Patient Information Leaflet for VENUS® POSTERIOR SPINAL IMPLANT SYSTEM

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What is in this leaflet?

This leaflet answers some common questions about the VENUS® posterior spinal implant system. It does not contain all the available information. It does not take the place of talking to your surgeon.
All medical devices and implants have risks and benefits. Your surgeon has weighed the risk of using this product against benefits that are expected. Follow your surgeon's advice even if it differs from what is in this leaflet.
Please read this leaflet carefully and keep it in a safe place, so you may refer to it in future if needed.

What is the VENUS® posterior spinal implant system and what is it used for?

The VENUS®-System is intended for the surgical treatment of diseases and injuries of the spine such as instabilities, degenerative disc disease, degenerative spondylolisthesis, degenerative stenosis, scoliosis, kyphosis, spinal fractures, and spondylitis, tumor as well as all conditions that necessitate revision surgery.
The VENUS® Mini Subsystem, which is part of the VENUS®-System is suitable for percutaneous surgeries.
The VENUS®-System, is used as an implant system for spinal surgery and consists of rods, pedicle screws, transverse connectors, rod connectors and extension units as well as different types of hooks. Various forms and sizes of these implants are available so that adaptations can be utilized to take into account the unique anatomy of individual patients.
Fenestrated Screws contain a series of fenestrations which allows polymethylmethacrylate (PMMA) bone cement to be injected into the treated site.

What is the VENUS® posterior spinal implant system made of?

Components of the VENUS-System are made out of the titanium alloy Ti6Al4V There are also rods included, that are made of cobalt-chromium alloy CoCr28Mo6. The Cementadapter CPS is made out of PEEK material.

How is the VENUS® posterior spinal implant system used?

The system can only be implanted surgically, by a qualified person according to the corresponding surgical technique.
As described above, the VENUS® posterior spinal implant system is made up of different components, which will be selected according to your anatomical needs by your surgeon during the surgical procedure. The information regarding the models of your VENUS® posterior spinal implants is then recorded in the implant card provided to you by your physician.

For whom is the VENUS® posterior spinal implant system used?

The VENUS® posterior spinal implant system is used for patients whose general skeletal growth is completed.

When should the VENUS® posterior spinal implant system not be used?

Do not use the VENUS® posterior spinal implant system in the following cases:

- Acute infectious process or significant risk of infection (immunocompromise)
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Grossly distorted anatomy caused by congenital abnormalities.
- Extreme malalignments, impairing the stability of the instrumentation
- Any other medical of surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC) or a marked left shift in the WBC differential count.
- Joint disease, bone absorption, osteopenia, osteomalacia, and/or osteoporosis. Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
- Any neuromuscular disease that would place excess strain on the implant during the healing period.
- Suspected or documented allergy or intolerance to the material used. Appropriate tests should be carried out.
- Any case not needing a bone graft and fusion.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- All cases which require the use of components other than the metals or alloys used in this system.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unwilling or not able to follow postoperative instructions.
- Any case not described in the indications.

If you are unsure whether the VENUS® posterior spinal implant system should be used in your treatment, talk to your surgeon.

Warnings

- Your physical activities have a significant influence on your implant's useful life. Every activity increases the risk of loss, loosening, dislocation, migration, bending or breakage of implant or implant components. Herewith we would like to inform you about limitations to your activities in the postoperative phase and also that postoperatively monitoring is a crucial factor in assessing the development of the surgical result and the condition of the implant.
- The above-mentioned effects may occur even if the implant is well integrated and the activity restrictions are complied with.
- Components of the VENUS® system may not be replaced by components/ products from other systems, from another source or from a different manufacturer. Furthermore, no direct connection of components/ products of the systems to components of other systems may be established. If this recommendation is not complied with or if the products are otherwise used or used improperly, HumanTech Spine GmbH assumes no liability responsibility.

Precautions

- The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. The insertion of implants must be carried out in accordance with the surgical and medical indications, the potential risks, and limitations related to this type of surgery; the contraindications, side effects, and precautions defined, and in the knowledge of the nature and physical, chemical, metallic, metallurgic and biological characteristics of the implants.
- Components of the VENUS® system may not be replaced by components / products from other systems from another source or from a different manufacturer. Furthermore, no direct connection may be made between components / products of the VENUS® system to components of other systems or to components/ products made of materials other than Ti6Al4V or CoCr28Mo6be established. If this is not complied with or if the products are otherwise used or used improperly, HumanTech Spine GmbH assumes no responsibility.
- Never reuse the implants. Even if the implant appears to be intact following revision, alterations within the implant or minute defects resulting from the loading and stressing to which the implant has been subjected can cause the implant to break.
- Implants that have already come into contact with a patient´s body fluids or tissues or have been soiled must not be reused.
- Handle removed implants in such a way that their reuse is not possible.
- The volumes of cement used for fenestrated / cannulated screws should ultimately be determined by the surgeon based on the individual patient anatomy.
- Bending of the rods / revision connector affect the biomechanical properties of the implant. Bending in the area of the fixation of the rod in the Poly- or Monoaxial Screw can have negative influences to the fixation of the rod – Bending in this area has to be avoided.
- The rods of the VENUS® Mini-System have marks. It is not allowed to use the area between the ends of the rod and the marks for the fixation of the pedicle screw. In this area the rods may also not be bended.
- The system stability can be increased with a ventral support. In the lumbal area, especially when the use of pedicle screws with a diameter of 5,5mm or smaller can't be avoided, a ventral support is strongly recommended.
- Proceed with extreme caution in the region of the spinal cord and the roots of the nerves, since damage to the nerves can lead to the impairment of neurological functions.
- Breakage, slippage or incorrect use of the instruments or implants can injure the patient or the operating staff or result in more time being required for surgery.
- Residues consisting of implant material and/ or not from implant material should be removed.
- Damaged implants must not be implanted.
- Components of the VENUS® system have not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. They have not been tested for heating, migration, or image artefact in the MR environment. The safety of components of the VENUS® system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Side effects / complications

The side effects and complications listed are not only due to the implants, but often also to the surgical procedure and include, but are not limited to:

- Delayed bone growth or no visible fusion and pseudarthrosis
- Neurological complications, paralysis, soft tissue lesions, and/or migration of the implant
- Breakage, loosening or deformation of the implant, as well as abrasion
- Implant breakage during implantation or when implanted
- Superficial or deep-set infection and inflammatory phenomena
- Allergic reaction to the implant material
- Reduction in bone density
- Neurological and spinal dura mater lesions from surgical trauma
- Genitourinary disorders, gastrointestinal disorders, vascular disorders including thrombus, bursitis, secondary bleeding, myocardial infarction, or death
- Disorder of anatomical structures.
- Fracture of a vertebra, the pedicle, and/or the sacrum.
- Presence of micro-particles around the implants, Metallosis
- Growth of the fused vertebra is altered
- Partial loss of the degree of correction achieved during surgery
- Modification of spinal curvature and stiffness of the vertebral column
- Pain, discomfort or abnormal sensations due to the presence of the implant.
- Pressure on the skin caused by components located in positions with insufficient tissue coverage over the implant, with potential penetration of the skin.
- Fracture, micro fracture, resorption, damage to or penetration of a vertebral body above or below the treated segment/s
- Physiological limitations, such as joint degeneration
- Bleeding and/or haematomas
- Revision surgery
- Development of respiratory problems, including pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.

Seek medical advice if you experience any of these symptoms. Moreover, consult your responsible surgeon to discuss the potential benefits and risk of your treatment options.

Expected Device Lifetime

5 years (shelf-life of sterile packaging), no limitations of lifetime for products delivered in unsterile state and no limitations of lifetime in implanted state.

Postoperative monitoring

A postoperative monitoring must be carried out in consultation with the responsible surgeon.

Reporting adverse effects

You should report any adverse effects you believe are a result of the VENUS® posterior spinal implant system, please talk to HumanTech Spine GmbH on:

Adress: Gewerbestraße 5
D-71144 Steinenbronn
Email: info@humantech-spine.de
Internet: www.humantech-spine.de

Reports should also be made directly to the Therapeutic Goods Administration via the website http://www.tga.gov.au/reporting-problems.