The Peridot Intervertebral Body Fusion System

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PURPOSE

This device is a PEEK (POLYETHERETHERKETONE) fusion device intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

DESCRIPTION

The Peridot Intervertebral body fusion system's implants are interbody fusion devices intended for use as an aid in spinal fixation. These hollow, rectangular implants are offered in a variety of widths, lengths, heights and lordotic angles designed to adapt to a variety of patient anatomies. They have serrations on the superior and inferior surfaces designed for fixation, ergonomically shaped anterior edges, and flat posterior edges. Radiopaque markers have been embedded within the implants, which are designed to allow for visualization in radiographic images

Surgical approach

- PLIF (Posterior Lumbar Intervertebral body Fusion) PEEK Cage System is to be implanted via posterior approach.
- TLIF (Transforaminal Lumbar Intervertebral body Fusion) PEEK Cage System is to be implanted via transforaminal approach.
- ALIF(Anterior Lumbar Intervertebral body Fusion) PEEK Cage System is to be implanted via anterior approach.
- LLIF (Lateral Lumbar Intervertebral body Fusion) PEEK Cage System is to be implanted via direct lateral approach. It can be used in an open approach and a percutaneous approach with MIS instrumentation.
- OLIF (Oblique Lumbar Intervertebral body Fusion) PEEK Cage System is to be implanted via oblique approach.

Raw Material: Cage Body – PEEK as per ASTM F2026, Tantalum Marker – Tantalum as per ASTM F560, Holder – Titanium alloy as per ASTM F136

INDICATIONS

The Peridot Intervertebral body fusion system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. The Peridot Intervertebral body fusion system is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

This device is not intended for cervical spine use.

Contraindications include, but are not limited to:

1. Infection, local to the operative site
2. Signs of local inflammation,
3. Fever or leukocytosis,
4. Morbid obesity,
5. Pregnancy,
6. Mental illness,
7. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Suspected or documented allergy or intolerance to composite materials,
9. Any case not needing a fusion,
10. Any case not described in the indications,
11. Any patient unwilling to cooperate with postoperative instructions.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. Spondylolisthesis unable to be reduced to Grade 1.
14. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
15. Any case that requires the mixing of metals from two different components or systems.
16. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
17. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
18. Prior fusion at the level to be treated.

Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. Severe bone resorption
2. Osteomalacia
3. Severe osteoporosis

POTENTIAL ADVERSE EFFECTS

Adverse effects may occur when the device is used either with or without associated instrumentation.

Potential adverse events include but are not limited to:

1. Implant migration.
2. Breakage of the device(s).
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection.
7. Bone fracture or stress shielding at, above, or below the level of surgery.
8. Non-union (or pseudoarthrosis).
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain.
10. Haemorrhage of blood vessels and/or hematomas.
11. Discitis, arachnoiditis, and/or other types of inflammation.
12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
13. Bone graft donor site complication.
14. Inability to resume activities of normal daily living.
15. Early or late loosening or movement of the device(s).
16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
18. 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.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
20. Loss of or increase in spinal mobility or function.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. Patients who smoke have been shown to have a reduced incidence of bone fusion.

These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and / or alcohol / drug abuse patients and those with poor muscle and bone quality and / or nerve paralysis are also poor candidates for spinal fusion.

The Peridot Intervertebral body fusion system has not been evaluated for safety and compatibility in the MR environment. The Peridot Intervertebral body fusion system has not been tested for heating or migration in the MR environment.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

This system should not be used with components of any other systems or manufacturers.

Based on fatigue testing results, when using this system, the physicians /surgeons should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

Hyperlordotic lumbar cages (>20 degree) the form of supplemental fixation should be an anterior plate system.

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.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

THE CHOICE OF IMPLANTS

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient. Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up implant fatigue and/or lead to deformation or failure of the implants. The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up. The surgeon must warn the patient of the surgical risks and made aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advice the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

PREOPERATIVE PRECAUTIONS

The surgical indication and the choice of implants must take into account certain important criteria such as:

- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests must be made prior to material implantation.
- Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

INTRAOPERATIVE PRECAUTIONS

- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by GBS Commonwealth.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.

POSTOPERATIVE PRECAUTIONS

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical

problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

IMPLANT REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, The Peridot Intervertebral body fusion system is not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:

- The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions.
- Pain or abnormal sensations due to the presence of the implants.
- Infection or inflammatory reactions.
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.

PACKAGING

Components should only be accepted if received with the factory packaging and labeling intact. All sets should be carefully inspected before use. In particular, check for completeness of the set and integrity of the components and/or instruments. Any damaged packaging and/or product must be returned to GBS Commonwealth.

EXAMINATION FOR GENERAL INSTRUMENTS

Instruments must always be examined by the user prior to use in surgery. Examination should be thorough, and in particular, should take into account a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, bruising or distortion, and that all components of the instrument are complete.

Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

STORAGE AND HANDLING

The Peridot Intervertebral body fusion system should be stored in a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

CLEANING AND STERILIZATION

Implants are supplied non-sterile and are for single use only. So all implants used in surgery must be sterilized by the hospital prior to use. Otherwise, Instruments are supplied non-sterile and may be re-used Implants and Instruments must be thoroughly cleaned prior to sterilization. Trained personnel must perform cleaning and mechanical inspection prior to sterilization.

- Do not stack trays during sterilization

Unless just removed from an unopened package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to GBS Commonwealth.

Manual Cleaning procedure

1. Use the neutral pH enzyme soaking solution that has been prepared.
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes (water temperature: 35-45°C). Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).

Note: The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.

3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO,DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas. (water temperature: 35-45°C).
4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz. (water temperature: 55°C).
6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream. (water temperature: 35-45°C).
7. Repeat Steps 5 and 6 with freshly prepared cleaning solution.
8. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.
9. We recommend to “thoroughly clean” the trays but are not limited. If it is not clean during visual inspection after final cleaning, perform the repeat cleaning procedure step.

Automated cleaning procedure

Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.

CAUTION:

- Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
- Verify that the instruments are in operation condition.
- We recommend to “thoroughly clean” the trays but are not limited. If it is not clean during visual inspection after final cleaning, perform the repeat cleaning procedure step.

STERILIZATION

All implants and instruments are supplied NON-STERILE. Prior to use, all implants and instruments should be placed in the instrumentation / implant case which will be either wrapped in an FDA cleared sterilization wrap or placed in a rigid sterilization container and placed in the autoclave for sterilization by the hospital using one of the following recommended cycles.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Gravity	270°F (132°C)	15Minutes (Dry time, 30Minutes)
Steam	Pre-Vacuum	270°F (132°C)	4Minutes (Dry time, 30Minutes)

Implants previously implanted should not be re-used. Inspect visually for damage or contamination by biological residue. If damage or biological residue is observed on the implant, it must be discarded.

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 distributor or GBS COMMONWEALTH CO. LTD.. Further, if any of the implanted spinal system component(s) 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 immediate. If any GBS COMMONWEALTH CO. LTD.’ 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.

SHELF-LIFE

This product is not sterilized product. The shelf-life is not applicable to our product.

FURTHER INFORMATION

Recommended directions for use of this system are available at no charge upon request. If further information is needed or required, please contact GBS COMMONWEALTH CO. LTD. Co., Ltd.

Manufactured For:

GBS Commonwealth Co., Ltd.

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SYMBOL TRANSLATION			
LOT	LOT NUMBER	REF	CATALOG NUMBER
	SINGLE USE ONLY	NON STERILE	NON-STERILE
	See package insert for labeling limitation		Consult instruction for use
	“DO NOT USE IF PACKAGE IS DAMAGED		KEEP AWAY FROM SUNLIGHT
	KEEP DRY		USE BY
QTY	QUANTITY		MANUFACTURER
	“DATE OF MANUFACTURE	35°C 1°C	STORE AT ROOM TEMPERATURE
Rx Only	Caution : Federal Law(USA) restricts this device to sale, distribution, or use by or on the order of a physician.		