HumanTech Spine

Patient Information Leaflet for TRISTAN® cages

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What is in this leaflet?

This leaflet answers some common questions about TRISTAN® cages. 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 are TRISTAN® cages and what are they used for?

TRISTAN® cages are a Cervical Interbody Fusion System and are used as an implant system for the fusion of vertebrae bodies in spine column surgery (cages). The implants serve as a replacement for the intervertebral disc to restore the original disc height.

TRISTAN® is intended for the operative treatment of diseases and injuries of the cervical spine in patients whose overall skeletal growth is fully developed, in particular for such indications as:

- disk herniation
- hard disk herniation
- mechanical instabilities
- calcification of the posterior longitudinal ligament
- osteochondrosis (for TRISTANflex reduced to Modic I and II)
- spinal canal stenosis

The cages are available in different dimensions to fit the unique anatomy of the individual patients. The following models are available: TRISTAN® PEEK and TRISTAN® PEEK S, TRISTAN®flex., TRISTAN R-PEEK-Ti coated, TRISTAN Ti.

What are TRISTAN® cages made of?

The implant base body is entirely made of the polymer PEEK Optima®. To achieve a better radiographic contrast, radiographic markers made out of titanium alloy respectively tantalum have been incorporated into the implant. In addition, for TRISTAN® PEEK S and TRISTAN®flex there are other components made out of titanium alloy Ti6Al4V included (e.g. spikes).

For TRISTAN titanium cages the implant base body is entirely made out of the titanium alloy TI6Al4V.

How is the TRISTAN® cage used?

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

For whom is TRISTAN® cage used?

TRISTAN® cages are used for patients whose general skeletal growth is completed.

When should TRISTAN® cages should not be used?

Do not use TRISTAN® cages in the following cases:

- All destructive and inflammatory diseases of one or more lumbar and lumbosacral vertebral bodies and vertebral motion segments such as tumors, spondylitis and fractures with a high degree of instability, with pronounced static and structural alterations of the vertebral body and segment structure, requiring the replacement of the vertebral body and other stabilizing measures for the reconstruction and stabilization of the segment
- Acute infections or significant risks of infections (weakened immune system)
- Indications of local inflammation
- Fever or leucocytosis
- Pathological obesity
- Pregnancy
- Psychological disorders
- Pronounced anatomical deformities resulting from congenital abnormalities
- Any other medical or surgical condition hindering possible improvement through the use of the implant, such as the existence of congenital abnormalities, fracture in the vicinity of the operating point, elevated deposition rate not indicated by other clinical pictures, elevated leucocyte count (white blood cells), or distinct leftward shift in the white blood cell differential blood count.
- Diseases of the joints, bone resorption, osteopenia, osteomalacia and/or osteoporosis are relative contraindications, since these can limit the degree of correction and stabilization that can be achieved.
- Any neuromuscular disease that would place excess strain on the implant during the healing period.
- Known hereditary or acquired brittleness of the bones or calcification problems
- Spondylolisthesis that cannot be reduced to the first degree
- 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 of different metals or alloys is necessary
- Already existing fusion in the segments treated
- All cases in which fusion is not necessary
- All cases in which the implant component selected for use is too large or too small to achieve a satisfactory result
- All patients with inadequate tissue structure on the operative side or inadequate bone or bone quality
- All patients in which the use of the implant would interfere with anatomical structures or restrict physiological performance
- All patients not willing to follow postoperative instructions
- All cases not described in the indications in the Instruction for Use

If you are unsure whether TRISTAN® cages 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 TRISTAN® 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

For sterile 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 has not to be used, as this material makes the removal of the components difficult or impossible. The heat produced by the hardening process can damage or deform the PEEK implants.
- Residues consisting of implant material and/ or not from implant material should be removed.
- Damaged implants must not be implanted.
- The implants have never to be reused. 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.
- The implants have never to be used, if they had contact with body fluids or third-party tissue.
- Removed implants have to be handled in such a way that their reuse is not possible.
- Components of the ADONIS® 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 ADONIS® system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- When using PEEK implants particular care in preparing the intervertebral disc space is needed to keep the placement forces low
- To achieve a good primary fixation, the TRISTANflex and TRISTAN PEEK…-S Cages have spiky and sharp spikes, therefore they must be carefully handled and a sufficient distraction is necessary.
- It is recommended to use an additional anterior plating if the bone quality or the implant site can't be evaluated pre- or interoperatively in question of primary fixation or if the implant site or the bone quality is expected not to ensure a proper primary fixation.

Adverse reactions

- Loosening of the implant
- Shifting of the implant
- Breakage of the implant, respectively detached parts of the implant and wear
- Foreign body reactions on the implant, including possible tumor formation, autoimmune disease and/or scar formation
- Scar formation with possible neurological impairments, nerve compression or pain
- Neurological complications
- Paralysis
- Soft tissue lesions
- Neurological or spinal lesions of the dura mater as a result of surgical trauma
- The migration of the implant in the posterior direction can cause a loss of neurological function, the occurrence of radiculopathy, dural tears and/or pain.
- Neurovascular impairment, including paralysis
- Temporary or permanent retrograde ejaculation in men, or other severe injuries
- Discharge of cerebrospinal fluid
- Inability to perform daily tasks
- Urinary retention or loss of control over the bladder, or other types of urinary system impairment
- Alteration of the curvature and stiffness of the spine
- Failure to achieve the desired result of surgery, malpositioning of the implant
- Partial loss of the degree of correction achieved during the operation
- Superficial or deep-seated infections and inflammations, such as discitis or arachnoiditis
- Bone fracture above or below the segments treated
- Late osseointegration or no visible fusion and pseudarthrosis
- Fracture, micro fracture, resorption, damage to or penetration of vertebral bone and/or the bone transplant and/or the bone transplant donor site above and below the segment treated
- Adjacent segment disease
- Bleeding and/or hematomas
- Deep-seated venous thrombosis, thrombophlebitis, pulmonary embolism
- Complications at the bone transplant donor site
- Herniated disk, disk destruction or disk degeneration at, above or below the segment treated
- Loss or enhancement of spinal mobility or functions
- Damage to the reproductive system, sterility and sexual functional disturbances
- Development of respiratory problems, for example pulmonary embolism, atelectasis, bronchitis, or pneumonia
- Alteration of the mental state
- Alteration in the growth of the fused spine
- Allergic reaction to the materials used
- Decrease in 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 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.

Postoperatively 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 TRISTAN® cage, please talk to HumanTech Spine GmbH on:

Adress: Gewerbestraße 5
D-71144 Steinenbronn
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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.