HumanTech Spine

Patient Information Leaflet for ADONIS® cages

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What is in this leaflet?

This leaflet answers some common questions about ADONIS® 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 ADONIS® cages and what are they used for?ADONIS® cages are a Lumbar Interbody Fusion System and are used as an implant system for long-term use 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 as a support element between two or more lumbar or lumbosacral vertebral bodies, and to correct the profile of the spine.

ADONIS® is intended for the surgical treatment of diseases and injuries of the lumbar and lumbosacral spine in patients whose general skeletal growth is completed, especially for indications such as: Prolapsed intervertebral disc, hard prolapsed intervertebral disc, mechanical instabilities, calcification of the posterior longitudinal ligament, osteochondrosis or lumbal spinal stenosis.

The cages are available in different dimensions to fit the unique anatomy of the individual patients. The following models are available depending on the operative technique your surgeon chooses: ADONIS® ALIF, ADONIS® PLIF, ADONIS® TLIF, ADONIS® UniLIF, ADONIS® LLIF.

What are ADONIS® cages made of?

For ADONIS PEEK cages 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.

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

How is the ADONIS® cage used?

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

For whom is ADONIS® cage used?

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

When should ADONIS® cages not be used?

Do not use ADONIS® cages in the following cases:

- acute infections or significant risks of infections (weakened immune system)
- all destructive and inflammatory diseases of the vertebral body or movement segment such as tumours, spondylitis and fractures with a high degree of instability, with a strong static and structural change of the vertebral body and segment structure, which require vertebral body replacement and other stabilising measures for reconstruction and stabilisation of the segment.
- indications of local inflammation
- fever or leucocytosis
- 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
- Severe anatomical deformities caused by congenital abnormalities
- Extreme malalignments which impair the stability of the instrumentation
- Missing intact adjacent segments
- bone resorption, osteopenia, osteomalacia and/or osteoporosis are relative contraindications, as these can limit the degree of achieveable correction/ stabilization
- 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 where 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 side or with inadequate bone stock or bone quality
- all patients in whom the use of the implant would interfere with anatomical structures or restrict physiological performance
- any patient who is unwilling to follow postoperative instructions
- 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 indicated by other clinical pictures, increase in leucocyte count (white blood cells), or marked left shift in the white blood cell differential blood count.
- spondylolisthesis that cannot be reduced to the first degree
- already existing fusion in the segments treated
- all cases not described in the indications

If you are unsure whether ADONIS® 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 ADONIS® 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 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 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.
- 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.
- When using PEEK implants particular care in preparing the intervertebral disc space is needed to keep the placement forces low
- 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.

Adverse reactions

- implant loosening
- implant migration
- implant subsidence
- implant breakage, respectively detached parts of the implant
- Signs of abrasion, for example occurrence of microparticles in the area of the implant
- neurological complications
- foreign body reactions to the implant, 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, irritation of the nerve roots (radiculopathy) and peripheral nerves
- Neurovascular impairment, including paralysis
- Soft tissue complications like lesion or heterotopic ossification
- Pressure on surrounding tissue, nerves or organs; injury of surrounding tissue, nerves or organs
- neurological or spinal lesions of the dura mater as a result of surgical trauma with the risk of loss of cerebrospinal fluid (CSF) or a CSF fistula
- Injury to the lymphatic vessels / lymph leakage
- Failure to achieve the desired surgical result, implant malpositioning
- fracture, micro fracture, resorption, damage to or penetration of vertebral bone and/or bone graft and/or the bone graft extraction site above or below the treated segment(s)
- Negative impairment of the adjacent segments
- late osseointegration or no visible fusion and pseudarthrosis
- superficial or deep-seated infections and inflammations, such as discitis or arachnoiditis
- allergic reaction to the materials used
- bleeding and/or hematomas in particular of the vertebral arteries
- deep vein thrombosis, thrombophlebitis, pulmonary embolism
- complications at the bone transplant donor site
- herniated disk, disk destruction or disk degeneration at, above or below the treated segment(s)
- loss or enhancement 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
- 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 in bone density
- bone fracture above or below the segments treated
- development of respiratory problems, for example pulmonary embolism, atelectasis, bronchitis, or pneumonia
- 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 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 postoperatively 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 ADONIS® cage, please talk to HumanTech Spine GmbH on:

Adress: Gewerbestraße 5
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Reports should also be made directly to the Therapeutic Goods Administration via the website http://www.tga.gov.au/reporting-problems.