SOUTHERN SPINE **StabiLink®** MIS Spinal Fixation System

IMPORTANT INFORMATION ON THE STABILINK® MIS SPINAL FIXATION SYSTEM

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READ INSTRUCTIONS FOR USE | SINGLE USE | Rx ONLY PRESCRIPTION USE ONLY | NON STERILE

REF TY-321

StabiLink® Instructions for Use

Purpose
The StabiLink® MIS Spinal Fixation System is an interlaminar/spinous process fixation device intended to provide temporary fixation of spinal segments in the thoracic, lumbar, and sacral spine while awaiting bony fusion to take place. As with all orthopedic surgical procedures, detailed preoperative planning is essential. Preoperative diagnostic evaluation followed by carefully executed surgical technique is required. Post-operative care, individualized to suit the particular injury/disease requirements, is essential for optimum outcome. The surgeon must be fully aware of the risks and complications inherent to this type of surgery. Only those individuals with specialized training and experience in spinal surgery should attempt use of the implants.

Device Description
The StabiLink® MIS Spinal Fixation System is a posterior attachment spinal fixation system composed of interlaminar/spinous process plates, dedicated surgical instruments, and sterilization cases. The components are used to build a construct to provide stabilization of spinal segments in the thoracic, lumbar and sacral spine to support fusion. It is essential to use the implants with their specifically designed instruments. After a solid fusion occurs, the system serves no functional purpose and should be removed. Removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. However, any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

Materials
The StabiLink® implants are made of titanium alloy, Ti-6Al-4V ELI per ASTM F136.

Indications for Use
The StabiLink® MIS Spinal Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/ attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radio-graphic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); tumor. It is not intended for stand-alone use.

Contraindications
Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation.
Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but are not limited to:
- An allergy to titanium, or foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to implantation.
- Known or suspected infection/immune system incompetence. Acute infectious process or significant risk of infection.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Morbid Obesity.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Open Wounds.
- Pregnancy.
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
- Any case requiring the mixing of components from other manufacturers' systems.
- Any case requiring the mixture of stainless steel with titanium, or stainless steel with cobalt chrome implant components.
- Fever or leukocytosis.
- Signs of local infection or inflammation.
- Senility, mental illness or substance abuse, of a severity that the patient may ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Previous history of infection.
- Alcoholism or heavy smoking.
- Any patient which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unwilling to follow postoperative instructions.
- Inadequate tissue coverage over the operative site.
- The StabiLink® device is also contraindicated for incompetent or missing posterior arch (e.g., laminectomy, pars defect, severe osteoporosis).

Possible Complications
Possible complications specific to the device may include:
- Early or late implant bending, breakage, failure, loosening or movement or migration
- Bone and/or spinous process fracture
- Allergic reaction to implant material

Other general complications associated with any spinal surgical procedure may include: non-union or delayed union, pseudoarthrosis; pain; second surgery; bleeding; infection, early and late; tissue or nerve damage, including dural tears or other neurological problems; incisional complications; scar formation; damage to blood vessels and cardiovascular system compromise; changes in mental status; damage to internal organs and connective tissue; complications due to the use of bone grafting, including graft donor site complications; respiratory problems; reactions to anesthesia and/or death.

Warnings
The safety and effectiveness of spinal fixation 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, lumbar and sacral spine secondary to severe spondylolisthesis of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. 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. Consider the extent of decompression, as well as the amount of intact bone remaining on the spinous processes, when using the StabiLink® device as the sole supplemental fixation for an interbody fusion procedure.

Cautions
The StabiLink® implants are for single use only. Never reuse any implant even if it appears unmarked or undamaged. Reuse of the implant components may result in reduced mechanical performance, malfunction, or failure of the device. Any device implanted and then removed must be discarded. Use only new implants for each case.
- The implantation of spinal fixation systems must only be performed by experienced spinal surgeons with specific training in the use of this system due to the technically demanding procedure presenting a risk of serious injury to the patient.
- Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- Preoperatively: The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contra-indications of this type of implant. The surgeon must have acquainted himself before the operation with the specific technique for insertion of the product, which is available from the manufacturer. As part of the preoperative examination, the surgeon must check that no biological, biomechanical or other factors will affect the correct conduct of the operation and the postoperative period. An appropriate range of implant sizes must be available at the time of the operation.
- Intraoperatively: The correct selection of the type and size of implant appropriate to the patient and the positioning of the implant are extremely important.
- Postoperatively: Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that regular postoperative follow-up is undertaken to detect early signs of failure of the implants and to consider the action to be taken. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implants. The implant can be removed after bony healing.
- The StabiLink® device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The StabiLink® device has not been tested for heating or migration in the MR environment.
- Federal law (USA) restricts this device to sale by or on the order of a physician

Directions for Use
The information contained in this instructions for use is necessary but not sufficient for the use of this device. This information is not intended as a substitute for the professional judgment, skill and experience of the surgeon in: careful patient selection; preoperative planning; device selection; knowledge of the anatomy and biomechanics of the spine; understanding of the material and the mechanical characteristics of the implants used; training and skill in both spinal surgery and use of associated instruments for implantation; securing the patient's cooperation in following an appropriately defined postoperative management program; and, conducting postoperative follow-up examinations.

Surgical Guidelines
Preoperative Procedure
- As part of the preoperative examination, the surgeon must check that no factors, especially biological and biomechanical, will affect the correct performance of the operation and postoperative period.
- Only patients that meet the criteria described in the Indications For Use should be selected.
- Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should not be selected.
- Care should be used in the handling and storage of the StabiLink® components. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery. The primary surgeon must be fully experienced with the required spinal fusion techniques.
- 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 have an impact on the performance of the StabiLink® components. An adequate inventory of implant sizes should be available at the time of surgery, including an excess of implant sizes expected to be used and implant sizes larger and smaller than those expected to fit the patient.
- Review and inspect all instrumentation and implants prior to sterilization. Replace or add any needed components for the planned surgery. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment, and should personally assemble each device to be used to verify that all parts and necessary instruments are present before the surgery begins. Note should be taken of the Torque Limiting Handle's calibration expiration date, to ensure that it does not come before the planned surgery date. Damaged or defective instruments should not be used. Contact the manufacturer for repair or replacement instructions.
- All components should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative Procedures
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may result in loss of neurological functions.
- Breakage, slippage or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- The correct selection of the type and size of implant appropriate to the patient, and positioning of the implant, are extremely important to allow for a successful surgical outcome.
- Bone grafts must be placed in the area to be fused and be in contact with viable bone.

Patient Preparation and Surgical Access
Position the patient in the prone position on the operating table. Identify the spinous processes at the level to be instrumented, using manual palpation and intraoperative imaging. Make a midline incision about 2-4 cm in length to expose the spinous processes at the correct level. Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joints. Depending on the surgeon's preferred technique, the supraspinous ligament may be left intact, reflected or removed entirely.

Preparation of the Implant Site
Clear the fusion site of connective and soft tissues, lightly decorticating the bone surfaces. When fusing through the spinous processes, a burr, ronguer or rasp may be used to remove the interspinous ligament. The interspinous ligament may optionally be incised/dilated without complete removal. If a decompression procedure is desired, perform a conservative laminotomy, partial facetectomy, foraminotomy or other decompression procedure as needed.
Caution: Do not remove excessive amounts of bone, particularly from the base of the spinous processes and midline lamina. Weakening the posterior arch by aggressive bone removal may increase the risk of intraoperative or postoperative fracture of the adjoining spinous processes or posterior arch. If the facets are hypertrophied and do not allow for proper anterior placement of the implant, the facets may be trimmed. Do not perform a complete bilateral facetectomy. Preserving a sufficient portion of the facets to provide biomechanical stability for axial rotation and transverse shear loads is required. If the interspinous ligament has been left intact, insert the Rasp Instrument and puncture the interspinous ligament, placing it as far anterior as possible.
Caution: Do not over-dilate the implant space. Excessive force may fracture the spinous processes. To assure tactile feedback during distraction, start with ratchet up, to dilate space. Once proper tension is achieved, move the ratchet down and determine implant size.

Inserting Base Plate Implant
Choose the appropriate StabiLink® implant to best match the bony anatomy, ensuring the "Tray" portion is sized to less than the space between the spinous processes as the Tray is not intended to be loaded, with the ultimate goal of placing the implant as far anterior as possible. It is important to make sure that the implant set screw is present in the lock side, and the set screw bottom is flush with the open slot surface.The PG® Precision Guided Inserter/Compressor is a separable instrument. In order to implant the Base Plate pieces separately (i.e. one piece at a time), the instrument should be disengaged. To disengage the arms, press on the lever at the circular pivot joint, and push down to separate the arms. The arms will disengage and separate. Load the Base Plate "Tray" side (marked "-") onto the correspondingly marked hex screw of the Inserter. Finger-tighten the hex screw into the Base Plate. Load the Base Plate "Lock" side (marked "=") onto the correspondingly marked hex screw of the Inserter. Finger-tighten the hex screw into the Lock Plate. Using the Hex Driver, insure that each of the implants are securely positioned and attached to each arm of the Inserter. Note: When fully attached, the "Lock" side, marked "=" can rotate up to 20 degrees to accommodate the variations in patient anatomy. Insert the "Tray" side of the implant along the spinous processes ensuring the tray is sized to less than the space between the lamina/spinous processes with the "Tray" centered in the space between the lamina/spinous processes, as the Tray is not intended to be loaded, carefully positioning it into the anterior position. Insert the "Lock" side of the implant into the surgical site while lining up the "pivot" joint in the middle of the PG® Precision Guided Inserter/Compressor and aiming just past the end of the "Tray" so that the slot can engage the "Tray". Engage the second "=" arm into the first arm "-" of the Inserter until it engages securely and locks into position. You will hear a "click" when engagement occurs. Once the two arms of the PG® Precision Guided Inserter/Compressor are fully engaged, correct alignment is assured. The "Tray" will automatically enter the receiving slot in the "Lock" side of the implant. The "notch" in the ratchet mechanism is designed to hold the instrument in position. Carefully lift the ratchet in order to begin compressing the arms of the PG® Precision Guided Inserter/Compressor. Carefully increase the pressure, to ensure that the implant spikes are properly seated into the spinous processes. The knob on the ratchet bar can be turned clockwise to increase compression. **CAUTION: DO NOT OVER-COMPRESS THE IMPLANT. EXCESSIVE COMPRESSION MAY LEAD TO FRACTURE OF THE SPINOUS PROCESSES.** Visually confirm that the implant spikes are fully seated in the bone, with proper apposition against the spinous processes. To ensure that the Set Screw is located over the "Tray" for locking, compress the handle as follows: for "Standard" (23mm Tray length) implants, compress the Handle until it at least covers the Black Square (■) on threaded RATCHET ARM and is located near the tip of the Black Triangle (◀); for "Short" (17mm Tray Length) implants, compress the Handle until it passes the Black Triangle (◀) on the

threaded RATCHET ARM and all three points of the triangle are clearly visible; for "Ultra-Short" (14mm Tray Length) implants, compress the Handle until it at least covers the Black Circle ( ) on threaded RATCHET ARM. For all implants, confirm that the tip of the tray is visible past the end of the Locking Plate. Confirmation of the implant alignment can now be performed using X-ray or any other image guidance tool as necessary. Load the Torque Driver into the Torque Handle. Ensure that the Driver shaft is engaged with the handle; this can be verified by pulling on the shaft. **CAUTION:** Do NOT use the Removal Handle for locking the set screw. Place the Torque Driver assembly into the Inserter shaft marked "=". The Torque Driver will guide itself into the "Lock" side of the implant and into the set screw. Tighten the set screw until the Torque Handle "clicks" twice. Once the set screw is tightened to specification, final confirmation of the implant placement can be made with the appropriate imaging tools. Disengage the Inserter by loosening the hex screws on each side of the implant with the Hex Driver and remove from the surgical site.

Bone Grafting and Closure

The StabiLink® device is intended to be used with bone graft material and not for stand-alone use. If performing an interbody fusion, disc preparation and interbody spacer placement are typically performed prior to placement of the StabiLink® device. If not previously performed, decorticate the bone surfaces, prepare the fusion site for grafting and place the bone graft material in the usual manner. If the supraspinous ligament was resected, bone graft may be packed posterior to the device between the tips of the spinous processes. If fusing through the facets, decorticate articular surfaces and place bone graft in the usual manner. If desired, additional posterior bone grafting material may be placed around the implant, in the posterolateral gutter and/or across the interlaminar space. After the construct is implanted and bone graft completed, close the surgical site using standard techniques. If the supraspinous ligament was reflected, it may be sutured back to the tips of the spinous process. The fascia may be closed back to the supraspinous ligament.

Removing the StabiLink® Implant

The StabiLink® device can be removed if necessary. Use the removal handle/driver to loosen the locking set screw. The Base Tray plate and the Base Lock plate can then be carefully separated with a Cobb elevator or similar instrument and removed from the lamina and or spinous processes.

Postoperative Care

- The physician's postoperative directions and warnings to the corresponding patient are important to allow for a successful surgical result. Detailed instructions on the use and limitations of the device should be given to the patient. Excessive weight bearing, early weight-bearing and excessive muscular activity are discouraged during the early postoperative rehabilitation period. The patient must be warned that such activity may result in complications, such as bending, loosening or breakage of the components. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active; or, if the patient is debilitated, demented, or using weight supporting devices. The patient should be warned to avoid falls or sudden jolts to lessen the possibility for bending, loosening or breakage of their internal fixation device.
- To allow for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility, and instructed to limit physical activities, especially lifting, twisting and any type of sport participation. The patient should be advised not to smoke, utilize nicotine products or consume alcohol or nonsteroidal anti-inflammatory drugs such as ibuprofen or aspirin during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s).
- The patient should be fully instructed in the appropriate postoperative care. The patient's ability and willingness to follow, as well as comprehension of the importance of following, instructions are one of the most important aspects of successful postoperative healing.
- Explanted surgical implants must never be reused.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics should be considered, especially for patients with increased risk for infection.

Packaging

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness, and all components, including instruments, to ensure there is no damage prior to use. Damaged packages or products should never be used and should be returned to the manufacturer.

Handling and Storage

The StabiLink® implants and instruments must be stored with care. Before use, inspect all instrumentation for proper function, possible damage, wear or nonfunction. Damaged or defective instruments should not be used. Contact the manufacturer for repair or replacement instructions.

Cleaning and Decontamination

The StabiLink® system implants and instruments are not supplied sterile. All packaging and labeling must be removed before the next steps. Cleaning must be done before processing the implants and instruments for sterilization.

Caution: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage some devices, particularly instruments. Such cleaning solutions should not be used.

Note: Some instruments may require disassembly prior to cleaning

Machine Cleaning Instructions (Recommended)

1. Prepare cleaning detergent
   a. Prepare an enzymatic detergent, following the manufacturer's instructions for preparation and use.
   b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
   c. The detergent should have a near-neutral pH to prevent pitting and tarnishing.
2. Prepare devices for soaking
   a. To prevent injury, separate out sharp and pointed devices and handle with care.
   b. Disassemble devices with removable parts.
   c. Open hinged, toothed or threaded joints.
   d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.
3. Clean and soak in detergent bath
   a. Immerse devices in prepared detergent bath.
   b. Allow devices to soak in detergent bath for the manufacturer's recommended soaking time.
   c. Brush all surfaces of the devices with a cleaning brush (do not use steel brushes) while they are submerged in the detergent bath ensuring that all visible soil is removed.
   d. Whenever applicable:
      i. Use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas.
      ii. Use a syringe to repeatedly apply rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves and hard to reach areas.
      iii. Repeatedly operate/bend/articulate movable joints while cleaning.
      iv. Brush the inside of hollow spaces along their entire length.
4. Load devices into washer
   a. Place devices so they do not collide during operation.
   b. Place heavy items at the bottom and hollow objects in the washing machine baskets.
   c. Ensure that no part is obstructed by large objects.
   d. Place articulating instruments in the fully open position and cannulated instruments horizontally.
   e. Place disassembled instruments in the washing machine baskets.
5. Washing and drying cycles
   a. 2 minutes: Prewash with cold water; drain.
   b. 5 minutes: Detergent wash with hot water; drain.
   c. 2 minutes: Neutralize with neutral pH detergent; drain.
   d. 2 minutes: Rinse with hot water; drain.
   e. Dry with hot air at a maximum of 115°C.
6. Inspect
   a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumen, cannulae, crevices, serrations, threading, etc.
   b. If visible soil remains, repeat the cleaning procedure.

Manual Cleaning Instruction

1. Prepare cleaning detergent
   a. Prepare an enzymatic detergent, following the manufacturer's instructions for preparation and use.
   b. Saline solutions should NOT be used, as saline has a corrosive effect on stainless steel.
   c. The detergent should have a near-neutral pH to prevent pitting and tarnishing.
2. Prepare devices for soaking
   a. To prevent injury, separate out sharp and pointed devices and handle with care.
   b. Disassemble devices with removable parts.
   c. Open hinged, toothed or threaded joints.
   d. Remove heavy or large debris using single-use, non-shedding wipes soaked in appropriate cleaning solution.
3. Clean and soak in detergent bath
   a. Immerse devices in prepared detergent bath.
   b. Allow devices to soak in detergent bath for the manufacturer's recommended soaking time.
   c. Brush all surfaces of the devices with a cleaning brush (do not use steel brushes) while they are submerged in the detergent bath ensuring that all visible soil is removed.
   d. Whenever applicable:
      i. Use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas.
      ii. Use a syringe to repeatedly apply rinsing solution under pressure to flush all cannulae, lumens, crevices, grooves and hard to reach areas.
      iii. Repeatedly operate/bend/articulate movable joints while cleaning.
      iv. Brush the inside of hollow spaces along their entire length.
4. Rinse
   a. Remove the devices from the soak bath.
   b. Thoroughly rinse the devices under running water for a minimum of 1 minute.
   c. Thoroughly flush cannulae, lumens and holes
5. Ultrasonic bath
   a. Prepare an ultrasonic bath containing a blood-dissolving detergent, following the manufacturer's instructions for preparat ion and use.
   b. Cover/seal the devices during transport from the rinse to the ultrasonic bath prevent contamination.
   c. Place devices in the ultrasonic bath.
   d. Ensure that the devices are completely submerged and do not overlap.
   e. Sonicate for 15 minutes. To avoid corrosion, do not exceed 15 minutes.
6. Rinse in sterile water
   a. Thoroughly rinse the devices with sterile purified water (i.e., RO or DI) for a minimum of 3 minutes.
7. Dry
   a. Dry the devices with single-use, non-shedding absorbent wipes and/or medical compressed air (e.g.,interiors of cannulae).
   b. Be sure to completely dry the devices immediately after rinse to inhibit corrosion.
8. Inspect
   a. Inspect the devices with the naked eye under normal lighting conditions to determine if all adherent visible soil (e.g., blood, protein substances and other debris) has been removed from surfaces, lumen, cannulae, crevices, serrations, threading, etc.
   b. If visible soil remains, repeat the cleaning procedure.

Lubrication

The use of instrument lubricant, compatible with the method of sterilization to be used, is recommended before sterilization of instruments. Ensure that instrument lubricant is diluted and maintained properly, according to the manufacturer's instructions. This type of lubricant is referred to as "instrument milk" and is usually applied by spraying the moving parts or by soaking the instruments in a solution. Lubricants that are too concentrated or too heavily applied will result in slippery instruments that will also be mistaken as wet after sterilization. After thoroughly cleaning instruments, proper application of lubricants to joints and torque handles will keep them moving freely and aid in protecting the surface from mineral deposits. Note that ultrasonic cleaners remove all lubrication; therefore this maintenance procedure should be done routinely after ultrasonic cleaning and before sterilization. Proper and timely lubrication is an integral step in maintaining the long-life of the surgical instrument. Lubrication will prevent the friction of metal on metal and preserve the smooth function of the instrument thus avoiding corrosion by friction. Furthermore, routine use of lubricating agents, on thoroughly clean instruments, will prevent hinged and other movable parts from sticking. Lubrication will aid in protecting the entire instrument surface from mineral deposits.

Sterilization

The StabiLink implants and instruments are supplied non-sterile. Implants and instruments must be sterilized prior to use. The recommended sterilization process is steam autoclave, using the parameters listed in the table below.

Method	Cycle	Temperature	Exposure	Minimum Dry Time
Steam	PreVacuum	132° C (270° F)	10 minutes	55 minutes
Steam	Gravity	132° C (270° F)	15 minutes	55 minutes

The recommended sterilization cycles have been validated to assure a Sterility Assurance Level (SAL) of at least 10-6. These gravity displacement and pre-vacuum sterilization cycles are not considered by the United States Food and Drug Administration (US FDA) to be standard sterilization cycles. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

Product Complaints

Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to Southern Spine - Tel: 478.745.0000. When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint and patient case number. Sterilize and return all component(s) to your local Southern Spine representative. Notify Southern Spine immediately of an incident resulting in patient death or serious injury.

Surgical Technique Guide

The surgical technique guide may be obtained by contacting Southern Spine customer service.

Further Information

If further directions for use of this system are needed, contact Southern Spine Customer Service,
Tel: 478.745.0000, Fax: 478.744.9996

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