**PEEK-OPTIMA® Rod System**

**ATTENTION OPERATING SURGEON**

**NOT FOR USE IN THE USA**

**DESCRIPTION**
The PEEK-OPTIMA® Rod System consists of a series of straight and contoured rods constructed of Polyetheretherketone (PEEK). The contoured rods form a circular arc. PEEK-OPTIMA® rods are available in a variety of lengths and diameters. The radiolucent PEEK-OPTIMA® material allows for visualization of the defect site on radiograph.

**MATERIALS**
Polyetheretherketone (PEEK)

**INDICATIONS**
The PEEK-OPTIMA® Rod System is designed to be used with Biomet® spine fixation systems, which are devices intended for use as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterolateral fixation system. The PEEK-OPTIMA® rods are intended to provide immobilization and dynamic stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the lumbar and sacral spine:

1. Spondylolisthesis up to Grade 1.
2. Recurrent disc herniation.
3. Degenerative Disc Disease (DDD).
4. Stenosis.
5. Facet osteoarthritis.

The PEEK-OPTIMA® Rod System is not currently cleared or approved for marketing in the United States.

**CONTRAINDICATIONS**
Contradictions include, but are not limited to:
1. Spondylolisthesis greater than Grade 1.
2. Osteoporosis.
3. Curvatures (scoliosis, kyphosis, and/or lordosis).
4. Treatment of the thoracic and cervical spine.
5. Previous lumbar fusion attempt(s) at the affected level(s).
6. Previous facetectomy at the affected level(s).
7. Spinal infection or inflammation.
8. Morbid obesity.
9. Mental illness, alcoholism or drug abuse.
12. Patients with inadequate tissue coverage over the operative site.
13. Open wounds local to the operative area.

**WARNINGS**
When used with Biomet spinal fixation systems, potential risks identified with the use of this device system that may require additional surgery include device component fracture, loss of fixation, non union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

Biomet spinal systems and PEEK-OPTIMA® rods should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.

1. Implant Strength and Loading. The use of PEEKOPTIMA® rods in conjunction with Biomet spine fixation systems is intended to assist healing and is not intended to replace normal bony 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 PEEK-OPTIMA® ROD SYSTEM 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 fatigue. The surgeon must be thoroughly knowledgeable in the medical, surgical, mechanical, and metallurgical aspects of Biomet spinal fixation systems and PEEK-OPTIMA® Rod Systems. 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.

2. **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.

**PRECAUTIONS**

1. **Single Use Only.** Never reimplant an explanted device, under any circumstances. Although the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

2. **Handling of Implants.** PEEK-OPTIMA® rods are supplied straight and pre-contoured. Additional contouring in the field is not recommended.

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

**POSSIBLE ADVERSE EFFECTS**

1. Nonunion (pseudarthrosis) or delayed union.
2. Bending, fracture, loosening, or migration of the implant.
3. Sensitivity or foreign body reaction.
4. Decrease in bone density due to stress shielding.
5. Pain, discomfort, or abnormal sensations due to presence of the implant.
6. Nerve, soft tissue, or blood vessel damage due to surgical trauma.
7. Fracture of bony structures.
8. Nerve root or spinal cord impingement.
11. Necrosis of bone.
13. Infection.

**STERILIZATION**

PEEK-OPTIMA® rods are provided sterile. The product is gamma radiation sterilized. The package should be inspected prior to use to ensure the sterile barrier has not been compromised. **Do not resterilize.**

**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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