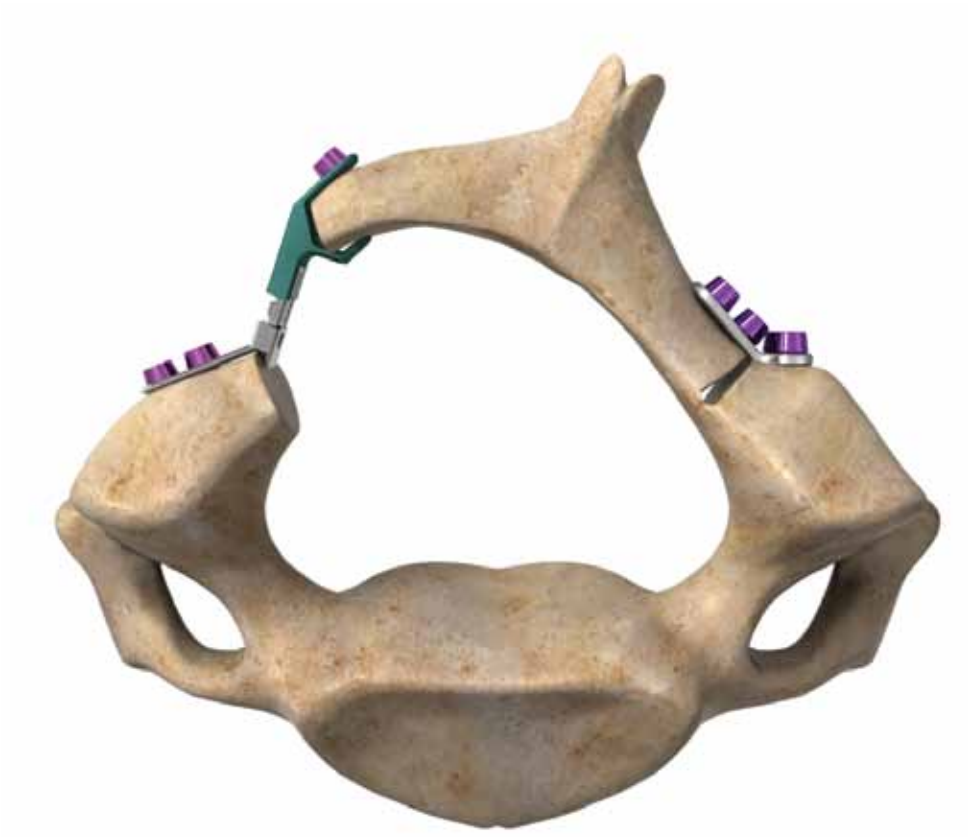
stryker®

Spine

Escalate™ Laminoplasty System

Surgical Technique

- Expandable Laminoplasty Plate
- Streamlined Procedure



Escalate™ Laminoplasty System
Surgical Technique

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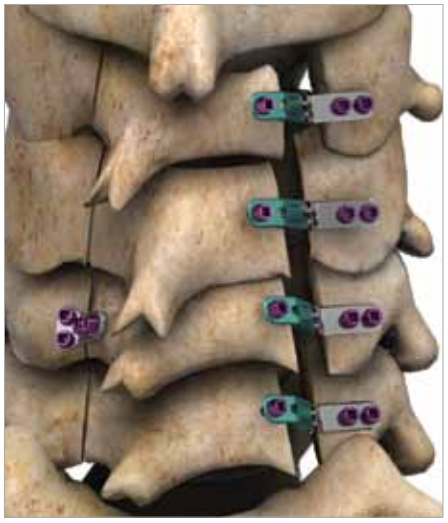
System Overview



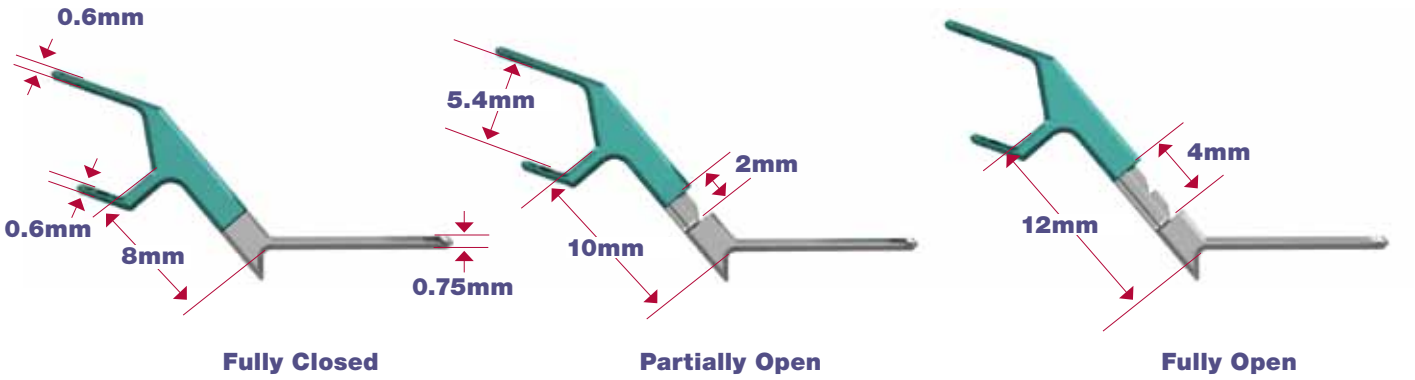
The Escalate™ System is a comprehensive set of implants and instruments designed for a systematic approach to cervical laminoplasty procedures. The system features an Expandable Laminoplasty Plate, a Base Laminoplasty Plate, **Bone Screws** for fixation, and a set of instruments to assist in implantation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



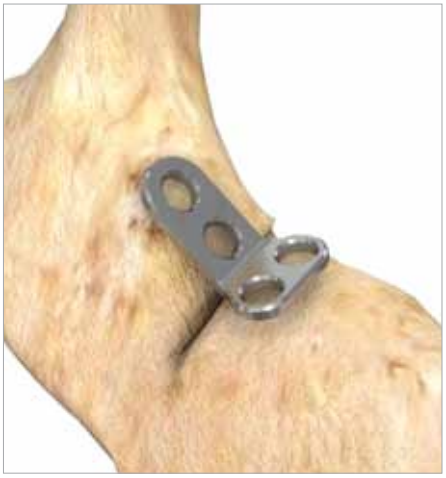
Fully Closed **Partially Open** **Fully Open**

Escalate™ Laminoplasty System
Surgical Technique

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).

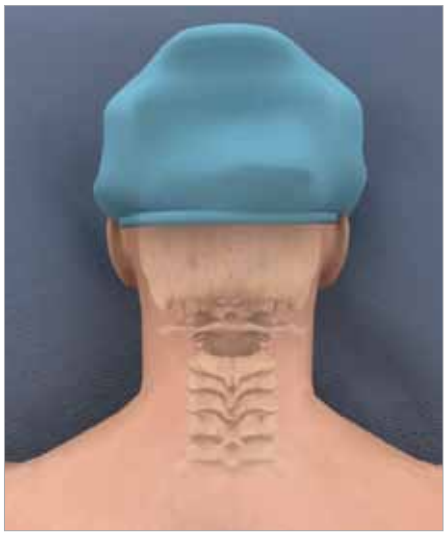
The screws feature a square drive for rigid attachment to the self-retaining screwdriver.

Square Drive of Screw

Ø2.0mm Self-Drilling Screw

Ø2.4mm Self-Tapping Screw

Surgical Procedure



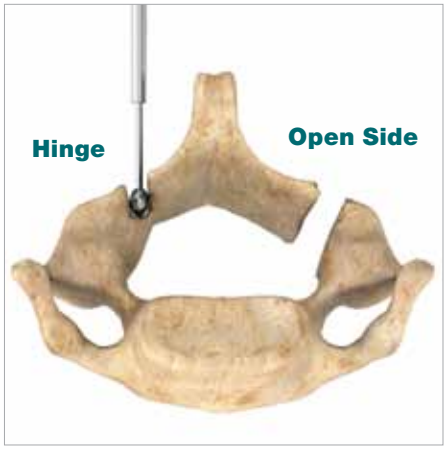
Patient Positioning

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.

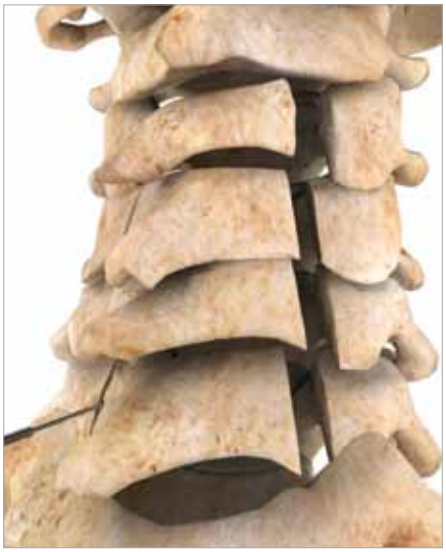


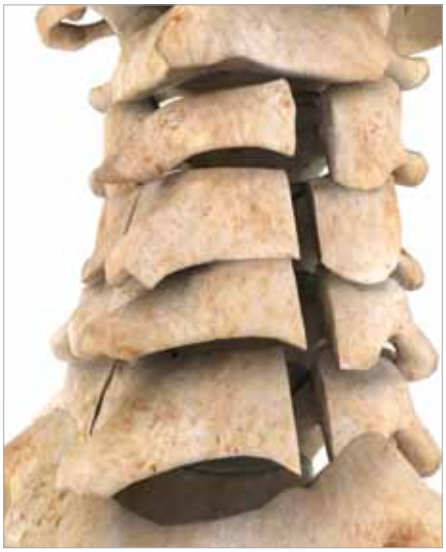
Implant Selection

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.





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

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).

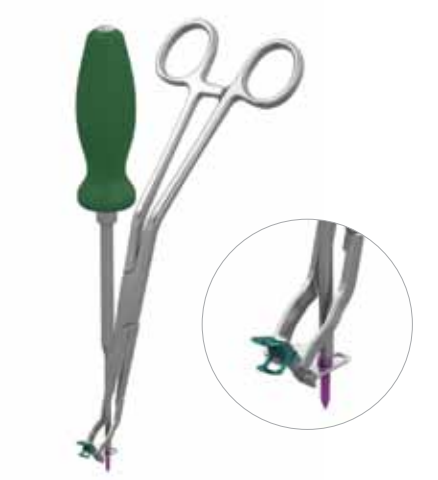
Plate Placement through Lamina Elevator

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).

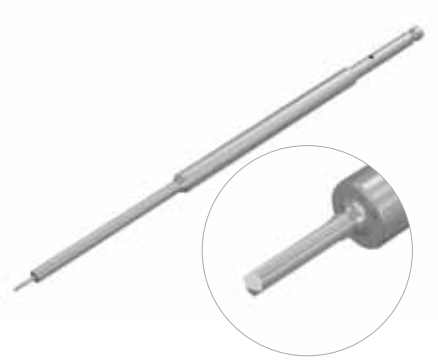
Once the mouth and the foot of the plate are positioned, the Lamina Elevator can be removed as the plate should hold the lamina open without assistance.

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



Preparing / Inserting Lateral Mass Side Screw

Awl
(48570102)



Drill Bit
(48570114, 48570116, 48570118)

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.

Screwdriver
(48570104)

Screwdriver Tip

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.

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

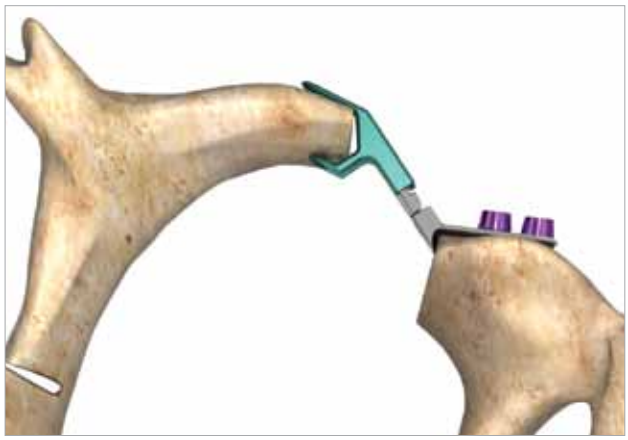


Plate in Position and Fastened to Lateral Mass

Expander Knob

Expander
(48570103)

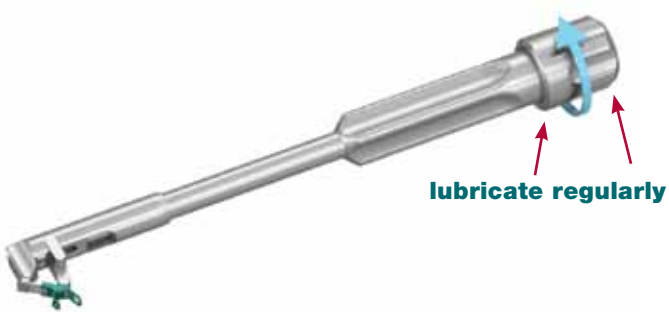
Plate Expansion

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.

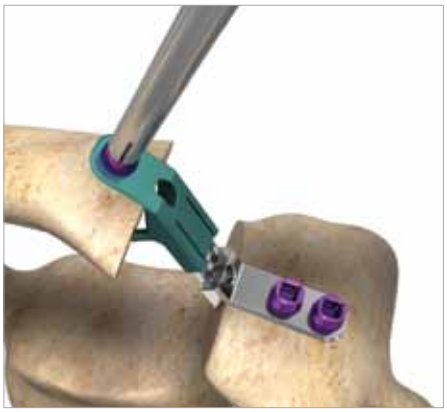
Note: Lubricate the handle of the Expander regularly to ensure proper functioning of the instrument.

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.



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.

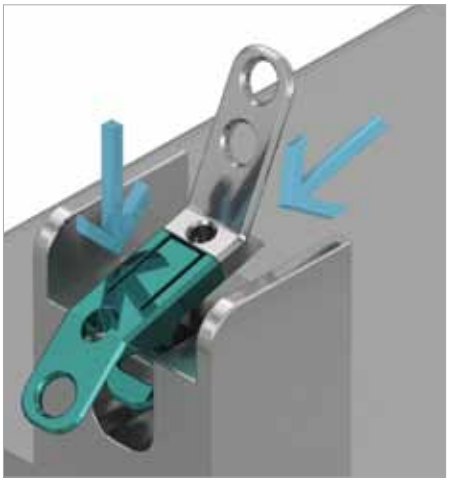
Note: In cases where the hinge is loose or unstable, the Lamina Elevator may be used to lift the lamina to the top of the plate to facilitate drilling or screw insertion.

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

Collapsing the Expandable Laminoplasty Plate

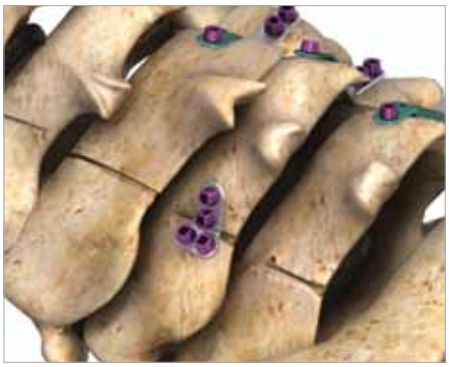
The Expandable Laminoplasty Plate can be returned to its original height or collapsed *ex situ* using the **Collapser Block**. To collapse the plate, place the mouth of the plate (green side) under the positioning bar. Push on the top of the plate, while sliding the bottom half (grey side) closed.

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.

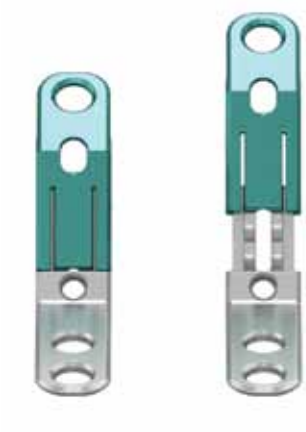


Base Laminoplasty Plate attached to the Hinge Side

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.

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	

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

IFU Reference Number: NORCESCALATE Rev 03

Stryker Spine Escalate™ Laminoplasty System

Non-sterile product

Description
The 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.

Materials
The implants in the Escalate™ Laminoplasty System are offered in Ti6Al4V Titanium alloy, as defined in the ISO 5832-3 and ASTM F136 standards.

Indications
The 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.

Adverse effects
While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials, which are placed within the body for the potential fusion of the Spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors, which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone. The following list is representative, though not all inclusive, of the potentially adverse effects that the surgeon must consider whenever implanting a spinal fixation system or device:

- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including plates and screws has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair. This risk is related to the surgical procedure. The intended use of the device does not require it to be close to the dura.
- Cessation of growth of the fused portion of the Spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) must be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Cervical Spine procedures may be associated with vascular and neural complications such as arterial injury or mechanical compromise, cord contusion and damage, peripheral nerve compromise and

damage, including but not limited to peripheral paralysis, sensory disorders, vascular disorders, loss or disturbance of bladder and bowel functions.

- Serious complications may be associated with any surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the Spine can occur due to implantation of the components. Postoperative fracture of the intervertebral body, pedicle, and /or lateral mass above and/ or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.
- Adverse effects may necessitate reoperation or revision.

The surgeon must warn the patient of these adverse effects as deemed necessary.

General conditions of use
The implantation of a spinal fixation system must be performed by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The information contained in this Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the Spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

Infection
Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Information for patients
The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion must be directed to the issues of premature weightbearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and make the patient aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warned them of the potential consequences. For patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

Instruments
Surgical instruments are provided by Stryker Spine and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments, which have experienced extensive use or extensive force, are more susceptible to fracture depending on the operative precaution, number of procedures, disposal attention. Instruments must be examined for wear or damage prior to surgery. Instruments must be properly cleaned, maintained and lubricated as usually recommended for all surgical instruments.

Reuse
An implant must never be reused. While it may appear undamaged, a used implant may have acquired blemishes or latent compromise of its integrity, which would reduce its service life.

Instruments labeled as single use must not be reused or resterilized. While a single-use instrument may appear undamaged, the instrument may have acquired contaminants that compromise sterility and/or blemishes, nicks or latent compromise of its integrity. Inspect the packaging for any visible damage or breaches prior to use. Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

Any device that is damaged or the packaging is compromised must not be used and should be returned to Stryker Spine or discarded.

Handling
Correct handling of the implant is extremely important. The operating surgeon must avoid notching or scratching the device.

Allergy and hypersensitivity to foreign bodies
When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.

Implant selection and use
The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient. Patients who are overweight may experience additional stresses and strains on the device, which may cause metal fatigue and/or lead to deformation or failure of the implants. The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates only is recommended if necessary according to the surgical technique of each system. Rods or plates must only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the Stryker Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

Metal components
Some of the alloys used to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomena.

System compatibility
While some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system must not be used in conjunction with components from any other manufacturer's spinal system. Any such use will negate the responsibility of Stryker Spine for the performance of the resulting mixed component implant.

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 causes 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.

Postoperative care
Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants, which may lead to fixation or implant failure and accompanying clinical problems. The surgeon must also instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected.

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.

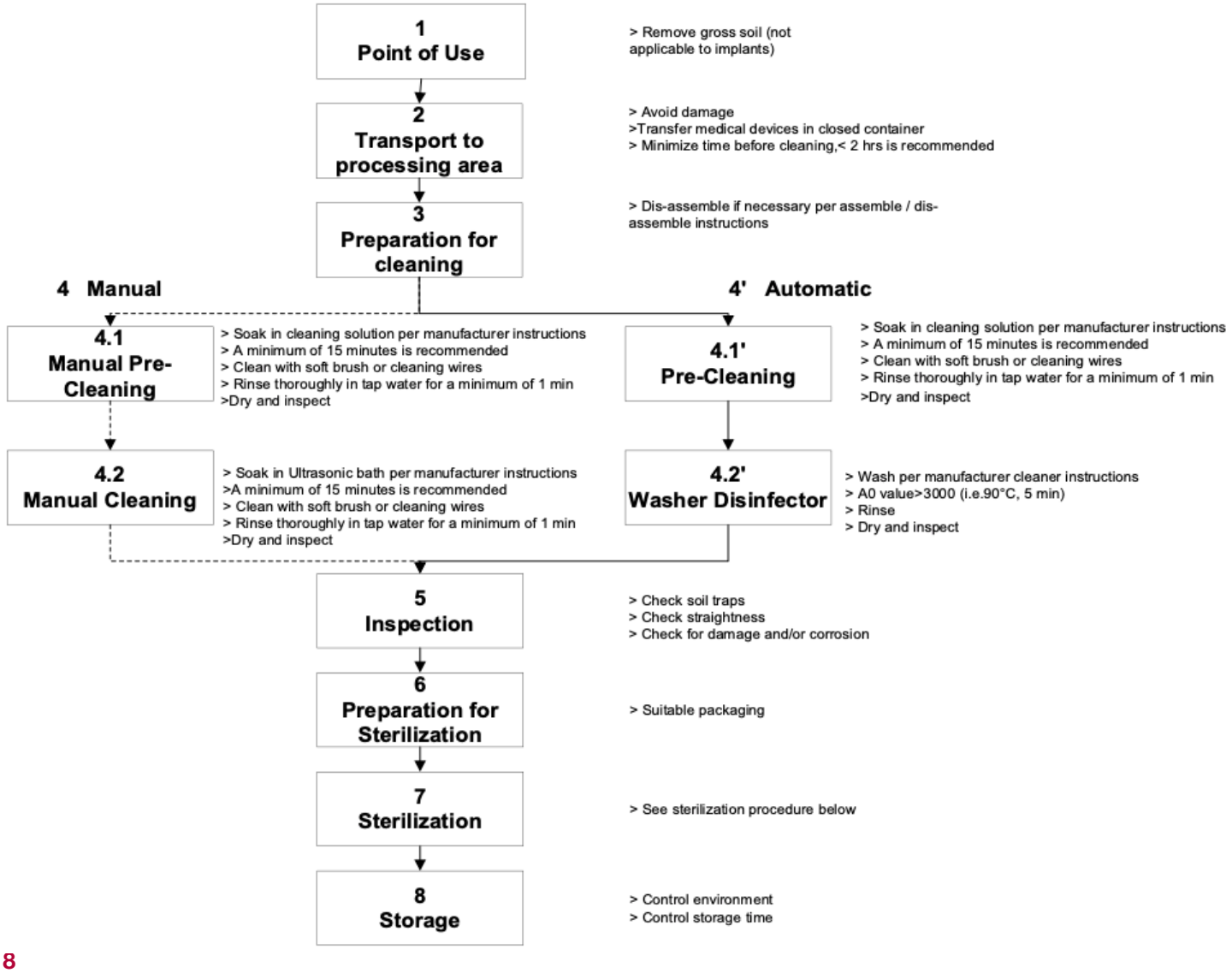
Packaging

The implants are delivered in packages; these must be intact at the time of receipt.

The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

Pre-cleaning / Cleaning and sterilization procedure recommended for Non-sterile medical device

For safety reasons, non-sterile devices must be pre-cleaned, cleaned and sterilized prior to use. Moreover, for good maintenance, reusable instruments must be pre-cleaned, cleaned and sterilized immediately after surgery following the sequence of steps described in the following chart.



Sterilization procedure recommended for Non-sterile medical devices including implants
Medical Devices should be sterilized in their container by means of moist heat steam sterilization in an autoclave in accordance with standard hospital procedure. The recommended sterilization methods have been validated according to ISO 17665-1 to obtain a Sterility Assurance Level (SAL) of 10-6.

Steam Sterilization with Commercially Available Sterilization Wrap

The following ranges of parameters have been validated on wrapped containers in fully-loaded autoclaves.

Minimal sterilization conditions:
Prevacuum (Porous Load) steam sterilization autoclave:

- Temperature: 132°C (270°F)
- Exposure Time: 4 Minutes
- Dry Time: 45 Minutes

Caution: For products being used in the United States (USA), an FDA cleared sterilization wrap is required to wrap the sterilization containers.

The autoclave must be validated by the hospital and regularly checked to guarantee the recommended sterilization temperature is reached for the entire exposure time.

If after having followed this sterilization method there is still water in the sterilization containers or on/inside the device, the device must be dried and sterilization repeated. Drying times for medical devices processed in containers and wrapped trays can vary depending upon the type of packaging, type of medical device, type of sterilizer, and total load. A minimum dry time of 45 minutes is recommended, but to avoid wet packs, extended dry times greater than 45 minutes may be needed. See Extended Dry Time Table in the Stryker Spine Instructions for: Cleaning, Sterilization, Inspection, and Maintenance of Non-Sterile Medical Devices NSRDEV_RG. For large loads verification of dry times by the health care provider is recommended.

Caution: Stryker Spine has not validated and does not recommend Flash Sterilization

Steam Sterilization with FDA-Cleared Rigid Containers Option:

In order to ensure proper sterilization of Stryker Spine devices when using the Aesculap SterilContainer (JN series) reusable, rigid sterilization containers, the information below must be followed:

1. Only the following Aesculap reusable rigid container configuration, FDA-cleared, shall be used in a pre-vacuum steam sterilization cycle for use in the USA:
   - JN442 – Aesculap SterilContainer, Full Size, 6-inch height, Perforated Bottom
   - JK489 – Aesculap SterilContainer, Full Size, 2000 Lid, Aluminum
   - US994 – Filter Paper, 7 ½ inches Round, Single Use
2. Aesculap SterilContainer instructions for use must be followed. If questions arise regarding the use of the Aesculap SterilContainer reusable, rigid sterilization container, Stryker Spine recommends contacting Aesculap directly for guidance
3. Sterilization instructions:

a. No more than two (2) individual Stryker Spine tray inserts can be placed directly into the Aesculap SterilContainer (JN Series) reusable, rigid sterilization container (perforated bottom)

b. Stryker Spine devices must be placed in their designated locations within the tray inserts. Stryker Spine's single devices or modules/caddies/racks may be placed into an Aesculap basket (JF223R or similar) which can be loaded into the Aesculap SterilContainer reusable, rigid sterilization containers. NOTE: Devices must be placed such that individual devices are not stacked and remain in an open position to allow uniform exposure to steam.

c. Stryker Spine Container lids must be removed prior to use with the Aesculap reusable, rigid sterilization container

d. Stryker Spine devices were validated under the following USA sterilization parameters for a pre-vacuum, three pulse steam cycle:
   - Temperature: 132°C (270°F
   - Exposure Time: 4 minutes
   - Cycle Dry Time: 30 minutes

e. Reusable, rigid sterilization containers must not be stacked within the autoclave, as doing so may negatively impact ventilation and sterilization.

Note: Medical devices may be individually wrapped and sterilized.

WARNING:

- Do not use solvents, abrasive cleaners, metal brushes, or abrasive pads. Cleaning agents with aldehydes, bromine, iodine, active chlorine, or chloride as the active ingredient are corrosive to stainless steel and are not to be used.

The parameters identified in this document are the minimum for effective cleaning and sterilization of Stryker Spine implants. Stryker Spine does not recommend the use of high pH detergents, however if a detergent with high pH is used Stryker Spine recommends a pH neutralizer to ensure full removal of the high pH solution. In circumstances where sterilization temperature and exposure time required by the hospital is greater than the temperature and time recommended in this document, the effectiveness of the cycle for the purposes of sterilization is assured. However, extended cycle temperature and time may accelerate wear. Medical devices should be examined for wear or damage prior to use.

For additional information refer to Stryker Spine Instructions for: Cleaning, Sterilization, Inspection, and Maintenance of Non-Sterile Medical Devices NSRDEV_RG.

Storage
Devices are packaged in individual packages or in containers. After they are used they must be stored in a clean, dry and temperate place.

Escalate™ Laminoplasty System

IFU Reference Number: NORCESCALATE Rev 03

Caution (U.S.A)
Federal law restricts this device to sale by or on the order of a licensed physician.

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.

Complaints
Any health professional having a complaint or grounds for dissatisfaction relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a device should notify Stryker Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, Stryker Spine or its representative must be advised immediately.

If a Stryker Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or Stryker Spine must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and a complete description of the event to help Stryker Spine understand the causes of the complaint.

For further information or complaints, please contact:

Stryker Spine
2 Pearl Court,
Allendale, NJ 07401-1677 USA
Tel. 201-760-8000
http://www.Stryker.com

Notes

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