

Medtronic

SURGICAL TECHNIQUE

Centerpiece™ 2.0 Plate Fixation System

The Centerpiece™ plate fixation system incorporates a variety of pre-cut, precontoured plate designs and offers a complete and versatile solution for laminoplasty procedures.

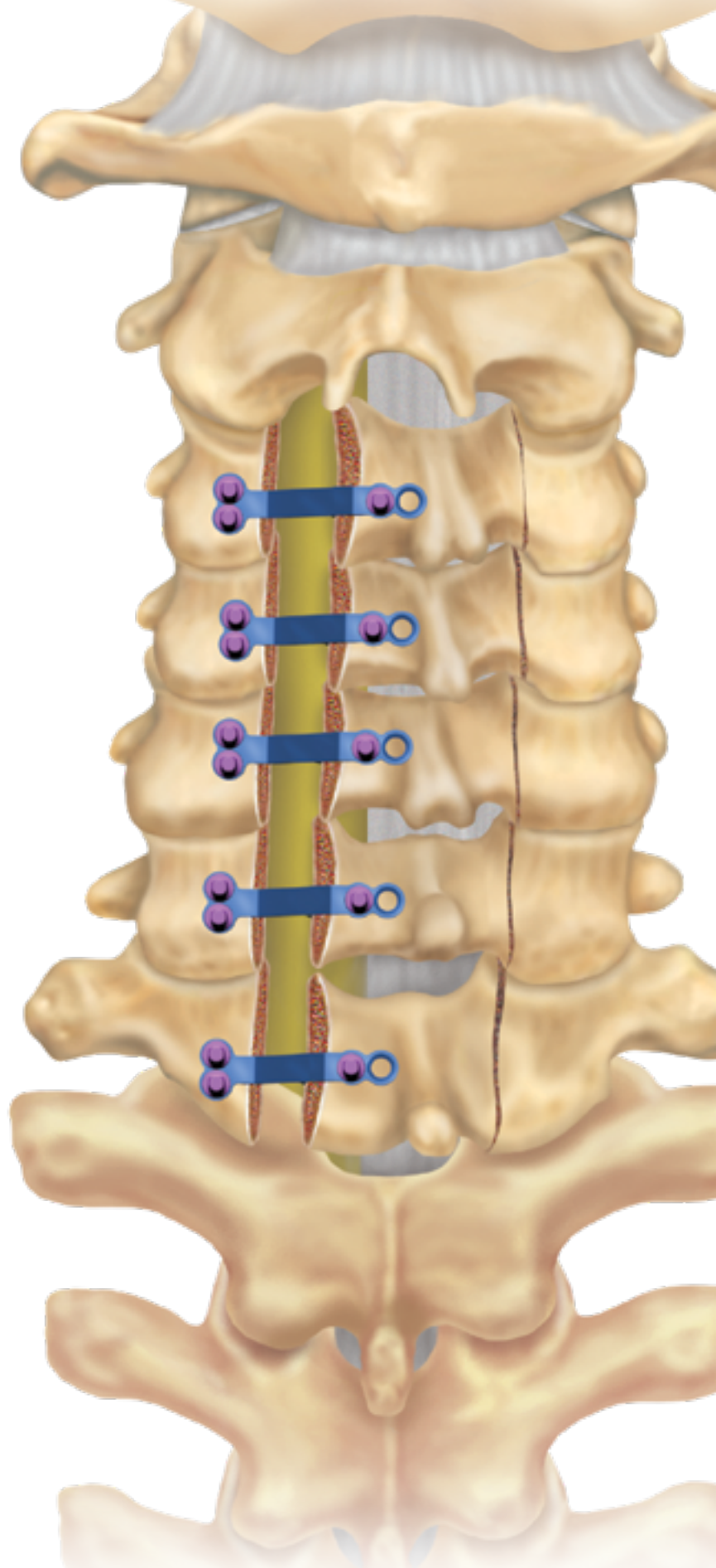


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Open door technique

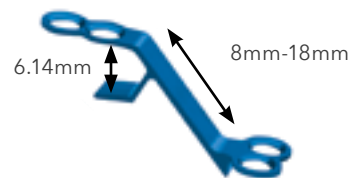
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Implant features

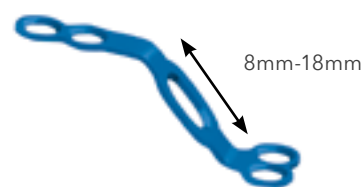
Open Door Plates

- Pre-cut, precontoured plate design
- Laminar shelf of plate allows for secure laminar fixation
- Multiple screw hole options for flexibility in screw placement
- Inherent stability provided by design of plate
- Available in 8mm to 18mm sizes in 2mm increments
- Color coded



Graft Plates

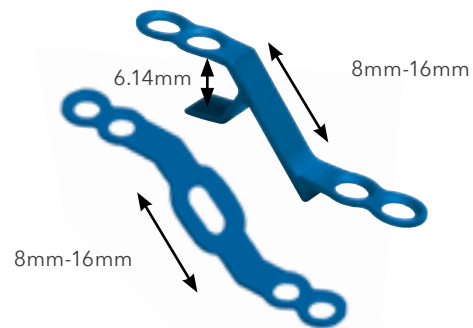
- Pre-cut, precontoured plate design
- Oval-shaped center screw hole in the graft plate allows for fine adjustments of the plate on the allograft
- Multiple screw hole options for flexibility in screw placement
- Available in 8mm to 18mm sizes in 2mm increments
- Color coded



Lateral Hole Plates

(Open Door and Graft Plate Designs)

- Medial/lateral orientation of the lateral mass screw holes allows for flexible screw placement in the event that the surface area of the lateral mass has been reduced in its cranial-caudal dimension, especially following supplemental foraminotomies
- Available in 8mm to 16mm sizes in 2mm increments
- Color coded



Trough Plates

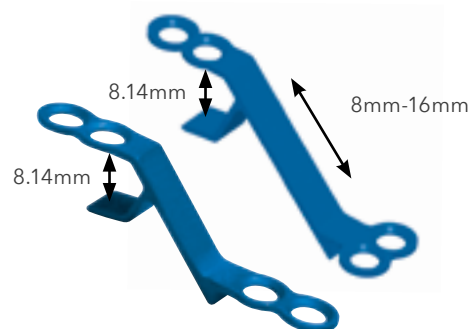
- Small, angled plate provides secure fixation for a floppy or displaced hinge



Wide Mouth Plates

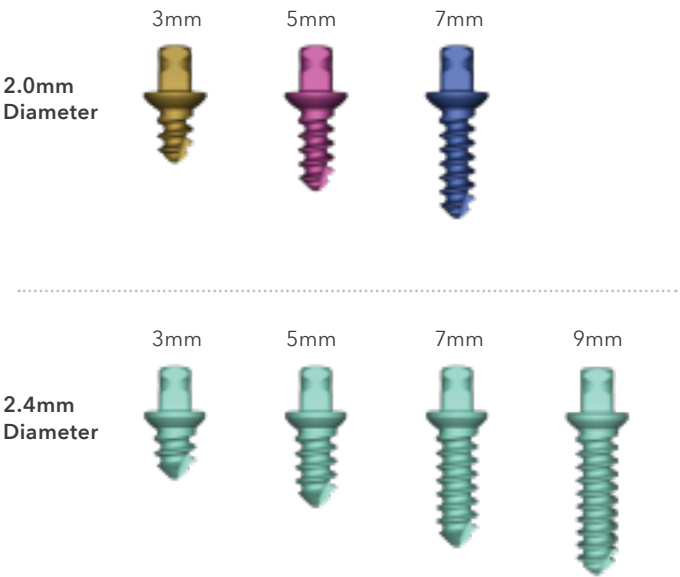
(Open Door Lateral Hole Plate and Open Door Standard Hole Plate)

- Wider laminar shelf used to accommodate thick laminae
- Available in 8mm to 16mm sizes in 2mm increments
- Color coded



Bone Screws

- Self-tapping
- Driver with stab-and-grab feature
- Available in 2 diameters:
 - 2.0mm in lengths of 3mm, 5mm, 7mm.
 - 2.4mm diameter in lengths of 3mm, 5mm, 7mm, and 9mm.
- 2.0mm screws are color-coded by length and 2.4mm screws are color-coded seafoam green



Note

The 9 mm drill will not have epoxy color-coding

Color Coding Reference

	Screw	Screw Color	Drill
2.0mm Ø	Ø2.0mm × 3mm	Gold	No drill*
	Ø2.0mm × 5mm	Magenta	8530636
	Ø2.0mm × 7mm	Blue	8530637
2.4mm Ø	Ø2.4mm × 3mm	Seafoam	No drill
	Ø2.4mm × 5mm	Seafoam	No drill
	Ø2.4mm × 7mm	Seafoam	No drill
	Ø2.4mm × 9mm	Seafoam	8530638 (Drill without a color band)

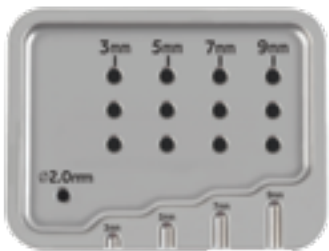
* See pre-drill options listed on page 12

Allograft

- All cortical graft provides added stability
- Simplifies surgical technique to eliminate the need to shape resected autograft
- Curved edges of allograft provide a secure fit between the lamina and lateral mass
- Predrilled center screw hole allows for immediate access for screw insertion, eliminating a procedural step
- Available in 8mm to 18mm sizes in 2mm increments
- Freeze-dried



Instrument set



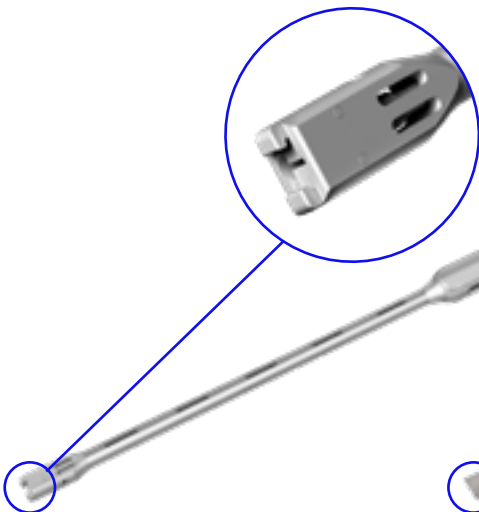
Loading Block
8530635



Universal Handle
6956016



Bone Trial
8mm-10mm 8530810
12mm-14mm 8530812
16mm-18mm 8530814



Graft Plate Holder
8530633

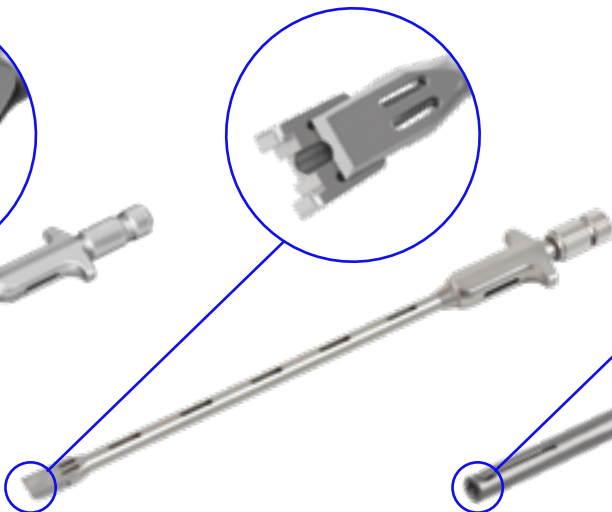
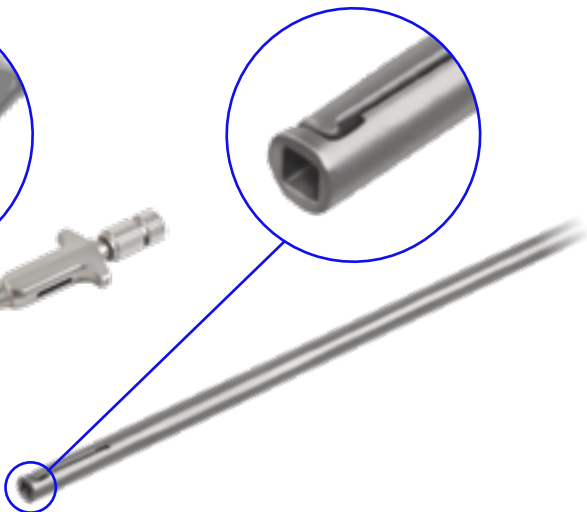
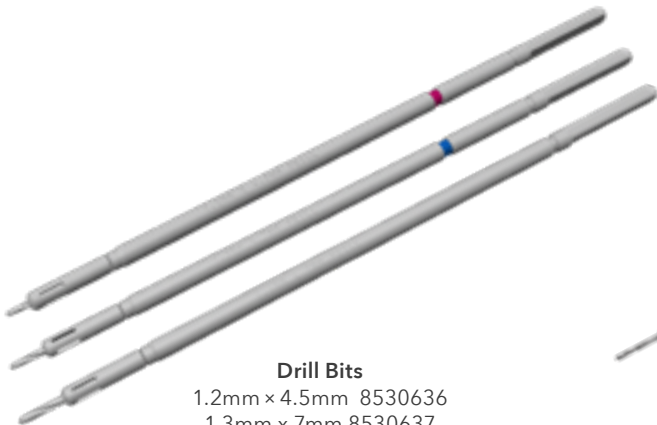


Plate Holder
8530634



Screwdriver Shaft
8531630



Drill Bits
1.2mm x 4.5mm 8530636
1.3mm x 7mm 8530637
1.6mm x 9mm 8530638



Midas™ Handle with End Adapter
*See page 21 for suggested items

Overview

Cervical laminoplasty can achieve spinal cord decompression commonly due to multisegmental spondylosis and/or ossification of the posterior longitudinal ligament (OPLL).^{1,2}

The most common reason for failure of laminoplasty has been restenosis due to hinge closure. Various techniques have been employed to hold the door open while the host heals the laminar hinge in the expanded position. Ideally, a method of achieving laminar fixation should be technically intuitive and provide secure maintenance of the lamina in the open position. The authors describe the use of the Centerpiece™ plate fixation system designed to accomplish these goals during open door laminoplasty. The technical issues relevant to performing the laminoplasty and securing the laminae are discussed.

Laminoplasty procedures using these plates will potentially allow the patient to engage in an early, active rehabilitation protocol, and may ultimately lead to better preservation of motion.

1. Heller JG, Edwards CC II, Murakami H, Rodts GE. Laminoplasty versus laminectomy and fusion for multilevel cervical myelopathy: an independent matched cohort analysis. *Spine*. June 15, 2001;26(12):1330-1336.

2. Yonenobu K, Heller JG, Oda T. Posterior Decompression for Myelopathy: Laminoplasty. In: Herkowitz HN, ed. *The Cervical Spine Surgery Atlas*. 2nd ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2003:203-218.

Patient positioning

The patient is positioned prone as for most other posterior cervical procedures, with the head secured in a Mayfield three-pin head holder, preferably in slight flexion (**Figures 1a and 1b**). Some cervical flexion helps reduce the overlap of the laminae and facet joints, which facilitates the laminoplasty itself. A reverse Trendelenburg position may help decrease bleeding from epidural and paravertebral veins.

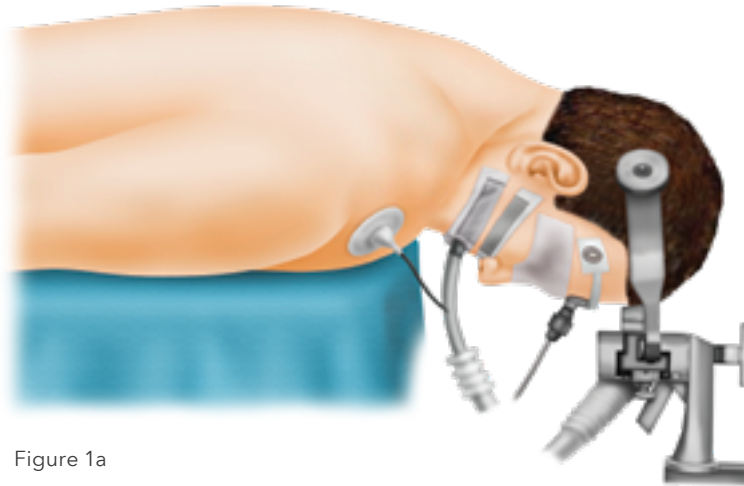


Figure 1a

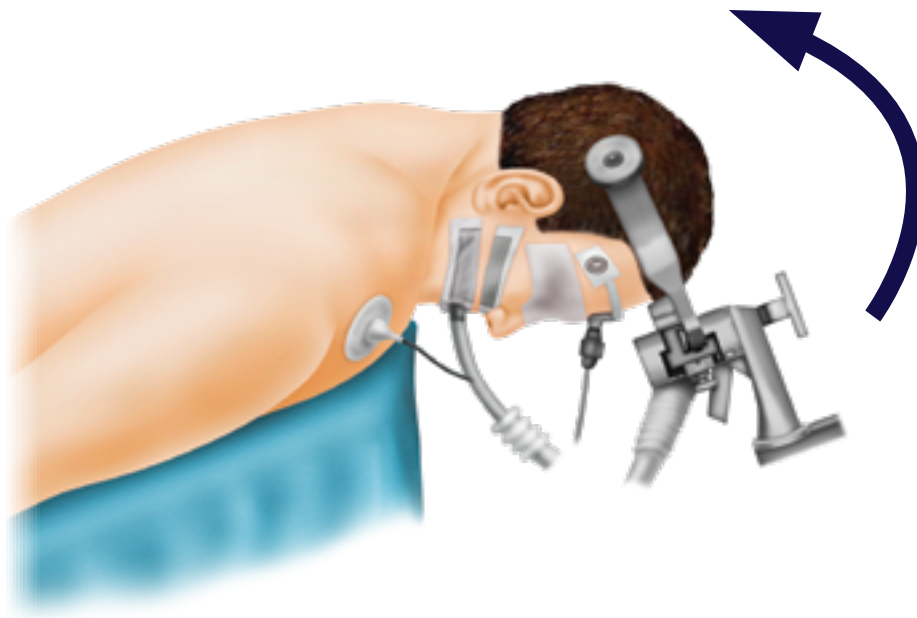


Figure 1b

Surgical exposure

The surgeon performs a midline posterior exposure from the inferior aspect of highest level to be decompressed to the superior aspect of the lowest level (**Figures 2 and 3**). The lateral dissection follows the subperiosteal plane out to the midportion of the lateral masses. Unlike the exposure required for a laminectomy and fusion, the muscle origins and insertions over the lateral half of the lateral masses are preserved. Should the levels to be decompressed

involve C3, the insertion of the extensor muscles is only detached from the lower laminar margin of C2 to afford access to the C2-C3 interlaminar space. The junction of the medial aspect of the lateral mass with the lateral portion of the lamina is identified at each level planned in the decompression. At this point, it is particularly helpful to correlate the local surface anatomy with the preoperative axial images.

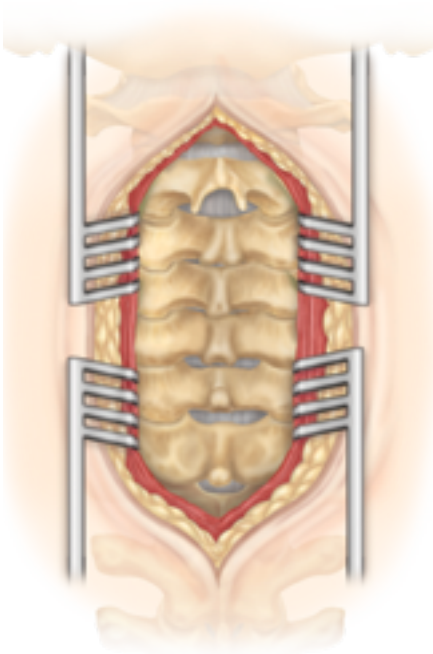


Figure 2



Figure 3

Helpful Hint

In the event that the posterior decompression should extend to the C2 level, this can be accomplished while respecting the integrity of the C2 posterior arch and the majority of its muscular origins and insertions. A “dome laminectomy” is performed by using a burr and Kerrison to remove the lower margin of C2, followed by the cancellous bone and ventral cortex (**Figures 4a, 4b, and 4c**).

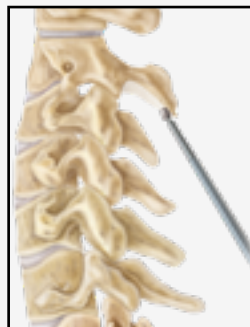


Figure 4a



Figure 4b



Figure 4c

Open door technique

Open-side trough preparation

The open-side trough is prepared with a burr along the junction of the lamina and the lateral mass. The Midas Rex™ portfolio of high speed burrs are available in various diameters and geometries, depending on surgeon preference and presentation of the anatomy. Three layers of bone must be removed: the dorsal cortex, followed by the cancellous layer and then the ventral cortex (**Figures 5a and 5b**).

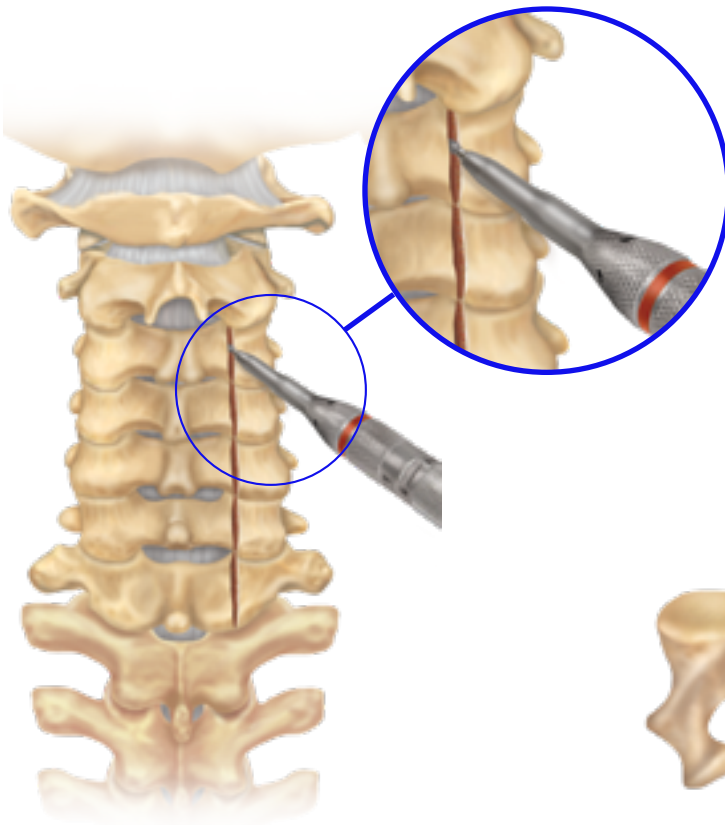


Figure 5a

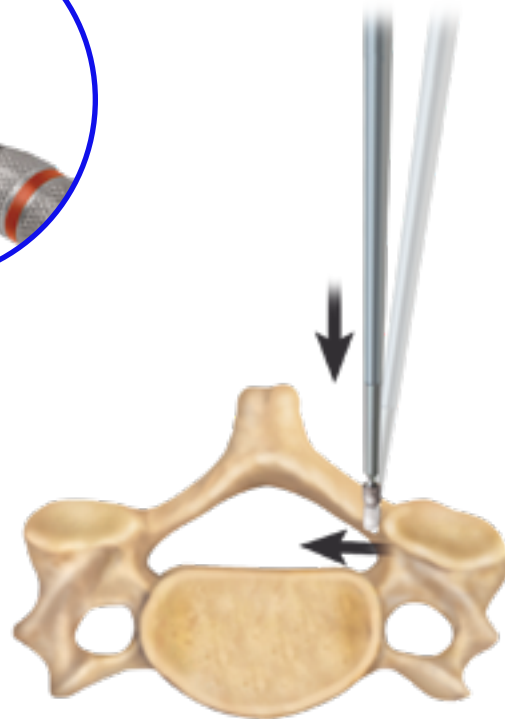


Figure 5b

Helpful Hint

The side of the spinal canal to be opened may be chosen for a number of reasons. Planned foraminal decompression may be more readily performed on the chosen open door side. If the patient shows radiographic evidence that there is central stenosis or OPLL lesion that is asymmetric this may help determine which side to choose as the open vs. hinge side. In addition, perioperative CT can help determine the thickness of

"hinged side" bone in order to determine its suitability to undergo plastic deformation. Finally, all things being equal, the choice may be influenced by the surgeon's dominant hand. A right-hand-dominant surgeon will probably wish to stand on the patient's left and open the left side. The converse would be the case for a left-handed surgeon.

Hemostasis of the bone surfaces can be achieved with the use of thin bone wax “match sticks” or applying a slurry of a hemostatic device and thrombin solution. The completion of the bone separation on the open side can be performed with a 1.0mm Kerrison rongeur. At this point, the objective is to ensure that bone separation has been achieved. Divide the ligamentum flavum as required. A 2.0mm or 3.0mm Kerrison punch may be used to excise the ligamentum flavum at the inferior and superior most levels. (**Figure 6**).

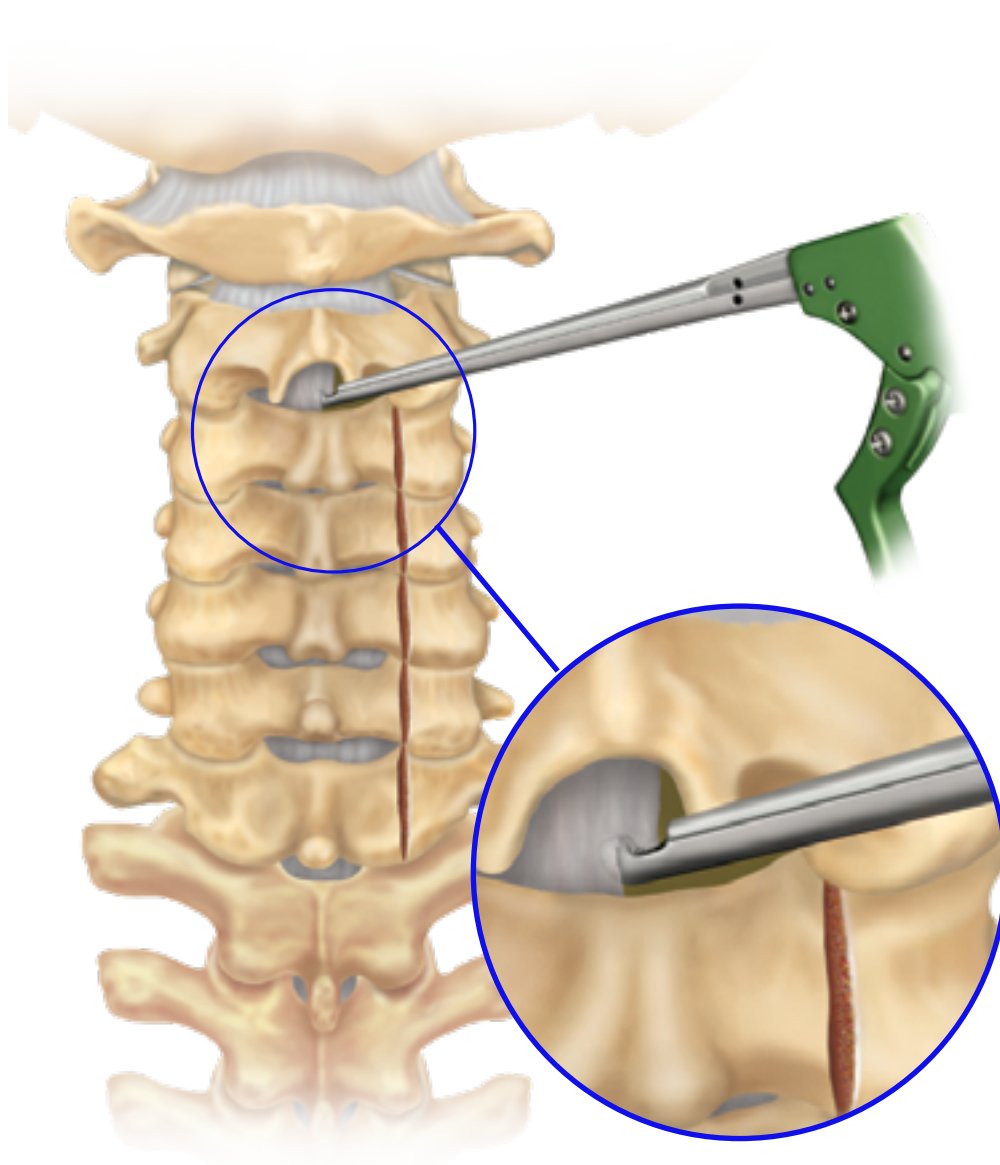


Figure 6

Open door technique

Hinge-side trough preparation

On the hinge side of the laminoplasty another trough is made with the burr of choice (**Figures 7a and 7b**). The cranial aspect of the hinge may be the thickest part. Many surgeons use a "diamond-tipped burr" for formation of the hinge side in particular. This will permit one to assess the stiffness of the hinge as it is prepared for each lamina. Care must be taken to avoid common errors: placing the trough too medially over the laminae which may not give an adequate decompression and may not leave enough bone to hold the hinge open with the plate on the lamina side, removing excessive bone, and/or placing the hinge too lateral which may violate the facet joint and destabilize the motion segment.

After removing the dorsal cortex and cancellous layer, assess the stiffness of the hinge at each level. The laminar hinge should yield slightly with a moderate bending force. The surgeon should err on the side of leaving more bone, as fine-tuning can be done once every level is at, or close to, the desired thickness. If the hinge fails to bend despite resection of what seems to be an adequate amount of bone, check to be sure that the bone was completely divided on the open side.

Helpful Hint

In a situation where a hinge is either too floppy or displaced, the surgeon could opt to use the trough plate. This small, angled plate may be used to secure the hinge when it is thought to be necessary. (**See page 19**)

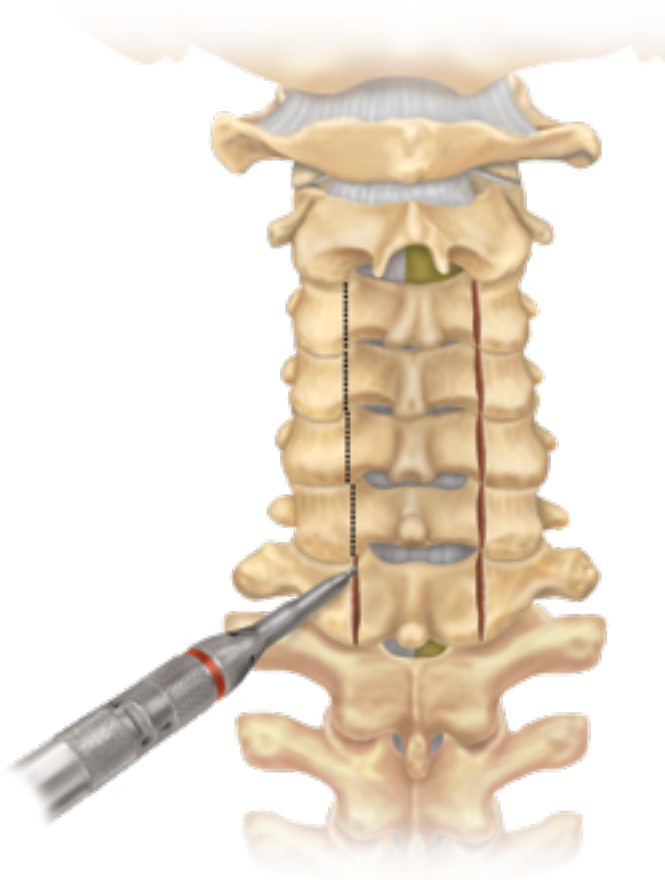


Figure 7a

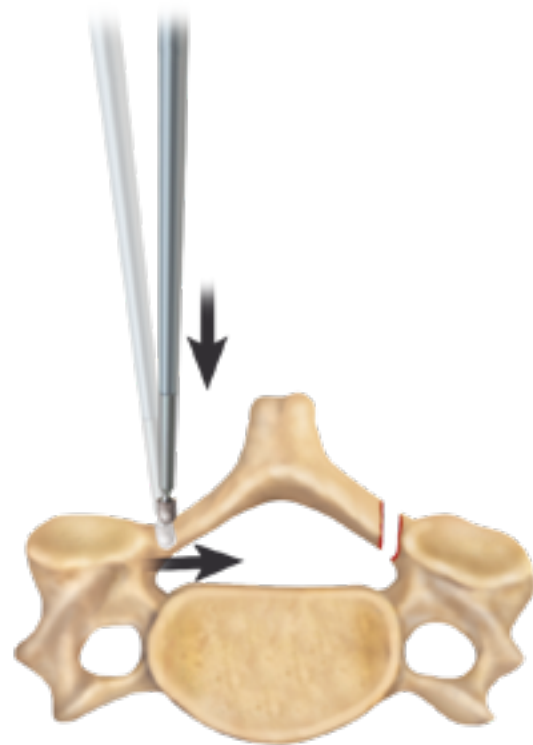


Figure 7b

Open door technique

Opening the laminoplasty

Following the hinge side preparation, divide the ligamentum flavum as required. A 2.0mm or 3.0mm Kerrison punch may be used to excise the ligamentum flavum at the inferior and superior most levels (**Figure 8a**). Bipolarelectrocautery may assist with hemostasis of the epidural venous plexus. The laminae are now sequentially opened from one end to the other. The hinges are fashioned to be somewhat stiff. Use an angled probe to ensure that any epidural adhesions have been lysed beneath the laminae before fully opening the laminoplasty (**Figures 8b and 8c**).

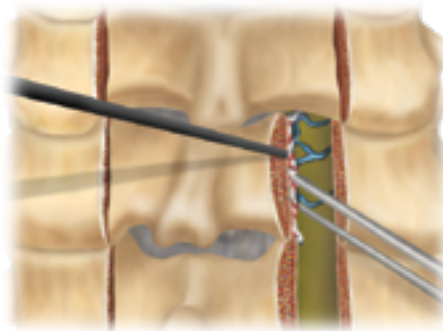


Figure 8b



Figure 8a



Figure 8c

Open door technique

Keeping the door open

A. Trialing and Using the Open Door Plate

Plate Positioning

The appropriate size laminoplasty plate for each level is selected using the bone trials (**Figure 9**). There are two plate holder types: one has a straight tip that is used with graft plates and the other has an angled tip that attaches to all other plates. Using the appropriate plate holder, insert the selected plate by fitting the cut edge of the lamina into the laminar shelf of the plate. Then seat the lateral portion of the plate onto the edge of the lateral mass (**Figure 10 and 10a**). The ventral prong on the underside of the plate should catch the cut edge of the lateral mass. If necessary, a needle driver can be used to contour the laminar and lateral mass aspects of the plate to fit the bony anatomy. This helps to stabilize the plate's position while completing the fixation, as well as reducing any shear loads on the lateral screws.

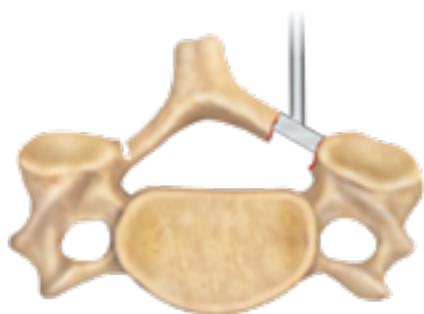


Figure 9

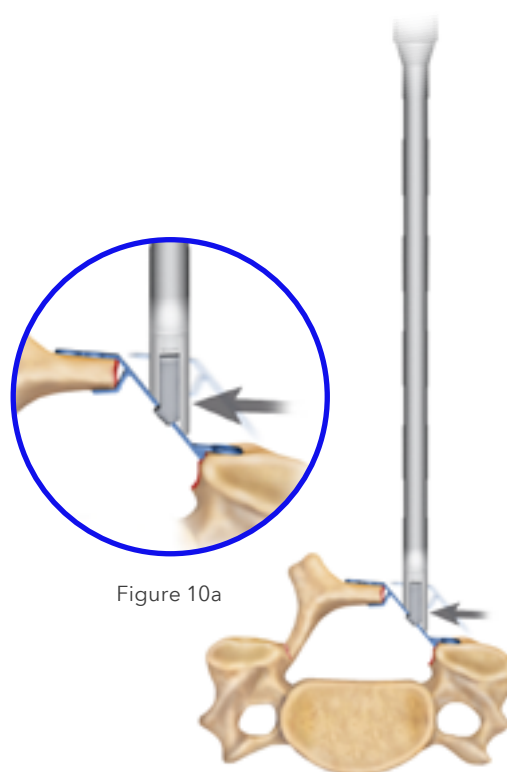


Figure 10a

Figure 10

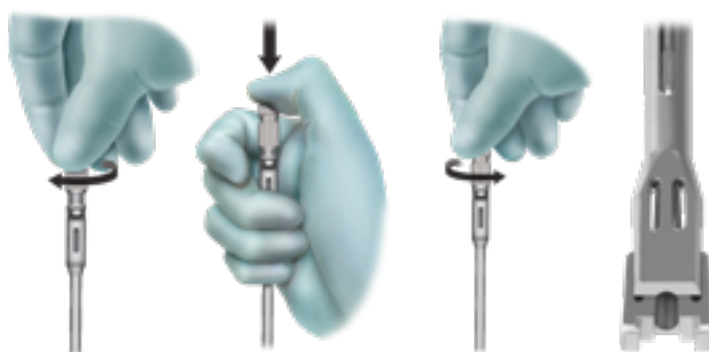


Figure 11

Helpful Hint

Fully un-thread and depress the spring-loaded plate holder which will actuate the jaws to capture and provisionally secure the plate. Ensure that the plate is fully captured by the jaws before releasing the knob. Turn the knob clockwise to lock the holder jaws to the plate (**Figure 11**). To detach the plate holder from the plate; fully un-thread the knob by turning it counterclockwise to unlock the holder jaws. Then fully fully depress the turn knob to release the plate. Ensure that the knob is fully depressed before detaching the holder to prevent the prongs from catching on the plate.

Drill and Screw Insertion

Each of the lateral mass screw pilot holes is made using the drill bit based on desired screw length. Alternatively, a pilot divot could be drilled for the desired points of screw fixation using an optional 1.0mm Midas Rex™ Burr. Preparing the surface of the lamina with a small divot could prevent skiving during screw insertion.

Optional

The drill bit may be attached to the universal handle for manual drilling or attached to a power drill (Figures 12 and 13).

Once the desired screw length has been determined, the screw is attached to the self-holding screwdriver shaft and universal handle with the help of the screw loading block or screw caddy for non-sterile screws. Ensure that the driver is fully seated on the screw head. Using the self-holding screwdriver, the self-tapping screws are inserted to anchor the plate to the lateral mass (Figure 14). The plate holder can remain attached to the plate to counter the screw insertion torque. Confirmation of screw position can be made using radiographs or intraoperative fluoroscopy.



Figure 12



Figure 13

Note

The 2.0 diameter hole on the screw loading block can be used to check the screw diameter. Only the 2.0 diameter screw can be fully seated into the diameter hole. The block also has a length verification tool.



Figure 14

Note

The 9 mm drill will not have epoxy color-coding.

Drill and Screw Insertion *continued*

Important

Care should be taken if the drill and universal handle are used as skiving could occur resulting in the drill contacting undesired anatomy.

Important

Fully seat the drill in the plate and keep drill (or burr) coaxial with plate hole. Do not apply excessive downward force when creating pilot hole or divots. When using a lateral hole plate, do not place the plate such that when a screw is inserted it violates the facet joint.

Important

When detaching the driver, pull the driver off the screw while maintaining alignment with the trajectory of the screw placement. Note: Detaching the driver from the screw off axis with respect to the screw can bind the driver/screw creating interference which can increase the detachment force.

Important

It is important to match drill length with the screw length. Do not apply excessive torque when using the driver to insert the screw. Damage to the screw or plate could occur due to excessive torque.

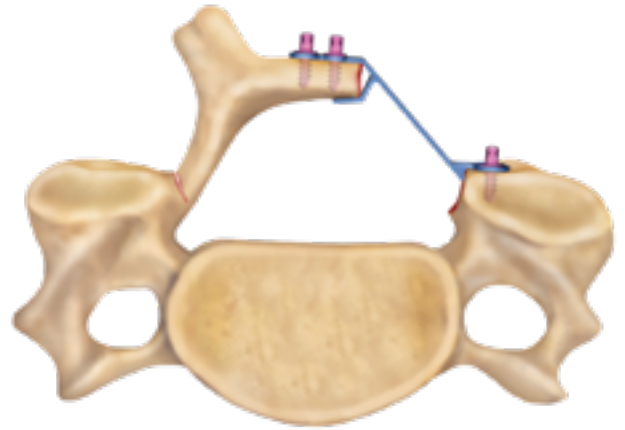


Figure 15

The laminar hole may then be drilled using the same technique as the lateral mass screw holes and then the plate can be secured with a self-tapping screw (Figures 16a and 16b).

A second screw may be placed in the lamina if desired (Figure 16b). In case of dense bone, the lamina may be stabilized with general surgical instruments and/or the plate holders during screw insertion. This may protect the hinged lamina from screw insertion torque and prevent bone damage.

Important

Only 3mm or 5mm screws should be used on the laminar shelf. 7mm and 9 mm drills should not be used through the lamina holes of the plate. Do not insert 7mm and 9mm length screws into the hole above the lamina shelf of the plate as the screws will contact the plate shelf (Figure 16b). Care should be taken to avoid contact.

Note

Ø2.4 screw can be used as a rescue option if any of the initial pilot holes are stripped.

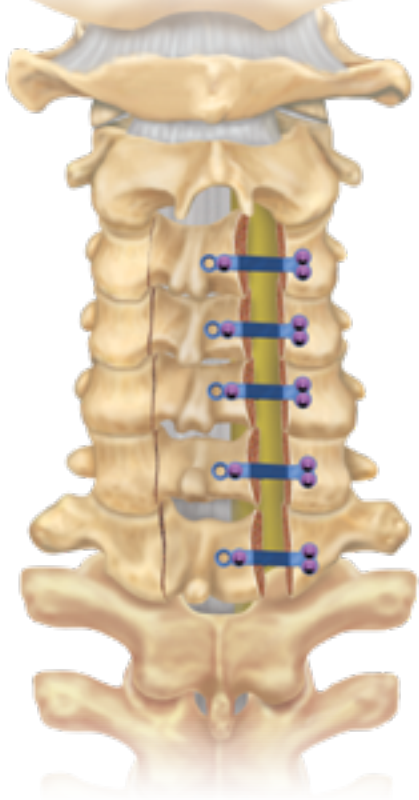


Figure 16a

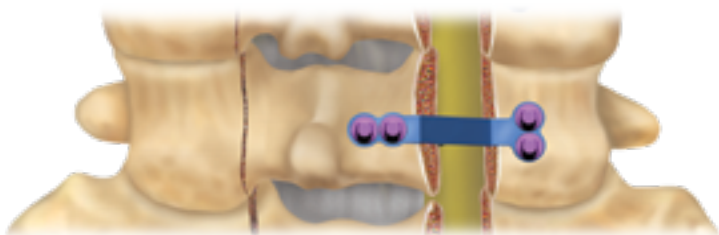
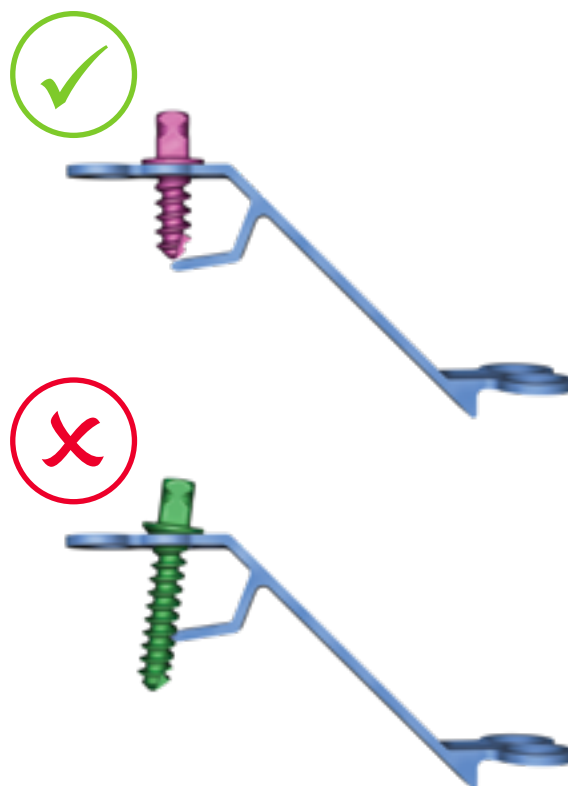


Figure 16b



B. Using the Graft Plate

An alternative technique, which allows for the placement of autograft or allograft on the open side of the laminoplasty, can be performed using the graft plate.

The initial surgical procedure is performed in the same manner as if preparing to use the open door plate as described on **pages 7-14**. After the laminoplasty has been “opened,” the appropriate size allograft is selected using the Bone Trials (**see Figure 9**).

As an example, a 12mm trial corresponds to a 12mm allograft. The allograft is then attached to the graft plate and secured by inserting a Ø2.4mm × 5mm screw through the predrilled center hole in the allograft (**Figures 17a and 17b**). The oval-shaped center screw hole in the graft plate allows for fine adjustments of the plate on the allograft. Use the graft plate holder to insert the allograft/graft plate construct between the cut edge of the lamina and the lateral mass (**Figure 17c**). To secure the allograft/graft plate construct to the bone and complete the fixation, drill and insert the self-tapping screws according to the procedural steps described on **pages 12 and 13 (Figure 18)**.

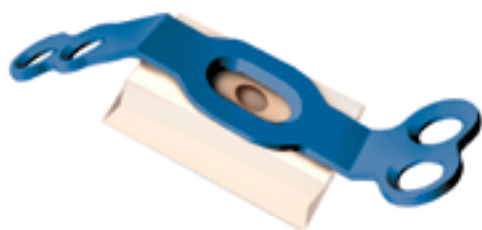


Figure 17a



Figure 17b

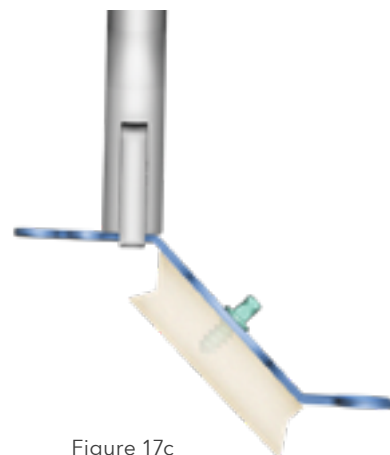


Figure 17c

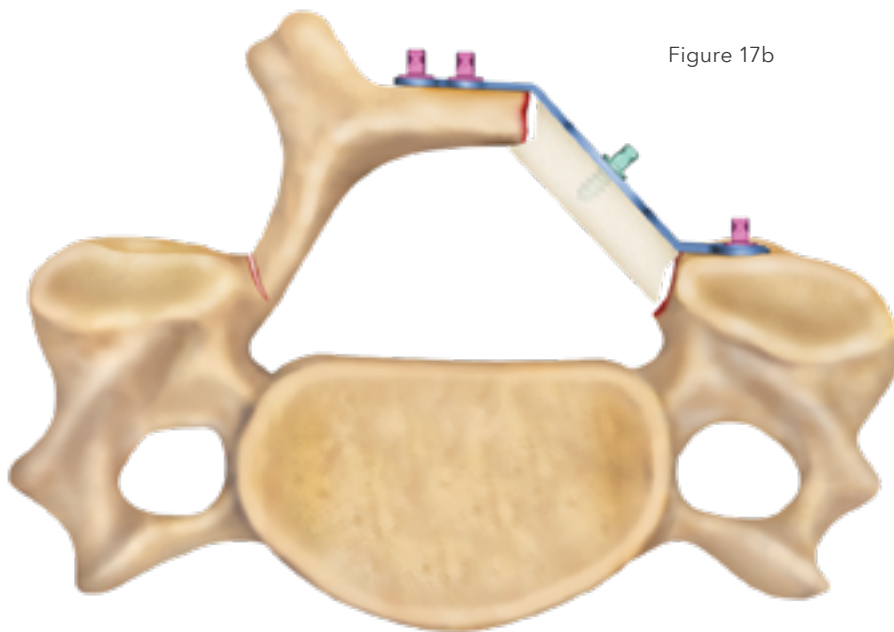


Figure 18

Open door construct options

The allograft/graft plate can be used at every level of the laminoplasty (**Figure 19a**), or may be used at desired levels in combination with open door plates per surgeon preference. (**Figure 19b and 19c**).

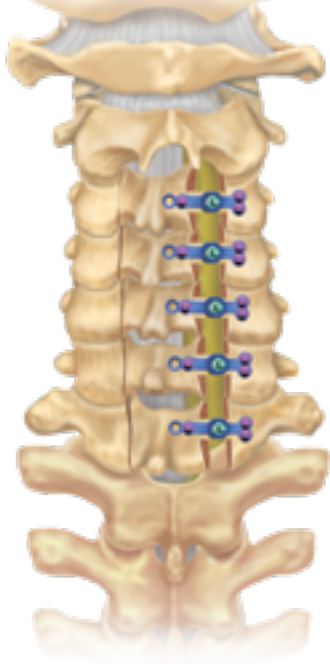


Figure 19a

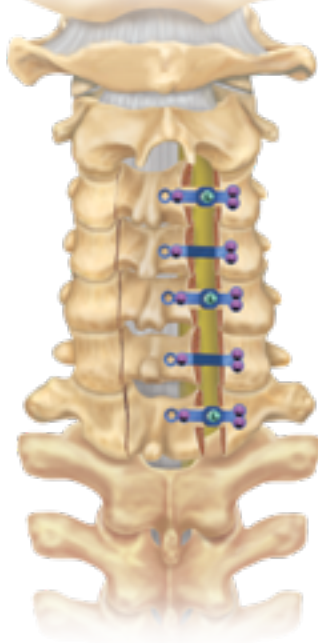


Figure 19b

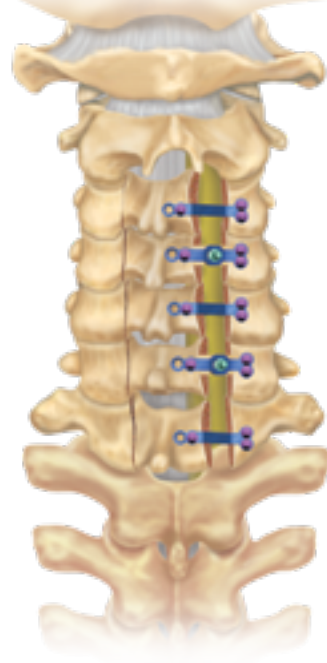


Figure 19c

Use of the lateral hole plate

In the event that the surface area of the lateral mass is either too small in its cranial-caudal dimension, or it has been reduced in the addition of one or more foraminotomies, one could opt to use the lateral hole plate (**Figure 20**). The sizing and method of insertion are the same as for the standard open door and graft plates, except that the orientation of the lateral mass screws is parallel to the long axis of the plate. The exposure may need to be widened slightly at any level where the lateral hole plates are used.

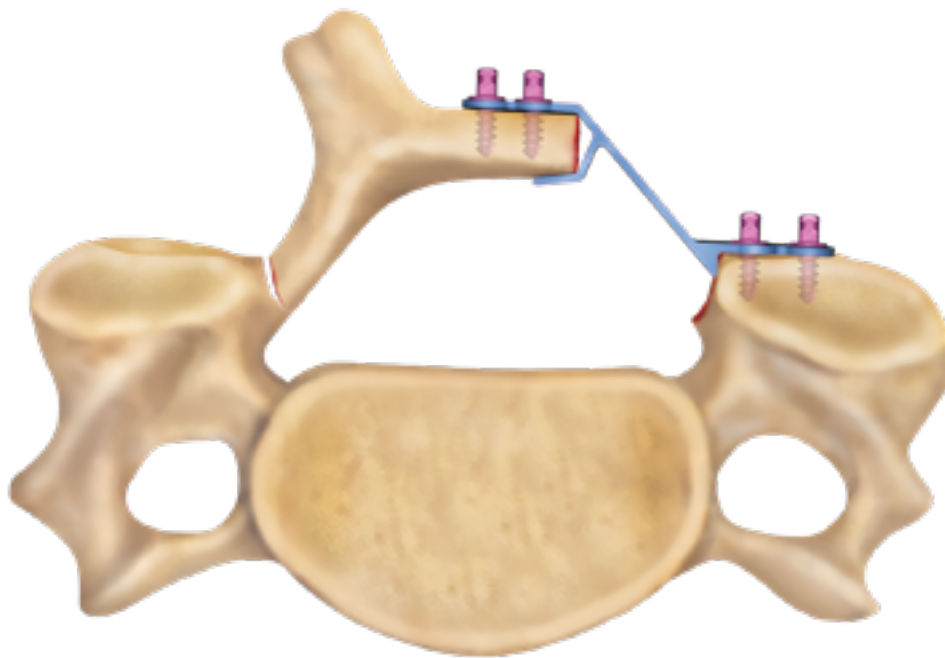


Figure 20

Use of the wide mouth plate

The wide mouth plate may be needed on occasion to accommodate thicker laminae (**Figure 21**). As an alternative to bending the laminar shelf of the standard open door plate, one could use the wide mouth plate to allow for easier placement onto the thicker lamina. The sizing and method of insertion are the same as for the standard open door plate.

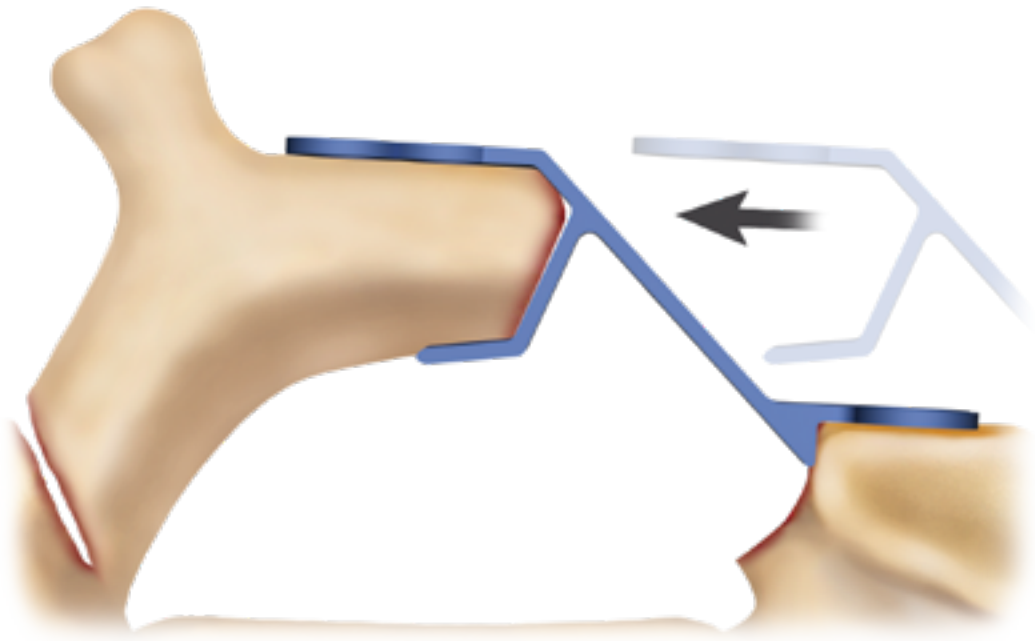


Figure 21

Use of the trough plate

The trough plate may be needed on occasion to secure a floppy or displaced hinge which threatens to impinge upon a nerve root or the dura (**Figure 22**). In the event that it is judged to be necessary, its application begins before opening the laminoplasty. The loose lamina should be grasped and stabilized with a suitable clamp (e.g. a ligamentum flavum clamp). It is held firmly while the laminar side screw holes are drilled with the $\text{Ø}1.2\text{mm} \times 4.5\text{mm}$ drill bit with depth-stop or Midas twist drills. The Trough Plate is then fastened to the

lamina with two 3mm or 5mm screws. The laminoplasty is then opened as usual. The lateral mass screw holes for the Trough Plate are then drilled for two additional screws and two screws are inserted, firmly fixing the hinge in place. The repair is inspected to confirm that the lamina remains elevated away from the canal and foramen. If there is concern for impingement, the segment may be converted to a laminectomy with laminoplasty continued at other levels.

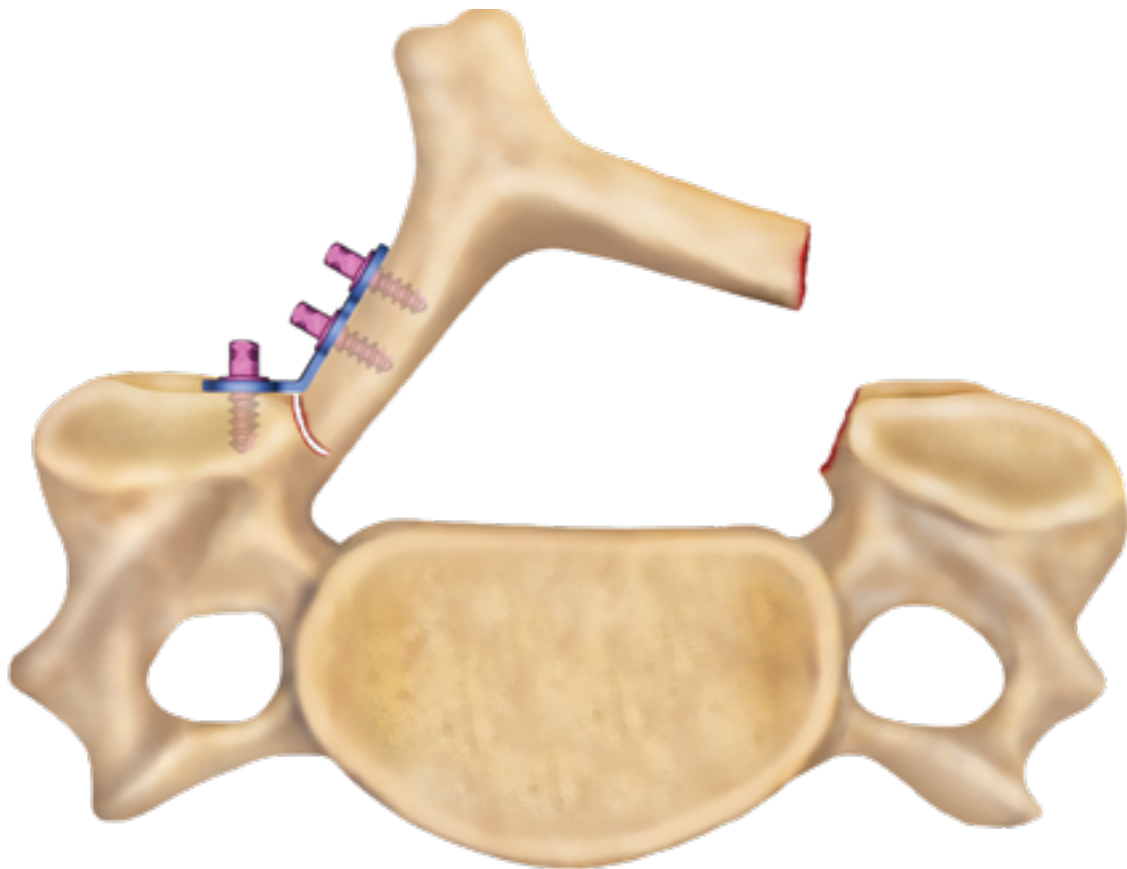


Figure 22

Implant removal

To remove any of the laminoplasty plates described throughout this technique, engage the screw head with the self-holding screwdriver, and in a counterclockwise motion, remove the screw from the bone. The plate can then be freely removed from the bone using the corresponding plate holder .

Note

Ensure that the screw threads are completely backed out of the bone prior to pulling the screw out to prevent the driver from unintentionally disengaging from the screw upon removal.

Product ordering information



US Set Configuration- SPS03179

CFN	Description
8539000	Instrument and Implant Tray
1850097	Lid for 8539000
176-854R	GP Plate Caddy
176-857R	GP Plate Caddy Lid
8530408	8mm Graft Plate
853-410	10mm Graft Plate
853-412	12mm Graft Plate
176-853R	OD Plate Caddy
176-856R	OD Plate Caddy Lid
8530008	8mm OD Plate
853-010	10mm OD Plate
853-012	12mm OD Plate
853-014	14mm OD Plate
8530110	OD Lateral Plate Caddy
8530110L	OD Lateral Plate Caddy Lid
853010LH	10mm Open Door Lateral Hole
853012LH	12mm Open Door Lateral Hole
853014LH	14mm Open Door Lateral Hole
8539004	Plate Module
8539005	Plate Module Lid
853008LH	8mm Open Door
8530000	Trough Plate
853008WM	8mm Open Door Wide Mouth
853010WM	10mm Open Door Wide Mouth
853012WM	12mm Open Door Wide Mouth
853014WM	14mm Open Door Wide Mouth
853010LW	10mm Open Door Lateral Hole Wide Mouth
853012LW	12mm Open Door Lateral Hole Wide Mouth
8539002	Screw Module
8539003	Screw Module Lid
8532065	Bone Screw ODLP 2.0 × 5mm
8532067	Bone Screw ODLP 2.0 × 7mm
8532465	Rescue Screw ODLP 2.4 × 5mm
8532467	Rescue Screw ODLP 2.4 × 7mm

Instruments

CFN	Description
6956016	Universal Handle
8531630	Screwdriver Shaft
8530810	8-10mm Bone Trial
8530812	12-14mm Bone Trial
8530814	16-18mm Bone Trial
8530633	Graft plate Holder
8530634	Plate Holder
8530635	Screw Loading Block

Sterile shelf order (Disposable instrument)

CFN	Description
8530636	1.2mm × 4.5mm Drill Bit
8530637	1.3mm × 7mm Drill Bit
8530638	1.6mm × 9mm Drill Bit

Midas Rex™

CFN	Description
8TD124	Legend 8cm 1.2mm × 4mm depth
AS08	Legend 8cm straight (b) 2.4mm attachment
AVS08	8cm variable straight attachment

All implants and instruments available

CFN	Description
Open Door Plates	
8530008	8mm
853-010	10mm
853-012	12mm
853-014	14mm
853-016	16mm
853-018	18mm
Graft Plates	
8530408	8mm
853-410	10mm
853-412	12mm
853-414	14mm
853-416	16mm
853-418	18mm
Lateral Hole Plates	
853008LH	8mm Open Door
853010LH	10mm Open Door
853012LH	12mm Open Door
853014LH	14mm Open Door
853016LH	16mm Open Door
853408LH	8mm Graft
853410LH	10mm Graft
853412LH	12mm Graft
853414LH	14mm Graft
853416LH	16mm Graft
Wide Mouth Plates	
853008WM	8mm Open Door
853010WM	10mm Open Door
853012WM	12mm Open Door
853014WM	14mm Open Door
853016WM	16mm Open Door
853018WM	18mm Open Door
853008LW	8mm Open Door Lateral Hole
853010LW	10mm Open Door Lateral Hole
853012LW	12mm Open Door Lateral Hole
853014LW	14mm Open Door Lateral Hole
853016LW	16mm Open Door Lateral Hole
Allograft	
853908	Tissue Centerpiece™ Strut 8mm Service Fee
853910	Tissue Centerpiece™ Strut 10mm Service Fee
853912	Tissue Centerpiece™ Strut 12mm Service Fee
853914	Tissue Centerpiece™ Strut 14mm Service Fee
853916	Tissue Centerpiece™ Strut 16mm Service Fee
853918	Tissue Centerpiece™ Strut 18mm Service Fee

CFN	Description
Trough Plate	
8530000	Trough Plate
Bone Screws	
8532063	Bone Screw ODLP 2.0 × 3mm
8532065	Bone Screw ODLP 2.0 × 5mm
8532067	Bone Screw ODLP 2.0 × 7mm
8532463	Rescue Screw ODLP 2.4 × 3mm
8532465	Rescue Screw ODLP 2.4 × 5mm
8532467	Rescue Screw ODLP 2.4 × 7mm
8532469	Rescue Screw ODLP 2.4 × 9mm
G8532063	Bone Screw ODLP 2.0 × 3mm Sterile
G8532065	Bone Screw ODLP 2.0 × 5mm Sterile
G8532067	Bone Screw ODLP 2.0 × 7mm Sterile
G8532463	Rescue Screw ODLP 2.4 × 3mm Sterile
G8532465	Rescue Screw ODLP 2.4 × 5mm Sterile
G8532467	Rescue Screw ODLP 2.4 × 7mm Sterile
G8532469	Rescue Screw ODLP 2.4 × 9mm Sterile

Sterile shelf order (Disposable instrument)

CFN	Description
8530636	1.2mm × 4.5mm Drill Bit
8530637	1.3mm × 7mm Drill Bit
8530638	1.6mm × 9mm Drill Bit

Instruments

CFN	Description
6956016	Universal Handle
8531630	Screwdriver Shaft
8530810	8-10mm Bone Trial
8530812	12-14mm Bone Trial
8530814	16-18mm Bone Trial
8530633	Graft plate Holder
8530634	Plate Holder
8530635	Loading Block 2.0

Important product information on the Centerpiece™ plate fixation system

Note: not all parts may be available in each geography.

PURPOSE

The Centerpiece™ plate fixation system provides a means to prevent expulsion of graft material after a laminoplasty is performed.

DESCRIPTION

The Centerpiece™ plate fixation system consists of a variety of sizes of plates and screws. Centerpiece™ plate fixation system components are fabricated from medical grade titanium or titanium alloy.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INTENDED POPULATION

The Centerpiece™ plate fixation system is intended to be implanted by healthcare professionals into (skeletally mature) adults with the following indications.

INDICATIONS

The Centerpiece™ plate fixation system is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The Centerpiece™ plate fixation system is used to hold the graft material in place in order to prevent the graft material from expulsion or impinging the spinal cord.

CLINICAL BENEFITS

The Centerpiece™ plate fixation system is Intended to achieve spinal cord decompression commonly due to multisegmental spondylosis and/or ossification of the posterior longitudinal ligament (OPLL).

CONTRAINDICATIONS

Contraindications include:

- Infection local to the operative site.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Medical or surgical condition which would preclude potential benefit of spinal implant surgery such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevated white blood count (WBC), or a marked left shift in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Suspected or documented metal allergy or intolerance.
- Cases needing to mix metals from different components.
- Cases not needing a laminoplasty procedure.
- Patients having inadequate tissue coverage over the operative site, or inadequate bone stock or bone quality.
- Any time implant use would interfere with anatomical structures or expected physiological performance.
- Patients unwilling to follow postoperative instructions such as drug/alcohol abuse patients, and those unwilling to restrict postoperative activities.
- Cases not described in the indications.
- Patients unwilling to follow the postoperative instructions.

Contraindications of this device are consistent with those of other posterior spinal instrumentation systems. This spinal implant system is not designed, intended, or sold for uses other than those indicated.

POTENTIAL ADVERSE EVENTS

- Early or late loosening of components.
- Implant migration.
- Disassembly, bending, loosening, slippage, and/or breakage of components or instruments.
- Foreign body reaction to implants including possible tumor formation, autoimmune disease, metallosis, and/or scarring.
- Pressure on the skin possibly resulting in skin breakdown from component parts where there is inadequate tissue coverage over the implant.
- Implant or graft extrusion through the skin and wound complications.
- Loss of proper spinal curvature, correction, height, and/or reduction.
- Infection.
- Bone fracture or stress shielding at, above, or below the level of surgery.
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
- Neurovascular compromise including paralysis or other types of serious injury.
- Cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and/or hematomas.
- Discitis, arachnoiditis, and/or other types of inflammation.
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
- Inability to resume activities of normal daily living.
- Death.

Note: additional surgery may be necessary to correct some of these anticipated adverse reactions.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise results. The purpose of the Centerpiece™ plate fixation system is to provide a means to prevent expulsion of graft material after a laminoplasty has been performed. Safety and effectiveness of the device when implanted in the anterior spine were not established.

Preoperative and operating procedures including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful use of the Centerpiece™ plate fixation system.

Further, proper selection and compliance of patients greatly affect results.

This device was designed for single patient use only. Do not reprocess or reuse this product. Reuse or reprocessing may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Physician note: although the healthcare professional is the learned intermediary between the company and the patient, the important medical information in this document should be conveyed to the patient.

For MRI information to convey to the patient, reference the MRI INFORMATION section of this document and the information provided in <https://manuals.medtronic.com/manuals/mri/region> by selecting the applicable region and searching by model number or product name.

USA For US audiences only

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

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Consult instructions for use at this website
www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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

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.

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