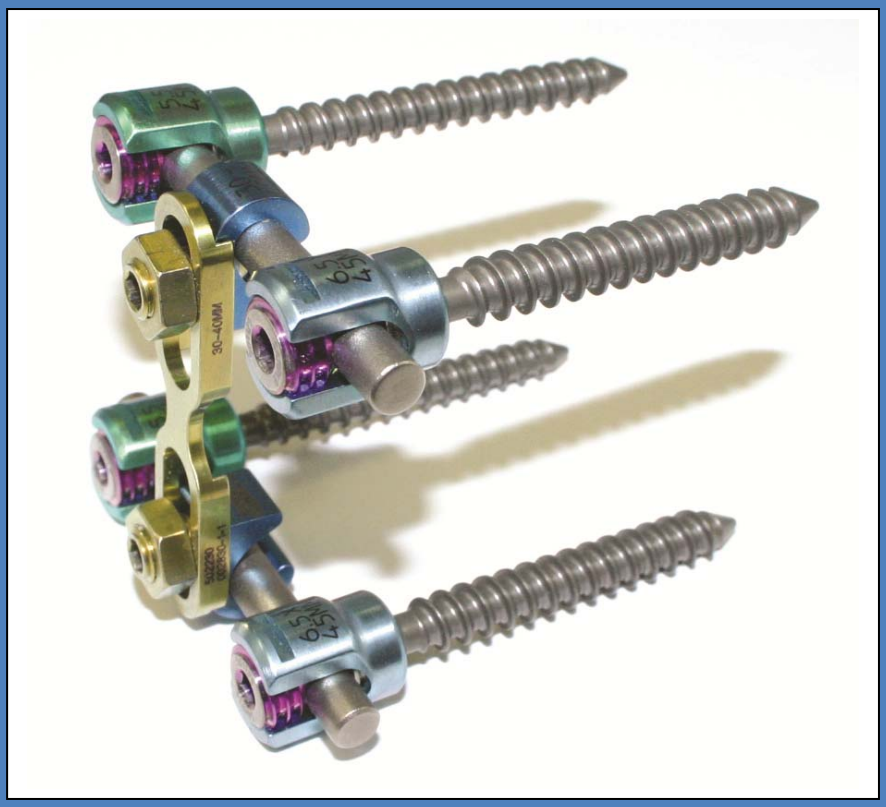
GS1 SPINAL SYSTEM

SURGICAL TECHNIQUE GUIDE



GOLD STANDARD ORTHOPAEDICS

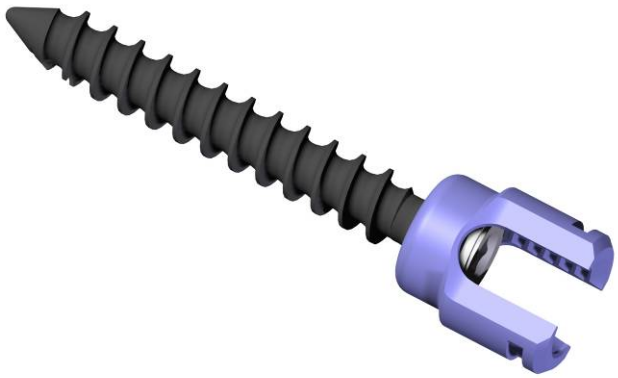
Introduction

The Gold Standard Orthopaedics, LLC GS1 Spinal System designed in conjunction with Richard Holt, M.D. incorporates both strength and function into a competitively priced Spinal Fixation System. The multi-axial head design with a full 28º of angulation in any direction allows for easier rod insertion. The sturdy 3-piece construction provides great strength.

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 surgical technique is that used by Richard Holt, M.D. of Louisville, KY. Gold Standard Orthopaedics, LLC as a manufacture does not practice medicine and does not recommend a specific surgical technique for use on any individual patient.

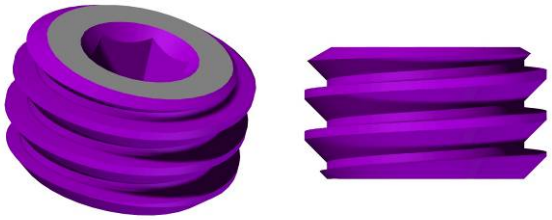
I. Implant Description



Multi-axial Screw:

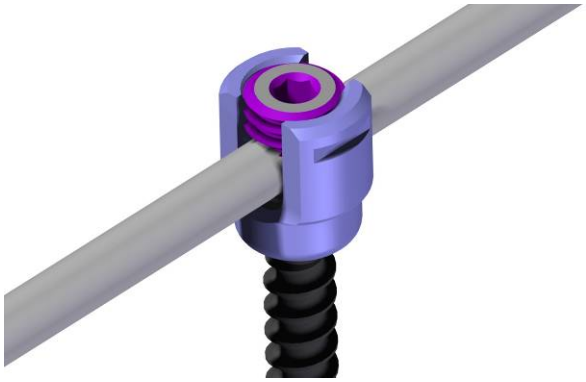
- 3 Piece Design
- Material: CP Titanium and Titanium Alloy
- 28º of Angulation in Any Direction
- Floating Cap Locks Position When Set Screw is Tightened
- Self-tapping Bone Screw
- Uses a 3.5mm Hex Drive
- Screw Heads are Clearly Marked for corresponding rod size use

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



Set Screw:

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



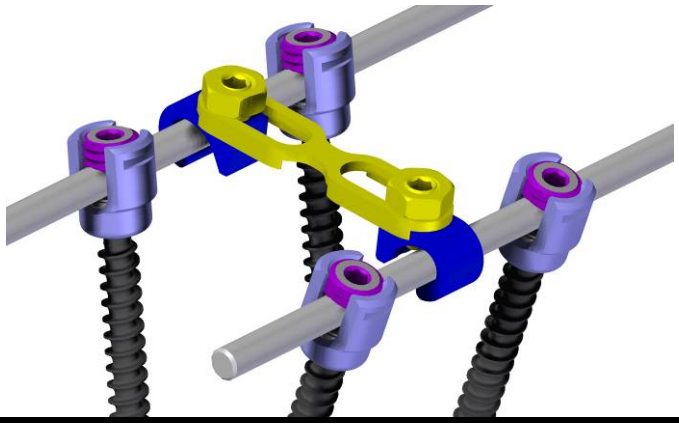
Rods:

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

30mm	70mm
35mm	75mm
40mm	80mm
45mm	90mm
50mm	100mm
55mm	110mm
60mm	120mm
65mm	19 Inches

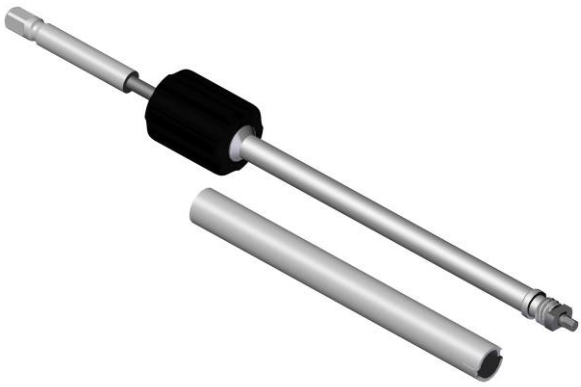
Hooks:

- Multiple Style are available with varying throat and foot designs to achieve a secure fit with vertebral anatomy
- Utilizes the same top load design of the screws and requires the same set screw



Cross Connectors:

- Material: Titanium
- Available in 3 Range Sizes:
  - 30 to 40mm
  - 40 to 50mm
  - 50 to 60mm



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. Optional Sleeve can be use to allow driver to turn freely without the change of unintentionally disengaging the driver from the screw.

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 preliminarily tighten the set screw into the Multi-Axial Screw Heads. The longer version is for manually engaging the set screw into the head and can be used in conjunction with the Anto-Torque instrument or the Mechanical Reducer. The other version is specially designed to fit over the multi-axial head of the screw, position it properly, and seat the set screw with perfect thread alignment.

Rod Bender
Rod Holder
Bone Awl
Probe
Ball Tip Probe
Quick Connect Handles
Rod Rotator
Soft Tissue Retractor
In-Situ Rod Benders
Taps

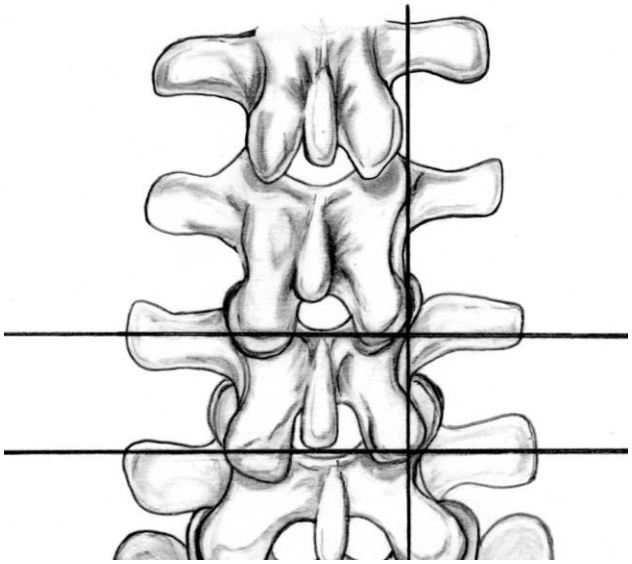
Common Instrumentation:

- 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

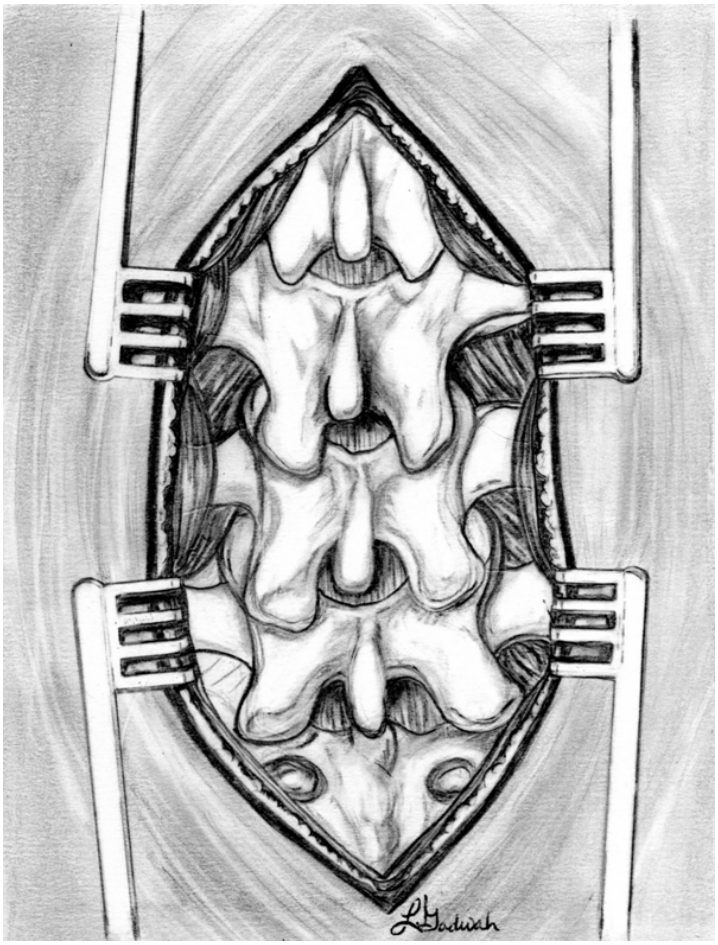
A. Preoperative Planning and Preparation

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.



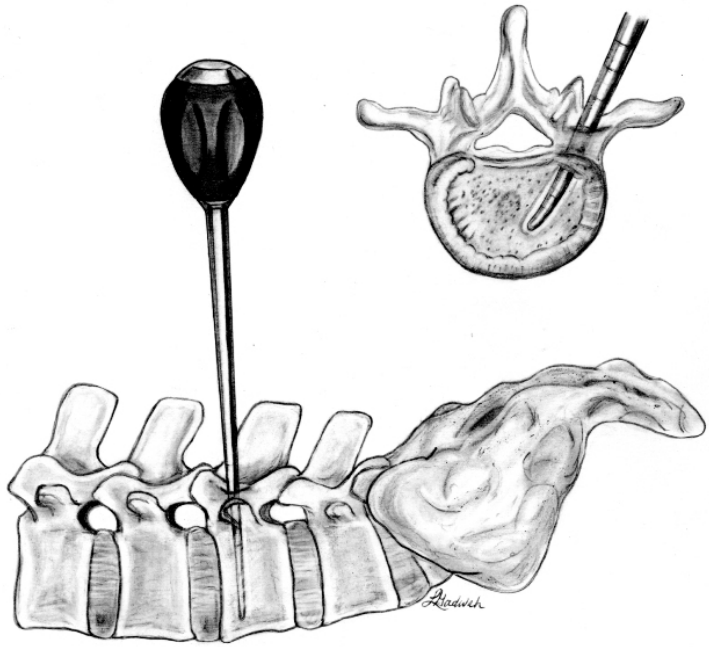
B. Patient Positioning and Preparation

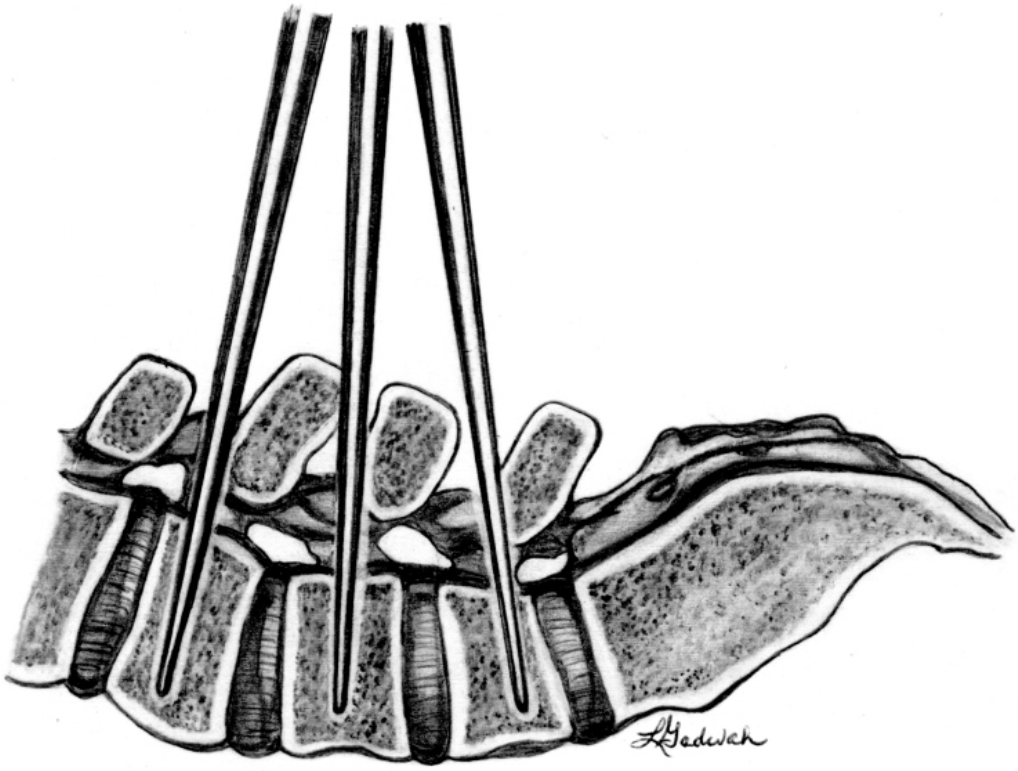
Patients may be positioned prone or laterally for a posterior approach. Prone is typically the most common choice. The spine is then exposed with a midline or paramedial incision. This is followed with a decompression if indicated. Decortication must be performed and bone graft must be placed into the 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 application. Penetrate the cortex of the vertebra using either an awl or rongeur. Define the pedicle canal using either a probe or appropriately sized drill bit. The use of a calibrated probe may help the surgeon determine the proper screw length. Use a feeler probe, EMG, or radiograph to verify position. Tapping the screw hole is advised for sclerotic bone and optional for non-sclerotic bone.

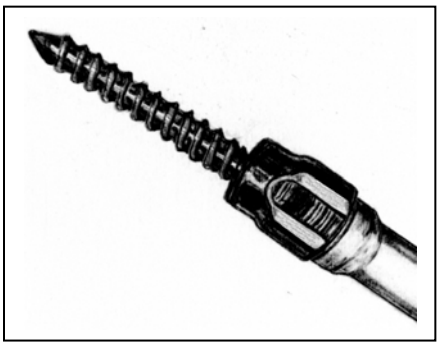


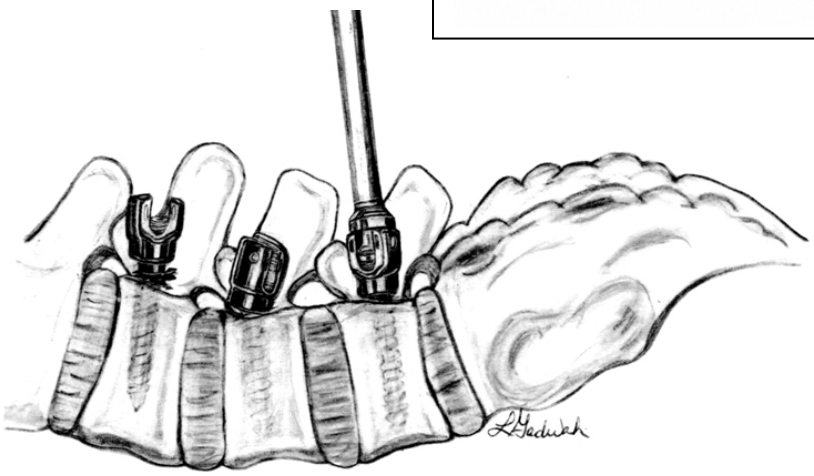


D. Screw Insertion

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 pedicle canal. Utilize care and tactile feedback for proper insertion. 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.

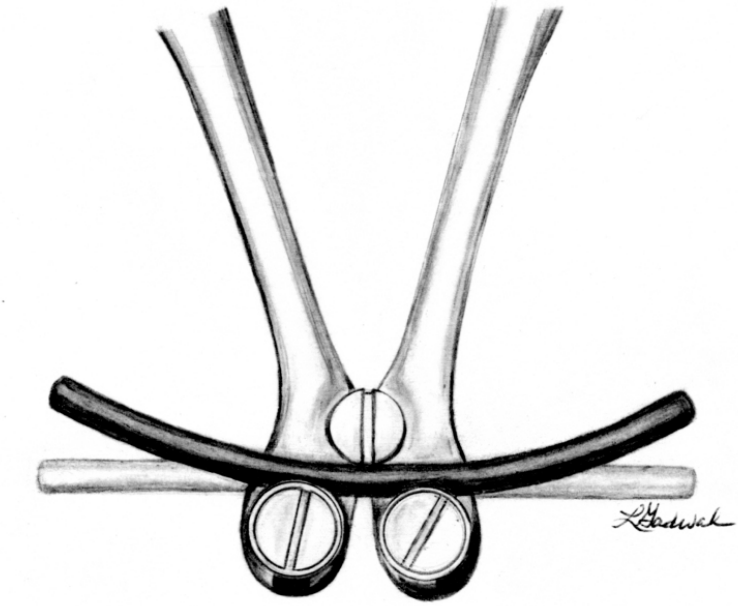
NOTE: USE ONLY SCREWS MARKED FOR 5.5MM RODS WITH 5.5MM RODS.





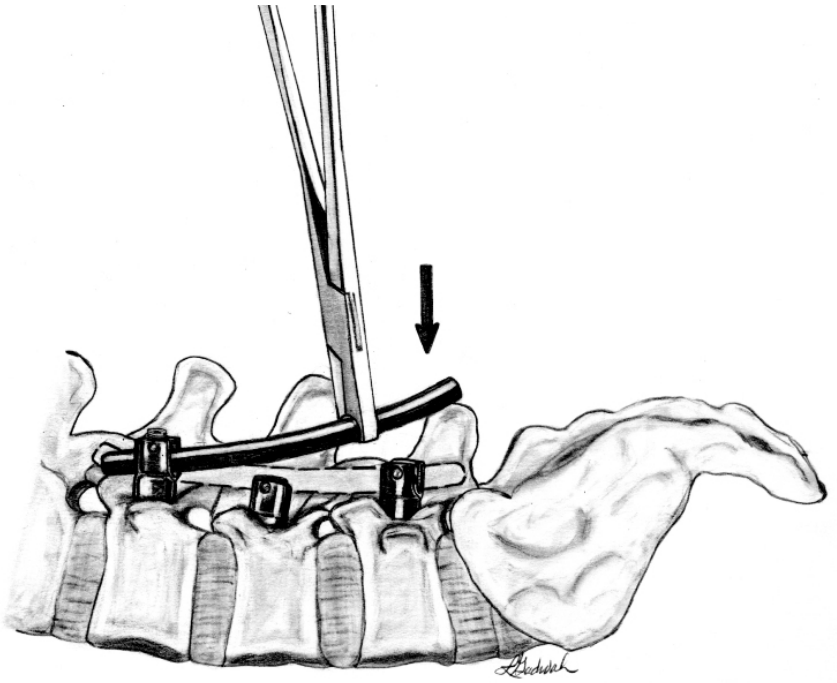
E. Rod Contouring

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.



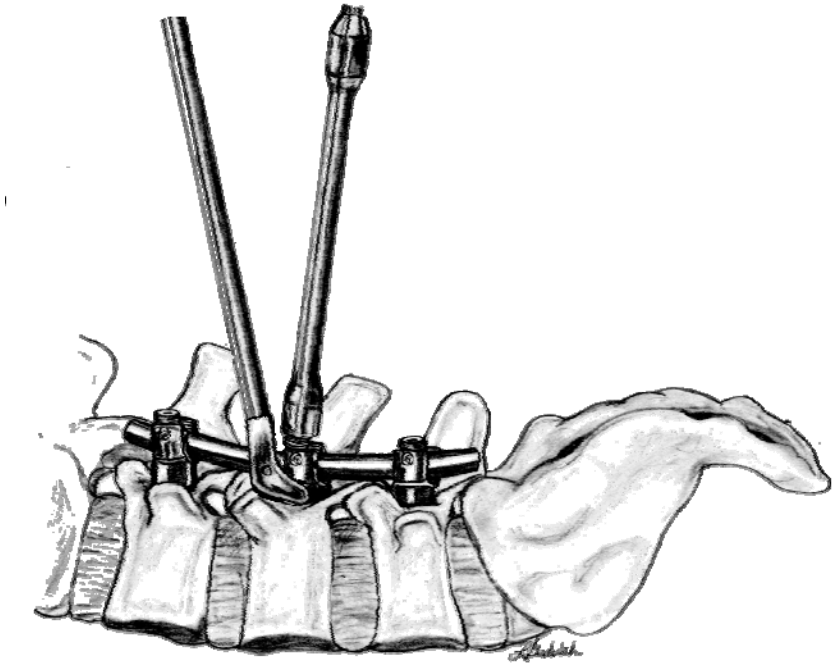
F. Rod Insertion

Insert Rod into position using rod holders. Place set screw in the first Multi-axial 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 Multi-axial Screw Heads placing Set Screw in each.



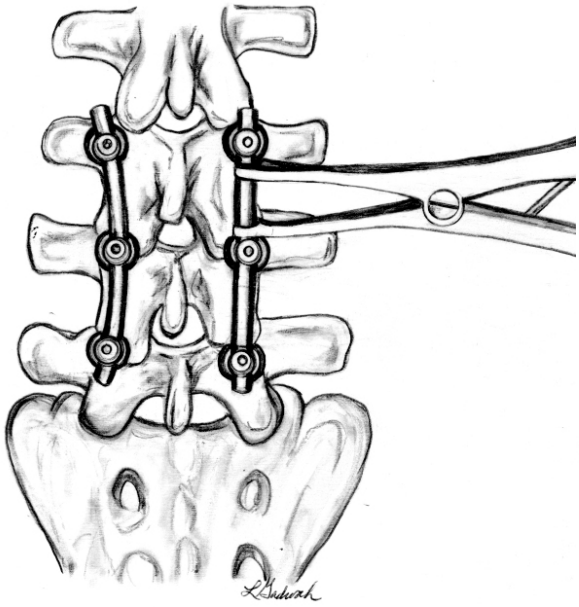
G. Rod Reduction

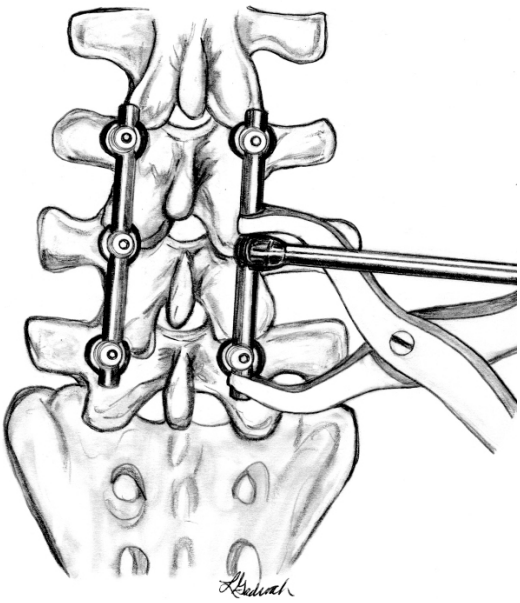
Use any of the variety of available rod reducers, if needed, to seat the rod inside the Multi-axial Screw Head. Once in the desired position, place the Set Screw with the same finger tight technique.



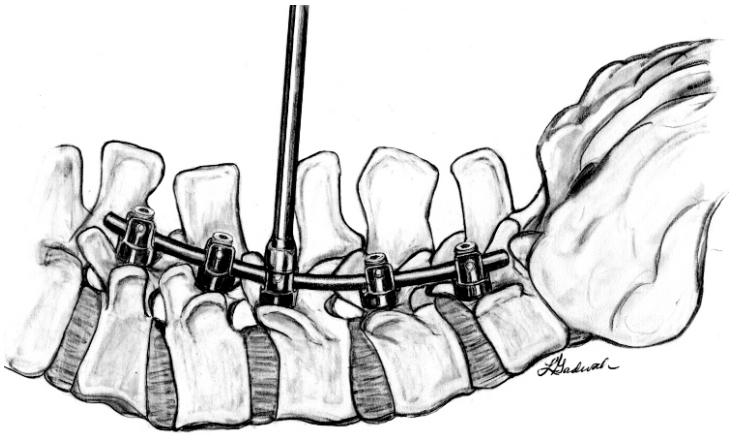
NOTE: SET SCREW SHOULD BE STARTED WITH THE SET SCREW STARTER USING FINGER TIGHTENING ONLY TO ENSURE PROPER THREAD ALIGNMENT. SET SCREWS SHOULD BE INSERTED WITH THE SILVER COLORED FACE UPWARDS. THREADS WILL NOT MATE IF SET SCREW IS INSERTED UPSIDE DOWN. FINAL TIGHTENING SHOULD BE PERFORMED WITH THE ANTI-TORQUE INSTRUMENT IN PLACE AND SET SCREWS SHOULD BE TIGHTENED TO 80 – 100 IN-LBS.

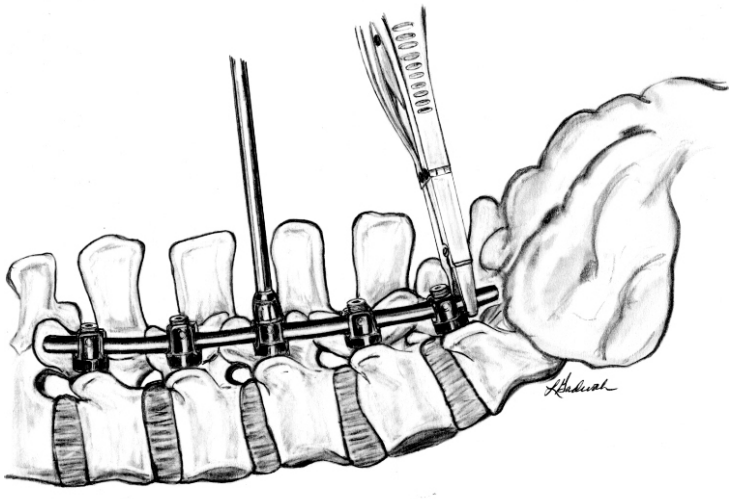
Once the set screws are preliminarily placed, use Compressors and Distractors as shown to position the spine in the desired position before tightening the set screws.



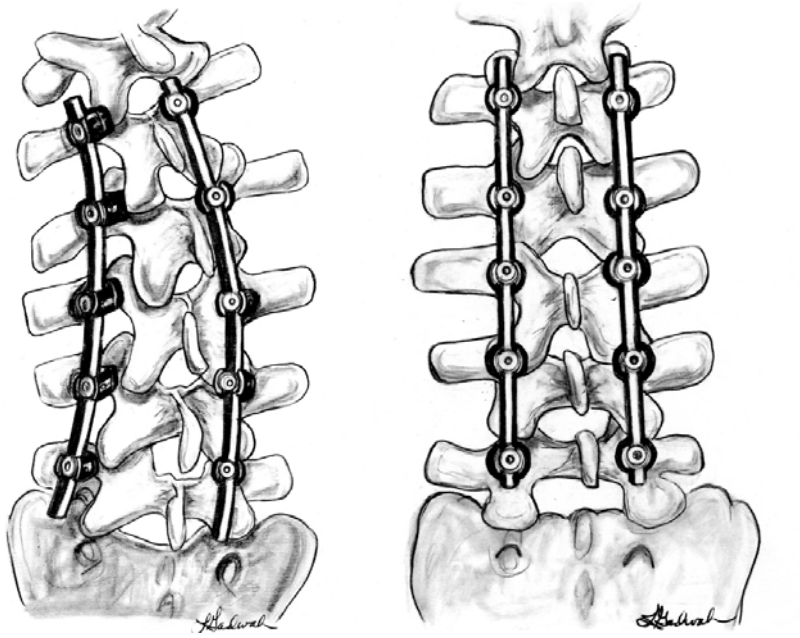


For Segmental Correction:
Firmly seat the contoured rod to one spinal screw using a set screw. Reduce the rod into the next screw head with manipulation via rod holder or rod reducer with tension between the screw head and the rod. Distract or compress between the screws as needed and provisionally tighten 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.



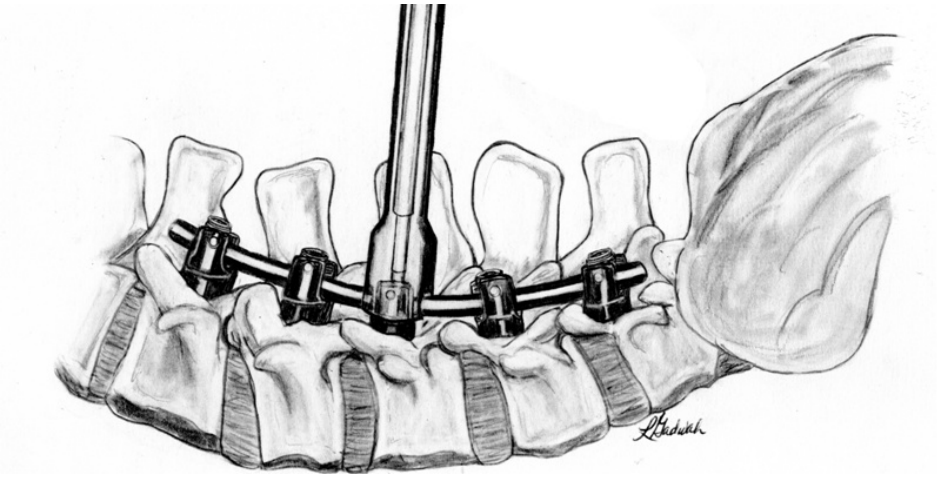


For Rotational Correction:
Contour the rod to the desired correction. Place the rod in one spinal screw using a loosely fit set screw. Rotate the rod to the corrected position and tighten the set screw provisionally. Apply compression or distraction between the screw heads as needed for additional correction. Apply a contra-lateral rod to conform to the screw head position. Apply Cross Connectors as needed. Confirm correction and neurologic 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.



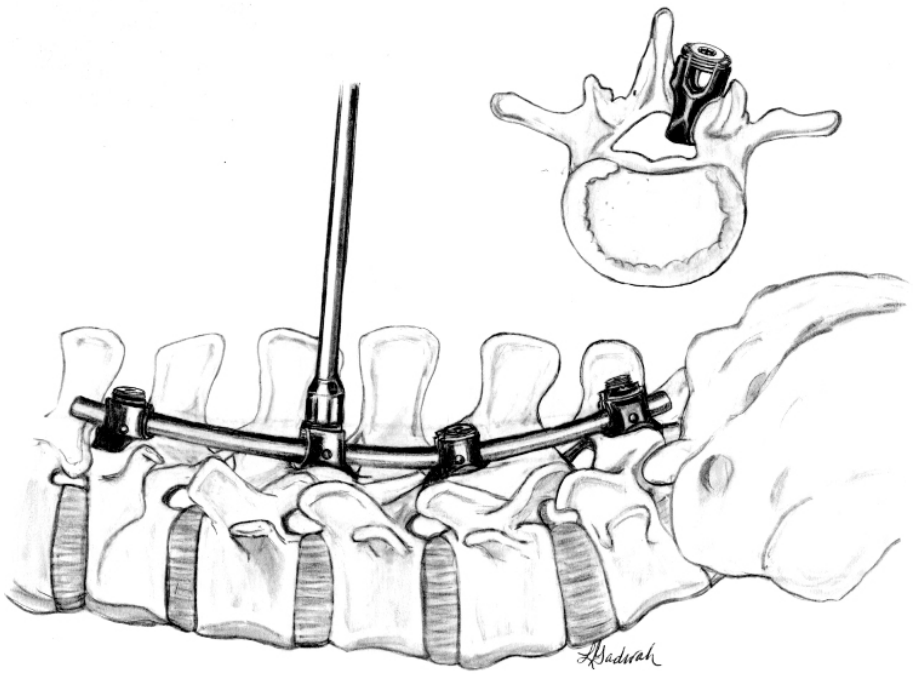
H. Final Tightening

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 Multi-axial 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 Screws and that the Set Screw is threaded properly in the Multi-axial 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.



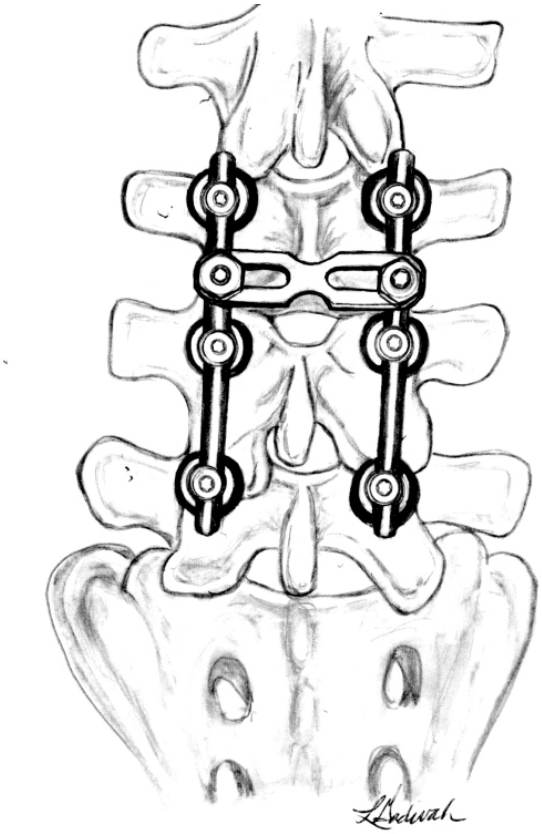
I. Hook Application

Hooks can be used as anchor points to the spine. When using hooks, consider the direction of the corrective force so that the contact of the hook on the spine will not loosen when the compressive or distractive force is applied. The appropriate hook sites can be supra of infra laminar, inter-facet, on the cephalad edge of a transverse process in the upper and mid thoracic spine, or intraosseous in previously fused spines. Care must be used to prevent neural compression when the hook foot is placed in an intra-canal position. Once hooks are placed, they are attached to the rods in the same manner as the Multi-axial screws using the same set screw and torque of 80 – 100 in-lbs. while using the anti-torque device.



J. Cross Connectors

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.



K. Closure

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

III. Indications for Use:

See package insert for complete information.

The GSO 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 GSO GS1 Spinal System should be removed after fusion.

As a pedicle screw system, the GSO 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 GSO 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 or an anterolateral, intervertebral body screw system, the GSO 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 pelvis 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 GSO GS1 screws are intended for sacral/iliac attachment only and the GSO GS1 hooks and Cross Connectors are intended for thoracic and/or lumbar use only.

For anterior use, the recommended levels of screw attachment are T5 – L5.

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

IV. Contra-Indications

See package insert for complete information.

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.

GS1 5.5mm System Part Number List

Multi-Axial Screws for 5.5mm System

Part Number	Description
501525	5.5mm x 25mm Screw Assembly
501530	5.5mm x 30mm Screw Assembly
501535	5.5mm x 35mm Screw Assembly
501540	5.5mm x 40mm Screw Assembly
501545	5.5mm x 45mm Screw Assembly
501550	5.5mm x 50mm Screw Assembly
501555	5.5mm x 55mm Screw Assembly
501560	5.5mm x 60mm Screw Assembly
501625	6.5mm x 25mm Screw Assembly
501630	6.5mm x 30mm Screw Assembly
501635	6.5mm x 35mm Screw Assembly
501640	6.5mm x 40mm Screw Assembly
501645	6.5mm x 45mm Screw Assembly
501650	6.5mm x 50mm Screw Assembly
501655	6.5mm x 55mm Screw Assembly
501660	6.5mm x 60mm Screw Assembly
501725	7.5mm x 25mm Screw Assembly
501730	7.5mm x 30mm Screw Assembly
501735	7.5mm x 35mm Screw Assembly
501740	7.5mm x 40mm Screw Assembly
501745	7.5mm x 45mm Screw Assembly
501750	7.5mm x 50mm Screw Assembly
501755	7.5mm x 55mm Screw Assembly
501760	7.5mm x 60mm Screw Assembly
501770	7.5mm x 70mm Screw Assembly
501780	7.5mm x 80mm Screw Assembly

Cross Connectors for 5.5mm System

Part Number	Description
502230	30-40 Adjustable Connector
502240	40-50 Adjustable Connector
502250	50-60 Adjustable Connector
502260	60-70 Adjustable Connector

Set Screw for 5.5mm System

Part Number	Description
501125	Set Screw

Rods for 5.5mm System

Part Number	Description
502100	5.5mm x 20” Rod
502180	5.5mm x 30mm Rod
502181	5.5mm x 35mm Rod
502182	5.5mm x 40mm Rod
502183	5.5mm x 45mm Rod
502184	5.5mm x 50mm Rod
502185	5.5mm x 55mm Rod
502186	5.5mm x 60mm Rod
502187	5.5mm x 65mm Rod
502188	5.5mm x 70mm Rod
502189	5.5mm x 75mm Rod
502190	5.5mm x 80mm Rod
502192	5.5mm x 90mm Rod
502194	5.5mm x 100mm Rod
502196	5.5mm x 110mm Rod
502198	5.5mm x 120mm Rod

Hooks for 5.5mm System

Part Number	Description
501212	Small Standard Hook
501213	Medium Standard Hook
501214	Large Standard Hook
501215	Small Wide Hook
501216	Medium Wide Hook
501217	Large Wide Hook
502218	Small Narrow Hook
502219	Medium Narrow Hook
501220	Large Narrow Hook
501221	Small Split Hook
501222	Medium Split Hook
501223	Large Split Hook

V. 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)	6 Minutes	30 Minutes

See package insert 502015 for complete information.

C. Surgical Technique Note

The surgical technique depicted in this brochure is that used by Richard Holt, M.D. of Louisville, KY. Gold Standard Orthopaedics, LLC as a manufacture does not practice medicine and does not recommend a specific surgical technique for use on any individual patient. The surgeon performing any implant procedure is responsible for determining the appropriate product or products for each patient and choosing the appropriate surgical technique for their implantation.

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