Anterior Cervical Plate System

NEO®-SL

SURGICAL TECHNIQUE GUIDE

Life Spine® Designs For Life.®

Anterior Cervical Plate System

neo®-SL

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NEO-SL Anterior Cervical Plate System

The NEO-SL Anterior Cervical Plate System takes anterior cervical plating to a new level of simplicity. The NEO-SL is an ultra slim anterior cervical plate system with an integrated locking mechanism that allows bone screws to be securely fixated without any additional locking components.

Plates

- Plates ranging in length to accommodate 1-5 levels
- Low profile plate

Intuitive Instrumentation

- Streamlined, surgeon-inspired instrumentation
- Provides intraoperative assurance and reliability

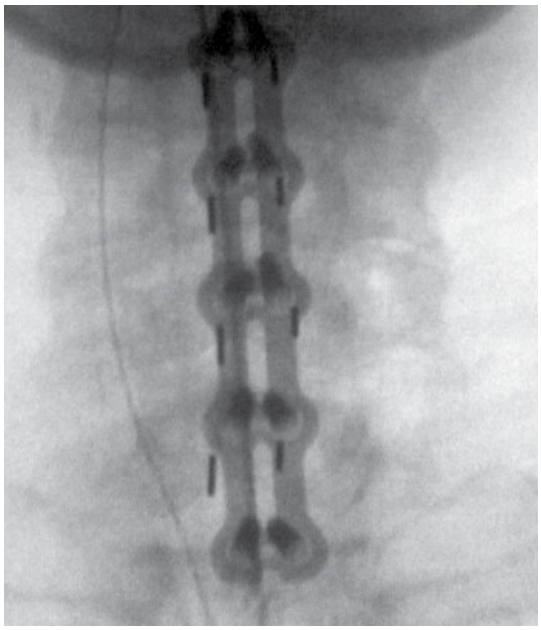
Bone Screws

» Bone screws available with a fast turn thread design in both fixed and variable angle configurations

Locking Mechanism

» Single step integrated locking mechanism

Post Operative X-Ray



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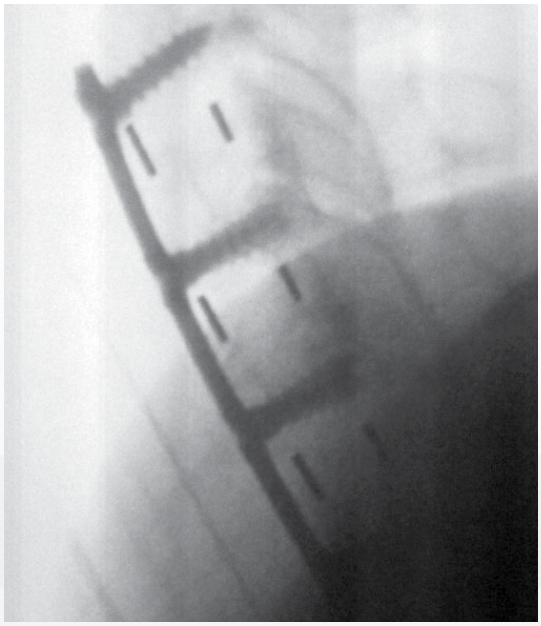


LATERAL

NEO-SL Plates

1 Level Anterior Cervical Plates

Catalog Number	Size	Qty/Set
SL1-020	20mm	2
SL1-022	22mm	2
SL1-024	24mm	2
SL1-026	26mm	2
SL1-028	28mm	2
SL1-030	30mm	2
SL1-032	32mm	2
SL1-034	34mm	2

2 Level Anterior Cervical Plates

Catalog Number	Size	Qty/Set
SL2-034	34mm	2
SL2-036	36mm	2
SL2-038	38mm	2
SL2-040	40mm	2
SL2-042	42mm	2
SL2-044	44mm	2
SL2-046	46mm	2
SL2-048	48mm	2
SL2-050	50mm	2

3 Level Anterior Cervical Plates

Catalog Number	Size	Qty/Set
SL3-052	52mm	2
SL3-055	55mm	2
SL3-058	58mm	2
SL3-061	61mm	2
SL3-064	64mm	2
SL3-067	67mm	2
SL3-070	70mm	2
SL3-074	74mm	2

4 Level Anterior Cervical Plates

Catalog Number	Size	Qty/Set
SL4-074*	74mm	2
SL4-078*	78mm	2
SL4-082*	82mm	2
SL4-086*	86mm	2
SL4-090*	90mm	2

5 Level Anterior Cervical Plates

Catalog Number	Size	Qty/Set
SL5-095*	95mm	2
SL5-100*	100mm	2
SL5-105*	105mm	2
SL5-110*	110mm	2

* Items are special order. Please contact customer service at 847.884.6117.

NEO-SL Bone Screws

Fixed Angle Fast Turn Bone Screw

Variable Angle Fast Turn Bone Screw

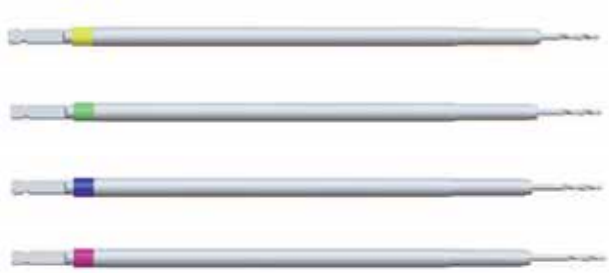
Emergency Variable Angle Fast Turn Bone Screw

Reference	Length	Qty/Set	Head	Threads
Fixed Angle Fast Turn Bone Screws				
301-010	4mm x 10mm	2	Sea Foam Green	Vector Purple
301-012	4mm x 12mm	8	Sea Foam Green	Green
301-014	4mm x 14mm	8	Sea Foam Green	Gold
301-016	4mm x 16mm	8	Sea Foam Green	Lt. Blue
301-018	4mm x 18mm	2	Sea Foam Green	Magenta
Variable Angle Fast Turn Bone Screws				
302-010	4mm x 10mm	2	Blue	Vector Purple
302-012	4mm x 12mm	8	Blue	Green
302-014	4mm x 14mm	8	Blue	Gold
302-016	4mm x 16mm	8	Blue	Lt. Blue
302-018	4mm x 18mm	2	Blue	Magenta
Emergency Variable Angle Fast Turn Bone Screws				
303-010	4.3mm x 10mm	2	Magenta	Vector Purple
303-012	4.3mm x 12mm	4	Magenta	Green
303-014	4.3mm x 14mm	4	Magenta	Gold
303-016	4.3mm x 16mm	4	Magenta	Lt. Blue
303-018	4.3mm x 18mm	2	Magenta	Magenta

NE0-SL Standard Instruments

113-903	Hexalobe T10 Screwdriver

113-106	Fixation Pin Driver



Standard Cervical Drills		
113-103	10mm	Gold
113-116	12mm	Green
113-117	14mm	Blue
113-118	16mm	Pink

Micro Cervical Drills		
113-132	10mm	Gold
113-131	12mm	Green
113-133	14mm	Blue
113-134	16mm	Pink

113-102	Fixed Awl

113-826	Cervical Plate Holder

113-825	SL ACP Adjustable Awl

113-112	AO Ratcheting Straight Handle

113-197	Variable Angle Micro Drill Guide (for use with micro drills)

NE0-SL Standard Instruments

113-956-1	SL Screw Remover Sleeve

113-954	Temporary Fixation Pin

113-956	SL Screw Remover Core

113-915	SL Plate Bender

113-226	Fixed Angle Drill Guide, 0^0 Intermediate

113-227	Fixed Angle Drill Guide, 0^0 Intermediate

NEO-SL Surgical Technique

1. Preparation and Exposure

Appropriate positioning of the patient is essential for optimal exposure of the anterior cervical spine. Traction may be necessary in the event of any unstable trauma. Depending upon the levels of arthrodesis or pathology, create a transverse or longitudinal incision to allow access to the anterior aspect of the cervical vertebral bodies, C2 through T1.

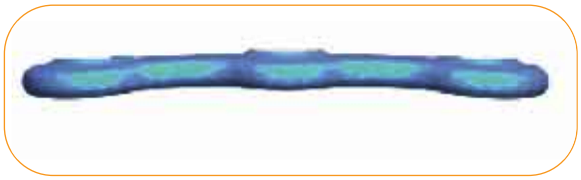
- Perform a discectomy
- The choice and usage of interbody graft is subject to the surgeon's preference

2. Appropriate Implant Selection

Adequate preoperative planning, including the utilization of radiographic and MRI data, should be noted when estimating the appropriate plate sizes. After the interbody grafts have been inserted, determine the appropriate plate size by measuring the distance of the plate from end-to-end. For intermediate levels, ensure that the bone screws are in the middle of the vertebrae. From these measurements, identify the proper plate size and level to accomplish the surgery.

3. Plate Placement

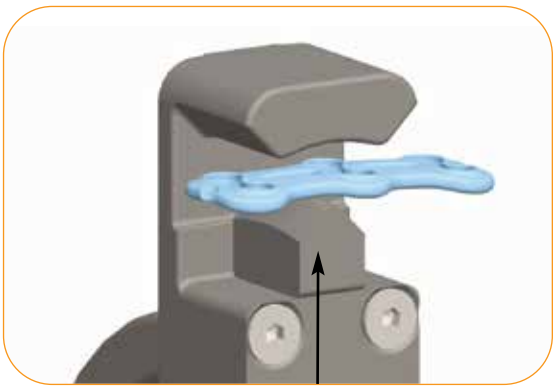
The NEO-SL Anterior Cervical Plates are pre-lordosed and contain curvature in the sagittal and coronal planes, simplifying anatomical placement.



Remove any osteophytes, often found in the degenerative vertebrae for optimal plate placement. Position the plate onto the exposed vertebral column to verify the plate length and size selection.

4. Plate Preparation

NEO-SL plates are pre-lordosed to a 180mm radius. Additional contouring may be accomplished by inserting a plate into the rigid plate bender and squeezing the handles.



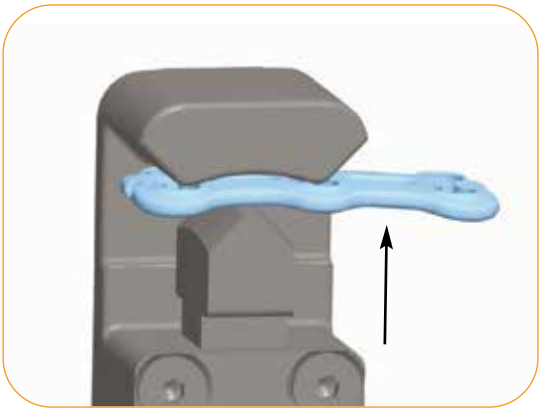
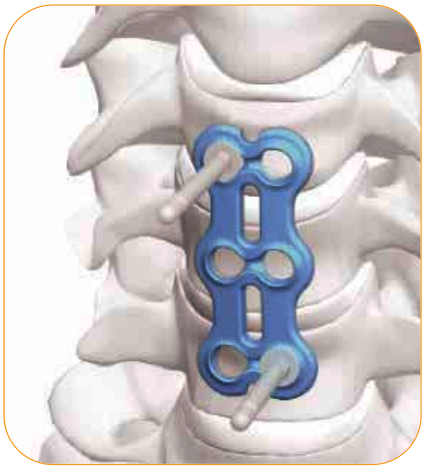


Plate Bender

5. Temporary Fixation Pins

Temporary Fixation Pins can be used to temporarily fixate the plate to the vertebrae. Attach the Fixation Pin Driver securely to the Ratcheting Handle. Utilizing the Fixation Pin Driver, drive the Temporary Fixation Pins into the cortical wall by placing the pin through the bone screw holes. The Temporary Fixation Pin has a self-cutting tip to allow the pin to be placed without additional hole preparation.

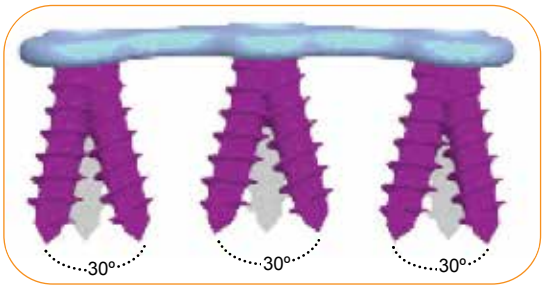
NOTE:*To achieve the most rigid temporary fixation, it is recommended to install a pin at the cephalad and caudal ends of the plate.*



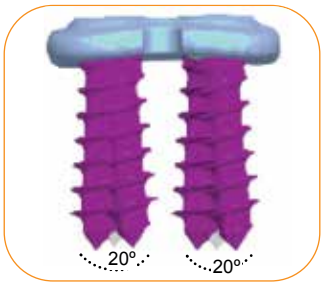
6. Bone Screw Hole Preparation

The NEO-SL ACP System provides considerable screw angulation.

Variable Angle Bone Screw Configuration



15˚ cephalad to caudal (30˚ inclusive)



10˚ lateral to medial (20˚ inclusive)

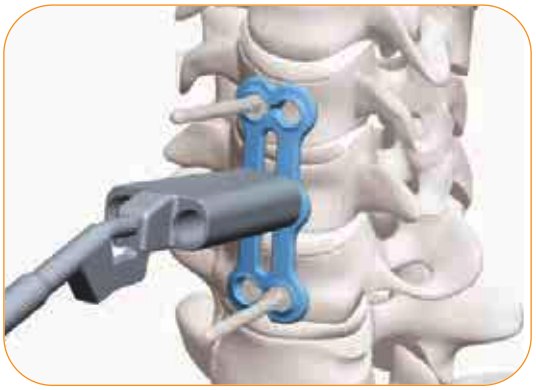
The NEO-SL ACP System is designed with two different drill guide styles, fixed and variable angle. The drills have been designed to be used with the guides to limit the penetration of the drill and to center the screw pilot hole for optimal screw placement.

All-in-One Drill Guide

The **Double-Barrel Drill Guide** acts as a plateholder through which an awl, drill and screws can be inserted, resulting in fewer steps.

- Utilize a 0^0 double-barrel drill guide at the intermediate screw holes of the plate.
- Utilize a 15^0 double-barrel drill guide at the distal screw holes of the plate
- Place the Double-Barrel Drill Guide securely to the plate, while ensuring alignment to the bone screw holes.
- Turn the knob on the shaft clockwise to lock the instrument to the plate.
- Proceed to awl, drill and insert screws
- Disengage the Double-Barrel Drill Guide from the plate by turning the knob on the shaft counterclockwise.

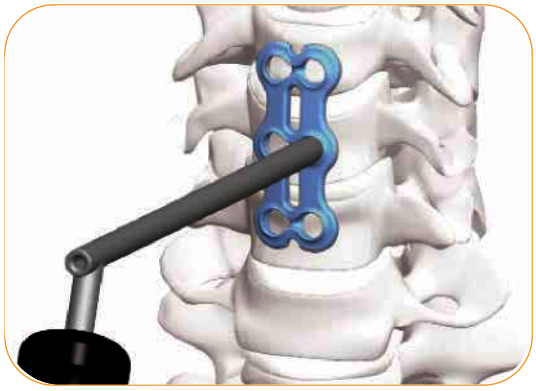
NOTE: *Bone screws should not exceed the defined angulation of the system.*



Variable Angle Micro Drill Guide

- Place the Variable Angle Micro Drill Guide securely into the desired bone screw hole.

NOTE: *Bone screws should be placed in the center of the screw pocket and not exceed the defined angulation of the system.*



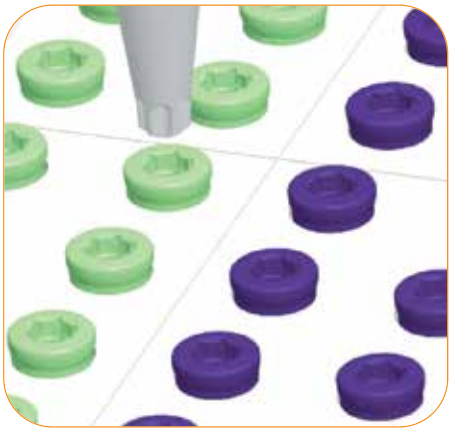
Variable Angle Micro Drill Guide

Variable Angle Micro Drill Guide with Micro Drill

7. Bone Screw Insertion

The screws are chosen according to their configuration, diameter, and length and can be easily identified by color coding. All screws are self-drilling/self-tapping to minimize the number of surgical steps.

Place selected screw onto the **Screw Driver** by pushing the tip of the **Screw Driver** forcefully into the selected screw while the screw is in the caddy.



8. Bone Screw Insertion (continued)

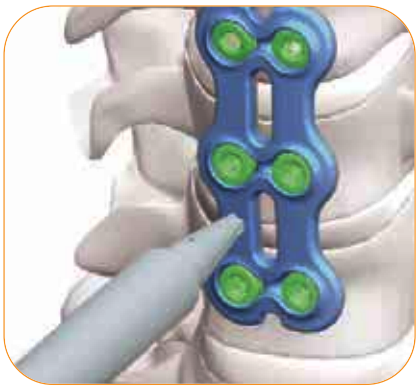
Insert the appropriate bone screw length into the prepared pilot hole until it is slightly above the integrated locking mechanism of the bone screw hole. Utilize the same technique to place remaining bone screws.

NOTE: *Confirm bone screw positions fluoroscopically prior to advancement of bone screws beyond the integrated locking mechanism.*

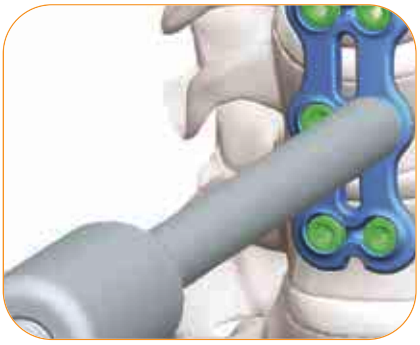
After confirmation of final bone screw positions, use the **Screwdriver** to tighten and advance bone screws past the integrated locking mechanism. Ensure that all bone screws are seated flush.

8. Bone Screw Removal

In the event of a revision or dismantling of a system, the **SL Screw Remover** must be utilized. Attach the **SL Screw Remover Core** securely into the Ratcheting Handle. Thread the **SL Screw Remover Sleeve** counter-clockwise over the **SL Screw Remover Core.** Insert the hexalobe of the **SL Screw Remover Core** into the hexalobe of the bone screw.

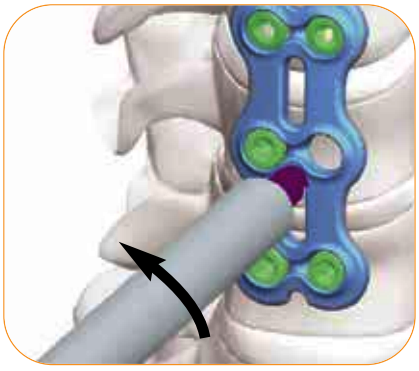


Thread the **SL Screw Remover Sleeve** clockwise over the bone screw hole.



While holding the **SL Screw Remover Sleeve** against the plate, rotate the **SL Screw Remover Core** counter-clockwise to remove the bone screw. After removal of the bone screw, the screw cannot be disengaged from the **SL Screw Remover Core**.

NOTE: *The Remover Core is single use only and should be discarded along with the removed bone screw.*



9. Closure

Wound closure is performed in the customary manner.

Revision (If Required)

All implants can be removed by performing the insertion steps in reverse.

NEO® SL Anterior Cervical Plate System

Important Information on the NEO SL Anterior Cervical Plate System

Purpose:
The NEO SL components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion.

Description:
The NEO SL consists of a variety of shapes and sizes of bone plates, screws, and associated instruments. Fixation is provided by bone screws inserted through the plates and into the vertebral body of the cervical spine using an anterior approach.

The NEO SL implant components are made from titanium alloy described by ASTM F136. Stainless steel and titanium implant components must not be used together in a construct. LIFE SPINE expressly warrants that these devices are fabricated from the foregoing material specification. No other warranties express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. Do not use any of the NEO SL components with the components from any other system or manufacturer.

Indications, Contraindications, and Possible Adverse Effects.
Indications: Properly used, this system is intended for anterior interbody screw fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The system is indicated for use in the temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with: 1) Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); 2) Spondylolisthesis; 3) Trauma (including fractures or dislocations); 4) Spinal cord stenosis; 5) Deformity or curvatures (i.e. kyphosis, lordosis or scoliosis); 6) Tumors; 7) Pseudarthrosis; and/or 8) Failed previous fusions.

Nota Bene: This device system is intended for anterior cervical interverterbral body fusions only.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Contraindications:
Contraindications include, but are not limited to:
1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any case not described in the Indications.
14. Any patient unwilling to cooperate with the post-operative instructions.
15. Any time implant utilization would interfere with anatomical structures or expected physiological performance

Potential Adverse Events:

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears.
8. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
9. Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
13. Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
16. Bone loss or decrease in bone density, possibly caused by stress shielding.
17. Graft donor site complications including pain, fracture, or wound healing problems.
18. Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
19. Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
20. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
21. Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
22. Change in mental status
23. Death.

Note: Additional surgery may be necessary to correct some of the anticipated adverse events.

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. The NEO SL is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the NEO SL is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative planning 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 NEO SL by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient. CAUTION: FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings are as follows:

Implant Selection :

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The NEO SL components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
3. When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
4. The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the costruct.
5. Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurological damage and bone necrosis.
7. Before closing the soft tissues, all of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none have loosened during the tightening of the other screws. Secure the screw locking tab into place to cover the portion of the seated screw heads. Failure to do so may result in screw loosening. Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
3. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.

5. The NEO SL implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and should be removed. In most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain, (2) Migration of implant position possibly resulting in injury, (3) Risk of additional injury from post-operative trauma, (4) Bending, loosening and/or breakage, which could make removal impractical or difficult, (5) Pain, discomfort, or abnormal sensations due to the presence of the device, (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding. While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.

6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the NEO SL components should ever be reused under any circumstances.

Packaging:
Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to LIFE SPINE.

Cleaning and Decontamination:
All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, certain instruments may require dismantling before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization:
NEO SL components are provided non-sterile. These products need to be steam sterilized by the hospital using the following method:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Gravity Displacement	250°F(121°C)	30 minutes	60 minutes

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum	250°F(121°C)	4 minutes	60 minutes

The Sterility Assurance Level (SAL) is 1 x 10-6, via the indicated methods.
No claims of pyrogenicity are made.
Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or (if applicable) returning to Life Spine.

Product Complaints: Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, LIFE SPINE. Further, if any of the implanted NEO SL component(s) ever "malfunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any LIFE SPINE product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested. Further Information: Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

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