The Prase-C Anterior Cervical Plate System

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IMPORTANT NOTE TO OPERATING SURGEON

The Prase-C Anterior Cervical Plate System implants, like other internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking the implant components. It is essential to instruct patients about restrictions on their activities in the postoperative period and to examine the patient postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used or if a pseudoarthrosis develops.

The surgeon may determine to remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

DESCRIPTION

The Prase-C Anterior Cervical Plate System is a fixation device consisting of cervical plates and screws made of titanium alloy as per ASTM F136.

The number of screws used for anterior cervical plates are different for each level and can be used at least 2 to a maximum of 12.

All of the components are available in variety of sizes to match more closely the patient's anatomy.

The system functions as an adjunct to fusion to provide immobilization and stabilization of cervical segments of the spine. The plates are offered in one-level, two-level, three-level, four-level and five-level fusion configurations (17mm~110mm). The plate lockers are fixed into the main plate body by rivet technique. The screws are 3.75mm and 4.25mm diameter bone screws. They are self-drilling and self-tapping self-tapping threaded.

Raw Material: Plate and Screw – Titanium alloy as per ASTM F136.

INDICATIONS

The Prase-C Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7). The System is indicated for use in the immobilization and stabilization of the spine as an adjunct to fusions in patients with:

- degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- spondylolisthesis,
- trauma (i.e. fractures or dislocations),
- tumors
- deformity (defined as kyphosis, lordosis, or scoliosis),
- pseudoarthrosis,
- failed previous fusion,
- spinal stenosis.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Active systemic infection or an infection localized to the site of the proposed implantation.
- Severe osteoporosis may prevent adequate fixation of screws and thus preclude the use of this or any other spinal instrumentation system.
- Patients who have been shown to be safely and predictably treated without internal fixation.
- Open wounds.

Relative contraindications include any entity or condition that totally precludes the possibility of fusion (e.g., cancer, kidney dialysis or osteopenia), obesity, certain degenerative diseases, and foreign body sensitivity.

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. Nonunion, delayed union.
2. Bending or fracture of implant. Loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. 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 postoperative period.
9. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
10. Bursitis.
11. Paralysis.
12. Esophageal perforation, erosion or irritation.
13. Screw back-out, possibly leading to esophageal erosion, implant loosening, and/or reoperation for device removal.
14. Damage to lymphatic vessels and/or lymphatic fluid exudation.
15. Spinal cord impingement or damage.
16. Fracture of bony structures.
17. Degenerative changes or instability in segments adjacent to fused vertebral levels.
18. Death.

USAGE

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

POSTOPERATIVE MOBILIZATION

Until maturation of the fusion is confirmed by radiographic examination, external immobilization (such as bracing) may be recommended, based on physician judgment.

Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

WARNINGS

The following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient before surgery.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, fracture of the vertebra, neurological injury, and vascular or visceral injury.

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be extremely important to the eventual success of the procedure:

A. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

B. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

C. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substan-tially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.

D. Foreign body sensitivity. The surgeon is advised that no pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

E. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

5. ETC.

- If bony fusion does not occur within an expected period of time, the screws may break due to the high and sustained loading of these devices. This has been noted in patients with delayed, psuedoarthrosis or non-union and can result in the need to revise the device(s).
- This system should not be used with components of any other systems or manufacturers.

Based on fatigue testing results, when using the Prase-C Anterior Cervical Plate 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.

- This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.
- This Prase-C Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Prase-C Anterior Cervical Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTIONS

1. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of metal implants should be done only with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage of the implant. Do not use implant if damage is suspected.

Excessive torque applied to the screws when seating the plate may cause failure of the bone resulting in stripped threads and/or compromised screw purchase.

3. BENDING THE CONSTRUCT. Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured it is recommended that a new construct is contoured correctly rather than reverse bending the over-contoured construct.

4. REMOVAL OF THE IMPLANT AFTER HEALING. If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or 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; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved in a second surgery.

5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and participating in any type of sports. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially

in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

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.

IMPLANT 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 Co., Ltd.

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 Prase-C Anterior Cervical Plate System should be stored in a dry environment, protected from direct sunlight and at an ambient temperature in their original packaging.

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,

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:

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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℃ 1℃	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.		