stryker®

Spine

LITe® Plate System
Lateral Surgical Technique

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Acknowledgments

We would like to thank the following surgeon for his contributions to this project.

Steven C. Fulop, MD

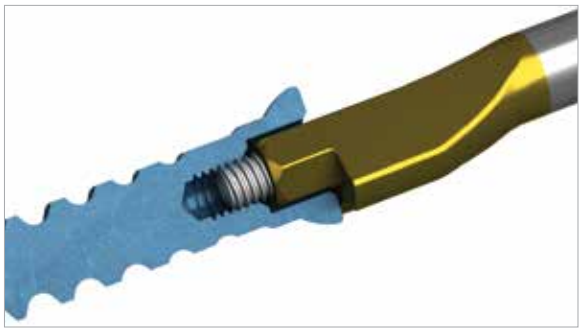
System Overview

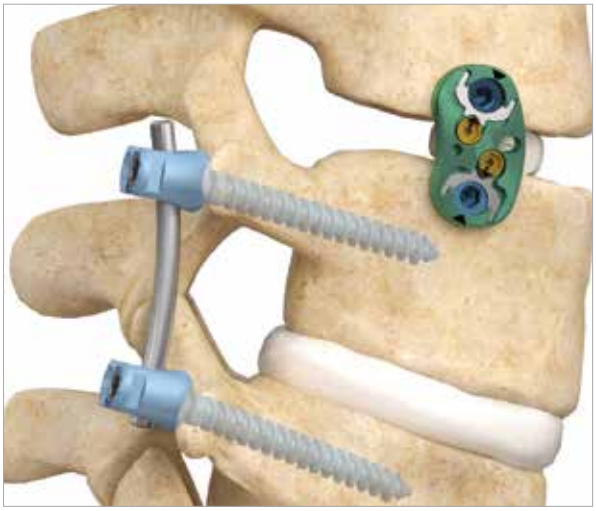
The LITe Plate System leverages Stryker's Aviator cervical plate locking mechanism to offer one-level lumbar plates with a unique dual-locking mechanism, high degree of angulation, and simplified instrumentation.

Aviator

The primary screw locking mechanism is a spring-loaded bar that automatically locks over the screw heads once they are inserted into the plate. Rotation of a secondary blocker locks the bar in place for added security with visual and tactile confirmation.

The system features variable screws allowing for insertion through a variety of approaches, including into vertebral bodies with pedicle screws already implanted. The 2-screw lateral plate offers screws in diverging coronal as well as cephalad/caudal trajectories. Threaded screws allow for additional security with the screwdrivers and reduce the possibility of stripping.





Multiple instrumentation options allow for a variety of insertion techniques and preferences.

The lateral plates are made of Ti6Al4V. The 2-Screw Lateral Plates are 4.5mm thick and 17mm wide. The 4-Screw Lateral Plates are 4.5mm thick and 21mm wide. Both plates feature a uniquely roughened undersurface for added stability during screw insertion through increased friction with the vertebral surface.

Implant Overview

Plates

The LITe Plate System includes a 2-screw and 4-screw lateral plate option for lateral fixation.

2-Screw Lateral

4-Screw Lateral

LITe Plate System			
Plate	Length	Width	Thickness
2-Screw Lateral	16mm-28mm	17mm	4.5mm
4-Screw Lateral	18mm-28mm	21mm	4.5mm

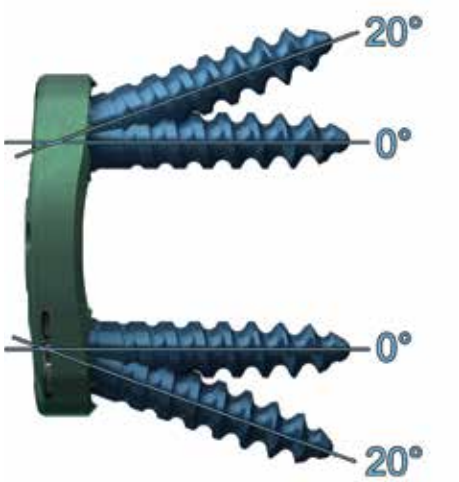
Screws

The LITe Plate System offers variable screws. Differing coronal and cephalad/caudal trajectories allow for a multitude of insertion options. The variable screws also allow the surgeon to lag the plates to the bone if desired. Screws are self-tapping with three cutting flutes and a blunt tip to avoid injury to soft tissue.

The screws are available in 5.0mm standard diameter and 5.5mm rescue diameter and lengths of 40mm-60mm. They are color-coded for easy identification.

Lateral plates are designed to allow for 20° cephalad angulation on the superior screw and 20° caudal angulation on the inferior screw.

The screws of the 2-Screw Lateral Plates diverge coronally at 3°. The screws of the 4-Screw Lateral Plates are straight-on to allow for a narrower width of the plate that accommodates insertion through a lateral retractor.



Surgical Technique

Step 1. Positioning and Establishing Access

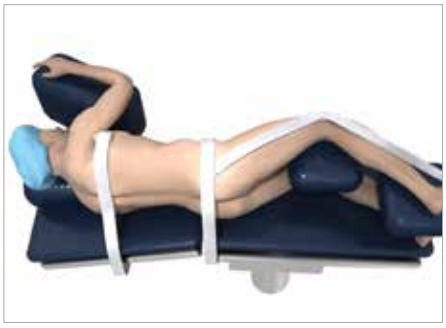


Figure 1. Patient Positioning

Place patient in a right or left lateral decubitus position. Positioning is dependent upon preoperative planning and image review (Fig. 1).

Localize the disc space of surgical interest by using AP and lateral fluoroscopy.

Insert the **Landmark Identifier Crosshair** into the **Quick Release Handle** by aligning the arrow on the tip of the Quick Release Handle to the flat end of the Landmark Identifier Crosshair.

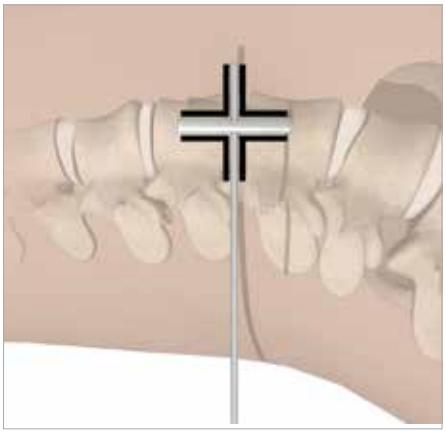
Place the Landmark Identifier Crosshair over the surgical level, centered over the indicated disc space under fluoroscopy (Fig. 2).

Mark the skin to serve as the location of the skin incision for the operative corridor.

Note: The Landmark Identifier Crosshair crossbar is approximately 27.5mm in length, approximating a 1 inch skin incision.

Landmark Identifier Crosshair
48755720

Quick Release Handle
48755702



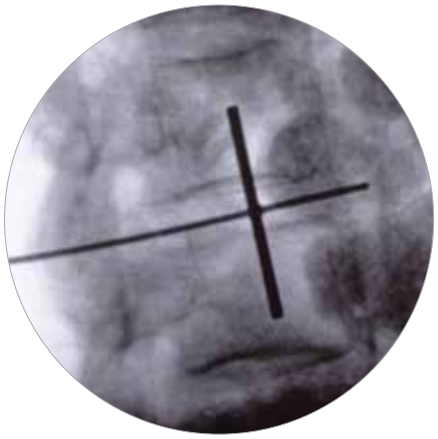


Figure 2. Surgical Level Identification

Use a retroperitoneal and transpsoas approach to access the desired level. Position the retractor (Fig. 3).

Figure 3. Retractor Placement

Step 2. Endplate Preparation and Interbody Placement

Figure 4. Interbody Placement

Once the correct level is identified, preparation of the disc space and placement of an interbody fusion device follows. Using the **ARIA** instruments, remove the disc and thoroughly prepare the endplates. Following the preparation, carefully place the interbody spacer (Fig. 4). Interbody preparation and placement should follow the surgeon's preferred technique. Please reference the **AVS ARIA Surgical Technique** for Stryker's lateral approach offerings and full detail of the positioning and exposure.

Step 3. Implant Selection and Preparation

Caliper
49177100

Use the **Caliper** to measure the distance between the desired screw locations for the appropriate size plate (Fig. 5).

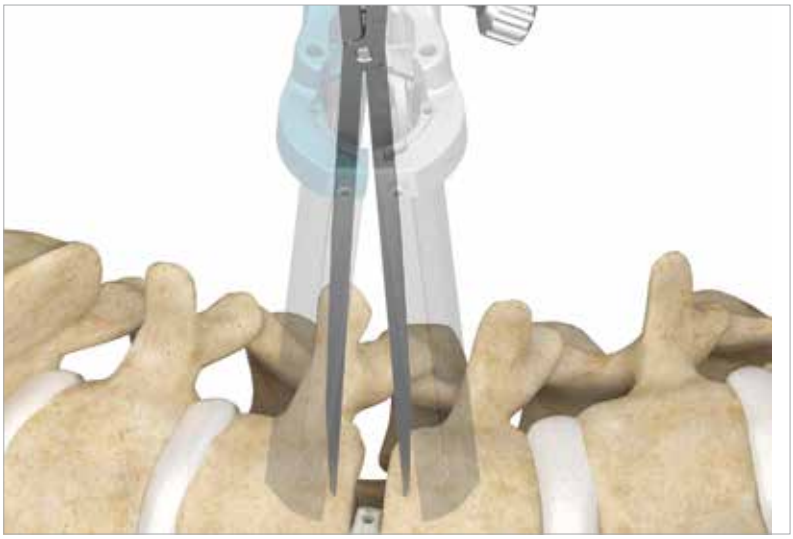


Figure 5. Plate Sizing

Note: The plate measurements correspond to the distance between the screw holes.

Osteophyte Remover
49177320

Osteophyte Removal

If desired, use the **Osteophyte Remover** to take down any osteophytes preventing a plate from sitting flush on the vertebral bodies (Fig. 6).

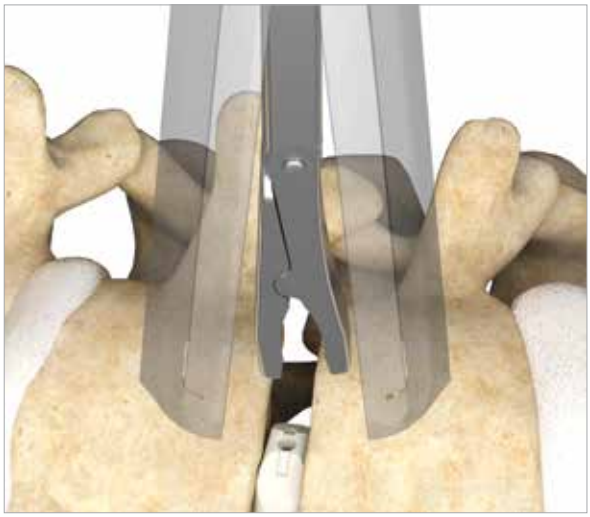


Figure 6. Osteophyte Removal

After determining the proper length of the plate, attach the plate to the **Plate Inserter** by pressing the tip of the Inserter into the corresponding hole on the plate (Fig. 7).

Plate Inserter
49177130

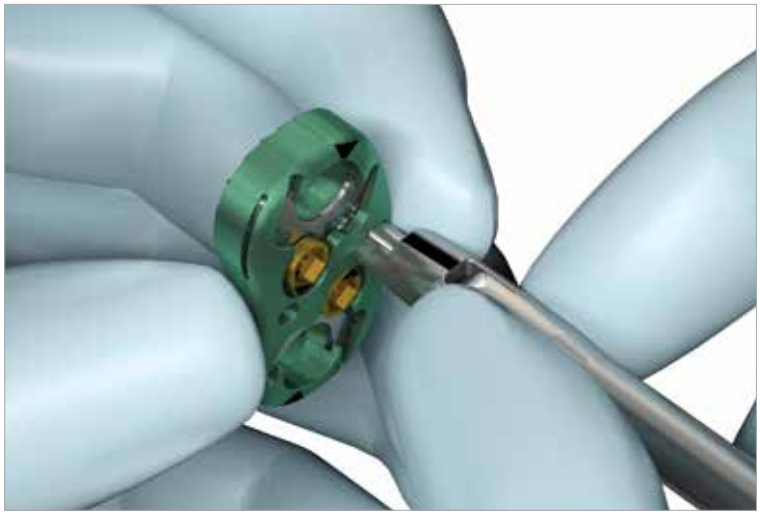


Figure 7. Attaching the Plate Inserter

Note: There are 2-screw and 4-screw lateral plates available for use.

Note: DO NOT ATTEMPT TO BEND THE PLATES.

Lower the plate to the surgical site.

Note: Fixation Pins or the Fixed Awl should not be used with the plate inserter technique.

Step 4. Screw Hole Preparation

Punch Awl
49177170

Use the **Punch Awl** to create a pilot hole for the screw (Fig. 8). Engage the distal tip of the Punch Awl with the plate using downward force until the tip seats fully into screw hole, depress the button on the side of the handle, and press or impact the Awl into the bone.

Figure 8. Screw Hole Preparation Using the Punch Awl

Note: **Do not try to redirect awls or screws while engaged with the bone. If a different trajectory is desired, remove the instrument completely and start a new hole.**

Note: **Use of the Punch Awl is mandatory if the Plate Guide is not used.**

Note: **An assistant may be used to stabilize the plate during impaction.**

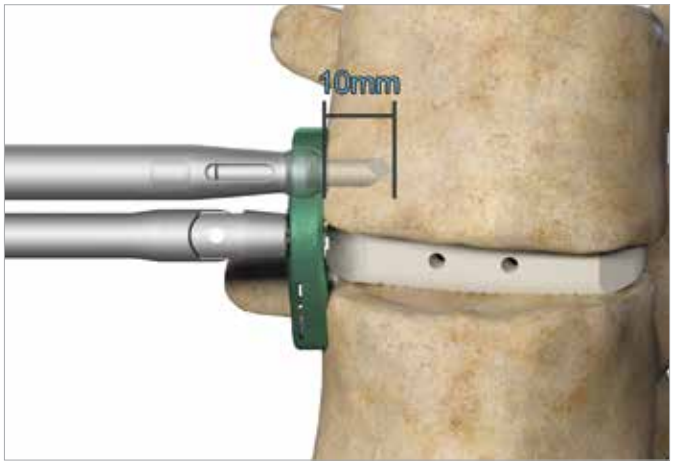


Figure 9

Note: **When fully deployed, the Punch Awl will penetrate 10mm into the bone.**

Figure 10

Note: **When the sleeve on the Punch Awl is fully retracted, the Awl will be fully deployed (Fig. 10).**

Step 5. Screw Insertion

Insertion Screwdriver
49177190

Round Handle, Ratchet
48231302

Use fluoroscopic guidance or the length of the interbody device as a reference to determine the proper screw length. Attach an appropriately sized 5.0mm screw to the **Insertion Screwdriver** shaft that is connected to the **Round Ratchet Handle** (Fig. 11).

Figure 11. Screwdriver Assembly

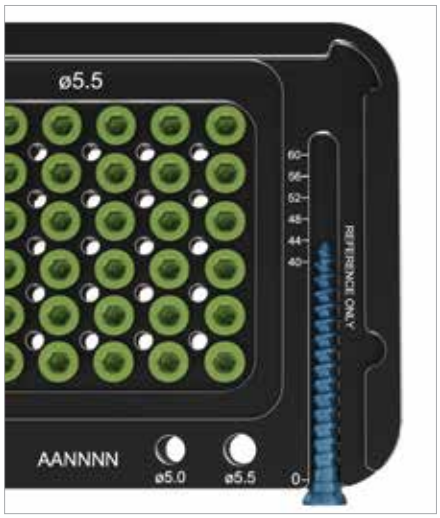


Figure 12. Screw Length Reference

Note: For reference only, screw length and diameter can be reviewed on the screw caddy (Fig. 12).

Alternatively, the **Quick Turn Screwdriver** can be used. Assemble the **Draw Rod** and Quick Turn Screwdriver. Seat the screw into the tip of the driver. The Draw Rod of the Screwdriver should protrude slightly from the handle. Thread the Draw Rod clockwise into the screw until finger tight (Fig. 13).

Note: The Draw Rods can be used with both the Quick Turn and Rescue Screwdrivers.

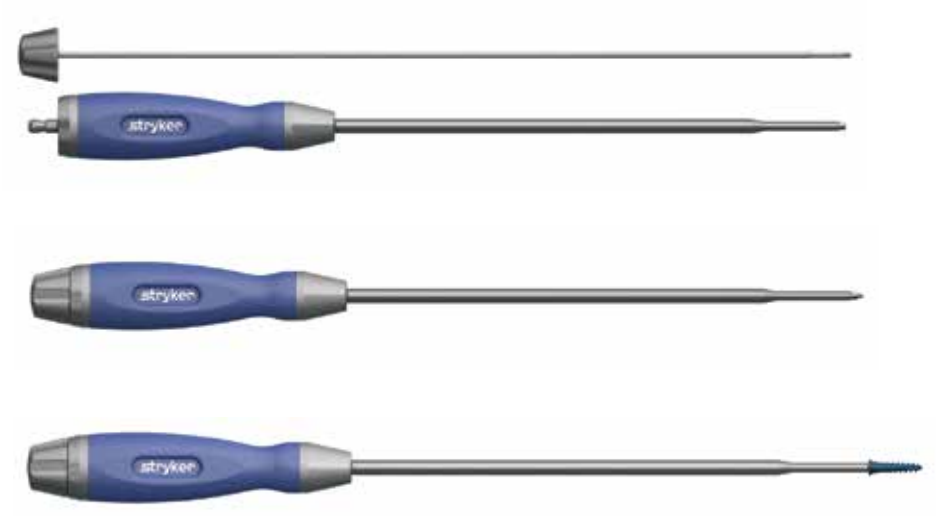


Figure 13. Quick Turn Screwdriver Assembly

Note: 5.5mm screws are intended to be used as rescue screws.

Quick Turn Screwdriver
49177200

Draw Rod
49177201

Insert the screw into the vertebral body until the locking bar of the plate covers the screw head (Fig. 14).

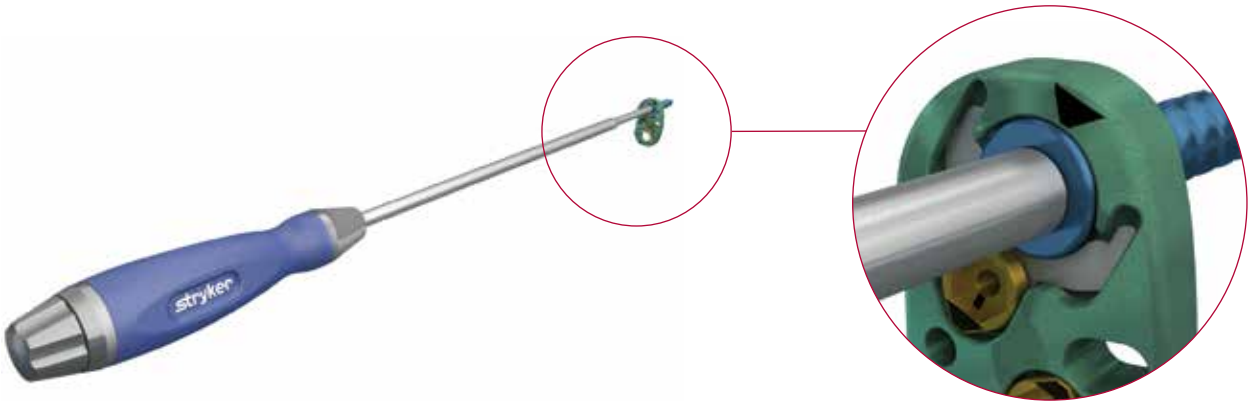


Figure 14. Screw Insertion

Note: When using the 4-screw plate, inserting the screws sequentially at opposite corners of the plate helps keep the plate flat against the bone.

Step 6. Locking the Plate

Solid Screwdriver
49177220

Once all screws are inserted, remove all inserters and/or guides from the plates. At this point, the **Solid Screwdriver** may be used to lag the bone to the plate for a secure fit. Visually confirm that each of the screw heads is fully seated below the spring bar (Fig. 15).

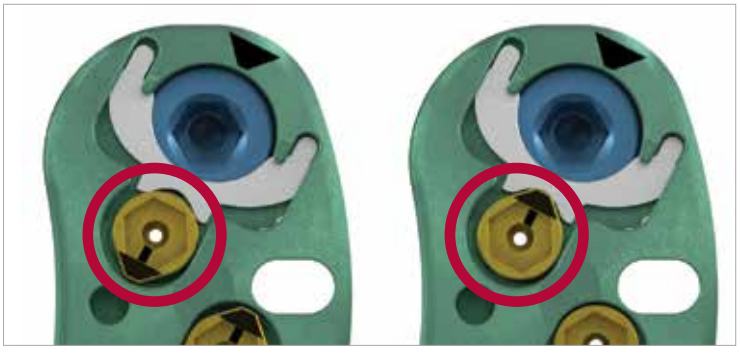
Figure 15. Screw Head Seating Comparison

Note: **Screws must be fully seated below the spring bar for the plate to lock.**

Note: **If the lagging technique is desired, use the Solid Screwdriver and take care not to over tighten the screws.**

Blocker Driver
49177225

Use the **Blocker Driver** to lock the plate. Insert the tip of the Blocker Driver into the gold plate blocker and rotate the blocker 180° until the arrows on the blocker and the plate align.



Note: **There is an arrow on the handle of the Blocker Driver to assist with visualization of the fully locked plate.**

Note: **The Blocker Driver is recommended for locking the plate, however all screwdrivers will fit into the blocker interface.**

Note: **Do not tighten the blocker past 180°.**

Figure 16. Locking the Plate

Alternate Method of Plate Insertion

Clip the chosen plate onto the corresponding size Plate Guide (Fig. 17).

	2 - Screw Plate Guides	4 - Screw Plate Guides
Description	Reference #	Reference #
16mm	49178516	––
18mm	49178518	49174118
20mm	49178520	49174120
22mm	49178522	49174122
24mm	49178524	49174124
26mm	49178526	49174126
28mm	49178528	49174128

Figure 17. Assembled Plate and Guide

Guide Inserter
49177120

Attach the plate and Plate Guide to the **Guide Inserter** by pulling up on the knob of the Guide Inserter handle, aligning the Guide and Inserter, and pushing the Inserter knob back down (Fig. 18).

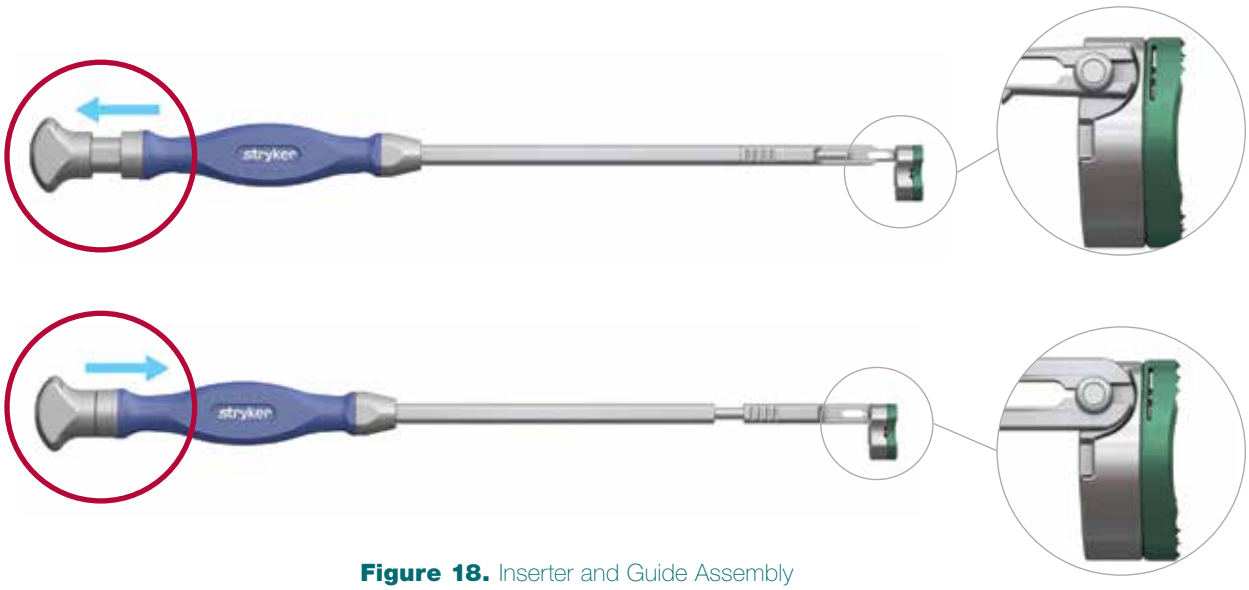


Figure 18. Inserter and Guide Assembly

Lower the plate and guide onto the surgical site.

Fixation Pin
49177161

Fixation Pin Inserter
49177160

Fixation Pins may be used to secure the plate temporarily. Attach the Fixation Pin to the **Fixation Pin Inserter** by pulling up on the quick release. Place the Pin inside the Inserter and let go of the quick release handle to securely attach the pin. Once the Pin is attached, place the Fixation Pin into the bone at the desired screw trajectory from the chosen screw hole of the plate for temporary stability. After the Pin has been placed in the bone, remove the Fixation Pin Inserter by pulling up on the quick release and removing the instrument (Fig. 19).

Note: Fixation Pins are 15mm in length.

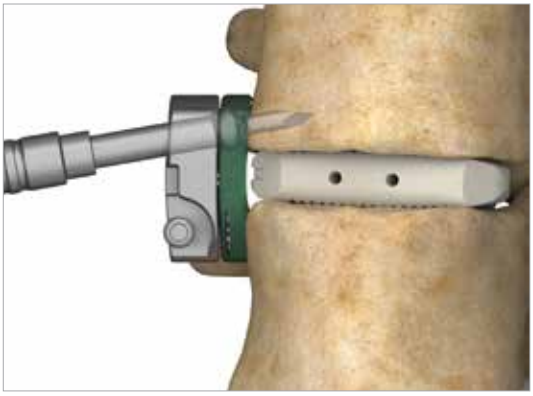


Figure 19. Fixation Pin Assembly and Insertion

Fixed Awl
49177180

T-Handle, Quick Connect
48061000

Using the **Fixed Awl** attached to the **T-Handle**, make a pilot hole for the screw (Fig. 20).

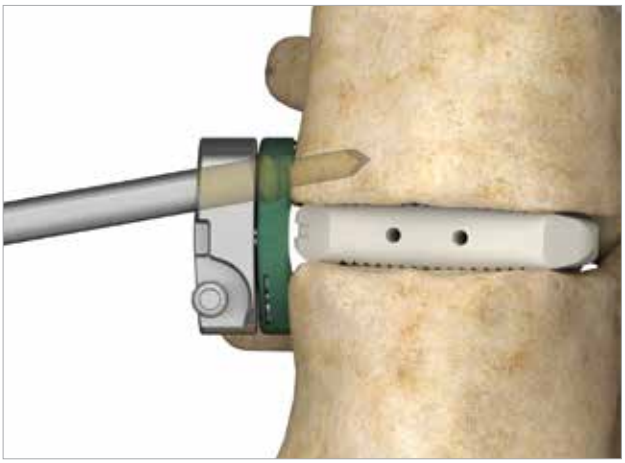


Figure 20. Screw Hole Preparation

Note: The Punch Awl is also compatible with the guide.

Note: The Plate Guide will restrict the angulation of the screw to what is acceptable for the plate.

Note: Use of Fixation Pins will adequately prepare screw pathway. Awling is unnecessary if Fixation Pins are used.

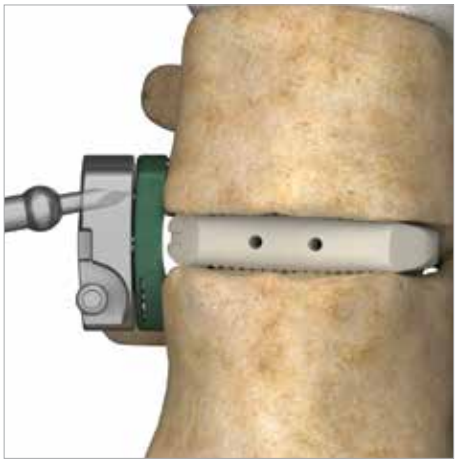


Figure 21. Fixation Pin Removal

Remove the Fixation Pin with the Fixation Pin Inserter, then repeat screw hole preparation and insertion with remaining screws (Fig. 21).

Note: The Pins and/or Guide Inserter can be removed at any time if they are encumbering screw insertion.

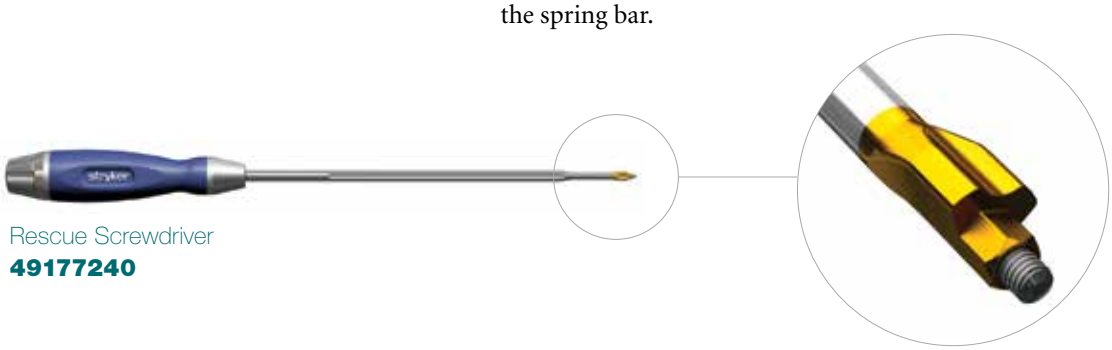
Insert the screw with the same technique as is used with the Plate Inserter.

Implant Removal

Use the Blocker Driver to disengage the plate blocker. Rotate the blocker 180° counterclockwise (Fig. 22). This will allow the spring bar to retract.

Figure 22. Unlocking the Plate

Use the **Rescue Screwdriver** to remove the bone screw. Seat the Rescue Screwdriver into the bone screw with the foot of the Rescue Screwdriver positioned 180° opposite the spring bar.



Rescue Screwdriver
49177240

Once the Rescue Screwdriver is fully seated, the Draw Rod will protrude slightly from the handle of the driver. Engage the Draw Rod by threading it into the bone screw until finger tight. Visually confirm that the blocker is in the unlocked position before attempting to remove the screw. Rotate the Rescue Driver counterclockwise so the spring bar is deflected as the screw backs out of the bone (Fig. 23). Continue turning until the screw is fully removed.

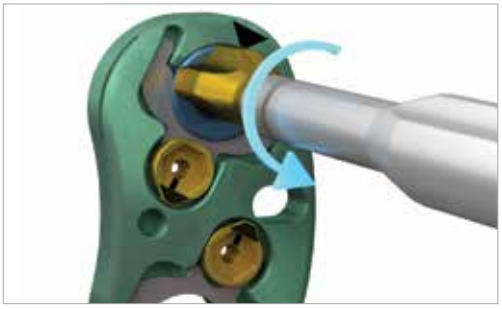


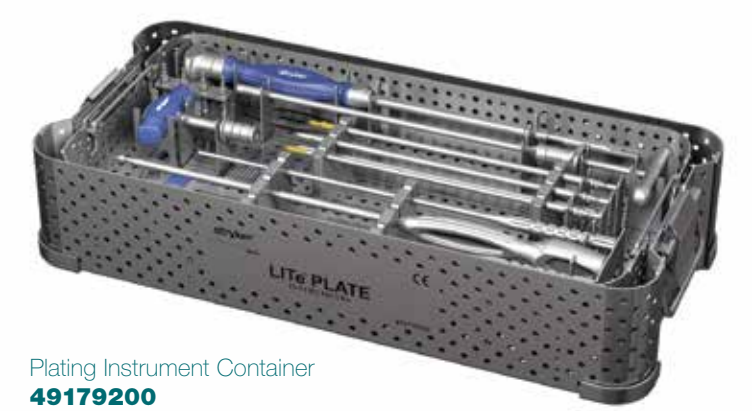
Figure 23. Screw Removal

Note: Do not attempt to pull the screw out prematurely.

CAUTION: Do not over-tighten the Draw Rod.

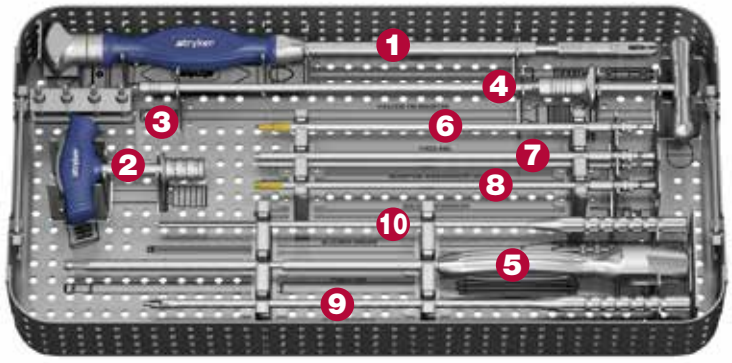
If necessary, 5.5mm rescue screws can be inserted at this point using the outlined screw insertion technique.

Tray Overview

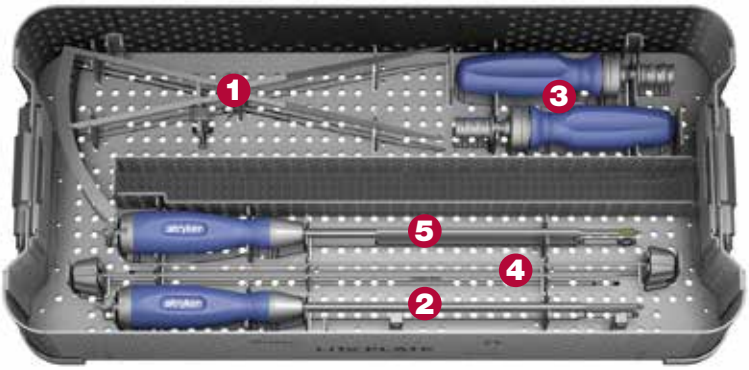


Plating Instrument Container
49179200

Top Tray		
	Description	Reference
1	Guide Inserter	49177120
2	T-Handle, Quick Connect	48061000
3	Fixation Pin	49177161
4	Fixation Pin Inserter	49177160
5	Punch Awl	49177170
6	Fixed Awl	49177180
7	Insertion Screwdriver	49177190
8	Solid Screwdriver	49177220
9	Plate Inserter	49177130
10	Blocker Driver	49177225



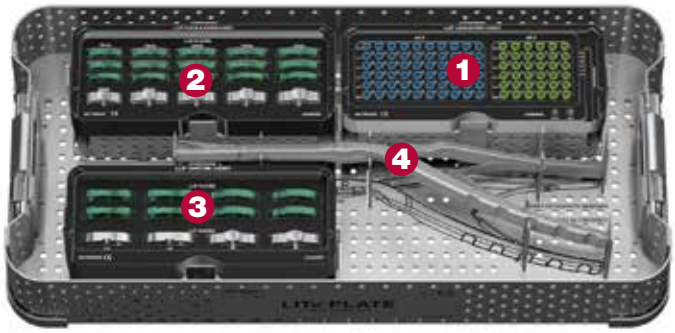
Bottom Tray		
	Description	Reference
1	Caliper	49177100
2	Quick Turn Screwdriver	49177200
3	Round Handle, Ratchet	48231302
4	Draw Rod	49177201
5	Rescue Screwdriver	49177240



Plating Instrument Container	49179200	
	Description	Reference
1	Plating Instruments Tray	49179200A
2	Plating Instrument Container Lid	49179200B
3	Plating Instrument Upper Insert	49179200C

LLIF Implant Container
49179000

LLIF Implant Container	49179000
Description	Reference
LLIF Implant Container Tray	49179000A
LLIF Container Lid	49179000B
LLIF Caddy Lid	49179000C
1 LLIF Long Screw Caddy	49179000D
2 LLIF Plate & Guide Caddy	49179000F
3 LLIF Custom Caddy	49179000G
4 Osteophyte Remover	49177320



Implants

	Reference	Description
	49173116	16mm 2-screw Plate
	49173118	18mm 2-screw Plate
	49173120	20mm 2-screw Plate
	49173122	22mm 2-screw Plate
	49173124	24mm 2-screw Plate
	49173126	26mm 2-screw Plate
	49173128	28mm 2-screw Plate
	49174118	18mm 4-screw Plate
	49174120	20mm 4-screw Plate
	49174122	22mm 4-screw Plate
	49174124	24mm 4-screw Plate
	49174126	26mm 4-screw Plate
	49174128	28mm 4-screw Plate
	49175040	Ø5.0 x 40mm Standard Screw
	49175044	Ø5.0 x 44mm Standard Screw
	49175048	Ø5.0 x 48mm Standard Screw
	49175052	Ø5.0 x 52mm Standard Screw
	49175056	Ø5.0 x 56mm Standard Screw
	49175060	Ø5.0 x 60mm Standard Screw
	49175540	Ø5.5 x 40mm Revision Screw
	49175544	Ø5.5 x 44mm Revision Screw
	49175548	Ø5.5 x 48mm Revision Screw
	49175552	Ø5.5 x 52mm Revision Screw
	49175556	Ø5.5 x 56mm Revision Screw
	49175560	Ø5.5 x 60mm Revision Screw

Instruments

	Reference	Description
	49178516	16mm 2-screw Plate Guide
	49178518	18mm 2-screw Plate Guide
	49178520	20mm 2-screw Plate Guide
	49178522	22mm 2-screw Plate Guide
	49178524	24mm 2-screw Plate Guide
	49178526	26mm 2-screw Plate Guide
	49178528	28mm 2-screw Plate Guide
	49178718	18mm 4-screw Plate Guide
	49178720	20mm 4-screw Plate Guide
	49178722	22mm 4-screw Plate Guide
	49178724	24mm 4-screw Plate Guide
	49178726	26mm 4-screw Plate Guide
	49178728	28mm 4-screw Plate Guide
	49177320	Osteophyte Remover
	49177100	Caliper
	49177120	Guide Inserter
	48061000	T-Handle, Quick Connect (RELIANCE LITe)
	49177161	Fixation Pin
	49177160	Fixation Pin Inserter
	49177170	Punch Awl
	49177180	Fixed Awl
	49177190	Insertion Screwdriver

Instruments

	Reference	Description
	49177200	Quick Turn Screwdriver
	48231302	Round Handle, Ratchet (Xia 3)
	49177201	Draw Rod
	49177220	Solid Screwdriver
	49177240	Rescue Screwdriver
	49177130	Plate Inserter
	49177225	Blocker Driver

IMPORTANT PRODUCT INFORMATION

DESCRIPTION
The Stryker Spine LITe Plate System is comprised of devices intended for the fixation of the non-cervical spine. It includes a variety of non-sterile plates and bone screws manufactured from Titanium Alloy.

MATERIALS
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: screws and plates.

INDICATIONS FOR LITE PLATE SYSTEM UNIVERSAL, SACRAL, 2 SCREW AND 4 SCREW PLATES
The LITe Plate System Universal, Sacral, 2 Screw and 4 Screw Plates are indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of the thoracic and thoracolumbar (T1-L5) spine or via an anterior approach below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine. The system is intended to provide additional support during fusion in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:
- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies);
- Pseudoarthrosis;
- Spondylolysis;
- Spondylolisthesis;
- Spinal stenosis;
- Tumors;
- Trauma (i.e. Fractures or Dislocation)
- Deformities (i.e. Scoliosis, Kyphosis or Lordosis)
- Failed Previous Fusion

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:
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection
- Excessive local inflammation
- Open wounds
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- 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 tumors, 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.

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. Surgeons must discuss the relative contraindications with the patients.

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

WARNINGS (U.S.A.)
These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

The safety and effectiveness of anterior or lateral plating spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

The LITe Plate System has not been tested for heating or migration in the MR environment.

PRECAUTIONS (U.S.A.)
The implanation of anterior or lateral plate spinal systems must be performed only by experienced spinal surgeons with specific training in the use of this spinal plate system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

GENERAL CONDITIONS OF USE
The implantation of spinal systems must be performed only 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 the 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.

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 should be directed to the issues of premature weightbearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn patients of the surgical risks and make them aware of possible adverse effects. The patient must be warned 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 warn 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. Such patients must be advised of this fact and warned of the potential consequences. For diseased 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.

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.

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 and after sterilization.

REUSE

Never reuse or re-implant spinal surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.

HANDLING

Correct handling of the implant is extremely important. The operating surgeon should 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.

PRE-OPERATIVE PRECAUTIONS

Anyone using Stryker Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from Stryker Spine directly. Those using brochures published more than two years before the surgical intervention are advised to get 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 can be reused after decontamination, cleaning and sterilization.

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 be responsible for additional stresses and strains on the device which can speed up 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 should 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 is recommended only if necessary according to the surgical technique of each system. Rods or plates should 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 utilized 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 plates, screws, 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.

INTRA-OPERATIVE PRECAUTIONS

- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by Stryker Spine.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.

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 may 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. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

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 designed 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.

Adverse effects include but are not limited to:

- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, 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.
- 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 designed 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.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal 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 graft or 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 bone graft, pedicle, and/or sacrum 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.

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
- Failure or mobilization of the implant

Standard ancillaries provided by Stryker Spine can 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 should 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.

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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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