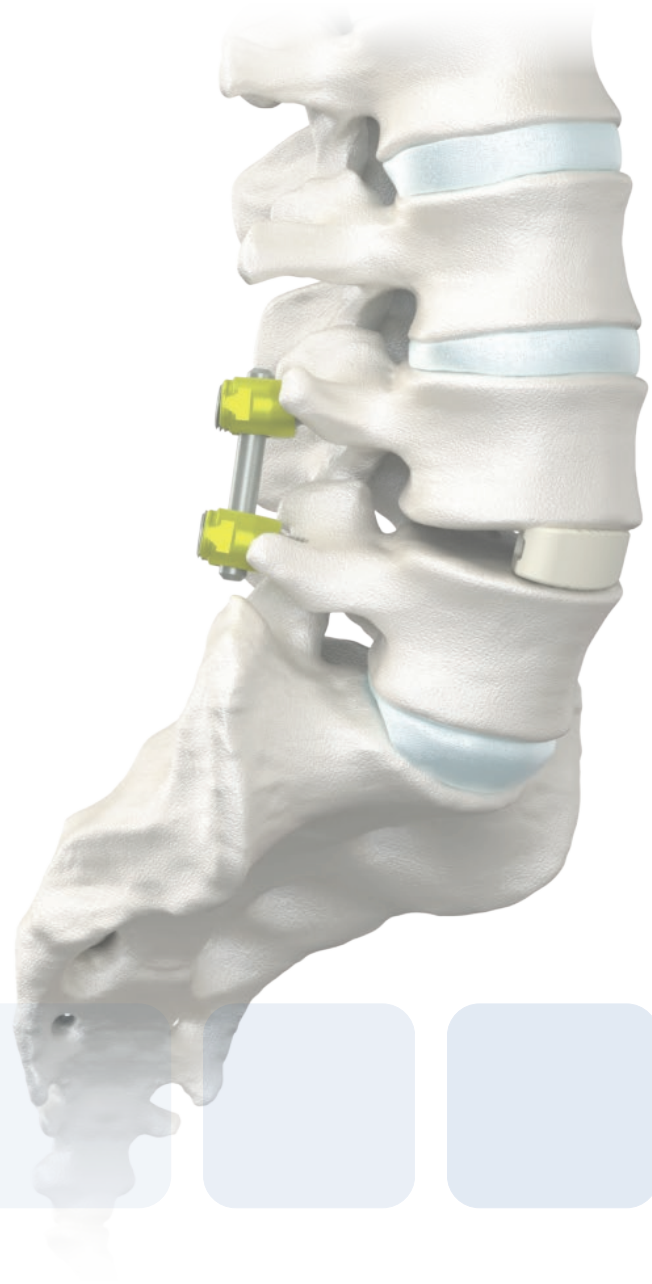


HumanTech Spine

ADONIS®

Transforaminal Lumbar Interbody Fusion

TLIF

The TLIF technique works with unilateral access to the intervertebral disc space. As a result, the TLIF procedure provides unilateral posterior access to a "360°" fusion, which offers, among other things, the following advantages over the PLIF technique:

- Preservation of the vertebral arch
- Preservation of the contralateral facet
- Minimal dural retraction
- Reduced risk of intradural scarring
- Revision strategy – only unilateral scarring

ADONIS®-TLIF 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

- The geometry is identical to the patient's own sectional and sagittal anatomy
- Generous contact surface – reduced risk of migration

Stable

- Antegrade toothing for stable anchoring
- Significantly increased extraction forces
- Extremely high friction coefficient

Fillable

- Large filling aperture for rapid fusion
- The conically shaped geometry of the cage which runs to the centre of the implant holds the filling material in the cage and increases the filling volume

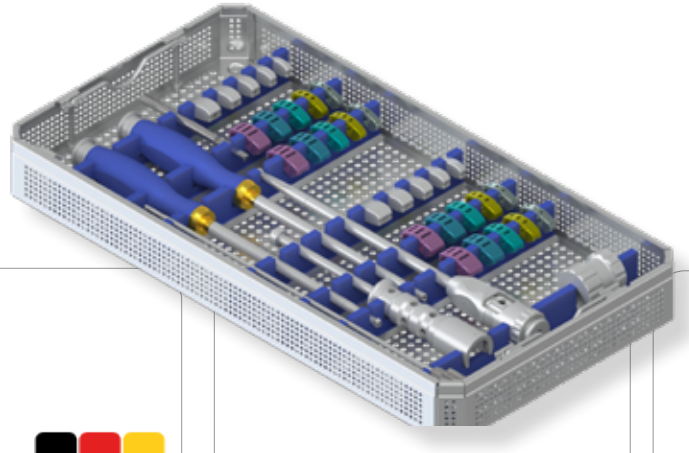
Modular

3 freely selectable material options:

• **Titanium alloy Ti6Al4V**
The titanium alloy Ti6Al4V has proven to be particularly biocompatible.

• **PEEK**
This material is biocompatible and is characterised by elasticity similar to that of bone. A further advantage is that the material does not cause X-ray artefacts.

• **PEEK titanium-coated**
The titanium coating affixed to the PEEK base body should enable the bone to attach directly to the implant.

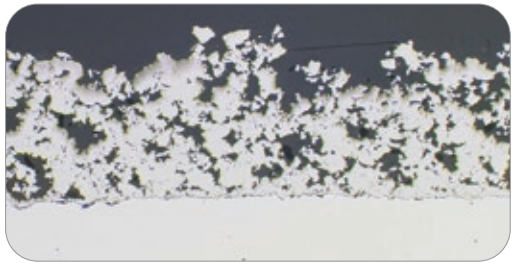


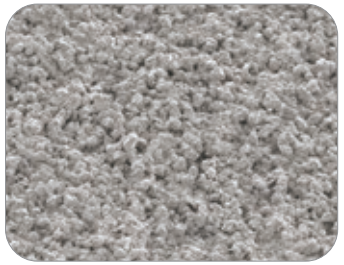
Made in Germany

ADONIS® -TLIF

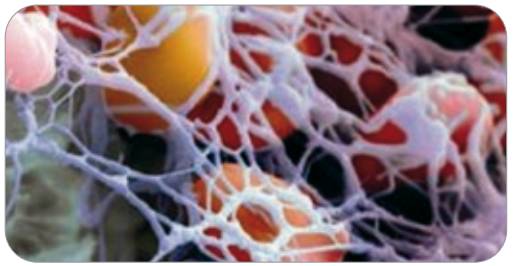
Interbody Device System

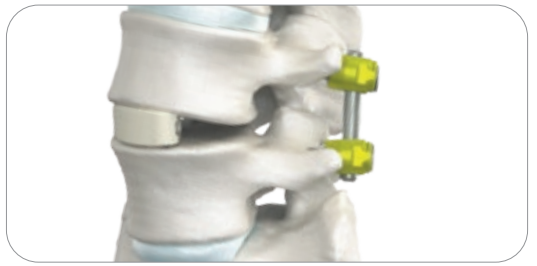
Product-specific benefits





- Anatomical
- Stable
- Fillable
- Modularity





ADONIS®-TLIF Titanium

ADONIS®-TLIF Titanium is a solid titanium interbody device system, making it a universally recognised product line for lumbar and lumbosacral indications. Combined with reliable and simple instrumentation, ADONIS®-TLIF Titanium becomes the solution for lumbar and lumbosacral interbody fusion. Only titanium alloy Ti6Al4V (DIN EN ISO 5832-3) is used. The titanium cages are available both as sterile-packed implants and in non-sterile form, stored directly in the implant tray.

TITANIUM

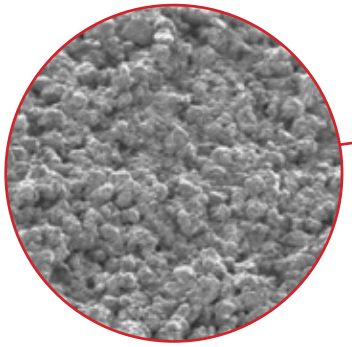
ADONIS®-TLIF PEEK

ADONIS®-TLIF PEEK is an implant made of biocompatible PEEK-Optima® for lumbar and lumbosacral interbody fusion and is used for degenerative disc disease and instability.
PEEK-OPTIMA® is a polyaromatic, semicrystalline thermoplastic, based on the formula (-C6H4-O-C6H4-O-C6H4-CO-)n, commonly known as polyetheretherketone. The radiotranslucent material allows quick and easy 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.

PEEK

ADONIS®-TLIF R-PEEK-Ti

The titanium coatings of the ADONIS®-TLIF R-PEEK-Ti- cages exploit the advantages of different 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 maximize the contact zone between the implant and the vertebral body surface. The titanium coating should allow the bone to attach directly to the implant.

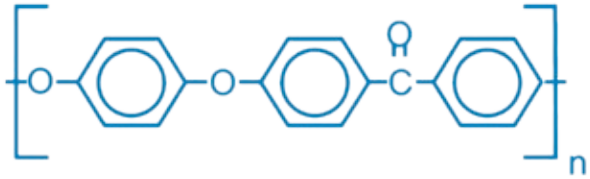


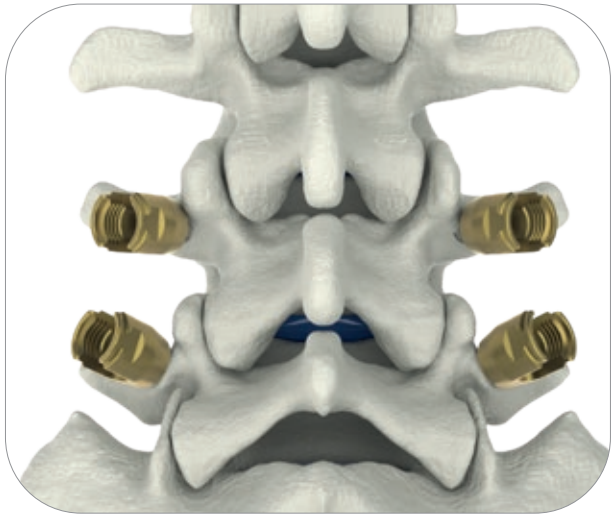
The titanium coating, which provides the optimal basis for its balance between pore depth, porosity and roughness, proves to be ideal for docking bone cells to the implant. The osteoinductive properties of titanium allow the bone to attach directly to the implant.

Properties of PEEK and R-PEEK-Ti

- PEEK is radiotranslucent and does not produce artefacts
- Position verification using X-ray markers
- Anatomical surface contour and toothed surface
- The semicircular surface contour ensures a maximum contact zone
- It can optionally be filled with bone or bone replacement material for improved bone grafting
- Fixed connection to the insertion instrument
- R-PEEK-Ti implants have the same positive properties as the PEEK implants in combination with an improvement in osseointegration due to the Ti-coated surface

PEEK-OPTIMA® is a polyaromatic semicrystalline thermoplastic based on the basic formula (-C6H4-O-C6H4-O-C6H4-CO-)n, commonly known as polyetheretherketone.

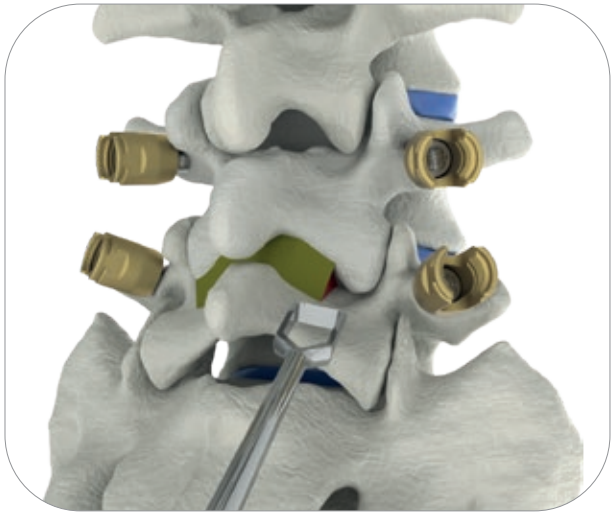




Inserting the pedicle screws

For stabilisation, an additional dorsal fixation (e.g. with the VENUS® screw rod system) is necessary. The additional stabilisation can be done either before or after the insertion of the cages, depending on the individual surgical methodology.

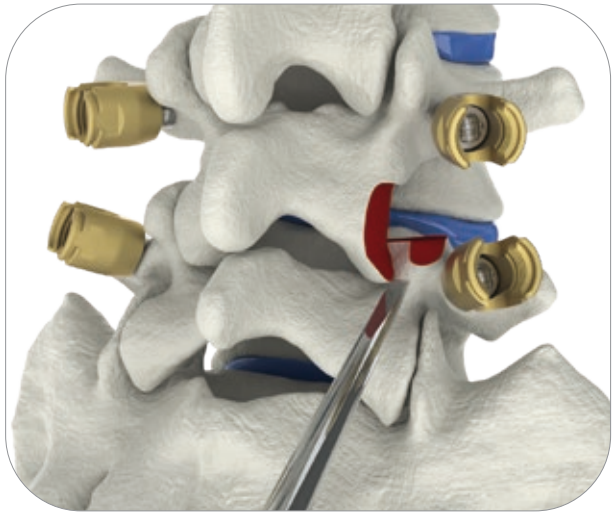
Details can be found in the respective surgical technique of the dorsal system used.



Removal of the ligamentum flavum

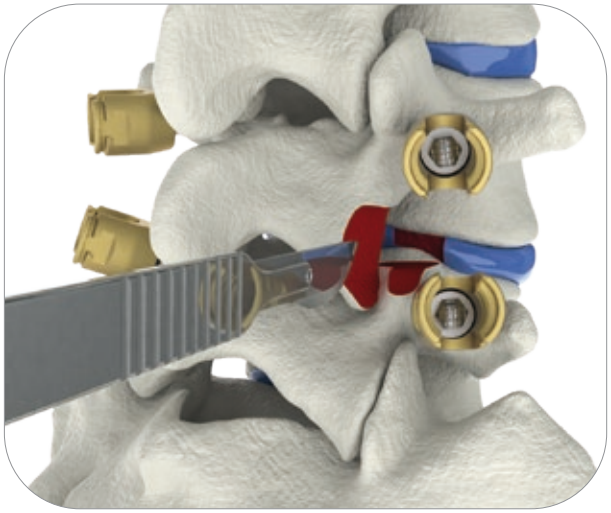
To gain transforaminal access to the disc space, a unilateral facetectomy is performed. Often, the site is targeted for access according to the location of the disease or the presence of scar tissue.

The ligamentum flavum is removed from the front of the lamina.



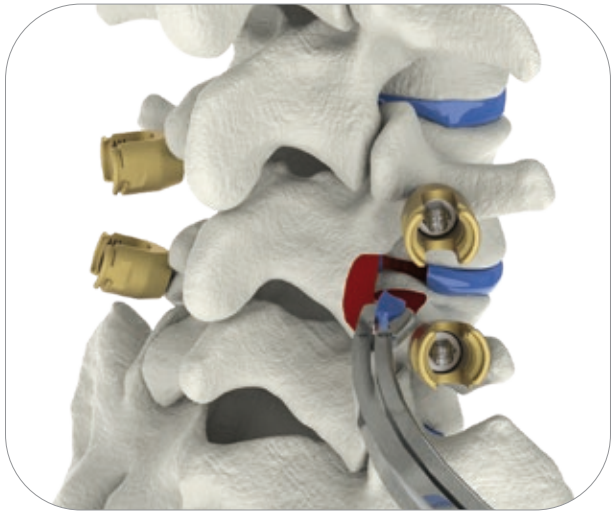
Preparation of the window for the transforaminal approach

The lower articular process is resected. The capsule part of the ligamentum flavum is now visible and can be separated. Now the upper articular process is resected to expose the foramen intervertebralis. The pedicle is visualised by removing the overhanging upper articular process to gain final access to the disc.



Final access to the disc

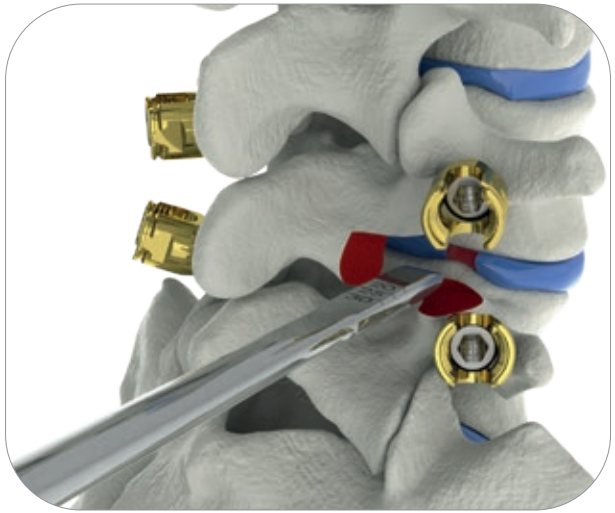
Complete meticulous haemostasis must be ensured at the entry point of the disc space. Above all, proceed with caution around the exiting nerve root and the lateral part of the dural sac. These structures can be protected at every stage of the operation with a dissector or nerve root retractor. A box-shaped cut in the annulus creates a window into the intervertebral disc space.



Preparation of the intervertebral disc space

Remove the disc material and the cartilaginous layer of the endplates to expose the bony endplate structure.
Improper preparation can result in weakening of the endplates and collapse of the cage.

Note:
Corresponding preparation instruments such as curettes in various embodiments and sharp spoons are included in the optionally available Disc Evacuation Set.

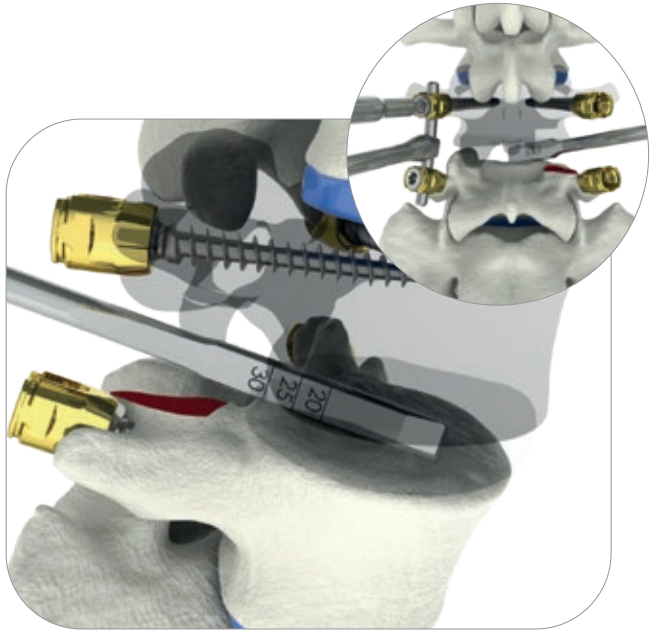


Distraction

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 pedicle screws
- Distraction via the spinous processes
- Distraction via spreader (Reamer Distractor, sharp or blunt)

The start spreader is inserted horizontally into the collapsed intervertebral disc space and then rotated 90 degrees to achieve distraction.

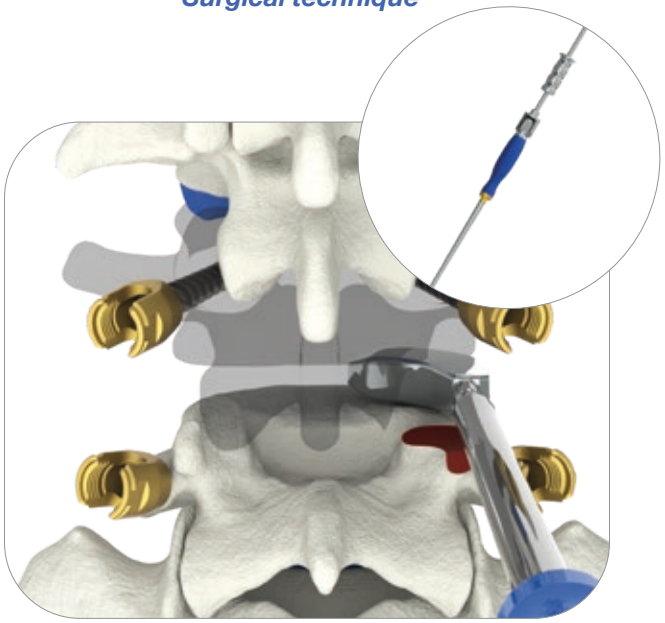
Note:
The sharp and blunt spreaders (Reamer Distractor sharp and blunt) are available in various dimensions according to implant heights in the optionally available Disc Evacuation Set.



Further distraction of the intervertebral disc space

Further distraction of the intervertebral disc space prior to insertion of the cage can be achieved by sequentially inserting the distractors into the cleared and prepared disc space until optimal tension is achieved by means of the distractors between the two vertebral bodies.

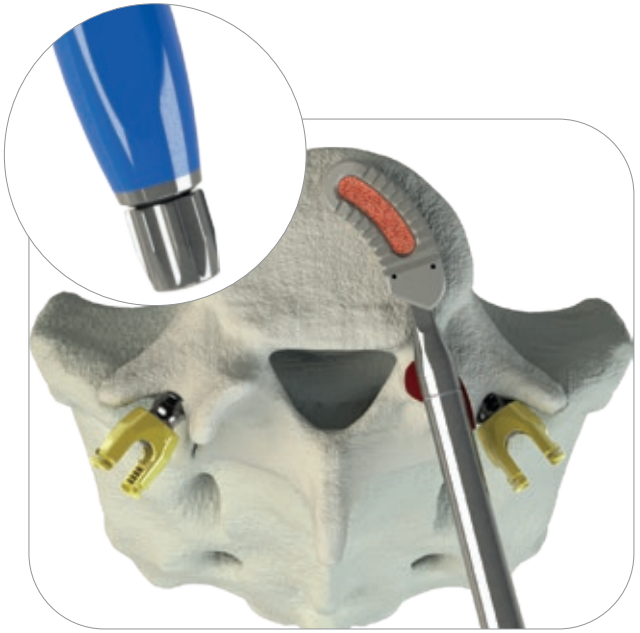
To maintain the distraction, the posterior instrumentation can be locked on the contralateral side.



Determine the implant size I

With the help of the trial implants (TLIF Trial), the implant size to be selected can be determined under X-ray control. To connect the trial implant with the trial insertion instrument (TLIF Trial Inserter), the bar of the trial insertion instrument must be positioned in the groove of the trial implant. By screwing the inner part of the trial insertion instrument into the trial implant, the trial insertion instrument is fixed to the trial implant. Subsequently, the trial implant is optionally introduced by light hammer taps into the intervertebral disc space. If the seat is unsatisfactory, the next size of the trial implant should be used. The trial implant must sit with a light press-fit into the intervertebral space and can be removed with the Extractor Handle or the Slap Hammer.

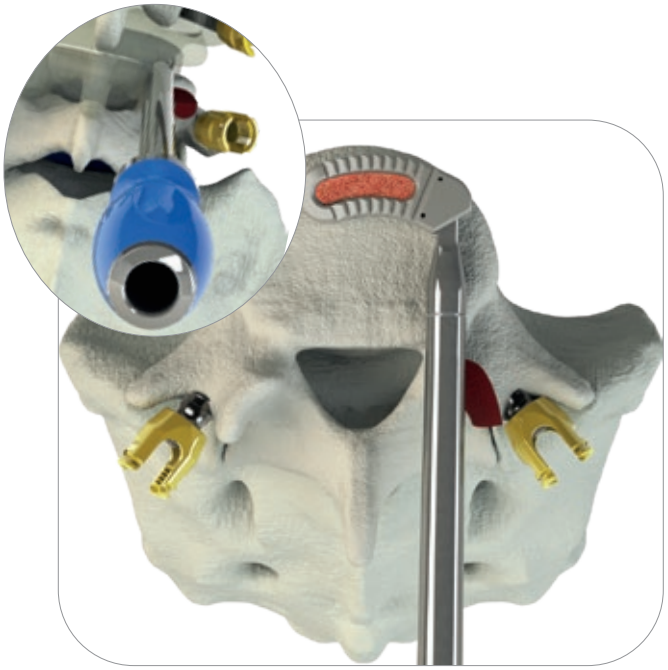
Note:
It must be ensured that the screwing-in of the inner part is carried out smoothly, since otherwise deformations of the threads can occur. If necessary, the alignment of the instruments with each other must be corrected. To avoid jamming when screwing in the inner part, first turn anti-clockwise until there is a clear "snapping in" of the thread. Subsequently, the inner part is screwed fully into the trial implant.



Insertion of the cage with the TLIF Inserter

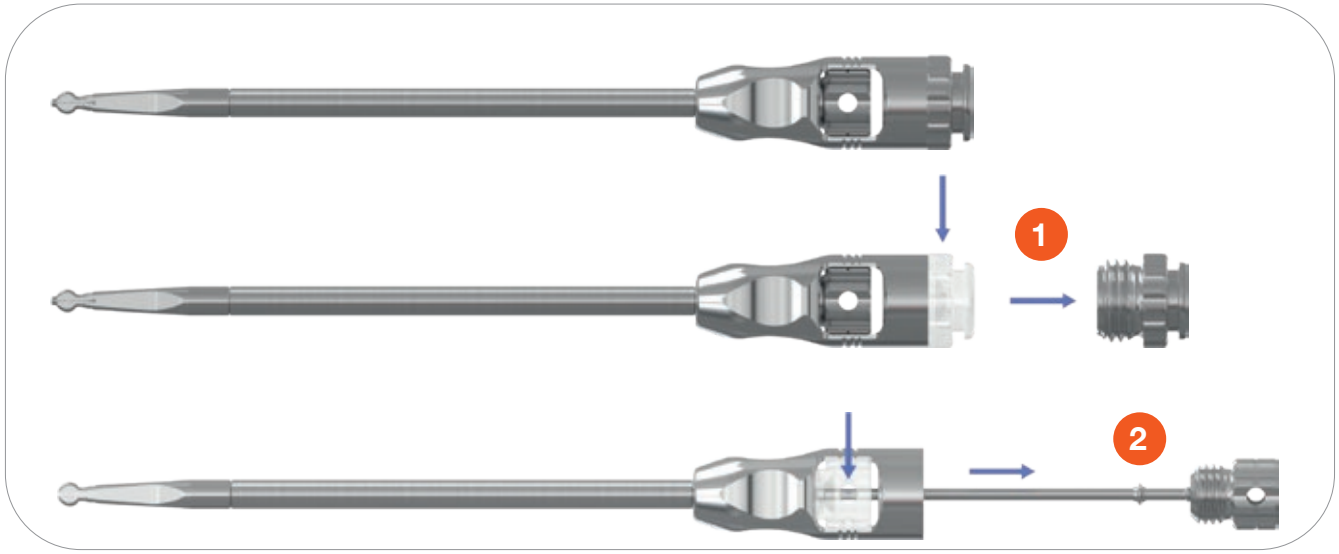
The implant corresponding to the trial implant is selected and the tip of the insertion instrument (TLIF Inserter) is positioned in the pocket-shaped instrument receptacle of the implant. By screwing the inner part of the insertion instrument into the internal thread of the implant, the insertion instrument is fixed to the implant. Subsequently, the cage can be filled with bone graft or bone substitute material.
For a solid interbody fusion, the disc space should be filled with as much bone graft or bone substitute as possible.

Note:
To avoid damaging the implant, the implant must be firmly connected to the insertion instrument. It must be ensured that the screwing-in of the inner part is carried out smoothly, since otherwise deformations of the threads can occur. If necessary, the orientation of the instrument to the implant should be corrected. To avoid jamming when screwing in the inner part, first turn anti-clockwise until there is a clear "snapping in" of the thread. Subsequently, the inner part is screwed fully into the implant.



Rotation of the cage

After inserting the implant, the inner part of the insertion instrument can be removed. To do this, loosen the inner part by turning it anti-clockwise and pull it out of the outer part of the insertion instrument. Make sure that the outer part still remains in the cage. The outer part can now be pivoted medially, yet remains in the instrument receptacle of the cage. By subsequently striking the outer part of the instrument, the cage can be rotated under X-ray control into its final position. It is important that the TLIF cage is placed anteriorly beyond the midline of the vertebral body. An X-ray image is used to verify the final placement of the cage. The X-ray markers inserted in the PEEK implants allow a precise intraoperative radiological assessment of the position.

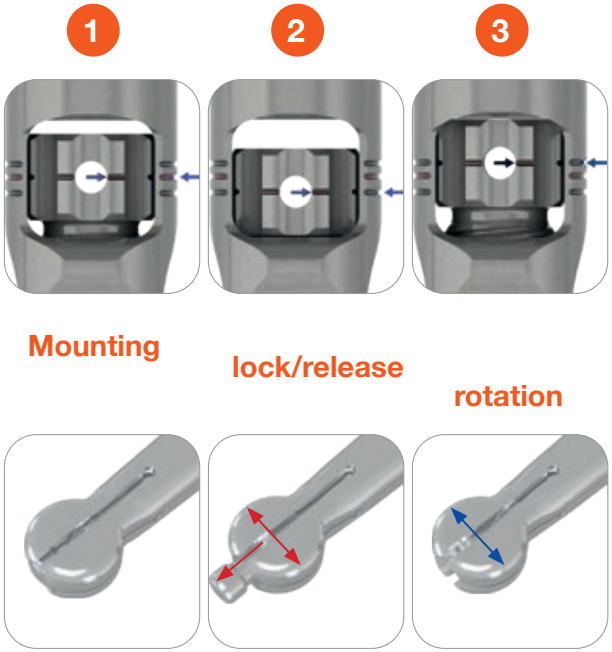


Assembly/Disassembly Multiaxial TLIF Inserter

The Multiaxial TLIF Inserter can be divided into three parts:

1. Unscrew and remove the cap
2. Unscrew expanding mandrel and remove

The assembly takes place in reverse order.



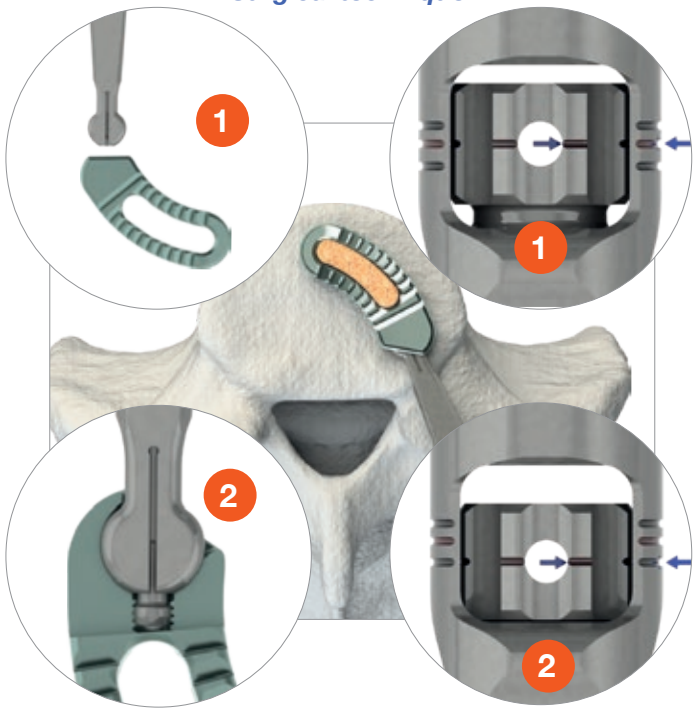
Using the Multiaxial TLIF Inserter (MTI) – Overview of switch positions

As an alternative to the standard insertion instrument, the multiaxial insertion instrument (Multiaxial TLIF Inserter) can also be used. The instrument has 3 handle/switch positions, which can be adjusted by rotation of the adjusting screw of the inner mandrel:

Switch position mounting (1)
- Adjusting screw in middle position
- Tip of the mandrel terminates flush with the implant receptacle
- Implant receptacle is flexible

Switch position lock/release (2)
- Adjusting screw on front end position
- Mandrel is fully extended
- Implant receptacle is spread

Switch position rotation (3)
- Adjusting screw on rear end position
- Mandrel has fully returned
- Implant receptacle is spread

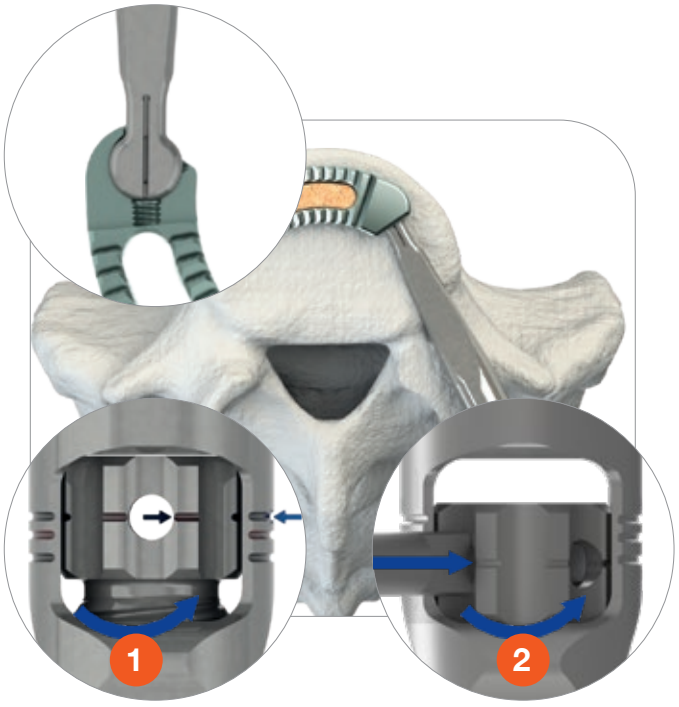


Use of the MTI – Assembly and insertion of the cage

To mount the implant, the adjusting screw of the internal mandrel of the MTI must be set to the mounting position (middle position) (1). The implant is then placed with light pressure onto the tip of the instrument. The implant is then aligned so that it abuts the lateral edge of the instrument receptacle on the instrument. In this position, the adjusting screw of the inner mandrel is turned clockwise to the front end position (2). As a result, the cage is clamped on the instrument and secured against rotation.
Now the cage can be filled with bone graft or bone substitute material and inserted into the intervertebral disc space.

Caution:
When placing the implant, make sure that the MTI is not too strongly twisted or swivelled. This could cause the implant to lose connection with the instrument or damage the internal mandrel.

Caution:
During insertion, the adjusting screw of the inner mandrel must be held manually in order to avoid unintentional loosening or a turning-back of the adjusting screw (e.g. due to vibrations during the hammering-in).

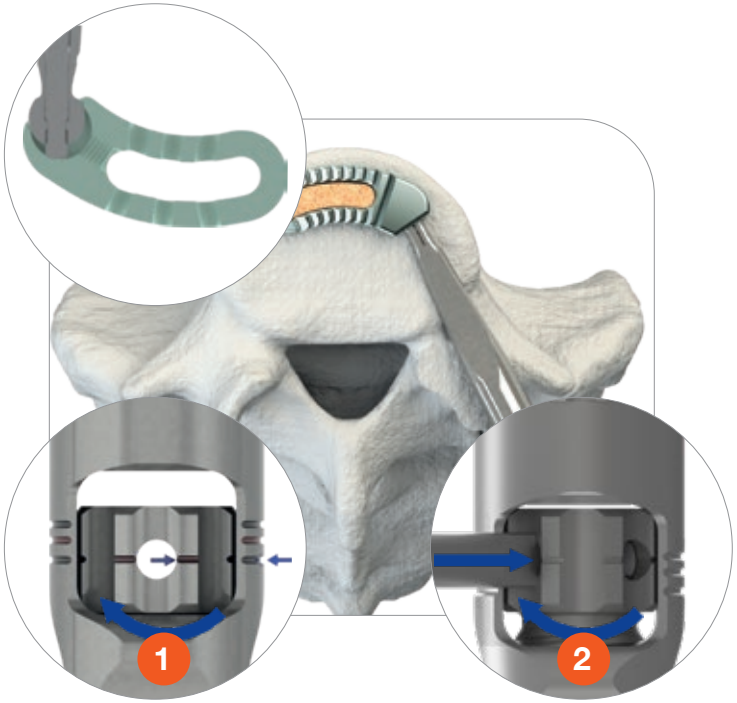


Use of the MTI – Rotation of the cage

After the implant has been positioned in an even orientation anterior to the midline of the vertebral body, the adjusting screw of the internal mandrel adjusting screw is moved to the rear end position (1). In this position, the implant is still firmly attached to the instrument but is not straightened. The MTI can now be pivoted medially, and by further gentle impact of the implant rotates into its final position.

Note:
In the event that the adjusting screw is difficult to turn in the rotation switch position, the release instrument (Release bar MTI) can be used as an aid. For this purpose, the instrument is inserted through the transverse bore of the adjusting screw of the MTI and the adjusting screw is turned counter clockwise in the direction of ROTATION (2).

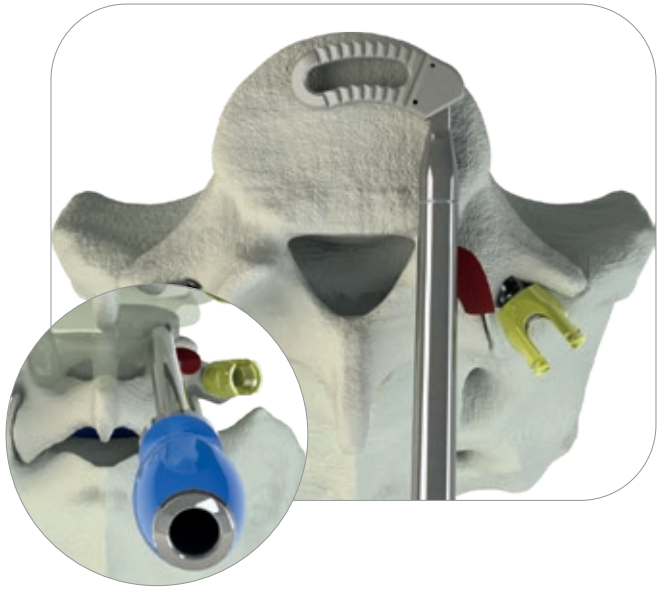
Caution:
Before pivoting the MTI, make sure that the adjusting screw of the inner mandrel is in the rear end position. Failure to do so may damage the internal mandrel or implant receptacle of the MTI.



Use of the MTI – Release the instrument

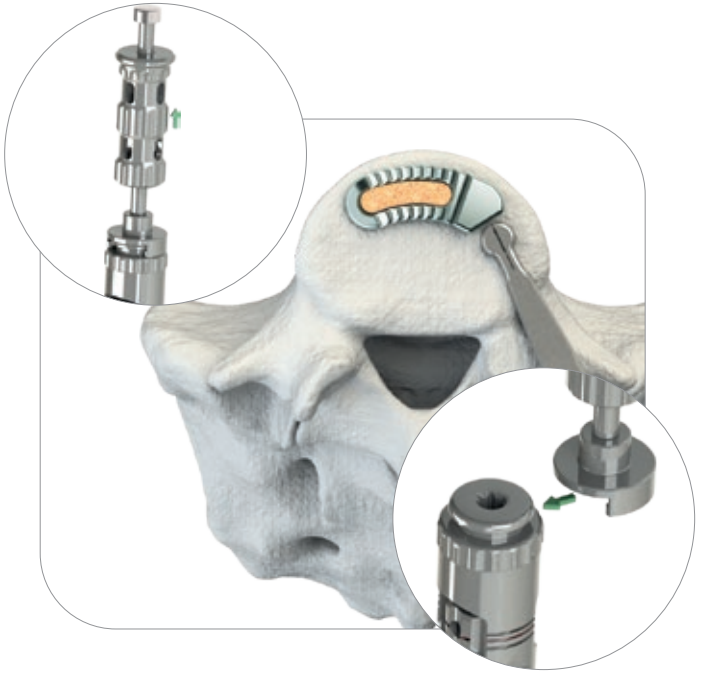
Once the implant has reached its final position, the instrument is released from the cage. For this purpose, the instrument is pivoted slightly laterally and the adjusting screw of the inner mandrel is again turned clockwise to the front end position (1). The instrument releases itself from the implant and can be removed.

Note:
In the event that the adjusting screw is difficult to turn in the LOCK/RELEASE switch position, the release instrument (Release bar MTI) can be used as an aid. For this purpose, the instrument is inserted through the transverse bore of the adjusting screw of the MTI and the adjusting screw is turned clockwise in the direction of LOCK/RELEASE (2).



Correction and adjustment of the cage position with the TLIF Inserter

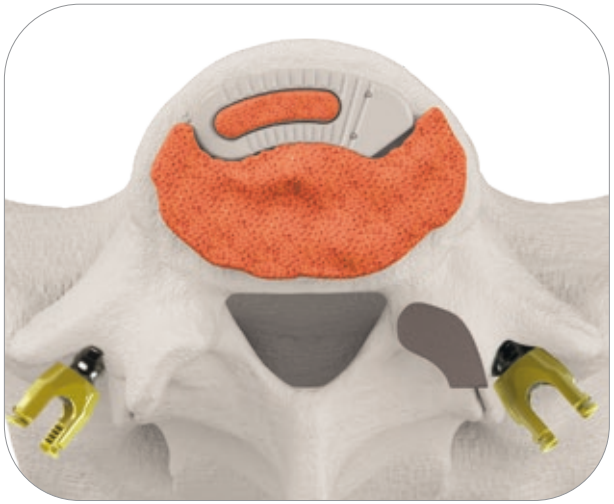
If the orientation of the cage after turning and after releasing the MTI is suboptimal, it is possible to guide the outer part of the TLIF Inserter into the instrument receptacle of the already implanted cage and to reposition the latter.



Revision of the cage

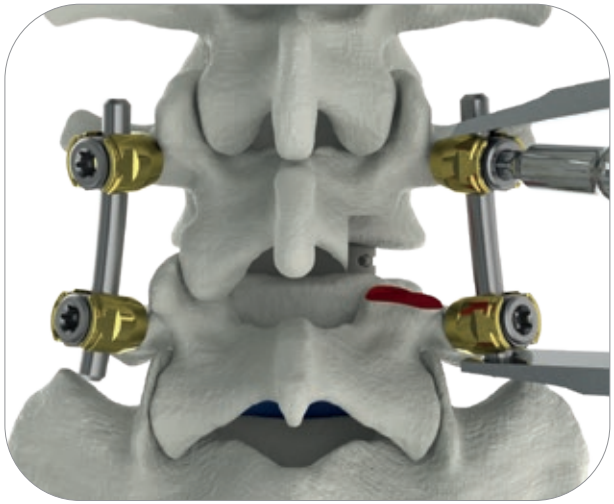
If the implant must be removed, the MTI can be inserted into the instrument receptacle of the implant. Make sure that the adjustment screw of the inner mandrel is in the mounting position (centre position). The instrument is then inserted into the instrument receptacle of the implant. As soon as the instrument is in the receptacle, the adjustment screw of the inner mandrel must be moved to the rear end position to secure the connection between the instrument and the implant. The implant can be removed by pulling on the instrument axially. To help, the Slap Hammer can be pushed on the instrument end. With light blows to the back, the implant can be removed.

Caution:
Revisions of PEEK cages must be undertaken carefully, as with this material a lesser holding force can be applied by the instrument.



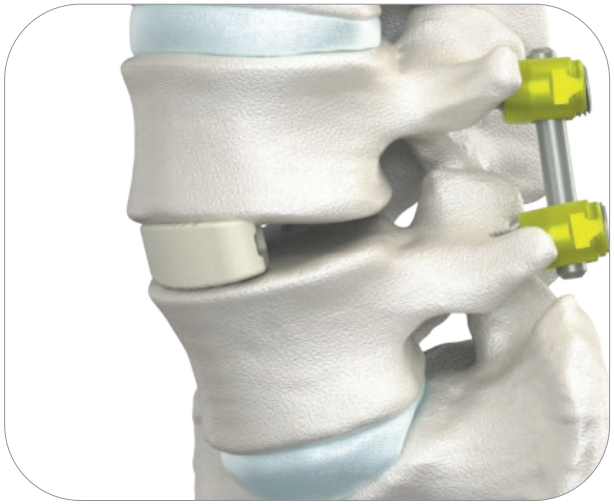
Introduction of bone graft

For a solid interbody fusion, the disc space should be filled with as much bone graft or bone substitute as possible.



Final compression

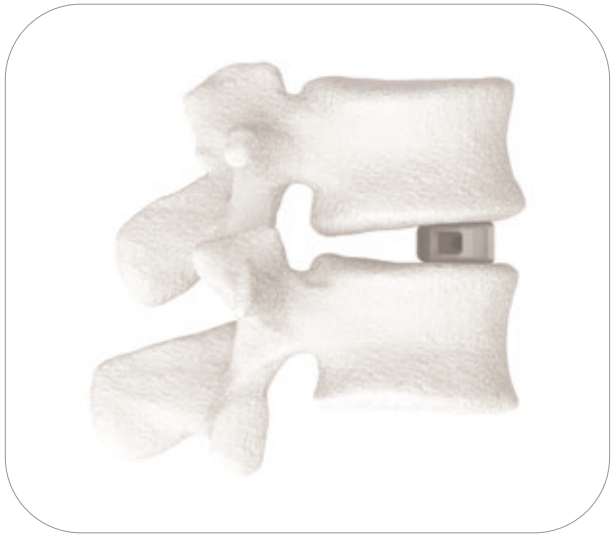
The final compression must be done via the dorsal instrumentation.



Final position

Check the position of the cage with respect to the vertebral bodies from the anterior and lateral directions. X-ray markers placed in the PEEK and coated PEEK implant allow accurate intraoperative radiographic assessment of the position.

AP view
of a centrally positioned TLIF cage

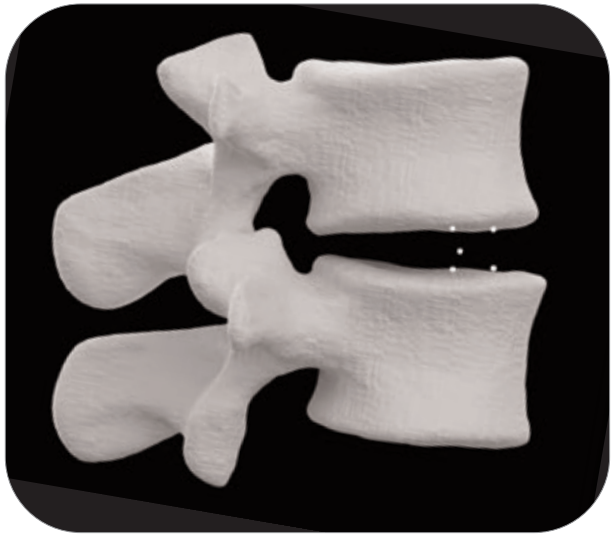


Sagittal view
of a centrally positioned TLIF cage

Positioning of the markers

To ensure the correct position of the cage, the cage must be turned into the central position after insertion into the disc space. The five tantalum markers in the TLIF PEEK cage and the TLIF R-PEEK-Ti version are used for fluoroscopic visualisation of the implant position and orientation. This allows the exact location of the cage to be assessed by X-ray images. The TLIF PEEK and TLIF R-PEEK-Ti, with regard to the direction of insertion, have a medial marker at the anterior implant end and four markers in an rectangular arrangement at the posterior implant end. The four rectangular markers show the outer dimensions of the cage.
For the TLIF PEEK and TLIF R-PEEK-Ti implants, the four posterior and the anterior marker appear in an implant positioned centrally in the disc space, as shown on the radiograph. The sagittal view corresponds to the five-face of a die.

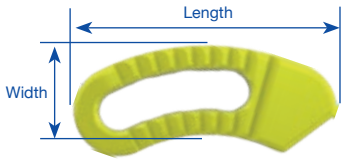
AP X-ray view
of a centrally positioned TLIF cage



Sagittal X-ray view
of a centrally positioned TLIF cage

Titanium sterile

STERILE



Item no.	Name	Length	Width	Height	Angle
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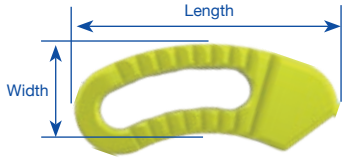
1801051209-S	Adonis TLIF Ti 35x12x09 sterile			09	
1801051211-S	Adonis TLIF Ti 35x12x11 sterile			11	
1801051213-S	Adonis TLIF Ti 35x12x13 sterile			13	
1801051215-S	Adonis TLIF Ti 35x12x15 sterile			15	
1801091207-S	Adonis TLIF Ti 35x12x07 5° sterile	35	12	07	5 °
1801091209-S	Adonis TLIF Ti 35x12x09 5° sterile			09	
1801091211-S	Adonis TLIF Ti 35x12x11 5° sterile			11	
1801091213-S	Adonis TLIF Ti 35x12x13 5° sterile			13	
1801091215-S	Adonis TLIF Ti 35x12x15 5° sterile			15	

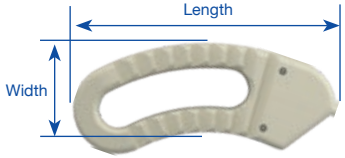
Titanium non-sterile



Item no.	Name	Length	Width	Height	Angle
1801051207	Adonis TLIF Ti 35x12x07	35	12	07	0 °
1801051209	Adonis TLIF Ti 35x12x09			09	
1801051211	Adonis TLIF Ti 35x12x11			11	
1801051213	Adonis TLIF Ti 35x12x13			13	
1801051215	Adonis TLIF Ti 35x12x15			15	
1801091207	Adonis TLIF Ti 35x12x07 5°	35	12	07	5 °
1801091209	Adonis TLIF Ti 35x12x09 5°			09	
1801091211	Adonis TLIF Ti 35x12x11 5°			11	
1801091213	Adonis TLIF Ti 35x12x13 5°			13	
1801091215	Adonis TLIF Ti 35x12x15 5°			15	

PEEK

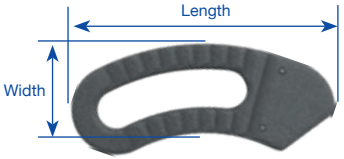
STERILE



Item no.	Name	Length	Width	Height	Angle
1801041207	Adonis TLIF PEEK 35x12x07	35	12	07	0 °
1801041209	Adonis TLIF PEEK 35x12x09			09	
1801041211	Adonis TLIF PEEK 35x12x11			11	
1801041213	Adonis TLIF PEEK 35x12x13			13	
1801041215	Adonis TLIF PEEK 35x12x15			15	
1801041307	Adonis TLIF PEEK 35x12x07 5°	35	12	07	5 °
1801041309	Adonis TLIF PEEK 35x12x09 5°			09	
1801041311	Adonis TLIF PEEK 35x12x11 5°			11	
1801041313	Adonis TLIF PEEK 35x12x13 5°			13	
1801041315	Adonis TLIF PEEK 35x12x15 5°			15	

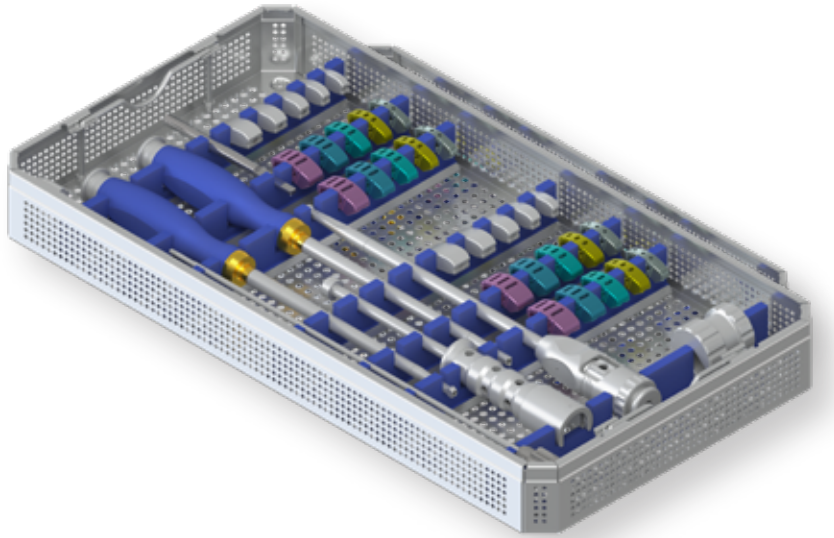
R-PEEK-Ti

STERILE

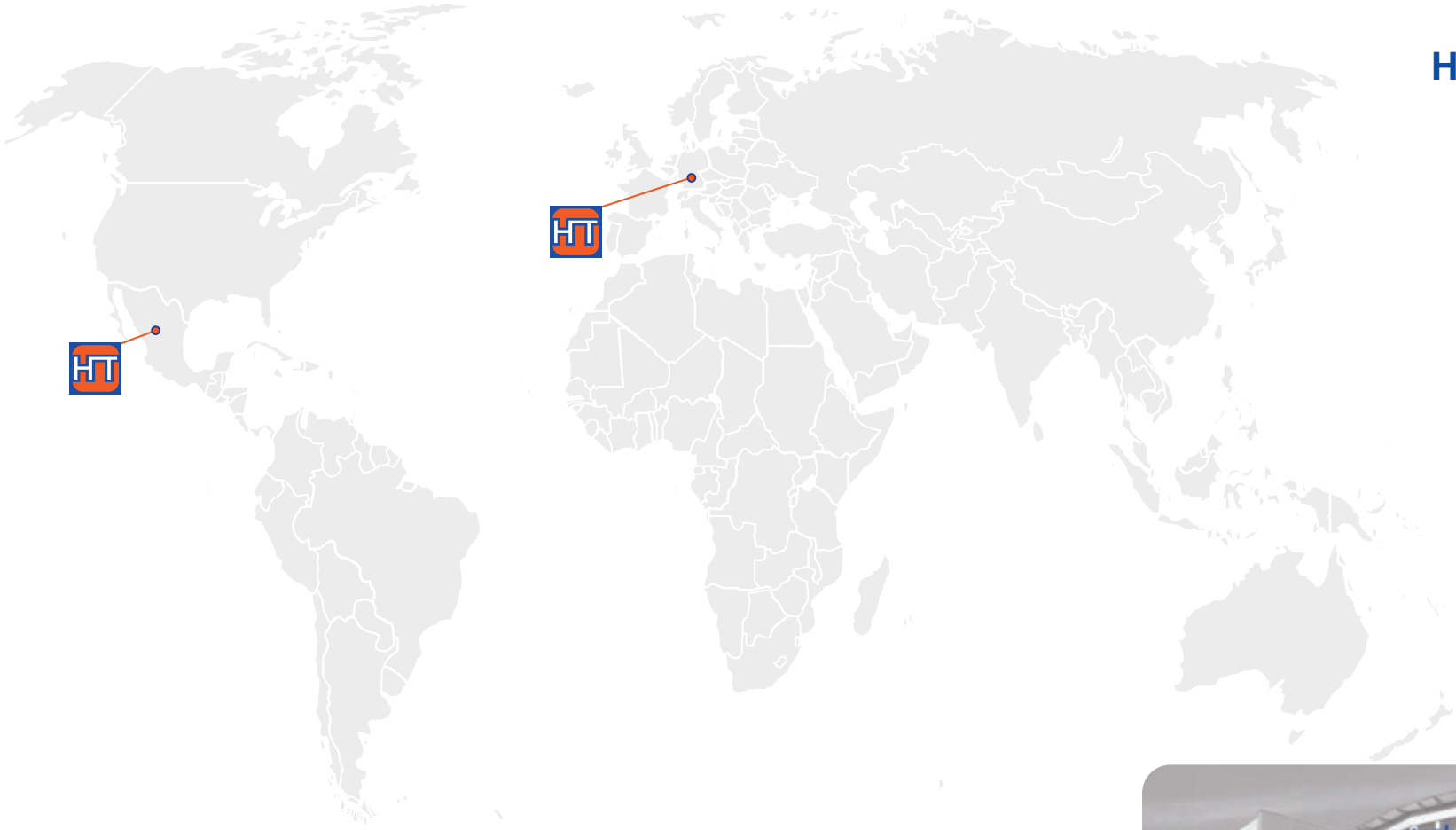


Item no.	Name	Length	Width	Height	Angle
1803061207	Adonis-TLIF R-PEEK-Ti 35x12x07	35	12	07	0 °
1803061209	Adonis-TLIF R-PEEK-Ti 35x12x09			09	
1803061211	Adonis-TLIF R-PEEK-Ti 35x12x11			11	
1803061213	Adonis-TLIF R-PEEK-Ti 35x12x13			13	
1803061215	Adonis-TLIF R-PEEK-Ti 35x12x15			15	

Item no.	Name	
1801011207 1801011209 1801011211 1801011213 1801011215 1801011307 1801011309 1801011311 1801011313 1801011315	TLIF Trial 35x12x07 mm TLIF Trial 35x12x09 mm TLIF Trial 35x12x11 mm TLIF Trial 35x12x13 mm TLIF Trial 35x12x15 mm TLIF Trial 35x12x07 mm 5° TLIF Trial 35x12x09 mm 5° TLIF Trial 35x12x11 mm 5° TLIF Trial 35x12x13 mm 5° TLIF Trial 35x12x15 mm 5°	
1801010403	TLIF Trial Inserter	
1801010401	TLIF Inserter	
1801010000	Multiaxial TLIF Inserter	
1801010004	Release bar MTI	
1801010002	Slap Hammer	
1701010600	Extractor Handle	 optional



HumanTech Spine



Manufacturing and Sales

HumanTech Spine GmbH

Gewerbestr. 5
D-71144 Steinenbronn

Germany

Phone: +49 (0) 7157/5246-71
Fax: +49 (0) 7157/5246-66
sales@humantech-spine.de
www.humantech-spine.de

Sales Latin America

HumanTech Mexico, S. DE R.L. DE C.V.

Rio Mixcoac No. 212-3
Acacias del Valle
Del. Benito Juárez
C.P. 03240 Mexico, D.F.
Mexico

Phone: +52 (0) 55/5534 5645
Fax: +52 (0) 55/5534 4929
info@humantech-solutions.mx
www.humantech-spine.de

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