



BLACKBIRDTM HLS

HINGED LAMINOPLASTY SYSTEM

SURGICAL TECHNIQUE

The ChoiceSpine Blackbird™ Hinged Laminoplasty System (HLS) design eliminates fitting plates through trial and error bending. The Blackbird HLS system provides a comprehensive, innovative solution to laminoplasty.



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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.



Fig. 1
Proper alignment

Exposure

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).

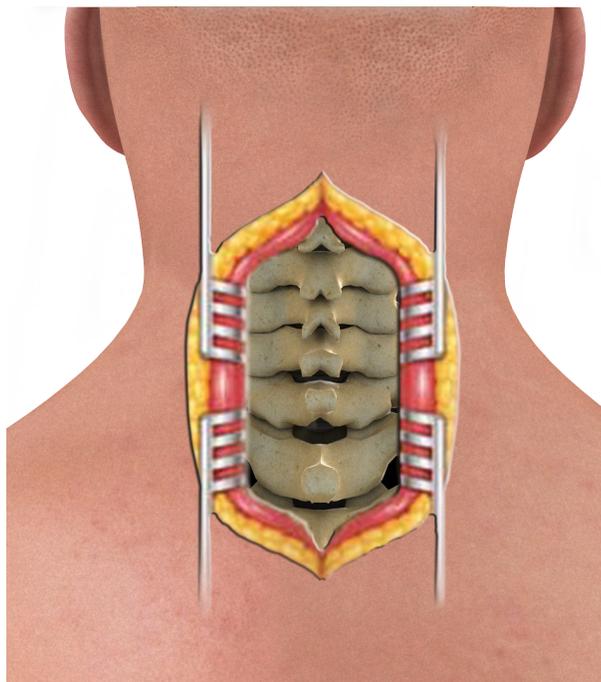


Fig. 2
Lateral dissection

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 lamina 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.

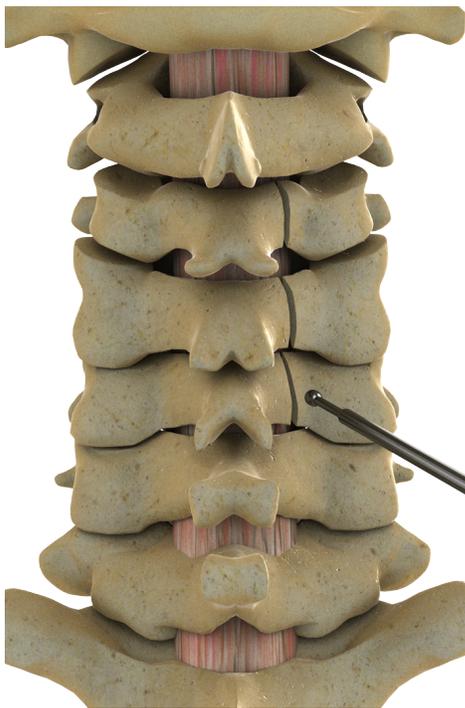


Fig. 3
Trough preparation

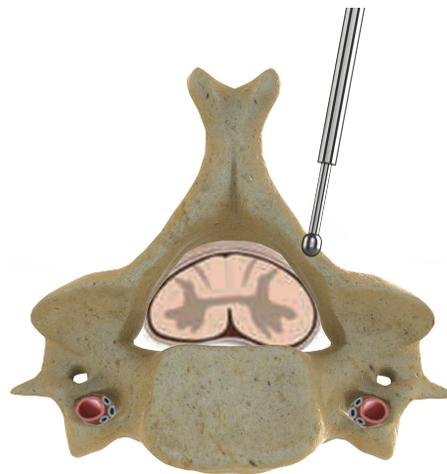


Fig. 4
Trough preparation detail

Trough Preparation Cont.

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 lamina-lateral mass junction. The amount of bone to be removed for the hinge should be sufficient to create a greenstick fracture (Figure 5). 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.

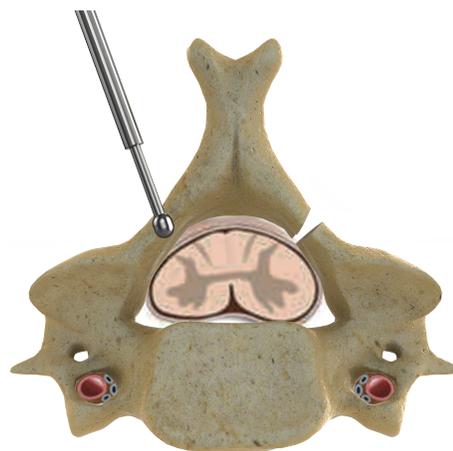


Fig. 5
Hinge preparation



Fig. 6

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 6).

Trial Sizing

Plates may be used with or without titanium spacers. Trials are used to determine both the size of the spacer and the size of the plate. Plates are available in 4 mm to 14 mm in increments of 2 mm. Plate sizing corresponds to the amount of distraction/spacing achieved between the lamina and lateral mass (Figures 7).

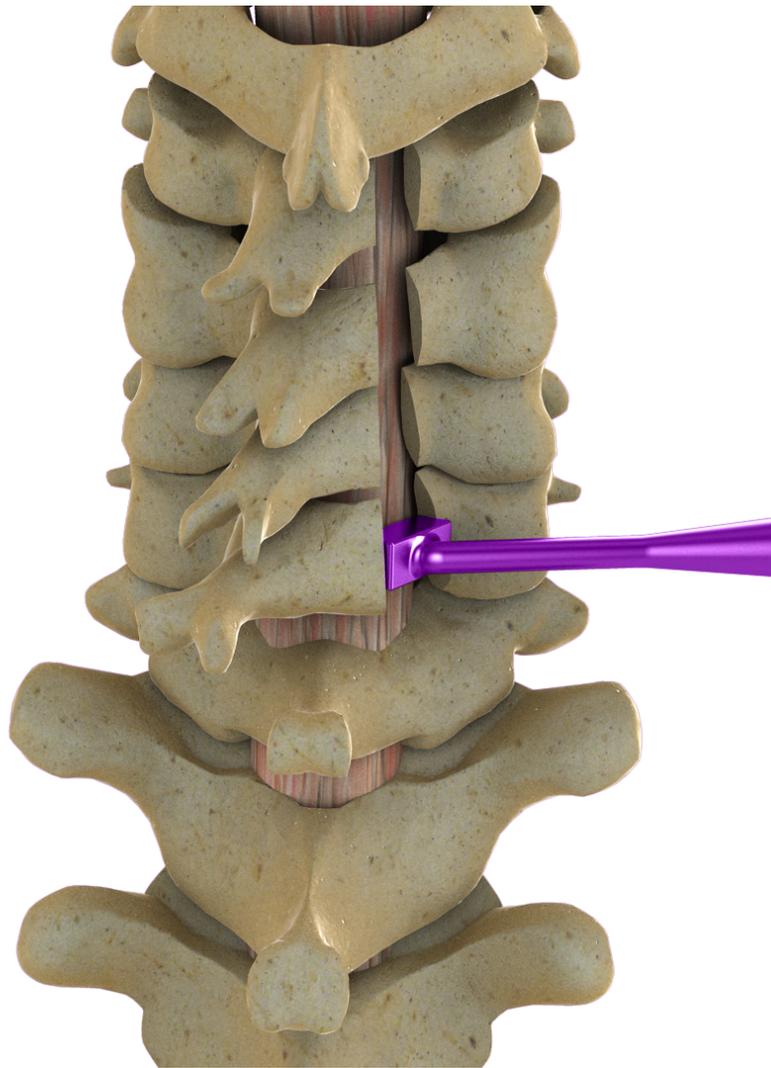


Fig. 7
Trial sizing

Spacer Attachment

After the appropriate spacer size has been determined through the use of the graft/plate trials, secure the titanium spacer to the plate with a Ø2.4x4.0mm self tapping screw through the pretapped hole.

- The spacer has been designed to fit the anatomy of the lateral mass and the lamina after the trough has been created (Figure 8/9).
- Titanium spacers are available from 4 mm to 14 mm in 2 mm increments.

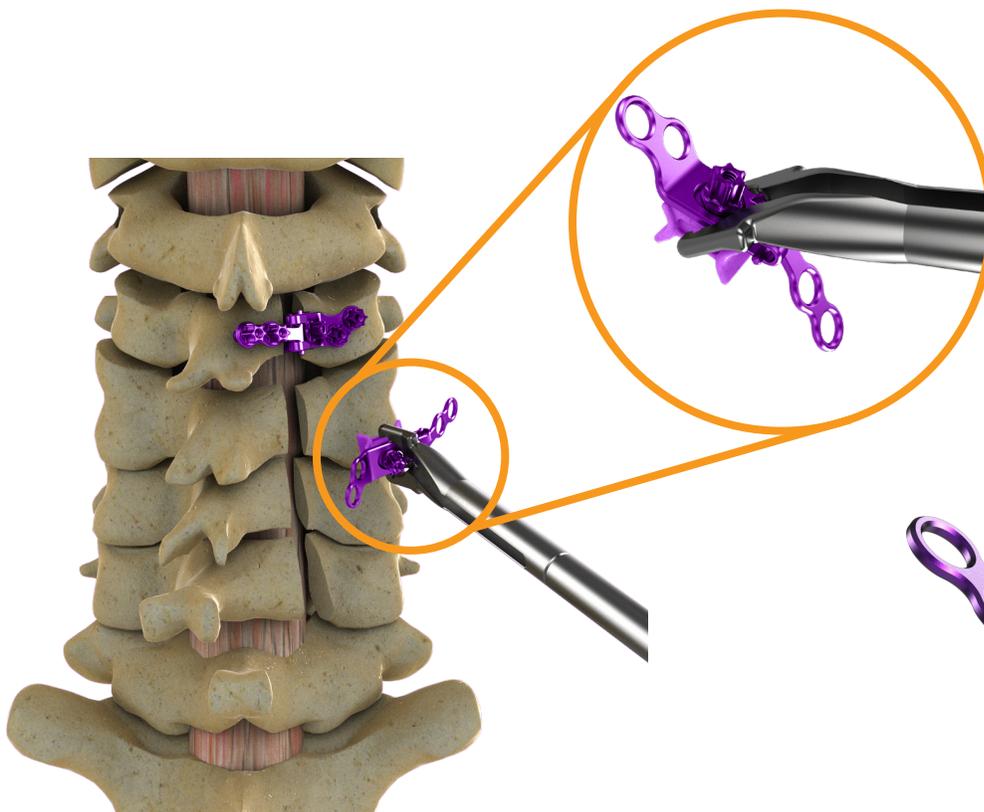


Fig. 9
Plate placement



Fig. 8
Spacer attachment

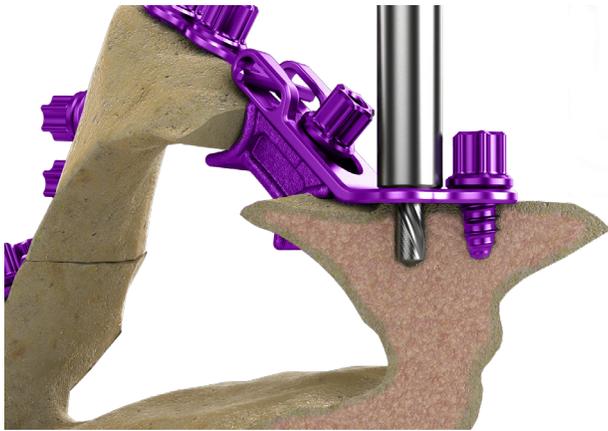


Fig. 10
Drilling

Drilling/Screw Insertion

Drilling is accomplished through the use of $\varnothing 1.75\text{mm}$ fixed 6mm drill (Figure 10). Thread the driver into the screw for secure screw fixation. Insert appropriate length $\varnothing 2.4\text{mm}$ self-tapping screw or $\varnothing 2.4\text{mm}$ self-drilling screw so that the screws are secured to the plate. Do not over tighten screws to the plate. $\varnothing 2.8\text{mm}$ rescue screws are provided.

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 Ti-6Al-4V ELI and can be contoured with the provided plate cutter/bender.



Fig. 11a
Multi level construct

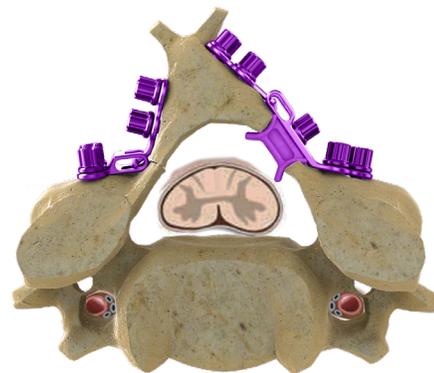


Fig. 11b
Construct detail

Hinge Plate

A hinge plate is provided in the event the hinge becomes weakened or displaced. The lamina should be stabilized and held firm for drilling. The hinge plate is then attached to the lateral mass with two screws followed by fixing the plate to the lamina with two screws (Figure 12). The lamina can then be opened as usual (Figure 13). Repeat this process for all levels.

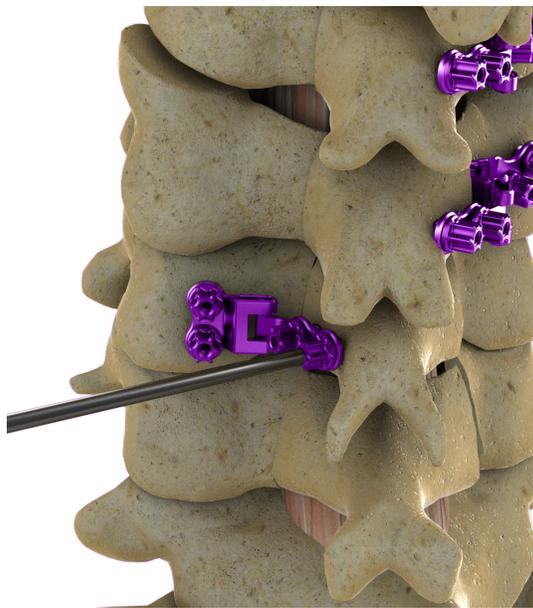


Fig. 12
Hinge plate attachment

Fig. 13
Hinge plate detail



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, secure the driver to the head of the screw and remove all screws from the bone. The plate can then move freely and be removed.

Instrument Listing

	Part Number	Description
	L090-4400	SPACER LOADING BLOCK
	L070-1001	SCREW DRIVER
	L070-1002	LAMINA LIFTER
	L070-1003	AXIAL RATCHET AO W/SPIN CAP HANDLE
	L070-1004	PLATE HOLDER 65°
	L070-1005	PLATE HOLDER 20°
	L070-1006	AWL/4MM DRILL
	L070-1007	TRIAL 4-6
	L070-1008	TRIAL 8-10
	L070-1010	PLATE HOLDER SLEEVE
	L070-1011	PLATE CUTTER/BENDER
	L070-0029	SHORT AO HANDLE

DEVICE DESCRIPTION:

The proposed Choice Spine BlackbirdTM HLS (Hinged Laminoplasty System) is an implant system that consists of various plates and screw configurations. The proposed plates are available in various configurations to address surgeon and patient needs as necessary. The proposed plate devices come preformed with holes for bone screws. The plate offered can be affixed to allograft or autograft material and secured with a bone screw from the system. A hinge plate is provided when additional stabilization is necessary. Screws are used to attach the plates to bone and are available in a variety of lengths and diameters to fit patient anatomy. The system components are made from medical grade Titanium Alloy Ti-6Al-4V ELI (ASTM F136), 17-4 SS (ASTM F899), 465 SS (ASTM A564), and 6061 T6 Aluminum (ASTM B221 and B209).

Indications for Use:

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

Contraindications:

Contraindications include, but are not limited to:

- infection, systemic or localized
- signs of local inflammation
- morbid obesity
- fever or leukocytosis
- mental illness
- alcoholism or drug abuse
- pregnancy
- severe osteopenia
- suspected or documented sensitivity allergies to the implant materials
- presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device
- any condition having inadequate tissue coverage over the operative site
- any circumstances not described
- under Indications for Use
- patients unwilling or unable to follow post-operative instructions
- rapid joint disease, bone absorption, osteopenia, and/or

osteoporosis

- Any 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.
- Suspected or documented metal allergy or intolerance.
- Any case needing to mix metals from different components.
- Any case not needing a laminoplasty procedure.
- Any patient having inadequate tissue coverage over the operative site, or inadequate bone stock or bone quality
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient who will not follow postoperative instructions, such as drug/alcohol abuse patients, and are unwilling to restrict postoperative activities.
- Any case not described in the Indications.
- Any patient unwilling to follow the postoperative instructions.

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 the results. This system is intended to be used to provide protection of the spinal canal. The safety and effectiveness of the device when implanted in the anterior spine have not been 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 utilization of the BlackbirdTM HLS (Hinged Laminoplasty System) by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results.
- PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.
- The Choice Spine BlackbirdTM HLS (Hinged Laminoplasty System) has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.



ChoiceSpineTM

Propelling Spinal Surgery

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