



**Device System Name:**

**Blackstone™ Surgical Mesh System**

**Description:** The Blackstone Surgical Mesh System is a diamond pattern, surgical mesh device. The body is manufactured from commercially pure (CP) titanium conforming to ASTM F67, the end rings, the standard ring, and the screws are titanium alloy that conforms to ASTM F 136. Because of the construction, the angle and the length of the mesh can be reduced incrementally to adjust it to individually anatomical conditions. The Surgical Mesh System is sold non-sterile.

**Indications:** The Blackstone Surgical Mesh System is indicated for use in the thoraco-lumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Surgical Mesh System is also indicated for treating fractures of the thoracic and lumbar spine.

The Surgical Mesh System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. Bone graft material is recommended to be packed inside of the mesh cage prior to implantation.

The Surgical Mesh System is intended for use with supplemental internal fixation. The supplemental internal fixation system that may be used with the Surgical Mesh System is the Blackstone Medical Spinal Fixation System.

**Contraindications:** The Blackstone Surgical Mesh, as with other metallic orthopedic appliances, is contraindicated for use in patients with active infections in which the use of an implant could preclude adequate and appropriate treatment of the infection. The device is also contraindicated for use in patients with known or suspected metal allergies.

**Potential Adverse Effects:** Potential adverse effects include, but is not limited to:

- 1) Failure of the device to provide adequate mechanical stability
- 2) Loss of fixation of the implant
- 3) Device component failure
- 4) Migration or bending of the device
- 5) Loss of bony alignment
- 6) Non-union
- 7) Fracture of bony structures
- 8) Resorption without incorporation of any bone graft utilized
- 9) Immunogenic response to the implant materials

**Note:** As with any surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.

**Warnings and Precautions:**

The surgeon should be aware of the following when using metallic implants:

- 1) The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human bones present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
- 2) The correct handling of the implant is extremely important. Contouring of the metal devices is to be avoided where possible. If contouring is necessary, it should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device.
- 3) Single use only. No metallic surgical implant should be reused. Any metal implant once used should be discarded. Even though the device appears undamaged, it may already have small defects and internal stress patterns which may lead to fatigue failure.
- 4) Nonsterile; the surgical mesh, and instruments are sold nonsterile, and therefore, must be sterilized before each use.
- 5) Postoperative care is important. The patient should be instructed in the limitations of the metallic implant and should be cautioned regarding weight bearing and body stress on the device prior to secure bone healing.

**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 NewBridge Laminoplasty Fixation System components are supplied NON-STERILE. Prior to use, all components should be steam 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

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system), who has any complaints, or who has experienced any dissatisfaction with 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)  
Burckhardtstrasse 1  
D-30163, Hannover  
Germany

**Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.**

