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Innovative Spine Solution

Surgical | Technique

GSS™

Surgical Technique

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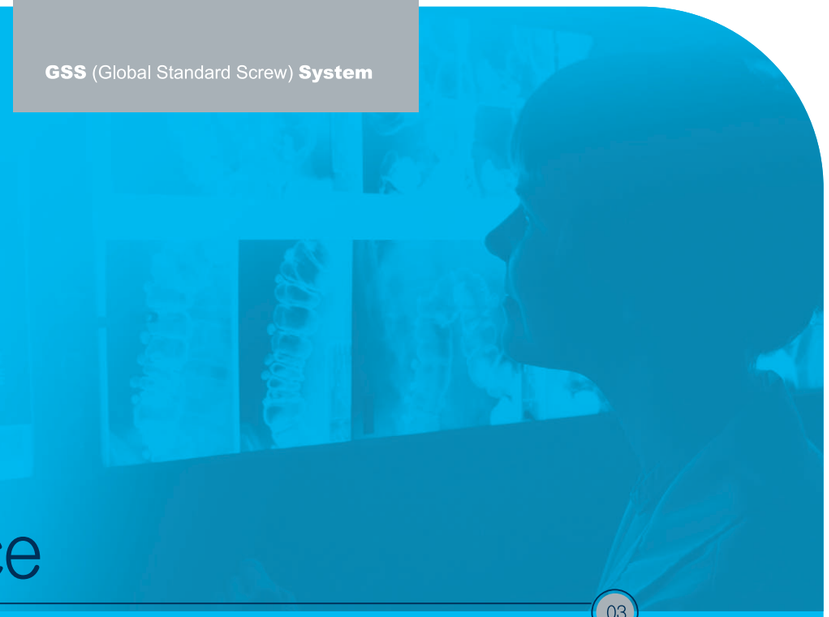
Distributor

Revision 4

GS Medical
Innovative Spine Solution

Contents

GSS (Global Standard Screw) **System**



Preface

Since first used by Dr. Paul Harrington in the late 1960' s, pedicle screws have gone through multiple phases of development. For several indications, pedicle screws are now regarded as a necessary adjunct to spinal fusion due to immediate fixation they provide.

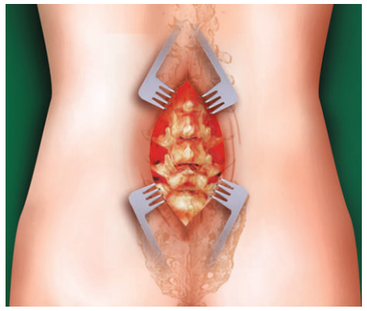
The versatile GS Medical's GSS Mono & Poly Axial screw systems were designed to facilitate the placement of pedicle screws with comfort and ease. This posterior pedicle screw fixation system intendeds to provide immobilization and stabilization to the thoracic, lumbar and sacral vertebrae.

The poly axial capability provides 20 degreess of freedom in any direction for a total 40. This poly axial capability allows for easier rod placement and reduction (even when the screws are not perfectly aligned). To enhance interbody fusion, compression and distraction can be easily applied with this system.

Other essential features of the GSS Poly axial screw systems include a buttress thread design, a single locking mechanism and top loading implants with 6.0mm rod system.

Patient Positioning

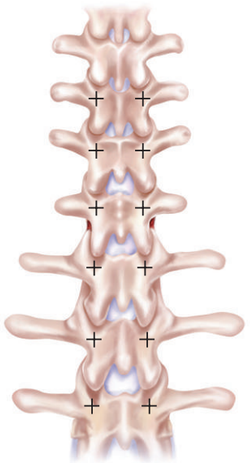
The patient is positioned prone on the operating table. (Four-poster, Relton-Hall or Jackson Frame)
All posts are adjusted keeping in mind the patient's width and height. This distributes the weight evenly on the chest and proximal thigh, decreases pressure on bony pressure points, and aids in some reduction of deformity.
It is important that the abdomen be free of pressure, so as to decrease pressure on the IVC and allow free venous drainage of the lower extremity. This minimizes blood loss during surgery, especially from epidural veins.



Exposure

For exposure of lumbar spine, a middle incision is made and paraspinal muscles dissected subperiosteally to expose the spinous process, lamina, facet joint capsule, pars interarticularis, and transverse processes.

After adequate surgical exposure is obtained, the levels are confirmed both clinically and by radiologically.



Pedicle Landmarks

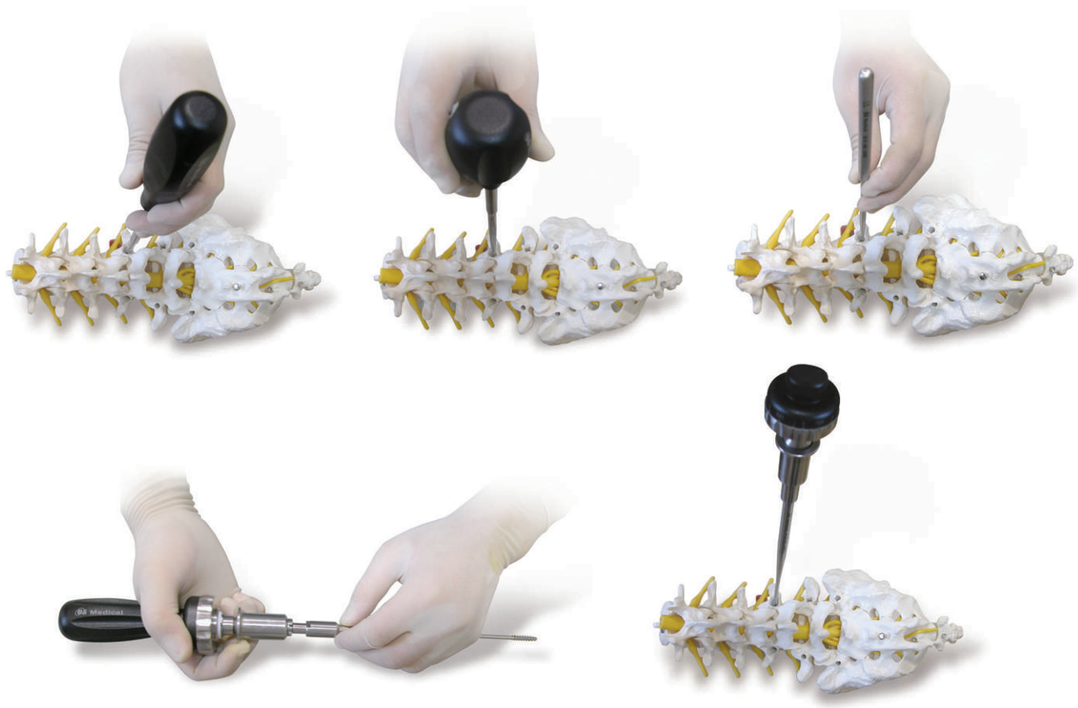
Identify the appropriate anatomical landmarks for creating the entry points for screw insertion in the pedicle.

The pedicle entry point, in the lumbar spine, is located at the junction of two lines. The vertical line is the extension of the facet joint in line with the bony crest arising from the inferior articular facet.

The horizontal line passes through the middle of the insertion of the transverse process, or 1mm below the joint line.

Pedicle Screw Preparation

Pedicle entry point is created using a selection AWL, and the path of the pedicles is probed with the pedicle Probes (Straight/Curved). The pedicle Probes which is calibrated at 5mm intervals helps in judging the length of the pedicle. To facilitate screw insertion, the pedicle is tapped with pedicle Tap (available from 4.0 ~ 7.0mm). Markings on the Tap provide further help in determining the final length of the screw to be inserted.



Assemble Mono/Polyaxial Screw and Screw Driver

1) Assemble the Mono/Polyaxial Screw Driver Shaft and T or T-Rachet handle.
2) Place tip of the Mono/Polyaxial Screw Driver in head of Screw.
3) Thread Screw Driver into head of the Screw making sure screw shank is straight.
4) Slide Screw Driver sleeve down over the head of Screw.

Mono/Polyaxial Screw Insertion

Insert the Mono/Polyaxial Screw into the pedicle hole till the desired depth by using Screw Driver. The inserted Mono/Polyaxial Screws should be parallel to the endplates. To release the sleeve, pull on the outer sleeve and remove the Screw Driver.

Rod Bending / Insertion

After the appropriate length of Rod has been selected, the Rod Bender is used to create the desired lordosis, as dictated by the patient's anatomy. (Figure 1) The placement of the Rod into the Mono/Polyaxial Screw heads is facilitated by the use of Rod Clamp, Rod Holder (Figure 2) or sometimes by Rod Pusher.
Rod Insertion Technique: The Rod must be seated in the head of GSS Screw for locking. There are 3 methods.

1) Rod Pusher: Pushing the Rod firmly, seats it into the GSS Screw head. (Figure 3)
2) Rod Fork: The Rod Fork is hooked under the head's reduction feature in a cranial / caudal direction. It is rocked away from the screw to seat the Rod into the Screw head. (Picture 4)
3) Persuader: Center the Persuader over the head and squeeze the handle to seat the Rod into the head. (Figure 5)

Figure 1

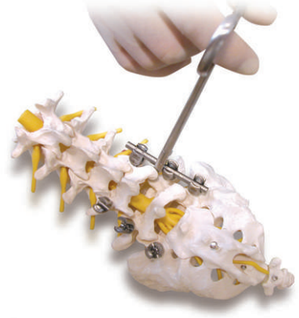


Figure 2

Figure 3

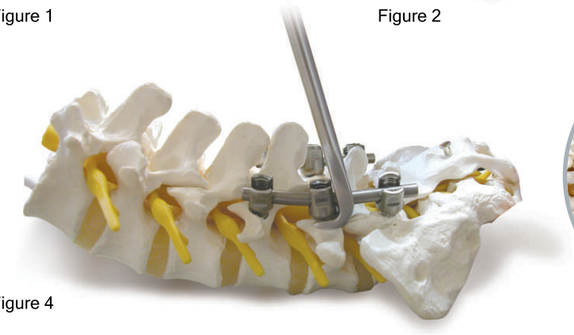


Figure 4

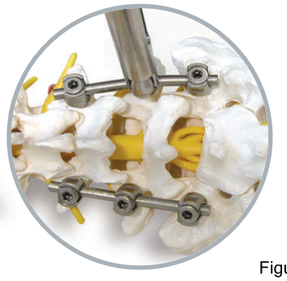
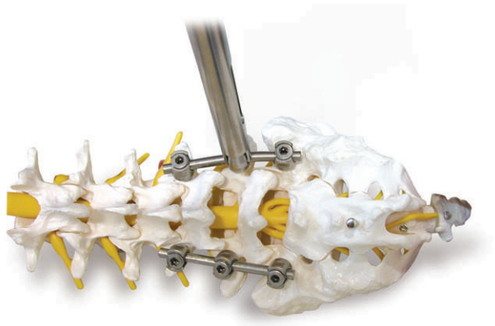


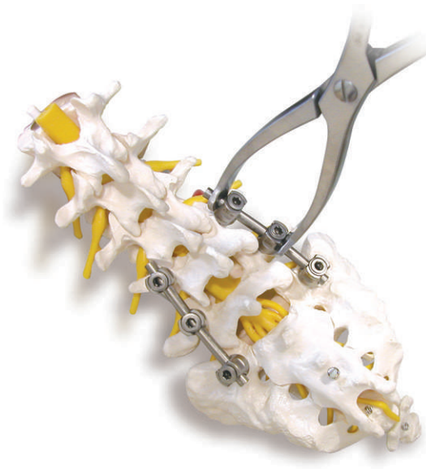
Figure 5



Locking with Set Screw

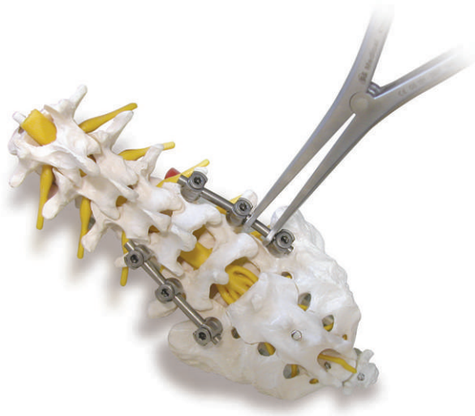
Insert the Set Screw Driver tip into a Set Screw and then insert the Screw Driver with the Set Screw into the lumen of the Persuader. Rotate the Screw Driver clockwise to tighten the Set Screw in the GSS Screw.

※ Caution: Do not over-tighten the Set Screw without the aid of the Anti-Torque Wrench.



Compression and Distraction

Once the Rod has been captured into all of the Mono/Polyaxial Screw heads, Compression or Distraction can be applied easily.
Compression is achieved using the Compressor.
The Compressor fits over the Rod and is placed on the outer side on the Screws, the provisionally tightened GSS Screw on one side and the GSS Screw to be compressed on the other side.
As the Compressor handle is closed, the loose GSS Screw is drawn toward the other provisionally-tightened GSS Screw.

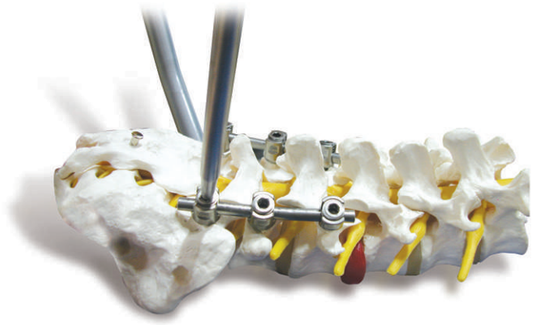


Distraction is accomplished using the Distractor.
The Distractor fits onto the Rod and is placed on the inner side of the Screws, the provisionally tightened GSS Screw on one side and the GSS Screw to be distracted on the other.

As the Distractor handle is closed, the loose GSS Screw is pushed away from the other provisionally-tightened GSS Screw.

Final Tightening

After compression and distraction has been achieved, the Anti–Torque Wrench and Torque Limiting Set Screw Driver are used for final tightening. The Torque Limiting Set Screw Driver is designed to deliver the required torque to tighten the Set Screw. If Set Screw Driver is used, it is inserted through the lumen of the Anti–Torque Wrench.
With the Anti–Torque Wrench inserted over the Screw, holding the Screw steady, the Screw Driver engages the Set Screw and is rotated clockwise till a torque of 10 N–m. Alternatively, if the Torque Limiting Set Screw Driver is used alone, the Screw Driver is slowly rotated clockwise until the optimal torque is achieved and is indicated by an audible "Click". Each additional Set Screw can then be secured in the same manner.



Transverse Link Connection - optional

The use of the Transverse Link Connector is recommended to increase the rotational stability of the construct. Removal of the spinous process may be required if the Transverse Link is used.

Choose a Transverse Link of appropriate length and apply the Transverse Link to the Rod.
The Transverse Link is secured to the Rods by tightening of the Set Screws on the connector with the Transverse Link Screw Driver.

Finally, Transverse Link Connection assembly is completed by tightening the hexagonal Screw in the middle of Transverse Link by using Transverse Wrench.

NOTE: Transverse Wrench & Driver Tip should be assembled with Torque Limiting Handle that is designed to give optimal torque up to 5 N–m

Bone Grafting

To achieve long term stability, bony fusion with a graft is recommended. To facilitate fusion, bone graft is often applied in the lateral gutters. A suitable bone graft substitute may also be used, either by itself, or in combination with autograft. Cancellous bone harvested from the posterior iliac crest yields excellent results.

Bone graft must be placed in the area to be fused and the graft material must extend from the upper to the lower vertebrae being fused.

IMPLANTS

GSS Monoaxial Pedicle Screw

Feature	Cat.No	Length(mm)
(Dia=4.5mm) 	GS0101-4520	20
	GS0101-4525	25
	GS0101-4530	30
	GS0101-4535	35
	GS0101-4540	40
	GS0101-4545	45
	GS0101-4550	50
	GS0101-4555	55
	GS0101-4560	60
(Dia=5.5mm) 	GS0101-5520	20
	GS0101-5525	25
	GS0101-5530	30
	GS0101-5535	35
	GS0101-5540	40
	GS0101-5545	45
	GS0101-5550	50
	GS0101-5555	55
	GS0101-5560	60
(Dia=6.5mm) 	GS0101-6520	20
	GS0101-6525	25
	GS0101-6530	30
	GS0101-6535	35
	GS0101-6540	40
	GS0101-6545	45
	GS0101-6550	50
	GS0101-6555	55
	GS0101-6560	60
(Dia=7.5mm) 	GS0101-7520	20
	GS0101-7525	25
	GS0101-7530	30
	GS0101-7535	35
	GS0101-7540	40
	GS0101-7545	45
	GS0101-7550	50
	GS0101-7555	55
	GS0101-7560	60
(Dia=8.5mm) 	GS0101-8520	20
	GS0101-8525	25
	GS0101-8530	30
	GS0101-8535	35
	GS0101-8540	40
	GS0101-8545	45
	GS0101-8550	50
	GS0101-8555	55
	GS0101-8560	60

GSS polyaxial Pedicle Screw

Feature	Cat.No	Length(mm)
(Dia=4.5mm) 	GS0102-4520	20
	GS0102-4525	25
	GS0102-4530	30
	GS0102-4535	35
	GS0102-4540	40
	GS0102-4545	45
	GS0102-4550	50
	GS0102-4555	55
	GS0102-4560	60
(Dia=5.5mm) 	GS0102-5520	20
	GS0102-5525	25
	GS0102-5530	30
	GS0102-5535	35
	GS0102-5540	40
	GS0102-5545	45
	GS0102-5550	50
	GS0102-5555	55
	GS0102-5560	60
(Dia=6.5mm) 	GS0102-6520	20
	GS0102-6525	25
	GS0102-6530	30
	GS0102-6535	35
	GS0102-6540	40
	GS0102-6545	45
	GS0102-6550	50
	GS0102-6555	55
	GS0102-6560	60
(Dia=7.5mm) 	GS0102-7520	20
	GS0102-7525	25
	GS0102-7530	30
	GS0102-7535	35
	GS0102-7540	40
	GS0102-7545	45
	GS0102-7550	50
	GS0102-7555	55
	GS0102-7560	60

IMPLANTS

GSS Monoaxial Reduction Screw

Feature	Cat.No	Length(mm)
(Dia=4.5mm) 	GS0103-4520	20
	GS0103-4525	25
	GS0103-4530	30
	GS0103-4535	35
	GS0103-4540	40
	GS0103-4545	45
	GS0103-4550	50
	GS0103-4555	55
	GS0103-4560	60
(Dia=5.5mm) 	GS0103-5520	20
	GS0103-5525	25
	GS0103-5530	30
	GS0103-5535	35
	GS0103-5540	40
	GS0103-5545	45
	GS0103-5550	50
	GS0103-5555	55
	GS0103-5560	60
(Dia=6.5mm) 	GS0103-6520	20
	GS0103-6525	25
	GS0103-6530	30
	GS0103-6535	35
	GS0103-6540	40
	GS0103-6545	45
	GS0103-6550	50
	GS0103-6555	55
	GS0103-6560	60
(Dia=7.5mm) 	GS0103-7520	20
	GS0103-7525	25
	GS0103-7530	30
	GS0103-7535	35
	GS0103-7540	40
	GS0103-7545	45
	GS0103-7550	50
	GS0103-7555	55
	GS0103-7560	60
(Dia=8.5mm) 	GS0103-8520	20
	GS0103-8525	25
	GS0103-8530	30
	GS0103-8535	35
	GS0103-8540	40
	GS0103-8545	45
	GS0103-8550	50
	GS0103-8555	55
	GS0103-8560	60

GSS Polyaxial Reduction Screw

Feature	Cat.No	Length(mm)
(Dia=4.5mm) 	GS0122-4520	20
	GS0122-4525	25
	GS0122-4530	30
	GS0122-4535	35
	GS0122-4540	40
	GS0122-4545	45
	GS0122-4550	50
	GS0122-4555	55
	GS0122-4560	60
(Dia=5.5mm) 	GS0122-5520	20
	GS0122-5525	25
	GS0122-5530	30
	GS0122-5535	35
	GS0122-5540	40
	GS0122-5545	45
	GS0122-5550	50
	GS0122-5555	55
	GS0122-5560	60
(Dia=6.5mm) 	GS0122-6520	20
	GS0122-6525	25
	GS0122-6530	30
	GS0122-6535	35
	GS0122-6540	40
	GS0122-6545	45
	GS0122-6550	50
	GS0122-6555	55
	GS0122-6560	60
(Dia=7.5mm) 	GS0122-7520	20
	GS0122-7525	25
	GS0122-7530	30
	GS0122-7535	35
	GS0122-7540	40
	GS0122-7545	45
	GS0122-7550	50
	GS0122-7555	55
	GS0122-7560	60

GSS (Global Standard Screw) System

IMPLANTS

GSS Set Screw

Feature	Cat.No	Length(mm)
	GS0104-0010	10mm(O.D)x 5.3mm(H)

GSS Transverse Link

Feature	Cat.No	Length(mm)
	GS0120-0035	35
	GS0120-0038	38
	GS0120-0042	42
	GS0120-0050	50

GSS Rod

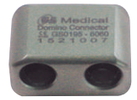
Feature	Cat.No	Length(mm)
	GS0150-0040	40
	GS0150-0050	50
	GS0150-0060	60
	GS0150-0070	70
	GS0150-0080	80
	GS0150-0090	90
	GS0150-0100	100
	GS0150-0110	110
	GS0150-0120	120
	GS0150-0130	130
	GS0150-0140	140
	GS0150-0150	150
	GS0150-0160	160
	GS0150-0170	170
	GS0150-0180	180
	GS0150-0190	190
	GS0150-0200	200
	GS0150-0250	250
	GS0150-0300	300
	GS0150-0350	350
	GS0150-0400	400
	GS0150-0500	500
	GS0150-0600	600

GSS ACCESSORY

Axial Rod Connector

Feature	Cat.No	Length(mm)
	GS0190-6060	11mm(O.D)x 29(L)

Domino Rod Connector

Feature	Cat.No	Length(mm)
	GS0195-6060	21mm(W)x 14(L)x11.5(H)

Lateral Rod Connector(Closed)

Feature	Cat.No	Length(mm)
	GS0192-0615	15
	GS0192-0620	20
	GS0192-0625	25
	GS0192-0630	30
	GS0192-0635	35
	GS0192-0640	40

Lateral Rod Connector(Open)

Feature	Cat.No	Length(mm)
	GS0191-0610	28
	GS0191-0615	33
	GS0191-0620	38
	GS0191-0625	43
	GS0191-0630	48
	GS0191-0635	53
	GS0191-0640	58

Lateral Rod Connector(Open)

Feature	Cat.No	Length(mm)
	GS0193-0615	15
	GS0193-0620	20
	GS0193-0625	25
	GS0193-0630	30
	GS0193-0635	35
	GS0193-0640	40

INSTRUMENTS

- Guide Pin(Left)

GS110-0110

- Guide Pin(Right)

GS110-0120

- Probe(curved)

GS110-0321

- Probe(straight)

GS110-0311

- AWL

GS110-0211

- Tester

GS110-0410

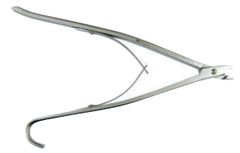
- Tap 4.0㎜ / 5.0㎜ / 6.0㎜ / 7.0㎜

GS110-0540
GS110-0550
GS110-0560
GS110-0570

- French Bender

GS110-1520

- Cutting Forcep



GS110-1410

- Rod Pusher

GS110-1711

- In-Situ Bender(Left)

GS110-1531

- Set Screw Driver(Short)

GS110-2420

- Mono Screw Driver / Poly Screw Driver
  Mono Reduction screw Dirver / Poly Reduction Screw Driver

GS110-0841
GS110-0941
GS110-0851
GS110-0951

- In-Situ Bender(Right)

GS110-1541

- Set Screw Driver(Long)

GS110-2430

GSS (Global Standard Screw) System

INSTRUMENTS

- Torque Limiting Set screw Driver

GS110-2441

- Persuader

GS110-1920

- Rod Fork

GS110-1811

- Transverse Wrench Tip

GS110-3311

- Transverse Driver Tip

GS110-3411

- T-Handle

GS110-0630

- T-Rachet Handle

GS110-0620

- Torque Limiting Hande

GS112-0610

- I-Handle

GS110-0640

- I-Rachet Handle

GS110-0610

- Rod Holder

GS110-1211

- Anti-Torque Wrench

GS110-2911

- Rod Clamp

GS110-1311

- Distractor

GS110-2811

- Compressor

GS110-2711

- Implant Tray

GS110-9011

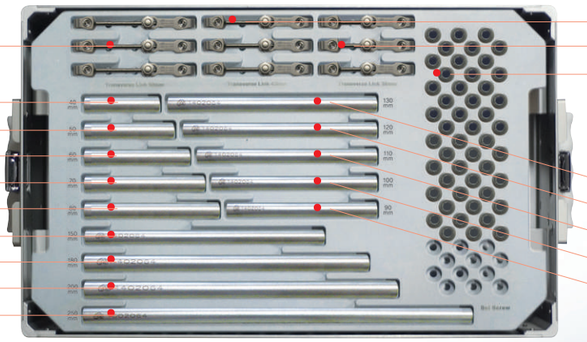
- Instrument Tray

GS110-9021

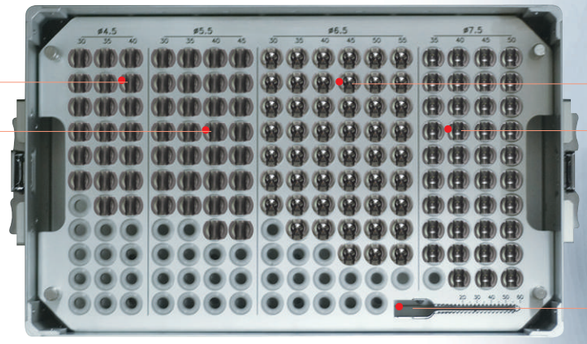
GSS (Global Standard Screw) System

Tray for IMPLANT

Top

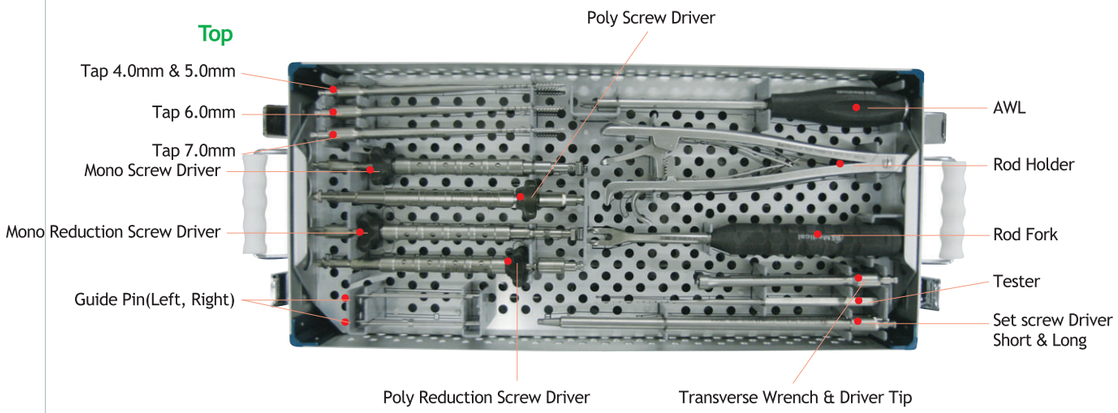


Bottom

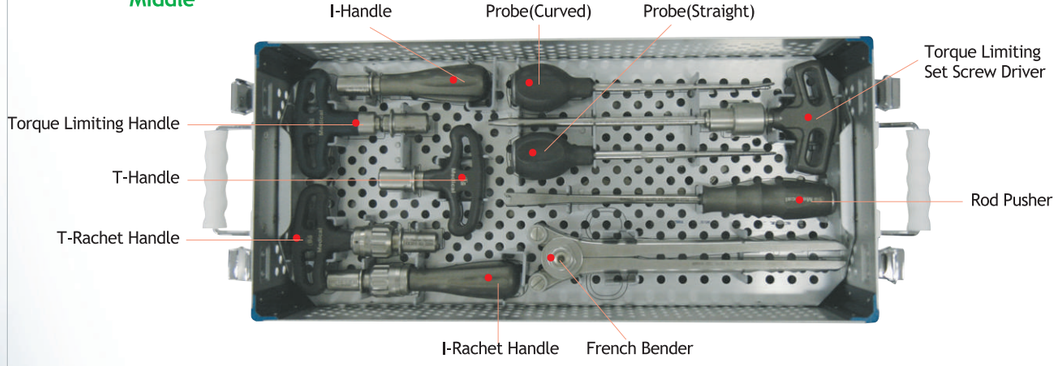


Tray for INSTRUMENT

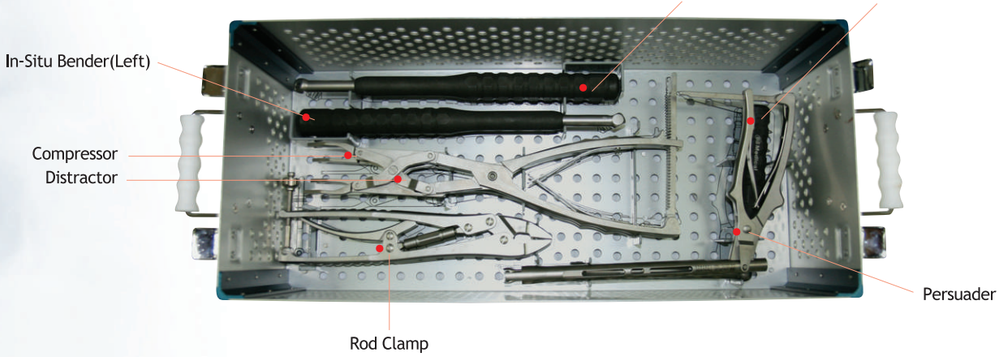
Top



Middle



Bottom



Important Information on the GSS Spinal System

PURPOSE

The GSS Spinal System is intended to help provide immobilization and stabilization of Spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION:

The GSS Spinal System consists of a variety of shapes and sizes of Rods, Screws, Transverse Link, as well as implant components which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.
GSS Spinal System implant components are made out of medical grade titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2. GS Medical expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the GSS Catalog for further information about warranties and limitations of liability.
Never use stainless steel and titanium implant components in the same construct. To achieve best results, do not use any of the GSS Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another GS Medical document. As with all orthopaedic and neurosurgical implants, none of the GSS Spinal System components should ever be refused under any circumstances.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS.

INDICATIONS:

The GSS System is intended for the following indications:
The GSS System is a non-cervical Spinal Fixation device intended for use as a posterior pedicle screw fixation system, a posterior non-pedicle screw fixation system, or as an anterolateral fixation system. Pedicle Screw Fixation is limited to skeletally mature patients.
The device is indicated for all of the following indications regardless of the intended use:
1. Degenerative Disc Disease(defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. Spondylolisthesis
3. Trauma (i.e. fracture or dislocation)
4. Spinal stenosis, deformities or curvatures (i.e, scoliosis, kyphosis, and/or lordosis)
5. Tumor
6. Pseudoarthrosis
7. Failed previous fusion

CONTRAINDICATIONS:

Contraindications include, but are not limited to:
1. Active infectious process or significant risk of infection (immunocomprise)
2. Signs of local inflammation
3. Fever or leukocytosis
4. Morbid obesity
5. Pregnancy
6. Mental illness
7. Grossly distorted anatomy caused by congenital abnormalities
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis.
   Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
10. Suspected or documented mental allergy or intolerance.
11. Any case not needing a bone graft and fusion
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result
13. Any case that requires that mixing of metals from two different components or systems.
14. Any patient giving inadequate tissue coverage over the operative site or inadequate bone stock of quality
15. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
16. Any patient unwilling to follow postoperative instructions
17. Any case not described in the indication

POSSIBLE 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:
1. Early or late loosening of any or all of the components
2. Disassembly, bending and/or breakage of any or all of the components
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from the component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, imitation, Fibrosis, necrosism, and/or pain. Bursitis, Tissue or never damage caused by improper positioning and placement of implants or instrument
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
6. Infection
7. Dural tears, pseudomeningocele, fistula, persistent CF leakage, meningitis
8. 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.
9. Cauda equine syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, imitation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain
12. Fracture, micro-fracture, 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.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stresses shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status
25. Death

None: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING AND PRECAUTIONS:

Federal law restricts this device to sale by or on the order of a licensed physician.
The safety and effectiveness of 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 and cervical spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).
Only experienced spinal surgeons should perform the implantation of spinal systems with specific training in the use of this spinal 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 should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

PHYSICIAN NOTE: Although the physician is the earned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient
CAUTION: National law restricts these devices to sale by or on the order of a physician.
CAUTION: FOR USE OR BY THE ORDER OF A PHYSICIAN ONLY.
Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

IMPLANT SELECTION:

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

Important Information on the GSS Spinal System

Device Fixation:
For self–breaking plugs, always hold the assembly with the Counter Torque device. Tighten and break–off the head of the Set Screw to leave the assembly at optimum fixation security. After the upper part of the self–breaking Set Screw has been sheared off, further re–tightening is not necessary and not recommended.
The head part should not remain in the patient. AFTER THE UPPER PART OF THE SELF BREAKING SET SCREW HAS BEEN SHEARED OFF, RE–ADJUSTMENT IS NOT POSSIBLE UNLESS THE SET SCREW IS REMOVED AND REPLACED WITH A NEW ONE.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical arts are involved, the surgeon should be familiar with the various components from another manufacturer. Different metal types should never be used together.
6. All components and instruments should be cleaned and sterilized before use.

Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. 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 as to create a flat, non–sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible use pre–cut rods of the length needed.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap.

Caution: Be careful that the guide wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide wire does not advance during tapping or screw insertion. Remove that the Guide–wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures. 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 the other possible adverse events listed elsewhere in this package insert.

6. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being used.
7. To assure maximum stability, use two more transverse link on two lower vertebrae being fused.
8. Bone cement should not be used because the safety and the effectiveness of bone cement has not been determined for spinal uses. And this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurological damage and bone necrosis.
9. Before closing the soft tissue, provisionally tighten (finger tighten) all of the set screws or screws, especially screws or set screws that have a break–off feature. Once this is completed go back and firmly tighten all of the screws and set screws. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other set screws or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patients, and the corresponding patient compliance, are extremely important. Detailed instructions on the used 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 which may occur as a result of excessive or early weight–bearing or muscular activity. The risk of bending loosening, or breakage of temporary internal fixation device during postoperative rehabilitation may be increased if the patient is activity, or if the patient is debilitate or demented. The patient should be wared to avoid falls or sudden jolts in spinal position. To allow the maximum chance for a successful surgical result, the patient or devices should not be exposed to mechanical vibration or shock that may loosen the device construct.
The patient should be warned of this possibility and instructed to limited and restrict physical activities, especially lifting and twisting motions and any type of sport 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 during the bone graft healing process. The patient should be advised to their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion. 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 banding, loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until from 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 closely supervised to insure cooperation until bony union is confirmed. 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.
The GSS 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 may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, 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. Any retrieved devices should be trained in such a manner that reuse in another surgical procedure is not possible.
As with all orthopedic implants, the GSS Spinal System components should never be reused under any circumstances.

PACKING:

The implants are delivered in packages; these must be intact at the time of receipt.
The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened GS Medical package, all instruments and implants must be disassembled and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product of GS Medical.
Cleaning and disinfecting of instruments can be performed with aldehyde–free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.
Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.
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.
Only sterile products should be placed in the operative field. For a 10–6 Sterility Assurance Level, these products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F(132°C)	4 Minutes
Steam	Gravity	250°F(121°C)	20 Minutes
Steam	Gravity	273°F(134°C)	20 Minutes

NOTE: Because of the many variables involved in sterilization, each medical should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. For outside the United States, some non–US, Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt–Jacob disease, especially of surgical instruments that could come onto contact with the central nervous system. Remove all packaging materials prior to sterilization.
Use only sterile products in the operative field.

PRODUCT COMPLIANTS

Any health professional having a compliant or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and/or its performance should notify GS Medical. Moreover, if a device malfunctioned, GS Medical or its distributor must be advised immediately.
If a GS Product has ever worked improperly and could have caused or contributed to the serious injury or death of a patient, the distributor must be informed as soon as possible by telephone, fax or in writing. For all complaints, please include the device name and reference along with the lot number of the component(s), your name and address and an exhaustive description of the event to help GS Medical understand the causes of the complaints. For further information or complaints, please contact as below address:

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