ENGLISH

AMEDICA®

Consult instructions for use | Single use only | Non sterile product | Rx ONLY Prescription use only

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

Taurus™ Pedicle Screw System

PREFERENCE
Pedicle Screw System

PURPOSE

The Preference and Taurus Pedicle Screw Systems are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION

The Preference and Taurus Pedicle Screw Systems are spinal fixation systems consisting of a variety of components including pedicle screws, modular and non-modular head bodies, various types and sizes of rods, as well as connecting components. The components are designed to be rigidly locked into a variety of configurations with each construct being appropriate for the individual patient. The Taurus Pedicle Screw System is also compatible with implant components from the Preference Pedicle Screw System including the curved and straight rods, set-screws, and cross-connectors.

The Preference and Taurus Pedicle Screw System implant components are fabricated from medical grade titanium, titanium alloy, or cobalt chrome alloy. Amedica Corp. expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. Never use stainless steel and titanium implant components in the same construct.

To achieve best results, do not use any of the Preference and Taurus components with components or instruments from any other manufacturer unless specifically recommended by Amedica. As with all orthopedic and neurosurgical implants, Preference and Taurus Pedicle Screw System implants should not be reused under any circumstances.

INDICATIONS, CONTRAINDICATIONS, AND POSSIBLE ADVERSE EFFECTS INDICATIONS

INDICATIONS

The Preference and Taurus Pedicle Screw Systems are intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine as follows:

The Preference and Taurus Pedicle Screw Systems are intended for posterior, non-cervical pedicle and non-pedicle fixation in skeletally mature patients for the following indications: 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; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the Preference and Taurus Pedicle Screw Systems are indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar- first sacral (L5-S1) vertebral joint, (b) who are receiving fusions using autogenous bone graft only, (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below), and (d) who are having the device removed after the development of a solid fusion mass.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Active infectious process or significant risks of infection (immuno-compromise).
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 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.
15. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
16. Any patient unwilling to follow postoperative instructions.
17. Any case not described in the indications.

POSSIBLE ADVERSE EFFECTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but are not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain, bursitis, tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.

WARNINGS AND PRECAUTIONS

WARNING: 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 neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

PRECAUTION: 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, proper reduction, and proper selection and placement of the implant 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.

The Preference and Taurus Systems have not been evaluated for safety and compatibility in the MR environment. The Preference and Taurus implant components have not been tested for heating or migration in the MR environment.

WARNING: This device is not intended for screw attachment or fixation to the posterior elements of the cervical spine.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient. 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. Metallic 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 metal 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 aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. The type of construct to be assembled for the case should be determined prior to beginning the surgery.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins.
6. Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. 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. 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 mid line of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. Caution: Do not over-tap or use a screw/bolt that is either too long or too large. Over-tapping or using an incorrectly-sized screw/bolt may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter that will fit into each pedicle.
6. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
7. To assure maximum stability, two or more cross connectors on two bilaterally-placed, continuous rods, should be used whenever possible.
8. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
9. Before closing the soft tissues, all nuts or screws should be tightened firmly. Re -check the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components. Immobilization of the spinal surgical site must be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
10. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
11. The Preference and Taurus Pedicle Screw System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, 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, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogensis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
12. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the Preference and Taurus Pedicle Screw System components should never be reused under any circumstances.

PACKAGING

Packages for each of the components should be intact upon receipt. Loaner or consignment system sets should be carefully checked for completeness. Carefully check all components including instruments for damage prior to use. Damaged packages or products should not be used and should be returned to Amedica Corp.

CLEANING AND DECONTAMINATION

All instruments must be disassembled (if applicable) and must first be cleaned using neutral cleaners before sterilization and introduction into a surgical field or (if applicable) returned to Amedica. Cleaning and disinfecting of instruments can be performed with aldehdye-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Automated cleaning may not be effective. A thorough, manual cleaning process is recommended. Refer to the Surgical Instrument Sets Care, Cleaning and Sterilization Instructions for Use for detailed information.

Product	Outer Barrier	Cycle	Temperature	Exposure Time	Dry Time
Preference	Polyproplene Wrapped Trays Only	Pre-Vacuum	270°F(132°C)	4 Minutes	60 Minutes[1]
Taurus	Polyproplene Wrapped Trays Only	Pre-Vacuum	270°F(132°C)	4 Minutes	30 Minutes[2]

Note: Validation exposure time required to achieve a 10^{-6} Sterility Assurance Level (SAL)

1 Dry time validated utilizing a 15 minute open door phase and 30 minute cool down time
2 Dry time validated utilizing a 5 minute open door phase and 30 minute cool down time

If outside of the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come onto contact with the central nervous system. Use only sterile products in the operative field.

No implant should be re-used once it comes into contact with human tissue or body fluid. Instruments should be cleaned and sterilized after use in surgery.

PRODUCT COMPLAINTS

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance should notify the distributor or Amedica Corp.

FURTHER INFORMATION

In case of complaint, or for supplementary information, or further directions for use of this system, please see the address above.