Patient Information Leaflet for SAMSON® VERTEBRAL BODY REPLACEMENT

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What is in this leaflet?

This leaflet answers some common questions about the SAMSON® Vertebral Body Replacement 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 SAMSON® Vertebral Body Replacement System and what is it used for?

The SAMSON® Vertebral Body Replacement System is an implant system for long-term use for anterior stabilization of the upper thoracic to lower lumbar spine in vertebral body replacement surgery. The implants serve as a replacement for one or more vertebral bodies.

The SAMSON® system is intended for the surgical treatment of tumorous, inflammatory and traumatic diseases which lead to instabilities around the anterior support, or compression of the neural structures, or for diseases which require treatment of an infection.

The SAMSON® system has been designed for use with an additional dorsal fixation system. Implants of SAMSON® system are not intended for stand-alone use.

What is SAMSON® Vertebral Body Replacement System made of?

The implant is entirely made of the titanium alloy Ti6Al4V.

How is the SAMSON® Vertebral Body Replacement System used?

The cervical body replacement can only be implanted surgically, by a qualified person according to the corresponding surgical technique.

The SAMSON® system is made up of several components, namely a main body and two endplates, which will be selected by your surgeon during the surgical procedure. The information regarding the models of the components of your SAMSON® implant is then recorded in the implant card provided to you by your physician.

For whom is the SAMSON® Vertebral Body Replacement System used?

The SAMSON® Vertebral Body Replacement System is used for patients whose general skeletal growth is completed.

When should the SAMSON® Vertebral Body Replacement System not be used?

Do not use the SAMSON® Vertebral Body Replacement System in the following cases:

- Extreme malalignments, impairing the stability of the instrumentation
- Suspicion of a metal allergy or intolerance, and documented metal allergy or intolerance. Appropriate tests should be carried out.
- All cases in which the selected implant components are too large or too small to achieve a satisfactory result
- Every patient in which the use of the implant would interfere with anatomical structures
- Any neuromuscular disease that would place excess strain on the implant during the healing period.
- Any patient who is not willing or able to follow post-operative instructions
- Morbid obesity
- Pregnancy
- Use in combination with implants made of different metals or alloys
- All cases which are not described in the indications
- Any other medical or surgical condition which prevents possible improvement through the use of the implant

If you are unsure whether the SAMSON® Vertebral Body Replacement 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 SAMSON® 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

In sterile delivered implants:

- The sterile packaging may only be opened immediately before the implant is inserted.
- The implants may be used only when the label on the outer packaging and also the inner packaging are intact. If the packaging is damaged or already open, the sterility of the implant is not guaranteed and the implant may not be used.
- The implants may not be used when the shelf life indicated has been exceeded.
- Do not resterilize the implants.

For all implants:

- Only surgeons with the required professional training in the field of spinal surgery may insert the implants. It is essential for them to follow the notes in the operating instructions (surgical technique) and also read the instructions for use.
- In case of complications, the surgeon must decide whether a revision of the implant or other measures should be taken, taking into account the well-being of the patient and the risks involved.
- The surgeon needs to 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.
- Bone cement is not to be used, as this material makes the removal of the components difficult or impossible.
- Residues consisting of implant material and/ or not from implant material should be removed.
- Damaged implants must not be implanted.
- Under no circumstance may the implants be re-used. Even if the implant appears to be intact after 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.
- Removed implants have to be handled in such a way that their reuse is not possible.
- Components of the SAMSON® 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 SAMSON® system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Adverse reactions

- Missing intact connection segments, bone resorption, osteopenia, osteomalacia and/or osteoporosis, as well as a diffuse spinal tumours and infections, can, in addition to other causes, lead to the reduction of instrumentation stability, limit the degree of obtainable correction and stabilisation or increase the risk of sintering as well as implant loosening or migration.
- Failure to achieve the desired result of surgery, malpositioning of the implant
- Fracture, micro fracture, resorption, damage to or penetration of a vertebral body above or below the treated segment/s
- Reduction of bone density
- Change in the curvature and stiffness of the spine
- Loss or increase in spinal mobility or functions
- Physiological limitations, such as adjacent segment degeneration
- Bending, fracture or loosening of the implant components, as well as abrasion
- Delayed bone growth or no visible regeneration and pseudarthrosis, delayed healing or lack of healing
- Neurological deterioration with paralysis, functional failures, loss of sensation and pain, e.g. caused by scarring
- Soft-tissue lesions
- Pressure on surrounding tissue or organs
- The occurrence of laceration of the dura with risk of cerebrospinal fluid loss or a CSF fistula
- Radiculopathy
- Superficial or deep infection and inflammation as discitis, arachnoiditis, etc.
- Inability to perform one's daily tasks
- Dysfunctions of the bladder and rectum
- Temporary or permanent retrograde ejaculation in men
- Damage to the reproductive system, sterility and sexual dysfunctions
- Deep vein thrombosis, thrombophlebitis, pulmonary embolus
- Development of respiratory problems, including pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Lung injuries
- Injuries of the large abdominal vessels
- Bleeding and/or haematomas
- Allergic reaction to the materials used
- Foreign body reaction to the implants, including possible tumour formation, autoimmune disease and or scarring
- Metallosis
- Bursitis
- Death
- as well as all common surgical risks.

Seek medical advice if you experience any of these symptoms. Moreover, consult your responsible surgeon to discuss the potential benefits and risks 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 SAMSON® Vertebral Body Replacement 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.