SpineLink®-II Spinal Fixation System

DESCRIPTION
The SpineLink-II Spinal Fixation System is a spinal fixation device made from titanium alloy (Ti-6Al-4V ELI). The system includes screws (fixed and polydirectional designs), various types and sizes of interconnecting links, transverse connectors, endcaps, locking nuts, hooks, and link ties. The locking nuts along with serrations on the link's interface form a tightly locked construct. Various instruments are also available as part of the SpineLink-II Spinal Fixation System for use by the surgeon to facilitate implantation of the device.

INDICATIONS FOR USE
The SpineLink-II Spinal Fixation System is a non-cervical spinal fixation device intended for use as a pedicle screw fixation system, a posterior hook and sacra/iliac screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and or lordosis), tumor, stenosis, pseudoarthrosis, and failed previous fusion. The transverse connector is not intended for anterior/anterolateral fixation.

CONTRAINDICATIONS
A. Spinal infection or inflammation
B. Morbid obesity
C. Mental illness, alcoholism or drug abuse
D. Pregnancy
E. Metal sensitivity/foreign body sensitivity
F. Patients with inadequate tissue coverage over the operative site
G. Open wounds local to the operative area

WARNINGS
1. The safety and effectiveness of pedicle screw spinal 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 severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. 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.
2. Implant Strength and Loading. The SpineLink-II Spinal Fixation System is intended to assist healing and is not intended to replace normal body structures. Loads produced by weight bearing and activity levels will dictate the longevity of the implant. These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing, and cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue. Therefore, it is important that immobilization of the operative site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. The surgeon must be thoroughly knowledgeable in the medical, surgical, mechanical and metallurgical aspects of the SpineLink-II Spinal Fixation System. Postoperative care is extremely important. The patient should be warned that noncompliance with postoperative instructions could lead to breakage of the implant and/or possible migration requiring revision surgery to remove the implant.
3. Selection of Implants. Selection of the proper size, shape and design of the implant increases the potential for success. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size and strength of implants.
4. **Corrosion.** Contact of dissimilar metals accelerates the corrosion process, which could increase the possibility of fatigue fracture of the implants. Therefore, only use like or compatible metals for implants that are in contact with each other.

5. **Link Tie.** When using the link tie in an interconnected construct, the interior interlink angle must be between 108° and 180°.

6. **Locking Bolt.** The locking bolt in the spherical head of the Polydirectional Screw is pre-set and should not be adjusted.

**PRECAUTIONS**

1. **Single Use Only.** Never reimplant an explanted metal device, under any circumstances. Although the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

2. **Handling of Implants.** If contouring of the link is required, avoid sharp bends and reverse bends. Avoid notching or scratching of the device, which could increase internal stresses and lead to early breakage.

3. **Implant Removal After Healing.** After healing is complete, the implant is intended to be removed since it is no longer necessary. Implants which are not removed may result in complications such as implant loosening, fracture, corrosion, migration, pain or stress shielding of bone, particularly in young, active patients. Implant removal should be followed by adequate postoperative management.

4. **Adequate Patient Instructions.** A patient must be instructed on the limitations of the metallic implant, and should be cautioned regarding physical activity and weight bearing or load bearing prior to complete healing.

5. **Surgical Techniques.** 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. Please refer to the specific surgical technique for this device for more information.

**POSSIBLE ADVERSE EFFECTS**

A. Nonunion (pseudarthrosis) or delayed union
B. Bending, fracture, loosening or migration of the implant
C. Metal sensitivity or foreign body reaction
D. Decrease in bone density due to stress shielding
E. Pain, discomfort, or abnormal sensations due to presence of the implant
F. Nerve, soft tissue, or blood vessel damage due to surgical trauma or device
G. Fracture of bony structures
H. Nerve root or spinal cord impingement
I. Dural leak
J. Bursitis
K. Necrosis of bone
L. Hemorrhage
M. M.Infection
N. Paralysis
O. Death

**STERILIZATION**

Unless supplied sterile, metallic internal fixation devices must be sterilized prior to surgical use. Product provided sterile is sterilized by exposure to a minimum dose of 2.5 Megarads (25kGy) gamma radiation. Where specified, do not use implants after expiration date. These guidelines also apply to devices provided sterile where the integrity of the packaging has been compromised and re-sterilization is required prior to initial use.

*Note: Allow For Cooling*
Since Biomet is not familiar with individual hospital handling methods, cleaning methods and bioburden, Biomet cannot assume responsibility for sterility of products provided as non-sterile even though the recommended guideline is followed.

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

INFORMATION
For further information, please contact the Customer Service Department at:

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U.S. Patent No. 5,607,425, No. 5,716,357, No. 6,010,504, No. 6,019,759, No. 6,017,343

Other Patents Pending

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