

Device System Name:
Blackstone Spinal Fixation System

Description: The Blackstone Spinal Fixation System is a temporary, titanium alloy, multiple component system comprised of a variety on non-sterile, single use components that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws, and hooks to the non-cervical spine. The Blackstone Spinal Fixation System consists of an assortment of screws, hooks, rods, spacers, staples, washers, dominos, lateral offsets, and cross connectors. The Blackstone Spinal Fixation System titanium implants are not compatible with components or metal from any other manufacturer's system.

Levels of Use: The Blackstone Spinal Fixation System is intended for non-cervical use in the spine. When used as a non-pedicle anterolateral fixation system it may be used from levels T1 to S1. When used with pedicle screw fixation, the Blackstone Spinal Fixation System will be used at L5-S1, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 and below). When used as a posterior non-pedicle fixation system it may be used from levels T1-S1. When used as a non-pedicle anterolateral screw fixation system to the non-cervical spine, the staple and washer may be used from levels T6 to L5.

Indications:	Applicability:
<p>The Blackstone Spinal Fixation System is intended for non-cervical use in the spine. The Blackstone Spinal Fixation System, when used for <u>pedicle screw fixation</u>, is intended only for patients:</p> <ul style="list-style-type: none"> a) Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint; b) Who are receiving fusion using autogenous bone graft only; c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and d) Who are having the device removed after the development of a solid fusion mass. 	<p>Pedicle Screws, Rods, Cross Connectors, Dominos, Lateral Offsets, and Spacers.</p>
<p>The Blackstone Spinal Fixation System, when used as a <u>pedicle screw system</u> in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:</p> <ul style="list-style-type: none"> a) Degenerative spondylolistheses with objective evidence of neurologic impairment; b) Fracture; c) Dislocation; d) Scoliosis; e) Kyphosis; f) Spinal tumor; and g) Failed previous fusion (pseudoarthrosis). 	<p>Pedicle Screws, Rods, Cross Connectors, Dominos, Lateral Offsets, and Spacers.</p>
<p>The Blackstone Spinal Fixation System, when used for <u>anterolateral non-pedicle screw fixation</u> to the non-cervical spine, is intended for the following indications:</p> <ul style="list-style-type: none"> a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies); b) Spondylolisthesis; c) Spinal stenosis; d) Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis); e) Tumor; f) Pseudoarthrosis; g) Failed previous fusion; and h) Trauma (i.e., fracture or dislocation). 	<p>Screws, Rods, Cross Connectors, Dominos, Lateral Offsets, Spacers, Staples, and Washers.</p>
<p>The Blackstone Spinal Fixation System, when used for <u>posterior non-pedicle screw fixation</u> system of the non-cervical spine, is intended for the following indications:</p> <ul style="list-style-type: none"> a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies); b) Spondylolistheses; c) Spinal stenosis; d) Spinal deformities (i.e., scoliosis, kyphosis, lordosis); e) Tumor; f) Pseudoarthrosis; g) Failed previous fusion; and h) Trauma (i.e., fracture or dislocation). 	<p>Hooks, Rods, Cross Connectors, and Dominos.</p>

Note: For all of these indications, bone graft must be used.

Contraindications include, but are not limited to:

1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Pregnancy
5. Metal sensitivity/allergies
6. Severe osteopenia
7. Patients unwilling or unable to follow post-operative care instructions
8. Any circumstances not listed under the heading indications.

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. Device component fracture
2. Loss of fixation
3. Non-union
4. Fracture of the vertebra
5. Neurological injury
6. Vascular or visceral injury
7. Early or late loosening of any or all of the components
8. Disassembly and/or bending of any or all components
9. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease
10. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
11. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
12. Infection
13. Pain, discomfort, or abnormal sensations due to the presence of the device
14. Hemorrhage
15. Cessation of any potential growth of the operated portion of the spine
16. Death

Note: Potential risks identified with the use of the device system may require additional surgery.

Warnings and Precautions

1. The safety and effectiveness of pedicle screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are: significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, Kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
2. When used as a pedicle screw implant system, the device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar – first sacral (L5-S1) vertebral joint.
3. The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusion above the L5-S1 joint.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
5. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
6. Single use only
7. Non-sterile; the screws, hooks, rods, dominos, lateral offsets, spacers, staples, washers, locking nuts, cross connectors, and instruments are sold non-sterile, and therefore must be sterilized before use.
8. To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.
9. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
10. Excessive torque applied to the screws may strip the threads in the bone.
11. DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.
12. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
13. Based on fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

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 Blackstone Modular Spinal Fixation System should be sterilized by the hospital using one of the following recommended cycles:

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 Information

Pre-operative:

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. Correct selection of the implant is extremely important.
4. Use care in handling and storage of implant components. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided. These, in turn, may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Inspection should be made to determine if components have been damaged during storage or previous procedures.
5. An adequate inventory of implant sizes should be available at the time of surgery.
6. Certain special surgical instruments are required to perform this surgery. Review of the use and handling of these instruments is very important.

Intra-operative:

1. The primary goal of this surgery is to arthrodese selected vertebrae. Adequate exposure bony preparation and grafting is essential to achieving this result.
2. Whenever possible, use pre-cut rods of the length needed. The rods should not be repeatedly or excessively bent any more than absolutely necessary. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched in any way. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field.
3. The use of two rods and cross connecting the rods will provide a more rigid construct.
4. The placement of screws should be checked radiographically prior to assembly of the rod construct.
5. Care should be taken when positioning the implants to avoid neurological damage.
6. To facilitate proper fusion below and around the location of the instrumentation, a bone graft should be used.
7. Confirm that the rods are fully seated in the bottom of the screw head. Rods that are not fully seated may prevent the device from locking together.
8. Before closing the soft tissues, all of the set screws should be tightened firmly with a torque wrench or screwdriver according to the operative technique. Recheck the tightness of all screws and nuts to make sure that none loosened during the tightening of the other set screws. Failure to do so may cause loosening of the other components.
9. Bone cement should not be used since this material will make removal of the component difficult or impossible. The heat generated from the curing process may also cause neurological damage and bone necrosis.

Postoperative:

1. Detailed instructions on the use and limitations of the implant should be given to the patient. The patient must be made aware of the limitations of the implant. Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation device.
2. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components.
3. Surgical implants must never be reused. Any retrieved devices should never be reused in another surgical procedure. The retrieved parts should be handled and disposed of in such a manner as to ensure that reuse is not possible.
4. To allow the maximum potential for a successful surgical result, the patient or device should not be exposed to mechanical vibration that may loosen the device construct.
5. These implants are temporary internal fixation devices. Internal fixation devices are designed to assist in the stabilization of the operative site during normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. In most cases removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, complication may occur as follows:
 - a) Corrosion, with localized tissue reaction or pain.
 - b) Migration of implant position resulting in injury.
 - c) Risk of injury from postoperative trauma.
 - d) Bending, loosening and/or breakage, which could make removal impractical or difficult.

- e) Pain, discomfort or abnormal sensations due to the presence of the device.
- f) Possible increased risk of infection.
- g) Bone loss caused by stress shielding.

Adequate postoperative management to avoid fracture, re-fracture or other complications should follow implant removal.

Packaging: Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Damaged packages or products should not be used and should be returned to Blackstone Medical, Inc.

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 company, Blackstone Medical, Inc., 90 Brookdale Drive, Springfield, MA 01104, USA, Telephone: (413) 731-8711, Fax: (413) 731-8712

Further information: Recommended surgical techniques for the use of this system are available upon request. Blackstone Medical, Inc., 90 Brookdale Drive, Springfield, MA 01104, USA, Telephone: (413) 731-8711,

Authorized European Representative:

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