PHAMEDICA INC.
Spinal Fixation System

15 Newtown Rd, Plainview
NY 11803
Ph: +1 (516) 469-9847
www.phamedica.com

Instructions For Use

PHA S1 Spinal Fixation System

Phamedica PHA S1 Spinal Fixation System is developed to address the advanced demands of surgical techniques. Enhanced and improved comparing to similar systems in the market, yet avoided the weaknesses and limitations. The PHA S1 Spinal Fixation System is low profile system featuring robust mechanism and versatile application. Phamedica PHA S1 Spinal Fixation System consists of Poly Axial Screws, Mono Axial Screws, Poly Axial and Mono Axial Reduction Screws, Rods, Set Screws, Transverse and Offset connectors made from Titanium Alloy Ti6AL4V which can be variously assembled for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine.

GENERAL

Before any surgery, the surgeon must be familiar with the sales literature and operative technique and must carefully read these instructions for use. Patient selection is as important as implant placement and positioning. Obesity or unsuitable functional requirements may generate exceptional stresses and reduce the implant life. The warnings must be heeded and the instructions for use must be strictly followed.
Like any other temporary internal fixation devices, Phamedica PHA S1 Spinal Fixation System implants have a finite useful life. The patient’s activity level has a significant impact on this useful life. Inform your patient that any activity increases the risk of loosening, bending, or breaking of the implant components. Instruct patients about postoperative activity restrictions and examine patients postoperatively to evaluate the fusion mass development and the implant status.
Please note that: The implant(s) can be prescribed and implanted only by a doctor legally authorized to perform this type of surgery.

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INDICATION

Phamedica PHA S1 Spinal System is intended for posterior non-cervical pedicle fixation of Thoracic, Lumbar, Sacral/Iliac Spine for all of the following indications:

- Degenerative Disc Disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal Stenosis
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion in skeletally mature patients.

The Implants are inteded to provide stabilization as an adjunct to fusion used with autogenous bone graft or allograft following reduction of fractures/dislocations or trauma in the spine.

Contraindications

Our system is contraindicated in the following cases:

- Any medical, mental or surgical condition precluding the potential benefit of spinal surgery or surgery in general including conditions that have been shown to be safely and predictably managed without the use of internal fixation devices
- Acute or chronic systemic, spinal or localized infections
- Active, severe systemic and metabolic diseases
- Morbid obesity (BMI>40 or weight more than 100 lbs over ideal body weight)
- Pregnancy
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism
- Lack of patient cooperation
- Foreign body sensitivity to the implant material
- Degenerative scoliosis greater than 25 degrees
- Any entity or condition that totally precludes the possibility of fusion, i.e., cancer,

kidney dialysis, or significant osteopenia
- Severe osteoporosis as it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system
- Patients who may place undue stresses on the implant during bony healing and may be at higher risk for implant failure because of their occupation or lifestyle
- Soft tissue deficit not allowing wound closure
- Congenital abnormalities, tumors or other conditions that would prevent secure component fixation that has the potential to decrease the useful life of the device
- Inadequate pedicles or vertebral body geometry of the thoracic, lumbar and sacral vertebrae
- Bony lumbar spinal stenosis
- Pars defect
- Clinically compromised vertebral bodies at affected level due to current or past trauma

ADVERSE EFFECTS

Adverse effects may occur when the implant is used either with or without associated instrumentation. Adverse events may necessitate re-operation or revision. A revision is a procedure, which adjusts or in any way modifies the original implant configuration

- Implant migration
- Disassembling, bending or breakage of the implant
- Sensitivity or allergic reaction, foreign body reaction
- Skin or muscle sensitivity
- Non-union or delayed union
- Infection
- Loss of proper spinal curvature, correction, height and / or reduction.
- Bone fracture or bone loss or decrease in bone density, possibly caused by stresses shielding at, above or below the level of surgery.
- Loss of bladder control or other types of urological system compromise
- Loss of neurological function, Dural tears, Pain and discomfort
- Bursitis
- Bone graft donor site pain

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- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction
- Cardiovascular disorders including deep venous thrombosis, thrombophlebitis and / or pulmonary embolus.
- Discitis, arachnoiditis and / or other types of inflammation.
- Death

Warnings and precautions

Only experienced spinal surgeon with specific training should perform the implantation of spinal pedicle screw. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. 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 human anatomy. Unless great care is taken in patient selection, placement of the implant and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage of the implant before the fusion process is complete, which may result in further injury or the need to remove the implant prematurely

Preoperative

Instruments must be inspected visually before the operation. Distorted or damaged instruments may result in malposition of the implant or implant failure.

- Patients who meet the criteria described in the indications should be selected.
- Patients with the conditions and / or predispositions such as those addressed in the contraindications should be avoided.
- Care should be taken in the handling and storage of the implant(s). They should not be scratched or damaged.
- The surgeon should be familiar with the various implants before use and should personally verify that all implants are present before the surgery begins.
- The surgeon should make sure all the implants and instruments are unpacked sterile and available prior to the surgery.

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- Implants and instruments should be protected during storage, especially from corrosive environments.
- The size of the implant(s) for the case should be determined prior to beginning 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.
- Additional sterile implants should be available in case of any unexpected need.

INTRAOPERATIVE

- The surgical manual technique should be carefully followed.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage or misuse of instruments or implants may cause injury to the patient or operative personnel.
- The implant surface should not be scratched or notched since such actions may reduce the functional strength of the implant.
- To ensure proper fusion below and around the location of the fusion, autogenous bone graft or autologous bone graft should be used.
- The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct.
- Utilize an imaging system to facilitate surgery.
- Do not over tap or use a screw that is either too long or too large. Over tapping, using an incorrectly sized screw, or accidentally advancing the guidewire during taps or screw insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.
- All implants are to be tightened firmly and rechecked before closing soft tissue.

Postoperative

- For best possible results, patients must be consulted to avoid lifting, twisting, physical activities, smoking, consuming alcohol and any activities that would compromise or delay the procedure of the healing.
- The patient should be advised of the inability to bend at the point of spinal fusion and be taught to compensate for this permanent physical restriction in body motion.
- It is important that the immobilization of the union is established and confirmed by radiographic examination.

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- Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended.
- After the spinal fusion is completed, the surgeon must consider removing the implant if not the following condition may occur:
    - Corrosion
    - Migration of implant position, possibly resulting in injury
    - Risk of additional injury from postoperative trauma
    - Bending, loosening and breakage, which could make removal impractical or difficult
    - Pain, discomfort, or abnormal sensations due to the presence of the device
    - Possible increased risk of infection
    - Bone loss due to stress shielding
    - Potential unknown and/or unexpected long-term effects such as carcinogenesis.

Packaging and sterilization

Phamedica PHA S1 Spinal System implants are packed in protective packaging that is labeled according to its contents. They are supplied as non-sterile and must be sterilized prior to use. Remove the entire package before sterilization. Damaged packages or products should not be used, and should be returned to the local distributor.

Cleaning of Reusable Instruments

1. Equipment: Germicidal Detergent (ex. - Vesphenee Ilse 8% solution), brush, running water & deionized water or equivalent.
2. Wipe instruments with alcohol.
3. Mix the Vesphenee Ilse detergent solution by adding 8.0 ml of Vesphene® Ilse to 992.0 ml of sterile water.
4. Bathe the contaminated instruments with detergent solution for 15 minutes at 40CC. The instruments shall be briskly moved to promote flushing.
5. Scrub instruments with a soft brush.
6. Rinse the instruments in cold water.
7. Submerge the instruments in detergent solution for an additional 15 minutes at 40CC.
8. Scrub instruments with a soft brush.
9. Rinse the instruments in deionized water.
10. Pat dry the instruments with a clean, disposable, absorbent Kimwipe or equivalent.

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11. Allow devices to air dry for a minimum of 20 minutes.
12. Visually inspect each device for any visible soil and repeat steps 5-11 if necessary. Reassemble the devices prior to extracting.
13. After cleaning, check for misalignment or damage. Mechanically test the working parts to verify that each device is functioning properly.
14. Prepare devices for sterilization.

STERILIZATION FOR IMPLANTS AND INSTRUMENTS

Warning: Phamedica Inc, does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded. All implants and instruments used in surgery must be sterilized by hospital prior to use. Remove all packaging materials prior to sterilization. Only sterilized products should be placed in operative field.
To achieve a sterility assurance level of SAL 10-6, Phamedica Inc. recommends the following parameters:

Method	Cycle	Temperature	Exposure Time	Drying Time
Steam	Gravity Displacement (Wrapped)	132C' (270'F)	15 Minutes	30 Minutes
Steam	Pre-Vacuum (Wrapped)	132C' (270'F)	4 Minutes	20 Minutes

- Note: An FDA Cleared Wrap must be used.

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

Single Use Only

STORAGE

The packages must be stored in a cool, dry place, not exposed to sunlight.

GUARANTEE

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The guarantee is only applicable if the device is used in accordance with normal conditions, as defined in this instruction and in conformity with the recommended surgical technique.

CAUTION

The Phamedica PHA S1 Spinal System has not been evaluated for safety and compatibility in the MR environment. The Phamedica PHA S1 Spinal System has not been tested for heating or migration in the MR environment.

CAUTION
Federal law (USA) restricts this device to sale by or on the order of a physician.

PICTOGRAMS