Libra Pedicle Screw System

Important Note: The users of the Libra Pedicle Screw System must read and acknowledge

the conditions of this insert prior to use.

Consult the product electronic instructions for use for all current languages and latest document revision.

Description –

The Libra Pedicle Screw System is an implant system used to provide immobilization and stabilization of the non-cervical spine while fusion occurs. The Libra System consists of screws, rods, and fastening set screws in various configurations which can be assembled to create a construct that meets the needs of the patient. Screws are provided in monoaxial and polyaxial configurations in a variety of lengths and diameters in either solid or cannulated designs. Rods are provided in a variety of lengths in both straight and pre-bent configurations. Rods can be further shaped inter-operatively with instruments provided to obtain necessary spinal curvature.

Implants in the Libra Pedicle Screw System are manufactured from the following materials:

1.) Medical grade titanium alloy (Ti6Al4V as per ISO 5832-3 and ASTM F136).

The pedicle screws are anodized to facilitate size selection. Changes or variation in color during use or preparation do not affect implant quality.

Do not use any of the Libra System components with components from any other manufacturer or system unless specifically allowed to do so in this or any other Spinal Balance document. None of the Libra implants or implant components should be reused under any circumstances. The Libra Pedicle Screw System Instrument Kit is provided specifically for the implantation of the Libra Pedicle Screw System implants.

Indications –

The Libra Pedicle Screw System is intended for immobilization and stabilization of the posterior thoracolumbar spine (T1-S1) in skeletally mature patients for spinal fusion, degenerative disc disease, spondylolisthesis, stenosis, deformity, lumbar disc herniation, discogenic low back pain, and radiculopathy.

Contraindications -

Do not use the Libra Pedicle Screw System in presence of following:

- Any active or suspected latent infection in or about the spine.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
- Bone stock compromised by disease, infection, or prior implantation which cannot provide adequate support and/or fixation to the implant.
- Obesity can produce loads on the spinal system which can lead to failure of the fixation of the device or, to failure of the device itself.

- Fever or hyper-leukocytosis.
- Bony abnormalities preventing safe screw fixation.
- Any patient where implantation would interfere with anatomical structures or negatively affect the expected physiological performance, including cases where the selected implant components would be inappropriately sized to achieve a successful result.
- Wound healing disorders.
- Suspected or documented allergy/intolerance to the implant materials.
- Rapid joint disease, bone absorption, osteomalacia, osteopenia and/or osteoporosis.
- Patients having inadequate tissue coverage over the operative site.
- Pregnancy.
- Excessive local inflammation.
- Other medical (for example : anesthetics risks) or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count, (WBC) or marked left shift in the WBC differential count.
- Any case not needing bone graft and fusion.
- Any case that requires mixing different components or systems.
- Any patient unwilling to comply with postoperative instructions.
- Any case not listed under Indications for Use.
- Alcoholism, drug abuse or pharmaceutical drug dependency.

Complications and Adverse Effects -

Use and/or misuse of this system may result in the following list of complications and potential adverse effects:

- Loosening of any or all of the components.
- Disassembly, bending and/or breakage of any or all of the components.
- Inadequate fixation.
- Non-union, delayed union or mal-union.
- Allergic reaction to implant material, debris, corrosion products including metallosis, staining, tumor formation, and/or autoimmune disease.
- Infection.
- Wound healing disorders or hematomas.
- Fracture, damage or penetration of any spinal bone.
- Post-operative change in normal spinal curvature, loss of correction, height.
- Pain, skin penetration, irritation, fibrosis caused by skin pressure by implant components.
- Bursitis.
- Fracture, microfracture, resorption, damage or penetration of any spinal bone at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption or disc degeneration at, above or below the level of surgery.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.

- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, parasthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/or visual deficit.
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/or muscle loss.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Damage to the urological, gastrointestinal, and/or reproductive systems resulting in compromises including urinary retention, loss of bladder control, gastritis, bowel obstruction, loss of bowel control, sterility, consumption, sexual dysfunction etc.
- Decrease in bone density potentially caused by stress shielding.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Limited ability to perform daily activities.
- Continuation of symptoms that were to be treated for by the implantation.
- Change in mental status.
- Development of respiratory problems, e.g. Pulmonary embolism, bronchitis, pneumonia, etc.
- Death.

Additional surgery may be required to correct these potential adverse events and/or outcomes.

Precautions -

The implantation of the Libra Pedicle Screw System is a technically demanding procedure presenting serious risks to the patient. Implantation must be performed only by experienced spinal surgeons who have a thorough knowledge of the Libra System, its limitations, and lumbar spine fixation techniques. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique can be requested from Spinal Balance by calling the phone numbers at the end of this document. No manufacturer can be responsible for complications resulting from erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the Libra Pedicle Screw System rely upon individual patient physiological response, and proper use of the device does not guarantee any result. Use of the system off-label is forbidden by Spinal Balance.

The surgeon should consider the level of implantation, the weight of the patient, the patient's activity level or general conditions and any other factor which may have an impact on the performance of the system based on published fatigue test results of the system.

The Libra Pedicle Screw System implants are available in titanium alloy and cobalt chrome alloy. It is imperative that the Libra System implants do not come into contact in-vivo with other dissimilar metals.

Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.

Patients who smoke have been shown to have an increased risk of non-unions. Such patients should be advised of this fact and warned of the potential consequences.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting of significant loads, or muscle strain), resultant forces can cause fracture(s) and/or deformation of the device, leading to insufficient rigidity of the construct to promote fusion.

In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life to the device. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.

Patients should be instructed in detail about the limitations of the implants, including but not limited to the impact of excessive loading through patient weight or activity, and should be taught to govern their activities accordingly. Internal fixation appliances are load sharing devices which hold a segment in alignment until healing occurs. If healing is delayed or does not occur, the implant is likely to eventually break due to metal fatigue. An active, debilitated or demented patient who cannot properly use weight supporting devices may be particularly at risk for overstressing the construct leading to deformation or fracture during postoperative rehabilitation.

Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and service life of implants).

Care must be taken to protect the components from being marred, nicked or notched as a result of a contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

Inspection and trial assembly are recommended prior to surgery to determine if the instruments have been damaged during storage or prior procedures. If any components are marred, nicked, scratched, bent, or notched, do not use those components and return them to Spinal Balance.

Sale of this product is restricted to physicians.

Warnings –

The safety and effectiveness of pedicle screw 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 degenerative spondylolisthesis (grades 3 and 4) 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 is unknown.

This device is not intended or expected to be the only mechanism of support of the spine. Regardless of the etiology of the spinal pathology for which implantation of this device was chosen, solid biological support is anticipated but is not always obtained. Without solid biological support provided by bony fusion, the device cannot be expected to support the spine indefinitely and will lose effectiveness in any of several modes. These modes include, but are not limited to, bone-metal interface failure, rod fracture or deformation, and/or bone failure.

Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudoarthrosis, disc height loss, adjacent level disc degeneration, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, and expulsion. Risks and potential benefits must be provided to patients for whom this treatment modality is suggested.

This device must not be reused. Reuse may result in patient injury or other complications including but not limited to component fracture and/or deformation, breakage, difficulty with implantation, incompatibility with mating components and infection. It is the physician's responsibility to discard all damaged or mishandled implants.

Contouring or bending of an implant, may reduce its strength from fatigue and cause its fracture or deformation. If spinal implants (including rods) are excessively bent, bent forward and then backward or otherwise damaged during insertion or adjustment, they may not be implanted and must be replaced. Rods must be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted and are to be discarded. See the Libra Pedicle Screw System surgical technique for descriptions of appropriate bending and excessive bending of rods.

Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant fracture or deformation may result.

The Libra Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the Libra Pedicle Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Sterility of Implants -

The implants in the Libra Spinal System are provided sterile using irradiation.

Do not clean and/or resterilize implants. Do not reuse or re-implant devices that have contacted tissue and/or bodily fluids. Reprocessing may compromise the integrity of the device and lead to diminished service life and may also result in patient illness, injury, or death. Implants should be stored in their original packaging. Do not remove the implants from packaging unless they are to be used immediately. Prior to removal of the implants from the packaging, verify the integrity of the package and the product

expiration date. Do not use products where there is any question of package integrity and similarly, do not use any product after its expiration date.

See *Preparation at Point of Use* for instrument sterilization instructions.

Packaging -

The implants of the Libra Pedicle Screw System are provided in a double sterile barrier enclosure system. Ensure that the packaging of each implant component is intact upon receipt and that the expiration date has not passed. Do not use damaged or expired products or components with damaged packaging. Contact Spinal Balance prior to returning products, and return the damaged/expired packages and products with a note indicating the reason for return.

Instruments sets are provided in trays suitable for steam sterilization. Carefully inspect each set for completeness and inspect all instruments carefully to ensure that there is no damage prior to use.

Preparation at the Point of Use –

The implants of the Libra Pedicle Screw System are provided clean, sterile, and do not require any preparation prior to use.

The instruments of the Libra Pedicle Screw System are supplied non-sterile and must be thoroughly cleaned and sterilized prior to surgical use. Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization. Remove all packaging that individual instruments may be provided in prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container. Some instruments in the Libra system must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.

Follow the *Instrument Cleaning* and *Instrument Sterilization* Procedures below.

Instrument Cleaning and Decontamination Procedure –

Instruments exposed to tissue must be thoroughly cleaned after use. Dried residues from surgery will make the cleaning process more difficult and/or ineffective. Maximum recommended time between use and cleaning is 4 hours. Instruments should not be exposed to elevated air temperatures (>100 °F).

Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.

Manual Cleaning Procedure –

1. All assembled instruments must be disassembled prior to cleaning. For the Libra system this includes complete disassembly of the following:
    - Persuader, set screw driver, and removal of any attached handles
    - Pedicle screw driver, revision pedicle screw driver, screw taps and removal of any attached handles

- Set screw driver, counter torque wrench and removal of any attached handles

2. Completely submerge the instrument in a lukewarm neutral pH enzyme solution (Enzol® or equivalent) and allow it to soak for a minimum of 1 minute. Use a soft-bristled brush to gently clean the instrument (particular attention must be given to crevices, cannulations, hinges, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Brushing steps should be performed while submerged to prevent aerosols. A lumen brush must be used to clean cannulations. The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
3. Remove the instrument from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled). Thoroughly flush cannulations, holes, and other difficult to reach areas with a syringe or equivalent tool.
4. Prepare a neutral pH cleaning solution (Prolystica® or equivalent) according to the manufacturer's instructions and place in an ultrasonic cleaning unit.
5. Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.
6. Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
7. Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
8. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated.
9. **NOTE:** Instrument cases, trays, and caddies must be thoroughly cleaned according to the above instructions. Inspect the containment devices and if found to not be visually clean, repeat the previous cleaning steps.

Automated Cleaning Procedure –

1. All assembled instruments must be disassembled prior to cleaning. For the Libra system this includes complete disassembly of the following:
   - Persuader, set screw driver, and removal of any attached handles
   - Pedicle screw driver, revision pedicle screw driver, screw taps and removal of any attached handles
   - Set screw driver, counter torque wrench and removal of any attached handles
2. Rinse device(s) under running tap water to remove gross soil. Flush cannulations, holes, and other difficult to reach areas using a syringe.
3. Place device(s) into washer unit under the following parameters:

Phase	Recirculation Time (min)	Temperature (°C)	Detergent Type and Concentration
Pre Wash 1	2:00	Cold Tap Water	N/A
Enzyme Wash	2:00	Hot Tap Water	Enzol® 1 oz/gal
Wash 1	2:00	65.5	Prolystica® 2x Neutral 1/8 oz/gal
Rinsing	1:00	65.5	N/A(RO/DI water)

Drying	7:00	90	N/A

4. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated.

Instrument Sterilization Procedure –

Instruments should be sterilized in the steam sterilization case provided. Trays are to be stacked within the case during sterilization. Only FDA-cleared wraps, such as Kimguard KC600 (or other FDA-cleared accessories), validated to maintain sterility after processing, are to be used. The sterilization parameters provided below are recommended to achieve a sterility assurance level equal to at least 10^{-6}. Saturated steam with a quality of 97-100% must be used. Flash sterilization of the Libra System instruments is not recommended.

For instrument sterilization within the US, only the following method is recommended.

Steam	**Steam Condition / Vacuum Level**	**Temperature Sterilization**	**Minimum Exposure Time**	**Minimum Drying Time**
Method 1	Forced Air Removal (Prevacuum) / 10 inHg	132ºC (270ºF)	4 min	40 min

For instrument sterilization outside the US, the following method may be used.

Steam	**Steam Condition / Vacuum Level**	**Temperature Sterilization**	**Minimum Exposure Time**	**Minimum Drying Time**
Method 2	Forced Air Removal (Prevacuum) / 10 inHg	134ºC (273ºF)	3 min	40 min

Instrument trays should be placed on a cool-down rack outside of chamber for 30 minutes prior to use to prevent burn risk.

The recommendations provided above are validated by Spinal Balance, Inc. as being effective to a sterility assurance level (SAL) of 10^{-6}. It is the responsibility of the instrument processor to ensure that these parameters are met during cleaning and sterilization. Processors must use a controlled, validated, and routinely monitored process operated by trained personnel to achieve properly sterilized instruments. Any deviation by the processor from the recommendations above must be evaluated for effectiveness and the potential for adverse outcomes.

Physician Notes –

All the important information regarding the surgical procedure and risks must be conveyed to the patient and patient's consent must be documented. The surgical procedure and potential surgical outcomes must be explained to the patient. The patient's understanding of the following information must be documented:

- The patient is aware of the risks associated with neurosurgery, general surgery, orthopedic surgery, and with general anesthesia.
- The implant can fail due to excessive load, wear and tear, or infection.
- The service life of the implant is determined by body weight and physical activity.
- The implant must not be subjected to overload through extreme strain, or through work-related or athletic activities.
- Corrective surgery may be necessary if the implant fails.
- The patient must have their physician carry out follow-up examinations of the implant at regular intervals.
- The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
- The patient must be informed of the radiographic limitations associated with the Libra Pedicle Screw System.

US federal law restricts the sale of these devices by or on the order of a physician.

The operating surgeon should take note that selection of the proper dimension, shape and implant component for each patient is crucial to the success of the surgery.

Great care needs to be taken in patient selection, proper placement of the implant and postoperative management to minimize stresses on the implant. Such stresses might cause fatigue and consequent fracture(s) and/or deformation of the implant before the natural healing process is complete and may result in further injury and need for premature removal of the implant.

The implant system is intended to provide sufficient stability of the fusion site to acquire bone growth/formation sufficient to produce a fusion for a nominal amount of time. No system is expected to provide stability and support beyond the time normally expected for bone growth/ formation sufficient to take over the functions of stability and strength.

Preoperative Precautions

- Select only the patients that meet the criteria described in the indications section. Avoid patient conditions and/or pre dispositions addressed in the contraindications section.
- Make sure that all required implant components are ready at hand and an adequate inventory of implants is available at the time of surgery.
- Protect the implants and instruments during storage especially from corrosive environments.
- Avoid scoring, notching or scratching of implant components as it can lead to weakening of the implant.

- Ensure that all required implantation instruments including specialized Spinal Balance instruments are available and in working order.
- Ensure that operating conditions are highly aseptic.
- The surgeon and the operating room team should be well versed with the operating technique and the available range of implants and instruments.
- Ensure that all components and instruments are clean and sterile before use.
- Consult the manufacturer if the preoperative situation is unclear and prior implants were found in the area to be operated upon.

Intraoperative Precautions –

- Take extreme caution while operating around the spinal cord and nerve roots.
- Always utilize an imaging system to facilitate surgery.
- Breakage, slippage or misuse of instruments/implant components may result in injury to patient or operative personnel.
- Use care when preparing the surgical site with awls, taps, and probes. Excessive forces, such as over torqueing, impacting, bending, or malleting of the instruments may result in injury to the patient and instrument breakage.
- Do not bend metal implant components except for the rods. Avoid repeatedly or excessively bending the rods. Do not reverse bend the rod in the same location. Use care when aligning the rods in the rod bending instruments to prevent dropping of the rod and/or improper contouring. Only use the bending instruments of Libra spinal system instrument set for bending the rods.
- Make sure that the rod is correctly position in the saddle of the pedicle screw head before mounting the set screw.
- Always use the specific instruments provided in the Libra spinal system instrument set for performing the compression, distraction and reduction maneuvers. Always ensure the instruments are fully seated on the implants.
- Do not over-tap or use a screw that is too large/too long. It may result in nerve damage, hemorrhage and other potential adverse effect listed previously.
- For tightening and loosening of the set screws, always use the screwdriver and the counter torque instrument. Always provisionally tighten components before final tightening.
- Always perform final tightening of the set screws with the use of the torque wrench and do not over tighten the set screw beyond the specified value. Always recheck the tightness of all set screws after finishing the construct to make sure that none of the other set screws loosened during the tighten of other screws. Failure to do so may result in premature loosening of construct or failure.
- Break off the extension tabs of the pedicle screw only after the set screw has been fully tightened.
- Always use the tab breaker from the Libra spinal system instrument set for this purpose.
- Bone graft must be used in the area to be fused and must extend between the operated vertebrae.
- Bone cement should not be used with the Libra System, as safety and efficacy of bone cement in combination with the System has not been determined.

Postoperative Precautions –

- The detailed limitations of the implant should be given to the patient. The patient should be notified that intense physical activity, extreme strain or sports can overload the implant component and lead to breakage or loosening.
- The patient should be warned to avoid falls or jolts to the spinal column.
- The patient should be advised not to smoke tobacco or use nicotine products, or to consume alcohol or non-steroids or anti-inflammatory medications as it presents a higher risk of bone fusion failure.
- The patient should be advised that a regular medical checkup of the implant components is necessary.
- The patient should be notified of their inability to rotate or bend at the point of fusion and should be taught how to compensate for this permanent restriction in body motion.
- It is necessary that the surgical site be immobilized until firm bony union occurs and is confirmed by radiological examination.
- In case of a failed /non-union or if the components break, loosen or bend, it is suggested that the device be revised and/or removed as serious injury can occur. The patient needs to be made aware of these hazards.
- Any retrieved implants should be treated/handled so that reuse in another surgical procedure is not possible. The Libra spinal system components should never be re-used under any circumstance.
- The Libra spinal system implants are internal fixation devices designed to stabilize the operative site during the normal healing process. After the spine is fused, the implants serve no function and may be removed. Decision on implant removal is at the discretion of the surgeon and patient. If the implants are not removed, further complications may occur including: Local tissue reaction or pain, implant corrosion, implant migration and possibly injury, breakage of implant making removal difficult, infection, bone loss due to stress shielding, and potential unknown or unexpected long term effects.
- Implant removal must be followed by adequate postoperative management to avoid additional fracture (bone and/or implant if some portions of the construct are not removed) or complications.

Procedure

The Libra Pedicle Screw System must be implanted only with the prescribed instruments. The Libra Pedicle Screw System instruments are available from the manufacturer. The procedure overview provided below is not sufficient to perform surgery using the Libra Pedicle Screw System. Physicians and other relevant surgical staff must be trained on proper use of the system and the Libra System Surgical Technique must be thoroughly understood.

Preoperative

The operating surgeon develops surgical plan specifying implant components and their dimensions, proper position of the implant components, intraoperative orientation points. Prior to installation of implants, the surgeon should ensure all implant components are available. All instruments must be cleaned and sterilized according to the instructions for use above, checked for functionality, and be

presented to the surgical field using aseptic techniques. The surgical staff must be thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied.

Consult preoperative precautions above.

WARNING: The use of an instrument for tasks other than those for which they are intended can result in patient injury or instrument damage.

Intra-operative

Verify the integrity of the sterile packaging, indicator for sterility, and check the product expiration date. Never use implants if the packaging is damaged. Never use implants that are past their expiration date. Prepare the surgical site for implant introduction. A variety of instruments are provided to prepare the pedicles prior to screw insertion. Pedicle probes have depth markings at intervals of 10mm accurate to ±1mm to assist in determining necessary screw length. Taps also have depth markings at intervals of 10mm accurate to ±1mm to assist in determining necessary screw length. Introduce the pedicle screws into the pedicles of the affected motion segment using the pedicle screw inserter.

Remove K-wires, if applicable. Measure the distance between the pedicle screws using the rod trial and select the appropriate size rod based on the trial. The rod trial has length markings at intervals of 10mm with an accuracy of ±1mm to facilitate rod selection. Place the rod using the rod gripper or rod holder, and then secure with a set screw using the set screw driver and ratcheting handle. If necessary, the persuader can be used for additional reduction. Only hand tighten the set screws until all rod maneuvers are complete. Use the distractor or compressor to achieve proper spinal alignment. Once aligned, use counter torque wrench to securely hold the construct during set screw tightening and prevent excessive torque on the construct. Final tightening of the set screws must be performed using the set screw driver and torque limiting handle. After tightening, remove any extension tabs using the tab breaker. Place bone graft in the posterolateral gutters to facilitate fusion of the segment.

Postoperative

Reiterate postoperative instructions to the patient. Ensure that the patient is aware of physical activity restrictions, environmental limitations, and possible adverse reactions.

Revision Surgery and Implant Removal

The implants of the Libra Pedicle Screw System are intended for permanent implantation and are required to be removed. However, removal may be advisable in the following situations:

- Development of a solid fusion mass where the Libra implants are no longer serving a clinical purpose
- Implant breakage
- Pain due to the implant
- Infection

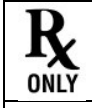
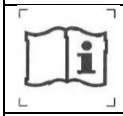
Implant removal must be performed using the supplied Libra Pedicle Screw System instruments. Implant removal must be performed by first removing all set screws using the set screw driver and counter torque wrench. Remove the rod(s), and then remove the pedicle screws using the revision pedicle screw driver.

Product Complaints -

Any customer or user of this system of products, who has any complaints or has experienced any dissatisfaction regarding the product quality, performance, durability, reliability, safety, and effectiveness should notify Spinal Balance.

Spinal Balance should be notified immediately if any of the implanted spinal system components does not meet any of its performance specifications or does not perform as intended.
If any Spinal Balance product may have contributed to the death or serious injury of a patient, Spinal Balance should notified immediately by telephone, fax and/ or written correspondence. Please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from Spinal Balance is requested.

Symbols Glossary –

Title of Symbol	Description	ISO 15223 Reference
 Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4
 Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4
 Prescription Required	N/A	N/A
 Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
 Material	N/A	N/A
 Caution	Indicates the need for the user to consult the instructions for use for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4
 Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
 Manufacturer	Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1
 Do not use if package is damdamaged. Do not use if the product sterilization	Indicates a medical device that should not be used if the package has been damaged or	5.2.8

barrier or its packaging is compromised.	opened.	
EC REP Authorized representative in the European Community	Indicates the Authorized representative in the European Community.	5.1.2

Copies of this document may be requested by calling the following numbers:

USA: 1(855)236-0910

Europe: +800 135 79 135

For further information, contact:

Manufacturer:
Spinal Balance, Inc.
11360 South Airfield Rd.
Swanton, OH 43558
USA

www.spinalbalance.us

Telephone: +1 (419)530-5940
Fax: +1(419)530-5932

EC REP
Authorized Representative:
Emergo Europe
Emergo Group
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

CE
2797

www.emergogroup.com
Telephone: +31 70 345 8570