GS Medical

GSS™ 6.0 AND AnyPlus® 5.5

PEDICLE SCREW SYSTEMS

SURGICAL TECHNIQUE GUIDE

Comprehensive posterior pedicle screw systems for stabilizing the thoracic, lumbar and sacral spine.

GSMedicleUSA.com

GSS™ 6.0 AND AnyPlus® 5.5

PEDICLE SCREW SYSTEMS

WELCOME TO GS MEDICAL USA AND THE GSS™ 6.0 AND ANYPLUS® 5.5 PEDICLE SCREW SYSTEMS. OUR GOAL AT GS MEDICAL IS TO OFFER COST-CONTAINED PRODUCTS WITH SUPERIOR QUALITY THAT PROVIDE INNOVATIVE SOLUTIONS FOR SPINE SURGEONS AND THEIR PATIENT'S NEEDS. THE GSS™ 6.0 AND ANYPLUS® 5.5 PEDICLE SCREW SYSTEMS FOLLOW THIS IDEOLOGY, AND WERE DEVELOPED TO PROVIDE THE SURGEON WITH A COMPREHENSIVE, STATE-OF-THE-ART SYSTEM FOR STABILIZING THE THORACIC, LUMBAR AND SACRAL SPINE.

There are several key differentiating features and benefits one will find within these systems including, but not limited to:

- *Unique buttress style cylindrical thread design optimizes a solid screw purchase to the vertebral bodies and pedicles*
- *Polyaxial screw head has a wide 40 Degree range of motion to position screw head and adjust in multiple planes for ease of insertion*
- *Ample variety of screw diameter and lengths available to meet surgeon preference and address any patient anatomical variants encountered by the surgeon*
- *Monoaxial screw option*
- *Reduction screw option*
- *Crosslink option*

All implants are made of TI-6AI-AV (ASTM F1 36-98), and are combined with biomechanical properties for advanced strength, stability and MRI scan compatibility.

It is our goal at GS Medical to continue to render new technology, whereby surgeons have a complete system for addressing degenerative thoracic, lumbar and sacral spinal conditions. The following surgical technique guide provides a sequential delineation of the product(s) and their use within the surgical setting, as well as a complete listing of the accompanying instrumentation.

GSS™ 6.0 AND AnyPlus® 5.5

PEDICLE SCREW SYSTEMS

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Intended Use

THE GSS™ AND ANYPLUS® PEDICLE SCREW SYSTEMS ARE NON-CERVICAL SPINAL FIXATION SYSTEMS AND WERE DEVELOPED TO PROVIDE SURGEONS WITH STRAIGHTFORWARD, WELL-DESIGNED, COMPREHENSIVE IMPLANT OPTIONS TO ACCOMMODATE ANATOMICAL PATIENT VARIATIONS, AND TO ADDRESS A MYRIAD OF SPINAL DISORDERS. THE FOLLOWING LIST IDENTIFIES INDICATIONS AND CONTRAINDICATIONS FOR APPROPRIATE USE OF THE GSS™ AND ANYPLUS® PEDICLE SCREW SYSTEMS.

Indications

(when fusion is necessary for any or all of the following spinal conditions):

- *Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;*
- *Spinal Stenosis;*
- *Disc herniation;*
- *Tumor;*
- *Isthmic Spondylolisthesis;*
- *Trauma: (i.e., fractures or dislocation);*
- *Deformities or curvatures (i.e., Scoliosis, Hyper-Kyphosis or Hypo-Kyphosis);*
- *Degenerative Spondylolisthesis;*
- *Pseudoarthrosis*

This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding (should only be performed after thorough training on instrumentation). Each surgeon must consider the particular needs of the patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for each insert for complete system descriptions, indications and warning. Additional questions should be directed to GS Medical USA, 1-866-904-8144.

Differentiating Features

Between the GSS™ 6.0 & AnyPlus® 5.5 Pedicle Screw Systems

In order to efficiently meet the needs of our surgeons we have created this technique guide combining the GSS™ 6.0 & AnyPlus® 5.5 Pedicle Screw Systems steps of use.

The GSS™ 6.0 & AnyPlus® 5.5 Pedicle Screw Systems are not interchangeable. The instrumentation in each of the sets has been specifically designed to accommodate the 5.5mm and 6.0mm rods and screws. The corresponding instruments should only be used with the designated sets.

The following key instruments should be kept separate:

- *Screw drivers*
- *Rods*
- *Pedicle screws*
- *Set screws*
- *Rod holders*
- *Rod reduction sheaths*
- *Rod rocker*
- *In-Situ Benders*

5.5 Anyplus Screw/Driver Interface

- *Secure cross pattern screw driver to tulip head interface*
- *Specifically designed to accommodate 5.5mm rod*
- *Set screws can be used with AnyPlus or AnyPlus NX Systems*

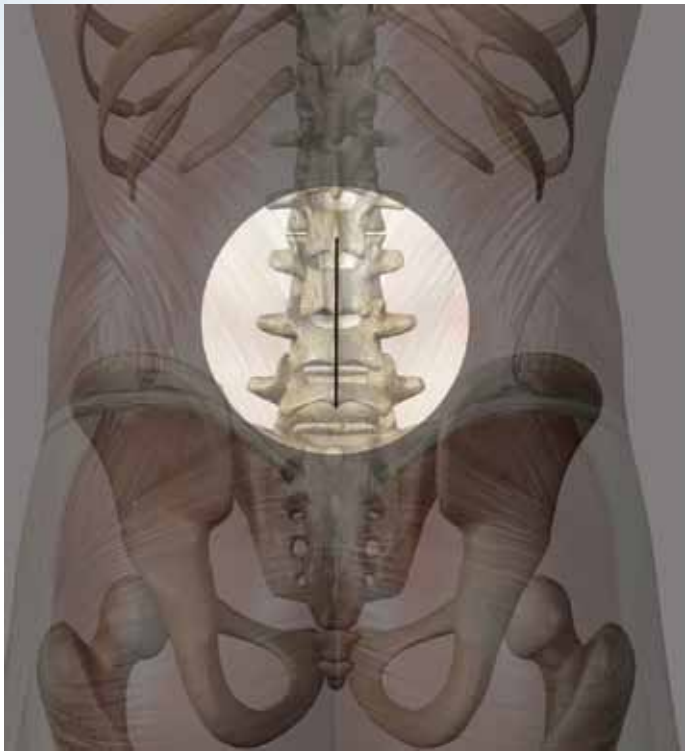
6.0 GSS Screw/Driver Interface

- *Strong three prong screw driver to tulip head interface*
- *Specifically designed to accommodate 6.0mm rod*
- *Set screws only work with GSS Pedicle Screws*

Surgical Technique Steps 1 2

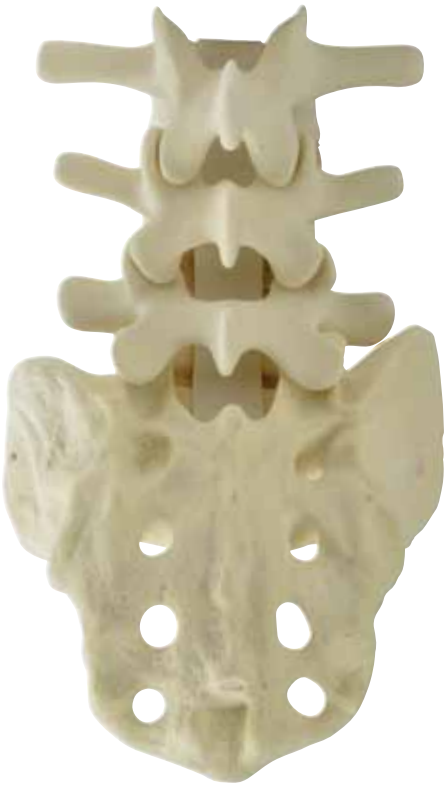
STEP 1
Patient Positioning & Incision

Place patient prone on radiolucent operating table and verify correct anatomical spinal alignment. Position the patient on operating table of choice (pads, frame, gel rolls) to allow for appropriate physiologic lumbar lordosis and thoracic kyphosis. Next locate appropriate operative levels by referencing radiographic images or topographical landmarks and mark intended incision. After skin prep apply sterile drapes around incision site and make incision.



STEP 2
Standard Operative Exposure of Bony Landmarks

Perform subperiosteal dissection to expose bony elements where fusion will occur.



Surgical Technique Steps

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STEP 3
Pedicle Identification & Preparation

Locate the pedicle landmark and use **GSS Awl** to breach the bony cortex. Remove the **GSS Awl** and insert the **GSS Probe** or **Thoracic Bone Probe** to identify the pedicle canal. Once exposed, the **Ball Tip Tester** can be inserted to confirm pedicle integrity, orientation and depth.

Optional: Taps, corresponding to available screw sizes, may be used to further prepare the pedicle depending upon surgeon preference and bone quality. GS Medical screws are self-tapping and may eliminate the need to use the Tap, unless bone structure is very dense. Please note that the taps 0.5mm undersized

Instruments used:
Curved Thoracic Bone Probe, Straight Thoracic Bone Probe, GSS Probe (Curved), GSS Probe (Straight), GSS Awl, Ball Tip Tester, Tap 4.5mm, Tap 5.5mm, Tap 6.5mm, Tap 7.5mm, Tap 8.5mm

Surgical Technique Steps

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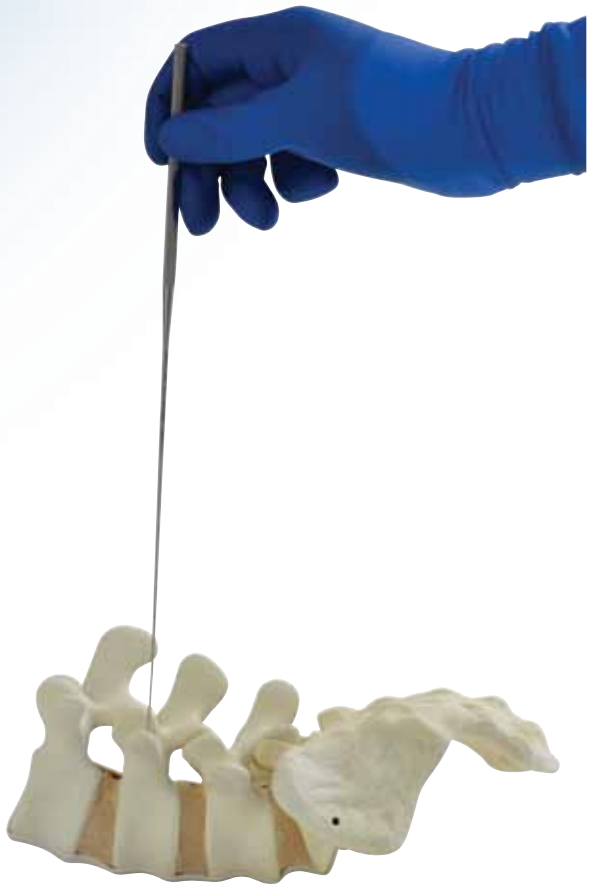
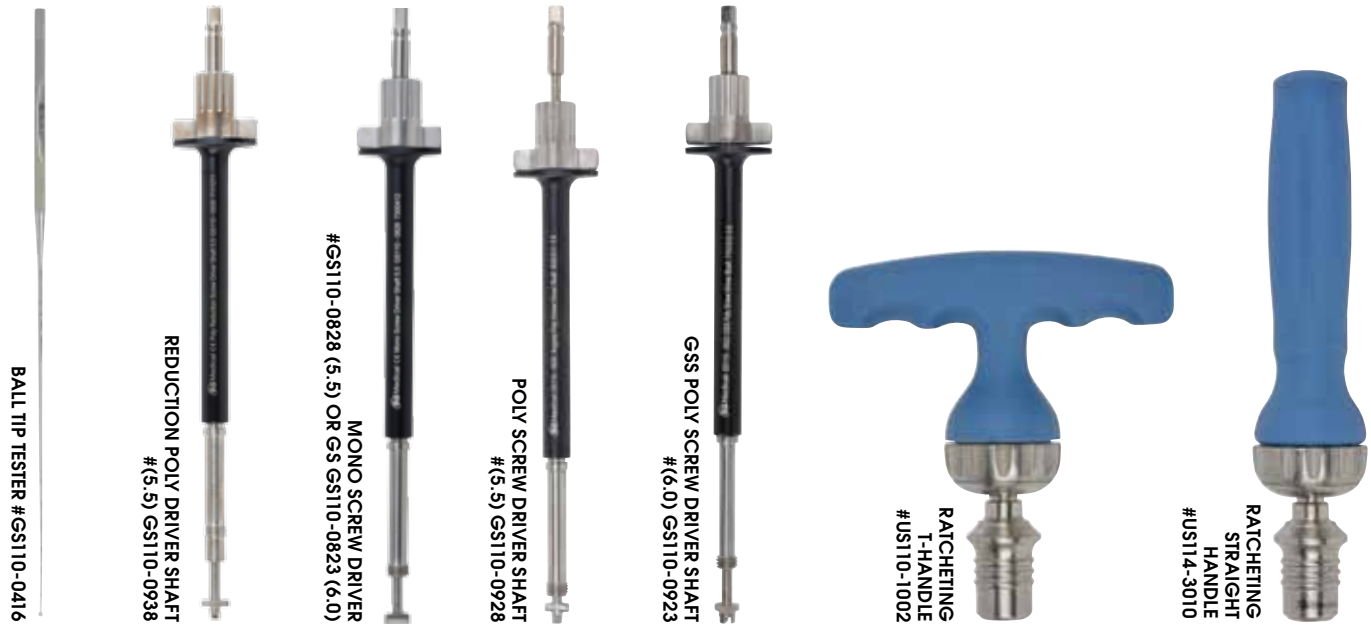
STEP 4
Screw Length Determination and Screwdriver Assembly

The **Pedicle Probe** comes equipped with depth markers along the insertion shaft and can be used to determine appropriate screw length. Once screw length is confirmed, load selected implant onto **Poly Screw Driver Shaft** and attach preferred handle. Loading of the screw is easiest from the screw caddy. Always measure screw sizes before implanting. Once assembled, insert screw into prepared pedicle pathway.

Note: GS Medical screw caddy's come equipped with built-in measuring blocks.



Instruments used:
Ball Tip Tester, Poly Reduction Screw Driver , Mono Screw Driver, Ratcheting T-Handle, Ratcheting Straight Handle



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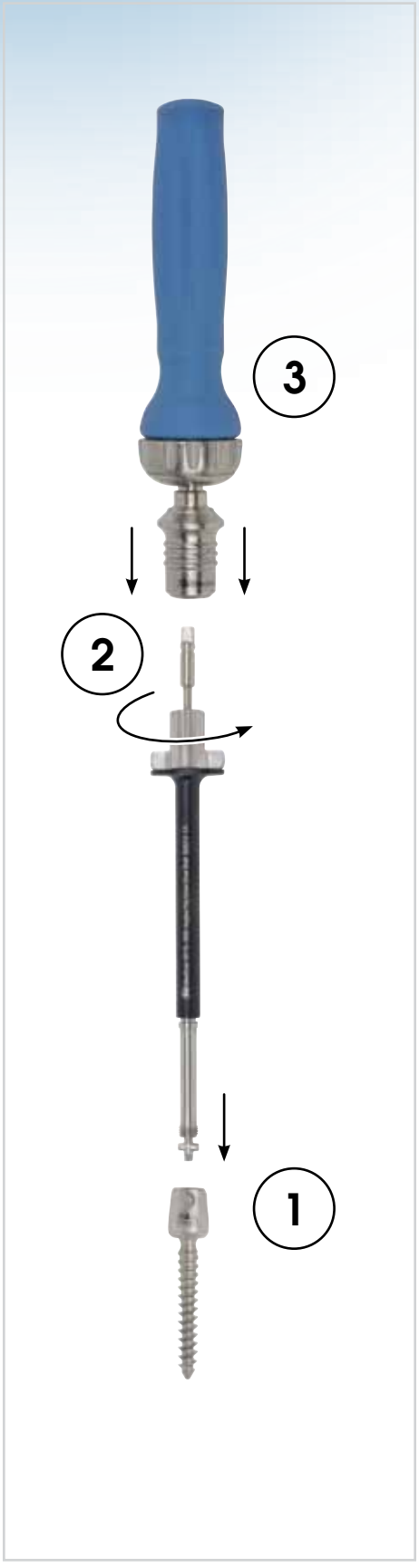
STEP 4 *continued*
Screwdriver and Screw Assembly

Select poly **Screwdriver** shaft. Attach the **Ratcheting Straight Handle** or **Ratcheting T-Handle** using the forward/reverse collar to the **Screwdriver** shaft by rotating in a clockwise direction. Align **Screwdriver** with screw, engage screw head to tip of **Screwdriver**, turn clockwise while applying firm pressure to secure connection. Connection is secured by threading the locking portion prongs of the **Screwdriver** into the screw head and sliding the sleeve down the **Screwdriver** shaft.



Surgical Technique Steps

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STEP 5
Screw Insertion

Insert screw into prepared pedicle pathway and rotate **Screwdriver** clockwise to advance screw in the pedicle. Release **Screwdriver** by rotating the sleeve counterclockwise. Repeat aforementioned steps 3 and 4 for each level of screw insertion. NOTE: If screw placement requires adjustment, use the **Screw Adjuster Shaft** to raise or lower screw to appropriate dorsal height. Additionally, it is pertinent that all screw heads align prior to rod application. Surgeon may elect to use **Poly Head Screw Adjuster** if necessary to align screw heads before proceeding. If reduction screws are implanted, use the **Long Arm Tab Breakers** to break off the long arm extension tabs from the screw heads.

Surgeon should note that only after distraction/ compression, final screw and rod tightening is performed, should the long tabs be broken off.

Optional: Radiograph or Neuromonitoring devices can be used to confirm appropriate screw placement prior to rod application.

Instruments used:
Poly Screw Driver, Mono Screw Driver, Poly Reduction Screw Driver, Poly Head Screw Adjuster, Long Arm Tab Breakers and Screw adjuster shaft

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STEP 6
Rod Contour and Length Determination

Select appropriate rod length to span construct. Rods are available in both straight and contoured options. If rod requires further contouring, use the **French Rod Bender** to bend rod to desired curvature. Additionally, **French Rod Bender** has an adjustment wheel to measure for rod diameter.

*Optional: The **In-Situ Bender** instruments are available, specified left or right approach, if the rod needs contouring and is already partially or fully seated in screw heads.*

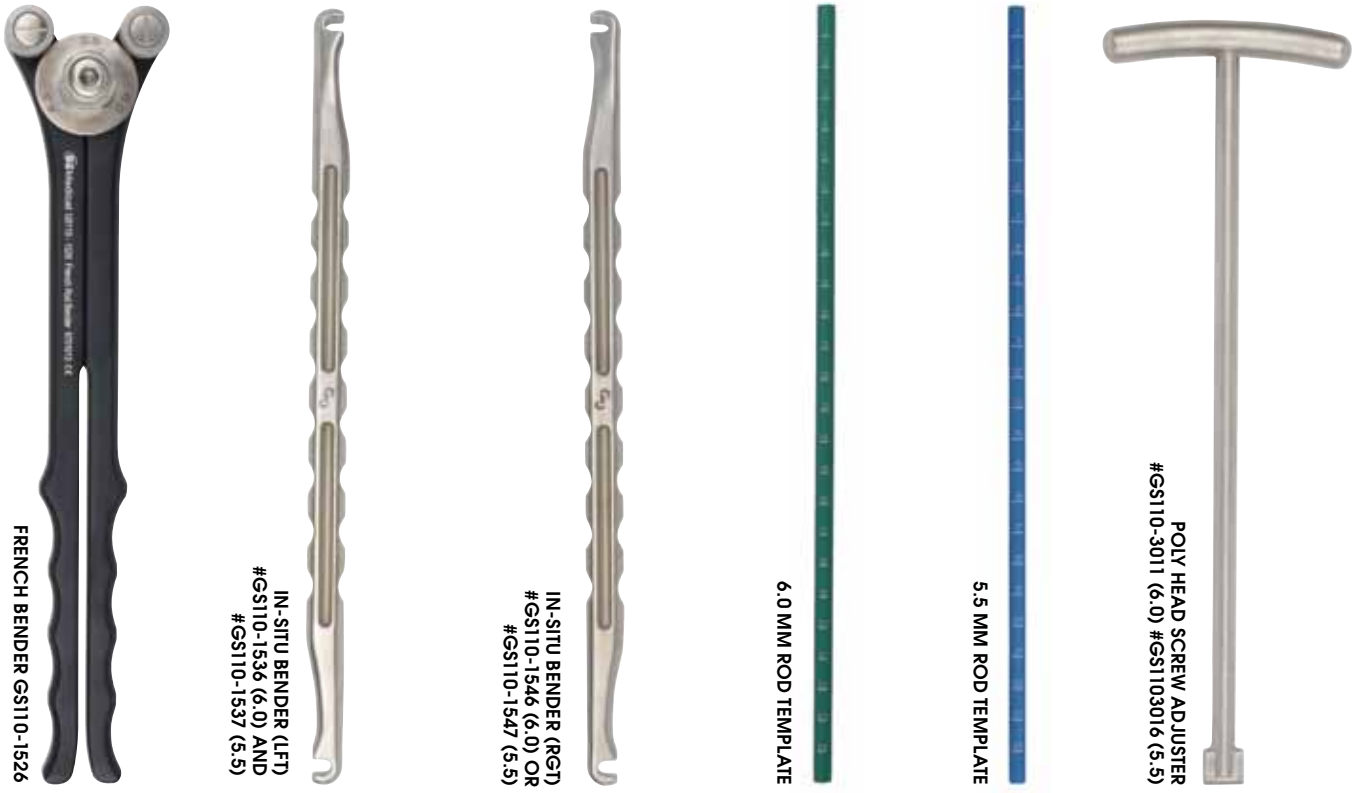
Optional: Rod template available for purchase, not included in standard set.

STEP 7
Rod Application – Placement

The **Poly Head Screw Adjuster** can be used to align screw heads prior to insertion of the rod. Grasp the rod using the **Ring-Handle Rod Holder**, position rod in screw heads and seat fully into screw.

*Note: GS Medical rods come premarked with a longitudinal rod marking along the vertical axis. This rod marking will allow the surgeon to align GS Medical's **French Bender** accordingly, and assist the surgeon with multi-planer rod contouring.*

Instruments used:
Poly Head Screw Adjuster, French Bender, In-Situ Bender (LFT) 6.0 or 5.5, In-Situ Bender (RGT)6.0 or 5.5, 6.0 mm Rod Template, 5.5 mm Rod Template



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STEP 8
Locking Set Screw Insertion

Attach set screw to **Set Screw Starter.** The set screw is securely loaded onto set screw starter by placing the set screw onto a flat surface and engaging with driver with direct downward pressure. Align **Set Screw Starter** assembly axially with screw head and turn clockwise to engage locking set screw.

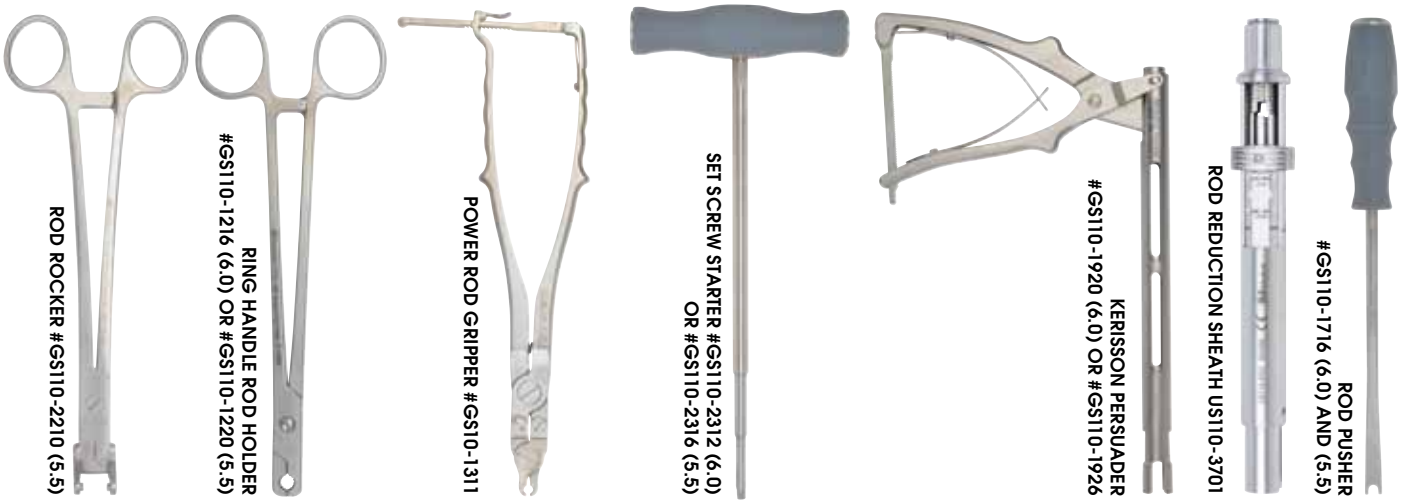
SET SCREW STARTER

STEP 9
Rod Reduction

If additional reduction is necessary, GS Medical offers four options for rod reduction. These include; the **Rod Pusher, Rod Rocker, Kerrison Persuader,** and the **Rod Reduction Sheath.**

*Note: GS Medical offers the **Rod Gripper**, which can be special ordered from our Deformity Set, and can assist the surgeon with more robust rod reductions.*

Instruments used:
Rod Rocker, Power Rod gripper, Set Screw Starter, Kerrison Persuader 5.5 and 6.0, Rod Reduction Sheath 5.5, Ring Handle Rod Holder 6.0 or 5.5, Rod Pusher 6.0 and 5.5



ROD ROCKER #GS110-2210 (5.5)

RING HANDLE ROD HOLDER #GS110-1216 (6.0) OR #GS110-1220 (5.5)

POWER ROD GRIPPER #GS10-1311

SET SCREW STARTER #GS110-2312 (6.0) OR #GS110-2316 (5.5)

KERISSON PERSUADER #GS110-1920 (6.0) OR #GS110-1926

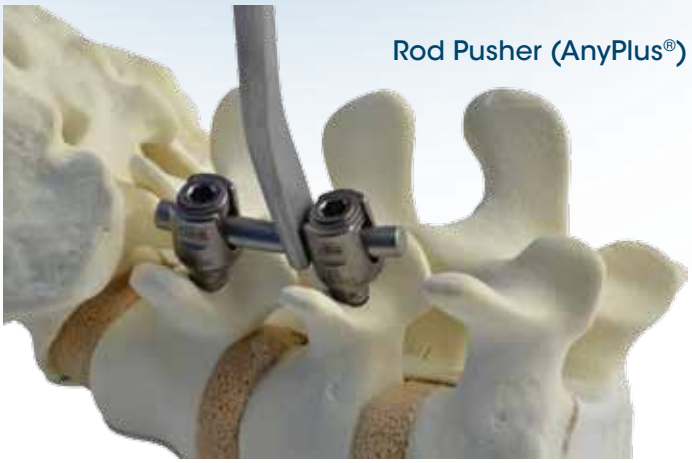
ROD REDUCTION SHEATH US110-3701

ROD PUSHER #GS110-1716 (6.0) AND (5.5)

Rod Reduction Techniques 9

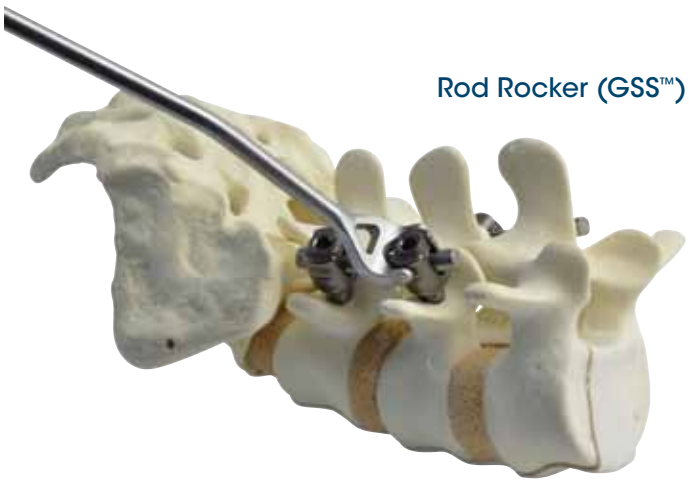
STEP 9 *continued*
Rod Reduction

ROD PUSHER (ANYPLUS®)
The **Rod Pusher** can be used when a minor gap exists between the rod and screw tulip head. Simply situate device on rod next to the tulip head of the pedicle screw and apply downward pressure to seat rod.



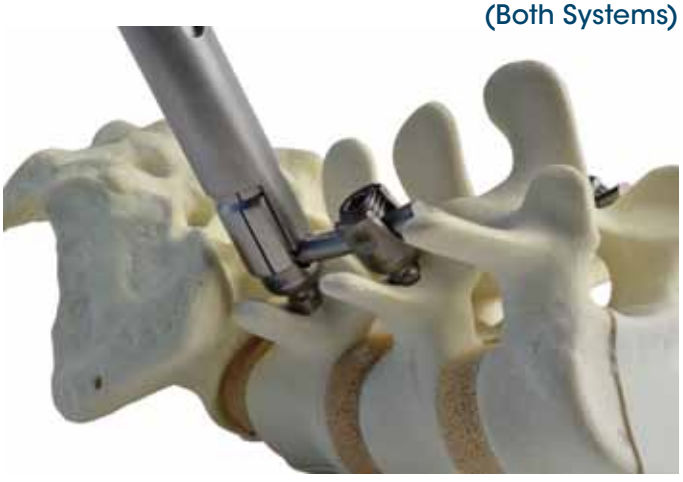
Rod Pusher (AnyPlus®)

ROD ROCKER (GSS™)
The **Rod Rocker** and AnyPlus® systems can also be used for slight reductions to fully seat the rod. The fork rounded ends fit over the lateral ridges on the tulip head of the pedicle screws. Proceed with reduction by pushing backward on the handle. This motion positions the rod into the head of the implant.



Rod Rocker (GSS™)

KERRISON PERSUADER (BOTH SYSTEMS)
The **Kerrison Persuader** is used for more substantial reductions. To use the **Kerrison Persuader**, position the instrument parallel to the rod and simultaneously engage the rod and screw head by squeezing the handles. When the desired amount of reduction has been achieved, insert the set screw through the **Kerrison Persuader** shaft using the Set Screw Starter.



Kerrison Persuader (Both Systems)

Surgical Technique Steps 9

STEP 9 *continued*

ROD REDUCTION SHEATH (ANYPLUS)
Place the **Reduction Sheath** with attached handle over the head of the tulip. Ensure the hinges of the tip of the reducer align with the grooves on the tulip head of the pedicle screw. Press downward on the reducer sheath ring. This will lock the tower onto the top of the pedicle screw. To complete reduction, turn the universal handle clockwise until desired reduction has been achieved. Slide up on reduction sheath ring to remove.

STEP A

STEP B

STEP C

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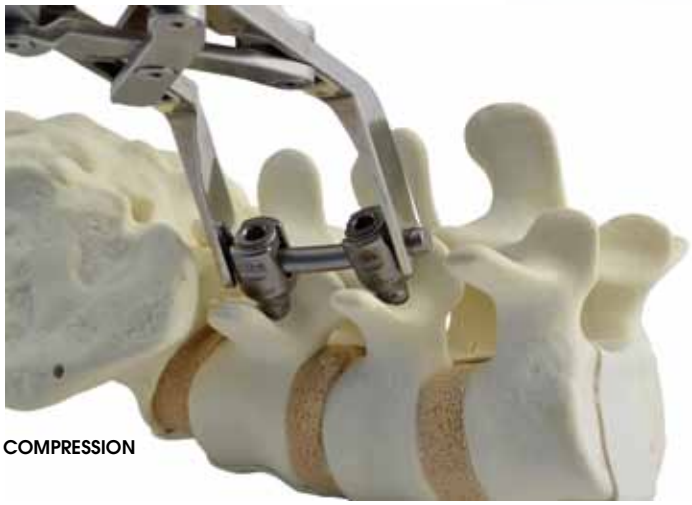
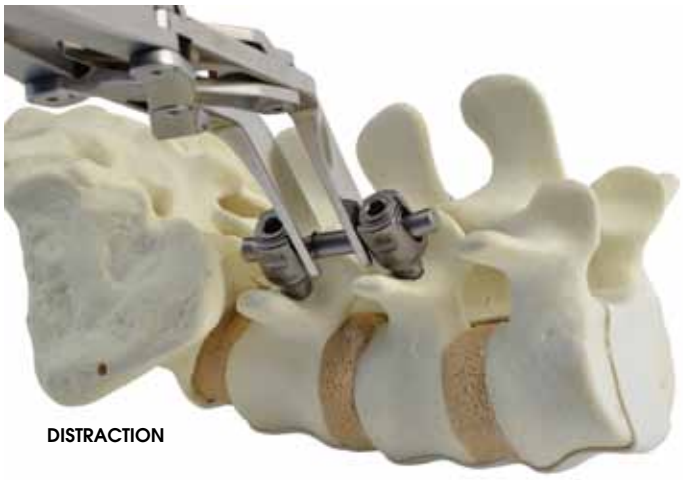
STEP 10
Compression and/or Distraction (If Indicated)

The **Compressor** allows the surgeon to approximate the pedicle screw implants. Compression can be accomplished by locking one implant, placing the instrument on the caudal and cephalad ends of the implants to be compressed, and finally squeezing the **Compressor** until the desired amount of compression is achieved. Conversely, the **Distractor** allows the surgeon to increase distance between implants. Affix the **Distractor** between the two screw heads to be distracted and squeeze the instrument until the desired level of distraction is accomplished.



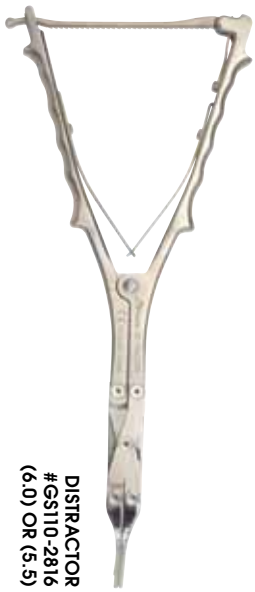
COMPRESSION



DISTRACTION

Instruments used: Compressor and Distractor

COMPRESSOR #GS110-2716 (5.5) AND (6.0)



DISTRACTOR #GS110-2816 (6.0) OR (5.5)

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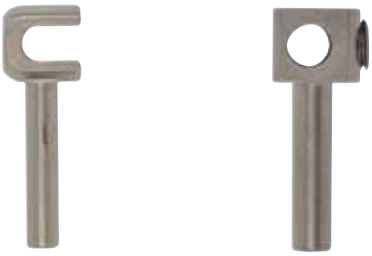
STEP 11
Deformity Correction

(available by order as an optional additional instrument set)

For additional options for deformity correction GS medical offers an additional set of implant and instrumentation options, including; **offset connectors, domino connectors and axial connectors.**

Offset connectors offer medial/lateral adjustability. These open and closed connectors are available in lengths of 15-40mm (in 5mm increments).



Domino Connectors (closed), Domino Connector (open), and **Axial Connectors allow** for 5.5mm x 5.5mm, 6.0mm x 6.0mm, 6.0mm x 5.5mm, and 5.5mm x 6.0mm rod to rod connections.

CLOSED OPEN

The Deformity Set comes standard with straight rod sizes up to 500mm.

To assist in the contouring of rods the deformity set offers the **Power Rod Gripper** and the **Rod Gripper.**

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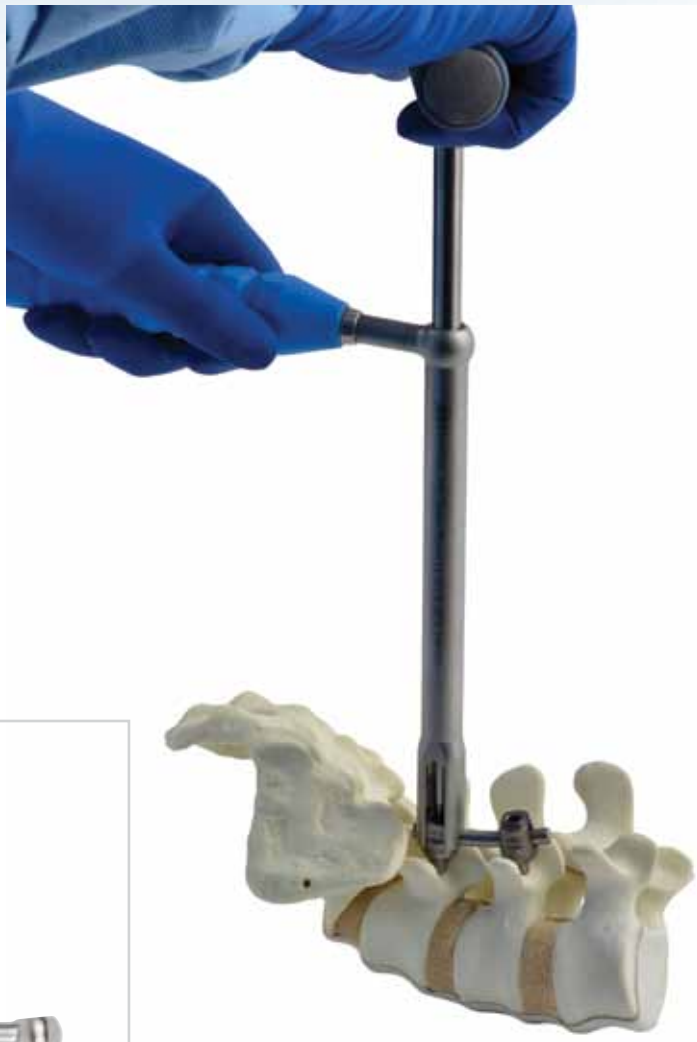
STEP 12
Final Tightening

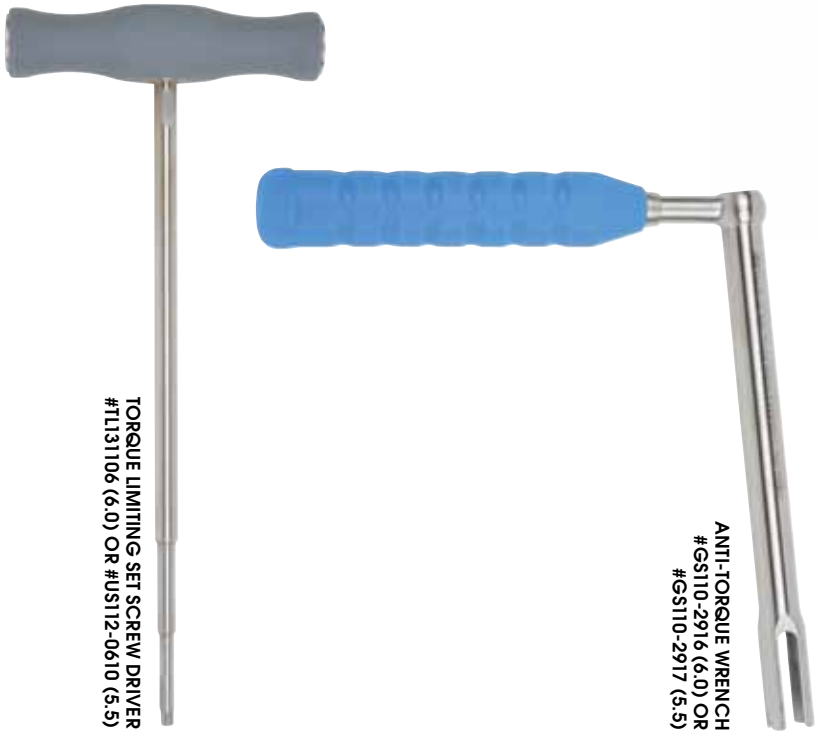
Final tightening is achieved by affixing the Anti-Torque wrench to the tulip head of the pedicle screw (either parallel or perpendicular to the rod). The Torque Limiting Set Screw Driver is then inserted into the **Anti-Torque Wrench** and 12 NM of pressure is applied for final tightening. An audible double click will be heard when final tightening has been achieved.

Note: If reduction screws were implanted during the procedure, make certain to break off screw tabs and remove from surgical field prior to closing the wound.

Note: Anti-Torque Wrench is appropriately engaged when smaller opening is affixed around rod.



Instruments used:
Anti-Torque Wrench, Torque Limiting Set Screw Driver



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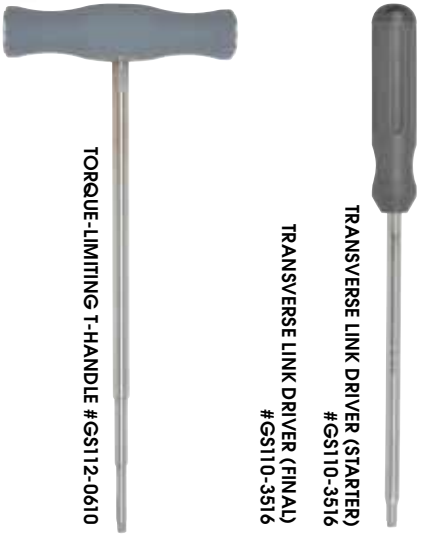
STEP 13
Connector Application (If Necessary)

CROSS LINK

GS Medical transverse connectors come pre-contoured, ready for implantation and are arch-designed to accommodate bone grafting. 5Nm (affix the 5Nm **Torque Limiting T-Handle**) on the **Transverse Link Driver (Starter)**. Use this instrument assembly to affix the crosslink to the rod on each side of the construct. Thereafter, secure and torque the nut on one side of the crosslink, and then the opposing side. Finally, tighten the middle nut. At each step, listen for the audible double click to ensure cross connector is correctly tightened. The **Transverse Link Driver (Final)** can be used as a final tightening agent.

Connectors are adjustable and come in a variety of lengths to accommodate patient anatomical variations.

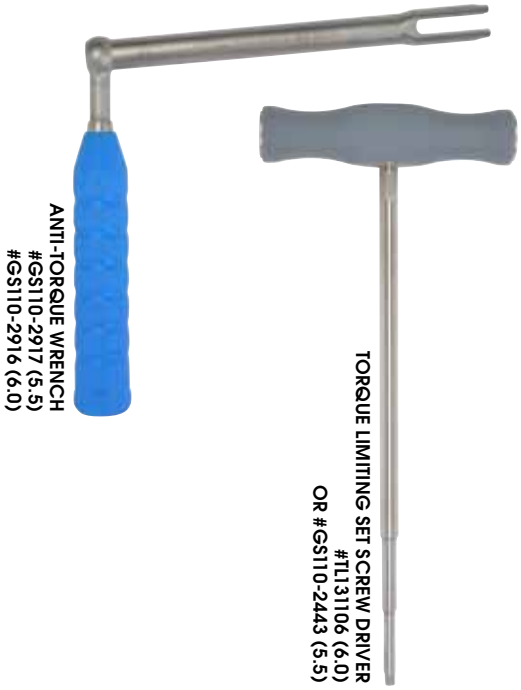
Instruments used:
Torque-Limiting T-Handle, Transverse Link Driver (Starter), Transverse Link Driver (Final)



STEP 14
Unlocking and Removal Technique

If it is necessary that any part of the construct should need revision or removal, the **Anti-Torque Wrench** and **Set Screw Driver** can be used to loosen previously tightened locking set screws. Removal of the system is performed by reversing the order of the implant procedure.

Instruments used:
Anti-Torque Wrench, Torque Limiting Set Screw Driver



GSS™ Implants

GSS™ Mono-Axial Pedicle Screw
DIAMETER 4.5mm

CATALOG NUMBER	LENGTH (MM)
GS0101 - 4535	35
GS0101 - 4540	40
GS0101 - 4545	45
GS0101 - 4550	50

GSS™ Mono-Axial Pedicle Screw
DIAMETER 5.5mm

CATALOG NUMBER	LENGTH (MM)
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

GSS™ Mono-Axial Pedicle Screw
DIAMETER 6.5mm

CATALOG NUMBER	LENGTH (MM)
GS0101 - 6530	30
GS0101 - 6535	35
GS0101 - 6540	40
GS0101 - 6545	45
GS0101 - 6550	50
GS0101 - 6555	55

GSS™ Mono-Axial Pedicle Screw
DIAMETER 7.5mm

CATALOG NUMBER	LENGTH (MM)
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 - 7565	60

GSS™ Mono-Axial Pedicle Screw
DIAMETER 8.5mm

CATALOG NUMBER	LENGTH (MM)
GS0101 - 8530	30
GS0101 - 8535	35
GS0101 - 8540	40
GS0101 - 8545	45
GS0101 - 8550	50
GS0101 - 8555	55

GSS™ Mono-Axial Pedicle Screw
DIAMETER 9.5mm

CATALOG NUMBER	LENGTH (MM)
GS0101 - 9535	35
GS0101 - 9540	40
GS0101 - 9545	45
GS0101 - 9550	50
GS0101 - 9580	80
GS0101 - 9590	90

GSS™ Poly-Axial Pedicle Screw
DIAMETER 4.5mm

CATALOG NUMBER	LENGTH (MM)
GS0102 - 4530	30
GS0102 - 4535	35
GS0102 - 4540	40
GS0102 - 4545	45
GS0102 - 4550	50
GS0102 - 4555	55

GSS™ Poly-Axial Pedicle Screw
DIAMETER 5.5mm

CATALOG NUMBER	LENGTH (MM)
GS0102 - 5530	30
GS0102 - 5535	35
GS0102 - 5540	40
GS0102 - 5545	45
GS0102 - 5550	50
GS0102 - 5555	55

GSS™ Poly-Axial Pedicle Screw
DIAMETER 6.5mm

CATALOG NUMBER	LENGTH (MM)
GS0102 - 6530	30
GS0102 - 6535	35
GS0102 - 6540	40
GS0102 - 6545	45
GS0102 - 6550	50
GS0102 - 6555	55
GS0102 - 6560	60

GSS™ Poly-Axial Pedicle Screw
DIAMETER 7.5mm

CATALOG NUMBER	LENGTH (MM)
GS0102 - 7530	30
GS0102 - 7535	35
GS0102 - 7540	40
GS0102 - 7545	45
GS0102 - 7550	50
GS0102 - 7555	55
GS0102 - 7560	60
GS0102 - 7565	65
GS0102 - 7570	70
GS0102 - 7575	75
GS0102 - 7580	80
GS0102 - 7590	90

GSS™ Poly-Axial Pedicle Screw
DIAMETER 8.5mm

CATALOG NUMBER	LENGTH (MM)
GS0102 - 8535	35
GS0102 - 8540	40
GS0102 - 8545	45
GS0102 - 8550	50
GS0102 - 8555	55
GS0102 - 8560	60
GS0102 - 8565	65
GS0102 - 8570	70
GS0102 - 8575	75
GS0102 - 8580	80
GS0102 - 8590	90

GSS™ Implants

GSS™ Poly-Axial Reduction Screw
DIAMETER 4.5mm

CATALOG NUMBER	LENGTH (MM)
GS0122 - 4525	25
GS0122 - 4530	30
GS0122 - 4535	35
GS0122 - 4540	40
GS0122 - 4545	45

GSS™ Poly-Axial Reduction Screw
DIAMETER 5.5mm

CATALOG NUMBER	LENGTH (MM)
GS0122 - 5530	30
GS0122 - 5535	35
GS0122 - 5540	40
GS0122 - 5545	45
GS0122 - 5550	50
GS0122 - 5555	55
GS0122 - 5560	60

GSS™ Poly-Axial Reduction Screw
DIAMETER 6.5mm

CATALOG NUMBER	LENGTH (MM)
GS0122 - 6530	30
GS0122 - 6535	35
GS0122 - 6540	40
GS0122 - 6545	45
GS0122 - 6550	50
GS0122 - 6555	55
GS0122 - 6560	60

GSS™ Poly-Axial Reduction Screw
DIAMETER 7.5mm

CATALOG NUMBER	LENGTH (MM)
GS0122 - 7530	30
GS0122 - 7535	35
GS0122 - 7540	40
GS0122 - 7545	45
GS0122 - 7550	50
GS0122 - 7555	55
GS0122 - 7560	60

GSS™ Poly-Axial Reduction Screw
DIAMETER 8.5mm

CATALOG NUMBER	LENGTH (MM)
GS0122 - 8535	35
GS0122 - 8540	40
GS0122 - 8545	45
GS0122 - 8550	50

GSS™ Set Screw DIAMETER 5.5mm

CATALOG NUMBER	LENGTH (MM)
GS0104 - 0010	10mm(O.D)X 5.3mm(H)

GSS™ Transverse Connector (Version. 1)

CATALOG NUMBER	LENGTH (MM)
GS0120 - 0035	35
GS0120 - 0038	38
GS0120 - 0042	42
GS0120 - 0050	50

GSS™ Transverse Connector (Version. 3)

CATALOG NUMBER	LENGTH (MM)
GS1306 - 6030	30
GS1306 - 6035	35
GS1306 - 6040	40
GS1306 - 6050	50

GSS™ Implants

ACCESSORIES

Axial Rod Connector

CATALOG NUMBER	LENGTH (MM)
GS0190 - 6060	11mm (0.D) X 29(L)

Domino Rod Connector

CATALOG NUMBER	LENGTH (MM)
GS0195 - 6060	10mm(0.D)X 14(L)X11.5(H)

Lateral Rod Connector (Closed)

CATALOG NUMBER	LENGTH (MM)
GS0192 - 0615	15
GS0192 - 0620	20
GS0192 - 0625	25
GS0192 - 0630	30
GS0192 - 0635	35
GS0192 - 0640	40

Lateral Rod Connector (Open)

CATALOG NUMBER	LENGTH (MM)
GS0193 - 0610	28
GS0193 - 0615	33
GS0193 - 0620	38
GS0193 - 0625	43
GS0193 - 0630	48
GS0193 - 0635	53
GS0193 - 0640	58

GSS™ Straight Rod DIAMETER 6.0mm

CATALOG NUMBER	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™ Rod Prebent DIAMETER 6.0mm

CATALOG NUMBER	LENGTH (MM)
GS0160 - 0035	35
GS0160 - 0040	40
GS0160 - 0050	60
GS0160 - 0060	60
GS0160 - 0070	70
GS0160 - 0080	80
GS0160 - 0090	90
GS0160 - 0100	100
GS0160 - 0110	110
GS0160 - 0120	120

AnyPlus® 5.5 Implants

AnyPlus® Mono-Axial Pedicle Screw DIAMETER 4.5mm

CATALOG NUMBER	LENGTH (MM)
0911-4525	25
0911-4530	30
0911-4535	35
0911-4540	40
0911-4545	45
0911-4550	50
0911-4555	55
0911-4560	60
0911-4565	65
0911-4570	70

AnyPlus® Mono-Axial Pedicle Screw DIAMETER 5.5mm

CATALOG NUMBER	LENGTH (MM)
0911-5525	25
0911-5530	30
0911-5535	35
0911-5540	40
0911-5545	45
0911-5550	50
0911-5555	55
0911-5560	60
0911-5565	65
0911-5570	70

AnyPlus® Mono-Axial Pedicle Screw DIAMETER 6.5mm

CATALOG NUMBER	LENGTH (MM)
0911-6525	25
0911-6530	30
0911-6535	35
0911-6540	40
0911-6545	45
0911-6550	50
0911-6555	55
0911-6560	60
0911-6565	65
0911-6570	70

AnyPlus® Mono-Axial Pedicle Screw DIAMETER 7.5mm

CATALOG NUMBER	LENGTH (MM)
0911-7525	25
0911-7530	30
0911-7535	35
0911-7540	40
0911-7545	45
0911-7550	50
0911-7555	55
0911-7560	60
0911-7565	65
0911-7570	70

AnyPlus® Mono-Axial Pedicle Screw DIAMETER 8.5mm

CATALOG NUMBER	LENGTH (MM)
0911-8525	25
0911-8530	30
0911-8535	35
0911-8540	40
0911-8545	45
0911-8550	50
0911-8555	55
0911-8560	60
0911-8565	65
0911-8570	70

AnyPlus® Poly-Axial Pedicle Screw DIAMETER 4.5mm

CATALOG NUMBER	LENGTH (MM)
0921-4525	25
0921-4530	30
0921-4535	35
0921-4540	40
0921-4545	45
0921-4550	50
0921-4555	55
0921-4560	60
0921-4565	65
0921-4570	70

AnyPlus® Poly-Axial Pedicle Screw DIAMETER 5.5mm

CATALOG NUMBER	LENGTH (MM)
0921-5525	25
0921-5530	30
0921-5535	35
0921-5540	40
0921-5545	45
0921-5550	50
0921-5555	55
0921-5560	60
0921-5565	65
0921-5570	70

AnyPlus® Poly-Axial Pedicle Screw DIAMETER 6.5mm

CATALOG NUMBER	LENGTH (MM)
0921-6525	25
0921-6530	30
0921-6535	35
0921-6540	40
0921-6545	45
0921-6550	50
0921-6555	55
0921-6560	60
0921-6565	65
0921-6570	70
0921-6580	80
0921-6590	90

AnyPlus® Poly-Axial Pedicle Screw DIAMETER 7.5mm

CATALOG NUMBER	LENGTH (MM)
0921-7525	25
0921-7530	30
0921-7535	35
0921-7540	40
0921-7545	45
0921-7550	50
0921-7555	55
0921-7560	60
0921-7565	65
0921-7570	70
0921-7580	80
0921-7590	90

AnyPlus® 5.5 Implants

AnyPlus® Poly-Axial Pedicle Screw DIAMETER 8.5mm

CATALOG NUMBER	LENGTH (MM)
0921-8525	25
0921-8530	30
0921-8535	35
0921-8540	40
0921-8545	45
0921-8550	50
0921-8555	55
0921-8560	60
0921-8565	65
0921-8570	70
0921-8580	80
0921-8590	90

AnyPlus® Poly-Axial Reduction Screw DIAMETER 4.5mm

CATALOG NUMBER	LENGTH (MM)
0941-4525	25
0941-4530	30
0941-4535	35
0941-4540	40
0941-4545	45
0941-4550	50
0941-4555	55
0941-4560	60
0941-4565	65
0941-4565	65
0941-4570	70

AnyPlus® Poly-Axial Reduction Screw DIAMETER 5.5mm

CATALOG NUMBER	LENGTH (MM)
0941-5525	25
0941-5530	30
0941-5535	35
0941-5540	40
0941-5545	45
0941-5550	50
0941-5555	55
0941-5560	60
0941-5565	65
0941-5565	65
0941-5570	70

AnyPlus® Poly-Axial Reduction Screw DIAMETER 6.5mm

CATALOG NUMBER	LENGTH (MM)
0941-6525	25
0941-6530	30
0941-6535	35
0941-6540	40
0941-6545	45
0941-6550	50
0941-6555	55
0941-6560	60
0941-6565	65
0941-6565	65
0941-6570	70

AnyPlus® Poly-Axial Reduction Screw DIAMETER 7.5mm

CATALOG NUMBER	LENGTH (MM)
0941-7525	25
0941-7530	30
0941-7535	35
0941-7540	40
0941-7545	45
0941-7550	50
0941-7555	55
0941-7560	60
0941-7565	65
0941-7565	65
0941-7570	70

AnyPlus® Poly-Axial Reduction Screw DIAMETER 8.5mm

CATALOG NUMBER	LENGTH (MM)
0941-8525	25
0941-8530	30
0941-8535	35
0941-8540	40
0941-8545	45
0941-8550	50
0941-8555	55
0941-8560	60
0941-8565	65
0941-8565	65
0941-8570	70

AnyPlus® Open System Pedicle Screw Set Screw

CATALOG NUMBER
0954-0002

AnyPlus® 5.5 Implants

AnyPlus® Open System Lordosed Rods

CATALOG NUMBER	LENGTH (MM)
GS0161-1035	35
GS0161-1040	40
GS0161-1050	50
GS0161-1060	60
GS0161-1070	70
GS0161-1080	80
GS0161-1090	90
GS0161-1100	100
GS0161-1110	110
GS0161-1120	120
GS0161-1130	130
GS0161-1140	140
GS0161-1150	150
GS0161-1160	160
GS0161-1170	170
GS0161-1180	180
GS0161-1190	190
GS0161-1200	200

AnyPlus® Open System Straight Rods

CATALOG NUMBER	LENGTH (MM)
0963-0040	40
0963-0050	50
0963-0060	60
0963-0070	70
0963-0080	80
0963-0090	90
0963-0100	100
0963-0110	110
0963-0120	120
0963-0130	130
0963-0140	140
0963-0150	150
0963-0160	160
0963-0180	180
0963-0200	200
0963-0250	250
0963-0300	300
0963-0350	350
0963-0400	400
0963-0500	500
0963-0600	600

Adjustable Transverse Connectors

CATALOG NUMBER	LENGTH (MM)
1306-5530	30-36
1306-5535	35-46
1306-5540	40-56
1306-5550	50-76

AnyPlus® Lateral Connector – Open

CATALOG NUMBER	LENGTH (MM)
1326-5515	15
1326-5520	20
1326-5525	25
1326-5530	30
1326-5535	35
1326-5540	40

AnyPlus® Axial Rod Connector

CATALOG NUMBER	LENGTH (MM)
1350-5555	55
1350-5560	60

AnyPlus® Domino Connector – Closed

CATALOG NUMBER	LENGTH (MM)
1360-5555	55
1360-5560	60

AnyPlus® Domino Connector-Open

CATALOG NUMBER	LENGTH (MM)
1370-5555	55
1370-5560	60

Instruments

GS110 - 0548
Tap 4.5mm

GS110 - 0558
Tap 5.5mm

GS110 - 0568
Tap 6.5mm

GS110 - 0578
Tap 7.5mm

GS110 - 0588
Tap 8.5mm

GS110 - 0416
Ball Tip Tester

GS110 - 1920 (6.0),
GS110 - 1926 (5.5)
Kerrison Persuader

GS110 - 2312 (6.0),
GS110 - 2316 (5.5)
Set Screw Starter

GS110 - 0928
Poly Screw
Driver Shaft

GS110 - 1536,
GS110-1536 (6.0),
GS110-1537 (5.5)
In-Situ Bender (LFT)

GS110-1546 (6.0),
GS110-1547 (5.5)
In-Situ Bender (RGT)

GS110 - 1716
Rod Pusher

GS110-3016(5.5),
GS110-0923 (6.0)
Poly Screw
Head Adjuster

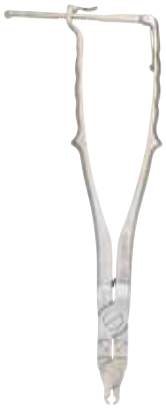
TL136106 (5.5)
TL131106(6.0)
Torque Limiting Final Driver
(11N ± 10%)

US14-3010
Straight Ratchet
Handle

US110-1002
T Style Ratchet Handle

GS110-2917 (5.5)
GS110-2916 (6.0)
Torque Wrench Handle
for Transverse Link (5N ± 10%)

GS110-1219 (5.5)
GS110-1218 (6.0)
Rod Gripper



GS110-1311
(5.5 and 6.0)
Power Rod Gripper

Instruments

GS110-1926 (5.5),
GS110-1920 (6.0)
Kerrison Persuader

GS1110-1217 (5.5),
GS110-1216 (6.0)
Ring Handle Rod Holder

GS110 - 2816
Distractor

GS110 - 2716
Compressor

GS110-2917 (5.5),
GS110-2916 (6.0)
Anti Torque Wrench

GS110 - 1526
French Rod
Bender

GS110 - 0316
Straight Bone Probe
(Steffee Tip)

GS110 - 0326
Curved Bone Probe
(Steffee Tip)

GS110 - 0317
Straight Thoracic
Bone Probe

GS110 - 0327
Curved Thoracic
Bone Probe

GS110-2210 (5.5)
Rod Rocker

GS110-0216
Bone Awl

TL136106 (5.5)
US112-0610 (6.0)
Wrench for
Transverse Link (V.1)

GS110-3516
(5.5 and 6.0)
Driver for
Transverse Link (V.1)

GS110 - 3516
Set Screw Driver for
Transverse Link (V.3)

C1202-019
(5.5 and 6.0)
Final Driver Shaft for
Transverse Link (V.3)

US110 - 3701 (5.5)
Rod Reduction Sheath

GS110-1416
(5.5 and 6.0)
Long Tab Breaker

GS110-2316 (5.5),
GS110-2312 (6.0)
Set Screw Starter

Instrument Cleaning, Care and Handling Policies

OVERVIEW
Surgical instruments are supplied NON-STERILE, and must be sterilized before use. After each use, instruments must be properly cleaned, disinfected, sterilized and stored. The following information outlines the proper steps for reprocessing GS Medical surgical instruments.

CLEANING ACCESSORIES

Water - Cold deionized or reverse osmosis water should be used, as temperatures above 140°F (60°C) will coagulate proteins, rendering them difficult to remove from contaminated items.

Detergent - Prepare detergent (i.e., LIQUI-NOX®, Alconox, Inc. 9.5 pH) per manufacturer recommendations ,or typical hospital grade instrument detergent or soap.

Manual Cleaning Accessories - Brushes, Gloves, Absorbent Disposable Cloth
(i.e., KIMWIPE®, Kimtech Science)

LIMITATIONS AND RESTRICTIONS OF REPROCESSING
Surgical instruments are designed for their durability and ability to reuse. GS Medical reusable instruments are typically manufactured from steel stainless steel, which permits a long life when handled and maintained properly. Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage to use.

CLEANING / DISINFECTING

Warnings - When handling sharp instruments use extreme caution to avoid injury; consult with an infection control practitioner to develop and verify safety procedures for all levels of direct instrument contact.

Clean Instruments as soon as possible after use. Do not allow blood or debris to dry on the instruments. If cleaning must be delayed, place groups on instruments in a covered container with water or an appropriate detergent to delay drying. Clean all instruments whether or not they were used or inadvertently contacted blood or saline solution.

Preparation for Cleaning - The cleaning process must be conducted so that all parts of the surgical instrument are exposed as permitted by design. The cleaning process should include an individual properly gowned with appropriate glove and personal protective equipment. Items with lumens, cannulations, etc. must be carefully cleaned to remove all visible debris from the item.

MANUAL CLEANING AND DISINFECTION
Clean instruments to remove gross contamination and disinfect instruments to reduce the number of viable microorganisms. Rinse in warm water to remove any gross contamination. Wash with a detergent with a pH of 7.0 to 10.0. Scrub the components with a soft brush. Rinse thoroughly with warm running water. Dry the instrument with a clean , disposable, absorbent cloth. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visibly inspected. If necessary re-clean / disinfect the instrument until it is visibly clean.

AUTOMATED CLEANING AND DISINFECTING
An automatic cleaning process may be used i.e. ultrasonic cleaner or other related type machine that cleans and decontaminates items provided their own unique instructions are followed. Be aware that loading patterns, instrument cassettes, and other external factors may change the effectiveness of the cleaning equipment.

INSPECTION, MAINTENANCE AND TESTING
Surgical instrument and instrument cases are susceptible to damage from prolong use, and through misuse or rough handling. Care must be taken to avoid compromising their exact performance. To minimize damage, the following should be done. Inspect the instrument and cases for damage when received and after each use and cleaning. Incompletely cleaned instruments should be recleaned, and those that need repair set aside and returned to GS Medical or its distributor. Instruments and instrument cases must only be used for their intended purpose.

PACKAGING
The GS Medical instrument case is intended to protect instrumentation during shipment. Any damage noted should be reported to GS Medical immediately. Damaged packaging may indicate the presence of unsafe product. If the product is damaged, the product should not be used and should be returned.

STERILIZATION
GS Medical surgical instruments manufactured of stainless steel or titanium may be steam sterilized with no detrimental effects. Steam Sterilization Cycle instruments are supplied NON-STERILE and must be sterilized before use. The recommended sterilization process is high temperature steam autoclave sterilization. It is also recommended that the trays be double wrapped using two standard sterilization wraps.

VALIDATED CYCLE IS:
Method: Steam Cycle Pre-vacuum Temperature 270°F (132°)
Exposure time: 4 minutes
Drying Time: 20 minutes

STORAGE
Surgical instruments that will not be utilized within a short period of time and will not be immediately returned to GS Medical must be stored clean, decontaminated, and completely dry. The packaging that items are sterilized in may offer an effective barrier to prevent contamination. Instruments should be stored in a clean area until ready for use.

STERILIZATION
All instruments must be sterilized according to the instructions outlined in the packaged insert-Instructions For Use (IFU) unless otherwise provided sterile.

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

Important Information on the AnyPlus® & GSS™ Spinal Systems

PURPOSE
The GSS™ and AnyPlus® Spinal Systems are intended to help provide immobilization and stabilization segments as an adjunct to fusion of the thoracic, lumbar, and /or sacral spine.

DESCRIPTION
The GSS™ and AnyPlus® Spinal Systems consist of a variety and sizes of rods, screws, transverse links, 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.

The GSS™ and AnyPlus® Spinal System implants 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 warranties and 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 implants in the same construct. To achieve the best result, do not use any of the GSS™ and AnyPlus® Spinal System 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™ and AnyPlus® Spinal System components should ever be reused under any circumstance.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS.
The GSS™ and AnyPlus® Spinal Systems are 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 devices are 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.)

DESCRIPTION
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. Mordid obesity
5. Pregnacy
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 diseases, bone absorption, osteopenia, osteomalacia and/or osteoporosis.
10. Suspected or documented metal 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 requires the mixing of metals from two different components or system.
14. Any patient giving inadequate tissue coverage over the operative site or inadequate bone stock or quality.
15. Any patient which implant utilization would interfere with anatomical structures or expected physiological performance.
16. Any patient unwilling to follow postoperative instruction.
17. Any case not describe in the indications.

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 (for, 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, irritation, fibrosis, necrosism, and/or pain. Bursitis. Tissue or neve 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 cerebrospinal fluid 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 equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, 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 cpmpression around nerves and/or pain.
12. 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.
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 spine.
16. Loss of or decrease 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 stress 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 compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stoke, 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

Note: 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.

continued

Important Information on the AnyPlus® & GSS™ Spinal Systems

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 and neurospinal 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 surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

WARNING AND PRECAUTIONS
Although the physician is the designated 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 for sale by or on the order of a physician.

CAUTION: FOR USE OR BY THE ORDER OF A PHYSICIAN ONLY.

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

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 id 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 component. The implant should not be scratched or otherwise damaged. Implant 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 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 GSS™ Spinal system components (described in the DESCRIPTION section) are not to be combined with the 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. Only patients that meet the criteria described in the indications should be selected.
2. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves may cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. 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.
5. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
6. To insert a screw properly, a guidewire should first be used, followed by a sharp tap. Caution: Be careful that the guidewire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guidewire does not advance during tapping or screw insertion. Remove the guidewire and make sure screw is intact. Failure to do so may cause the guidewire or part of it to advance through the bone and into a location that may cause damage to underlying structures. Do not overtap 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.
7. Bone graft may be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. To assure maximum stability, two additional transverse connectors may be implanted on the two lower adjacent vertebrae being fused.
9. 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.
10. Before closing the soft tissues, 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
It is important that 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 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™ and AnyPlus® 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 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

continued

Important Information on the AnyPlus® & GSS™ Spinal Systems

difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) 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 treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the

GSS™ and AnyPlus® Spinal System components should never be reused under any circumstances.

PACKAGING
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 to 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 or surgery center 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:

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperature, 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 COMPLAINTS
Any health professional having a complaint or grounds for dissatisfaction relating to the quality of the product, its identity, its durability, its reliability, safety, effectiveness and/or 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 complaint.

For additional information on the products listed in this guide, please contact the GS Medical Customer Service Department:

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Caution: Federal Law (USA) restricts these devices for sale by or on the order of a physician.

The surgical technique described hereafter in this surgical technique guide is considered standard use by the manufacturer, GS Medical, Ltd. The guide is put forth as a recommendation and should be used in tandem with the surgical knowledge of the surgeon.

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