



ADONIS[®]

TRANSFORAMINAL LUMBAR INTERBODY FUSION





The TLIF technique works with a unilateral access to the intervertebral disc space through the foramen intervertebralis. Thus, the TLIF procedure provides for a unilateral posterior approach to a „360 °“ fusion, which offers the following advantages against the PLIF technique:

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

ADONIS®-PLIF is an intelligent - and by virtue of the associated set of instruments - highly rational interbody device system and is a widely accepted product line offering the following decisive advantages:

Anatomy

- Geometry comparable with the patient's own sectional and sagittal anatomy
- Generous contact surface - reduced risk of migration

Stability

- Antegrade toothing for stable anchorage (not in all versions)
- Cranial convex contact surfaces for secure, permanent and high precision seating
- Significantly increased extraction forces
- Extremely high friction coefficient

Integrity

- Large filling aperture for rapid fusion (not in all versions)
- Internal annular groove holds the filling material in the cage and increases the filling volume

Modularity

Due to free choice among 3 materials:

• Titanium

The metal titanium has proved itself to be especially bio-tolerable and correspondingly modifiable. It has been proven that the various reactions of human cells are only caused by the oxidised surface layer of titanium materials, which is only a few nanometres thick.

• PEEK

Our PEEK material has been tested as per ISO 10993, classified according to US P-VI, and FDA Device and Drug Master Files are available.

• PEEK titanium-coated

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

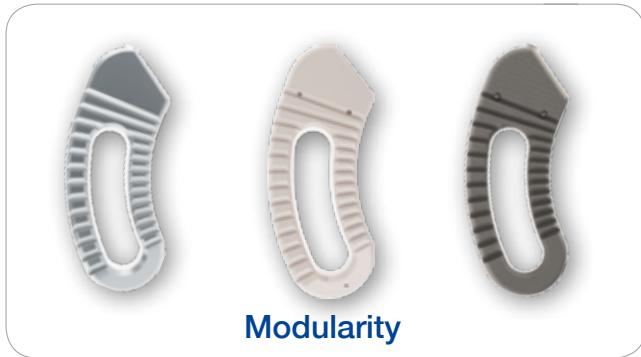




ADONIS® -TLIF

Interbody Device System

Product-Specific Advantages



Modularity



Integrity



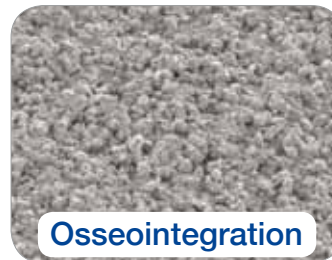
Stability



Anatomie

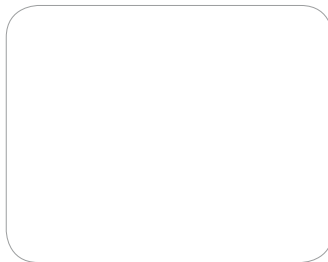
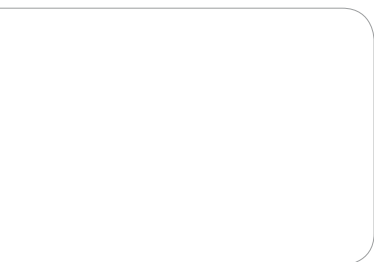


Osseointegration

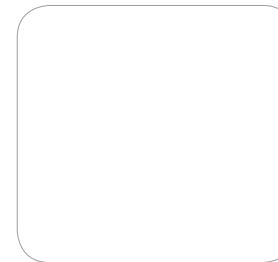


Osseointegration

1. Modularity
2. Integrity
3. Stability
4. Anatomy
5. Osseointegration



Osseointegration





ADONIS®-TLIF Classic

ADONIS® Classic is a solid titanium interbody device system and is a generally accepted product line for thoracolumbar indications.

In combination with a tried & tested, intuitive set of instruments, ADONIS® Classic is the ideal solution for thoracolumbar interbody fusions.

The latest scientific findings are factored into the production of titanium implant materials with tailor-made surface properties. We exclusively use titanium Ti 6Al-4V ELI (as per DIN ISO 5832-3).



ADONIS®-TLIF

ADONIS®-TLIF Avantgarde

ADONIS® Avantgarde is an implant made of biotolerable PEEK-Optima® for thoracolumbar interbody fusion and finds application in degenerative intervertebral disc disease and instability.

This material, which is radiotranslucent, enables rapid and straightforward assessment of the bone structure and fusion process. Positional verification is aided by X-ray markers. The mechanical rigidity of 3.6 GPa enables optimum force transmission between the implant material and the natural bone, thus stimulating the bone regeneration process.

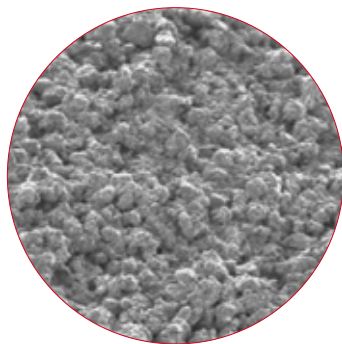
Our PEEK material has been tested according to ISO 10993 and classified as per USP-VI, the corresponding FDA Device and Drug Master Files are available. PEEK is predestined for use as an implant material because of its properties and usage authorisations.





ADONIS® Exclusive

ADONIS® Exclusive is rewriting standards 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.

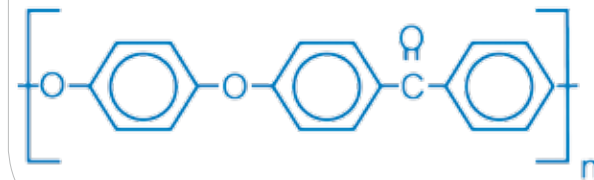


The titanium coating that, due to its balanced relationship between pore depth, porosity and roughness, affords an optimum substrate has proven to be ideal for docking bone cells in the implant. The osteoinductive properties of titanium encourage bone to take root directly on the implant.

Characteristics PEEK und PEEK Ti-coated

- PEEK is radiotranslucent and does not create any artefacts
- Positioning verifiable by means of X-ray markers
- Anatomical form and toothed or Ti-coated surface
- The semi-circular form maximises the contact zone
- It can optionally be filled with bone or bone replacement material for improved bone grafting in pure Peek cages
- Firm connection to the application instrument

PEEK-OPTIMA® is a polyaromatic, semicrystalline thermoplastic, based on the $(-C_6H_4-O-C_6H_4-O-C_6H_4-CO-)_n$ formula and generally known as a polyether ether ketone.





Classic Titanium

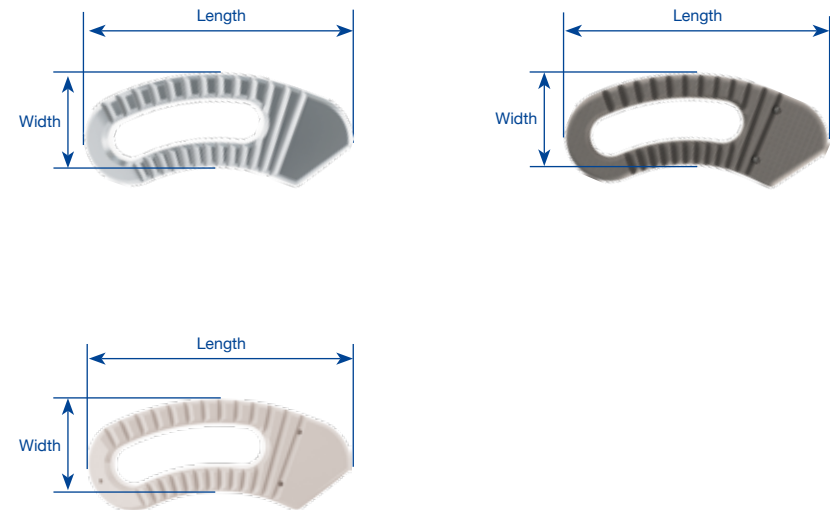
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|------------|----------------------------|--------|-------|--------|-------|
| 1801051207 | Adonis TLIF Ti 35x12x07 | 35 | 12 | 07 | |
| 1801051209 | Adonis TLIF Ti 35x12x09 | 35 | 12 | 09 | |
| 1801051211 | Adonis TLIF Ti 35x12x11 | 35 | 12 | 11 | |
| 1801051213 | Adonis TLIF Ti 35x12x13 | 35 | 12 | 13 | |
| 1801051215 | Adonis TLIF Ti 35x12x15 | 35 | 12 | 15 | |
| 1801091207 | Adonis TLIF Ti 35x12x07 5° | 35 | 12 | 07 | 5° |
| 1801091209 | Adonis TLIF Ti 35x12x09 5° | 35 | 12 | 09 | 5° |
| 1801091211 | Adonis TLIF Ti 35x12x11 5° | 35 | 12 | 11 | 5° |
| 1801091213 | Adonis TLIF Ti 35x12x13 5° | 35 | 12 | 13 | 5° |
| 1801091215 | Adonis TLIF Ti 35x12x15 5° | 35 | 12 | 15 | 5° |

Exclusive R-PEEK-Ti-coated

| Art.No | Description | Length | Width | Heigth | Angle |
|------------|--------------------------------|--------|-------|--------|-------|
| 1803061207 | Adonis-TLIF R-PEEK-Ti 35x12x07 | 35 | 12 | 07 | |
| 1803061209 | Adonis-TLIF R-PEEK-Ti 35x12x09 | 35 | 12 | 09 | |
| 1803061211 | Adonis-TLIF R-PEEK-Ti 35x12x11 | 35 | 12 | 11 | |
| 1803061213 | Adonis-TLIF R-PEEK-Ti 35x12x13 | 35 | 12 | 13 | |
| 1803061215 | Adonis-TLIF R-PEEK-Ti 35x12x15 | 35 | 12 | 15 | |

Avantgarde PEEK

| Art.No | Description | Length | Width | Heigth | Angle |
|------------|------------------------------|--------|-------|--------|-------|
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| 1801041209 | Adonis TLIF PEEK 35x12x09 | 35 | 12 | 09 | |
| 1801041211 | Adonis TLIF PEEK 35x12x11 | 35 | 12 | 11 | |
| 1801041213 | Adonis TLIF PEEK 35x12x13 | 35 | 12 | 13 | |
| 1801041215 | Adonis TLIF PEEK 35x12x15 | 35 | 12 | 15 | |
| 1801041307 | Adonis TLIF PEEK 35x12x07 5° | 35 | 12 | 07 | 5° |
| 1801041309 | Adonis TLIF PEEK 35x12x09 5° | 35 | 12 | 09 | 5° |
| 1801041311 | Adonis TLIF PEEK 35x12x11 5° | 35 | 12 | 11 | 5° |
| 1801041313 | Adonis TLIF PEEK 35x12x13 5° | 35 | 12 | 13 | 5° |
| 1801041315 | Adonis TLIF PEEK 35x12x15 5° | 35 | 12 | 15 | 5° |





| Art.No | Description | Image |
|--|---|-------|
| 1801011207 1801011209 1801011211 1801011213 1801011215 1801011307 1801011309 1801011311 1801011313 1801011315 | TLIF Trial 35x12x07mm TLIF Trial 35x12x09mm TLIF Trial 35x12x11mm TLIF Trial 35x12x13mm TLIF Trial 35x12x15mm TLIF Trial 35x12x07mm 5° TLIF Trial 35x12x09mm 5° TLIF Trial 35x12x11mm 5° TLIF Trial 35x12x13mm 5° TLIF Trial 35x12x15mm 5° | |
| 1801010403 | TLIF Trial-Inserter | |
| 1701010600 | Extractor Handle | |
| 1801010401 | TLIF Inserter | |
| 1006082000 | TLIF Repositioner | |



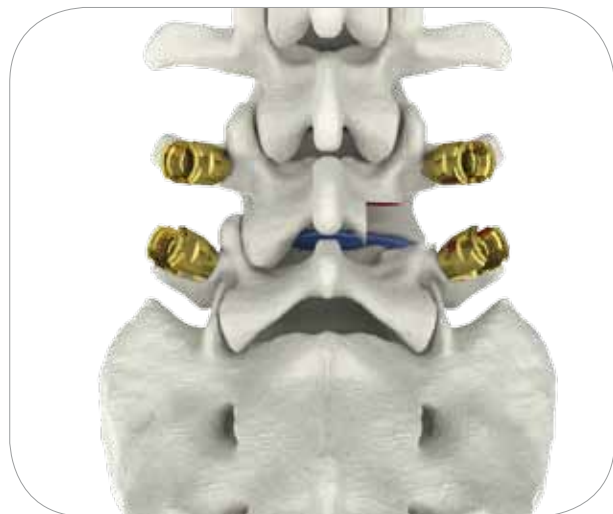


Fig. 1

Insertion of the pedicle screws

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 can be obtained in the respective operation manuals of the applied dorsal system.

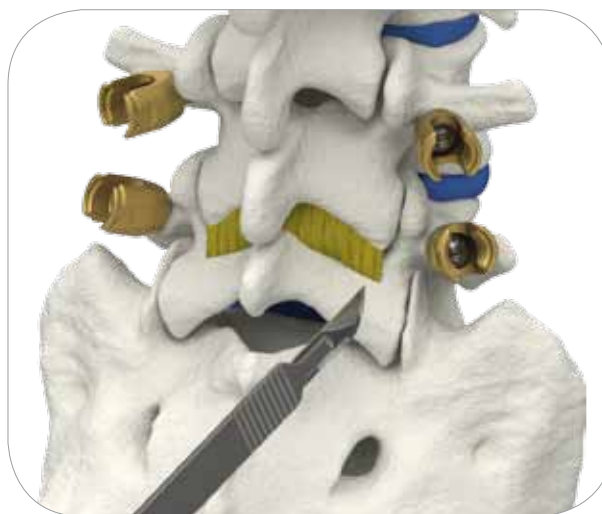


Fig. 2

Removal of the ligamenta flava

Incise the skin at the centre line, after lateral preparation and location of the spinous process and the plate of the respective segment or segments.

Das Ligamentum flavum wird mit einer Kürette von der Vorderseite der Lamina entfernt (Fig. 2).



Fig. 3

Preparation of the aperture for the transforaminal approach

The lower articular process (Fig. 3) is resected with a straight osteotome or a Kerrison punch. The capsular section of the ligamenta flava is now revealed and can be detached. The upper articular process is now resected with a straight osteotome or a Kerrison punch to expose the intervertebral foramen.

The pedicle is exposed by the removal of the pendent articular process with a Kerrison punch to obtain final access to the intervertebral disc.

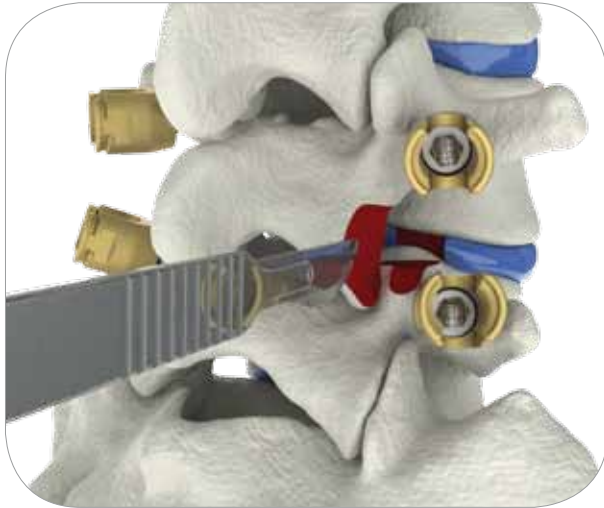


Fig. 4

Final approach to the intervertebral disc

The upper articular process is resected to reveal the intervertebral foramen (Fig. 4).

The pedicle is prepared by removal of the pendent upper articular process with a Kerrison punch so that final access to the intervertebral disc is obtained. Bleeding at the access point to the intervertebral space must be carefully staunched. Above all, care should be taken with the outgoing nerve root and the lateral section of the dural sac. These structures can be protected in every stage of the operation with a dissector or nerve root retractor.

The annulus is sectioned in rectangular fashion to create an aperture to the intervertebral space.



Fig. 5

Initial distraction

An initial distraction of the intervertebral space is required to obtain access to the intervertebral disc for a radical discectomy. A distraction can be achieved by one of the following methods:

- Distraction via the pedicle screws
- Distraction via the spinous processes
- Distraction via retractors

The initial retractor is inserted horizontally with respect to the collapsed intervertebral disc space and then turned through 90 degrees to obtain a distraction.

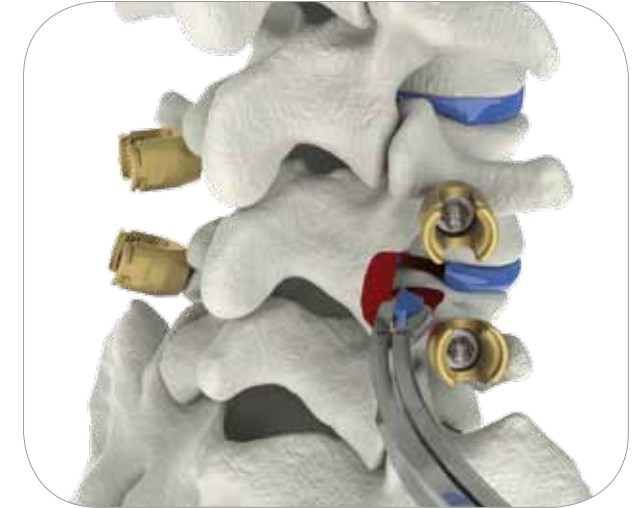


Fig. 6

Removal of the intervertebral disc

A radical discectomy is performed with a combination of curettes, chisels and Luer cannulas. It is important to ensure that the end plates are not damaged during this process. A chisel or rasp can be used for preparing the end plates. A straight or angled Luer or punch is then used to completely remove the loose disc material. Possibly a straight osteotome can be used to resection the posterior lips of the top and bottom end plates to facilitate introduction of the cage. It is important during the preparation to create a straight, parallel surface for the introduction of the interbody implant.

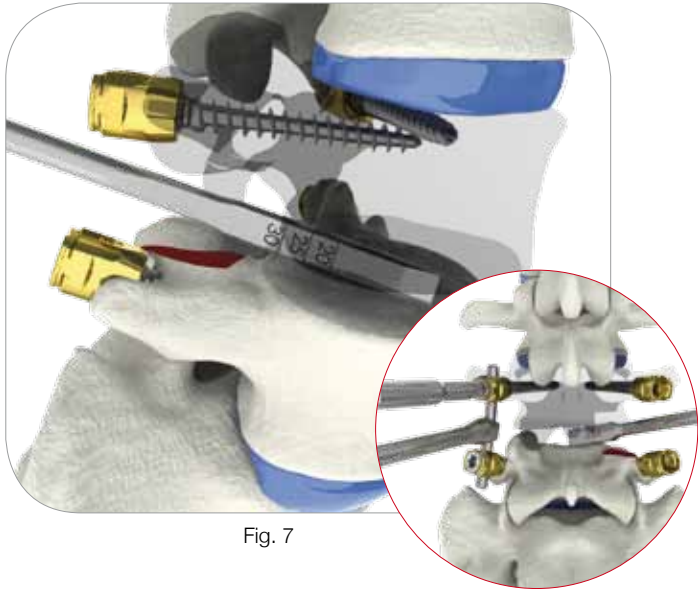


Fig. 7

Secondary distraction of the intervertebral disc space

Additional distraction of the intervertebral disc space before introduction of the cage can be achieved by using the entire range of retractors. They are used one after another in ascending order of size until optimum tension of the annulus is achieved.

To maintain the distraction, the dorsal instruments are locked on the contralateral side (Fig. 7).

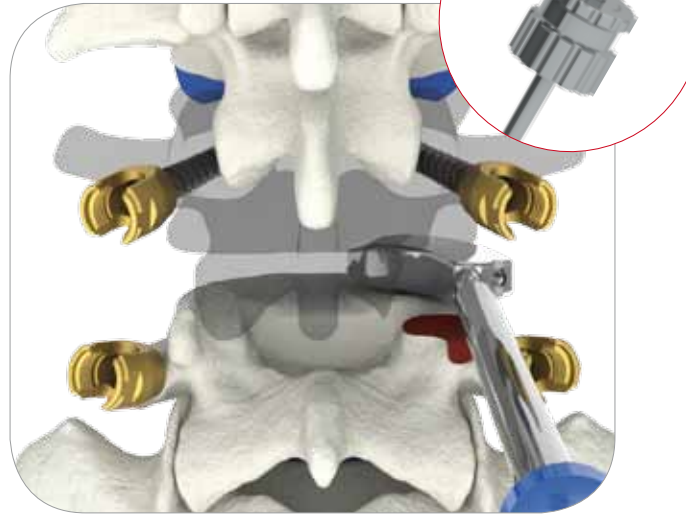


Fig. 8

Introduction of the bone graft

For a solid inter-body fusion, the intervertebral disc space should be filled with as much bone graft material as possible. The front third of the intervertebral disc space is filled with bone graft.

Note:

The cage does not have to be filled with bone graft when the ADONIS Exclusive is used.

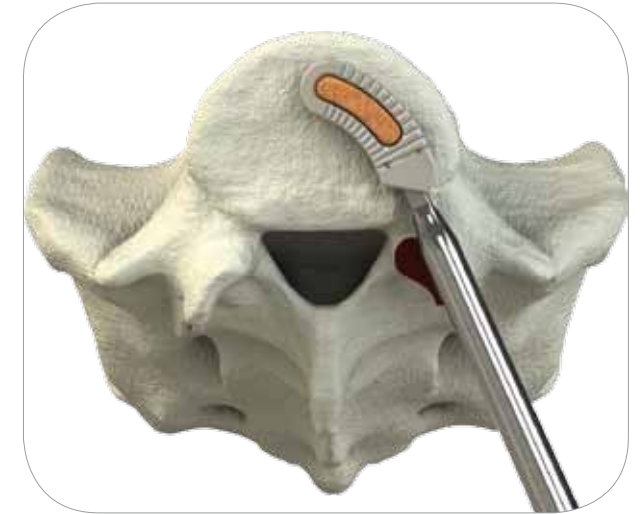


Fig. 9

Trial cage

Before the permanent implant is introduced, the correct positioning and the presence of the required intervertebral disc height are tested with a trial implant.



Fig. 10



Fig. 11

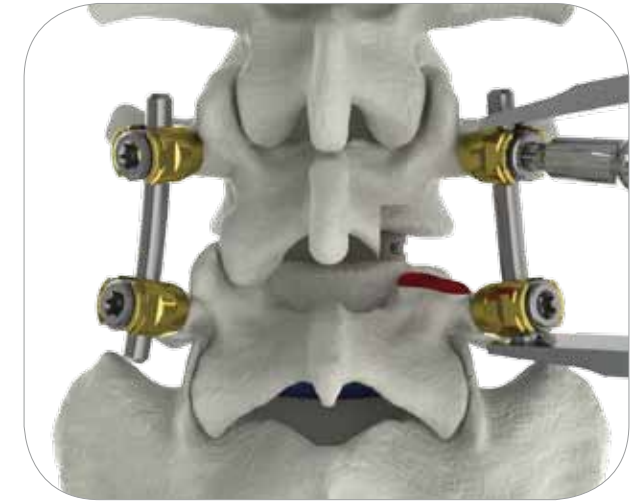


Fig. 12

Introduction of the cages

The implant is mounted on the insertion instrument. The insertion instrument may not be screwed too tightly to the cage. After the implant has been screwed on to the insertion instrument, the cage is filled with bone graft by means of a filler block.

Before the second cage is placed, the anterior and medial sides of the intervertebral space are filled with autogenous cancellous bone or with a bone substitute material.

Note:

When using ADONIS® Exclusive, the cage does not have to be filled with bone graft.

Adjustment of cage position

When the implant has been introduced, the cage can be detached from the insertion instrument and, if necessary, its positioning can be improved with the same instrument.

The final location of the cage is checked by an X-ray image. The presence of X-ray markers enables the cage position to be precisely determined in the sagittal, coronal and axial planes.

Final compression

Final compression must be performed by means of the dorsal instruments.



Marker



Position of the markers

To ensure the correct position of the cage, the cage must be placed in a central position after insertion into the intervertebral disc space. The five tantalum markers in the illustrated TLIF PEEK-Cage and TLIF R-PEEK Ti-coated used for fluoroscopic view of the implant position. This makes it possible to assess the exact position of the cage by radiographs.

In the TLIF four markers are located medially at the posterior implant margin and one marker on the anterior implant margin. By the anterior marker, the maximum width of the cage is shown. In combination with the four markers posterior the implant depth can be estimated. In the TLIF PEEK and TLIF R-PEEK Ti-coated implants, the four posterior and the anterior marker appear at a centrally positioned in the disc space implants, as visible on the radiograph.



AP-View
of a central positioned TLIF-Cage



Sagittal View
of a central positioned TLIF-Cage



AP-View XRay
of a central positioned TLIF-Cage



Sagittal View XRay
of a central positioned TLIF-Cage



The implant surface has a big importance for anchoring the implant and for the 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 optimized, and thus an earlier functional loading of implants can be achieved.

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 implant surface.

The composition, roughness and topography of the implant surface at the interface are playing an important role for the primary stability and a safe osseointegration.

Rough implant surfaces will influence and stimulate the cellular activity of surrounding bony structures. The cell proliferation and cell differentiation, matrix synthesis and production of the „Tissue Growth Factors,“ are promoted and will lead to a dense bone-implant connection.

Specific surface roughness of the implant will promote the regeneration potential at the interface and thus the clinical implant fixation.

Compared to machined implant surfaces the moderately rough surface (Fig. 14 - „HENIAPORE-K“) of ADONIS® Exclusive shows denser bone apposition with

significantly increased withdrawal force (load removal) and an extremely high coefficient of friction for primary stabilization.

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

| Attribute | Value |
|---------------------|-----------|
| Roughness | Rz > 70 |
| Coat thickness | 50 -150µm |
| Coat porosity | > 20% |
| Adhesion | > 22 MPa |
| Shearing resistance | > 20 MPa |



Fig. 13

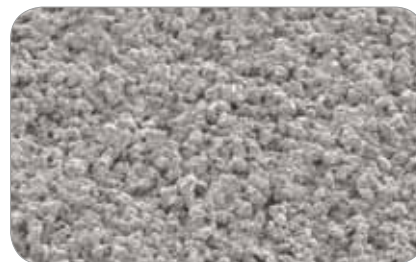


Fig. 14



Fig. 15

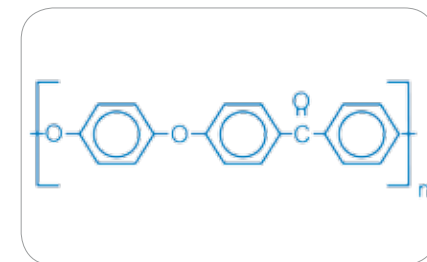
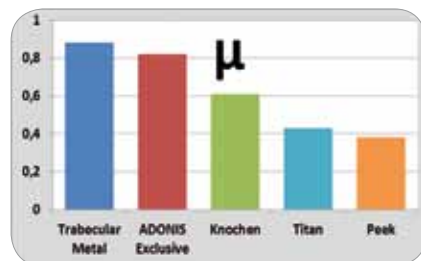


Fig. 16



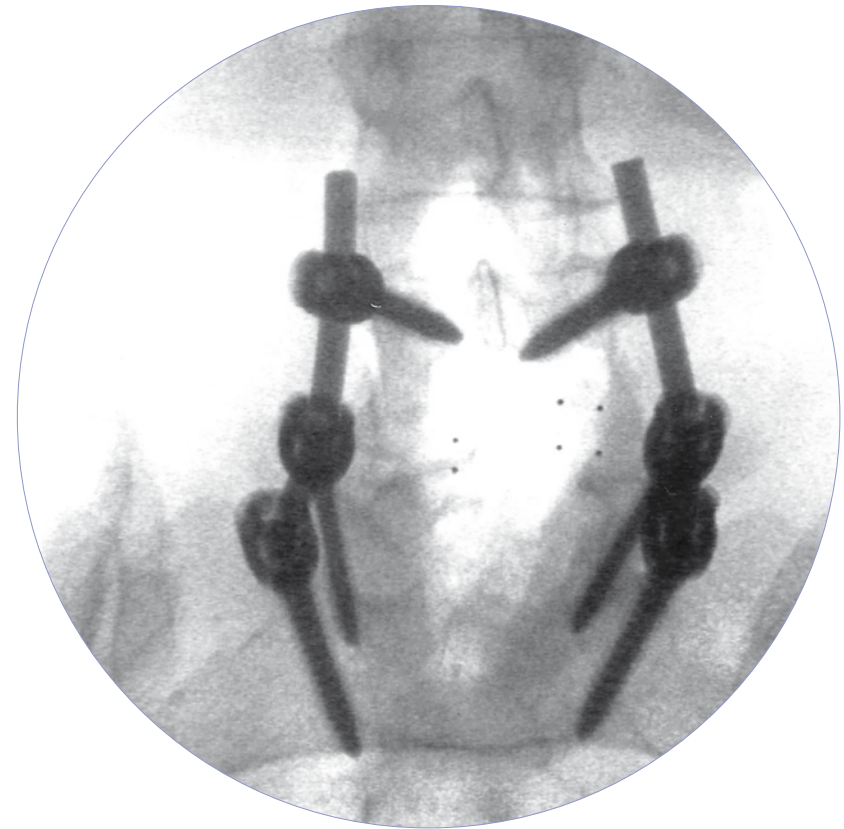
GENERAL CONDITIONS FOR USE

- We recommend that you do not use ADONIS[®] in combination with implants from another source or another manufacturer. HumanTech Germany GmbH is not 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. The patient must be informed that every activity increases the risk of loss, bending or breakage of the implant components. Informing the patient about limitations to his or her activities in the postoperative phase and postoperatively monitoring the patient are decisive for 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. It is therefore necessary to make the patient aware that implant components can also bend, break or become loosened when the patient limits his or her activities.
- In the event of implant breakage, the doctor must decide in view of the patient's condition and the risks which could occur whether to perform a revision of the implant.
- Following the notes in the operating instructions (surgical technique) is essential.
- 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.





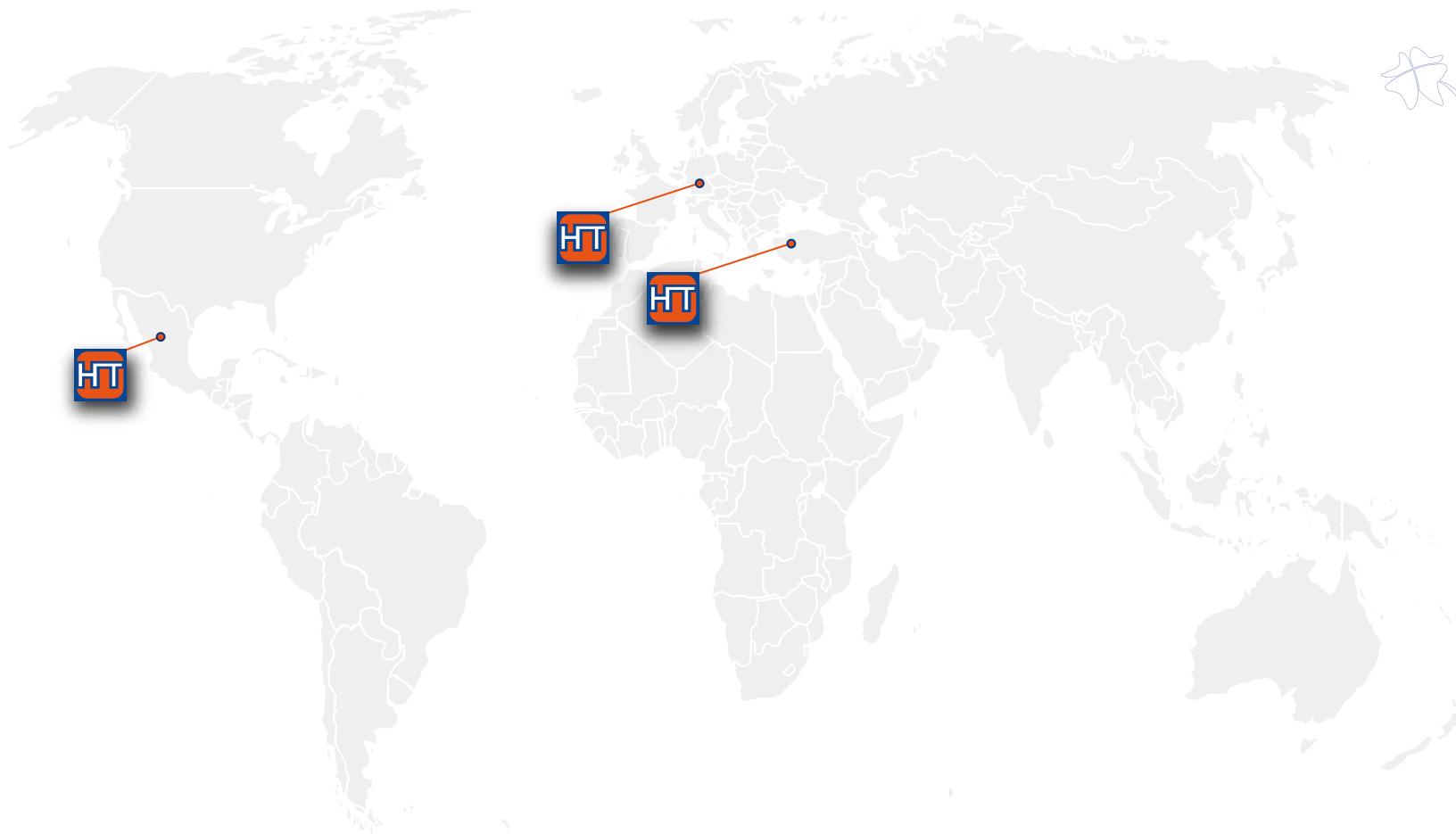
- The implants are supplied STERILE. They may be used only when the label on the outer packaging and also the inner packaging are intact. If the packaging is damaged or already open, the sterility of the implant is not guaranteed and the implant may not be used.
- The implants may not be used when the shelf life indicated has been exceeded.
- The implant may not be resterilized.
- Handle and store the implant components carefully. Damage to the implant can significantly reduce the stability and long-term stability of the implant system and can cause cracking and/or higher internal stresses, possibly resulting in the breakage of the implant.
- Storage of the implants and instruments should be at room temperature. Ambient influences, such as salty air, humidity, and chemicals, 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.



ADONIS® -TLIF

Interbody Device System





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