinge plate to the lateral mass (Figure 21).

FIGURE 21



Repeat for all levels.

IMPLANT REMOVAL

To remove both the plates and the screws, it is recommended that a plate holder engage the plate before attempting screw removal. To remove the screws, engage the square tip driver shaft into the head of the screw and remove all screws from the bone. The plate can then move freely and be removed.

IMPLANTS

Code	Description
1883-70-004	2.30mm X 4mm Screw
1883-70-006	2.30mm X 6mm Screw
1883-70-008	2.30mm X 8mm Screw
1883-70-010	2.30mm X 10mm Screw
1883-70-012	2.30mm X 12mm Screw
1883-70-104	2.60mm X 4mm Screw
1883-70-106	2.60mm X 6mm Screw
1883-70-108	2.60mm X 8mm Screw
1883-70-110	2.60mm X 10mm Screw
1883-70-112	2.60mm X 12mm Screw



1883-70-200	Hinge Plate
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1883-70-306	6mm Inline Side-by-Side Plate
1883-70-308	8mm Inline Side-by-Side Plate
1883-70-310	10mm Inline Side-by-Side Plate
1883-70-312	12mm Inline Side-by-Side Plate
1883-70-314	14mm Inline Side-by-Side Plate
1883-70-316	16mm Inline Side-by-Side Plate
1883-70-318	18mm Inline Side-by-Side Plate



1883-70-406	6mm Inline Plate
1883-70-408	8mm Inline Plate
1883-70-410	10mm Inline Plate
1883-70-412	12mm Inline Plate
1883-70-414	14mm Inline Plate
1883-70-416	16mm Inline Plate
1883-70-418	18mm Inline Plate



INSTRUMENTS

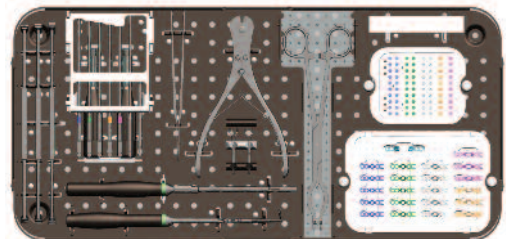
Code	Description
2883-20-002	Square Driver Tip
2883-20-204	Driver Sleeve
2883-20-106	1.8mm Drill Bit, 4mm
2883-20-104	1.8mm Drill Bit, 6mm
2883-20-108	1.8mm Drill Bit, 8mm
2883-20-110	1.8mm Drill Bit, 10mm
2883-20-112	1.8mm Drill Bit, 12mm

2883-20-210	Plate Holder, Tweezer style
2883-20-245	Screw-First Template
2883-20-214	Lamina Stabilizer
2883-20-213	Allograft Holder
2883-20-216	Straight Graft Tip
2883-20-217	Angled Graft Tip
2883-20-406	Sizing Trial assy 4/6mm
2883-20-408	Sizing Trial assy 8/10mm
2883-20-412	Sizing Trial assy 12/14mm

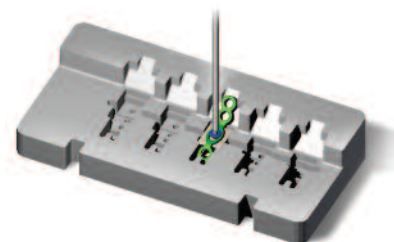


2865-20-000	Quick Couple Handle
7825-150	Plate Cutter

2883-90-800	Case
2883-90-810	Laminoplasty Case Lid
2883-90-811	Drill Caddy
2883-90-820	2.3mm Screw Caddy
2883-90-821	2.6mm Screw Caddy
2883-90-822	Inline Side-by-Side Plate Caddy
2883-90-823	Inline Plate caddy



2883-90-202	Graft Loading Block
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Laminoplasty System

INDICATIONS

Caution: USA Law restricts this device to sale by or on the order of a physician.

The MOUNTAINEER Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The MOUNTAINEER Laminoplasty System is used to hold or buttress the allograft or autograft material in place in order to prevent the allograft or autograft material from expulsion or impinging the spinal cord.

CONTRAINDICATIONS

1. Use of this system is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implant.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Patients who have been shown to be safely and predictably treated without internal fixation. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS CONCERNING SPINAL FIXATION IMPLANTS

Following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to devices such as the MOUNTAINEER Laminoplasty System implants. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.** The potential for a satisfactory laminoplasty procedure is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
3. **MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices which come into contact with other metal objects must be made from like or compatible metals. Avoid coupling of stainless steel with these implants.
4. **CLINICAL OUTCOMES MAY VARY.** Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.
2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of metal implants should be done only with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage of the implant.
3. **REMOVAL OF SUPPLEMENTAL FIXATION AFTER HEALING.** If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management. If, for example, the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.
4. **ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone fusion is complete. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration to the devices and damage to nerves or blood vessels.

Limited Warranty and Disclaimer: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

To order in the US, call DePuy Spine Customer Service (1-800-227-6633).

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767
USA
Tel: +1 (800) 227-6633

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