# Premia Spine Ltd. Polyaxial Head Pedicle Screw (Single Use and Sterile) Instructions for Use

**Description:**
The Polyaxial Head Pedicle Screws are used in conjunction with implants for fixation to the vertebrae. The screws are made from medical-grade titanium alloy. The Polyaxial screws are available in a variety of diameter-length combinations. Set screws are used to tighten the polyaxial screw system to the implant.

**Intended Use:**
The Polyaxial Head Pedicle Screws and Set Screw are intended to be used for stabilizing the affected vertebral level following decompression surgery in the treatment of lower back and leg pain at one or more vertebral levels in the thoracic and lumbar spine. The Polyaxial Head Pedicle Screws and Set Screws are indicated for patients between 40 and 75 years of age.

**Indications:**
The Polyaxial Head Pedicle Screws are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (DDD; 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; deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. Refer to the specific Premia Spine fusion and non-fusion systems for further instructions and indications.

The Polyaxial Head Pedicle Screws are used in conjunction with Premia Spine's fusion and non-fusion implants with 6.0mm rod attachments to the Polyaxial Head Pedicle Screws.

**Precautions:**
Selecting suitable patients for the implantation of the Premia Spine Pedicle Screws is extremely important. Use of the Polyaxial Head Pedicle Screws should only be undertaken after the surgeon has become thoroughly knowledgeable about the spinal anatomy and biomechanics, the patient's pathology, has had experience with posterior approach spinal surgeries and has had training in the implantation of the Polyaxial Head Pedicle Screw and the device attaching to the Pedicle Screws.
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.
Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

**Warnings:**
Do not use Polyaxial Head Pedicle Screws with components of any other manufacturer's system. The Polyaxial Head Pedicle Screws MUST be implanted with implants supplied by Premia Spine.
The safety and effectiveness of Polyaxial Head Pedicle Screws 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.
The Polyaxial Head Pedicle Screws 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 Polyaxial Head Pedicle Screws in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**Storage and Handling:**
The Polyaxial Head Pedicle Screw (along with a Set Screw) are provided sterile via gamma irradiation in a double-blister pack sealed with a Tyvek lid and contained in a carton cardboard box. Additional Set Screws may be provided non-sterile and must be sterilized in the hospital according to the sterilization instructions of Premia Spine Instrumentation Set. The Polyaxial Head Pedicle Screws and Set Screw must be stored dry, at room temperature, in a clean environment, protected against vermin and direct sunlight. The integrity of the packaging should be confirmed to ensure the sterility of the contents is not compromised. Do not use if package has been compromised. Damaged or operatively removed Polyaxial Head Pedicle Screws should not be reused under any circumstances.

**Instructions for Use:**
Always remove the Polyaxial Head Pedicle Screws from the packaging using standard aseptic techniques only after the correct size has been determined. Do not reuse or re-sterilize even if the device appears undamaged (for single use only). The "use by" date must be checked. Do not use if the package has an expired label. The Set Screw is supplied together with the Polyaxial Head Pedicle Screws.

Use care when handling the Polyaxial Head Pedicle Screws to ensure it does not come into contact with objects that could damage the device. Do not handle the Polyaxial Head Pedicle Screws with any instrument other than the mating end of the device Inserter. If the Polyaxial Head Pedicle Screws are dropped or mishandled in any way do not use.

The Polyaxial Head Pedicle Screws should not be over tightened on insertion, and the correct length and diameter should be selected. Over tightening can lead to loosening, and incorrect size selection can lead to damage to the nerve or blood vessel structures.
Correct selection of the appropriate size of the Polyaxial Head Pedicle Screws is important to assure the correct function. Patients should be instructed in the postoperative care procedures and should be advised of the importance of adhering to those procedures for successful treatment with the Pedicle Screws.

Extreme caution and care are essential close to the bone marrow, nerve roots and the cauda equina. Any damage to these structures may cause neurological deficits. Breakage, slippage or incorrect use of instruments can injure patients and theatre staff.
It may be necessary to remove Pedicle Screws in the following cases and situations:

- Corrosion with painful reactions
- Loosening, dislocation, movement or breakage of the implants together with pain and/or neurological deficit, soft tissue injury or joint injury
- Subjective pain or unusual sensations due to the implant
- Infections or signs of inflammation
- Local changes in bone density due to unequal mechanical strain

**Contraindications**
The contraindications listed below can be relative or absolute depending on the specific situation of each patient, and must be taken into account by the attending physician when considering the overall position:

- Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
- Any patient not needing a bone graft and fusion, or where fracture healing is not required.
- Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the screws and their fixation without risk of impairment to anatomical structures or physiologic performance.
- Patients with a suspected or documented metal allergy or intolerance.
- Inadequate tissue coverage over the operative site.
- Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
- Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.
- Signs of local inflammation.
- Grossly distorted anatomy caused by congenital abnormalities.
- 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.
- Osteoporosis and other bone metabolism, joint and bone substance dis-eases which cannot be treated by instrumental spinal fixation because of mechanical factors,
- Malnutrition and alcohol abuse,
- Pregnancy,
- Mental impairment making it impossible for the patient to comply with medical instructions,
- Patients below the age of 40 year or above the age of 75 years
- Local and systemic infections, fever, leucocytosis, risks of infection and conditions associated with impaired immune defense,

- Excessive bodily strain due to pareses of the trunk and back musculature, stress due to professional activities, sport or obesity,
- Known or suspected allergies and intolerance of metals,
- Any condition not requiring intervertebral fusion or where this procedure has been rejected,
- Any condition in which the selected implants are not the correct size for the patient's anatomy,
- Any condition in which the patients selected do not have enough soft tissue covering the fixator which is to be inserted,
- Malformations, congenital anatomical abnormalities and significant changes to spinal anatomy of iatrogenic origin.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.

**Potential Adverse Events:**

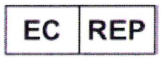
Specific side effects associated with dorsal instrumentation include the following:

- Foreign body or allergic reaction, including adverse response to wear debris
- Implant migration, subsidence, corrosion, loosening or dislocation
- Fracture or breakage of the implant
- Overload on vertebra that may cause failure
- Misplaced screws in pedicle
- Herniated nucleus pulposus
- Nerve root or spinal cord impingement
- Neurological deterioration
- Subsequent surgical interventions
- Adjacent segment degeneration
- Increased spondylolisthesis
- Foot Drop
- Back pain
- Heterotopic ossification
- Loosening of one or more components of the internal fixator occurring at an early stage or subsequently,
- Intraoperative failure of the pedicle and/or vertebra when preparing and implanting the screws,
- Dislocation, warping and/or breakage of one or more components of the internal fixator,
- Presence of microparticles in the area of the implants,
- Effect of pressure on the skin in the form of fibrotic, ulcerous or neuralgic surrounding tissue reactions if there is not enough soft tissue covering the fixator that has been inserted,
- Damage to nerve and blood vessel structures if the implants are not correctly inserted or positioned, and incorrect use of instruments,
- Neurological deficit or stimulation syndromes, taking the form of radicular paralysis or paraplegia, paresthesia, dysesthesia, hypeaesthesia, hypaesthesia, root compression syndrome or cauda equina syndrome, chronic pain, neuroma formation, spasticity, analgesia and/or sight loss, and neuropathy, arachnoiditis, reflex deficit and muscular atrophy,
- Urination disorders, difficulty in passing stools or loss of bowel control, sexual function and procreative capacity,
- Post-operative changes to the position of the stabilised section of the spine with kyphosis and/or vertebral sintering,
- Superficial or deep local infections and signs of inflammation,
- Dura mater injury, temporary or persistent cerebrospinal fluid fistula, pseudomeningocele or meningitis,
- Scarring in the area of the entire surgical access route, compromising nerve structures and subsequently causing the aforementioned neurological deficit or stimulation syndromes,
- Fracture, microfracture, resorption, penetration of or damage to the bone substance of the stabilised and adjacent vertebra and the site from which the bone chip was taken, including dislocation of other implants and autologous bone chips,
- Changes to the shape of the spine with stiffness in the area where surgery was performed,
- Worsening of the degree of correction achieved by the operation,
- Disc protrusion and prolapse in the area of the spondylodesis and adjacent segments,
- Insufficient or absent bone fusion with formation of pseudarthrosis,
- Loss or impairment of mobility in the stabilised area of the spine,
- Changes to or absence of growth of the vertebra on which surgery was performed in the case of children and adolescents,
- Impairments in activities of daily living,
- Loss or reduction of bone substance due to inadequate strain,
- Pain syndrome, fracture, soft tissue hernia or impaired wound healing at the site from which the bone chip was taken,

- Ileus, subileus, gastritis, loss of bowel control and other gastrointestinal function disorders,
- Haemorrhage, haematoma, seroma, oedema, hypertensive crisis, embolism, thrombosis, cerebral infarction, phlebitis, thrombosis, wound necrosis, wound dehiscence, damage to major blood vessels and other forms of cardiovascular damage,
- Onset of pulmonary problems in the form of pulmonary embolism, alectasis, bronchitis, pneumonia, pleural effusion inter alia, mental changes,
- Death.

N.B.: These situations may make additional surgery necessary.

**Symbols and labels:**

| | | | | | |
|---|---|---|---|---|---|
| 1 |  | Manufacturer | 9 |  | Consult instructions for use |
| 2 |  | Authorized representative in the European Community | 10 |  | Do not use if package is damaged |
| 3 |  | Use-by date | 11 |  | Temperature limit |
| 4 |  | Batch code | 12 |  | Humidity limitation |
| 5 |  | Catalogue number | 13 |  | Keep dry |
| 6 |  | Serial number | 14 |  | Sterilized using irradiation |
| 7 |  | Do not re-use | 15 |  | Do not resterilize |
| 8 |  | Caution | | | |

**Technical Specifications**

| **Environmental Conditions for Storage and Operation** | |
|---|---|
| Temperature | 15°C to 22°C |
| Relative humidity | Up to 70% |
| **Environmental Conditions for Shipping (up to 72 hours)** | |
| Temperature | -29°C to +60°C |
| Relative humidity | Up to 85% |

**Instruments:**

Refer to the appropriate Premia Spine Instrumentation Instructions for Use.

**Further Information:**

For further information, please contact:

|  | **EC REP** |
|---|---|
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