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Important Information Concerning the GS1 Spacer

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

DEVICE DESCRIPTION: The GSO GS1 Spacer is a slightly curved, hollow spacer with pyramidal teeth on the superior and inferior ends to resist expulsion. The device contains openings to allow the surgeon to pack the device with bone graft (autograft or allograft) prior to insertion. Openings in the anterior-posterior direction permit bone growth through the device. The GSO GS1 Spacer is intended for use with supplemental internal fixation.

The GSO GS1 Spacer is fabricated from medical grade titanium alloy and can be installed with any suitable instrumentation.

INDICATIONS: The GSO GS1 Spacer is intended for use in the thoracolumbar spine (i.e., T1 - L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The GSO GS1 Spacer is also indicated for treating fractures of the thoracic and lumbar spine. The GSO GS1 Spacer is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period of time. Supplemental internal fixation is required to properly utilize this system.

CONTRAINDICATIONS: Contradictions include, but are not limited to:

1. Active infectious process or significant risk of infection (immunocompromise).
2. Fever or leukocytoses.
3. Any patient with bone absorption, osteopenia, osteomalacia and/or osteoporosis.
4. Any case not requiring bone graft and fusion.
5. Pregnancy.
6. Any case where the components would be too large or too small to achieve a successful result.
7. Signs of local inflammation.
8. 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.
9. Any patient with inadequate soft tissue coverage of operative site or inadequate bone from any previous surgery.
10. Morbid obesity.
11. Any patient with allergy or intolerance of the implant material.
12. Any patient in whom utilization would interfere with anatomical structure or physiological function.
13. Any patient unwilling to follow post-operative instructions.
14. Any case not directed in indications.

WARNINGS:

1. Correct selection of the appropriate implant size is extremely important.
2. Mixing metals can cause corrosion and may lead to device failure. Dissimilar metals in contact, such as titanium and stainless steel, may accelerate the corrosion process of stainless steel. The presence of corrosion can accelerate fatigue fracture of implants. The amount of metal compounds released into the body system could also increase.
3. Post-operative care should include external immobilization (such as a TLSO brace), which is recommended for the first month. Patients should be asked to avoid bending, lifting, stooping, or twisting for at least 3 months, and to avoid heavy activity for 6 months.
4. Surgical implants must never be reused or reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
5. As the number of previous surgeries at the involved spinal level(s) increases, the potential for intra-operative dural tears increases.

PRECAUTIONS:

The implantation of vertebral body replacement devices should be performed only by experienced spinal surgeons with specific training in the use of this spinal system. This is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning of spinal device system constructs able to withstand trauma or deformity induced body load concentrations is an important consideration for achieving bony fusion and successful surgical outcomes. The surgeon is responsible for preoperative planning, familiarity with operative techniques and ancillary instrumentation, and preoperative consultation with experienced associates as required to achieve successful post surgical results. 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, failure 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.

POSSIBLE ADVERSE EVENTS: The following potential adverse events (singly or in combination) could result from the implantation of the GSO GS1 Spacer:

1. Bursitis.
2. Decrease in bone density due to stress shielding.
3. Degenerative changes or instability of segments adjacent to fused vertebral levels
4. Fracture of bony structures.
5. Implant material sensitivity, or allergic reaction to a foreign body.
6. Infection, early or late.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Non-union (or pseudarthrosis). Delayed union. Mal-union.
9. Discomfort or abnormal sensations due to the presence of the device.
10. Paralysis.
11. Spinal cord impingement or damage.
12. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late post-operative period.
13. Post-operative change in spinal curvature, loss of correction, height and/or reduction.
14. Dural tears, pseudomeningocele, fistula, persistent CSF leakage and meningitis.
15. Loss of neurological function (e.g. sensory and/or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, or paresthesia, appearance of radiculopathy and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation and/or visual deficits.
16. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis and/or muscle loss.
17. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
18. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
19. 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.
20. Change in mental status.

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

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. Non-sterile products are recommended to be steam sterilized by the hospital using the following process parameters:

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

STERILE PRODUCTS: The sterile GSO GS1 Spacers have been sterilized by exposure to gamma irradiation. Packing material should be inspected for damage prior to use. If the seal of either the inner or outer barrier is damaged, the product should be considered non-sterile. In the event of damage to the sterile barrier or inadvertent contamination, the component may not be resterilized and should not be used.

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 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 item number, lot number, 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.

	Use By, Expiration Date
	Do Not Re-use, Single Use Only

