SpineEX®, Inc.

⚠ Instructions for Use

Sagittae® Lateral Lumbar Interbody Fusion System

Type of Devices in System:

- Sterile Implants-Single Use
- Non-Sterile Instruments-Reusable

STERILE R

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN. FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

Please carefully read these instructions for use, the corresponding surgical techniques, and cleaning and sterilization instructional documents for the accompanying reusable surgical instruments carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Intended Use

The SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices are indicated for interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment. Supplemental fixation is required with SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices along with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. These devices are intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g. posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). Hyperlordotic interbody fusion devices (≥20° lordosis) must be used with at least anterior supplemental fixation.

Description

The SpineEX Sagittae® Lateral Lumber Interbody Fusion Devices are manufactured out of medical grade Ti-6Al-4V (Grade 5) and Ti-6A-4V (ELI) alloy that conforms to ASTM F1472 and ASTM F136. The devices are multi-component assembly implants that accept an operating rotational motion (" input torque") and translate that motion into a linear expansion motion in the superior and inferior directions allowing for various device height and lordosis configurations following implantation.

The device has an anterior drive shaft (1) and a posterior drive shaft (2) component that both interface with various accompanying surgical torque limiting instruments, that safely transfer the applied rotation to the device during operation . The anterior drive shaft (1) and posterior drive shaft (2) components allow for various operating adjustment options depending on the desired final device configuration. Simultaneous operation of the anterior drive shaft (1) and posterior drive shaft (2) will expand the anterior and posterior sides of the device across the intervertebral disc space together in equal increments creating a device configuration with parallel height. Independent operation of the anterior drive shaft (1) or posterior drive shaft (2) will expand only the anterior or posterior side of the device creating a device configuration with an offset height, or an added angle. Device configuration options allow for optimal disc height and angle of lordosis restoration unique to each particular patients' anatomical requirements. If needed the applied rotation of the anterior drive shaft (1) and posterior drive shaft (2) can both be operated in the reverse rotational directions to undo an added device configuration or contract the device back to its initial starting configuration.

The device has two extension springs (3) that are welded to the outer shells (4) to allow for a secure secondary connection of the two outer shells (4) to each other while the device is being transferred from the sterile field into the intervertebral space. Open interior space in the implant allows for packing of graft prior to implantation and expansion adjustments, and/or the option to inject graft with delivery instruments following implantation and device configuration expansion adjustments. Ridged textures on the outer surfaces contact the vertebral endplates. The device is designed for placement between two vertebral bodies.

Various device length footprints are available all offering the same expansion adjustment configuration options to accommodate a variety of patient's bodies. SpineEX prepares Surgical Technique Guides showing the use of SpineEX implants and instruments. Please contact your SpineEX sales representative to obtain copies of these Surgical Technique Manuals.

Please refer to the Surgical Technique Guides for additional important information about the SpineEX Lateral Lumbar Interbody Fusion Devices.

Contraindications

This device is not intended for cervical spine use. Contraindications include, but are not limited to:

1. Infection, local to the operative site
2. Signs of local inflammation,
3. Fever or leukocytosis,
4. Morbid obesity,
5. Pregnancy,
6. Mental illness,
7. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count,
8. Suspected or documented allergy or intolerance to implant's materials,
9. Any case not needing a fusion,
10. Any case not described in the indications,
11. Any patient unwilling to cooperate with postoperative instructions.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
14. Spondylolisthesis unable to be reduced to Grade 1.
15. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
16. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
17. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
18. Prior fusion at the level to be treated.

Potential Adverse Events

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or Pseudarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury. Cerebral spinal fluid leakage.
10. Haemorrhage of blood vessels and/or hematomas.
11. Discitis, arachnoiditis, and/or other types of inflammation.
12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
13. Bone graft donor site complication.
14. Inability to resume activities of normal daily living.
15. Early or late loosening or movement of the device(s).
16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
18. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
20. Loss of or increase in spinal mobility or function.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Cessation of any potential growth of the operated portion of the spine.
25. Death.

Warnings and Precautions

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 result. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Preoperative and operating procedures, including knowledge of surgical technique, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by SpineEX, Inc. In the interests of patient safety, it is therefore recommended that SpineEX, Inc. implants are not used with instruments from any other source.

Never, under any circumstances, reuse a SpineEX Lateral Lumbar Interbody Fusion Device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Magnetic Resonance Environment

The SpineEX Lateral Lumbar Interbody Fusion Devices have not been evaluated for safety and compatibility in the MR environment. The SpineEX Lateral Lumbar Interbody Fusion Device has not been tested for heating or migration in the MR environment.

OTHER PREOPERATIVE, INTRAOPERATIVE, AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS:

Implant Selection

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

Preoperative

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the afore mentioned contraindications should be avoided.
3. Care should be taken in the handling and storage of the device(s). They should not be scratched or damaged. Devices should be protected during storage especially from corrosive environments.
4. Further information about this system will be provided upon request.
5. The surgeon should be familiar with the various devices before use and should personally verify that all devices are present before the surgery begins.
6. The size of device for the case should be determined prior to the beginning of the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Unless supplied sterile, all devices should be cleaned and sterilized before use.

Intraoperative

1. The instructions in any available SpineEX Lateral Lumbar Interbody Fusion Devices surgical technique guide should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
5. Proper selection of the shape, size, and design of the implant by the surgeon and subsequent placement during surgery are extremely important. Refer to the SpineEX Lateral Lumbar Interbody Fusion Device Surgical Technique Guide for specific instructions related to the surgical procedure.
6. The surgeon must be thoroughly familiar not only with the medical aspects of the SpineEX Lateral Lumbar Interbody Fusion Device, but must also be aware and instruct the patient on the use and limitations of implants.

Postoperative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.
2. The patient should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
3. The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and / or break, the devices should be revised and / or removed immediately before serious injury occurs.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

Packaging

Packages containing implants or instruments should be intact upon receipt. Do not use if the seal is broken. Do not implant the sterile device past the expiration date. Use proper aseptic technique to transfer the contents of the sterile package to the surgical field. Surgical cases serve to hold devices on customized trays during sterilization, and subsequent storage and transportation. Prior to use, all packages of implants and instruments should be checked for completeness and to ensure that there is no damage. Damaged packages, implants or instruments should not be used and should be returned to the distributor or SpineEX, Inc.

Implant Sterilization

All the SpineEX Sagittae® Lateral Lumbar Interbody Fusion Device implants are irradiated by gamma radiation with a minimum dose of 25 kGy and are delivered sterile. The packaged implant is sterile for 5 years provided that the packaging remains intact. All implants are for single use and should not be re-sterilized.

Reusable Instrument Cleaning

All devices should be positioned to allow sterilant to come in contact with all surfaces. Care should be taken to protect devices from mechanical damage.

1. Disassemble device, if device can be disassembled, prior to reprocessing.
2. Further detailed instrument Dismantling instructions are available from your local sales representative.
3. Open devices with ratchets, box locks or hinges.
4. Remove sharp devices for manual cleaning or place into a separate tray.
5. Lumens/cannula of devices should be manually processed prior to cleaning. Lumens/cannula should first be cleared of debris. Lumens/cannula should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannulation to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannulation may not effectively clean the surface of a lumen/cannulation.
6. Pre-Cleaning: Remove gross contaminants by immersing the devices in room temperature neutral pH enzymatic cleaner (i.e. Metrizyme). Scrub with appropriate soft bristle brush until visibly and thoroughly clean.
7. Washing: Immerse devices in washer/cleaner with room temperature neutral pH enzymatic cleaner and wash for 10 minutes.
8. Rinsing: Thoroughly rinse the devices with deionized or distilled water for 2 minutes, three (3) times.
9. Verification: Examine devices under normal lighting to ensure no visual contamination. Repeats steps 1-4 if not visibly clean.
10. Drying: Allow devices to air dry a minimum of 45 minutes prior to inspection and sterilization preparation.
11. Preparation: After cleaning/disinfection, visually inspect the devices. Check for burrs or scraps.

Sterilization: It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specified in this package insert.

Reassembly of instruments can be accomplished by following step 2 in reverse.

It is recommended that devices should be reprocessed as soon as is reasonably practical following use.

Visually inspect all reusable devices for signs of wear and tear before each use. Any devices with corrosion, discoloration, or cracked seals should be disposed of properly.

Automated (Mechanical) Instrument Cleaning

Pre-Cleaning Method for Automated Process:

1. Rinse the device components under running lukewarm tap water (22° - 43° C (72º - 110ºF)) for a minimum of one (1) minute. After rinsing, remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth.
2. Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
3. Fully immerse the device components in the fresh, newly prepared enzymatic cleaning solution for a minimum of five (5) minutes.
4. After soaking, manually clean the device components for a minimum of two (2) minutes using a soft-bristled brush to remove soil and debris from the device and device lumens. Brush the device while fully immersed to prevent aerosolization of contaminants. After cleaning, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 mL of the cleaning solution.
5. Remove the instrument from the cleaning solution and place the device components in a bath of lukewarm tap water (22 - 43°C (72º - 110ºF)) for a minimum of one (1) minute. Ensure that the water immerses the components. Once the rinse time has elapsed, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 mL of the water.

Automated Process

1. Place the device components in the automated washer.
2. Perform the automated cycle noted in the table below.
3. Visually inspect the device; it should be clean, dry and residue-free.

Cycle	Time (Minutes: Seconds)	Minimum Temperature	Type of Detergent
Enzyme Wash	4:00	Heated Hot Water (60ºC (140ºF))	Enzymatic Cleaner per the Manufacturer's Instructions
Wash	2:00	Hot Water	Neutral Detergent per the Manufacturer's Instructions
Rinse	2:00	Heated Deionized or High Purity Water	NA
Dry	15:00	80ºC (176ºF)	NA

Instrument Sterilization

Products are supplied non-sterile. Non-sterile devices must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. For instruments with moving parts, lubricate mechanisms and rotating part-on-part contact points with a steam-permeable, water soluble instrument lubricant, and place the product in an FDA cleared wrap or container prior to steam sterilization. The following parameters have been validated to a sterility assurance level of 10^{-6}.

Method	Steam
Cycle Type	Pre-Vacuum
Temperature	132ºC
Full Cycle Time	4 minutes
Minimum Dry Time	30 minutes

Product Complaints

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the manufacturer, SpineEX, Inc. Further, if any of the implanted SpineEX Lateral Lumbar interbody Fusion Device 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 manufacturer should be notified immediately. If any SpineEX, Inc. product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone or written correspondence. When filing a complaint, 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 the manufacturer is requested.

Recommended directions for use of this device (Surgical technique guide) are available at no charge upon request. If additional information is needed or required, please contact:

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