Patient Information Leaflet for HERO® Cervical Plate System

HumanTech Spine GmbH
Gewerbestraße 5
D-71144 Steinenbronn
Tel: +49 (0) 7157/5246-71
Fax: +49 (0) 7157/5246-33
e-mail:info@humantech-spine.de
www.humantech-spine.de

CE 0297

What is in this leaflet?

This leaflet answers some common questions about the HERO® Cervical Plate 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 HERO® Cervical Plate System and what is it used for?

The HERO® Cervical Plate System is designed for the surgical treatment of diseases and injuries of the cervical spine from C2 to C7 in patients in whom general skeletal growth has ceased, in particular for indications such as:

- degenerative diseases of the discs
- fractures
- tumors
- pseudarthrosis
- spinal canal stenosis
- cervical myelopathy
- deformities (i.e. cyphosis, lordosis and/or scoliosis)
- surgical revisions

What is the HERO® Cervical Plate System made of?

All components are made of titanium alloy Ti6Al4V.

How is the HERO® Cervical Plate System used?

The cervical body replacement can only be implanted surgically, by a qualified person according to the corresponding surgical technique.
The HERO® system is made up of several components, namely plates of differing sizes and screws, which will be selected by your surgeon during the surgical procedure. The information regarding the models of the components of your HERO® implant is then recorded in the implant card provided to you by your physician.

For whom is the HERO® Cervical Plate System used?

The HERO® Cervical Plate System is used for patients whose general skeletal growth is completed.

When should the HERO® Cervical Plate System not be used?

Do not use the HERO® Cervical Plate System in the following cases:

- All destructive and inflammatory diseases of the cervical vertebrae and of the motor segments such as tumors, spondylitis and fractures with a high degree of instability, with pronounced static and structural alteration of the spine and the segment structure, which require a vertebral body replacement and other measures to reconstruct and stabilize the segment.
- acute infections or significant risks of infection (weakened immune system)
- signs of local inflammations
- fever or leucocytosis
- morbid obesity
- pregnancy
- physical diseases
- severe anatomical deformities caused by congenital abnormalities
- Any other medical or surgical condition, which prevents a possible improvement by the use of the implant, such as the presence of congenital abnormalities, a fracture close to the operation site, increase of the deposition rate which is not explained by other disease patterns, elevated white blood cell count (WBC) or a pronounced leftward shift in the differential WBC.
- Articular diseases, bone resorption, osteopenia, osteomalacia and/or osteoporosis are relative contraindications as these may limit the degree of achievable correction or stabilization.
- Any neuromuscular disease that would place excess strain on the implant during the healing period.
- known hereditary or acquired bone brittleness or calcification problems
- Suspicion of a metal allergy or intolerance, and documented metal allergy or intolerance. Appropriate tests should be carried out
- all cases in which the use of components made of various metals or alloys is required
- all cases in which no fusion is required
- all cases in which the implant components selected for use are too big or too small to achieve a satisfactory result
- 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 implant is hindered by anatomical structures or where these structures would restrict the physiological performance.
- any patient who is unwilling to follow postoperative instructions
- all cases not described under the indications

If you are unsure whether HERO® Cervical Plate 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 HERO® 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 may only be emplaced by surgeons who have successfully completed the necessary training in the field of spinal surgery. The decision to use implants must be made in accordance with the surgical and medical indications, taking into account the potential dangers and the limitations associated with this type of surgical intervention, as well in knowledge of the contraindications, side effects and the defined precautionary measures and in awareness of the properties and the physical, chemical and biological characteristics of the implant.
- For complications, the doctor 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.
- Proceed with extreme care in the vicinity of the spinal cord and the nerve roots, as any damage to nerves can result in the loss of neurological functions.
- Fracture, slipping or incorrect use of instruments or implants can result in injury to the patient or surgical personnel.
- Bone cement may not be used as it makes the removal of components difficult or even 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 intact after the revision, there may be alterations within the implant or small defects, which are attributable to the action of loads and strain and which may result in fracture of the implant.
- Implants that have already come into contact with a patient´s body fluids or tissues or have been soiled must not be reused.
- Once removed implants are to be treated so as to render any re-use impossible.
- Bending of the plates can have in an adverse effect on the biomechanical properties of the implant. Deformations in the vicinity of locating holes can adversely affect the anchoring of the system. Any bending in this area is to be avoided.
- Components of the HERO® 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 HERO® 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:

- loosening of the implant
- fracture of the implant
- foreign body reactions to the implants including possible formation of tumors, autoimmune disease or scar formation
- neurological complications
- paralysis
- lesions of soft tissue
- neurological or spinal lesion of the dura mater due to surgical trauma
- swallowing difficulties (dysphagia), hoarseness
- damage to the lymph vessels / lymph leakage
- changes to the curvature and rigidity of the spinal column
- failure to achieve the desired result of surgery, implantation failure
- partial loss of degree of correction achieved in operation
- superficial or internal infections and inflammations such as discitis, arachnoiditis
- delayed engraftment of bone or no visible fusion and pseudarthrosis
- fracture, microfracture, resorption, damage or penetration of a vertebra and/or bone transplant and/or bone transplant extraction site above or below the treated segment
- bleeding and/or hematomas
- deep vein thrombosis, thrombophlebities, lundenembolus
- complications at bone transplant donor site
- herniated disc, spinal disc destruction or degeneration, above or below the treated segment
- loss or increase of spinal mobility or functions
- damage to the reproductive system, sterility and sexual dysfunction
- development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia etc.
- changes in the mental condition
- changed growth of the fused spinal column
- allergic reaction to the Ti6Al4V alloy
- appearance of microparticles in the vicinity of the implant
- reduction of bone density
- bursitis
- death

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 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.