



NewBridge[®]

LAMINOPLASTY FIXATION SYSTEM



Laminoplasty Fixation

INTERNATIONAL EDITION

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Orthofix Spinal Implants wishes to thank the following surgeons for their contribution to the development of the technique:

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INTRODUCTION

Cervical laminoplasty is a surgical alternative to laminectomy or multiple level anterior cervical corpectomy and fusion for patients with symptomatic cervical stenosis. Laminoplasty has grown in popularity and acceptance and may often be the treatment of choice for patients with congenital or acquired stenosis involving multiple levels from C3 to T3. Laminoplasty may result in less postoperative deformity than a laminectomy in addition to maintaining a greater range of motion. Candidates for laminoplasty should not have significant instability or kyphosis.

The NewBridge Laminoplasty Fixation System was developed as an alternative to fixation techniques for maintaining the open door expansion of the lamina. NewBridge offers improved stability and ease of application. The surgical technique is presented in a simple, stepwise fashion that will enable trained, experienced spinal surgeons to obtain reproducible success.



Fig. 1

1. PATIENT POSITIONING

Patient positioning is critical during laminoplasty to avoid complications. Laminoplasty can be a technically demanding procedure when operating on myelopathic patients. The patient's head should be supported in a headrest system. The upper part of the cervical spine to the lower cervical spine should be easily accessible and in a neutral position or a slightly flexed alignment. A preoperative lateral x-ray or fluoroscopic image should be obtained to verify alignment.

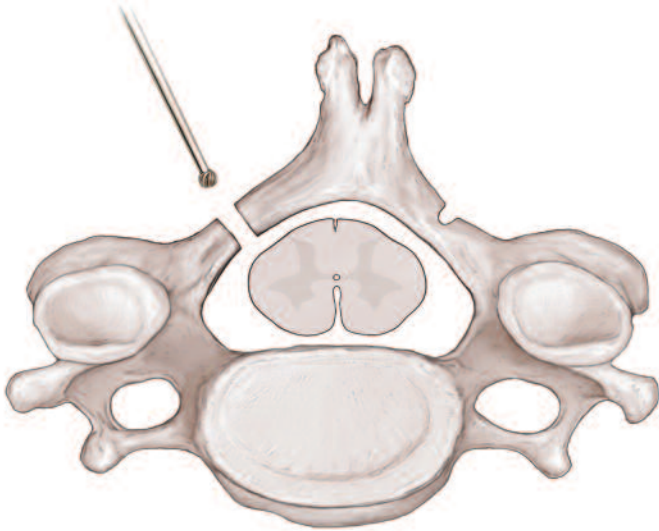


Fig. 2

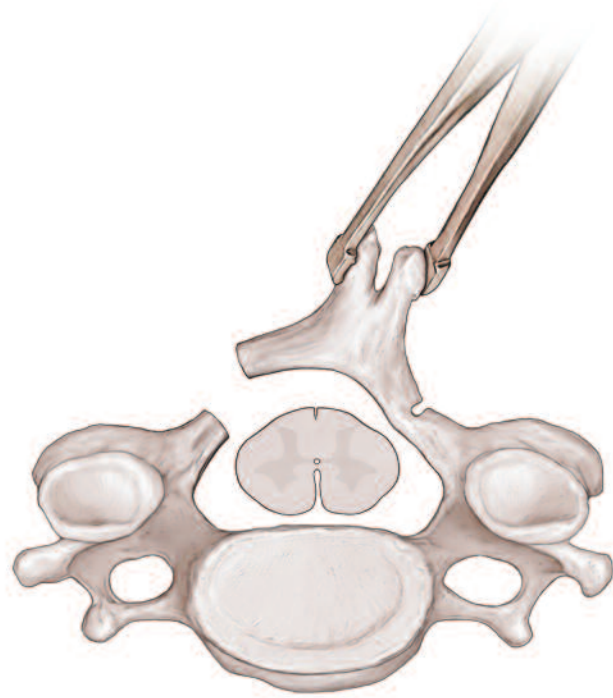


Fig. 3

2. TRANSECTION

Completely transect the lamina medial to the junction of the lateral mass and the lamina. Create a hinge in the lamina on the contralateral side by scoring half the thickness of the lamina. It is critically important that the burr trajectory be perpendicular to the lamina-lateral mass junction. Incorrect trajectory of the burr may result in penetration of the lateral mass and potential difficulty in dividing the lamina-lateral mass junction. Complete release of the ligamentum flavum with Kerrisons and fine curettes is necessary, particularly at the junctional segments, to allow detachment of the lamina from the adjacent fixed segments.

3. LAMINA EXPANSION

Grasp the spinous process with the lamina elevator and slowly expand toward the hinged side to allow for plastic deformation of the lamina. A fine angled curette may be used to lift the laminar edge and verify detachment of any underlying dural adhesions. Be sure to avoid traction on the spinal cord or nerve roots.

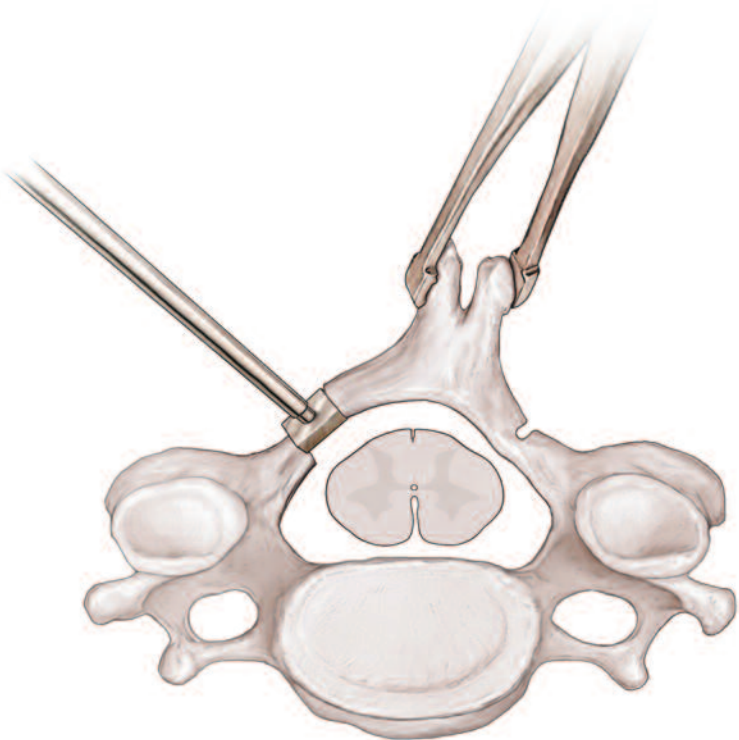


Fig. 4

4. ALLOGRAFT SELECTION

Insert trial spacers in the expanded laminar gap to determine the allograft strut size. Laminar gaps of about 10mm, depending on patient size, are common.

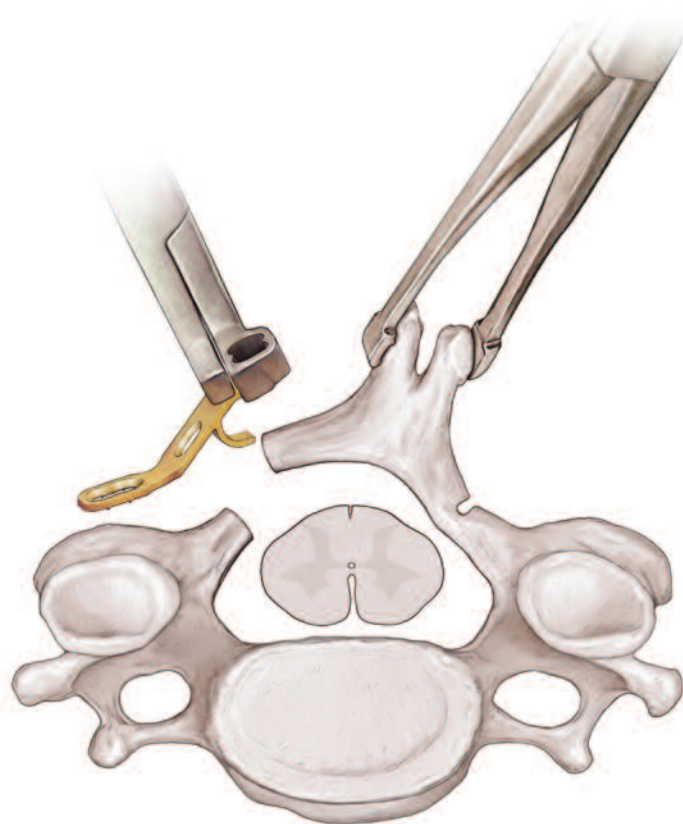


Fig. 5

5. PLATE SELECTION

Attach the plate holder to the plate and trial fit the plate to the lateral mass and lamina. Three plate sizes are available to accommodate varying patient anatomy. Gentle contouring of the plate and tab, with supplied pliers and bending iron, may be necessary to customize the implant for each patient.

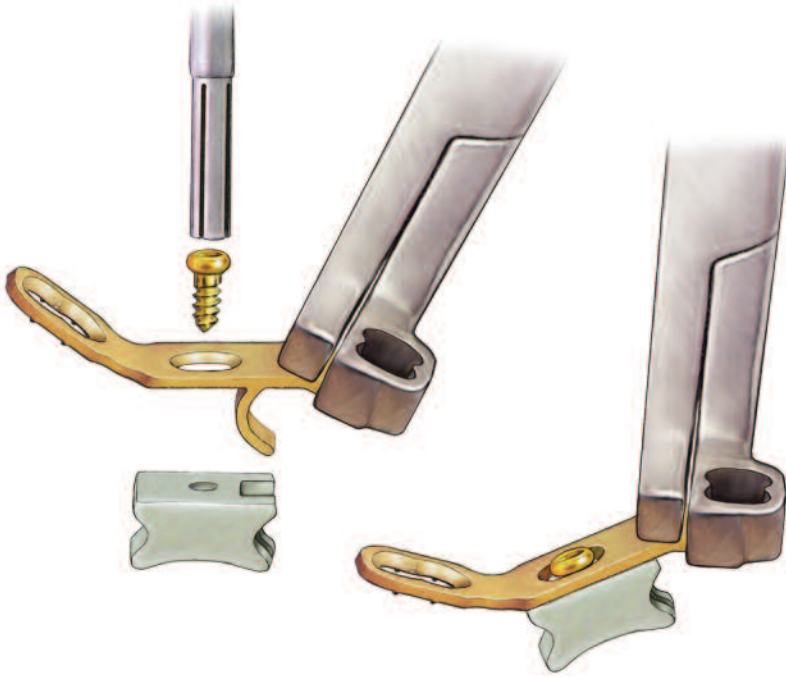


Fig. 6

6. PLATE-GRAFT ASSEMBLY

Attach the lamina screwdriver to the modular handle. Secure the allograft strut to the plate at the center screw position. The plate tab should fit securely into the allograft strut slot.

NOTE: Allograft Struts are not available in international markets outside the United States.

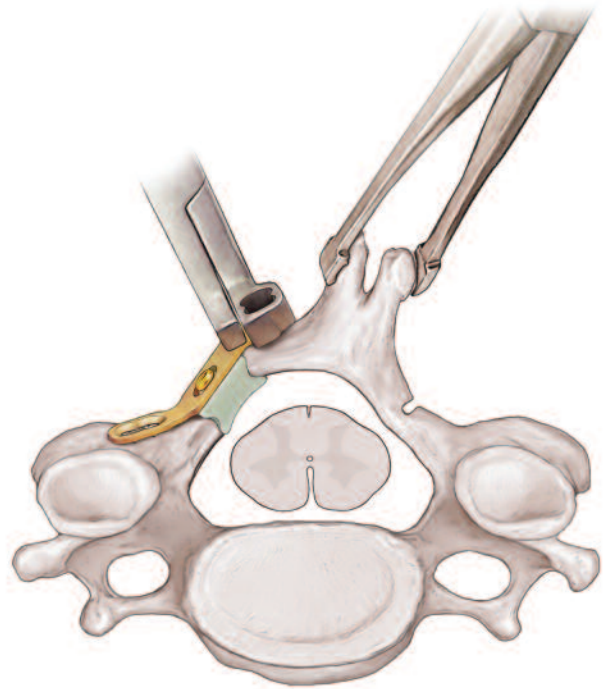


Fig. 7

7. PLATE-GRAFT PLACEMENT

Use the plate holder to position the plate-graft construct between the cut lamina edges. Position the slotted portion of the plate on the lateral mass and the opposite end on the lamina. The lamina edges should fit securely within the allograft strut. It is recommended that the slotted portion of the plate be positioned in the upper 60% of the lateral mass to prevent the screw from perforating the inferior articular process of the facet.

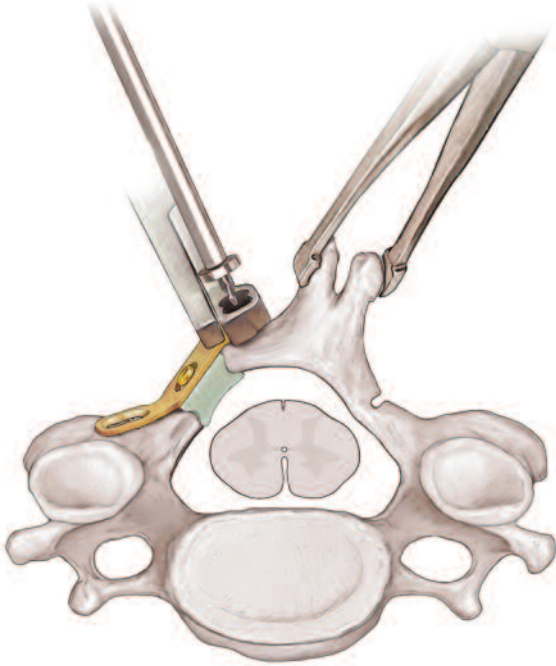


Fig. 8

8. DRILL LAMINA

Attach the appropriate length drill to the modular handle. Drill each pilot hole in the lamina to the desired depth. The plate holder is designed to guide the drills thereby preventing instrument penetration.

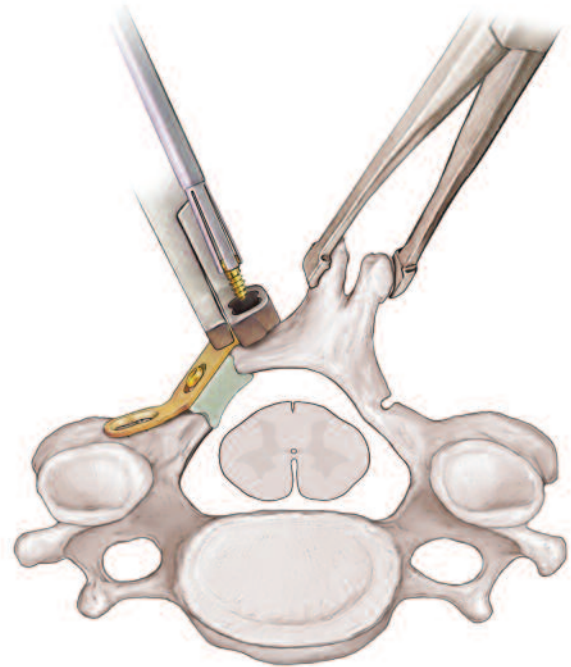


Fig. 9

9. LAMINA SCREW PLACEMENT

Attach the lamina screwdriver to the modular handle. Place two self-tapping screws in the drilled lamina holes to secure the plate. Rescue screws are available if ideal purchase is not achieved.

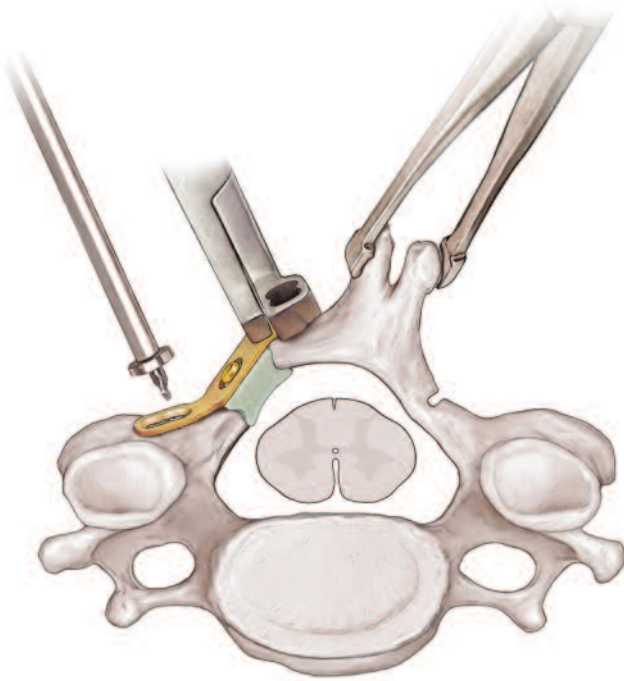


Fig. 10

10. DRILL LATERAL MASS

Attach the appropriate length drill to the modular handle. Drill the lateral mass hole to the desired depth. Lateral fluoroscopic imaging should be obtained to access lateral mass screw length.

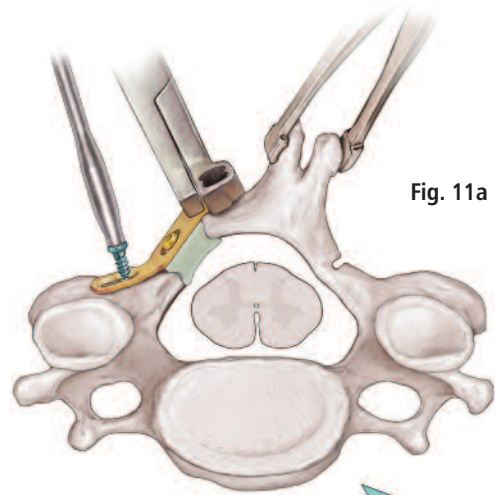


Fig. 11a

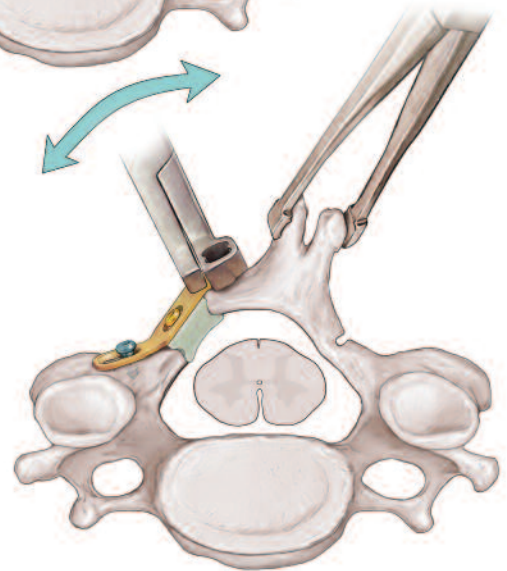
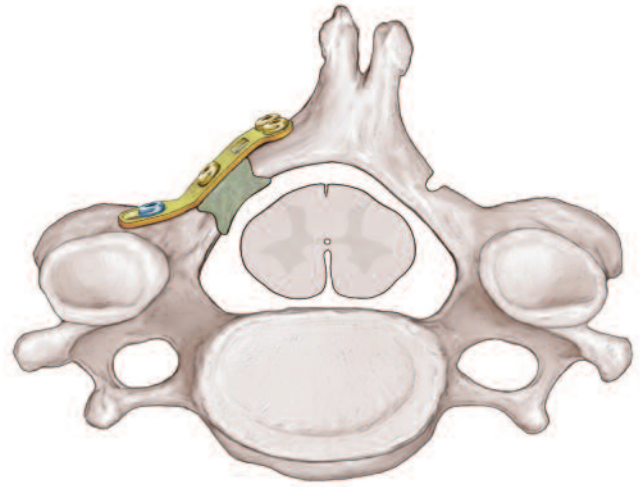
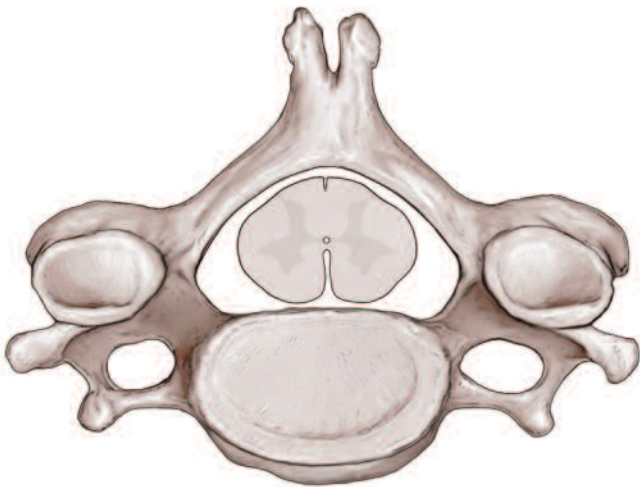


Fig. 11b

11. LATERAL MASS SCREW PLACEMENT

Attach the lateral mass screwdriver to the modular handle (**Fig. 11a**). Position the appropriate length self-tapping lateral mass screw in the slotted portion of the plate.

Prior to fully seating the lateral mass screw, the plate can be adjusted by moving the plate holder allowing for a more secure fit (**Fig. 11b**). Gentle compression will be placed on the allograft strut to increase fixation and fusion potential. Tighten the lateral mass screw into final position.



12. FINAL RESULT

The final result is an expanded spinal canal with decompression of the spinal cord. The procedure can be combined with unilateral or bilateral foraminotomies to allow for specific nerve root decompression. Sufficient residual lateral mass must be retained to allow for plate fixation.

LAMINOPLASTY PLATES

40-0001	Small Plate
40-0003	Medium Plate
40-0005	Large Plate

RESCUE BONE SCREW - LAMINA

40-2505	2.5mm x 5mm, Rescue Screw
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RESCUE BONE SCREWS - LATERAL MASS

40-3205	3.2mm x 5mm, Rescue Screw	296
40-3206	3.2mm x 6mm, Rescue Screw	296
40-3207	3.2mm x 7mm, Rescue Screw	
40-3208	3.2mm x 8mm, Rescue Screw	

INSTRUMENTATION

40-1000	Left Handed Plate Holder
40-1001	Right Handed Plate Holder
40-1002	2.0mm Lamina Screw Driver
40-1003	2.7mm Lateral Mass Screw Driver
40-1012	Bending Iron
40-1013	Lamina Elevator
40-5004	4mm Allograft Trial Spacer

PRIMARY BONE SCREW - LAMINA AND GRAFT

40-2005	2.0mm x 5mm, Primary Screw
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PRIMARY BONE SCREWS - LATERAL MASS

40-2705	2.7mm x 5mm, Primary Screw
40-2706	2.7mm x 6mm, Primary Screw
40-2707	2.7mm x 7mm, Primary Screw
40-2708	2.7mm x 8mm, Primary Screw

DISPOSABLE INSTRUCTION

40-1005	2.0mm Drill Bit, 3mm Length
40-1006	2.0mm Drill Bit, 5mm Length
40-1007	2.7mm Drill Bit, 5mm Length
40-1008	2.7mm Drill Bit, 8mm Length

40-5005	6mm Allograft Trial Spacer
40-5008	8mm Allograft Trial Spacer
40-5010	10mm Allograft Trial Spacer
40-5012	12mm Allograft Trial Spacer
60-0025	Modular Handle
74-0045	Bending Pliers
40-1015	System Case

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

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

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