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Important Information Concerning the Posterior Cervical Thoracic (PCT) Spinal System

Caution: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

PURPOSE: The purpose of the GSO PCT Spinal System is to assist in providing immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. It is intended to be used as a temporary construct that assists normal healing and is not intended to replace normal body structures. The GSO PCT Spinal System should be removed after fusion.

DESCRIPTION: The GSO PCT Spinal System consists of rods, multi-axial screws, hooks, and cross connectors that can be locked rigidly into various configurations, with each construct being customized for each individual case. The implants are attached to the spine posteriorly by means of screws and/or hooks joined with rods. Cross connector components are used to attach two rods in parallel.

GSO implants can be installed with any suitable instrumentation. In all cases, instrumentation must be at least 1 cm from any major vessel.

The GSO PCT Spinal System components are fabricated from medical grade titanium and titanium alloy. No warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for specific purposes or use are explicitly excluded.

Never use titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct. Never use stainless steel and titanium implant components in the same construct.

For optimal results, do not use any of the GSO Spinal System Implant components with components from any other system or manufacturer unless expressly allowed to do so in this document. GSO Spinal System components should never be reused or combined with components from other manufactures under any circumstances.

INDICATIONS:

The PCT Spinal System is intended to promote fusion of the cervical spine and cervico-thoracic junction (C1-T3), and is indicated for the following:

1. Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Spondylolisthesis
3. Spinal stenosis
4. Fracture or dislocation
5. Revision of previous cervical or cervico-throracic spine surgery
6. Tumors

The use of multi-axial pedicle screws is limited to placement in the upper thoracic spine (T1-T3) for the purpose of anchoring the construct. The multi-axial pedicle screws are not intended to be placed in the cervical spine.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

a. Active infectious process or significant risk of infection (immunocompromise).
b. Fever or leukocytoses.
c. Any patient with bone absorption, osteopenia, osteomalacia and/or osteoporosis.
d. Any case not requiring bone graft and fusion.
e. Pregnancy.
f. Any case where the components would be too large or too small to achieve a successful result.
g. Signs of local inflammation.
h. Any pathological condition that would preclude the potential benefit of spinal implant surgery such as presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count or a marked left shift in the WBC differential count.; elevation of sedimentation rate unexplained by other disease or elevation of white blood cell count or a marked left shift in the WBC differential count.
i. Any patient with inadequate soft tissue coverage of operative site or inadequate bone from any cause for implants.
j. Morbid obesity.
k. Any patient with allergy or intolerance of the implant materials.
l. Any patient in whom utilization would interfere with anatomical structure or physiological function.
m. Any patient unwilling to follow post operative instructions.
n. Any case not directed in indications.

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 degenerative 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 this device for any other conditions are unknown.

These implants are not permanent prostheses. In the absence of fusion, the instrumentation and/or one or more of its components can be expected to bend, loosen, disassemble and/or break as a result of exposure to everyday mechanical stresses.

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.

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.

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.

Physician Note: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

POTENTIAL ADVERSE EVENTS: 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 is not limited to:

a. Early or late loosening of any or all of the components.
b. Infection.
c. Post-operative change in spinal curvature, loss of correction, height and/or reduction.
d. Disassembly, bending and/or breakage of any or all of the components.
e. Urinary retention or loss of bladder control or other types of urological system compromise.
f. Non-union (or pseudarthrosis). Delayed union. Mal-union.
g. Foreign body (allergic) reaction to implants, debris and corrosion of products (from crevice, fretting and/or general corrosion), including metallosis, staining, tumor formation and/or autoimmune disease.
h. Dural tears, pseudomeningocele, fistula, persistent CSF leakage and meningitis.
i. 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.
j. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis and/or pain and bursitis. Tissue or nerve damage caused by improper positioning or placement of implants or instruments.
k. Neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, quadriplegia, quadriparesis, reflex deficits, irritation, arachnoiditis and/or muscle loss.
l. Vertebral artery injury.
m. Fracture, microfracture, resorption, damage or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above and/or below the level of surgery. Retropulsed graft.
n. Herniated nucleus pulposus, disc disruption or degeneration at, above or below the level of surgery.
o. Cessation of any potential growth of the operated portion of the spine.
p. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
q. Loss of increase in spinal mobility or function.
r. Inability to perform the activities of daily living.
s. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
t. Bone loss or decrease in bone density, possibly caused by stress shielding.
u. Graft donor site complications, including pain, fracture or wound healing problems.
v. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
w. Hemorrhage, hematoma, vascular occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
x. Reproductive system compromise, including sterility, loss of consortium or sexual dysfunction.
y. Change in mental status.
z. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

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Other preoperative, intraoperative and postoperative warnings and precautions:

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 the 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, that may result in further injury or the need to remove the device permanently.

DEVICE FIXATION:
When tightening the set screws, always hold the assembly with the Counter Torque device. Tighten the head of the set screw to 40 in-lbs. to leave the assembly at optimum fixation.

PREOPERATIVE:

a. Only patients that meet the criteria described in the indications should be selected.
b. All implants and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of unexpected need.
c. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
d. Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should be avoided.
e. An adequate inventory of implants should be available at the time of the surgery, normally a quantity in excess of what is expected to be used.
f. 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. The GSO PCT Spinal System implants (described in the DESCRIPTION Section) are not to be combined with the implants from another manufacturer.

INTRAOPERATIVE:

a. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological function.
b. Utilize an imaging system to facilitate surgery.
c. Breakage, slippage or misuse of instruments or implant components may cause injury to the patient or operative personnel.
d. 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.
e. 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 to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rod outside of the operative field. Whenever possible, use pre-cut rods of the length needed.
f. Caution: Do not over-tap or use a screw that is either too long or too large. Over tapping or using an incorrectly sized screw may cause nerve damage, hemorrhage or other possible adverse events listed elsewhere in the package insert. If screws are being inserted into spinal pedicles, use as large a screw diameter that will fit into each pedicle.
g. To assure maximum stability, two or more cross connectors on two bilaterally placed, continuous rods, should be used whenever possible.
h. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws. Once this is completed, go back and firmly tighten all of the screws and nuts. Recheck the tightness of all the nuts or screws. After finishing, ensure that none loosened during the tightening of the other nuts and screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE: The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

a. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications that may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
b. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities. The patient should be advised not to smoke tobacco or utilize nicotine products or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin and other COX-1 and COX-2 inhibitors and Ketorolac Promethamine during the bone graft healing process.
c. 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.
d. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening or breakage of the device(s). It is important that the immobilization of the spinal surgical site 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 ensure cooperation until bony union is confirmed.
e. The GSO PCT Spinal 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 patient and surgeon, 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: Corrosion, with localized tissue reaction or pain; Migration of implant position, possibly resulting in injury; Risk of additional injury from postoperative trauma; Bending, loosening and/or breakage, that could make removal impractical or difficult; Pain, discomfort, or abnormal sensations due to the presence of the devices; Possible increased risk of infection; Bone loss due to stress shielding; and Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture or other complications.
f. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, the GSO PCT Spinal System components should never be reused under any circumstances.

PACKAGING: Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to the Gold Standard Orthopaedics distributor.

STERILIZATION: Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified otherwise, these products are recommended to be steam sterilized by the hospital using the following process parameters:

Method	**Cycle**	**Temperature***	**Exposure Time***
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes

*Note: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for the equipment. For 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 into contact with the central nervous system.

CLEANING AND DECONTAMINATION: Unless just removed from an unopened GSO package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into the sterile surgical field or (if applicable) return of the product to Gold Standard Orthopaedics. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments. These solutions should not be used. Also, many instruments require disassembly before cleaning. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

PRODUCT COMPLAINTS: Any Health Care Professional (e.g. customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the Gold Standard Orthopaedics distributor. Further, if any spinal system component ever malfunctions (i.e. does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Gold Standard Orthopaedics product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION: If further details for the use of this system are needed, please check with the Gold Standard Orthopaedics distributor. If further information is needed or required, please see the address on this document.

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