The ATHLET® VBR System
Instructions for Use

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.

The ATHLET VBR components are manufactured from polyetheretherketone (PEEK-OPTIMA® LT1, Invibio™) as described by ASTM F2026. Integral marker pins are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136 / ISO 5832-3.

Indications for use:

The ATHLET VBR 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 VBR System is intended for use with supplemental fixation and should be implanted in pairs.

Caution:

- These implants are 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 implants 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.
8. It is imperative that dissimilar metals do not come into contact in vivo. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.
9. The ATHLET VBR System has not been evaluated for safety and compatibility in the MR environment. The ATHLET VBR System has not been tested for heating or migration in the MR environment.

How supplied:

The ATHLET VBR System is provided sterile. All sterile products are labelled "STERILE." Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave sterile implants.

The associated instruments are provided clean but not sterile. Instruments are provided in an autoclavable tray. All instruments must be disassembled (if applicable) and cleaned before sterilization and introduction into a sterile surgical field.

Cleaning:

During use, keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. Thoroughly clean all instruments as soon as possible after use. Implant inserters must be disassembled prior to cleaning. This is accomplished by pulling on the knob end of the threaded inserter to withdraw the component from the cannulated outer shaft.

Pre-Cleaning:

Manual pre-cleaning is performed to remove gross contaminants. Immerse the instrument without any bubbles at minimum of 5 min, in cold regular tap water. All movable components must be repeatedly mobilized under running water, until no visible contamination remains. Brush all exposed surfaces with a nylon bristle brush.

Instruments with cavities as well as jointings, threads, hinges and springs have to be soaked in an ultrasonic bath for 10 min. at 40°C with 0,5% solution of alkanine cleaner (neodisher FA) and then rinsed from the inside and outside with a water spray gun at 58 psi (4 bar) static power for minim 20 s with cold regular tap water.

Automated cleaning:

Automated cleaning is the preferred cleaning method. Manual cleaning (above) should be performed prior to using automated cleaning equipment. Instruments have to be placed in the instrument tray of the purifier / disinfector (e.g Miele G7735). Instruments with cannula must be placed in the tray for micro-invasive surgery (MIS) instruments and must be connected to the spray nozzle system.

Clean the instruments by using a program with analogue parameters (e.g. Vario TD):

- Minimum 2 min pre-washing with cold regular tap water
- Drain
- Dosing of e.g. neodisher FA (Dr. Weigert, Hamburg) at 40°C
- At 55°C, for 5 min cleaning with Neodisher FA forte, 0.5% (Miele, Princeton NJ) or alternative cleaning with an adequate purifier
- Drain
- 3 min neutralization with warm water (> 40°C)
- Drain
- 2 min rinsing with warm water (> 40°C)
- Drain with demineralised water

Disinfection:

Manual disinfection:

Disinfect the instruments by using an FDA cleared disinfectant (VAH-list of the Association for Applied Hygiene). Cavities as well as joints, threads, hinges and springs must be water-rinsed inside and outside.

Automated operation:

Automated thermal disinfection, at a maximum temperature of 93°C in the purifier / disinfector (part of the above mentioned Vario TD program) is performed under consideration of national requirements regarding the thermal disinfection performance of the equipment in use (e.g. A0=Value according standard EN ISO 15883-1).

Drying:

Manual drying:

Dry the instrument with a fluff-free fabric. Cavities as well as joints, threads, hinges and springs have to be dried by compressed air. Also, the application of a vapor-permeable lubricant, suitable for steam sterilization based on paraffin/white-oil basis, should be used on moving parts.

Automated operation:

Drying of the instrument in the purifier / disinfector (one drying cycle, part of the Vario TD program) if applicable, the instrument can be dried by a fluff-free fabric. Cavities as well as joints, threads, hinges and springs have to be dried by compressed air. The application of a vapor-permeable lubricant, suitable for steam sterilization based on paraffin/white-oil basis, should be considered at these parts, too.

After cleaning/disinfecting, the disassembled instruments should be re-examined for visible soil. If visible soil is found, repeat the cleaning process. Following re-examination, the instruments should be dried using a soft cloth and placed in their proper locations in the instrument cases. The disassembled inserter components are reassembled by introducing the

threaded inserter shaft into the cannulated outer shaft until the two pieces are engaged.

Inspection:

Unless marked otherwise, instruments may be reused after reprocessing and sterilization. Before each reuse, inspect instruments including inaccessible areas, joints and moving parts for possible damage, wear or non-functioning parts. Carefully inspect the critical, inaccessible areas, joints and all movable parts. Damaged or defective instruments should not be used or processed. Contact your local sales representative for repair or replacement.

Sterilization:

Sterilization validation studies have shown the following recommendations for instrument sterilization are effective to an SAL of 10-6. The use of an FDA approved sterilization wrap is recommended.

Method:	Steam sterilisation
Cycle:	4 times pre-vacuum
Temperature:	Minimum 270°F (132°C) maximum 280°F (137°C)
Exposure Time:	4 minutes
Drying Time:	20 minutes

Storage:

Store the sterilised instruments in a dry, clean and non-fuzzing environment at room ambient temperature.

Further Information:

Recommended directions for the use of these systems (surgical operative techniques) are available at no charge upon request. For additional information please contact:

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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.