Instructions For Use are subject to change, the most current version of each Instruction For Use is always available online.
Important information – please read prior to use.

Spinal Pedicle Screw System

Manufacturer Name	S.H. PITKAR ORTHOTOOLS PVT. LTD. EL-32, "J" Block, MIDC Bhosari, Pune 411026, India Tel: +91 20 40706464 Fax: +91 20 46768107 Email: info@pitkar.net
Method Code	**Processing of the Spinal Pedicle Screw System Medical Devices**
Symbol	Attention, see instructions for use
Device(s)	The PITKAR Spinal Pedicle Screw System NOT SUPPLIED "STERILE"
Limitations and restrictions on reprocessing	PRODUCTS LABELED FOR SINGLE-USE MUST NOT BE REUSED. (IMPLANTS ARE SINGLE USE AND INSTRUMENTS ARE RE-USABLE)

DESCRIPTION AND INDICATIONS FOR USE	The Pitkar Spinal Pedicle Screw System is comprised of non-sterile, single use, titanium alloy components for creating an anterior or posterior spinal implant construct. The system attaches to the spine through a component system comprised of screws, D Connectors and rods The system is designed to stabilize the spine during the intervertebral fusion process. **Indications:** 1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) 2. spondylolisthesis 3. trauma (i.e., fracture or dislocation 4. spinal stenosis, 5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), 6. tumor, 7. pseudoarthrosis, and 8. failed previous fusionin skeletally mature patients
MATERIALS	Titanium Alloy (Ti-6Al-4V ELI)
ASSOCIATED DEVICE SYSTEM WITH THESE INSTRUCTIONS FOR USE	Unilock Spinal System, Trigen Spinal System, ProMIS Spinal System containing Pedicle screw, Polyaxial Pedicle screw, Reduction screw, V-locx screw, Rods, D connector, PolyaxialElliac screw, Elliac connector, Domino Connector
CONTRAINDICATIONS	Contraindications include, but are not limited to: 1. Active infectious process or significant risk of infection (immunocompromised). 2. Signs of local inflammation. 3. Fever or leukocytosis. 4. Morbid obesity. 5. Pregnancy. 6. Mental illness. 7. Grossly distorted anatomy caused by congenital abnormalities. 8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count. 9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or

	osteoporosis. Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation. 10. Suspected or documented metal allergy or intolerance. 11. Any case not needing a bone graft and fusion. 12. Any case where the implant components selected for use would be too large or too small to achieve a successful result. 13. Any case that requires the mixing of metals from two different components or systems. 14. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
NOT FOR USE	Do not use PITKAR products in conjunction with those of other manufacturers, unless otherwise specified, as the combination is not converted by the necessary validation.
WARNINGS	**Intra-Operative**: 1. The two primary goals of surgery with the Spinal Fixation System are to correct the deformity presented and to arthroses selected vertebrae. Adequate exposure bony preparation and grafting is essential to achieving these results. 2. Whenever possible, use pre-cut rods of the length needed. The rods should not be repeatedly or excessively bent any more than absolutely necessary. 3. 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 in any way. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. 4. The use of two rods and cross connecting the rods will provide a more rigid construct. 5. The placement of screws should be checked radiographically prior to assembly of the rod construct. 6. Care should be taken when positioning the implants to avoid neurological damage. 7. To facilitate proper fusion below and around the location of the instrumentation, a bone graft should be used. 8. Confirm that the rods are fully seated in the bottom of the screw head. Rods that are not fully seated may prevent the device from locking together. 9. Before closing the soft tissues, all of the set screws should be tightened firmly with a torque wrench or screwdriver according to the operative technique. Recheck the tightness of all screws and nuts to make sure that none loosened during the tightening of the other set screws. Failure to do so may cause loosening of the other components 10. Implants are single use only. No metallic surgical implant should be reused. Any metal implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patters which may lead to fatigue failure. 11. "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. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe 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 are unknown."

	12. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient." **Post-Operative:** 1. Detailed instructions on the use and limitations of the implant should be given to the patient. The patient must be made aware of the limitations of the implant. Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation device. 2. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. 3. Surgical implants must never be reused. Any retrieved devices should never be reused in another surgical procedure. The retrieved parts should be handled and disposed of in such a manner as to ensure that reuse is not possible. 4. To allow the maximum potential for a successful surgical result, the patient or device should not be exposed to mechanical vibration that may loosen the device construct. 5. These implants are temporary internal fixation devices. Internal fixation devices are designed to assist in the stabilization of the operative site during normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. In most cases removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, complication may occur as follows: • Corrosion, with localized tissue reaction or pain. • Migration of implant position resulting in injury. • Risk of injury from postoperative trauma. • Bending, loosening and/or 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 caused by stress shielding. Adequate postoperative management to avoid fracture, re-fracture or other complications should follow implant removal.
PRECAUTIONS	• The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. • A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. • This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. • Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the

	system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.
POSSIBLE ADVERSE EVENTS	All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes: 1. Device component fracture 2. Loss of fixation 3. Non-union 4. Fracture of the vertebra 5. Neurological injury 6. Vascular or visceral injury 7. Early or late loosening of any or all of the components 8. Disassembly and/or bending of any or all components 9. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease 10. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain 11. Post-operative change in spinal curvature, loss of correction, height, and/or reduction 12. Infection 13. Pain, discomfort, or abnormal sensations due to the presence of the device 14. Hemorrhage 15. Cessation of any potential growth of the operated portion of the spine 16. Death 17. Potential risks identified with the use of the device system may require additional surgery
MRI SAFETY INFORMATION	The PTKAR Spinal Pedicle Screw System have not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the PRO-MIS Spinal Systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury
STORAGE AND HANDLING	1. Packaged implants & instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/ humidity extremes. 2. Care must be exercised in handling of wrapped cases or individual implants & instruments to prevent damage to the sterile barrier. 3. The health care facility should establish a shelf life for sterilized implants & instruments based upon the type of sterile wrap or rigid container used. 4. Sterile implants & instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised **Note:** Maintenance of sterile package integrity is generally event related. If a sterile wrap is torn, perforated, shows any evidence of tampering or has been exposed to moisture, the instrument set must be cleaned, repackaged and sterilized**.**
RISKS DUE TO THE RE-	The "SINGLE USE" implantable device* of PITKAR Spinal Pedicle Screw System is

USE OF "SINGLE USE" IMPLANTABLE DEVICE*	identified through symbol reported on the product label. After the removal from the patient, the implantable device* has to be dismantled. The re-use of implantable device* introduces contamination risks for users and patients. The re-use of implantable device* cannot guarantee the original mechanical and functional performances compromising the effectiveness of the products and introducing health risks for the patients. (*): Implantable device: Any device intended to be totally/partially to be introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device. Product/s shall be stored in their original packages, in specific area protected against warmth source, humidity and dust, at Standard Conditioning Atmosphere. Product/s shall be protected from direct sunlight, ionizing radiation, extreme temperatures, particulate or microbial contamination. Product/s shall be protected during the transport to avoid potential damage. They do not require controlled temperature transport.
INSTRUCTIONS FOR REPROCESSING OF REUSABLE DEVICES (INSTRUMENTS)FOR SUBSEQUENT RE-USE	
GENERAL	•All Pitkar medical devices must be sterilized prior to surgical use. •A new product means any device taken out of its original Pitkar packaging.
NOTE	Pitkar has validated reprocessing of reusable device & advices do not reprocess reusable devices more than 250 times.
AT THE POINT OF USE	The drying of gross soil (blood, tissue and/or debris) on devices following surgical use should be avoided. It is preferred that gross soil is removed from devices following use and in preparation for transportation to a processing area. Gross soil can be removed using sponges, cloths, or soft brushes. Water and/or cleaning detergents (labelled for use on medical devices) may be used. If gross-soil cannot be removed at the point of use, the devices should be transported to prevent drying (e.g., covered with a towel dampened with purified water) and cleaned as soon as possible at a designated processing area.
PREPERATION BEFORE CLEANING	It is recommended that devices should be reprocessed as soon as is reasonably practical following surgical use. Instruments must be cleaned separately from instrument trays and cases. Care should be taken in the handling and cleaning of sharp devices. These are recommended to be cleaned separately to reduce risks of injury. All devices with lumens need to be manually flushed to remove debris and brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brush size should be approximately the same diameter of the lumen 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 lumen. Refer to any technique guides or other supplemental information for specific device lumen diameters. After brushing, rinse with water by flushing and blow clean compressed air through all lumens.

CLEANING-AUTOMATED	**Equipment required:** 1. Washer/disinfector from Getinge (Getinge 46 series, 46-4). 2. Getinge Clean Enzymatic Liquid 3. Getinge Disinfection AB 4. Getinge Clean Rinse Aid liquid. **Instructions**: 1. Before the automated processing, rinse the re-usable instruments under running water. No residues from the cleaning/disinfection agent should be transferred to the Washer/disinfector. 2. Place the instruments in a suitable instrument rack. 3. Place the instrument rack in the Washer/disinfector so that the spray jet comes into direct contact with the instruments. 4. Pour in the cleaning/disinfection agent according to the specifications of the manufacturer and Washer/disinfector manufacturer. 5. Normally the preset parameter settings of the installed programs are used, but in special cases it may be necessary to adjust certain parameters for matching to a specific wash process. Set parameters are as follows: Pre-wash- at 50°C with Enzyme wash- at 50°C with 0.5% Wash-neutralization with warm tap water Rinse - with warm distilled water Chemical disinfection with distilled water, at 90°C for at least 5 min. Automatic drying, at 90°C for 30 min **Procedure:** 1. Open the door and take out the loading trolley. 2. Check and clean the strainer filter. A dirty coarse strainer may prevent water from circulating and create the conditions for the growth of bacteria. 3. Fill the detergent container with Getinge Clean Enzymatic Liquid solution (Dosing – 5ml/lit.) and surfactant container with Getinge Clean Rinse Aid solution (Dosing – 0.5 ml/lit.). 4. Use distilled water for washing and disinfecting process. 5. Load the washing crates with instruments to be cleaned. Maximum weight allowed is 50 Kg. 6. Load the trolley in washing chamber of machine. Make sure that the rotary washer arms can rotate freely without touching the instruments. 7. Close the door and make sure that the door handle is in the locked position. 8. Put 'ON' the main switch to start the machine. 9. Select suitable program P1 to P6 from control panel using selection keys. 10. Start the washing program by pressing 'START' key on control panel. Monitor the washing program for temperature, yellow lamp indicator showing cycle is in process and status of cycle displayed on control panel screen. 11. Green lamp indicator will lit after completion of washing program. 12. Put 'OFF' the main switch to stop the machine. 13. Open the door and unload the trolley from washing chamber. 14. Close the door and forward cleaned instruments for next procedure. If there is still residual contamination after the automatic processing, cleaning and disinfection should be repeated until all visible traces of contamination have been eliminated.
CLEANING-ULTRASOUND	Equipment required: • An ultrasonic washer with lid which will hold enough liquid so that the items of equipment to be cleaned can be fully immersed. • A sufficient number of supporting racks or trays for stacking items to be

<table>
<tr><td></td><td>processed.
• A timing device.
• A compatible water-detergent solution at dilution and temperature, recommended by manufacturer.
• A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility.
• Ultrasonic cleaning solution- Spectra UCP

Procedure:
• Ensure the ultrasonic washer is clean and dry prior to use.
• Wear protective equipment, fill the fluid reservoir with sufficient water/disinfectant to ensure complete immersion of items.
• Disinfectants with fluoride, chloride, bromide, iodide, or hydroxyl ions [free halogen ions or sodium hydroxide] must not be used;
• Use the 2% Spectra UCP or equivalent phenolic disinfectant solution as per the guidelines provided by the disinfectant manufacturer
• Switch on ultrasonic cleaner and proceed as per routine procedure.
• Switch off, lift the lid, remove the item and drain before transferring to a clean-rinse receptacle.
• Rinse thoroughly for 15 minutes with distilled water as per the routine procedure to ensure the proper cleaning of instruments
• Place the cleaned instrument in a drying cabinet for 15 minutes
• Complete the documentation.
• Proceed with sterilization.</td></tr>
<tr><td>MAINTENANCE AND INSPECTION</td><td>Instruments should be visually inspected under ambient lighting, to verify that the devices do not have visible soil, damage or moisture.
Inspect devices for:
• Lack of moisture- If moisture is detected, manually drying should be performed.
• Cleanliness- If any residual soil is discovered during inspection, repeat the cleaning steps on those devices until all visible soil is removed from the device.
• Damage- including but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks and wear</td></tr>
<tr><td>PACKAGING</td><td>• The package should be prepared using the AAMI double wrap or equivalent method. . The sterilization wrap used should be FDA cleared.
• Sterilization Containers: Instruments may be loaded into a dedicated (Pitkar) instrument tray, or general-purpose sterilization tray. Cutting edges should be protected and the recommended content or maximum weight not exceeded as indicated by manufacturer i.e. 22 lbs</td></tr>
<tr><td>STERILIZATION INSTRUCTION</td><td>• Steam (moist heat) sterilization shall be performed in a locally approved, gravity cycle. The steam sterilizer should be validated to the requirements of any local standards and guidance such as EN 285 or AAMI/ANSI ST8.
• The steam sterilizer should be installed and maintained in compliance to manufacturer’s instructions and local requirements.
• Sterilize by steam autoclaving, utilizing a gravity cycle as following –

<table>
<tr><td>Steam Sterilizer Type</td><td>Gravity</td><td>Gravity</td></tr>
<tr><td>Minimum Exposure Temperature</td><td>121°C (250°F).</td><td>132°C (270°F).</td></tr>
<tr><td>Pressure</td><td>15 psi</td><td>30 psi</td></tr>
<tr><td>Minimum Exposure Time</td><td>30 Minutes</td><td>15 Minutes</td></tr>
<tr><td>Drying Time</td><td>30 Minutes</td><td>30 Minutes</td></tr>
<tr><td>Drying temperature</td><td colspan="2">Between 60°C to 100°C</td></tr>
</table>
The user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying. Extended drying within the sterilizer or in an external drying cabinet in accordance with manufacturer’s instructions may</td></tr>
</table>

	be necessary. Do not exceed 140°C (284°F) during drying
ADDITIONAL INFORMATION	• Cleaning agent information: Examples of detergents that have been used during cleaning validations. • The chemical quality of the water used during reprocessing can impact device safety. Facilities should use the recommended water quality requirements for device reprocessing in accordance with local guidance.

Disclaimer: "The instructions provided above have been validated by Pitkar as being a true description of the preparation of a device for first clinical use or for re-use or multiple use devices.
The institution or practitioner bears full responsibility for using cleaning and sterilization methods other than Pitkar recommendation for reusable devices for subsequent use**.**

EC REP

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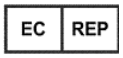
Symbol	Meaning	Symbol	Meaning
	Caution, consult accompanying documents		Batch code
	Date of manufacture		Manufacturer
	Do not reuse		Non sterile
	Do not use if package is damaged		Catalogue Number
	Humidity limitations		Temperature limit
	Authorized representative in the European Community		Use by date
	"CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician."		Protect from moisture

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