Patient Information Leaflet for LEANDER® Cervical Vertebral Body Replacement System

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What is in this leaflet?
This leaflet answers some common questions about the LEANDER® Cervical 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 LEANDER® Cervical Vertebral Body Replacement System and what is it used for?
The LEANDER® Cervical Vertebral Body Replacement System is an implant system for long-term use for stabilization of the cervical spine in cervical vertebral body replacement surgery. The implants serve as a replacement for one or more cervical vertebral bodies.
The LEANDER® system is intended for the surgical treatment of tumorous, inflammatory and traumatic diseases and injuries of the cervical spine, which lead to instabilities in the cervical spine or compression of nerves or for diseases requiring infection repair. The LEANDER® system is intended for use with an additional fixation system, e.g. HERO®. Implants of the LEANDER® system are not suitable for stand-alone use.

What is LEANDER® Cervical Vertebral Body Replacement System made of?
The implant is entirely made of the titanium alloy Ti6Al4V.

How is the LEANDER® Cervical 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 LEANDER® 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 LEANDER® implant is then recorded in the implant card provided to you by your physician.

For whom is the LEANDER® Cervical Vertebral Body Replacement System used?
The LEANDER® Cervical Vertebral Body Replacement System is used for patients whose general skeletal growth is completed.

When should the LEANDER® Cervical Vertebral Body Replacement System not be used?
Do not use the LEANDER® Cervical Vertebral Body Replacement System in the following cases:
- Acute infections or significant risks of infections (weakened immune system)
- Any signs of local inflammation and bone tumors in the adjacent segments
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental disease
- Drug or alcohol abuse
- Wound healing disorders
- Any neuromuscular disease that would place an exceptionally high load on the implant during the healing period
- Missing intact adjacent segments, joint diseases, bone resorption, osteopenia, osteomalacia and/or osteoporosis are relative contraindications, as these can limit the degree of achievable correction/stabilization
- Severe anatomical deformities caused by congenital abnormalities
- Extreme malalignments which impair the stability of the instrumentation
- Known hereditary or acquired bone brittleness or calcification problems
- Suspected allergy or intolerance, as well as documented allergy or intolerance, to the material used. Appropriate tests must be carried out.
- All cases in which fusion is not required
- All cases in which the implant components selected for use are too big or too small to achieve a satisfactory result
- All cases where the use of components of different metals or alloys is necessary.
- Any patient with inadequate tissue structure at the surgical site or with inadequate bone stock or bone quality
- Any patient in whom the use of the implant would disturb anatomical structures or limit physiological performance
- Any patient who is unwilling to follow postoperative instructions
- All cases which are not described in the indications
- Any other medical or surgical condition that prevents possible improvement through the use of the implant, such as the presence of congenital abnormalities, fracture near the surgical site, increase in deposition rate not described by other conditions, increase in leukocyte count (WBC), or a marked left shift in the WBC differential blood count

If you are unsure whether the LEANDER® Cervical 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 LEANDER® 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.
- Safety and compatibility of the device in the setting of magnetic resonance (imaging) have not been evaluated. No thermal test or test of migration has been performed on the device in this setting.

Precautions
- 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.
- 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 LEANDER® system have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artefact in the MR environment. The safety of components of the LEANDER® system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Adverse reactions
- Implant loosening
- Implant migration
- Implant subsidence
- Implant breakage
- Bending, fracture or loosening of implant components
- Signs of abrasion, for example occurrence of microparticles in the area of the implant (metallosis)
- Foreign body reaction to the implants including possible tumor formation, autoimmune disease and/or scar formation
- Neurological complications with paralysis, functional failures, loss of sensitivity and pain, e.g. due to scarring or durotomy
- Neurological complications like irritation of spinal cord root nerve or peripheral nerves
- Paralysis
- Soft tissue complications like lesion or heterotopic ossification
- Pressure on surrounding tissue or organs
- Neurological or spinal lesion of the dura mater due to surgical trauma with a risk of loss of cerebrospinal fluid (CSF) or CSF fistula
- Injury to the esophagus and coughing and vomiting as well as difficulty swallowing (dysphagia) or hoarseness (dysphonia)
- Injury of the lymphatic vessels / lymph leakage
- Failure to achieve the desired surgical result, implant malposition
- Fracture, microfracture, resorption, damage or penetration of a vertebral bone and/or bone graft and/or bone graft extraction site above or below the treated segment(s)
- Negative impairment of the adjacent segments
- Late bone growth or no visible fusion and pseudarthrosis or (pseudo-) arthrodesis
- Superficial or deep-seated infections and inflammations such as discitis, arachnoiditis and sepsis
- Allergic reaction to the implant material Ti6Al4V
- Reduction of bone density
- Bleeding and/or haematomas in particular of the vertebral arteries
- Deep vein thrombosis, thrombophlebitis, pulmonary embolism
- Complications on the bone transplant donation system
- Herniated disc, disc destruction or degeneration in, above or below the treated segment(s)
- Loss or increase of spinal mobility or functions
- Physiological restrictions, such as adjacent segment degeneration
- Damage to the reproductive system, sterility and sexual dysfunction
- Temporary or permanent retrograde ejaculation in men or other serious injuries
- Inability to perform daily tasks
- Urinary retention or loss of bladder control or other types of impairment of the urological system
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change of mental state
- Changed growth of the fused spine
- Partial loss of the degree of correction achieved during the operation
- Changes in the curvature and stiffness of the spine
- Negative complications of bony structures, e.g. fracture of a vertebral body, necrosis, reduction of bone density
- Bursitis
- Death
- Revision surgery
- As well as all general surgical risks, like high blood pressure, coagulation disorder (coagulopathy), blunt trauma, fever, pleural effusion and neck stiffness

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 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 LEANDER® Cervical 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.