INSTRUCTION FOR USE
OF ATHLET™ VBR SYSTEM

Device Description:

The ATHLET™ VBR System is a lordotic, modular vertebral body replacement system. One cranial and one caudal component are assembled to create a device construct. These components are available in a variety of sizes. This enables the surgeon to choose the size suited to the individual pathology and anatomical condition. The assemble device comprises a central cannula for bone graft and lateral fenestrations for bony in-growth. Teeth cover the ends of the device construct for improved in situ fixation.

The ATHLET™ VBR components are manufactured from polyetheretherketone (PEEK-OPTIMA® Invibio™, ASTM F2026). Integral marker pins are manufactured from titanium alloy (Ti-6Al-4V, ASTM F136).

Indications For Use:

The ATHLET™ System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The ATHLET™ system is intended for use with supplemental fixation and should be implanted in pairs.

Caution:

- The ATHLET™ is intended for single use only and should not be re-implanted.
- **Federal law restricts this device to sale by or on the order of a physician**

Contraindications:

- Advanced osteoporosis
- Specific metal allergy (Titanium Only)
- Infection.

Complications:

The patient should be informed of the following possible complications:

- Haematoma
- Pain
- Implant impaction
- Local or systemic infection
- Paraplegia
- Damage to local structures

Precautions:

1) These devices are supplied sterile. Do not use if sterile packaging is opened or damaged. These devices are intended for single use only. Do not re-implant, re-sterilize, reprocess, or reuse.

2) The physician / surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions which may impact the performance of the system.

3) Throughout the entire procedure particular care must be exercised to protect nerve roots.

4) Carefully check and remove any bone splinters following resection.

5) Prior to implantation, check the required implant size.

6) Do not use excessive force to introduce the implants.

7) The selection of size and implantation of the implant remain the exclusive responsibility of the user surgeon who must be experienced in spinal surgery.

Product Guarantee:

SIGNUS Medizintechnik GmbH guarantees that each individual spinal implant is manufactured with the greatest of care and from selected material. The entire process, from manufacture to final packaging, is under constant quality control. However, given that SIGNUS Medizintechnik GmbH has no influence over the selection or use of the implant, the diagnosis of the patient or the surgical technique used, or the handling of the implant following dispatch from our company, no guarantees can be given regarding a successful surgical result or the lack of complications.

FURTHER INFORMATION:

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If any further information is requested, please contact:

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