INSTRUCTIONS FOR USE

Single Planar Multi Axial (SPMA) Pedicle Screw System

IMPORTANT NOTE

Users of the Trinity Orthopedics Single Planar Multi Axial (SPMA) Pedicle Screw System acknowledge that they have read and agree on the conditions in this insert.

DESCRIPTION

The SPMA Pedicle Screw System is an internal spinal fixation system comprised of pedicle screws with heads capable of up to 30 degrees angulation from midline (within a single plane), straight and contoured connecting rods and transverse rod connectors.

MATERIAL

The pedicle screw, set screw, saddle, washer, rod and Cross Link of the SPMA Pedicle Screw System are made of Ti-6Al-4V ELI, a titanium-based alloy conforming to ASTM F 136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*. The axel pin and a version of the rod are made from BioDur® CCM conforming to ASTM F 1537 *Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants* (UNS R31537, UNS R31538, and UNS R31539).

INDICATIONS FOR USE

The Single Planar Multi Axial (SPMA) Pedicle Screw System is 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 thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, spinal stenosis, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis, and failed previous fusion.

LEVEL OF FIXATION

The SPMA Pedicle Screw System is intended for use in the thoracic, lumbar, and sacral spine.

GENERAL CONDITIONS OF USE

An in-depth understanding of normal spinal anatomy as well as the patient's individual pathology and clinical needs are essential to the safe implantation of pedicle screw systems. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant.

The Trinity SPMA Pedicle Screw System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. Components of the Trinity SPMA Pedicle Screw System are intended for SINGLE USE ONLY and should never be reused after implantation or any other circumstance that has subjected any component to damage or mechanical stress.

The SPMA Pedicle Screw System is designed to stabilize the spine until fusion has occurred. The device serves no functional purpose once fusion has occurred and may be removed. However, when explanting the system is being considered the surgeon and patient must weigh the relative risks and benefits of a second surgical procedure.

The SPMA Pedicle Screw System has developed and been tested as a bipedicular, bilateral construct. No representations have been made and no assurances can be given that the device will provide sufficient mechanical support as a unipedicular or unilateral device. In addition, pedicle screw spinal implants must not be relied upon to provide support to the anterior spinal column. In cases where the structural integrity of the anterior spinal column is compromised supplemental support should be provided.

CONTRAINDICATIONS

Contraindications to using the SPMA Pedicle Screw System are similar to those of other pedicle screw systems and consist of the following:

- Patients who are obese or whose occupational or recreational activities include heavy lifting and/or repetitive bending, twisting or stooping, to a degree that would produce excessive loads on the spinal system leading to failure of fixation or implant failure.
- Patients who do not require bone graft and fusion or in whom fracture healing is not required.
- Patients with bony abnormalities or significant anatomic distortion that would preclude proper screw fixation and/or hardware placement without risk of anatomic and/or physiologic impairment.
- Patients with known or suspected intolerance or allergy to implant materials.
- Patients who do not have sufficient soft tissue at the operative site to enable adequate postoperative wound closure and healing.
- Patients with active or recent infection adjacent to the spine or spinal structures. The presence of remote and/or systemic infection such as an open wounds, fever or leukocytosis are relative contraindications.
- Patients whose bone quality is diminished to the extent that the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction may be significantly impaired. In addition to radiographic evidence, the possible presence of bone quality compromise should be considered in patients with a history of certain degenerative diseases, postoperative irradiation, smoking or previous spinal fixation failure.
- Patients with conditions that may compromise their ability to comprehend and adhere to post-operative care instructions such as diminished mental capacity, mental illness, alcohol or drug abuse.
- Patients who are pregnant.

POTENTIAL COMPLICATIONS AND ADVERSE EFFECTS

Potential complications and adverse effects of the SPMA Pedicle Screw System are similar to those of other pedicle screw systems many of which may require additional surgery and include the following:

- Loosening of the components
- Partial loss of correction achieved during surgery
- Failure of fixation, breakage, deformation and/or migration of the implant, pseudarthrosis, fusion failure, or nonunion (pseudarthrosis)
- Pedicle failure while inserting or preparing to insert the pedicle screw
- Cessation of any potential growth in the opened segment of the spine
- Modification of spinal curvature and stiffness of the vertebral column
- Loss of spinal mobility or altered remodeling of the fused vertebra
- Bone loss due to resorption or altered distribution of mechanical stresses (stress shielding)
- Misalignment of anatomical structures
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, or wound dehiscence
- Bone graft donor complications (pain, fracture, infection or compromised wound healing)
- Fracture, damage, degenerative changes or instability of spinal elements adjacent to the site of surgery
- Pain and abnormal sensations due to hardware presence
- Foreign body (allergic) reaction to the implants.
- Presence of micro-particles around the implants
- Neurologic complications including partial or complete paralysis, dysesthesia, hyperesthesia, paresthesia, anesthesia radiculopathy; development or continuation of pain, dural tears, reflex deficits, bilateral paraplegia, and/or arachnoiditis
- Superficial or deep-seated infection and inflammatory phenomena
- Bursitis
- Atelectasis
- Gastrointestinal system compromise
- Vascular damage resulting in excessive bleeding
- Loss or impairment of bowel, sexual, and/or bladder function and other types of urologic compromise
- Death

WARNINGS

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.

The benefit of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with a stable spine.

Potential risks associated with the use of this system, which may require additional surgery, include device component fatigue fracture, loss of fixation, non-union, and fracture of the vertebra; neurological injury and vascular or visceral organ injury.

Until maturation of the fusion mass is confirmed, the patient is at increased risk for implant failure if the device is subject to the stress of full weight bearing. Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone.

Contouring or bending of a screw may reduce its fatigue strength and increase the risk of failure. Screws must be replaced if bent or otherwise damaged during hardware insertion or adjustments. They must be discarded and replaced.

Rods should be contoured only with the proper contouring instruments. Rods must be discarded and replaced if they have been incorrectly contoured or contoured repeatedly and/or excessively.

An implant must never be reused, even though it may appear undamaged.

Internal fixation devices that come into contact with other metal objects such as rods, screws, and washers must be made from like or compatible materials (such as the titanium alloy and cobalt chromium alloy used in the SPMA Pedicle Screw System). Although some degree of corrosion occurs on all implanted metals and alloys, contact of dissimilar metals may accelerate the corrosion process which leads to the release of metal compounds into the body. Fatigue fracture of the implants may be accelerated by corrosion.

Components of the SPMA Pedicle Screw System should only be used with considerable caution and attention to material and dimensional compatibility in conjunction with components from any other manufacturer's spinal system because different manufacturers employ different materials, varying tolerances, manufacturing specifications and differing design parameters.

Removal of a tightened spinal screw may require special instruments. The technique may require practice in the laboratory before being attempted clinically.

A decision to remove the internal fixation device should take into consideration factors such as the risk of damage or injury when encountering difficulty in removing the hardware as well as the general risks presented by any surgical procedure.

Implant removal should be followed by adequate postoperative management to avoid fracture.

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.
SPMA Pedicle Screw System should only be used by surgeons familiar with pre-operative and surgical techniques, cautions, and potential risks associated with this type of spinal surgery. The surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the type of spinal fixation system prior to its clinical use. Essential elements of a successful surgical outcome include knowledge of relative surgical techniques, adequate anatomic reduction, proper selection and placement of implants, and careful pre and post-operative patient management.
The surgeon should carefully consider the level of implantation, the weight, activity level and general condition of the patient, and any other factor that may have an impact on the performance of the system.

As with all prosthetic implants, numerous biologic, biomechanic, and demand related factors limit the durability of these components. To maximize the useful service life, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential.

Even when implant selection has been optimized, the size and shape of human bones present limitations on the size, shape and strength of the implants.

The patient should be informed that a metallic implant does not have remodeling potential. Therefore, excessive demand beyond the fatigue limit of the implant can lead to bending loosening and a fracture. Patients who are excessively active or impaired in their ability to observe post-operative activity restrictions may be particularly at risk during post-operative rehabilitation.

In some cases progress of degenerative disease may also be so advanced at the time of implantation that the experienced useful life of the implant will be substantially decreased. The incidence of nonunion has been shown to increase in patients receiving perioperative steroids or postoperative non-steroidal anti-inflammatory agents. Patients who smoke are also at risk for nonunions. Such patients should be advised of these risks and warned of their potential consequences.

SURGICAL TECHNIQUE
Placement of Components

Pedicle Screws

Pre-operative evaluation of CT Scans and MRI scans is essential in planning the appropriate size, insertion angle and depth of pedicle screws. Careful attention to these factors is essential for establishing secure pedicle screw fixation and achieving a successful surgical outcome.

Entry Point

The conventional pedicle entry point is defined by the intersection of the horizontal line that intersects the transverse processes and vertical line that connects the lateral edges of the pars inter-articularis. Decorticate the intended pedicle entry point using a rongeur or burr then create a small cortical opening using an awl. Repeat the process at each intended point of pedicle screw insertion.

Orientation

Insert the ball handle pedicle finder through the cortical defect then advance into the pedicle canal in the sagittal and axial direction to a depth determined by preoperative imaging. Repeat the process at each pedicle screw insertion point. Use a beaded wire to palpate the superior, inferior, medial and lateral walls of the pedicle canal, frequently following pedicle channel tapping.

Confirmation of proper positioning and orientation, may be achieved radiographically by first placing guide pins into each of the pedicle canals. Angle the image intensifier along the pedicle axis to insure proper positioning in the sagittal and axial directions.

Length

After confirming satisfactory guide pin orientation, confirm appropriate length. Advance the guide pin to a point representing 60% to 80% of the depth of the vertebral body as viewed on a true lateral image. The appropriate pedicle screw length is determined by marking the guide pin at the pedicle entry point and subsequently measuring the distance between that point and the tip of the guide pin.

Screw Insertion

Tap: Use the bone tap to thread the proximal portion of the pedicle screw pilot hole.
In general, the appropriate bone tap size will be 1mm smaller than the pedicle screw diameter.
Pedicle screwdriver: Affix the pedicle screw to the appropriate screwdriver by inserting the tip of the driver within the proximal end of the screw.
Insertion: Insert the pedicle screw/driver assembly to the desired depth by turning in a clockwise fashion. Disengage the driver after satisfactory placement by turning counter-clockwise while holding the sleeve stationary and withdrawing in an axial manner.

Rods
Selection

Rods included in the SPMA Pedicle Screw System are available in straight and lordotic contours of various lengths and in either titanium alloy or cobalt chromium alloy. Rod length should allow for extension beyond the most superior and most inferior pedicle screw bodies. Rod contour selection depends on the specific surgical goals of each individual procedure. Typical procedures will employ the conventional titanium alloy rods whose modulus of elasticity is closer to that of bone than that of the stiffer cobalt chromium rods. Cobalt chromium rods are available for use in certain cases where excessive loads or demands (such as anterior column disruption or morbid obesity) are anticipated.

Contour

Use a rod bender and/or bending irons to enhance correction or to help ensure complete seating of the rod within the proximal body of each top-loading pedicle screw. Care should be taken to avoid off-plane bending.

Placement

Place the contoured rods within the open portions of the bodies of the pedicle screws. The single planar multi axial design of the SPMA Pedicle Screw System allows adjustment of the screw head to the orientation of the rod.

Set Screws

Set screws are threaded into the pedicle screws bodies after the rods have been reduced and positioned within the receiving elements of the pedicle screws. Set screws should remain loosely placed until rod rotation (and other necessary adjustments) can be accomplished once all of the set screws have been applied. Use the set screw inserter to hold the set screw during placement.

Rod Rotation

If necessary use the rod holders to turn the contoured rod into lordosis after both of the rods have been placed within the pedicle screw bodies and all set screws are in place.
Following rotation, tighten the superior most screw to hold the rod in position. Do not tighten any remaining screws: the rod should remain loose in all other pedicle screw bodies to allow any necessary compression and distraction.

Alignment and Tightening

Alignment: The reduction cannula attaches to the saddle component of the pedicle screw assembly and allows for orienting the saddle, aligning the set screw. After the construct has been properly assembled, tighten each set screw provisionally beginning at one end of the construct and proceed to the other end.
Use the rod compressor and/or distractor to apply segmental compression and/or distraction as needed to adjust deformities in the frontal and/or sagittal planes as indicated. Using the set screw insertion tool, provisionally tighten each set screw as each segment interval is adjusted. Over-tightening of the set screw at this stage of the procedure could lead to unintended loosening of the pedicle screw and should be avoided.

Final Tightening: Final tightening of the set screws is conducted after provisional tightening has been accomplished and satisfactory compression and distraction has been achieved throughout the construct.

Final tightening is accomplished by first placing the set screw anti-torque device into the set screw over the pedicle screw then turning the screw clockwise until the set screw is engaged. Tightening is accomplished by turning the driver in a clockwise manner until the torque limiter prevents further tightening. The anti-torque device is then withdrawn in an axial manner. Periodic (e.g. yearly) calibration of the torque limiting insertion driver is recommended (acceptable values between 90 and 100 Newton-Meters).

Cross Link Placement

The Cross Link transverse connector optionally may be placed between adjacent rods to enhance the torsional stability of the overall construct. Determine the appropriate size connector and place on the rods in the desired location. The angulation of the Cross Link is adjustable by means of the pivot joint until stabilization by tightening of the locking screw. Press down firmly on the connector ensuring each side of the Cross Link engages the spined surface of the rod. The connector is fixed to the rods by pressing a wedge pin through each end of the connector. The connector is then locked in final position by tightening the hexagonal locking screw. If removal of the connector is necessary, the removal tool is used to advance the wedge pin completely through each end of the Cross Link connector, disengaging the rod. Loosen the hexagonal locking screw to free the pivot joint and remove the Cross Link.

Closure

Perform a layered closure of the deep fascia, superficial fascia, subcutaneous tissue and skin. Drains may be included if deemed necessary.

Post-operative Care

Use standard post-operative patient management protocols. Post-operative bracing is employed as necessary based on factors such as the location and strength of bone fixation and the degree of pre-operative instability. Radiographs to assess alignment and fusion are generally taken at one month, three months and six months post-operatively.

PACKAGING, LABELING and STORAGE

Components of the SPMA Pedicle Screw System are supplied NON-STERILE. They must be cleaned and sterilized before use.
Implants may be delivered as individual components or as a complete set. All packaging must be intact at the time of receipt. Implants and instruments are stored in specially designed trays or cases, which can be sterilized directly.
Proper care in handling and storage of the implant components is essential. In addition to readily apparent damage resulting from dropping, cutting scratching or sharply bending, improper handling can induce microscopic cracks and/or internal stresses that can ultimately lead to failure after implantation. Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, etc. Inspection and trial assembly of components prior to surgery is recommended to help detect otherwise unapparent damage that may have occurred during cleaning, storage or prior procedures.

STERILIZATION PROCEDURES

The SPMA Pedicle Screw System components are supplied non-sterile and are intended to be sterilized prior to use. Trinity Orthopedics has balidated and recommends prevacuum, wrapped at 270° F (132ºC) for a minimum of 10 minutes. Dry time should be at least 30 minutes. Implants must be sterilized within a sterilization tray prior to use.

<u>Caution:</u> Federal Law (USA) restricts this device to sale by or on the order of a physician.

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