Important Information on the RELIANCE CERVICAL IBF SYSTEM - STERILE COMPONENTS (PEEK & PEEK-HA IMPANTS)

Purpose:

The RELIANCE CERVICAL IBF System is intended for use at one level in the Cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined at neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

Description:

The RELIANCE CERVICAL IBF device consists of intervertebral spacers of various shapes, sizes, and angulation. Each RELIANCE CERVICAL IBF has anti-migration teeth on the superior and inferior surfaces to engage the adjacent vertebral body. The RELIANCE CERVICAL IBF System implant components are made of medical grade PEEK-Optima LT1 described by ASTM Standard F-2026. These components also have radiographic markers made of Tantalum embedded in the PEEK material.

The RELIANCE CERVICAL IBF System must be used with additional anterior and/or posterior spinal instrumentation to augment stability.

Do not use implant components from any other manufacturer with RELIANCE CERVICAL IBF System components. As with all orthopedic implants, in no case may the implants be re-used.

Indications, Contraindications and Possible Adverse Effects.

Indications:

The RELIANCE CERVICAL IBF System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with legally cleared supplemental spinal fixation cleared for the implanted level.

The RELIANCE CERVICAL IBF System is intended for use at one level in the cervical spine, from C3 to T1, for treatment of cervical degenerate disc disease (DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The RELIANCE CERVICAL IBF System is to be used in patients who have six weeks of non-operative treatment.

Contraindications:

The RELIANCE CERVICAL IBF device is not intended for thoracolumbar nor posterior surgical implantation.

1. Contraindications include, but are not limited to:
2. Infection, local to the operative site.
3. Signs of local inflammation.
4. Fever or leukocytosis.
5. Morbid obesity.
6. Pregnancy.
7. Mental illness.
8. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or 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, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
10. Suspected or documented metal allergy or intolerance.
11. Any case needing to mix metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any patient unwilling to co-operate with postoperative instructions.
14. These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
15. Titanium implants should not be placed in contact with stainless steel implants.
16. Prior fusion at the level(s) to be treated.
17. Contraindications of this device are consistent with those of other spinal systems.

Possible Adverse Effects:

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

1. Early or late loosening of the components. Implant migration.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
4. Infection.
5. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
6. Tissue or nerve damage, irrigation, and/or pain caused by improper positioning and placement of implants or instruments.
7. Loss of neurologial function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance or radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss and/or spasms.
8. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
9. Scar formation possibly causing neurological compromise around nerves and/or pain.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Bone loss or decrease in bone density, possibly caused by stress shielding.
12. Subsidence of the device into vertebral body(ies).
13. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
14. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
15. Non-union (or pseudarthrosis). Delayed union. Mal-union.
16. Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft, or at the bone graft harvest site-at, above, and/or below the level of surgery.
17. Graft donor site complications including pain, fracture, infection, or wound healing problems.
18. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
19. Ileus, gastritis, bowel obstruction or other types of gastrointestinal system compromise.
20. Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
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.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

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 a bone graft may 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 selection and placement of the implant and good reduction are important considerations in the success of surgery. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Reliance Medical Systems because the combination with other instrumentation may be incompatible, and may not be guaranteed.

Once the device has been assembled, do not disassemble. The connection mechanism may become damaged in doing so. **Never reuse an internal fixation device under any circumstances**. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage. Damage to the connection mechanism will reduce the stability of the instrumentation.

The Reliance CERVICAL IBF System has not been evaluated for safety and compatibility in the MR environment. The Reliance CERVICAL IBF System has not been tested for heating or migration in the MR environment.

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.

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 the performance of the system.' and 'Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery

PHYSICIAN NOTE: Although the physician is the learned intermediary, the information contained in this document must be conveyed to the patient. To aid in that process, the physician may provide the following paragraph to the patient:

PATIENT INFORMATION: The internal fixation device used in your recent spinal surgery is a plastic polymer implant that attaches to the bone and aids in the healing of bone grafts.

The RELIANCE CERVICAL IBF System, when used as an Intervertebral Body Fusion device is also intended for use at either one level in the Cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined at neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).

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

CAUTION: For use on or by the order of a physician only.

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. Plastic polymer 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 plastic 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. Further information on the use of this system will be made available on request.
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. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. 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. The instructions in any available applicable surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
3. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the instrumentation, a bone graft should be used. When using the RELIANCE CERVICAL IBF device, autogenous bone graft should be used.
5. Bone cement should not be used since 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.

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 or breakage of the device are complications which can occur as a result of excessive 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, demented or otherwise unable to use crutches or other weight supporting devices. 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 device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume excess alcohol during the bone graft healing process.
3. The patients should be advised of their inability to bend 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 eventual bending, loosening, or breakage of the device. It is important that immobilization of the union is established and confirmed by roentgenographic examination. Where there is a non-union, or if the components loosen, bend, and/or break, the device should be revised and/or removed immediately before serious injury occurs.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

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 should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to Reliance Medical Systems. Implants will be shipped in sterile and will not require sterilization prior to use. Label on the Implant package (pouch) will contain a Gamma Steridot. Steridot color changes from ORANGE to RED after sterilization. Always check to confirm the color of the Steridot to be RED prior to usage. Remove all packaging material prior to sterilization of the instruments. Only sterile implants and instruments should be used in surgery. Always check the label to confirm before using the implant that it is within the 5 year shelf life period. Always immediately re-sterilize all instruments which have been previously in the operation area. This process must be performed before handling or returning products to Reliance Medical Systems.

Symbols Used in Labelling	
	Do Not Reuse
	Do Not Re-sterilize
	Sterilized Using Irradiation
	Caution: Federal (USA) law restricts this device to sale and use by, or on the order of a physician
	Caution, consult accompanying documents
	Use By Date
	Do Not Use If Package Is Damaged

Cleaning and Decontamination:
All instruments must first be cleaned before sterilization and introduction into a sterile surgical field. Additionally, all instruments that have been previously taken into a sterile surgical field must first be decontaminated and cleaned before sterilization and reintroduction into a sterile surgical field. Implants are shipped sterile and should not be resterilized.

Implant Cleaning and Decontamination:
No cleaning and decontamination is required for the implants. Implants are pre-sterilized before being shipped in 5 year shelf life packaging.

Instrument Cleaning and Decontamination:
Certain instruments may require dismantling before cleaning.
All inserters should be disassembled by unthreading and removing the internal shaft.
All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device
Manual Cleaning:
Rinse items under warm water to remove gross soil. Soak in Enzol prepared per manufacturer's recommendations for at least 55 seconds. Actuate moving parts to ensure all surfaces are reached. Scrub the entire device using a soft bristled brush paying close attention to hard to reach areas. Use a syringe and pipe cleaner to clean cracks, crevices, and other hard to reach areas. Remove the devices from the detergent and rinse under lukewarm water for at least one minute. a
Prepare Prolystica 2x concentrate neutral detergent according to manufacturer's recommendations. Immerse devices in detergent for at least one minute. Actuate moving parts to ensure all surfaces are reached. Scrub the entire device using a soft bristled brush paying close attention to hard to reach areas. Use a syringe and pipe cleaner to clean cracks, crevices, and other hard to reach areas. Remove the devices from the detergent and rinse under lukewarm water for at least one minute.
Dry devices using a clean soft cloth and filtered pressurized air (less than 40 psi). Ensure that the devices are thoroughly cleaned. Visually inspect the devices for any visible soil. If visible soil remains, repeat the entire cleaning procedure.

Automated Cleaning:
Rinse items under warm water to remove gross soil. Set washer to high, and use the following parameters:

Phase	**Time (minutes)**	**Temperature**	**Detergent Type and Concentration**
Pre-Wash	02:00	Cold tap water	N/A
Enzyme Wash	01:00	Hot tap water	Enzol 1oz/gallon
Wash 1	02:00	Heated 66°C	Prolystica 2x Concentrate neutral detergent 1/8 oz/gallon
Rinse 1	00:15	Hot tap water	N/A
PURW rinse	00:10	66°C	N/A
Drying	07:00	115.5°C	N/A

Ensure that the devices are thoroughly cleaned. Visually inspect the devices for any visible soil. If visible soil remains, repeat the entire cleaning procedure.
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.
Sterilization:
Unless marked sterile and clearly labeled as such, the RELIANCE CERVICAL IBF System components, as well as those implants from other Reliance Medical Systems spinal systems specifically indicated for use with the RELIANCE Car to use. If the Reliance Medical Systems components described in this insert are sterilized by the hospital in a tray or case, they should be sterilized in the tray or case provided by Reliance Medical Systems. Reliance Medical Systems recommends the usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation.
NOTE: The following note applies to the process parameter identified with the * below: For use of this product and instruments outside 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.
Dynamic-Air-Removal (Prevacuum) Steam Sterilization Cycle

Item	Exposure time at 132°C (270°F)	Drying Time
Wrapped Instruments	4 minutes	30 minutes

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, Reliance Medical Systems. 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 immediately. If any Reliance Medical Systems 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:
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:
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