Guardinium™ Premier

Teslake, Inc.

Please Read the Instruction for Use carefully before using the product.

1. System Description

The Guardinium Premier consists of a variety of shapes and sizes of rods, hooks, screws, crosslinks, and connecting components. Care should be taken so that the correct components are used in the spinal construct.

The Guardinium Premier hooks are intended for posterior use only. The Guardinium Premier implant components are fabricated from titanium and titanium alloy which conform with ISO5832-2 and ISO5832-3. Teslake, Inc. 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 Guardinium Premier implant components with components from any other unless specifically allowed to do so in this or another Guardinium Premier document. As with all orthopaedic and neurosurgical implants, none of the Guardinium Premier components should ever be reused under any circumstances.

2. Indications for Use

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Guardinium Premier is indicated for one or more of the following:

1) degenerative spondylolisthesis with objective evidence of neurologic impairment.
2) fracture.
3) dislocation.
4) scoliosis.
5) kyphosis.
6) spinal tumor, and/or
7) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, Guardinium Premier is indicated for skeletally mature patients:

(a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (LS-SI) 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.

3. Contraindications

Contraindications include but are not limited to:

1) Active infectious process or significant risk of infection (immunocompromise).

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, ostcopenia, ostcomalacia and/or ostcoporosis. Ostcoporosis or ostcopenia 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.
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.

4. Warnings & precautions

- Safety Warning

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:

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, imitation, 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, pscudomeningocele, fistula, persistent CSF leakage, meningitis.

8. Loss of neurological function (c.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.
12. 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. Retro pulsed graft.
13. Hemiated nucleus pulpous, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stresses shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Ileuses, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding. Phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.|

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

WARNING 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 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.

PRECAUTION: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgcons 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.

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 and precautions 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 hunan bones. Unless greal 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.

Device Fixation:

For self breaking plugs, always hold the assembly with the Counter Torque device. Tighten and break-off the head of the plug to leave the assembly at optimum fixation security. After the upper part of the self breaking plug has been sheared off, further re-tightening is not necessary and not recommended. The head part should not remain in the patient. **AFTER THE UPPER PART OF THE SELF BREAKING PLUG HAS BEEN SHEARED OFF, RE-ADJUSTMENT IS NOT POSSIBLE UNLESS THE PLUG IS REMOVED AND REPLACED WITH A NEW ONE.**

When using Crosslink plates, the plug should be tightened to between & and 9 Nm. (70 to S0 inch-lbs).

- Preoperative

1) Only patients who meet the criteria described in the indication´s section should be chosen.

2) Patient should be carefully examined regarding contraindications. The user should also inform the patient about the potential risks and adverse events.
3) The implants should be handled and stored carefully. Collision, bending, scratching may greatly reduce the strength and lifetime of the implants. Implants and instruments should be protected from corrosive environments.
4) All non-sterile parts should be cleaned and sterilized before use.
5) Devices should be inspected for damage and integrity before use.
6) Care should be taken to avoid damage to the device(s) and injury to the patient.

- Intraoperative

1) The user should follow the instructions in the surgical technique manual.
2) Breakage, slippage and misuse of instruments or implants may cause injury to the patient or operative personnel.
3) The user should be extremely careful when using implants or instruments around the spinal cord and nerve roots. Damage to nerves will cause severe injuries to the patient.
4) To avoid over-reduction or over-extension, it is advised to operate under X-ray or spinal cord monitoring.
5) If bone cement is deemed necessary by the user for more robust screw fixation, its injection should be carefully monitored and maximum 3 mL bone cement is allowed per screw.
6) Attention to be paid on cement working time. When the working time is almost over, remaining cement should not be used to avoid solidification during injection.

- Postoperative

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre dispositions 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 otherwise damaged. Implants and instruments should be protected during storage, espocially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
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.Teslake Guardinium Premier components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer. Different metal types should never be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

- Intrapoerative

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 midline 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. To insert a screw properly, a guide wire should first be used, followed by a sharp tap.
6. Caution: Do not overtap 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 as will fit into each pedicle.
7. 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.
8. To assure maximum stability, two or more crosslink plates on two bilaterally placed, continuous rods, should be used necessarily.
9. 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 neuralgic damage and bone necrosis.
10. Before closing the soft tissues, all of the nuts or screws should be tightened firmly. Recheck the tightness of all nuts or screws after finishing making sure that none loosened during the tightening of the other nuts or 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.

1. 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 which may occur as a result of excessive or carly 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.
2. 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, especially hiting and twisting motions and any type of sport participation.

3. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidal or anti-inflammatory medications such as aspirin during the bone graft healing process. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. 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 immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgen graphic examination. If a state of nonunion persists or if the components loosen, bend, and/or break, the devise(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.
5. 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.
6. Tesalke Guardinium Premier implants are temporary interal fixation devices. Intemal 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 carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. 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 Spinal System components should never be reused under any circumstances. If the Spinal System components is reused, one or more of the following complications may occur: (I) 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; (S) 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 carcinogenesis.

6. Packaging

Packages for each of the components should be intact upon receipt. Damaged packages and products must not be used and returned to Teslake, Inc.

7. Storage

Spinal systems shall be stored in house with relative humidity not higher than 80%, and with good aeration, without caustic gas.

8. Sterilization

CLEANING AND DECONTAMINATION:

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a demonized

Note: certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Gravity	121ºC (250ºF)	20 Minutes
Steam	Pre-Vacuum	134ºC (273ºF)	4 Minutes

Also, certain instruments may require dismantling before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

STERILIZATION:

Unless marked sterile and clearly labeled as such, the Spinal System components, as well as those implants from other Shandong Weigao Orthopaedic Device Company Limited spinal systems specifically indicated for use with the Spinal System, described in this insert are provided non-sterile and must be sterilized prior to use. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

Note: Because of the many variables involved in sterilization, each medical facility should do validation of sterilization, and cleaning (e.g. temperatures, times) used for their equipment.

9. Surgical Technique Guides

To obtain copies of the surgical technique guides contact Teslake, Inc. customer service or your local sales representative.

10. Product Complaints

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any product should notify Teslake, Inc., or, where applicable, their distributor. In the event of an incident, or risk of an incident, having resulted in, or that may potentially result in, the death or severe deterioration in the state of health of a patient or user, Teslake, Inc. or the distributor must be notified as soon as possible. When filing a complaint, please provide the component(s) reference number, manufacturing lot number(s), your name and address, and the nature of the complaint in full detail, as well as notification of whether a written report is requested.

13. Further information

For further information, please contact:

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