



Device System Name:
Reliant™ Anterior Cervical Plating System

Description: The Reliant™ Anterior Cervical Plating System consists of an assortment of implantable titanium alloy plates, and bone screws, that are provided non-sterile.

Indications: The Reliant™ Anterior Cervical Plating System is a temporary implant, intended for anterior fixation to the cervical spine from C2 to C7. The specific clinical indications include:

- a) degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by patient history and radiographic studies)
- b) spondylolisthesis
- c) fracture
- d) spinal stenosis
- e) deformities (i.e., scoliosis, kyphosis, and/or lordosis)
- f) tumor
- g) pseudoarthrosis
- h) revision of previous surgery

Contraindications: The Reliant™ Anterior Cervical Plating System is contraindicated in patients with a systemic infection, with a local inflammation at the bone site, or with rapidly progressive joint disease or bone absorption syndromes such as Paget's disease, osteopenia, osteoporosis, or osteomyelitis. Do not use this system in patients with known or suspected metal allergies. Use of the system is also contraindicated in patients with any other medical, surgical or psychological condition that would preclude potential benefits of internal fixation surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other disease, elevation of white blood cells or a marked shift in white blood cell differential count.

Potential Adverse Events: All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible 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, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease
- 4) Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
- 5) Post-operative change in spinal curvature, loss of correction, height, and/or reduction
- 6) Infection
- 7) Vertebral body fracture at, above, or below the level of surgery
- 8) Loss of neurological function, including paralysis (complete or incomplete)
- 9) Non-union, delayed union
- 10) Pain, discomfort, or abnormal sensations due to the presence of the device
- 11) Hemorrhage
- 12) Cessation of any potential growth of the operated portion of the spine
- 13) Death

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

Warnings and Precautions:

- 1) Single use only
- 2) The Reliant™ Anterior Cervical Plating System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine
- 3) Nonsterile; the plates, bone screws and instruments are sold nonsterile, and therefore, must be sterilized before each use
- 4) Always orient the plate along the midline of the spine
- 5) When performing a corpectomy procedure using a Reliant™ Anterior Cervical Plate, ensure that the top locking mechanisms are only used on the superior and inferior portions of the cervical plate prior to final tightening the top locking plates to avoid potential plate performance deterioration.
- 6) To optimize bony union, perform an anterior microdiscectomy or corpectomy as indicated
- 7) To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used
- 8) Excessive torque applied to the screws when seating the plate may strip the threads in the bone
- 9) Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct
- 10) Do not reuse implants; discard used, damaged, or otherwise suspect implants.

Cleaning:

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization: The Reliant™ Anterior Cervical Plating System should be sterilized by the hospital using the recommended cycle:

- Method: Steam
Cycle: Gravity
Temperature: 250° F (121° C)
Exposure time: 30 minutes
- Or:
- Method: Steam
Cycle: Prevac
Temperature: 270° F (132° C)
Exposure time: 8 minutes

Physician's Manual:

Patient Selection: Patient selection is an extremely important factor in the success of implant procedures. It is important that the candidates be carefully screened and the optimal therapy selected.

Preoperative:

- 1) Carefully screen the patient, choosing only those that fit the indications described above
- 2) Care should be exercised in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Store away from corrosive environments
- 3) An adequate inventory should be available at surgery than those expected to be used
- 4) All components and instruments should be cleaned and sterilized prior to each use. Additional sterile components should be available in case of an unexpected need

Intraoperative:

- 1) Instructions should be carefully followed
- 2) Extreme caution should be used around the spinal cord and nerve roots
- 3) The implant surface should not be scratched or notched since such actions may reduce the functional strength of the construct
- 4) Bone grafts must be placed in the area to be fused such that the graft fits snugly against the upper and lower vertebral bodies
- 5) Bone cement should not be used as it will make removal of the components difficult or impossible

6) Before closing soft tissue, check each screw to make sure that none have loosened

Postoperative:

- 1) Detailed instructions should be given to the patient regarding care and limitations, if any
- 2) To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process
- 3) The patient should be advised of their limitations and taught to compensate for this permanent physical restriction in body motion
- 4) If a non-union develops, or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred
- 5) The implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the spine during the normal healing process. After the spine is fused, the devices serve no functional purpose and should be removed

Patient Information: The temporary internal fixation device used in your recent spinal surgery are metallic implants that attach to the bone and aid in the healing of bone grafts. These implants have been shown to be valuable aids to surgeons in the treatment of bony fusions. These devices do not have the capabilities of living bone. Intact living bone is self repairing, flexible and occasionally breaks and/or degrades. The anatomy of the human body places a size limitation on any artificial fixation device used in surgery. This maximum size limitation increases the chances of the mechanical complication of loosening, bending, or breaking of the devices. Any of these complications could result in the need for additional surgery. Accordingly, it is very important that you follow the recommendations of your physician. Use braces as instructed. By following these instructions, you can increase your chances of a successful result and reduce your risk of injury and/or additional surgery.

Product Complaints: Any Healthcare 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 Blackstone Medical, Inc., 90 Brookdale Drive, Springfield, MA 01104, USA, Telephone: 413-731-8711.

Further information: A recommended surgical technique for the use of this system is available upon request from Blackstone Medical, Inc., 90 Brookdale Drive, Springfield, MA 01104, USA, Telephone: 413-731-8711.

Authorized European Representative:

Medical Device Safety Service (MDSS)
Schiffgraben 41
D-30175, Hannover
Germany

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

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