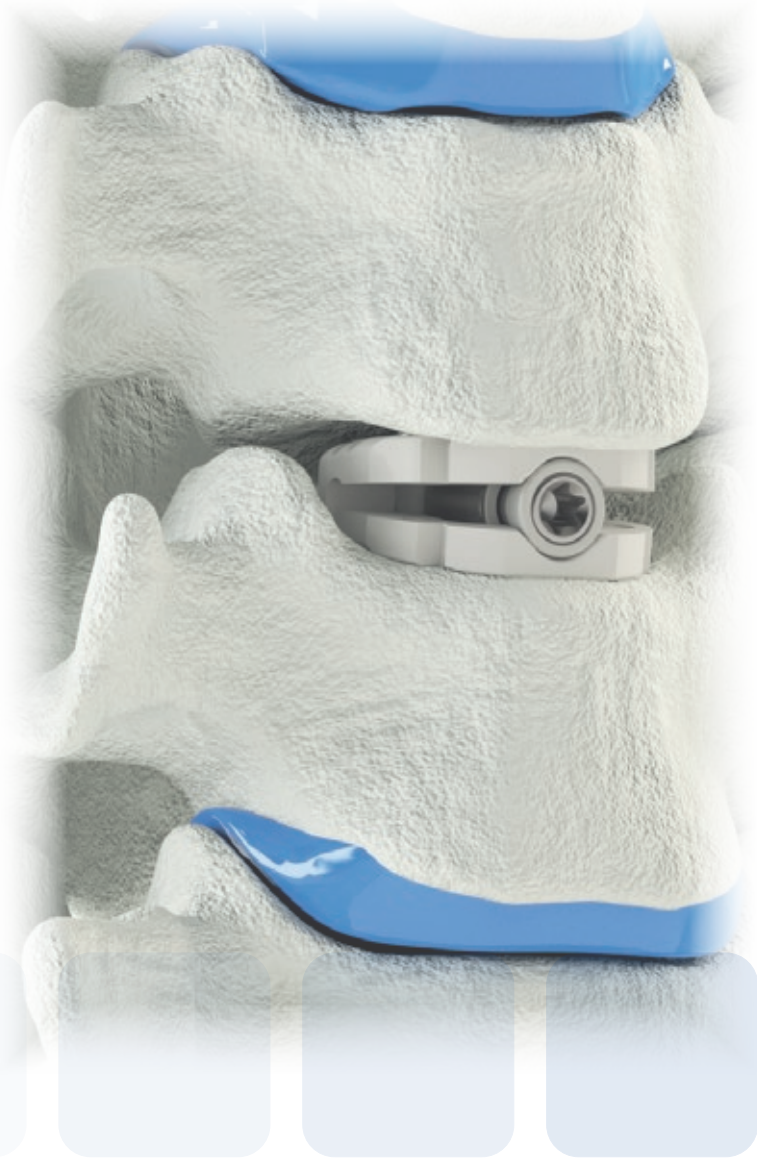


HumanTech Spine

TRISTAN® flex

Cervical Interbody Fusion

TRISTAN® Cervical Interbody Fusion is an implant system which is intended as a disc replacement for a long-term usage for anterior stabilization in the cervical spine from C3 to C7 in patients whose general skeletal growth has ended.

The system includes implants of various dimensions and heights, whereby the unique anatomy of the individual patient can be taken into account.

TRISTAN®flex is an extension of the existing Tristan system. Thanks to the integrated expansion mechanism, TRISTAN®flex enables an inividual adjustement of the angulation of the implant and thus a patient-specific restoration of the natural lordosis.

TRISTAN®flex system is used via an anterior access and cervical discectomy and offers the following product-specific advantages:

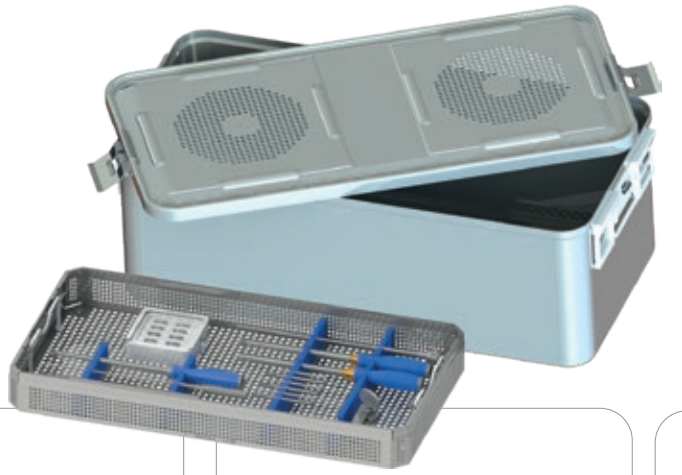
anatomical
- Geometry is identical to the patient‘s own sectional and sagittal anatomy with planar base and convex cover plate
- Generous contact surface
- Adjustable angulation (5 ° -10 °) for direct reconstruction of the sagittal profile in situ

stable
- Antegrade toothing for stable anchorage with additional spikes for optimal primary fixation
- Latch mechanism to secure the selected angulation
- Fixed connection to the inserter by a clamping mechanism

reliable
- Filling aperture for rapid fusion

biocompatible
- The base body of the TRISTAN®flex consists of the biocompatible material PEEK, which is characterized by a bone-like elasticity.
- The other components of the TRISTAN®flex consist of the biocompatible titanium alloy Ti6Al4V.

safe
- Radiopaque markers for identification under X-ray control

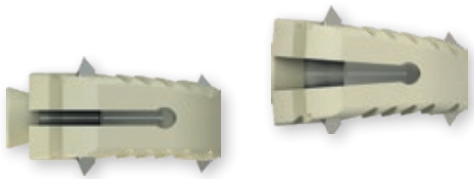


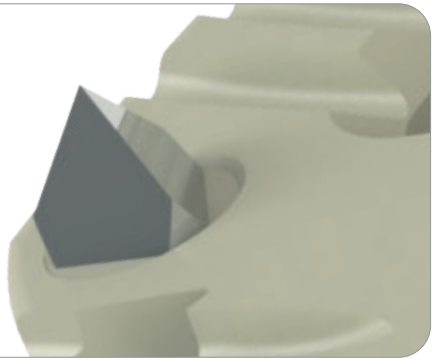
Made in Germany

TRISTAN®flex

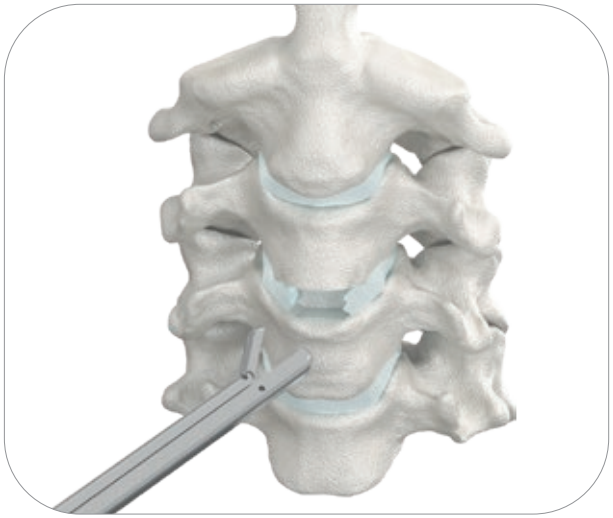
Interbody Device System

product specific advantages





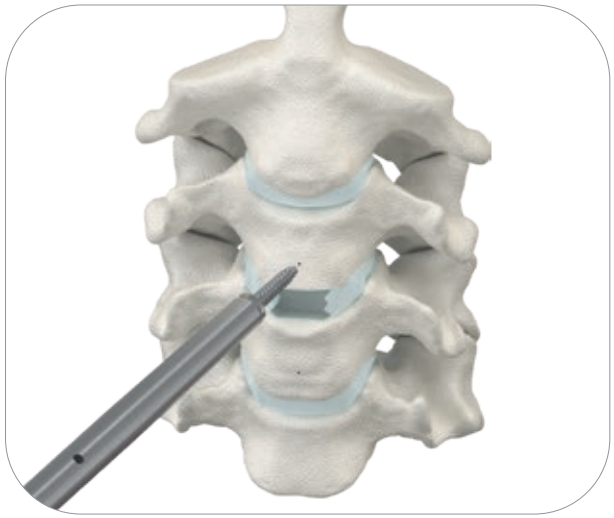
- adjustable angulation (5°-10)
- integrated locking mechanism to secure the adjusted angulation
- reconstruction of the sagittal profile in situ
- generous contact surface and primary fixation via spikes



Exposure of the intervertebral space

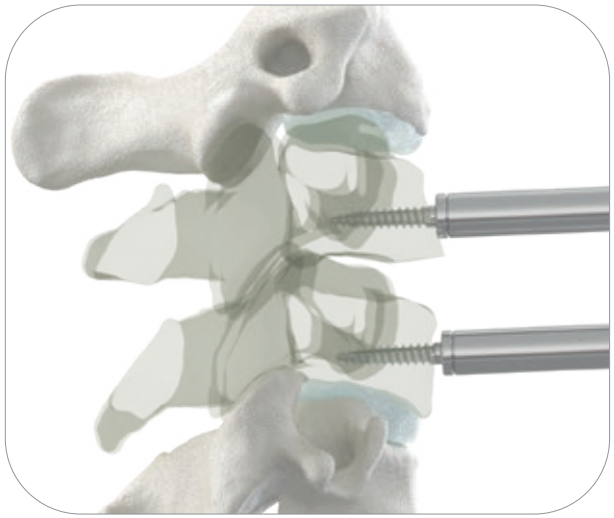
Opening up the intervertebral space by fenestration of the anterior longitudinal ligament and excision of the annulus fibrosus. Resection of the anterior osteophytes using a punch and rongeur, if necessary, milling with the aid of a high-speed milling device.

Note:
The anatomical anterior edge of the vertebral body must remain intact.



Inserting the Distraction Pins I

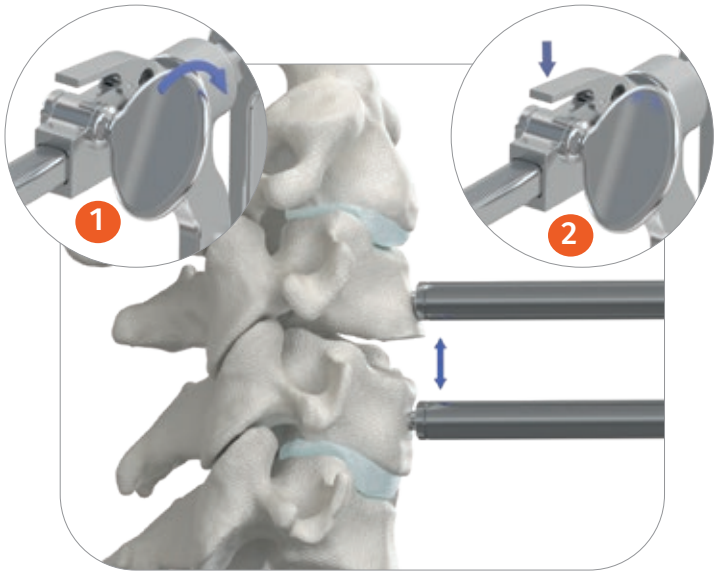
The Distraction Pin is inserted into the end of the Pindriver from below until it locks into place by the locking spring located on the Pindriver. Care should be taken to align the hexagonal profile so that the Distraction Pin is correctly positioned in the Pindriver.
The Distraction Pins are then placed in the caudal and cranial vertebrae adjacent to the section to be treated. It is important to ensure that the Distraction Pins are positioned as centrally as possible in the vertebral body during this process. In osteoporotic bone conditions, the Distraction Pins can also be inserted close to the endplates in order to achieve better and more secure anchoring and retraction stability.



Inserting the Distraction Pins II

The correct length for the Distraction Pins is determined via X-ray. Once the Distraction Pin has been screwed in, the Pindriver is carefully removed by pulling it backwards.

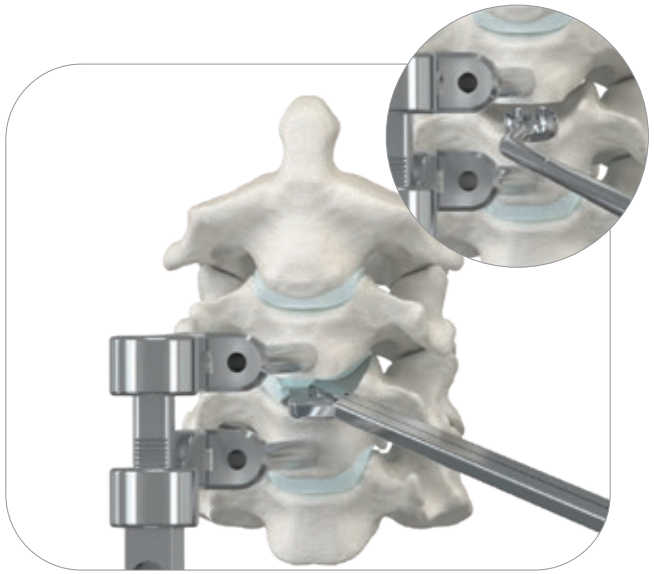
Caution:
The Distraction Pins must not perforate the posterior edge of the vertebral body. The Distraction Pins must not be introduced into a hole that has been used previously. Otherwise the Distraction Pins' purchase in the bone is reduced and they may be pulled out of the bone when the Pindriver is withdrawn. The Distraction Pins are designed for single use only.



Expansion of the intervertebral space

The Retrieval Body Retractor is placed onto the protruding ends of the Distraction Pins from above. The intervertebral space is then carefully expanded by turning the setting wheel (1) on the Retrieval Body Retractor clockwise, thereby exposing the intervertebral space as far as the posterior edge.

Note:
The degree of expansion that is set on the Retrieval Body Retractor is retained via a locking mechanism. To release the expansion or correct the position, press the lever (2) located on the instrument.

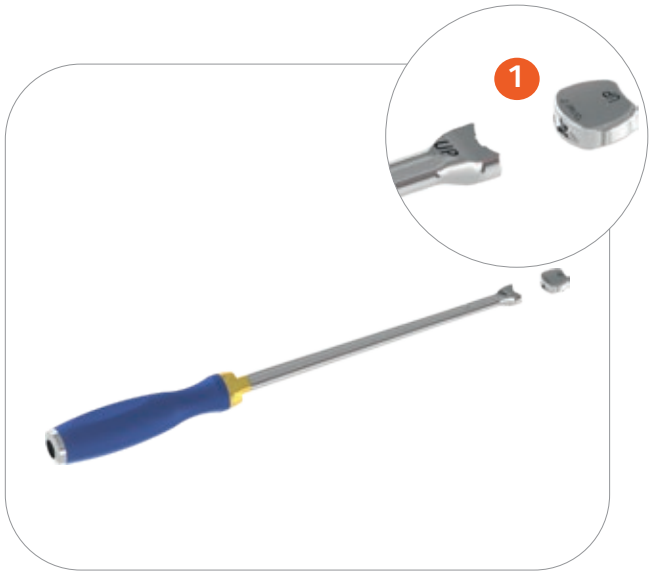


Preparing the intervertebral space and the implant bed

Complete excavation of the intervertebral space using the rongeur and preparation of the endplates. Removal of the disc tissue.

Preparation of the implant bed and careful refinement of the endplates using a curette and/or high speed milling device.

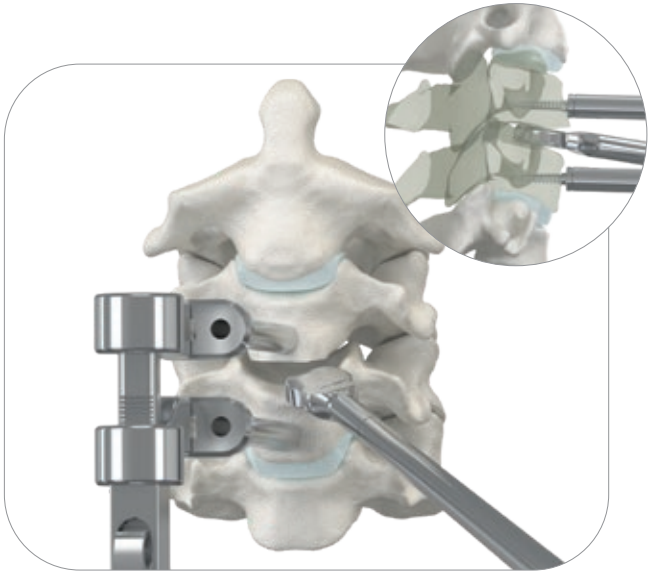
Caution:
Make sure that the end plates remain intact. Damage to the end plates or excessive partial ablation at the end plates can lead to sintering of the implant and loss of segmental stability.



Assembly of the Trial

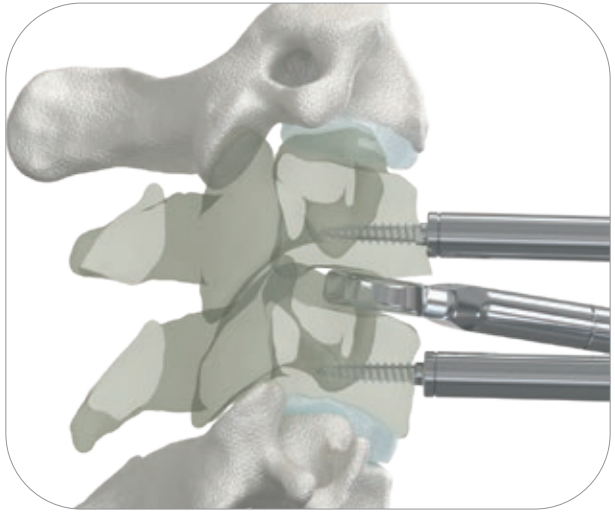
The correct implant size can be determined under X-ray control using the TF Trials. To connect the TF Trial to the Cage Inserter, the bar of the Cage Inserter must be positioned in the groove of the TF Trial. Tristan Inserter B is screwed into the TF Trial in order to fix it to the Cage Inserter.

Caution:
Care should be taken to ensure that the TF Trial is correctly aligned with the Cage Inserter. The sides marked “up” must both face in the same direction (1).



Determining the implant size I

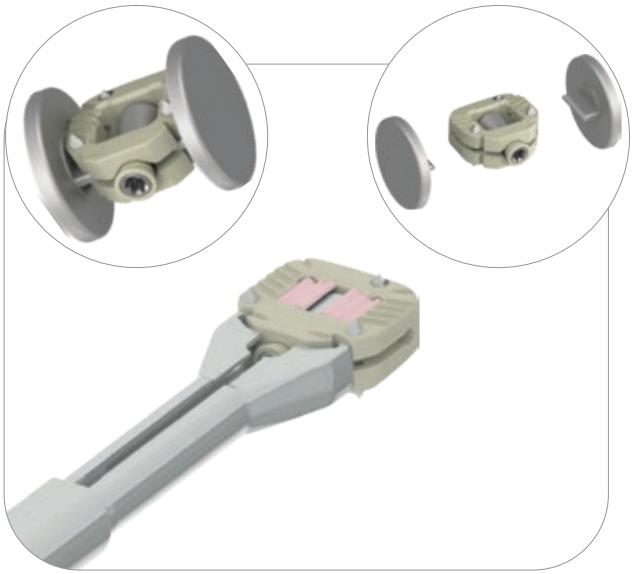
The TF Trial is introduced into the disc space, using light hammer taps if necessary. The TF Trial should fit as snugly as possible in the prepared intervertebral space. If necessary, further preparation of the implant bed should be carried out until the required fit accuracy is obtained. Correct fitting of the TF Trial is achieved when the anterior edge is positioned around 1-2 mm behind the anterior edge of the vertebral body and the cage length occupies around 4/5 of the anteroposterior expansion of the intervertebral space and ends in front of the posterior edge of the vertebral body.



Determining the implant size II

If the seating is not satisfactory, the TF Trial of the next size up should be used. The lateral profil and the distraction can be assessed by X-ray control.

Caution:
The TF Trial provides information about the height of the implant in the retracted state without spikes. In order to minimize violations of the endplates of the vertebral body by the titanium spikes, a further distraction (1-2mm) has to be provided initialy. Overdistraction should be avoided. Once the implant size has been determined, the TF Trial is removed and released from the Cage Inserter.

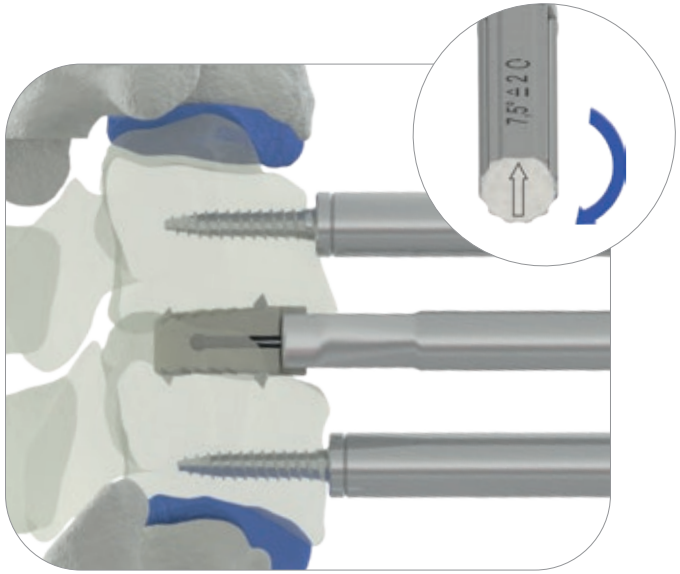


Mounting of the implant

The implant corresponding to the trial implant is selected and removed from the sterile outer packaging. The two packaging aids on the implant are then removed from the implant by pulling.
The bar of the Tristan F Inserter flat is positioned in the groove of the implant. Turning the handle on the back of the Tristan F Inserter clockwise will clamp the implant to the Tristan F Inserter flat. After assembly on the Tristan F Inserter flat, for faster and more secure fusion, the cage can be filled with autologous bone material or with allogenic or other bone replacement material.

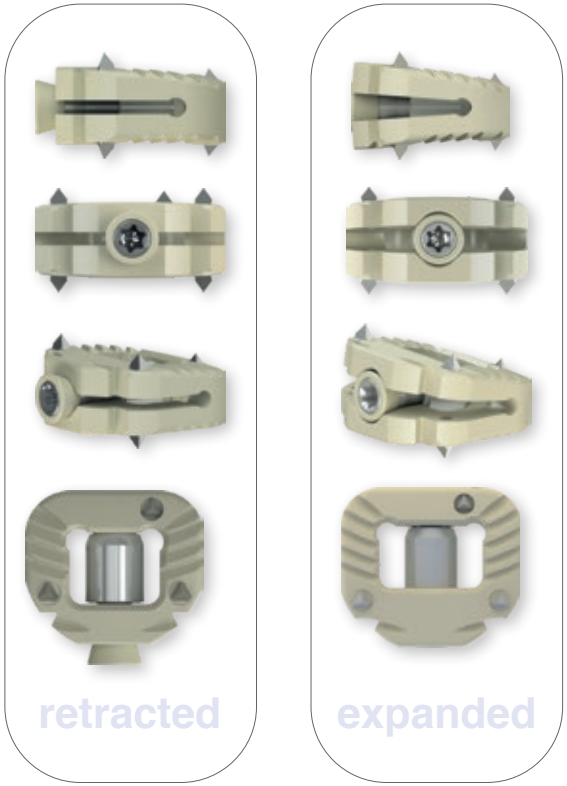
Insertion of the cage

If necessary, the implant is inserted into the intervertebral disc space using light hammer taps if necessary. The direction of the insertion of the implant must be observed. The arrow on the implant must point cranially. Once the implant is correctly positioned in the intervertebral space, the Tristan F Inserter flat must be loosened by half a turn of the rear handle counterclockwise. If the implant is not optimally positioned, the Tristan F Repositioner can also be used. Make sure that the distraction screw is in the recess of the Tristan F Repositioner flat to avoid hitting the screw and damaging the thread.

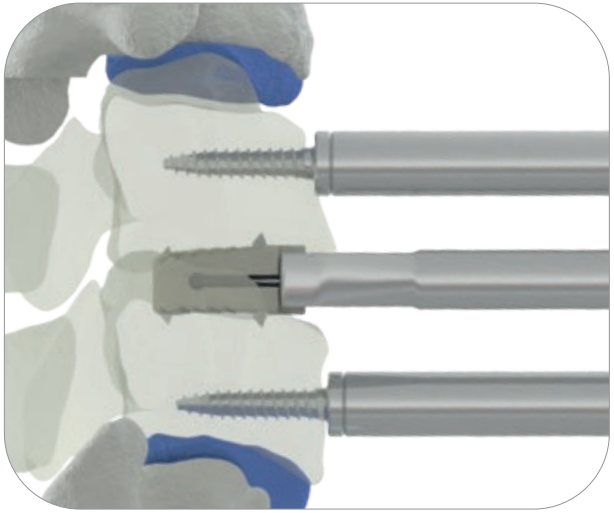


Expansion of the cage

To expand the cage, the Tristan F Driver is inserted from behind through the hole in the Tristan F Inserter flat. Care must be taken to ensure that the torx of the Tristan F Driver is guided into the torx geometry of the distraction screw. The distraction screw is then screwed into the implant by turning the Tristan F Driver clockwise. The implant has three stages in which the position of the screw is secured. In the initial position the implant has an angulation of 5°, in the intermediate stage 7.5° and 10° with complete distraction. To achieve the intermediate stage of 7.5°, the Tristan F Driver should be turned approx. 2 turns to the right (see small picture). For complete distraction, the distraction screw is turned to the stop. Care must be taken that the distraction screw is not overtightened. Final check of the implant seat using X-ray.



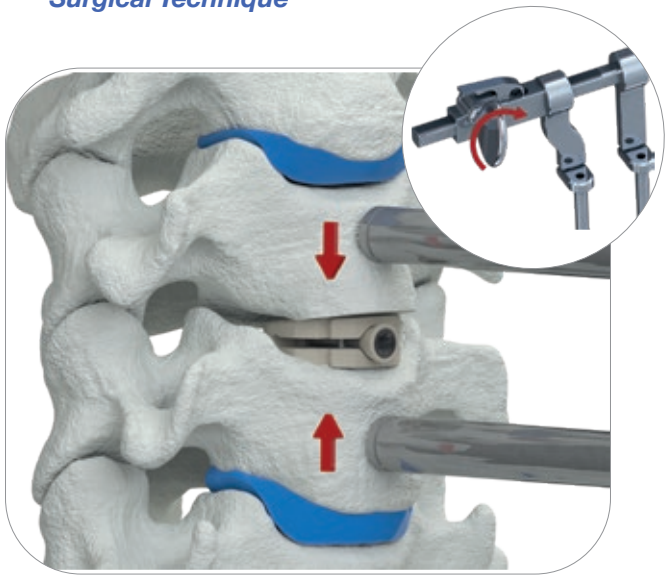
TRISTAN®flex
Interbody Device System



Subsequent correction of the cage position

The Tristan F Inserter flat can also be used for eventually necessary correction of the position or revision of the implant. For this, the bar of the Tristan F Inserter flat must be positioned in the groove of the implant. Turning the handle on the back of the Tristan F Inserter flat clockwise will clamp the implant to the Tristan F Inserter flat. By axial pulling on the Tristan F Inserter flat, the implant can be corrected anteriorly or removed from the intervertebral disc space.

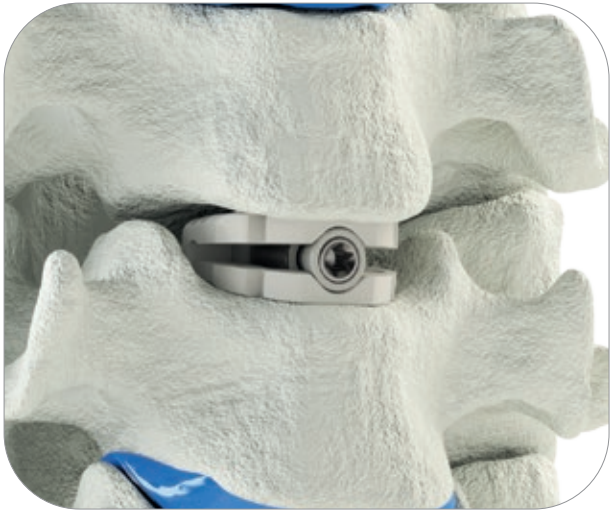
Caution:
Correction of the position or revision of the implant must be performed in the fully compressed state of the implant. To do so, turn the distraction screw counterclockwise by turning the Tristan F Driver counterclockwise (at least 4 turns) until the integrated mechanical stop is reached.



Compression of the vertebral bodies

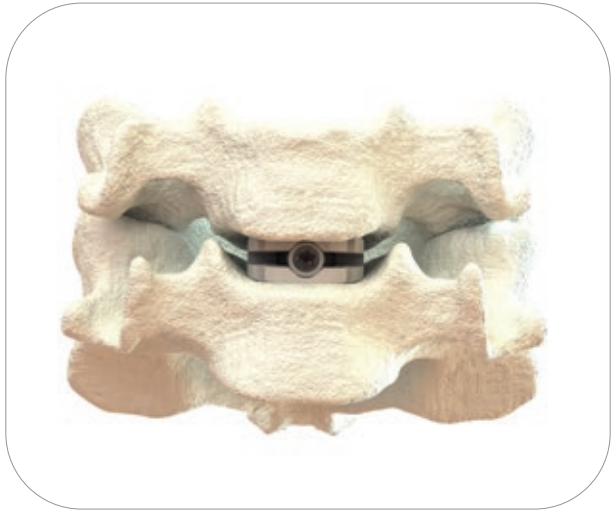
After insertion and expansion of the cage to its final position, care should be taken to ensure that the spikes of the cage penetrate the base plate and cover plate of the adjacent vertebral bodies. This is achieved by compression of the adjacent vertebral bodies using the Retrieval Body Retractor. Finally, the Retrieval Body Retractor and Distraction Pins are removed. To do this, the Pindriver is pushed onto the Distraction Pin until it stops. Care should be taken to align the hexagonal profile. The locking spring located on the Pindriver ensures that the Distraction Pin can not get lost.

Note:
In order to compress the vertebral bodies with the Retrieval Body Retractor, the lever on the locking mechanism must be held down. By turning the setting screw in the opposite direction to the distraction, the vertebral bodies can then be compressed until the spikes penetrate the base plate and cover plate. Alternatively, the arms of the instrument can be carefully pushed together by hand, holding the lever of the locking mechanism pressed down.



Final construction

Final check of the construction with X-ray control images taken in two planes. Cleanse the surgical area and close the wound.

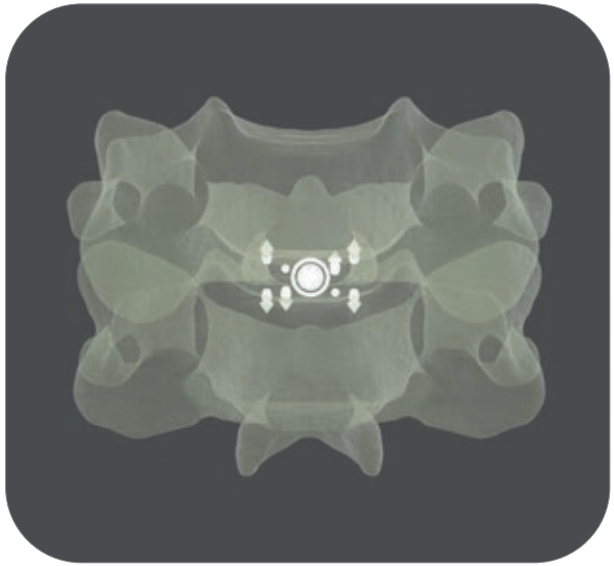


AP-view
of a centrally positioned
TRISTAN®flex cage

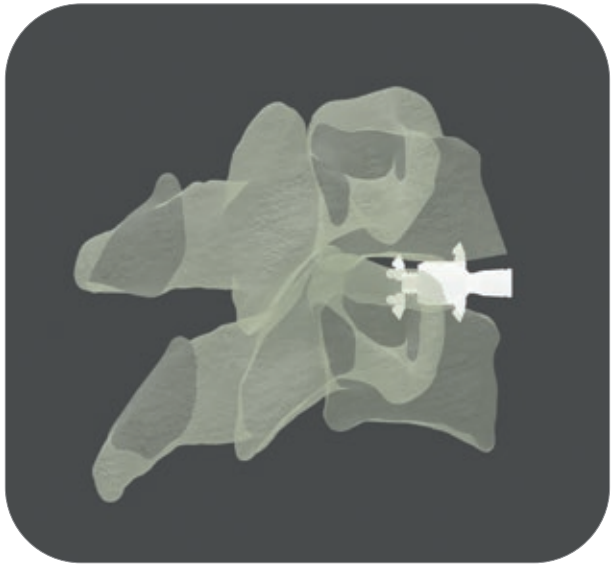
Sagittal view
of a centrally positioned
TRISTAN®flex cage

Positioning of 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. Both tantalum markers and the six titanium spikes shown in the TRISTAN®flex cage are used for the fluoroscopic representation of the implant's position. This makes it possible to assess the exact position of the cage based on the X-rays.
The TRISTAN®flex has two tantalum beads and 2 titanium spikes each positioned diagonally offset on the posterior edge of the implant and four titanium spikes in the lateral area of the anterior implant edge. The four anterior markers are used to indicate the maximum width of the cage. The implant depth can be estimated in combination with the posterior markers. With TRISTAN®flex implants, the four posterior and four anterior markers appear as shown in the X-ray image when the implant is positioned centrally within the disc space. The expansion screw and the interior shell of the implant are also clearly visible.



AP-X-ray view
of a centrally positioned
TRISTAN®flex cage



Sagittal X-ray view
of a centrally positioned
TRISTAN®flex cage

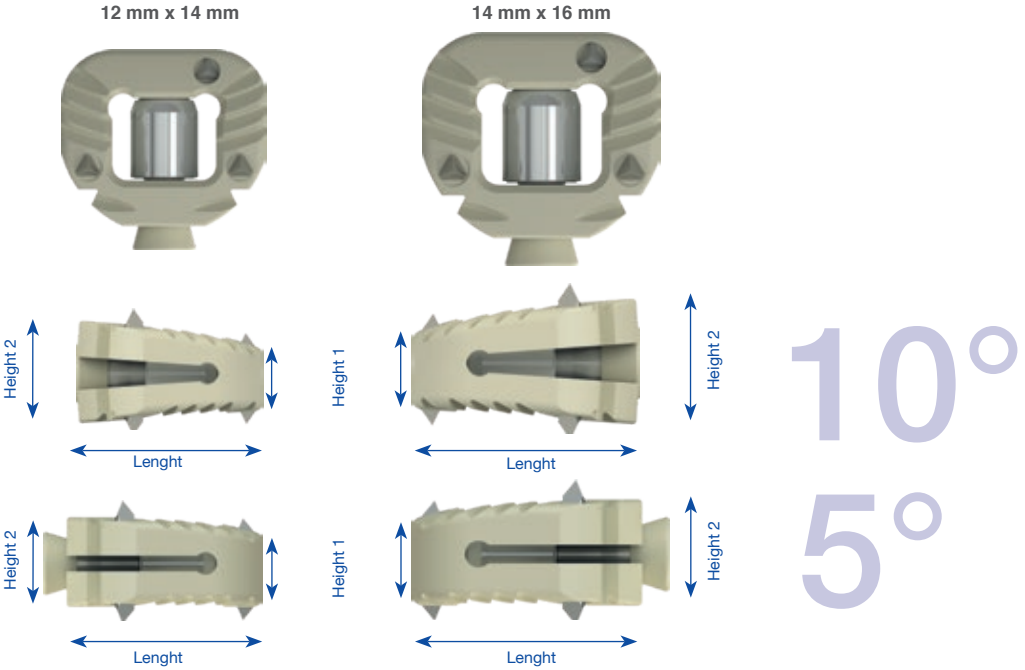
TRISTAN®flex STERILE

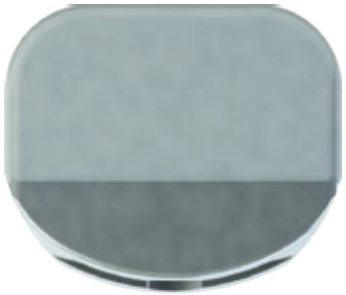
Item no.	Description	Length	Width	Height 1	∢ 5° Height 2	∢ 7.5° Height 2	∢ 10° Height 2
1503121405	Tristan Flex 12x14x05	12	14	4.2	5.4	5.9	6.4
1503121406	Tristan Flex 12x14x06	12	14	5.2	6.4	6.9	7.4
1503121407	Tristan Flex 12x14x07	12	14	6.2	7.4	7.9	8.4
1503121408	Tristan Flex 12x14x08	12	14	7.2	8.4	8.9	9.4
1503141605	Tristan Flex 14x16x05	14	16	4.2	5.4	6.1	6.7
1503141606	Tristan Flex 14x16x06	14	16	5.2	6.4	7.1	7.7
1503141607	Tristan Flex 14x16x07	14	16	6.2	7.4	8.1	8.7
1503141608	Tristan Flex 14x16x08	14	16	7.2	8.4	9.1	9.7

TF trial implants

Item no.	Description
1503012145	TF Trial 12x14x05 5°
1503012146	TF Trial 12x14x06 5°
1503012147	TF Trial 12x14x07 5°
1503012148	TF Trial 12x14x08 5°
1503014165	TF Trial 14x16x05 5°
1503014166	TF Trial 14x16x06 5°
1503014167	TF Trial 14x16x07 5°
1503014168	TF Trial 14x16x08 5°

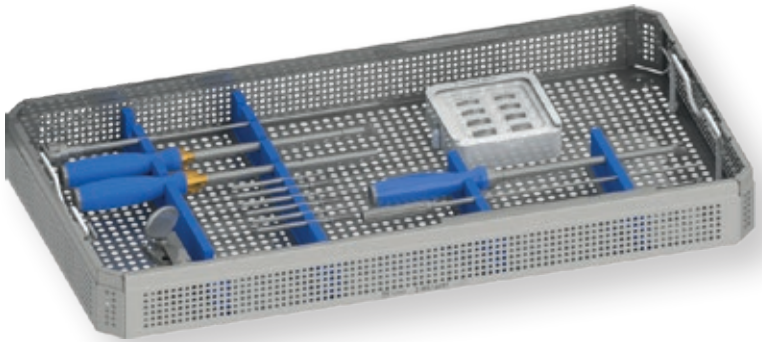
5°



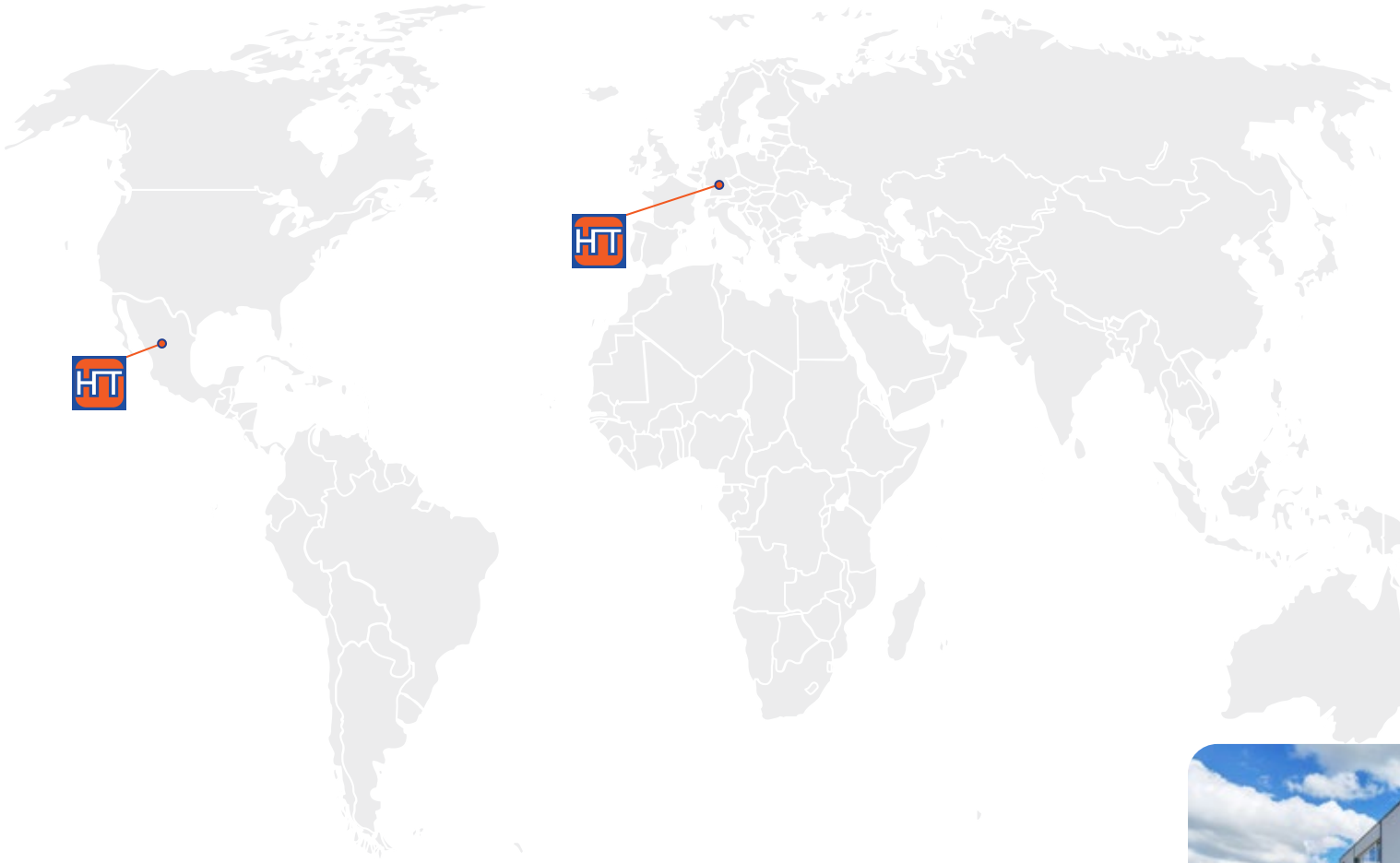


Item no.	Description	
1501010001	Cage Inserter	
1501010001B	Tristan Inserter B	
1503200003	Tristan F Inserter Flat	
1503200000	Tristan F Inserter optional	
1503200001	Tristan F Driver	
1503200002	Tristan F Repositioner	
1501010011	Pindriver	
1501010022	Distraction Pin 14 mm	-For single use only- 
1501010023	Distraction Pin 16 mm	-For single use only- 
1501010024	Distraction Pin 18 mm	-For single use only- 
1501010010	Retrival Body Retractor	
1501010022-S	Distraction Pin 14mm sterile	STERILE -For single use only- 
1501010023-S	Distraction Pin 16mm sterile	STERILE -For single use only- 
1501010024-S	Distraction Pin 18mm sterile	STERILE -For single use only- 

available soon



HumanTech Spine



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