

Escalate™ Laminoplasty System

Surgical Technique

- Expandable Laminoplasty Plate
- Streamlined Procedure



Escalate™ Laminoplasty System

Surgical Technique

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Escalate™ Laminoplasty System

Surgical Technique

System Overview



The Escalate™ System is a comprehensive set of implants and instruments designed for a systematic approach to cervical laminoplasty procedures. The system features an Expandable Laminoplasty Plate, a Base Laminoplasty Plate, **Bone Screws** for fixation, and a set of instruments to assist in implantation and removal of the device, if necessary.

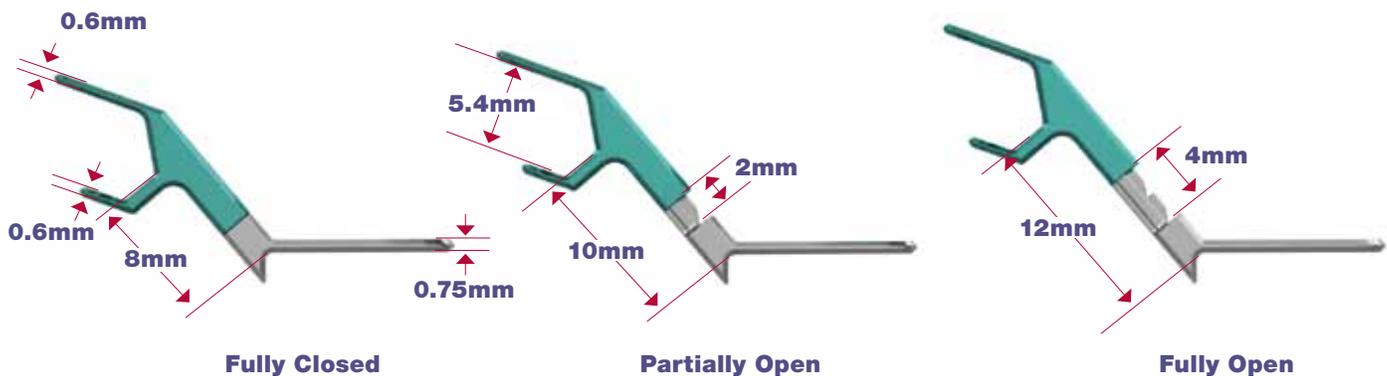
Expandable Laminoplasty Plate

The open end of the **Expandable Laminoplasty Plate** attaches to the open lamina while the straight end of the plate corresponds to the lateral mass. The plate can then be expanded *in situ* (from 8-12mm in 2mm increments). This design allows for a single implant to be used in varying patient situations, obviating the need for trialing.

The plate is made of titanium alloy (Ti6Al4V), is 5mm wide, and features a laminar mouth (5.4mm wide) designed to capture the lamina during plate expansion and screw insertion.



Expandable Laminoplasty Plate
(48570300)



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Base Laminoplasty Plate

(48570301)

Base Laminoplasty Plate

The **Base Laminoplasty Plate** can be used to reinforce an unstable hinge after a laminoplasty procedure. It can be attached directly to the lamina above and to the lateral mass beneath the hinge.



The Base Laminoplasty Plate features two screw holes which can be used to secure the plate to the laminar hinge and two holes which can be used to attach the plate to the lateral mass.

Bone Screws

The Escalate™ Laminoplasty System features a 2.0mm diameter self-drilling screw in lengths of 4-10mm (magenta color). The system also contains a 2.4mm diameter self-tapping rescue screw in lengths of 4-10mm (purple color).

The screws feature a square drive for rigid attachment to the self-retaining screwdriver.



Square Drive of Screw



Ø2.0mm Self-Drilling Screw



Ø2.4mm Self-Tapping Screw

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Patient Positioning

Patient Positioning and Exposure

The patient is placed in the prone position with the head and neck adequately secured. A midline incision is made sub-periosteally, exposing the spinous processes and lamina at the desired levels.

To perform an open-door laminoplasty procedure, create a vertical trough completely through the lamina on one side of the posterior arch (the “open side”) and a unicortical trough on the contralateral side (the “hinge”).

Care must be taken not to remove an excessive amount of bone when creating the trough opposite the open side as this may result in an unstable hinge.



Implant Selection

There is only one size Expandable Laminoplasty Plate. The following techniques may be utilized depending on surgeon preference:

Option 1: Expand all levels together. In this technique, each plate is secured on the lateral mass side only. With all plates in place, expand each plate sequentially to achieve a controlled and incremental opening of the hinge. Once all plates are expanded to the desired height, the laminar screws may be inserted.

Option 2: Expand one level at a time. In this technique, a plate is secured at each level. After placing the first plate, secure the plate to the lateral mass, expand the plate, and insert the laminar bone screw. Repeat steps for each level.



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Expandable Laminoplasty Plate Technique

Lifting the Lamina



Lamina Elevator
(48570100)

After the laminar trough and hinge have been prepared, the **Lamina Elevator** can be used to lift the fully-cut lamina. This instrument is designed such that the Expandable Laminoplasty Plate can fit between the prongs of the Lamina Elevator. The Lamina Elevator can remain attached to the lamina during plate placement.

Note: Care should be taken not to use excessive force when lifting the lamina as this may result in hinge loosening.



Lifting the Lamina

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Plate Holder
(48570101)

Placing the Plate

Attach the **Plate Holder** to the plate by clamping the Plate Holder onto the top half of the plate (green side).



Plate Placement through Lamina Elevator

To insert the plate, hold the Plate Holder / Expandable Laminoplasty Plate assembly with the green side facing up. Insert the mouth of the plate around the lifted lamina and place the foot of the plate (grey side) against the lateral mass of the open side. If necessary, lift the lamina using the plate, with a “scooping action” so that the foot can be placed.

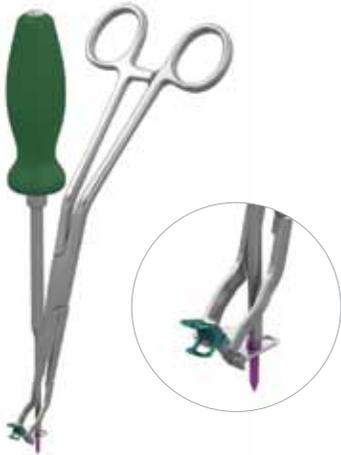
Tip: The Lamina Elevator can be left in place during this step, as the plate can fit between its prongs (see image to the left).

Once the mouth and the foot of the plate are positioned, the Lamina Elevator can be removed as the plate should hold the lamina open without assistance.

Tip: The Plate Holder can be left in place for screw hole preparation.

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Preparing / Inserting Lateral Mass Side Screw

Screw Hole Preparation

Note the recommended steps for screw hole preparation and screw insertion:

- a) Prepare / insert lateral mass side screws**
- b) Expand plate**
- c) Insert laminar screw**

This order is recommended to allow the plate to be positioned in the desired location before it is locked down.

Keeping the Plate Holder attached, prepare the screw hole on the lateral mass side of the plate using either the **Awl** or a **Drill Bit**.

To use the Awl, align the pointed tip in the center of the plate screw hole such that it is perpendicular to the plate, then gently press and twist to penetrate the bone. The Awl point tip is 3mm in length and features a stop. When deployed through the plate, the Awl penetrates approximately 2.5mm of bone.

Once the Awl has reached a 2.5mm depth the stop surface will contact the plate, preventing further penetration into bone.

If drilling is preferred, attach the included Drill Bit to a Stryker Spine quick release handle (e.g. Aviator™ part # 48770600) or to a power drill with an A/O connection. Drill Bits are available in 4, 6, and 8mm lengths and have a diameter of 1.2mm. The drill bits are designed to drill at the labeled depth when inserted through the plate.

Align the Drill Bit tip in the screw hole so that it is perpendicular to the plate. The Drill Bit features a stop which has been designed to prevent over-drilling. Carefully drill a pilot hole in the lateral mass until the shaft of the drill touches the plate.



Awl
(48570102)



Drill Bit
(48570114, 48570116, 48570118)

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Screw Insertion

The self-retaining **Screwdriver** features a square split tip to hold the screw head securely. To load bone screws, fully insert the tip of the Screwdriver into a screw head while the screw is in the screw caddy. Use the gauge in the screw caddy to confirm screw length.



Screwdriver
(48570104)



Screwdriver Tip

Note: Following either technique for screw preparation (Awl or Drill), use the 2.0mm self-drilling screws (magenta). The 2.4mm self-tapping screws should only be used as a rescue screw after a 2.0mm screw has been inserted into (and removed from) the screw pathway. Prior to insertion, confirm screw type by looking at the tip. The self-drilling screws have a sharper tip and cutting flute.

With the Plate Holder still attached to the Expandable Laminoplasty Plate, insert bone screws one at a time through the Plate Holder and into the previously-prepared pilot holes. Turn the Screwdriver clockwise to advance the screw. Tighten the screw until it feels secure in bone and is flush with the plate. Do not continue to advance the screw beyond this point, as this may lead to stripping of the screw or screw hole. Gently rock the Screwdriver to disengage. Repeat this process to insert the second screw.

Release the Plate Holder from the Expandable Laminoplasty Plate. The Expandable Laminoplasty Plate should now be properly fastened to the lateral mass of the chosen vertebral level and be holding the lamina in its mouth (as shown below).



Insert Lateral Mass Screws through Plate Holder

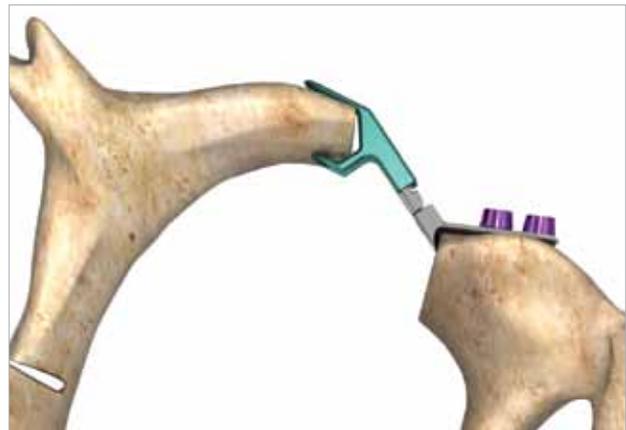


Plate in Position and Fastened to Lateral Mass

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Expander Knob



Expander
(48570103)

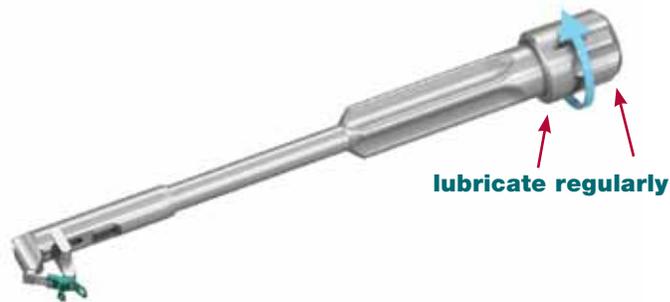
Plate Expansion

If the Expandable Laminoplasty Plate is at a desired height, the laminar screw hole can be prepared. If more opening is required, use the **Expander** to expand the plate. Position the Expander so that the bottom (flat side) pin engages the hole on the bottom (grey) half of the plate, then engage the top (angled side) pin in the hole at the top (green side) of the plate.

Tip: To set the Expander in the “Start” position, rotate the handle counterclockwise until it stops. Then rotate clockwise for one full revolution.

Tip: The grooves on the underside of the Expander are designed to fit over the screws on the lateral mass side of the plate. Use the grooves to help align the Expander to the plate.

Tip: Keep Expander tilted forward to ensure engagement of its top pin with the Expandable Laminoplasty Plate.



To expand, be sure the Expander pins are fully seated in the plate, and gently turn the knob clockwise. The first click indicates that the Expandable Laminoplasty Plate has been adjusted to a height of 10mm; the second click indicates that the Expandable Laminoplasty Plate has been adjusted to a height of 12mm. Rotate the knob approximately 1.5-2 complete turns for 1 click. The Expander and the plate both feature stops which are designed to prevent over-expansion or plate disassembly. After the desired height has been achieved, gently turn the Expander knob counterclockwise a half-turn and pull backwards on the instrument to disengage it from the plate.

Note: Do not apply cantilever loads while the pins of the Expander are engaged with the plate as this may lead to pin breakage.

Note: Lubricate the handle of the Expander regularly to ensure proper functioning of the instrument.

Alternate Technique for Plate Expansion

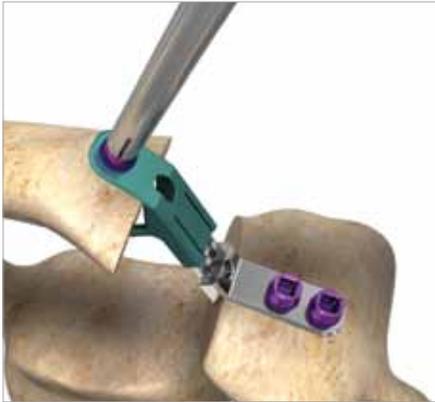
The Lamina Elevator can also be used to expand the plate. To follow this technique, apply counter force on the lateral mass side of the plate by placing the Screwdriver in the screw hole. Then place the Lamina Elevator under the lamina (around the plate). Lift up on the lamina while holding the Screwdriver in the lateral mass side screw hole. The plate will expand as needed.

Note: Do not apply excessive force using this technique.

Note: The Alternate Technique for Plate Expansion requires insertion of the laminar screw prior to plate expansion.

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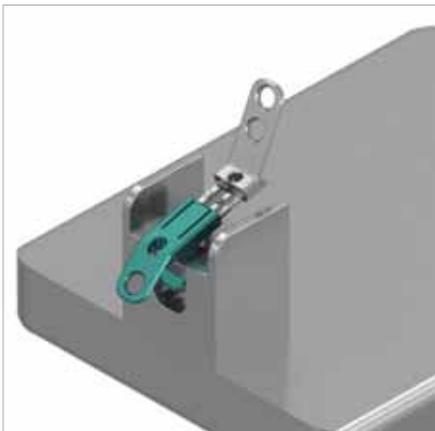
Insert Laminar Screw

Prepare Laminar Screw Pathway and Insert Screw

With the plate in its expanded position, prepare the laminar screw pathway using either the Awl or Drill Bit (as described previously). Then insert the appropriate screw using the Screwdriver.

Note: Care should be taken while inserting the laminar screw as the Plate Holder is no longer attached for use as a guide.

Note: In cases where the hinge is loose or unstable, the Lamina Elevator may be used to lift the lamina to the top of the plate to facilitate drilling or screw insertion.

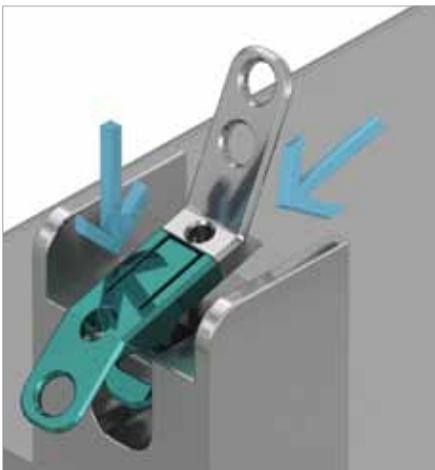


Place Mouth of Plate under Positioning Bar of the Collapser Block (48570107)

Collapsing the Expandable Laminoplasty Plate

The Expandable Laminoplasty Plate can be returned to its original height or collapsed *ex situ* using the **Collapser Block**. To collapse the plate, place the mouth of the plate (green side) under the positioning bar. Push on the top of the plate, while sliding the bottom half (grey side) closed.

Note: The Expandable Laminoplasty Plate can be expanded and collapsed a maximum of 3 times.



Push Down on Green Side, while Sliding Grey Side Closed

Note: When pressing down to collapse the Expandable Laminoplasty Plate try to keep pressure off the plate's expandable tab.

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Base Laminoplasty Plate attached to the Hinge Side

Base Laminoplasty Plate Technique

The Base Laminoplasty Plate can be used to provide additional support for a loose hinge. Use the Plate Holder to place the plate on the hinge so that the short side rests by the lateral mass and the longer side rests in-line with the lamina. Prepare screw holes and insert screws on the lateral mass side first, and then repeat for the lamina side. Repeat as needed for each desired level.

Implant Removal



Expandable Laminoplasty Plate

To remove the Expandable Laminoplasty Plate, follow the implantation procedure in reverse. First, attach the Plate Holder to the Expandable Laminoplasty Plate making sure it grasps the plate securely. Next, seat the Screwdriver in the laminar screw and turn counterclockwise to back out the bone screw. Complete the same procedure for the lateral mass bone screws. Once all bone screws have been removed use the Lamina Elevator to pull back on the lamina, and remove the Expandable Laminoplasty Plate with the Plate Holder.



Base Laminoplasty Plate

To remove the Base Laminoplasty Plate, follow the implantation procedure in reverse. Seat the Screwdriver in the laminar screw and rotate counterclockwise to back out the bone screw. Complete the same procedure for the other laminar screw. Next, seat the screwdriver in one of the lateral mass screws and rotate counterclockwise to back out the screw. Complete the same procedure for the second lateral mass side screw. The Base Laminoplasty Plate is not compatible with the Plate Holder.

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Surgical Technique

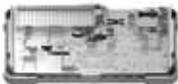
Implants

Description	Part #	
Expandable Laminoplasty Plate	48570300	
Base Laminoplasty Plate	48570301	
Ø2.0mm Self-Drilling Screw, 4mm	48570204	
Ø2.0mm Self-Drilling Screw, 6mm	48570206	
Ø2.0mm Self-Drilling Screw, 8mm	48570208	
Ø2.0mm Self-Drilling Screw, 10mm	48570210	
Ø2.4mm Self-Tapping Screw, 4mm	48570244	
Ø2.4mm Self-Tapping Screw, 6mm	48570246	
Ø2.4mm Self-Tapping Screw, 8mm	48570248	
Ø2.4mm Self-Tapping Screw, 10mm	48570240	

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Instruments

Description	Part #	
Laminoplasty Container	48570000	
Lamina Elevator	48570100	
Plate Holder	48570101	
Awl	48570102	
Expander	48570103	
Screwdriver	48570104	
Collapser Block	48570107	
Drill, 4mm	48570114	
Drill, 6mm	48570116	
Drill, 8mm	48570118	
Laminoplasty Screw Rack	48570000A	
Laminoplasty Plate Caddy	48570000B	
Laminoplasty Outer Case	48570000C	
Laminoplasty Inner Tray	48570000D	

Escalate™ Laminoplasty System

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Product Information

STRYKER SPINE Escalate™ Laminoplasty System

NON STERILE PRODUCT

DESCRIPTION

The STRYKER Spine Escalate™ 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 features an expandable plate, a hinge plate, bone screws, and a set of instruments to assist in implantation and removal of the devices. The screws to be used with the plates are available in various sizes and are designed to match the anatomical requirements.

INDICATIONS

The STRYKER Spine Escalate™ Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3-T3) in laminoplasty procedures. The system is intended to hold the lamina open following a laminoplasty procedure.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Pathological bone conditions including, but not limited to, severe osteoporosis involving the spine, osteopenia, or certain metabolic disorders affecting osteogenesis.
- Active (fever, leukocytosis) or previous history of infection.
- Open wounds.
- Any neuromuscular deficit, which places an unusually heavy load on the device during the healing period.
- Any case not needing a laminoplasty procedure.
- Morbid Obesity that may result in inordinate loading of the device.
- Pregnancy
- A condition of senility, mental illness, or substance abuse potentially rendering the patient non-compliant with post-operative protocols.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to material selection or implantation.

- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.
- Any case not described in the Indications.

As in any surgical condition, these contraindications can be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive.

PRE-OPERATIVE PRECAUTIONS

Surgical Technique brochures may be by requested from a distributor or from STRYKER Spine directly. Those using brochures published more than two years before the surgical intervention are advised to obtain an updated version.

STRYKER Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by STRYKER Spine. For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable STRYKER Spine Surgical technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels.

Unless otherwise specified on the label, the instruments may be reused after decontamination, cleaning and sterilization.

REMOVAL OF IMPLANTS

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains
- Bone growth restraint due to the presence of the implants
- Failure or mobilization of the implant

Instruments are provided by STRYKER Spine to be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal must be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

WARNINGS & PRECAUTIONS

The STRYKER Spine Escalate™ Laminoplasty System has not been evaluated for safety and compatibility in the MR environment. The STRYKER Spine Escalate™ Laminoplasty System has not been tested for heating or migration in the MR environment.

CAUTION

Federal law (USA) restricts these devices to sale by or on the order of a licensed physician.

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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