HumanTech
Smart German Solutions

ADONIS®

POSTERIOR LUMBAR INTERBODY FUSION

PLIF

ADONIS®-PLIF cages are indicated for posterior 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®-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.

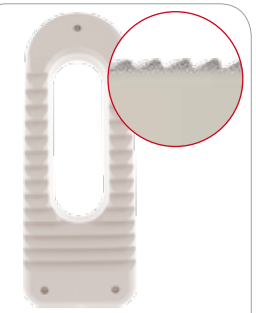
ADONIS® -PLIF

Interbody Device System

Product-Specific Advantages

Modularity

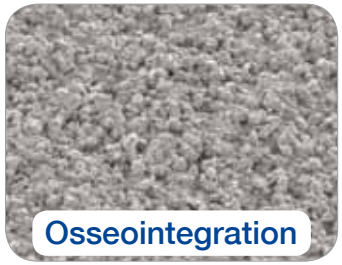
Integrity



Stability

Anatomie

Osseointegration



Osseointegration

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

Osseointegration

ADONIS®-PLIF 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®-PLIF 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.

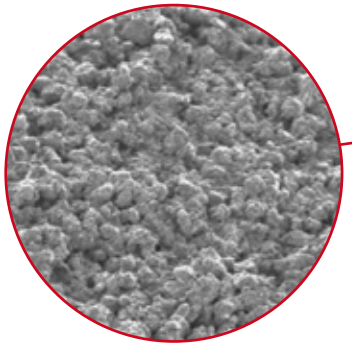
This material, which is radiotranslucent, enables rapid and straightforward assessment of the bone structure and fusion process. Positional verification is aided by X-ray markers. The mechanical rigidity of 3.6 GPa enables optimum force transmission between the implant material and the natural bone,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

PEEK Ti-coated

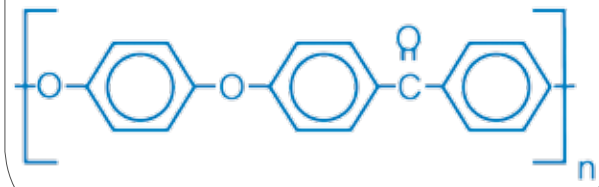


The titanium coating that, due to its balanced relationship between pore depth, porosity and roughness, affords an optimum substrate has proven to be ideal for docking bone cells in the implant. The osteoinductive properties of titanium encourage bone to take root directly on the implant.

Eigenschaften PEEK und PEEK Ti-coated

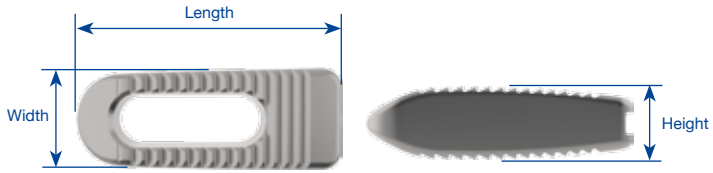
- PEEK is radiotranslucent and does not create any artefacts
- Positioning verifiable by means of X-ray markers
- Anatomical form and toothed or Ti-coated surface
- The semi-circular form maximises the contact zone
- It can optionally be filled with bone or bone replacement material for improved bone 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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1701050607	Adonis-PLIF Ti 30x09x07	30		
1701040309	Adonis-PLIF Ti 24x09x09	24	09	09
1701040409	Adonis-PLIF Ti 26x09x09	26		
1701040509	Adonis-PLIF Ti 28x09x09	28		
1701040609	Adonis-PLIF Ti 30x09x09	30		
1701040311	Adonis-PLIF Ti 24x09x11	24	09	11
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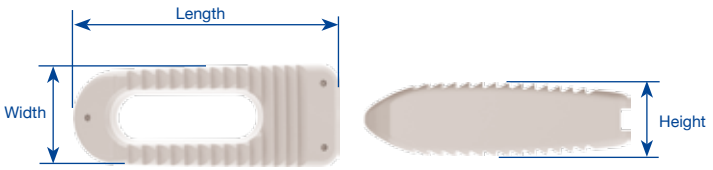
Avantgarde

PEEK



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1701040311	Adonis-PLIF PEEK 24x09x11	24	09	11
1701040411	Adonis-PLIF PEEK 26x09x11	26		
1701040511	Adonis-PLIF PEEK 28x09x11	28		
1701040611	Adonis-PLIF PEEK 30x09x11	30		
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1701040515	Adonis-PLIF PEEK 28x09x15	28		
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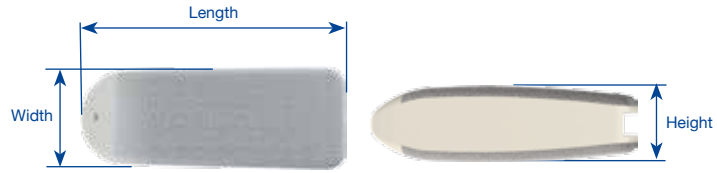
ADONIS® -PLIF

Interbody Device System

Exclusive

PEEK/Ti-coated



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Instrumente

ADONIS®-PLIF

Art.Nr.	Name	Image
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1701012807 1701012809 1701012811 1701012813 1701012815	PLIF Trial 28x09x07 PLIF Trial 28x09x09 PLIF Trial 28x09x11 PLIF Trial 28x09x13 PLIF Trial 28x09x15	
055079	Handle Straight	
1701010000	PLIF-Inserter	

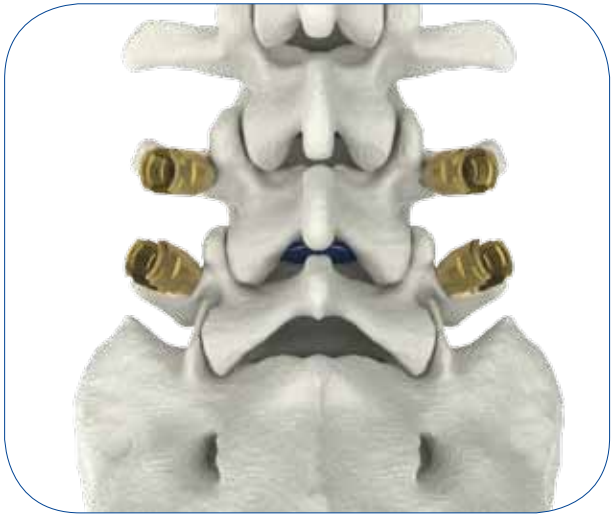


Fig. 1

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.

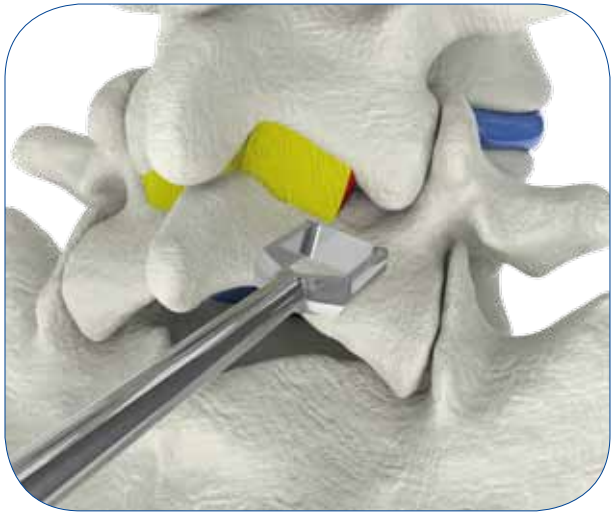


Fig. 2

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.

The ligamentum flavum is removed with a curette from the front of the lamina (Fig. 2).

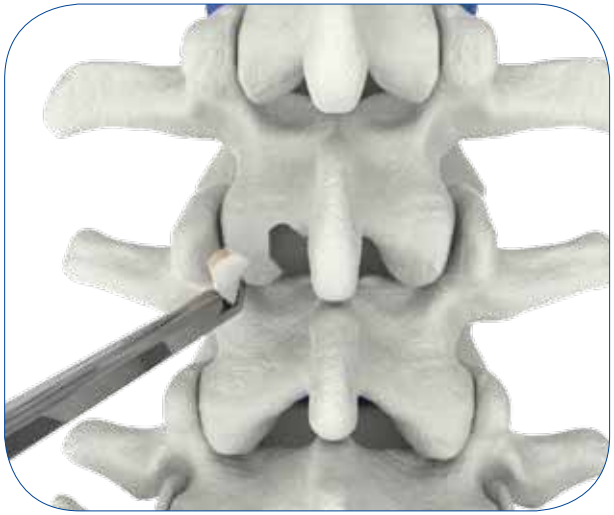


Fig. 3

Preparing the aperture for the posterior approach

Retain as much as possible of the facets, as these stabilise the intervertebral segment. Perform a laminotomy on the medial side of the facet with the osteotome or high speed drill.
Hold back the dura mater to open an aperture of approx. 13 mm in the intervertebral space.

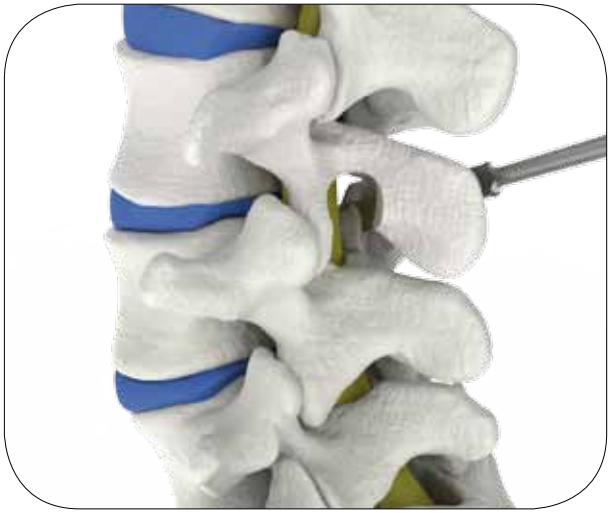


Fig. 4

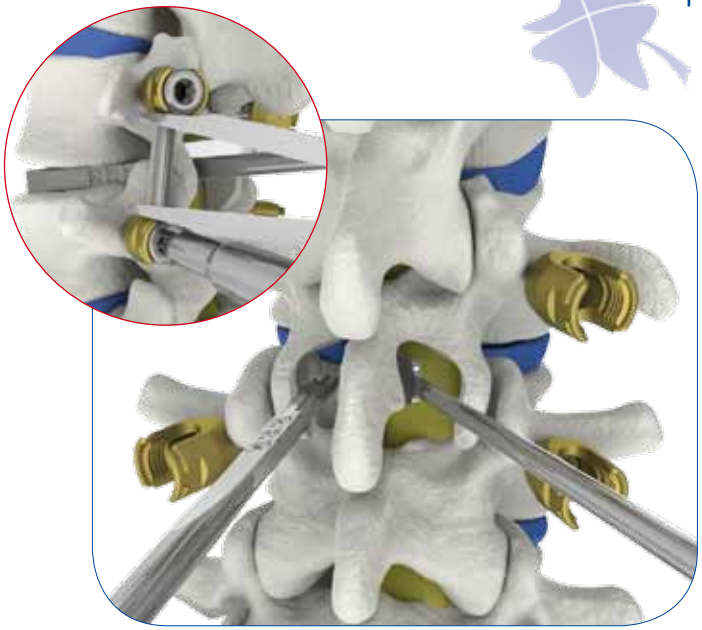


Fig. 5

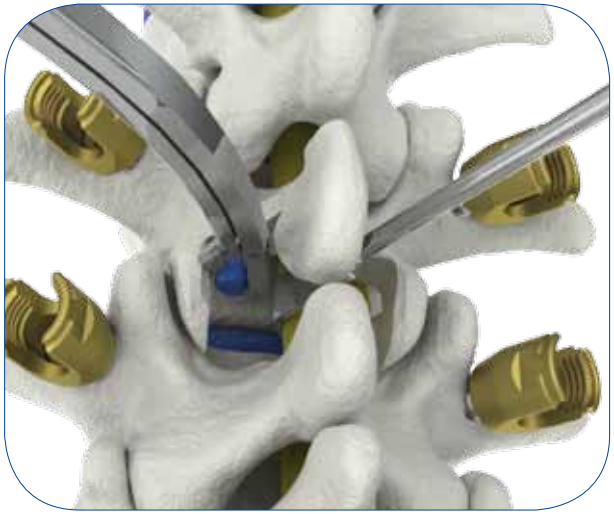


Fig. 6

Final approach to the intervertebral disc

The upper articular process is resectioned to expose 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. At the access point to the intervertebral space, bleeding 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.

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.

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).

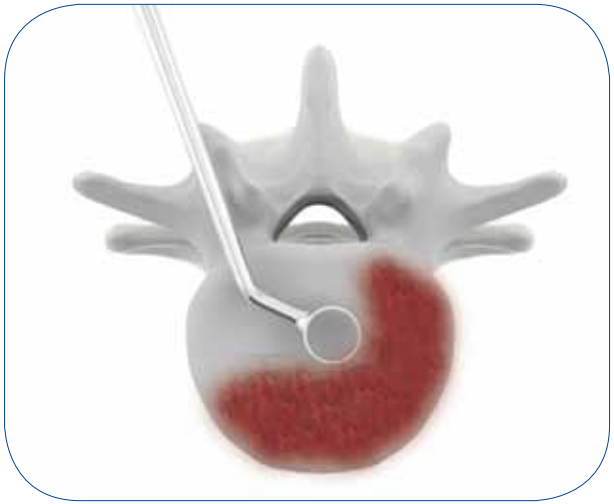


Fig. 8

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.

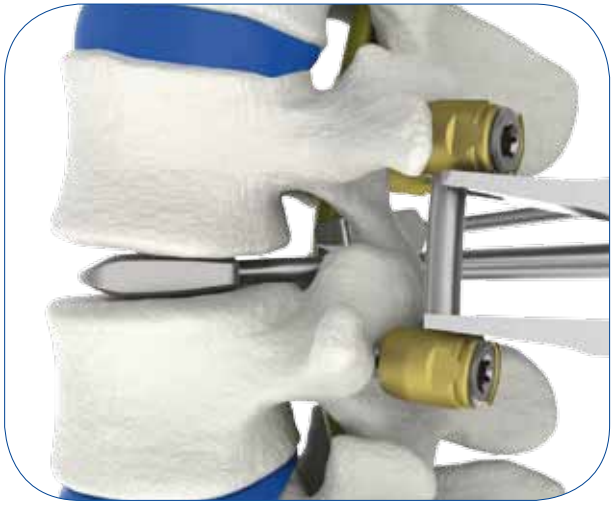


Fig. 9

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.

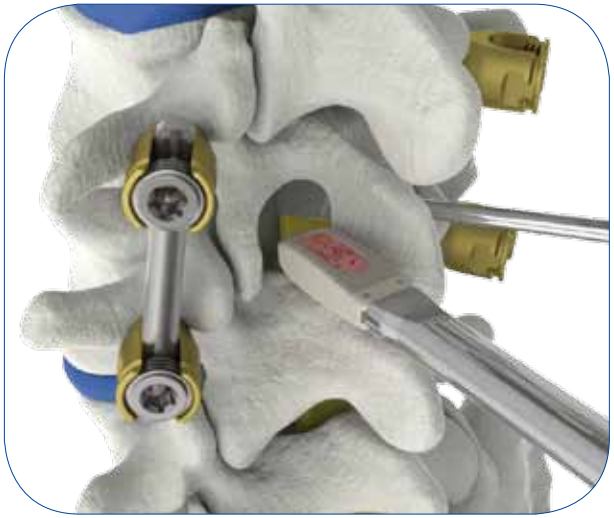


Fig. 10

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.

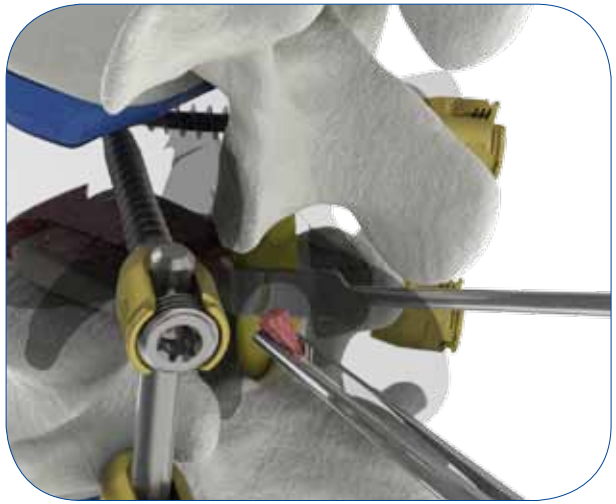


Fig. 11

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.

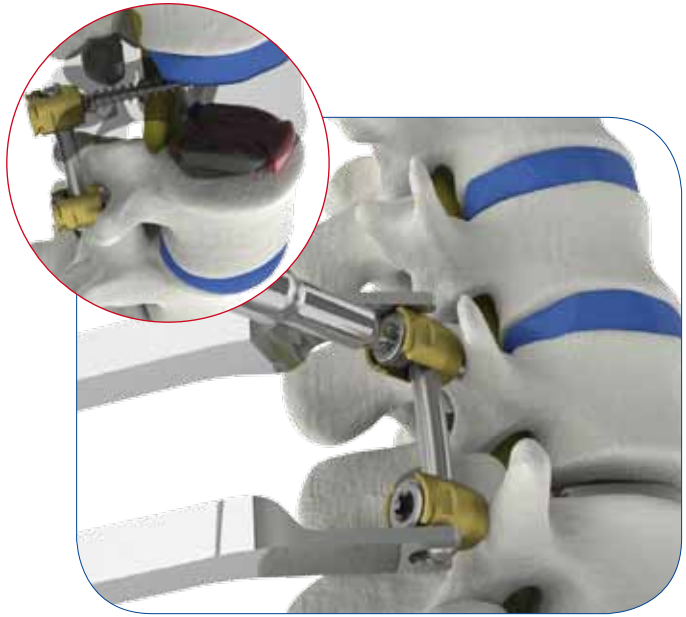


Fig. 12

Final compression

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

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.

Immediately after introducing the implant there are induced complex biological processes between the surrounding tissue and the implant surface. The bone- and wound healing can be divided in 3 phases.

During the first and most important healing phase, the first blood contact builds a fibrin network (Fig 13) on the implant surface. This is connected with the aggregation
of thrombocytes and blood coagulation.
The hereby emerging 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 building of new bone through edifying a bone specific extracellular matrix (collagen) on the implant surface.

On the next step there is built a mineralized boundary surface. This is equivalent to a thin collagene-free coat on one osteon outer side in the natural bone tissue.
In the third, slow healing phase, the bone is reconstructed until reaching his final load-bearing characteristics.

The time required for the three phases of healing time is called osseointegration time and describes the time in which the bone substance links to the implant surface in a sufficient and permanent efficiency.

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

Beside the surface-topography, the osseointegration of the implant can be improved through chemical coatings on the surface. The moderately rough suface (Fig. 14 - „HENIAPORE-K“) of ADONIS® Exclusive leads to a better bone adherence.

HENIAPORE-K has been developed in order to optimize the implant surface in a way, fast and postoperative adherence of young bones is encouraged (Fig. 15). A review of clinical- and animal studies of Shalabi et Alvi affirms this statement.

Actually the vacuum-plasma-injection-procedure used for ADONIS® Exclusive is the most successful method in creating biocompatible surfaces. Due to this very extensive manufacturing process an optimum wettable implant surface is conserved while preserving the same surface topography.

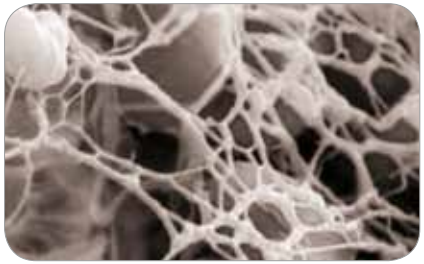


Fig. 13

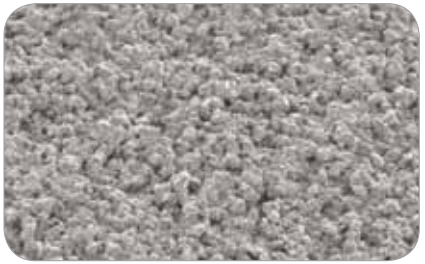


Fig. 14


Fig. 15

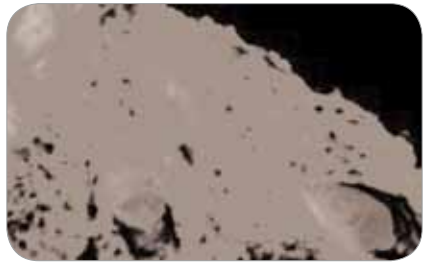


Fig. 16

The osseointegration can be accelerated through the improved wettablity and there is reached a higher implant stability at the early osseointegration phase, as is shown in clinical data and animal studies.

This method is globally proved for hip-, knee-, shoulder-, wrist- and tooth implants. The spinal application thus appears to be logical.

Nowadays commercially successful implant systems have an optimal and reproducible surface topography. Additional to those, ADONIS® Exclusive has an optimized and reproducible surface chemistry, which leads to an improved wettability and hereby a more homogenic blood contact with the implant surface.

The result of this is a faster implant osseointegration, facilitating an earlier load.

Summery

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.

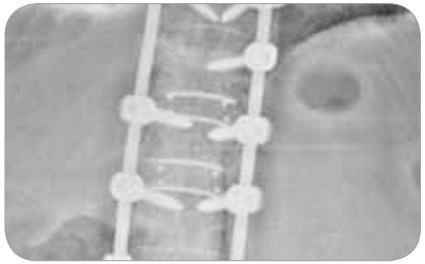
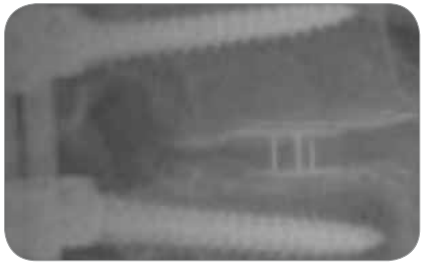
Rough implant surfaces will influence and stimulate the cellular activity of surrounding bony structures. The cell proliferation and cell differentiation, matrix synthesis and production of the „Tissue Growth Factors," are promoted and will lead to a dense bone-implant connection.

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


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.

- The activities and physical activity of the patient have a significant influence on the useful life of the implant. 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.

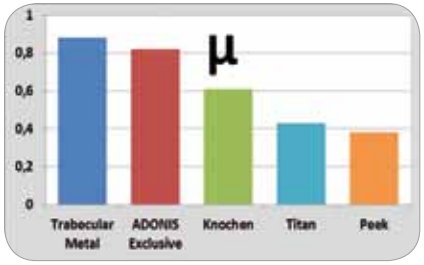
- Following the notes in the operating instructions (surgical technique) is essential.

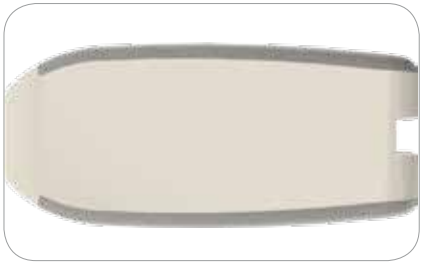
- Proceed with extreme caution in the region of the spinal cord and the roots of the nerves, since damage to the nerves can lead to the impairment of neurological functions.

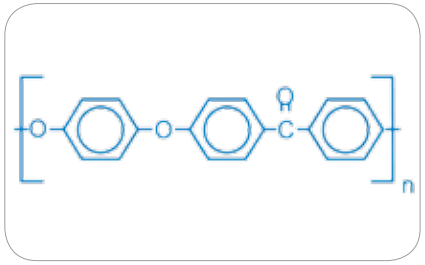
- Breakage, slippage or incorrect use of the instruments or implants can injure the patient or the operating staff.

- 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.

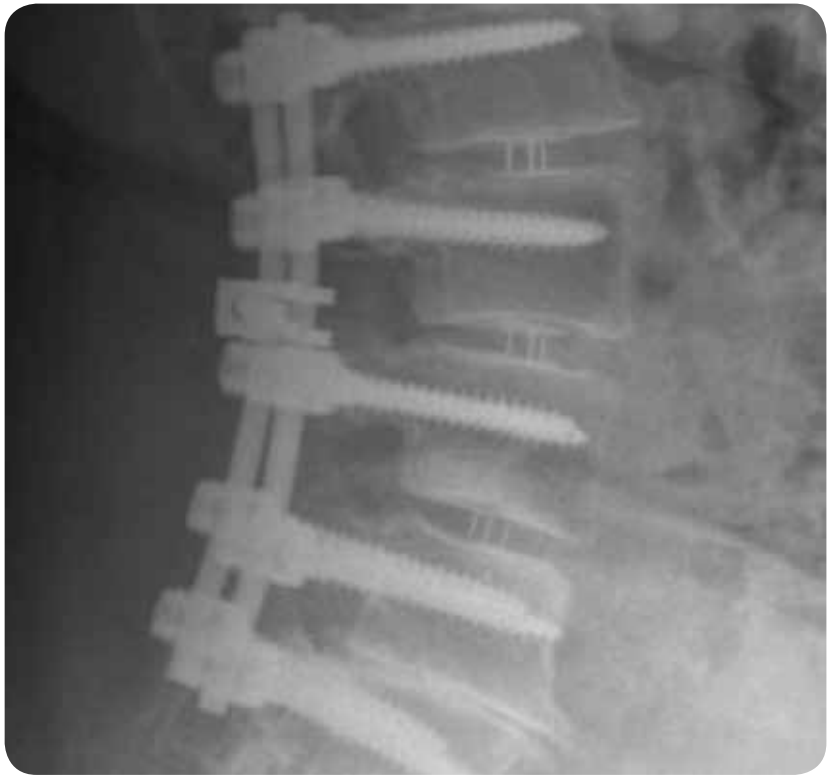
- Handle removed implants in such a way that their reuse is not possible.

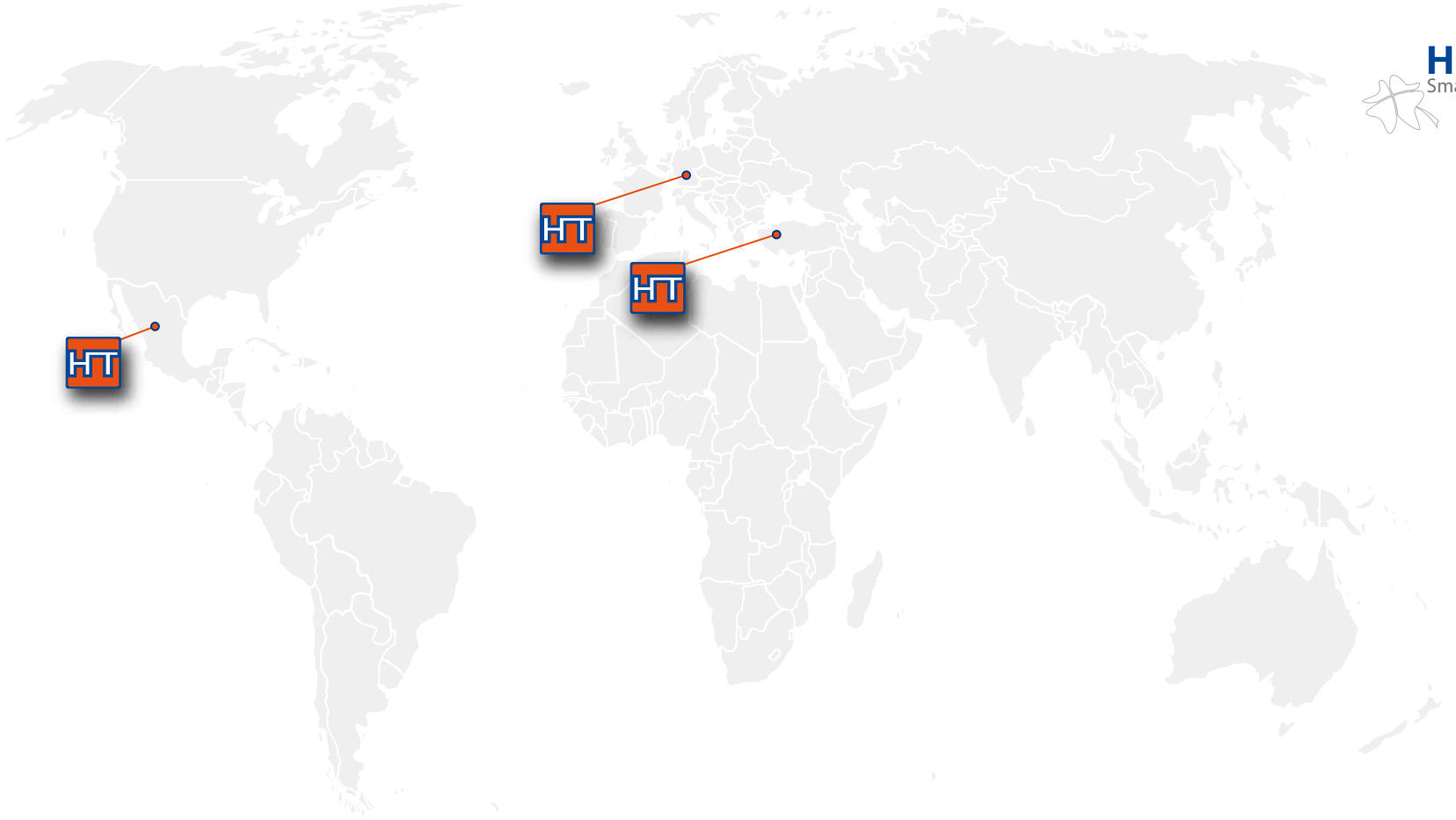






- The implants are supplied STERILE. They may be used only when the label on the outer packaging and also the inner packaging are intact. If the packaging is damaged or already open, the sterility of the implant is not guaranteed and the implant may not be used.
- The implants may not be used when the 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.





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