Anterior lumbar interbody fusion

ADONIS®

HumanTech Spine
ADONIS®-ALIF cages are indicated for anterior lumbar vertebral body fusion. The implants are designed to be perfectly adapted to the anatomy of vertebral bodies in order to re-establish lordosis for reliable normalisation of the alignment of the spinal column and to provide stability and optimum conditions for fusion with the following indications:

- herniated discs
- calcified herniated discs
- mechanical instabilities
- calcification of the posterior longitudinal ligament
- osteochondrosis
- spinal canal stenosis

ADONIS®-ALIF is an intelligent and, by virtue of the associated set of instruments, highly rational interbody device system that is a widely recognised and accepted product line offering the following benefits:

**Anatomical**
- Geometry is identical to the patient’s own sectional and sagittal anatomy
- Generous contact surface - reduced risk of migration

**Stable**
- Antegrade toothing for stable anchorage
- Cranial convex contact surfaces for secure and permanent high precision seating
- Significantly increased extraction forces
- Extremely high friction coefficient

**Reliable**
- Large filling apertures for rapid fusion
- Internal annular groove holds the filling material in the cage and increases the filling volume

**Modular**
Thanks to the choice of 3 materials:

- **Titanium**
The metal titanium has proven to be especially biocompatible and correspondingly easy to modify. It is proven that the various reactions of human cells are initiated by the surface oxides of the titanium materials, which are just a few nanometres thin.

- **PEEK**
The material exhibits a high level of biocompatibility and is characterised by a bone-like elasticity. A further advantage lies in the material’s abstract-free properties

- **PEEK titanium-coated**
The titanium coating which, due to the relation between pore depth, porosity and roughness, provides an optimum substrate, has proven to be ideal for the docking of bone cells to the implant. The osteoinductive properties of titanium enable bone to take root directly on the implant.
ADONIS®-ALIF
Interbody Device System

Product-specific advantages

- Modular
- Reliable
- Stable
- Anatomical
**ADONIS®-ALIF Classic**

ADONIS® Classic is a solid titanium interbody device system and is a generally accepted product line for thoracolumbar indications. Coupled with a reliable and simple set of instruments, ADONIS® Classic is an ideal solution for thoracolumbar interbody fusions. The latest findings are used in the manufacturing of titanium implant materials with tailor-made surface properties. We exclusively use titanium Ti 6Al-4V ELI (as per DIN ISO 5832-3).

**ADONIS®-ALIF Avantgarde**

ADONIS® Avantgarde is an implant made from biocompatible PEEK-Optima® for the thoracolumbar interbody fusion used to treat degenerative disc diseases and instabilities.

This X-ray transparent material enables rapid and straightforward assessment of the bone structure and the fusion process. X-ray markers serve to verify positioning. A mechanical stability of 3.6 GPa allows for optimal load transmission between the implant material and natural bone. This stimulates bone healing processes.

Our PEEK material has been tested in accordance with ISO 10993 and classified in accordance with US P-VI, and the relevant FDA Device and Drug Master Files are available. Thanks to its material properties and its approval certificates, PEEK is predestined for use as an implant material.
ADONIS® Exclusive

ADONIS® Exclusive sets new benchmarks in the area of thoracolumbar interbody fusion. The titanium coatings of the new ADONIS® Exclusive cages combine the advantages of various materials in one implant. The basis of the implant is a solid PEEK core. This core is coated with titanium to increase the surface area and thus also to maximise the contact zone between the implant and the vertebral body surface.

The titanium coating that, due to its balanced relationship between pore depth, porosity and roughness, affords an optimum substrate has proven to be ideal for docking bone cells in the implant. The osteoinductive properties of titanium enable bone to take root directly on the implant.

Properties of PEEK and R-PEEK-Ti-coated

- PEEK is transparent to X-rays and does not produce artefacts
- Position verification using X-ray markers
- Anatomical form and toothed or Ti-coated surface
- The semi-circular shape provides for a maximum contact area
- It can optionally be filled with bone or bone replacement material for improved bone grafting
- Firm connection to the application instrument

PEEK-OPTIMA® is a polyaromatic, semi-crystalline thermoplastic, which is based on the basic formula (-C6H4-O-C6H4-O-C6H4-CO-)n and generally known as a polyether ether ketone.
Positioning of the patient

Anaesthetisation of the area and use of a small stab incision for the puncture. Palpation of the anterior upper area of the iliac crest. The access point should be at least 2 cm laterally removed from the anterior upper iliac crest to avoid damage to the nerves.

Anterior approach

Surgical approach depends on the segment to be treated. The correct intervertebral disc level is identified by means of an image intensifier and a corresponding linear metal axis at the side of the patient. This ensures crisp delimitation of the intervertebral disc space on both sides of the vertebral body centre line. Depiction of the vertebral disc segment to be operated on via a standard retroperitoneal approach.

Preparation of an anterior aperture

For the anterior approach, the intervertebral disc space is presented so that enough space is available in relation to the implant widths on both sides of the vertebral body middle line. If it proves difficult to clear vessels and / or tissue to a sufficient extent, an anterolateral approach is recommended. Cut a rectangular aperture in the anterior longitudinal ligament and the fibrous ring, corresponding to the width of the implant. The aperture width can be checked with a trial implant. Retain as much of the anterolateral, lateral and posterior annulus as possible in order to ensure the required stability of the segment operated on.
Preparation of the intervertebral disc space

Remove the intervertebral disc material and the cartilaginous layer of the end plates to reveal the osseous end plate structure. Incorrect use of the curettes results in a weakening of the end plates and can lead to a breach of the cage.

Note:
It is important that the nucleus and the inner annulus are removed to prevent a displacement of this material into the spinal canal during implantation and to avoid adversely affecting the bone in-growth.

Distraction

Distraction is essential for re-establishing the height of the intervertebral disc and the initial stability of the implant. For this, the sharp or blunt spreader can be inserted horizontally into the intervertebral space and rotated about 90°.

Determination of the implant size

Select an appropriate test implant and fix it to the insertion tool. In order to ensure that the implant is symmetrically introduced in the intervertebral space, the centre line should therefore be aligned with the anterior centre line of the vertebral bodies. Push the trial implant by means of light hammer blows into the intervertebral space. Use the next size, if the placement of the implant is not satisfactory. The trial implant must sit firmly when gently pressed in the intervertebral space and can be removed with the extractor handle.
**Preparation of the implant**

Select an implant size corresponding to the trial implant. After the implant has been introduced onto the insertion instrument, it can be filled with a sufficient amount of bone graft to ensure optimum contact with the end plates.

**Introduction of the implant**

Slide the implant into the intervertebral space. To ensure that the implant is symmetrically introduced, the centre line should be aligned with the anterior centre line of the vertebral bodies. Push the implant by means of gentle hammer blows. The implant must be gently pressed into place in the intervertebral space.

**Note:**

In order to avoid damage to the cage, the implant must be firmly attached to the implant holder.

**Removing the instruments**

After the implant has been correctly positioned, the insertion tool can be removed, so that the implant remains in its optimum position.
**Verification of the implant seating**

The optimum implant placement is when the implant is exactly centred between the end plate boundaries. Depending on the vertebral size, the anterior edge of the implant should be approx. 3 mm from the anterior edge of the adjacent vertebrae.

**X-ray examination**

Examine the position of the cage in relation to the vertebrae in the anterior and lateral direction. The X-ray markers that are integrated in the implant mean that the position can be exactly determined intra-operatively by X-ray.

**Supplementary fixation**

Determine the approach positions of the pedicle screws. The optimum position is at the intersection of the transverse process and the pars interarticularis. The pedicle screws are implanted and their position verified by means of an X-ray image.

More information about the introduction of the pedicle screws is available in the respective operation manual for the dorsal system utilised.
Position of the markers

To ensure the correct positioning of the cage, the cage must be brought into a central position once it has been inserted into the intervertebral disc space. The eight tantalum beads in the ALIF PEEK cage illustrated are used for a fluoroscopic view of the implant position. This makes it possible to assess the exact position of the cage by radiography. In the ALIF, four markers are located medially at the posterior implant margin and four markers are at the lateral anterior implant margin. The maximum width of the cage is shown by the four anterior markers. The implant depth can be estimated in combination with the four posterior markers. In the ALIF PEEK and R-PEEK-Ti implants, the four posterior and four anterior markers are visible on the X-ray for an implant positioned centrally within the disc space.
HumanTech - Medical Devices

**Implants/Instruments**

### Classic Titanium

- **7°**
  - Item no. 190112209
  - Name: Adonis ALIF Ti 32x22x09 7°
  - Length: 22
  - Width: 32
  - Height 1: 9
  - Height 2: 6.3
  - Angle: 7°

- Item no. 190112211
  - Name: Adonis ALIF Ti 32x22x11 7°
  - Length: 22
  - Width: 32
  - Height 1: 11
  - Height 2: 8.3

- Item no. 190112213
  - Name: Adonis ALIF Ti 32x22x13 7°
  - Length: 22
  - Width: 32
  - Height 1: 13
  - Height 2: 10.3

- Item no. 190112215
  - Name: Adonis ALIF Ti 32x22x15 7°
  - Length: 22
  - Width: 32
  - Height 1: 15
  - Height 2: 12.3

- Item no. 1901162211
  - Name: Adonis-ALIF Ti 32x22x11 12°
  - Length: 22
  - Width: 32
  - Height 1: 11
  - Height 2: 6.3
  - Angle: 12°

- Item no. 1901162213
  - Name: Adonis-ALIF Ti 32x22x13 12°
  - Length: 22
  - Width: 32
  - Height 1: 13
  - Height 2: 8.3

- Item no. 1901162215
  - Name: Adonis-ALIF Ti 32x22x15 12°
  - Length: 22
  - Width: 32
  - Height 1: 15
  - Height 2: 10.3

- Item no. 1901162217
  - Name: Adonis-ALIF Ti 32x22x17 12°
  - Length: 22
  - Width: 32
  - Height 1: 17
  - Height 2: 12.3

### Exclusive R-PEEK-Ti

- **7°**
  - Item no. 1903142209
  - Name: Adonis ALIF R-PEEK-Ti 32x22x09 7°
  - Length: 22
  - Width: 32
  - Height 1: 9
  - Height 2: 6.3
  - Angle: 7°

- Item no. 1903142211
  - Name: Adonis ALIF R-PEEK-Ti 32x22x11 7°
  - Length: 22
  - Width: 32
  - Height 1: 11
  - Height 2: 8.3

- Item no. 1903142213
  - Name: Adonis ALIF R-PEEK-Ti 32x22x13 7°
  - Length: 22
  - Width: 32
  - Height 1: 13
  - Height 2: 10.3

- Item no. 1903142215
  - Name: Adonis ALIF R-PEEK-Ti 32x22x15 7°
  - Length: 22
  - Width: 32
  - Height 1: 15
  - Height 2: 12.3

- Item no. 1903172211
  - Name: Adonis ALIF R-PEEK-Ti 32x22x11 12°
  - Length: 22
  - Width: 32
  - Height 1: 11
  - Height 2: 6.3
  - Angle: 12°

- Item no. 1903172213
  - Name: Adonis ALIF R-PEEK-Ti 32x22x13 12°
  - Length: 22
  - Width: 32
  - Height 1: 13
  - Height 2: 8.3

- Item no. 1903172215
  - Name: Adonis ALIF R-PEEK-Ti 32x22x15 12°
  - Length: 22
  - Width: 32
  - Height 1: 15
  - Height 2: 10.3

- Item no. 1903172217
  - Name: Adonis ALIF R-PEEK-Ti 32x22x17 12°
  - Length: 22
  - Width: 32
  - Height 1: 17
  - Height 2: 12.3

### Avantgarde PEEK

- **7°**
  - Item no. 1902112209
  - Name: Adonis ALIF PEEK 32x22x09 7°
  - Length: 22
  - Width: 32
  - Height 1: 9
  - Height 2: 6.3
  - Angle: 7°

- Item no. 1902112211
  - Name: Adonis ALIF PEEK 32x22x11 7°
  - Length: 22
  - Width: 32
  - Height 1: 11
  - Height 2: 8.3

- Item no. 1902112213
  - Name: Adonis ALIF PEEK 32x22x13 7°
  - Length: 22
  - Width: 32
  - Height 1: 13
  - Height 2: 10.3

- Item no. 1902112215
  - Name: Adonis ALIF PEEK 32x22x15 7°
  - Length: 22
  - Width: 32
  - Height 1: 15
  - Height 2: 12.3

- Item no. 1902152211
  - Name: Adonis ALIF PEEK 32x22x11 12°
  - Length: 22
  - Width: 32
  - Height 1: 11
  - Height 2: 6.3
  - Angle: 12°

- Item no. 1902152213
  - Name: Adonis ALIF PEEK 32x22x13 12°
  - Length: 22
  - Width: 32
  - Height 1: 13
  - Height 2: 8.3

- Item no. 1902152215
  - Name: Adonis ALIF PEEK 32x22x15 12°
  - Length: 22
  - Width: 32
  - Height 1: 15
  - Height 2: 10.3

- Item no. 1902152217
  - Name: Adonis ALIF PEEK 32x22x17 12°
  - Length: 22
  - Width: 32
  - Height 1: 17
  - Height 2: 12.3

### Instruments

**ADONIS®-ALIF**

- Item no. 190111009
  - Name: ALIF Trial 32x22x09 7°
  - Image: ALIF Trial 32x22x09 7°

- Item no. 190111011
  - Name: ALIF Trial 32x22x11 7°

- Item no. 190111013
  - Name: ALIF Trial 32x22x13 7°

- Item no. 190111015
  - Name: ALIF Trial 32x22x15 7°

- Item no. 190111111
  - Name: ALIF Trial 32x22x11 12°

- Item no. 190111113
  - Name: ALIF Trial 32x22x13 12°

- Item no. 190111115
  - Name: ALIF Trial 32x22x15 12°

- Item no. 190111117
  - Name: ALIF Trial 32x22x17 12°

- Item no. 190111001
  - Name: ALIF Inserter

- Item no. 1701010600
  - Name: Extractor Handle
Osseointegration with ADONIS® Exclusive

The implant surface has major importance for anchoring the implant and for implant compatibility at the interface implant/adjacent tissue. The success and speed of osseointegration are significantly influenced by the surface of the implant. Using an ideal implant surface, the biological responses between implant and bone can be optimised, and thus an earlier functional loading of implants can be achieved.

Immediately after introducing the implant, complex biological processes are induced between the surrounding tissue and the implant surface. The bone and wound healing can be divided into three phases.

During the first and most important healing phase, the initial blood contact forms a fibrin network (Fig. 13) on the implant surface. This is associated with an aggregation of thrombocytes and blood coagulation. The resulting blood coagulum is an important matrix for the invasion and migration of osteogene cells to the implant surface and thereby plays a deciding role for wound healing and osseointegration.

The osteogene cells differentiate at the implant surface and activate the generation of new bone by forming a bone-specific extracellular matrix (collagen) on the implant surface (Fig. 16).

On the next step, a mineralised boundary surface is formed. This is equivalent to a thin collagen-free layer on the outer side of an osteon in the natural bone tissue.

In the third, slow-healing phase, the bone is reconstructed until reaching its final load-bearing characteristics.

The time required for the three phases of healing time is referred to as osseointegration time and describes the time in which the bone substance links to the implant permanently and with sufficient strength.

ADONIS® Exclusive has an optimised and reproducible surface topography. The relation between surface topography and successful osseointegration has been studied intensively in the past three decades and is well described today.

Besides the surface-topography, the osseointegration of the implant can be improved through chemical coatings on the surface. The moderately rough surface (Fig. 14 - “HENIAPORE-K”) of ADONIS® Exclusive leads to a better bone adherence. HenniaPore has been developed in order to optimise the implant surface so as to promote rapid and postoperative adherence of the young bone (Fig. 15). A review of clinical and animal studies by Shalabi et Alvi affirms this statement.

The vacuum-plasma injection procedure used for ADONIS® Exclusive is currently the most successful method for creating biocompatible layers. Due to this very extensive manufacturing process, an optimum wettable implant surface is retained while preserving the same surface topography.

Osseointegration can be accelerated through this improved wettability and a greater implant stability is attained in the early phase of osseointegration, as revealed in animal studies and clinical data.

This method is proven worldwide for hip, knee, shoulder, wrist and tooth implants. Spinal application thus appears to be logical.

Nowadays, commercially successful implant systems usually have an optimised and reproducible surface topography. In contrast to this, the surface of ADONIS® Exclusive also has an optimised and reproducible surface chemistry, which leads to improved wetting and hence more homogeneous blood contact with the implant.
surface.

Summary:
The long-term success of an implant therapy concept is determined by multiple factors, but mainly by the bone density of the implant bed, the implant design and the implant surface. The composition, roughness and topography of the implant surface at the interface play an important role in primary stability and safe osseointegration. Rough implant surfaces will influence and stimulate the cellular activity of surrounding bony structures. Cell proliferation and cell differentiation, matrix synthesis and production of “tissue growth factors” are encouraged and lead to a dense bone-implant connection.

Specific surface roughness on the implant surface will encourage the regeneration potential at the interface and thus the clinical implant fixation.

Compared to machine-processed implant surfaces, the moderately rough surface (Fig. 14 - HENIAPORE-K") of ADONIS® Exclusive exhibits denser bone apposition with significantly increased withdrawal force (removal load) and an extremely high coefficient of friction for primary stabilisation.

This results in an accelerated osseointegration of these implants and the possibility of an earlier exposure.
Conditions of use

General conditions for use

• We recommend that you do not use ADONIS® in combination with implants from another source or another manufacturer. HumanTech Germany GmbH shall not be liable if this recommendation is not followed.

• Never reuse the implants. Even if the implant appears to be intact following 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 from the ADONIS® range have a limited useful life. The activities and physical activity of the patient have a significant influence on this useful life. Patients must be informed that every activity increases the risk of loss, bending or breakage of the implant components. Informing patients about limitations to their activities in the postoperative phase and postoperatively monitoring patients are crucial factors in assessing the development of the fusion and the condition of the implant. Even when permanent bone fusion has occurred implant components can still bend, break or loosen. Patients must therefore be informed that implant components may also bend, break or loosen even if they comply with the restriction in their activities.

• If an implant does break, the doctor must decide whether a revision of the implant should be performed, taking into account the well-being of the patient and the risks involved.

• The instructions in the Surgical Technique operation manual must be followed at all times.

• 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.

• Do not use bone cement, 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.

• Handle removed implants in such a way that their reuse is not possible.
• The PEEK and R-PEEK-Ti implants are supplied STERILE. They may be used only if the labels on the outer packaging and 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.

• The implants may not be resterilised.

• Handle and store the implant components carefully. Damage to the implant can significantly reduce the strength and long-term stability of the implant system. Cracking and/or higher internal stresses can result, possibly resulting in the breakage of the implant.

• The implants and instruments should be stored at room temperature. Environmental factors, such as salt-laden air, humidity, chemicals etc., must not be allowed to act on the implants.

• Thorough inspection is recommended before operating in order to ensure that the instruments or implants have not been damaged during storage or previous procedures.