

## **Ibex™ Spine System - PEEK-OPTIMA®**

### **INDICATIONS FOR USE**

The **Ibex-PEEK-OPTIMA®** is indicated for use in the thoracolumbar spine (i.e., T1 to L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is also indicated for partial vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The device 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.

### **DESCRIPTION OF DEVICE**

The **Ibex-PEEK-OPTIMA®** is a curved implant constructed of Polyetheretherketone, medical grade (PEEK-OPTIMA® LT1) as described by ASTM F-2026. The pyramidal teeth on the superior and inferior ends resist expulsion in all directions. The device is open in the transverse plane to allow insertion of bone graft into the device prior to placement. The tantalum markers used for this product are made to the voluntary standard ASTM F-560. The radiolucent PEEK-OPTIMA® material allows visualization of the defect site on radiograph to assess bone growth.

The **Ibex-PEEK-OPTIMA®** is provided sterile in heights of 5mm to 17mm in both 0° and 6° lordotic angles.

### **INSTRUCTIONS FOR USE**

**Caution:** The **Ibex-PEEK-OPTIMA®** should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to the Surgical Technique Manual for complete Instructions for Use.

### **CONTRAINDICATIONS**

Contraindications include, but are not limited to:

1. infection, systemic, spinal or localized;
2. morbid obesity;
3. signs of local inflammation;
4. fever or leukocytosis;
5. metal sensitivity/allergies to the implant materials;
6. any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
7. grossly distorted anatomy due to congenital abnormalities;
8. rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft);
9. any case not needing a bone graft and fusion or where fracture healing is not required;
10. any case requiring the mixing of metals from different components;
11. any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition;
12. any case not described in the indications;
13. any patient unwilling to cooperate with the postoperative instructions;
14. any time implant utilization would interfere with anatomical structures or expected physiological performance.

### **WARNINGS**

The surgeon should be aware of the following:

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 spine presents 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 surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. All instruments must be cleaned and sterilized prior to surgery.
4. As with all orthopaedic implants, the **Ibex-PEEK-OPTIMA®** should never be reused under any circumstances.
5. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
6. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

## **PRECAUTIONS**

### **Preoperative:**

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the Contraindications Section should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. All instruments should be cleaned and sterilized before use.

### **Intraoperative:**

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions.
3. Bone grafts may be placed in the area to be fused.

### **Postoperative:**

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of an internal fixation device during post operative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the **Ibex-PEEKOPTIMA®** components should ever be reused under any circumstances.

### **POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS**

Possible adverse effects include, but are not limited to:

1. bending, loosening or fracture of the implants or instruments;
2. loss of fixation;
3. sensitivity to a metallic foreign body, including possible tumor formation;
4. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
5. nonunion or delayed union;
6. infection;
7. nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
8. gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
9. pain or discomfort;
10. bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra);
11. hemorrhage of blood vessels and/or hematomas;
12. malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height;
13. bursitis;
14. bone graft donor site pain;
15. inability to resume activities of normal daily living;
16. reoperation;
17. death.

### **STERILIZATION**

The **Ibex-PEEK-OPTIMA®** is 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 re-sterilize.

### **CAUTION**

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

### **INFORMATION**

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

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