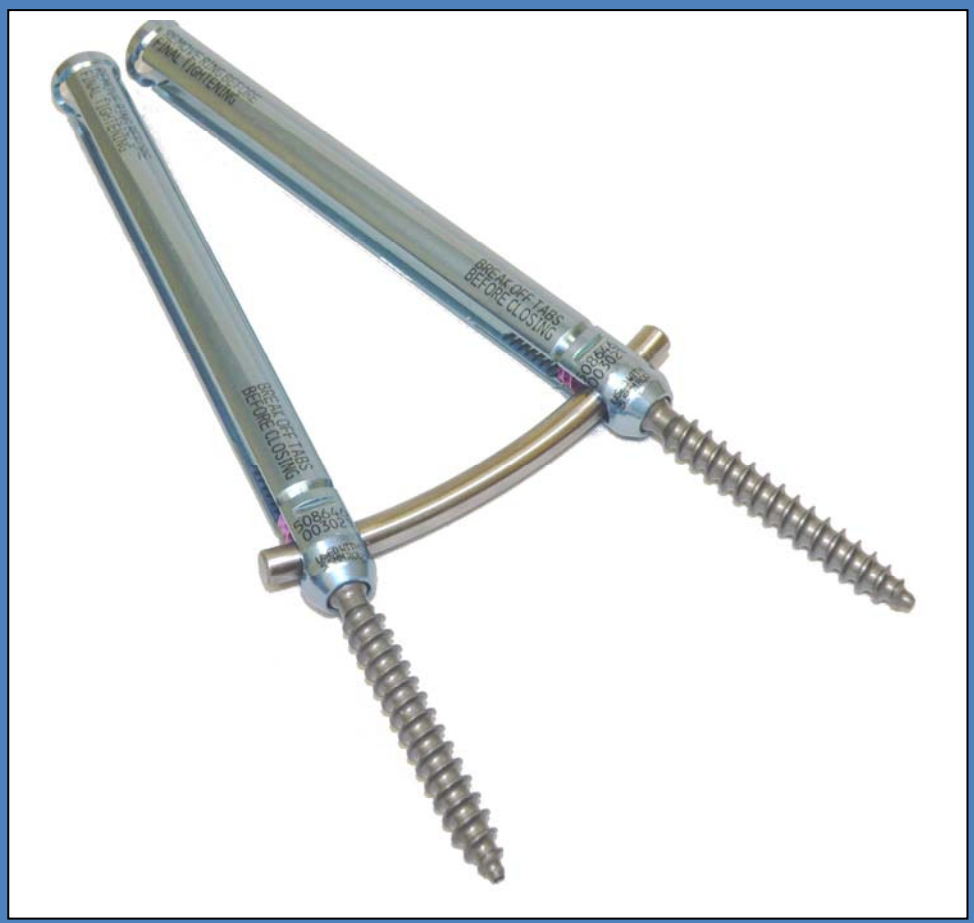
Unified Spine

GS1 SPINAL SYSTEM CANNULATED SCREW

SURGICAL TECHNIQUE GUIDE



Introduction

The Unified Spine, LLC GS1 Cannulated Screw Spinal System was designed in conjunction with practicing spine surgeons to incorporate function into a competitively priced Spinal Fixation System. The multi-axial head design has a full 28º of angulation in any direction (56º total).

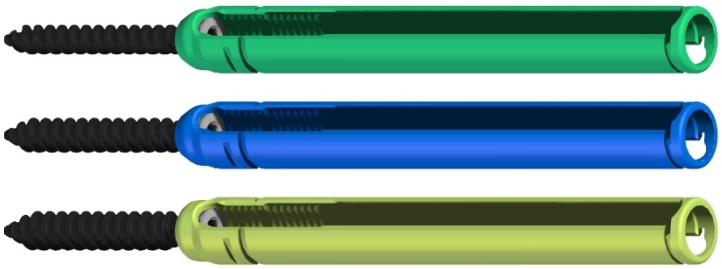
The GS1 Spinal system is designed for the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine. This is achieved using the multiple available sizes of multi-axial screws, rods, hooks, and cross connectors.

The following Unified Spine Surgical Technique Guide outlines proper installation of the GS1 Cannulated Screw System. Unified Spine, LLC as a manufacture, does not practice medicine and does not recommend specific surgical procedures for use on any individual patient.

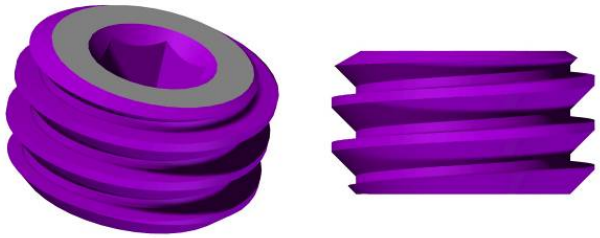
I. Implant Description

Multi-axial Cannulated Screw:

- 3 Piece Design
- Material: CP Titanium and Titanium Alloy
- 28º of Angulation (56º Total) in Any Direction
- Floating Cap Locks Position When Set Screw is Tightened
- Self-tapping Bone Screw
- Uses a 3.5mm Hex Drive
- Screw Heads are Clearly Marked for corresponding rod size use
- Cannulated Screws for use with a Guide Wire

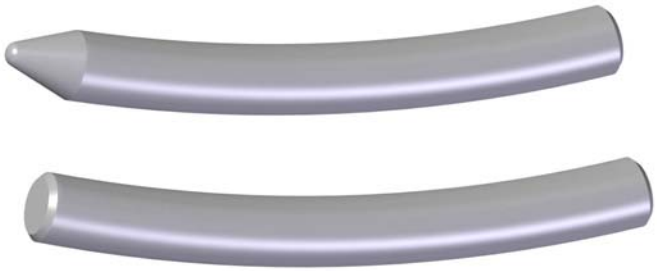


COLOR CODED HEADS allow easy visual distinctions for the 5.5mm, 6.5mm, and 7.5mm diameter Multi-Axial Screws.



Set Screw:

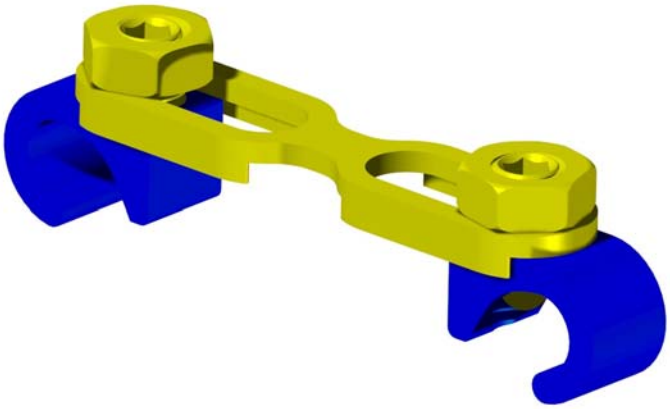
- Material: Titanium Alloy
- Buttress Thread for Secure Locking
- Standard 3.5mm Hex Driver
- Torque Limiting Driver Assures Proper Tightening



Rods:

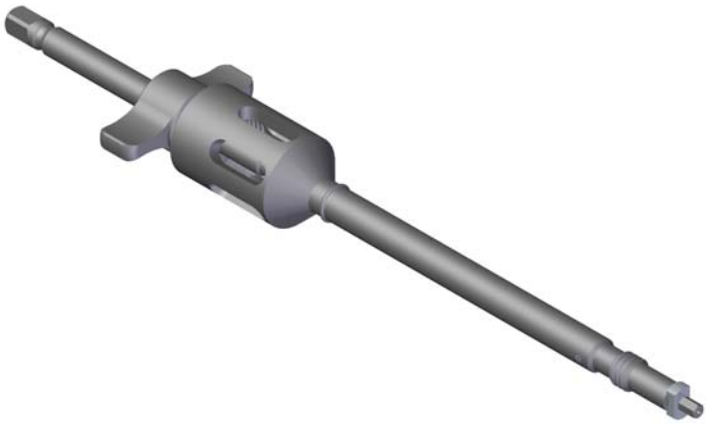
- Material: Titanium Alloy
- Available in 5.5mm diameters
- Available in lengths of:

30mm	70mm
35mm	75mm
40mm	80mm
45mm	90mm
50mm	100mm
55mm	110mm
60mm	120mm
65mm	480mm



Cross Connectors:

- Material: Titanium Alloy
- Available in 4 Range Sizes:
  - 30 to 40mm
  - 40 to 50mm
  - 50 to 60mm
  - 60 to 70mm



Implant Specific Instrumentation:

- This System is designed to use a minimal amount of implant specific instrumentation. This instrumentation includes:

Multi-Axial Screw Inserter – Designed to grasp the Multi-Axial screw head and engage the bone screw for implant insertion. The Wing Nut is tightened after the Outer Handle is tightened to ensure a rigid assembly and prevent unintentional loosening of the Inserter during use.

Anti-Torque Instrument – Designed to shield the torsional force applied from tightening the set screw from undesired forces on the head and screw that may transfer to patient anatomy.

Set Screw Starter – Used to start and preliminarily tighten the set screw into the Multi-Axial Screw Heads. The driver tip is designed to retain the set screw. The larger handle is used in conjunction with the extended tab reduction heads to provide rod reduction at each level. The set screws should only be provisionally tightened with the final tightening only being performed with the anti-torque device in place.

Rod Bender
Rod Holder
Cannula/Dilator
Cannulated Probe
Guide Wire
Ring Breaker
Quick Connect Handles
Hex Driver
Compressor
Distractor
Cannulated Taps

Common Instrumentation:

- This System is designed to be compatible with most common instruments currently available in an operation room equipped for Spine Surgery. These Items are listed to the left.

II. Surgical Technique

A. Preoperative Planning and Preparation

Preoperative planning of spinal device system constructs able to withstand trauma or deformity induced body load concentrations is an important consideration for achieving bony fusion and successful surgical outcomes. The surgeon is responsible for preoperative planning, familiarity with operative techniques and ancillary instrumentation, and preoperative consultation with experienced associates as required to achieve successful post surgical results.

Even though the GS1 Cannulated Screw System is adaptable to many specific surgeon techniques, the instructions for use remain the same. GS1 Cannulated Screws can be placed through an incision or percutaneously. The site preparation for the fusion can be performed via an open, mini-open, or portal type approach.

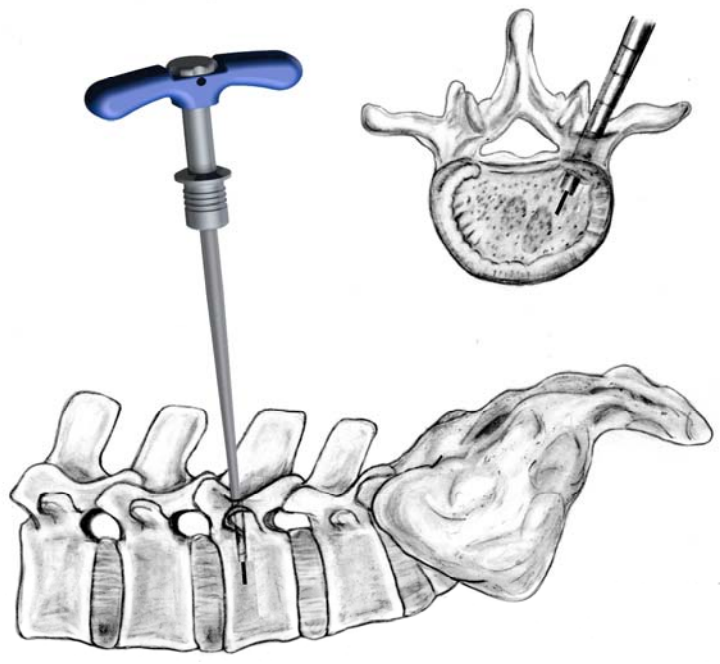
B. Patient Positioning and Preparation

Patients may be positioned prone or laterally for a posterior approach. Prone is typically the most common choice. The disc space is accessed with a midline incision, a paramedial incision, or a portal. This is followed with a decompression if indicated. Decortication must be performed and bone graft must be placed into the posterolateral gutters before or after the implantation of the GS1 Spinal System.

C. Site Preparation

After adequate exposure is achieved, identify the preferred insertion site. This should be the dorsal aspect of the pedicle. Use a screw trajectory that will not endanger neural vascular or visceral structures and still provide adequate spacing between screw heads for the application of Reducers, Compressors, Distractors, and Anti-Torque instrument. Penetrate the cortex of the vertebra using either an awl, burr, or rongeur.

Define the pedicle canal using either a cannulated probe or Jamshidi needle. EMG or radiograph can be used to verify position. Once inserted in the proper position, remove the trocar from the cannulated probe or Jamshidi needle. Insert the guide wire into the cannulation. While holding the guide wire in place, remove the probe or needle leaving the guide wire in place. A tap can be used over the guide wire that is in place. Tapping the screw hole is advised for sclerotic bone and optional for non-sclerotic bone.



D. Loading Inserter

The Inserter consists of three components; the Inner Shaft, Outer Shaft, and Locking Wing Screw. The inserter can be disassembled for cleaning. To assemble, place the Inner Shaft inside the Outer Shaft and secure with the Locking Wing Screw by threading roughly 1 turn.

1)

The driver is easier to load when attached to the quick connect handle. Make sure the Locking Wing Screw is only threaded in by roughly 1 turn.

2)

To load the screw, insert the hex portion of the inserter into the hex of the bone screw by holding the screw by the threads.

3)

Turn the Outer Handle to advance the threads into the head of the screw. With attached ratchet handle in the locked or reverse position, tighten the Outer Handle securely. Make certain the screw is rigid on the driver.

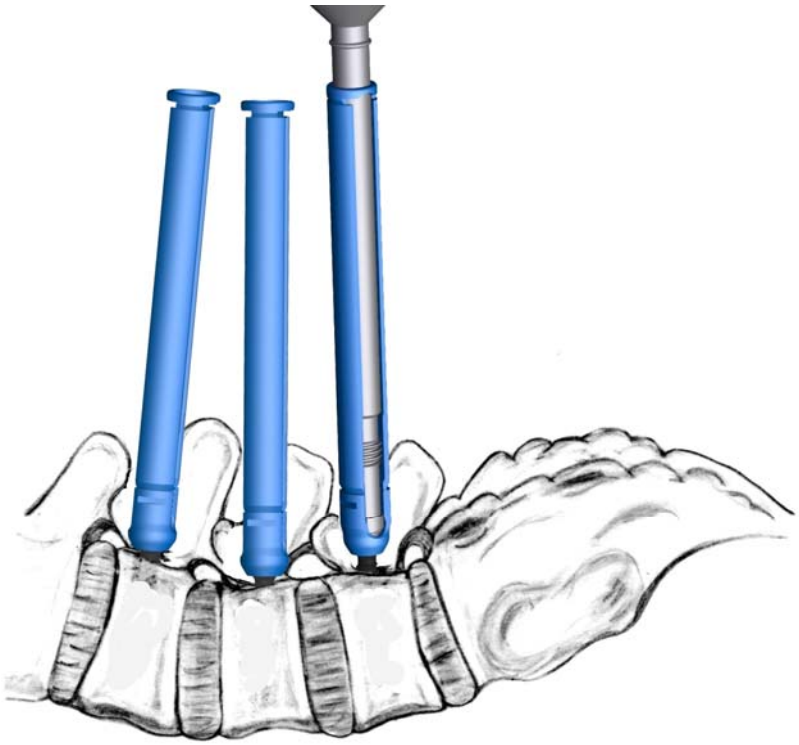
4)

With the ratchet handle in the same position, tighten the Locking Wing Nut as the final step. Return the ratchet handle to the forward position to be ready for use.

E. Screw Insertion

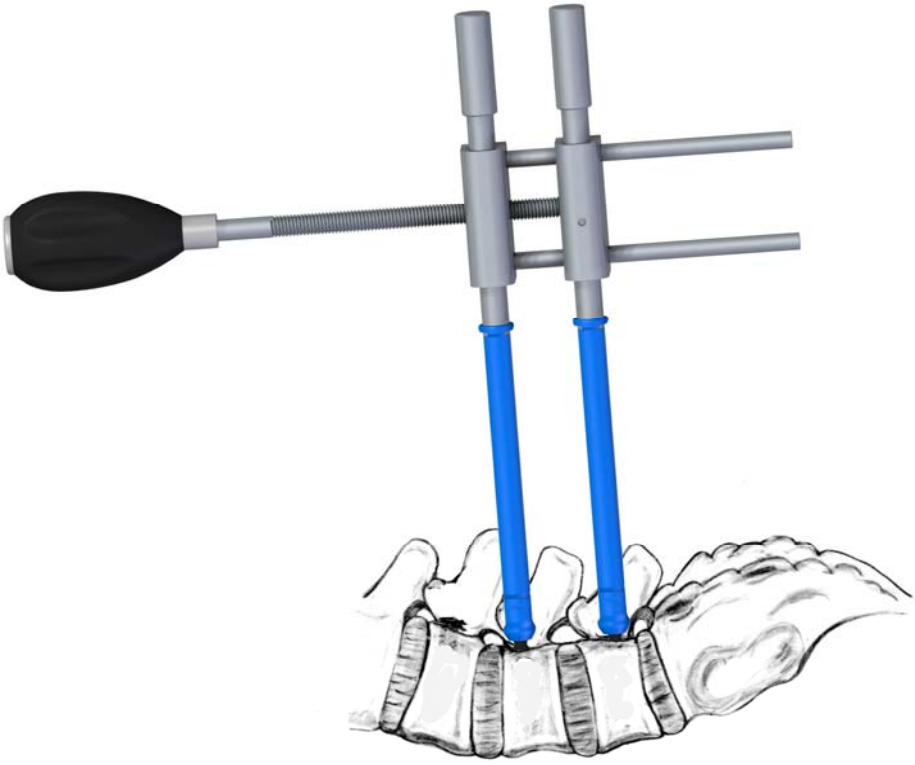
Load the selected Multi-Axial Screw on the inserter by engaging the hex drive and tightening the threaded sleeve into the threads in the screw head. Insert the screw into the prepared site following the previously placed guide wire. **REMOVE THE GUIDE WIRE WHEN THE SCREW ENGAGEMENT INTO THE BONE IS 20 TO 30MM.** Utilize care and tactile feedback for proper insertion. Multi-Axial Screw heads should not be driven tightly to bone to prevent loss of multi-axial motion. Screws heads should be positioned to form a smooth arc to facilitate rod contouring. Verify screw positioning by radiograph, electro-diagnosis, or palpation of the pedicle wall.

NOTE: USE ONLY SCREWS MARKED FOR 5.5MM RODS WITH 5.5MM RODS.



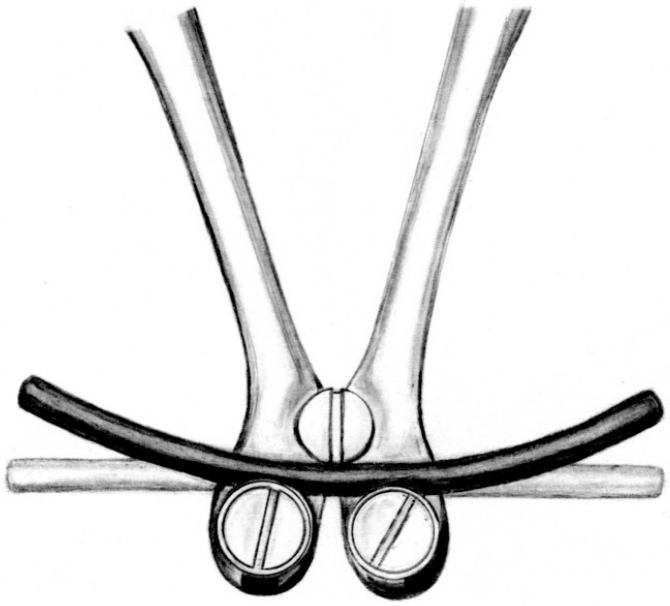
F. Distraction (optional)

Distraction may be desired to open the disc space for preparation of the endplates for fusion. Distraction is commonly done on the contralateral side for better access to the disc space. After the screws to be used for distraction are placed, the distractor is adjusted to parallel and the threaded rods are placed thru the distractor and threaded into the Multi-Axial Screw heads. To distract, turn the handle clockwise. To remove the distractor, turn the handle counterclockwise until the threaded rods turn freely. Remove both rods and the instrument.



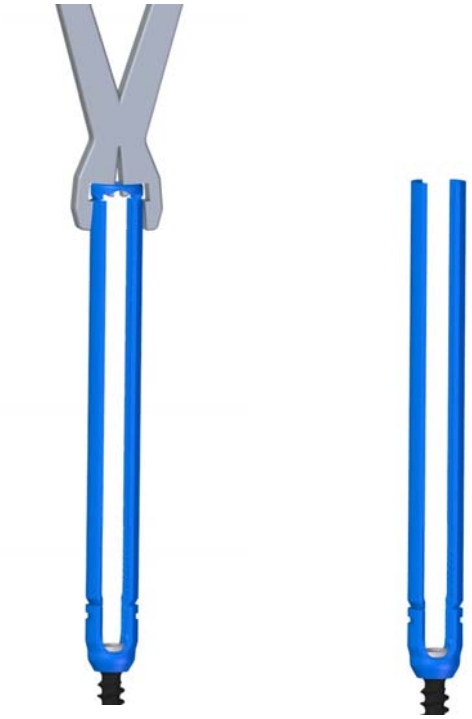
G. Rod Contouring

Contour the rod to fit the screws and stabilize the spine in the desired position. Use the appropriate contour to address any deformity correction. Contour the rods with gentle bends and smooth arcs. Avoid repeated bending and the use of sharp angles.



H. Ring Breaker Use

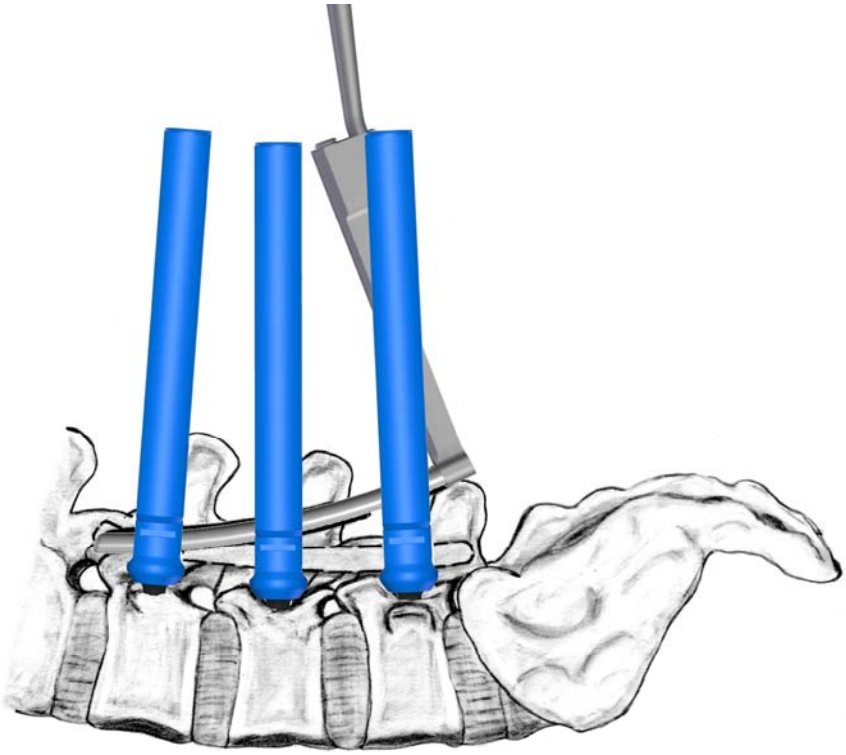
Insert Rod into position using rod holders. Place set screw in the first Screw Head using the Set Screw Starter. The Set Screw Starter is designed to allow the set screw to be easily started and tightened only finger tight. Once the first Set Screw is in place, move to all subsequent Screw Heads placing Set Screw in each.



I. Rod Insertion

Insert Rod into position using rod holders. Place set screw in the first Screw Head using the Set Screw Starter. The Set Screw Starter is designed to allow the set screw to be easily started and tightened only finger tight. Once the first Set Screw is in place, move to all subsequent Screw Heads placing Set Screw in each.

NOTE: SET SCREWS MUST BE INSERTED WITH THE SILVER FACE UPWARDS. THREADS WILL NOT MATE IF SET SCREW IS INSERTED UPSIDE DOWN. FINAL TIGHTENING MUST BE PERFORMED WITH THE ANTI-TORQUE INSTRUMENT IN PLACE AND SET SCREWS SHOULD BE TIGHTENED TO 80 – 100 IN-LBS.

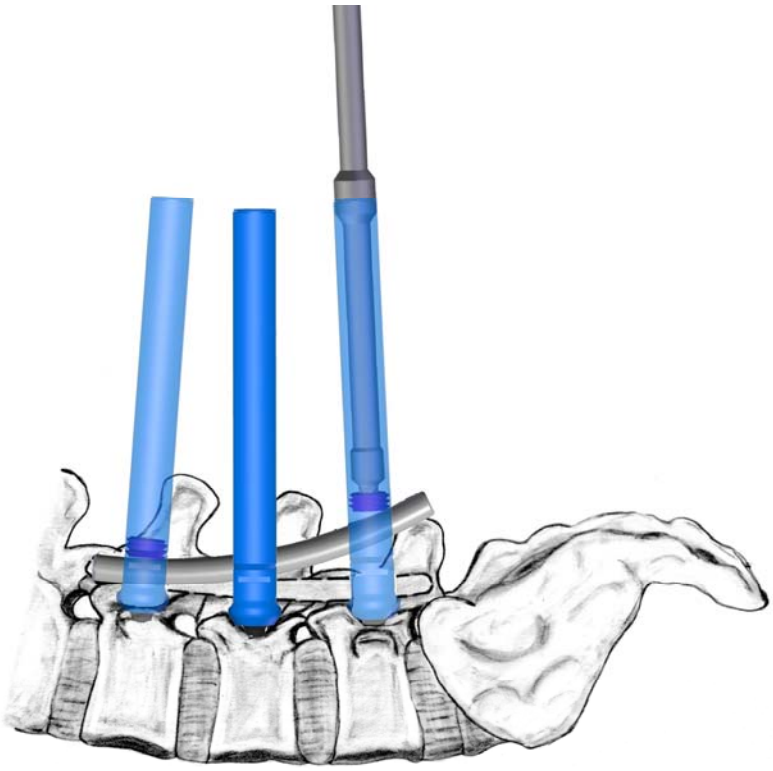


J. Rod Reduction

Reduction Head Screws can be used to allow the rod to be captured in a rough approximation and then be gently reduced into its proper location using the set screw in the head. Once the rod is in place and the set screws are provisionally tightened, the extended tabs are broken off.

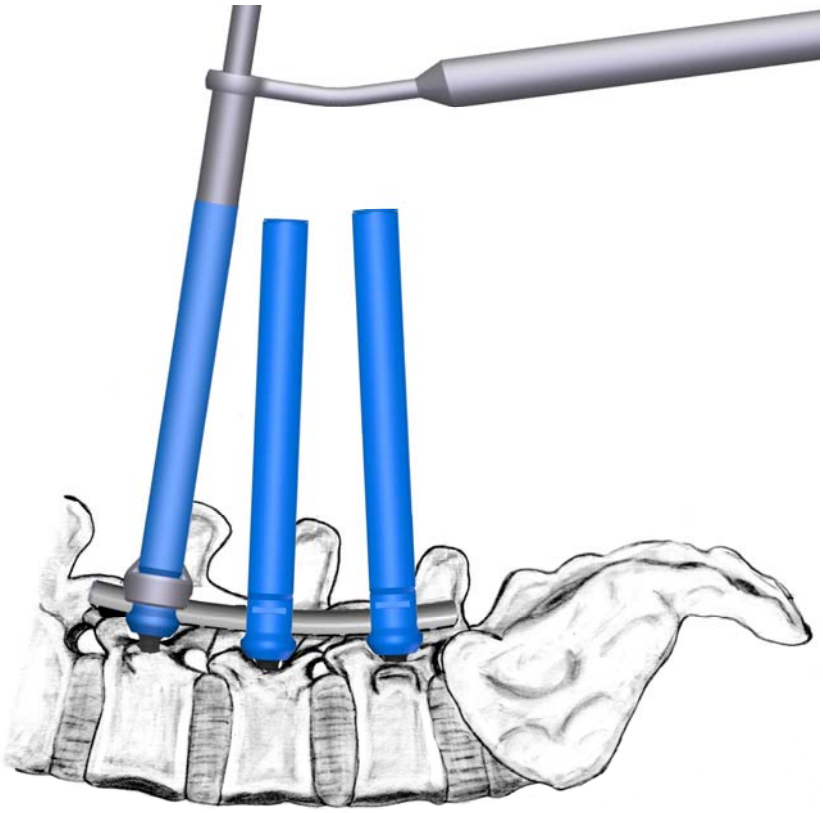
For Segmental Correction:

Firmly seat the contoured rod to one spinal screw using a set screw. Reduce the rod into the next screw head with manipulation via rod holder or rod reducer with tension between the screw head and the rod. Distract or compress between the screws as needed and provisionally tighten set screws to achieve correction. Verify correction and neutral integrity. Then apply final torque to each set screw using the torque limiting driver. All tightening must be performed with the anti-torque device in place.



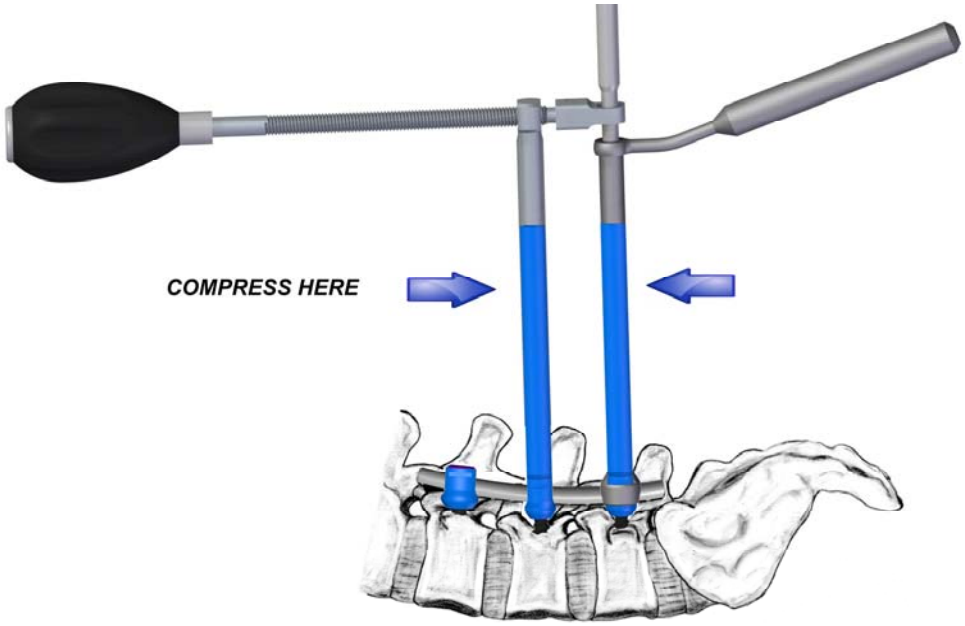
K. Final Tightening

Once the rod is placed in the desired position with the Set Screws finger tight, final tightening can be performed. The anti-torque device must be placed over the head of the Screw. The Set Screw is then tightened to 80-100 in-lbs. using a torque measuring or torque limiting driver to ensure proper tightening. Ensure the driver is fit properly into the Set Screw and that the Set Screw is threaded properly in the Screw Head. Avoid cross threading as this renders the screw head unable to clamp and lock the rod securely. All Set Screws will be tightened with this method taking care not to miss any Set Screws.



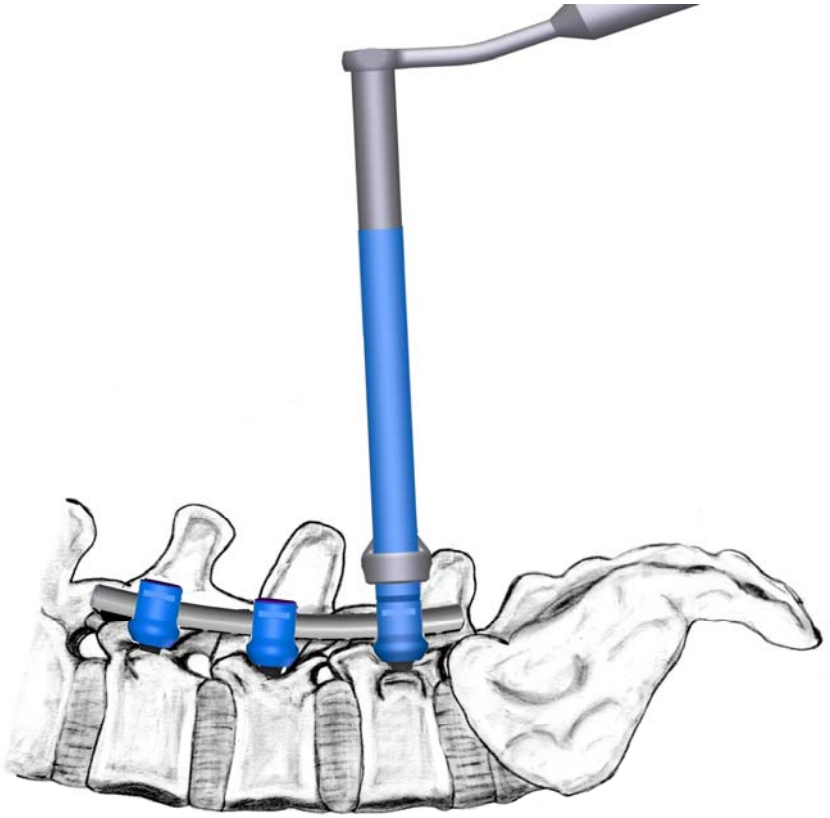
L. Compression (optional)

Tighten the Set Screw of the Multi-Axial Screw to be used as the anchor point using the Anti-Torque Instrument and Torque Limiting Driver. Place the Anti-Torque in the Multi-Axial Screw that will be moved. Then place the leg of the Compression Instrument in the tightened screw and then insert the Torque Limiting Driver in the Anti-Toque Instrument thru the hole at the end of the Compression Instrument. Apply force to the construct in the approximate position shown using a common compression instrument. While holding compression, tighten the set screw with the Torque Limiting Driver to secure.



M. Break Off Tabs

Cross Connectors are used to increase the strength and stability of the construct. Choose the location desired for the cross connector and apply the "J" brackets to the rods and preliminarily tighten the set screw. Choose the shortest cross connector plate to span the distance from one "J" bracket to the next. After placing the cross connector plate, apply and preliminarily tighten the nut to each set screw. Apply final tightening to the set screws followed by final tightening of the nuts.



N. Closure

After implantation is complete, wound closure should be performed according to the surgeon's standard protocol.

III. Indications for Use:

SEE PACKAGE INSERT FOR COMPLETE INFORMATION

Important Information Concerning the Unified Spine GS1 Spinal System

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

PURPOSE: The purpose of the Unified Spine GS1 Spinal System is to assist in providing immobilization and stabilization of spinal segments as an adjunct to the fusion of the thoracic, lumbar and/or sacral spine.

DESCRIPTION: The Unified Spine GS1 Spinal System consists of rods, non-cannulated and cannulated screws, hooks and adjustable crosslink components that can be locked rigidly into various configurations, with each construct being customized for each individual case. The implants are attached to the spine posteriorly by means of screws and/or hooks joined with rods. Crosslink components are used to attach two rods in parallel. Unified Spine implants can be installed with any suitable instrumentation.

The Unified Spine Spinal System Implant components are fabricated from medical grade titanium and/or titanium alloy. No warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for specific purposes or use are explicitly excluded.

Never use titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy components with stainless steel components in the same construct.

Do not use, reuse, or combine any of the Unified Spine Spinal System Implant components with components from any other manufacturer under any circumstances unless expressly allowed to do so in this document.

INDICATIONS: The Unified Spine GS1 Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. It is intended to be used as a temporary construct that assists normal healing and is not intended to replace normal body structures. The Unified Spine GS1 Spinal System should be removed after fusion.

As a pedicle screw system, using either non-cannulated or cannulated screws, the Unified Spine GS1 Spinal System is intended for patients: (a) having severe spondylolisthesis (Grade 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); (c) who are receiving fusions using autogenous bone graft only; and (d) who are having the device removed after the development of a solid fusion mass.

In addition, when used as a pedicle screw system, the Unified Spine GS1 Spinal System is indicated for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a posterior, non-cervical, non-pedicle screw and/or hook fixation system the Unified Spine GS1 Spinal System is indicated for:

1. Degenerative disc disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Idiopathic scoliosis
3. Kyphotic deformities of the spine
4. Paralytic scoliosis and/or pelvic obliquity
5. Vertebral fracture or dislocation
6. Neuromuscular scoliosis associated with pelvic obliquity
7. Vertebral fracture or dislocation
8. Tumors
9. Spondylolisthesis
10. Stenosis
11. Pseudarthrosis
12. Unsuccessful previous attempts at spinal fusion

For posterior, non-pedicle, screw use, the Unified Spine GS1 screws are intended for sacral/iliac attachment only and the Unified Spine GS1 hooks and crosslinks are intended for thoracic and/or lumbar use only.

CONTRAINDICATIONS: Contraindications include, but are not limited to:

a. Active infectious process or significant risk of infection (immunocompromise).
b. Fever or leukocytoses.
c. Any patient with bone absorption, osteopenia, osteomalacia and/or osteoporosis.
d. Any case not requiring bone graft and fusion.
e. Pregnancy.
f. Any case where the components would be too large or too small to achieve a successful result.
g. Signs of local inflammation.
h. Any pathological condition that would preclude the potential benefit of spinal implant surgery such as presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count or a marked left shift in the WBC differential count.; elevation of sedimentation rate unexplained by other disease or elevation of white blood cell count or a marked left shift in the WBC differential count.
i. Any patient with inadequate soft tissue coverage of operative site or inadequate bone from any cause for implants.
j. Morbid obesity.
k. Any patient with allergy or intolerance of the implant materials.
l. Any patient in whom utilization would interfere with anatomical structure or physiological function.
m. Any patient unwilling to follow post operative instructions.
n. Any case not directed in indications.

WARNINGS: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation as described in the INDICATIONS Section. The safety and effectiveness of this device for any other conditions are unknown.

These implants are not permanent prostheses. In the absence of fusion, the instrumentation and/or one or more of its components can be expected to bend, loosen, disassemble and/or break as a result of exposure to everyday mechanical stresses.

In all cases, instrumentation must be at least 1cm from any major vessel.

PRECAUTIONS: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in their use because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning of spinal device system constructs able to withstand trauma or deformity induced body load concentrations is an important consideration for achieving bony fusion and successful surgical outcomes. The surgeon is responsible for preoperative planning, familiarity with operative techniques and ancillary instrumentation, and preoperative consultation with experienced associates to achieve successful post surgical results. A

successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can 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 and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system 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 abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

Physician Note: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

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

a. Early or late loosening of any or all of the components.
b. Infection.
c. Post-operative change in spinal curvature, loss of correction, height and/or reduction.
d. Disassembly, bending and/or breakage of any or all of the components.
e. Urinary retention or loss of bladder control or other types of urological system compromise.
f. Non-union (or pseudarthrosis). Delayed union. Mal-union.
g. Foreign body (allergic) reaction to implants, debris and corrosion of products (from crevice, fretting and/or general corrosion), including metallosis, staining, tumor formation and/or autoimmune disease.
h. Dural tears, pseudomeningocele, fistula, persistent CSF leakage and meningitis.
i. Loss of neurological function (e.g. sensory and/or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation and/or visual deficits.
j. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis and/or pain and bursitis. Tissue or nerve damage caused by improper positioning or placement of implants or instruments.
k. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis and/or muscle loss.
l. Fracture, microfracture, resorption, damage or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above and/or below the level of surgery. Retropulsed graft.
m. Herniated nucleus pulposus, disc disruption or degeneration at, above or below the level of surgery.
n. Cessation of any potential growth of the operated portion of the spine.
o. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
p. Loss of increase in spinal mobility or function.
q. Inability to perform the activities of daily living.
r. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
s. Bone loss or decrease in bone density, possibly caused by stress shielding.
t. Graft donor site complications, including pain, fracture or wound healing problems.
u. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
v. Hemorrhage, hematoma, vascular occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
w. Reproductive system compromise, including sterility, loss of consortium or sexual dysfunction.
x. Change in mental status.
y. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

Other preoperative, intraoperative and postoperative warnings and precautions:

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 the 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, that may result in further injury or the need to remove the device permanently.

DEVICE FIXATION:
When tightening the set screws, always hold the assembly with the Counter Torque device. Tighten the head of the set screw to at least 80 to 100 in-lbs. to leave the assembly at optimum fixation.

PREOPERATIVE:

a. Only patients that meet the criteria described in the indications should be selected.
b. All instruments should be cleaned and sterilized before use. Implants, if not provided sterile, must be sterilized before use. Additional sterile components should be available in case of unexpected need.
c. 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.
d. Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should be avoided.
e. An adequate inventory of implants should be available at the time of the surgery, normally a quantity in excess of what is expected to be used.
f. 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 Unified Spine GS1 Spinal System implants (described in the DESCRIPTION Section) are not to be combined with the implants from another manufacturer.

INTRAOPERATIVE:

a. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological function.
b. Utilize an imaging system to facilitate surgery.
c. Breakage, slippage or misuse of instruments or implant components may cause injury to the patient or operative personnel.
d. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
e. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rod outside of the operative field. Whenever possible, use pre-cut rods of the length needed.
f. When tapping a Cannulated screw, a Guide-wire should first be used. Caution: Be careful that the Guide-wire is not inserted too deep, becomes bent, and/or breaks. When properly positioned, as confirmed by x-rays, the Guide-wire should be followed by the proper bone tap.
g. Caution: Ensure that the Guide-wire does not advance during tapping or screw insertion.
h. Caution: Do not over-tap or use a screw that is either too long or too large. Over tapping or using an incorrectly sized screw may cause nerve damage, hemorrhage or other possible adverse events listed elsewhere in the package insert. If screws are being inserted into spinal pedicles, use as large a screw diameter that will fit into each pedicle.

i. To assure maximum stability, two or more crosslinks on two bilaterally placed, continuous rods, should be used whenever possible.
j. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws. Once this is completed, go back and firmly tighten all of the screws and nuts. Recheck the tightness of all the nuts or screws. After finishing, ensure that none loosened during the tightening of the other nuts and screws. Failure to do so may cause loosening of the other components.

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

a. 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 and/or breakage of the device(s) are complications that may occur as a result of excessive or early weight-bearing or 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 or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
b. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock 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 sports participation. The patient should be advised not to smoke tobacco or utilize nicotine products or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin and other COX-1 and COX-2 inhibitors and Ketorolac Promethamine during the bone graft healing process.
c. As a precaution before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high risk patients.
d. The patient should be advised of his or her inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
e. 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 the eventual bending, loosening or breakage of the device(s). It is important that the immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
f. The Unified Spine GS1 Spinal System 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. 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: Corrosion, with localized tissue reaction or pain; Migration of implant position, possibly resulting in injury; Risk of additional injury from postoperative trauma; Bending, loosening and/or breakage, that could make removal impractical or difficult; Pain, discomfort, or abnormal sensations due to the presence of the devices; Possible increased risk of infection; Bone loss due to stress shielding; and Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture or other complications.
g. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, the Unified Spine GS1 Spinal System components should never be reused under any circumstances.

MRI: The Unified Spine GS1 Spinal System has not been evaluated for safety and compatibility in the MR environment. The Unified Spine GS1 Spinal System has not been tested for heating or migration in the MR environment.

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 including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to the Unified Spine distributor.

CLEANING AND DECONTAMINATION: Implants are supplied clean in sealed packaging.

For surgical instruments refer to Important Information Concerning Unified Spine Surgical Instruments for instrument cleaning and care instructions.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices. These solutions should not be used. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION: Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared, intact steam sterilization compatible wrap to maintain sterility.
Only sterile products should be placed in the operative field. Unless specified otherwise, these products are recommended to be steam sterilized by the hospital using the following process parameters:

Method	Cycle	Temperature*	Exposure Time*	Drying Time*
Steam	Pre-Vacuum	270F (132C)	4 Minutes	30 Minutes

*Note: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for the equipment. For outside of the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

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 Unified Spine distributor. Further, if any spinal system component 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 Unified 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: If further details for the use of this system are needed, please check with the Unified Spine distributor. If further information is needed or required, please see the address on this document.

Additional Information

A. Implant Removal

Removal of the GS1 Spinal System is accomplished by following the reverse order of the surgical procedure.

B. Sterilization Recommendations

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be cleaned and sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field.

Note: Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared, intact steam sterilization compatible wrap to maintain sterility. Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for the equipment.

[1]Validated steam sterilization time required to achieve a 10^{-6} sterility assurance level (SAL).

Implants

Unless specified otherwise, these implant products are recommended to be steam sterilized by the hospital using the following parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	[1]Pre-Vacuum	270F (132C)	4 Minutes	30 Minutes

See package insert 502001 for complete information.

Instruments

Unless specified otherwise, these instrument products are recommended to be steam sterilized by the hospital using the following parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	[1]Pre-Vacuum	270F (132C)	4 Minutes	30 Minutes

See package insert 502015 for complete information.

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