Surgical Technique as described by:
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Historically, severe disability from major deformity of spondylolisthesis at L5-S1 of grades 3 & 4 has presented a major challenge for the surgeon and difficult courses of treatment for the patient. Aims have been to obtain solid arthrodesis and where possible to effect reduction to at least improve the “slip angle” so the mobile spine above has a more normal angle of support in relation to the horizontal. Attempts at closed reduction have been difficult and relatively unsuccessful. Prolonged immobilization has been up to 3 months on a Stryker frame or in a plaster bed to allow successful maturation of the fusion mass. In an effort to allow some degree of mobilization while fusion occurred, plaster body casts of the hip spica type were used and finally braces including the thigh. Despite the magnitude of these treatments for the patient, there was still an unfortunately high rate of failure.

The use of internal fixation has provided an excellent internal splint to stabilize the spine, dramatically improving the fusion rate while at the same time offering a reasonable degree of effective reduction with improvement of the “slip angle” or lumbosacral angulation.

The LIBERTY™ Spinal System provides the opportunity of segmentally connecting and immobilizing the spine while allowing spinal fusion to be carried out with more room for autogenous bone due to reduced volume implant design.

The LIBERTY Spinal System was also designed for in-situ contoured spinal correction with frontal and sagittal plane Jackson Benders to improve and maintain the patient’s spinal alignment and balance.

LIBERTY System STAR™ connectors provide Simultaneous-Translation-Angulation-Rotation freedoms in 3 planes for the screws with respect to the rods. These unique connectors greatly facilitate insertion of the rods and connection of the implants when the screws are not well aligned. This decreases the difficulty and time of the operation.

The LIBERTY Spinal System is designed to assist in spinal stabilization with implantation of less metal, while at the same time not compromising strength, stiffness or fatigue of the rods.

Sincerely,

Roger P. Jackson, MD, F.A.C.S.

NOTE: Illustrations have been simplified for clarity.
LIBERTY SPINAL SYSTEM IMPLANTS

Open Screw  Closed Screw  Closed Oblique Screw

Closed STAR® Connector  Open Implant Saddle

Open STAR® Connector  Break-off Set Screw

LOW PROFILE CROSSLINK® SYSTEM

CROSSLINK Plate
LIBERTY SPINAL SYSTEM INSTRUMENTS

- Captive Twist Driver
- Counter Torque
- Saddle Pliers
- Rod Introducer
- Open Screw Screwdriver
- Closed Screw Screwdriver
- Set Screw Retaining Block
- Set Screw Extractor
- Long Saddle Holder
The Jackson Benders are for implant connections and spinal corrections.
STEP 1

Preoperative Planning

The necessary lordotic alignment can be determined through careful review and analysis of the lateral standing plain film. The appropriate LIBERTY<sup>™</sup> Screw also can be determined at this time.

CT scans (axial images) can be used preoperatively to measure the diameter of the pedicles and select the appropriate length and diameter of the pedicle screws to be implanted (Fig. 1). The width of the pedicle is measured at its isthmus. Two measurements are taken: (a) medial cortical wall to lateral cortical wall, and (b) medial to lateral endosteal cortical diameter.

The medial angle of the pedicles also should be assessed as a guide to screw placement.

The appropriate screw diameter is one that completely fills the endosteal cortical canal of the pedicle. The screw length should extend 50-80% into the vertebral body.

NOTE: Remember to account for the X-ray, CT or MRI magnification factor when taking these measurements.
The patient is positioned on the operating table in the prone position (Fig. 2). A spine surgery table or frame should be used which allows the abdomen to be free, thereby avoiding vena caval compression. Hypotensive anesthesia, autotransfusion and a cell-saver also may be used to reduce intraoperative blood loss. Radiographic guidance and control, either fluoroscopic with image intensifier or quality X-rays, are used intraoperatively. Prior to skin preparation and draping, the patient’s position may be checked radiographically (C-arm or X-ray) to determine the axial direction of the pedicles to the horizontal. With the patient fully relaxed under general anesthesia and properly positioned, some reduction in the slip and improvement in the slip angle or lumbosacral angulation will be seen in most cases.
The surgical approach is carried out through a standard midline incision to the spinal column over the anatomic position of the spinous processes. The incision should be long enough to ensure exposure of L3 through S1. Initially, the positions of the spinous processes are identified through palpation and the lumbar fascia is incised on the sides of each of the spinous process. The supraspinous and interspinous ligaments should be preserved particularly above the area of instrumentation, as these are important posterior stabilizers.

Meticulous sub-periosteal exposure of the posterior elements is performed. The paraspinal musculature is detached to the outer margins of the transverse processes.

When indicated, soft tissue and bony decompression is performed to relieve neurological compression. The capsule and articular cartilage of the facet joints to be included in the fusion are excised. When necessary, decompressive laminectomies are performed to correct any stenosis in the central canal along with lateral recess and neural foraminal decompressions.
DEVELOPING THE FUSION BED

The transverse processes, lateral gutter and sacral alae are carefully dissected free of all covering periosteal tissues and are decorticated. Removal of facet joint articular surfaces and decortication of the pars, facet wall and laminae are carried out (Fig. 3). Disruption or impingement of the facet at the superior end of the construct must be avoided, if at all possible. Meticulous development of the fusion bed enhances the potential for achieving solid fusion.
Identification of the Pedicles

The entrance to the intramedullary canal of the pedicle is located at the point where the middle of the transverse process, superior facet and pars interarticularis converge (Fig. 4).

The entrance to the S1 pedicle is caudal and just slightly lateral to the superior articular process.

The pedicle canals of L4, L5 and S1 are entered with a power burr or rongeur at the junction of the facet and transverse process (Fig. 5).

With the use of radiographic guidance, the pedicle is probed with a blunt pedicle probe orienting inwards according to the preoperative imaging studies. Proper cranio-caudad orientation also is important and is assisted by the preoperative standing lateral and intraoperative lateral radiographs. The probe should have good contact with the bone at all times within the pedicle. A 5\(^{\circ}\) x 1mm diameter K-wire can be inserted into the canal prepared in the pedicle and the positions checked radiographically with AP and lateral X-rays or image intensifier views.

**NOTE:** The K-wire is correctly positioned in the center of the pedicle canal when, in an A/P view, only the diameter of the wire is seen and the pedicle canal completely surrounds the image of the wire.
PREPARATION OF THE PEDICLE CANAL

The preparation of the pedicle canal requires that attention be given to three key aspects:

1. Instruments should not be allowed to penetrate the walls of the pedicle. Such penetration can cause damage to neural and vascular structures.

2. The angle of entry to the pedicle canal should be considered in relation to the position of superiorly placed screws and the individual anatomy.

3. The anterior cortex of the vertebral body should not be violated.

As each K-wire is removed, an awl is used to open the proximal pedicle canal. A pedicle probe is then used to deepen the hole to the desired length. As the pedicle probe is gently worked down the pedicle canal, the surgeon should feel the sensation of the soft cancellous bone (Fig. 6). If resistance is felt during this process, the position should be checked radiographically. A change in the feel of the probe, i.e., resistance or change in bone density, is a warning that caution should be exercised.
Tapping of the pedicles is usually not required. However, in patients with hard bone and relatively “narrow” pedicles, tapping is recommended and will make subsequent screw insertion easier.

It is not necessary to tap more than a partial length of the pedicle as this will provide enough of a prepared track for the screw to follow.

**NOTE:** Two-hand control of pedicle instruments, including the probe, tap and screwdriver, is essential at all times for the surgeon to have control of direction and force.

Insert the appropriate tap into the tap shaft. The tap shaft with tap may then be inserted into a ratcheting or non-ratcheting handle. The pedicle is then tapped (Fig. 7).

After tapping, curved and straight ball tip Holt probes may be used to follow the tap threads and check for violation of the pedicle walls (Fig. 8).
Determining Screw Length

Once the pedicle has been tapped and the walls checked with probes, the straight ball tip probe, calibrated at 10mm intervals (Fig. 9), may be used to determine screw length.

**NOTE:** For maximum construct biomechanical strength, the screw length selected should allow the screw to be inserted 50-80% into the vertebral body.

![Fig. 9](image-url)
With the pedicle canals prepared and the screw length determined, the LIBERTY™ screws are sequentially inserted from S1 to L4, bilaterally, using the open or closed screwdriver.

The open screwdriver is attached to the open screw by placing the distal flanges and shaft of the screwdriver into the screw head with the outer knurled shaft and smaller paddle handle pulled back at a 90° angle to the larger paddle handle. To lock the open screwdriver onto the open screw, push the outer shaft down firmly using the knurled portion, and turn the smaller paddle handle until it is parallel with the larger paddle handle, and the screwdriver and screw are firmly attached.

The screws are inserted into the pedicle until the desired position is obtained (length, longitudinal, transverse) (Fig. 10). The position of the screwdriver paddle handle should terminate in a longitudinal orientation, to allow for insertion of rod. Small adjustments may be necessary. When using a STAR™ connector, the paddle handle should terminate in a transverse orientation.
With the S1 and L5 screws already in place, the closed screw is loaded into the closed screwdriver.

The closed screwdriver is attached to the closed screw by threading the obturator into the head of the closed screw. To remove the screwdriver once the closed screw has been implanted, loosen the obturator to release the screwdriver.

When fully inserted, the screws should extend 50-80% into the vertebral body and be parallel to the vertebral body end plate (Fig. 11).
Prior to inserting the rods, the lordotic alignment of the spine should be checked with the intraoperative lateral X-ray or image view and compared to the preoperative lateral standing view. Restoration of the lordosis over the instrumented levels is very important.

Due to the differences in the angle of the pedicles as measured from the midline (spinous processes), screw alignment as viewed posteriorly may be off-line (Fig. 12). The LIBERTY™ System includes STAR™ connectors which compensate for lateral placement and sagittal angulation of screws.

Closing mechanisms include saddles, STAR connectors and set screws.
Rod Selection, Cutting and Bending

Rods are available with a 6.35mm diameter having a smooth (shot peened) or knurled finish. The smooth rods can be selected according to their degree of stiffness and flexibility: Rigid, Flex and Super Flex.

A rod template may be used to determine the rod length and contour needed for construct assembly (Fig. 13). A sterile marking pen may be used to mark the rod at the point to be cut. The table top rod cutter is used to cut the rods to the appropriate length outside the operative field.

The cut sections of rod may now be bent into lordosis using “French Benders” (Fig. 14) or sagittal plane Jackson Benders (Fig. 15). The amount of lordosis bent into the rod is based on the amount of further reduction desired after positioning, if any. The sagittal plane Jackson Benders are helpful for contouring short sections of rod.
Rod Insertion With Rod Introducer

The rod is inserted into the closed screw at L4 on the left side from a caudad to cephalad direction using the rod holder. A break-off set screw is loaded into the captive twist driver and provisionally tightened onto the L4 closed screw.

The rod introducer is used to push the rod into the open screw at S1. To attach the rod introducer to the open screw at S1, slide the distal flanges of the rod introducer underneath the screw head in the direction shown (Fig. 17). The T-handle of the corkscrew is then turned clockwise to allow the distal end of the instrument to engage with the rod and reduce it into the bottom of the screw head (Fig. 16/17).
Attaching saddle/set screw to long saddle holder

Attach a break-off set screw to the open implant saddle.

**NOTE:** Do not insert set screw into saddle more than one and a half turns.

The open implant saddle is then attached to the long saddle holder (Fig. 18).

**NOTE:** The distal portion of the long saddle holder with the extension lip must be aligned with the side of the saddle with the laser etched pyramid logo.

The long saddle holder and saddle are introduced into the open screw head in the direction indicated by the arrows at the distal end of the saddle holder and the sides of the saddle.
**STEP 13**

**Inserting A saddle into open screw with saddle holder & rod introducer**

The rod introducer allows the long saddle holder, with a saddle and a set screw attached, to be passed through it from the open side of the rod introducer.

The saddle is placed into the S1 screw by rocking it into the open screw head until the saddle is fully seated and the proximal end of the long saddle holder makes contact with the rod introducer shaft (Fig. 19).

*The saddle can only be introduced into the implant using a “sweeping arc motion.”*

If saddle is not fully seated after removal of rod introducer, seat saddle with saddle plier.
The L5 screw is turned laterally to accommodate a STAR™ connector. A STAR connector of the appropriate length is selected to address the lateral offset of the L5 screw, (7, 10 or 20mm lengths are available). If a closed STAR connector is used, as in this example, a 6.35mm retaining clip can be loaded onto the STAR connector and rod from above to stabilize the STAR connector (Fig. 20).

After preloading the closed STAR connector and attaching the retaining clip onto the rod, the rod is inserted into the L4 closed screw from a caudal direction using the rod holder (Fig. 21).
The ST AR™ connector is placed into the L5 open screw on the right side.

The L4 set screw is provisionally tightened (Fig. 22).

The ST AR connector is positioned in the L5 screw, and the saddle/set screw is inserted into the open screw. The saddle plier can be used to fully seat the saddle into the L5 open screw. The L5 set screw is then provisionally tightened. The retaining clip at L5 can then be removed, and the ST AR connector set screw inserted and provisionally tightened (Fig. 23).
In-situ rod contouring

In-situ rod contouring to achieve further reduction, create additional lumbosacral lordosis and provide for L5-S1 foraminal distraction is accomplished by placing one sagittal plane Jackson Bender onto the rod between L4 and L5, and the other sagittal plane Jackson Bender between L5 and S1, as shown on the right side. The handles of the angled benders are manipulated toward each other while pushing down firmly in the sagittal plane to achieve the desired correction (Fig. 24).

The rods should be contoured in increments from side to side.
Final Tightening

Final tightening of all open implants is accomplished by seating the counter torque and captive twist driver onto the open screw, saddle, and set screw, and turning the T-handle of the captive twist driver clockwise while firmly holding the counter torque (Fig. 25).

The internal obturator of the captive twist driver will be raised 1/4” from the black T-handle.
Set screws on the closed screws at L4 are tightened and broken off by clamping the rod holder to the rod below L4, placing the captive twist driver onto the set screw and turning it clockwise until the set screw breaks off (Fig. 26).

The captive twist driver will hold the broken-off portion of the set screw and will release it by pushing down on the internal obturator until it is flush with the black T-handle (Fig. 27).
break-off set screw removal

To remove the set screw after break off, the set screw extractor is inserted into the set screw and turned counterclockwise. The threaded distal portion of the set screw extractor will engage the set screw and remove it. (Fig. 28)

To remove the set screw from the extractor, insert distal portion of extractor with the set screw attached into the set screw retaining block and turn clockwise (Fig. 29/30).
Bone Grafting and Crosslink PLATING

Decortication, if delayed, and bone grafting can now take place. This is done in the usual manner. CROSSLINK® Plates also may be added at this time and technical details regarding use of the Low Profile CROSSLINK System are as follows.

Following the securing of the screws and rods, the appropriate size of the Low Profile CROSSLINK Plate is determined with the measuring template. The rods may be spread or compressed as necessary.

With the use of the CROSSLINK Plate Holder, the CROSSLINK Plate is pressed down onto the rods.
Low Profile CROSSLINK® Plates should be placed ideally at the cephalad and caudad end of the construct.

Provisionally engage both set screws of the CROSSLINK Plate prior to final tightening (Fig. 31).
Postoperative Care and Mobilization

Patients must be warned to avoid physical activities that would place excessive stress upon the implant or bone graft, which could delay or prevent healing. However, regular graduated mild to moderate activity is beneficial to bone formation particularly when the vertebrae have been adequately stabilized internally. Patients should use adequate external support until bony fusion has been established. They should be instructed in the proper methods of getting in and out of bed, from a sitting position, etc.

Please see the package insert for Warnings, Precautions and Possible Adverse Events.
IMPORTANT INFORMATION ON THE LIBERTY® POSTERIOR SPINAL SYSTEM

PURPOSE:
The LIBERTY® POSTERIOR SPINAL SYSTEM is a temporary implant used for the correction and stabilization of the spine. The system is also intended to assist temporary stabilization and augment and the development of a solid spinal fusion. These implants are not intended to be removed after the development of a solid fusion mass.

DESCRIPTION:
The LIBERTY® POSTERIOR SPINAL SYSTEM consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors and connecting components. The LIBERTY® POSTERIOR SPINAL SYSTEM implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual patient.

The LIBERTY® POSTERIOR SPINAL SYSTEM implant components are fabricated from medical grade stainless steel described by such standards as ASTM F718, Grade 2, or its ISO equivalent. This material is not compatible with titanium or titanium alloy. To achieve best results, do not use any of the LIBERTY® POSTERIOR SPINAL SYSTEM implant components with the components from any other system or manufacturer. The only exceptions to this restriction are the stainless steel TSPH™ Spinal System and CCD™ Spine System implant components listed in the NOTA BENE section of the package insert for which continued design, material, and labeling compatibility can be assured. As with all orthopaedic implants, none of the LIBERTY® POSTERIOR SPINAL SYSTEM components should ever be reused under any circumstances.

Sofamor Danek expressly warrants that these devices are fabricated from the foregoing material specifications. No other warranties, expressed or implied, are made.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS:
The LIBERTY® POSTERIOR SPINAL SYSTEM is intended for use in adults who present with: (a) degenerative disc disease; (b) severe spondylolisthesis; (c) previous failure of fusion; (d) pseudoarthrosis; (e) spondylothesis; or (f) spinal stenosis.

CONTRAINDICATIONS:
Contraindications include, but are not limited to:
1. Active infective process or significant risk of infection (immunocompromised).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy due to 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. Where life expectancy would otherwise be expected to be short lived.
10. 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.
11. Suspected or documented metal allergy or intolerance.
12. Any case not needing a bone graft and fusion.
13. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
14. Any case mixing of metals from two different components or systems.
15. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
16. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
17. Any patient unwilling to follow postoperative instructions.
18. For pedicle screw cases, missing or congenital deformed pedicles of the fifth lumbar (L5) vertebrae.

POSSIBLE ADVERSE EVENTS:
All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible 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 of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products, including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis. Tissue damage caused by improper positioning and/or placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/ or reduction.
6. Infection.
7. Dural tears.
8. Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neurona, or tingling sensation.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
10. Loss of bowel and/or bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise 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.
14. Loss of the functional gain of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
15. Bone loss or decrease in bone density, possibly caused by stress shielding.
16. Graft donor site complications including pain, fracture, or wound healing problems.
17. Asepsis, lesions, gusitis, herniated nucleus pulposus, retracted graft.
18. Hemorrhage, hematoma, seroma, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
19. Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
20. Development of respiratory problems, e.g., pulmonary embolism, bronchitis, pneumonia, etc.
21. Change in mental status.
22. Death.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

WARNING AND PRECAUTIONS:

WARNING:
• When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar-first sacral (L5-S1) vertebral joint.
• The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
• Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
• Potential risks identified with the use of this device system, which may require additional surgery, include:
  1. Device component fracture.
  2. Loss of fixation.
  3. Non-union.
  4. Fracture of the vertebral.
  6. Vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be used as the sole means of spinal support. Use of this product without a bone graft or in a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and comprehension of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle tone and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician. Other preoperative, intraoperative, and postoperative warnings are as follows:

**PREOPERATIVE:**
1. Only patients that meet the criteria described in the indications should be selected. 1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. The maximum fixation device system is intended only for grade 3 or 4 spondylolysis. The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions. 6. Fracture or 1-901-396-3133 1-800-933-2635 or 901-396-3133 (after 1 Oct 96) When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and/or the anatomy of the human body places a size limitation on any artificial fixation device used in surgery. This maximum size limitation increases the chance of the mechanical complications of loosening, bending, or breakage of the device(s). Any of these complications could result in the need for an additional surgery. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.

**PRODUCT COMPLAINTS:** Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effective- ness and/or performance, should notify the distributor or Sofamor Danek at either of the addresses below. Further, if any of the implanted LIBERTY™ POSTERIOR SPINAL SYSTEM component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Sofamor Danek product ever "malfunctions," Sofamor Danek will either make certain that the "malfunction" does not recur or replace, at its discretion, and at no charge to the customer, the entire Sofamor Danek device system and/or the component(s) involved. In an event of a Sofamor Danek product "malfunction," it is important to properly notify the customer and the patient as soon as possible.

**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, pre-cut rods of the length needed.
4. Do not use the LIBERTY™ POSTERIOR SPINAL SYSTEM hook trials in any type of prying action. The trial may bend or break, especially at the tip. Also, the trial or other nearby hardware may suddenly change position, possibly causing damage or injury.
5. To properly insert a screw, a guide wire should first be used, followed by a sharp tap. Caution: Do not overlap or use a screw that is either too long or too large. Overlapping or using an incorrectly sized screw may result in nerve damage or hemorrhage.
6. Bone graft must be placed in the area to be fused and grafts must be extended from the upper to the lower vertebrae to be fused. When using LIBERTY screws as pedicle screws, only autogenous bone graft should be used.
7. To increase stability, two or more TSRH CROSSLINK® plates on two bilaterally placed, continuous rods must be used whenever possible. The TSRH CROSSLINK® plate must be aligned with the rod as described in the operative technique.
8. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal use, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
9. Before closing the soft tissues, all of the nuts should be tightened firmly with a torque wrench according to the operative technique. Tighten the threads of all nuts after finishing to make sure that none loosen during the tightening of the other nuts. Failure to do so may cause loosening of the other components.

**POSTOPERATIVE:**
1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct.
3. The patient should be warned that this postoperative phase should be observed for neurological 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-steroidal or anti-inflammatory medications such as aspirin, until the bone graft healing process is complete.
4. The patient should be advised of 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 will result in loosening of the bone graft or in compromise of the spinal fusion site.
5. When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and/or the anatomy of the human body places a size limitation on any artificial fixation device used in surgery. This maximum size limitation increases the chance of the mechanical complications of loosening, bending, or breakage of the device(s). Any of these complications could result in the need for an additional surgery. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.
For product availability, labeling limitation, and more information, contact your SOFAMOR DANEK USA Sales Associate, or call SOFAMOR DANEK USA Customer Service toll free: 800-933-2635.