

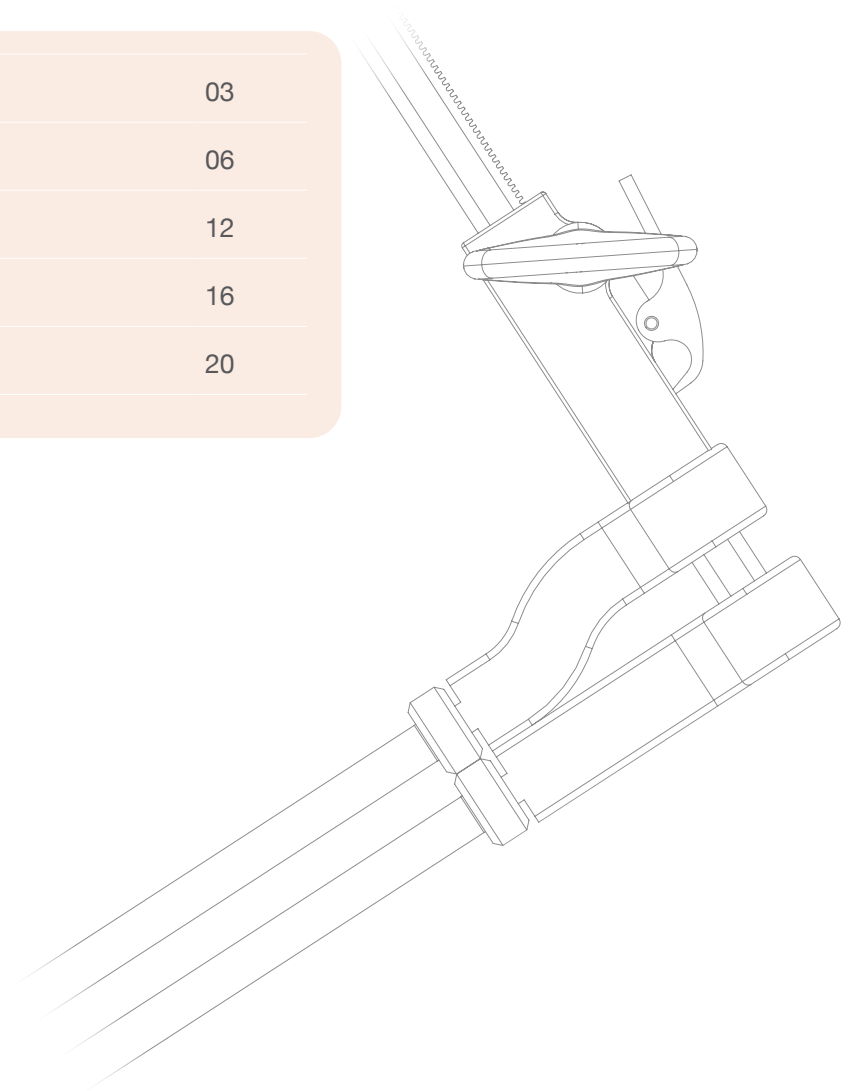


TRISTAN[®]

Cervical Interbody Fusion



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System

TRISTAN® Cervical Interbody Fusion is intended for cervical interbody fusion from C3 to C7.

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

TRISTAN® is implanted via an anterior approach following cervical discectomy and offers the following product-specific benefits:

Anatomical

- The shape with its flat base plate and convex cover plate is inspired by the anatomical cross-section and sagittal profile of the cervical interbody space

Primary Stability

- Antegrade toothings facilitates insertion and offers resistance when pulling out
- For PEEK-S additional spikes promote primary stability

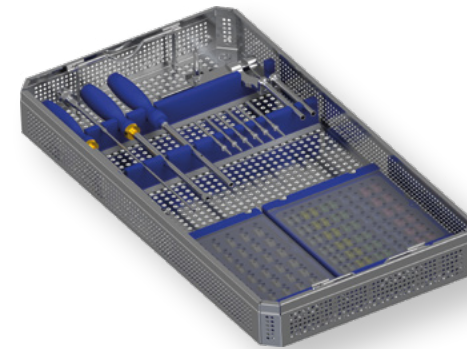
Fillable

- Filling apertures to promote fusion
- The geometry of the apertures is designed to hold the filling in place

Modular

Three freely selectable material options:

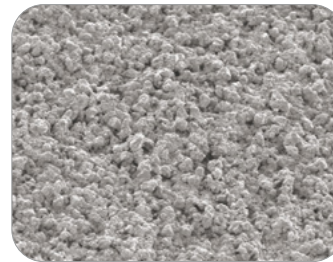
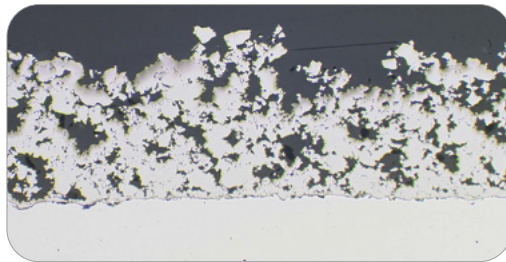
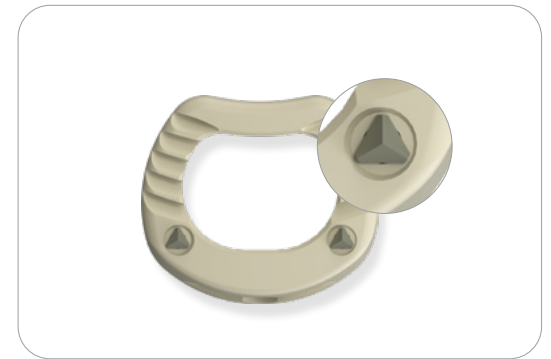
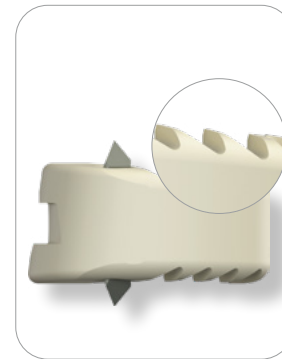
- Titanium alloy Ti6Al4V
- PEEK
- PEEK titanium-coated



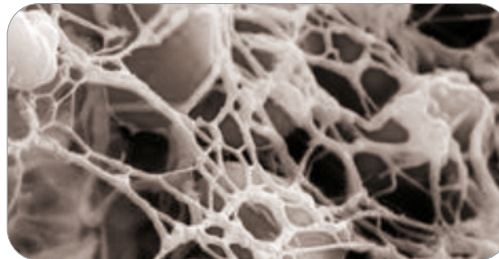
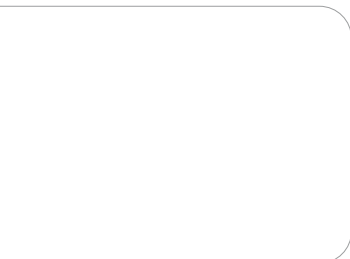
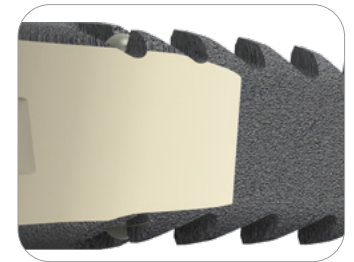
TRISTAN®

Interbody Device System

Product-specific benefits



- Anatomic
- Primary Stable
- Fillable
- Modular



Properties of TRISTAN® Titanium, PEEK-S and R-PEEK Ti

TRISTAN® Titanium

TRISTAN® titanium is a solid titanium interbody device. Only titanium alloy Ti6Al4V (DIN EN ISO 5832-3) is used which has well-known osseointegrative properties. The titanium cages are delivered in both non-sterile and sterile packaged condition.

TRISTAN® PEEK-S

TRISTAN® PEEK-S is an implant made from biocompatible PEEK-Optima. The radiotranslucent material allows assessment of the bone structure and the fusion process. The titanium spikes on the top and bottom promote anchoring in the correct position. Additional X-ray markers serve to verify three-dimensional positioning. The mechanical stability and elasticity of PEEK Optima is closer to natural bone compared to titanium.

TRISTAN® R-PEEK Ti

The titanium coating of the TRISTAN® R-PEEK Ti cages combines the advantages of two different materials in one implant. As basis of the implant serves a solid PEEK core with mechanical stability and elasticity closer to natural bone compared to titanium. This PEEK core is coated with titanium to promote its osseointegration. The coating further increases the surface area due to its roughness and thus maximize the contact zone between the implant and the vertebral body surface.

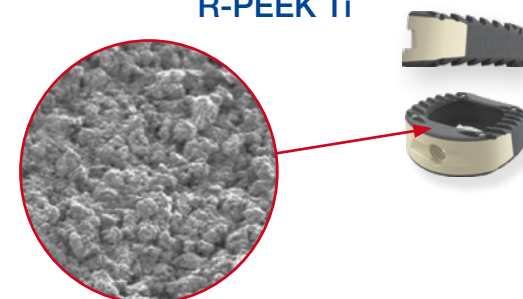
Titanium non-sterile/sterile



PEEK-S



R-PEEK Ti



Surgical technique



Exposing the intervertebral space

The intervertebral space is opened and resected by fenestration of the anterior longitudinal ligament.

Note:

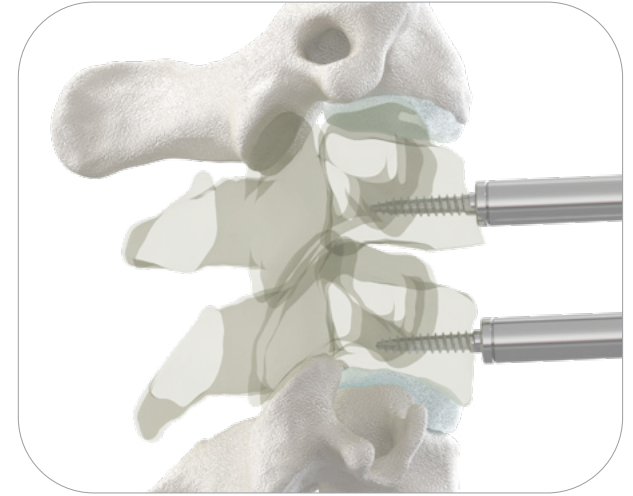
The anatomical anterior edge of the vertebral body must remain intact.



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.

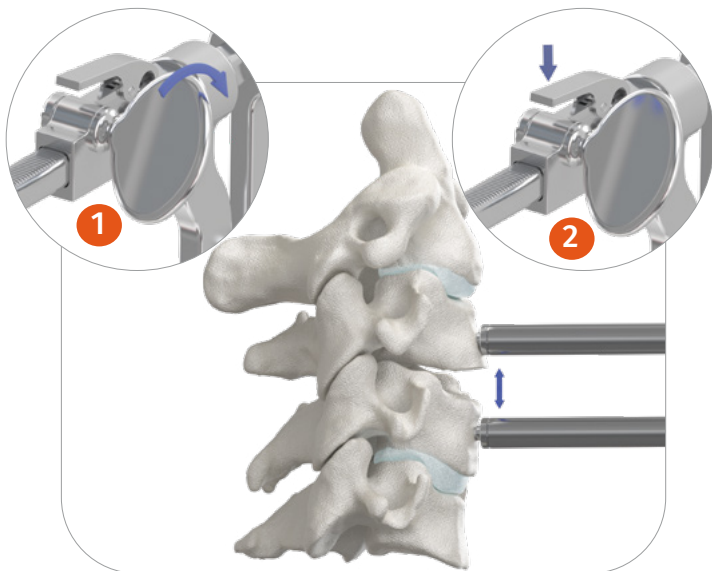


Inserting the Distraction Pins II

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.



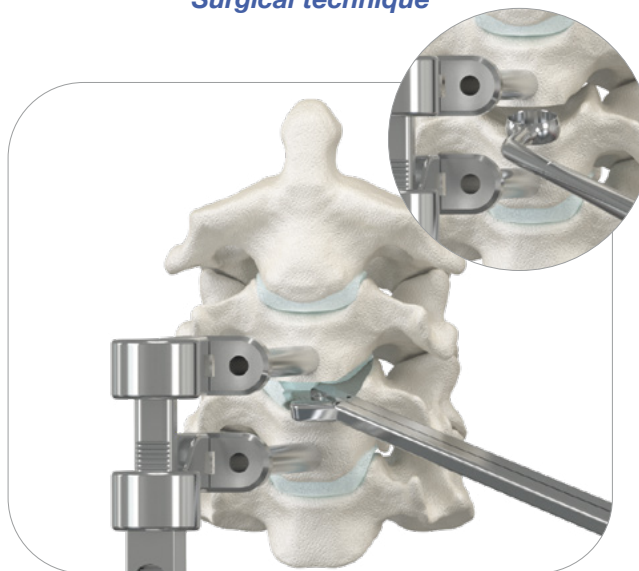
Expansion of the intervertebral space

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, 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.

Surgical technique



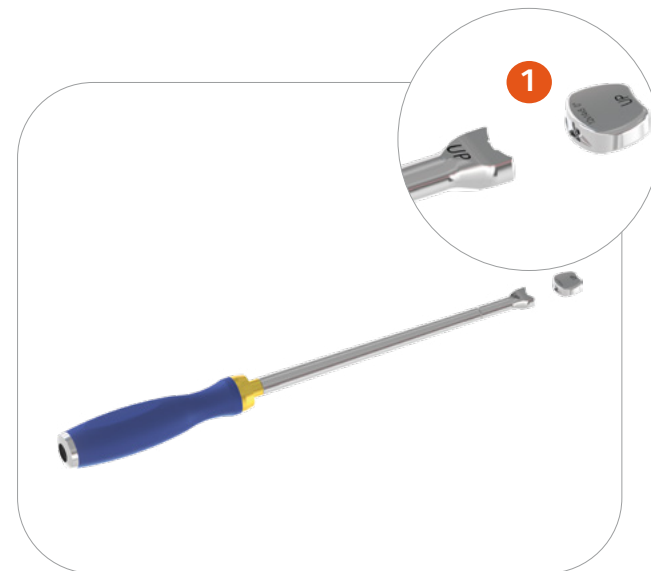
Preparation of the intervertebral space and implant bed

The intervertebral space is fully cleared and disc material is removed.

The implant bed is prepared and the endplates are freshened up e.g. using curettes.

Caution:

Care should be taken to maintain the integrity of the endplates. Damage to the endplates or excessive partial abrasion of the endplates can lead to sintering of the implant and loss of segmental stability.



Assembling the TRISTAN Trial

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

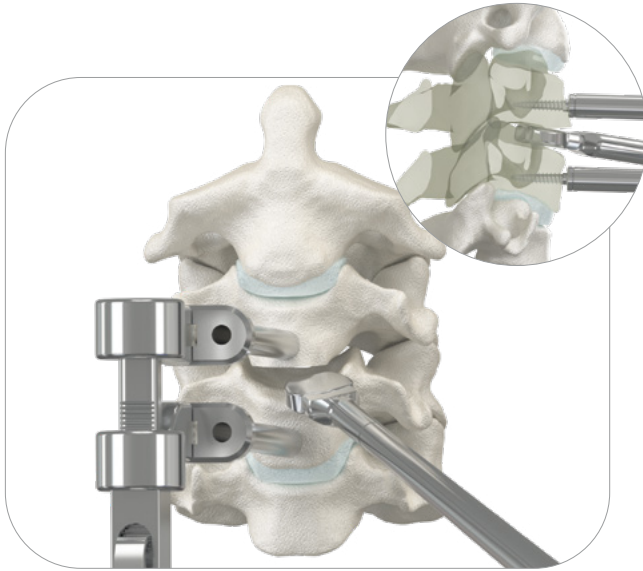
Caution:

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

Note:

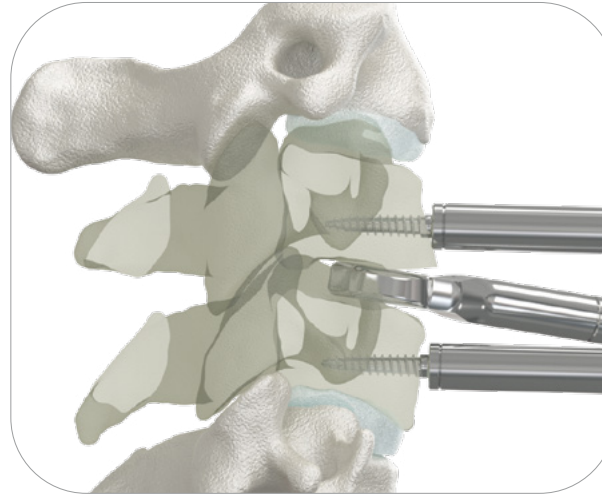
Two models of the Cage Inserter are available – one variant with a depth stop (Cage Inserter with stop) and one without (Cage Inserter).

Surgical technique



Determining the implant size I

The TRISTAN Trial is introduced into the disc space, using light hammer taps if necessary. The TRISTAN 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 TRISTAN 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 TRISTAN Trial of the next size up should be used. The lateral profile and the distraction can be assessed by X-ray control.

Caution:

The TRISTAN Trial provides information about the height of the implant. Overdistraction should be avoided. Once the implant size has been determined, the TRISTAN Trial is removed and released from the Cage Inserter.



Assembling the implant I

The implant corresponding to the TRISTAN Trial is selected and the bar of the Cage Inserter is positioned in the groove of the implant. Tristan Inserter B is screwed into the implant in order to fix it to the Cage Inserter. When assembling the cage, care should be taken to ensure that the sides marked "up" both face upwards.

Note:

To avoid damaging the implant, the implant must be firmly connected to the Cage Inserter.

Attention:

When using Tristan PEEK-S implants, the colored packaging protection must be removed after removing the implant from the sterile packaging.

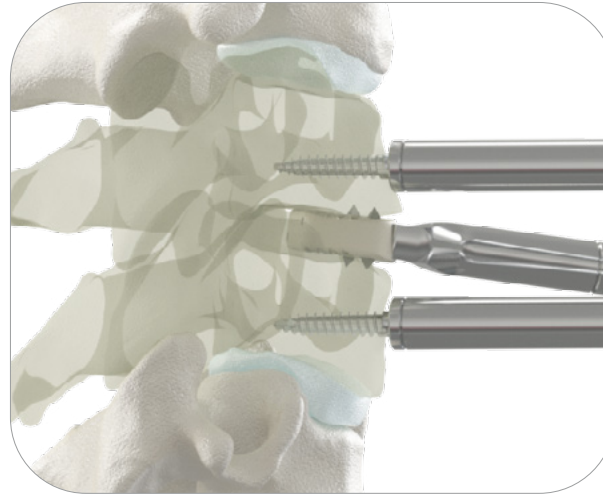
Surgical technique



Assembling the Implant II

Care should be taken to ensure that Tristan Insert B is screwed in smoothly in order to avoid deforming the thread. If necessary, the orientation of the instrument to the implant should be corrected. To prevent cross-threading while screwing in Tristan Insert B, first turn the Tristan Insert B anticlockwise until you clearly feel the thread catch. Tristan Insert B is then fully screwed into the implant.

After screwing the implant onto the Cage Insert, the cage can be filled with autologous bone material, allogeneic or other bone substitute material for faster and more secure fusion.



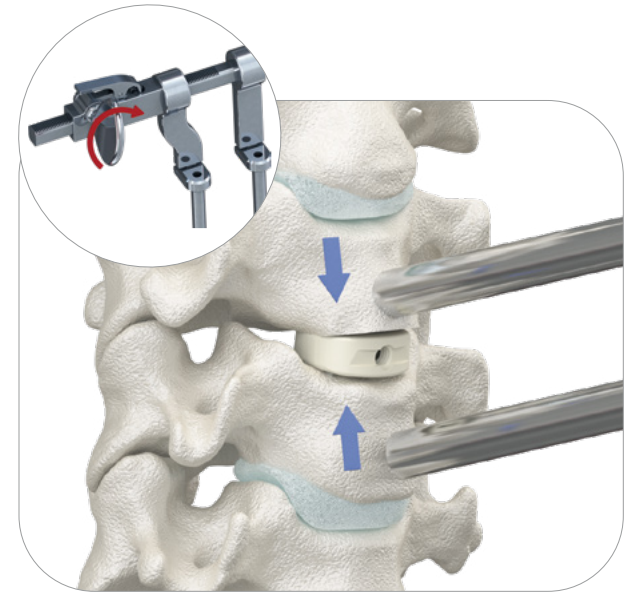
Inserting the cage

The implant is introduced into the disc space, using light hammer taps if necessary. If necessary, the implant can be hammered further using the Cage Insert without stop in order to attain optimal seating of the cage within the intervertebral space. Final seating of the implant must be checked using X-ray.

The insertion instrument can also be used to correct the position of the implant. For this, the bar of the Cage Insert must be positioned in the groove of the implant. Tristan Insert B is screwed into the implant in order to fix it to the Cage Insert. When setting up the inserter subsequently, care should be taken to ensure that the sides marked "UP" face upwards.

Note:

To avoid damage to the implant, the implant must be firmly connected to the Cage Insert.



Compressing the vertebral bodies (where TRISTAN® PEEK-S implants are used)

Once the cage has been inserted into its final position, care should be taken to ensure that the spikes of the cage penetrate the base plate and cover plate. 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.

Positioning the markers in TRISTAN® PEEK-S and TRISTAN® R-PEEK Ti

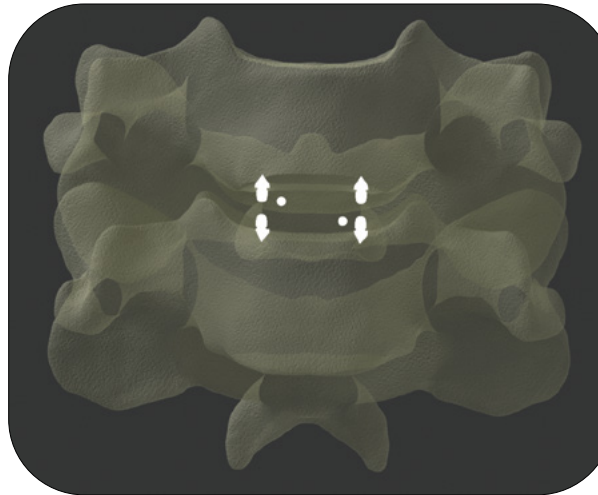
To ensure the cage is positioned correctly, it must be placed in a central position after insertion into the disc space.

The X-ray markers fitted within PEEK implants allow the implant position to be visualised using a fluoroscope. This enables the exact location of the cage to be assessed using X-ray images.

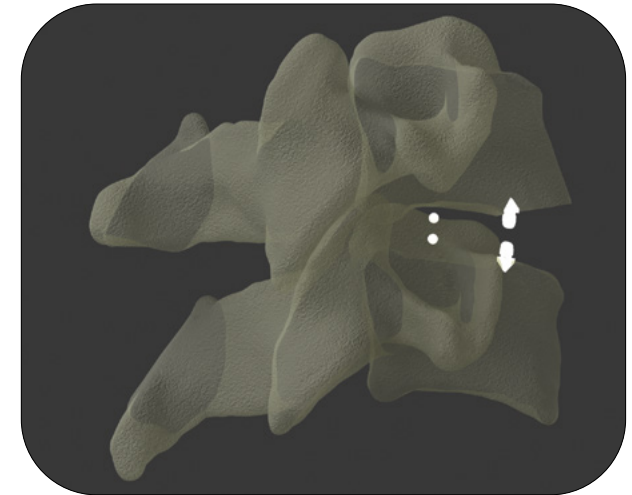
Two markers are built into TRISTAN® PEEK-S implants on the posterior implant margin, along with 4 spikes at the lateral anterior implant margin which also serve as markers. The four anterior markers show the maximum width of the cage. In combination with the two posterior markers, these allow the implant depth to be assessed. For TRISTAN® PEEK-S implants, the markers appear as shown in the X-ray image when the implant is positioned centrally within the disc space.



**TRISTAN®
PEEK-S**



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



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

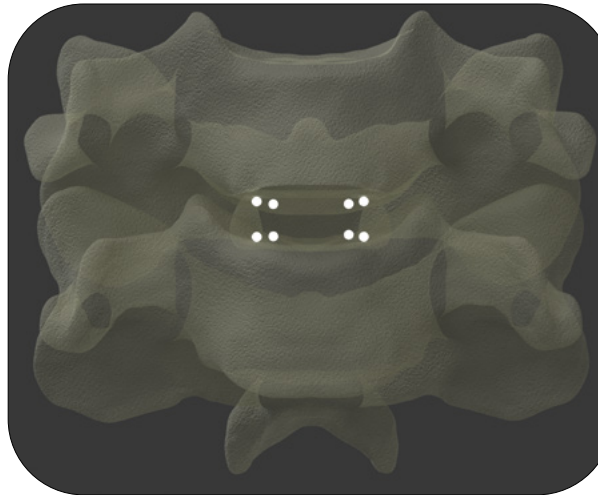
Positioning the markers in TRISTAN® PEEK-S and TRISTAN® R-PEEK Ti

In TRISTAN® R-PEEK Ti implants, four markers are located at the posterior implant margin and four markers are located laterally at the anterior implant margin.

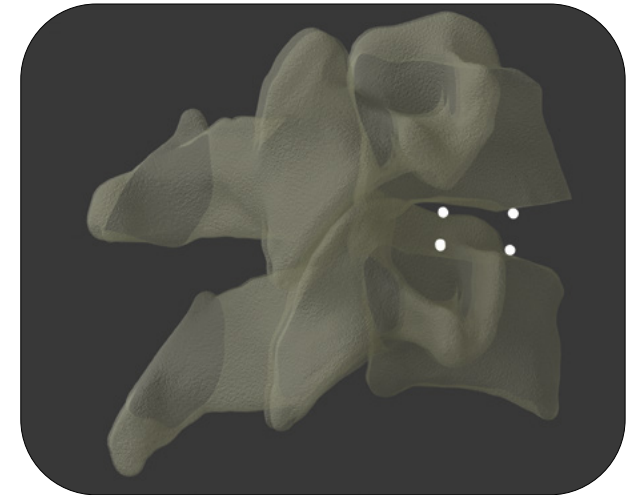
The four anterior markers show the maximum width of the cage. In combination with the four posterior markers, these allow the implant depth to be assessed. In TRISTAN® R-PEEK Ti implants, the four posterior and four anterior markers appear as shown in the X-ray image when the implant is positioned centrally within the disc space.



**TRISTAN®
R-PEEK Ti**



AP view X-ray
of a centrally positioned TRISTAN® R-PEEK Ti
cage



Sagittal view X-ray
of a centrally positioned TRISTAN® R-PEEK Ti
cage

TRISTAN® Titanium (sterile)

Implants



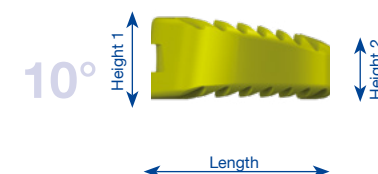
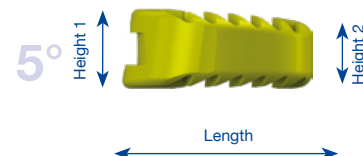
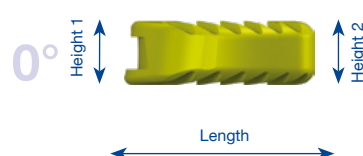
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1501040307-S	Tristan Ti 12x14x7 10° sterile	12	14	9	7	10°
1501040308-S	Tristan Ti 12x14x8 10° sterile	12	14	10	8	10°
1501050304-S	Tristan Ti 14x16x4 10° sterile	14	16	6	4	10°
1501050305-S	Tristan Ti 14x16x5 10° sterile	14	16	7	5	10°
1501050306-S	Tristan Ti 14x16x6 10° sterile	14	16	8	6	10°
1501050307-S	Tristan Ti 14x16x7 10° sterile	14	16	9	7	10°
1501050308-S	Tristan Ti 14x16x8 10° sterile	14	16	10	8	10°
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1502071205-S	Tristan Ti 12x14x5 5° sterile	12	14	6	5	5°
1502071206-S	Tristan Ti 12x14x6 5° sterile	12	14	7	6	5°
1502071207-S	Tristan Ti 12x14x7 5° sterile	12	14	8	7	5°
1502071208-S	Tristan Ti 12x14x8 5° sterile	12	14	9	8	5°
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1502071405-S	Tristan Ti 14x16x5 5° sterile	14	16	6	5	5°
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1502071408-S	Tristan Ti 14x16x8 5° sterile	14	16	9	8	5°

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1502081208-S	Tristan Ti 12x14x8 0° sterile	12	14	8	8	0°
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1502081406-S	Tristan Ti 14x16x6 0° sterile	14	16	6	6	0°
1502081407-S	Tristan Ti 14x16x7 0° sterile	14	16	7	7	0°
1502081408-S	Tristan Ti 14x16x8 0° sterile	14	16	8	8	0°

12 mm x 14 mm



14 mm x 16 mm



TRISTAN® Titanium (non-sterile)



Implants

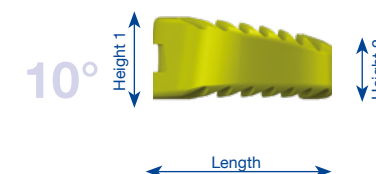
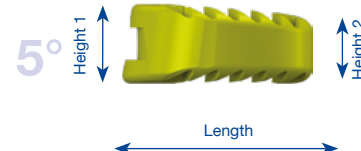
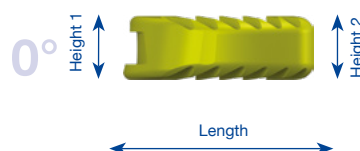
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1501040307	Tristan Ti 12x14x7	12	14	9	7	10°
1501040308	Tristan Ti 12x14x8	12	14	10	8	10°
1501050304	Tristan Ti 14x16x4	14	16	6	4	10°
1501050305	Tristan Ti 14x16x5	14	16	7	5	10°
1501050306	Tristan Ti 14x16x6	14	16	8	6	10°
1501050307	Tristan Ti 14x16x7	14	16	9	7	10°
1501050308	Tristan Ti 14x16x8	14	16	10	8	10°
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1502071207	Tristan Ti 12x14x7 5°	12	14	8	7	5°
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1502071405	Tristan Ti 14x16x5 5°	14	16	6	5	5°
1502071406	Tristan Ti 14x16x6 5°	14	16	7	6	5°
1502071407	Tristan Ti 14x16x7 5°	14	16	8	7	5°
1502071408	Tristan Ti 14x16x8 5°	14	16	9	8	5°

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1502081207	Tristan Ti 12x14x7 0°	12	14	7	7	0°
1502081208	Tristan Ti 12x14x8 0°	12	14	8	8	0°
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1502081407	Tristan Ti 14x16x7 0°	14	16	7	7	0°
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12 mm x 14 mm



14 mm x 16 mm



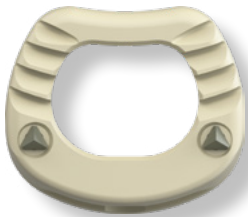
TRISTAN® PEEK-S (sterile)



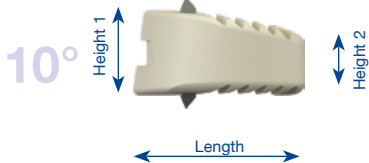
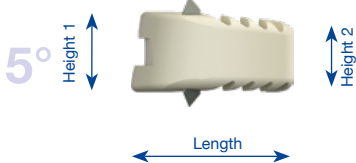
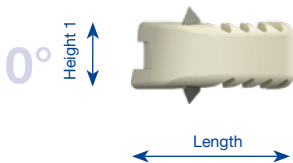
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1502101307	Tristan PEEK - S 12x14x7 0°	12	14	7	7	0°
1502101308	Tristan PEEK - S 12x14x8 0°	12	14	8	8	0°
1502101504	Tristan PEEK - S 14x16x4 0°	14	16	4	4	0°
1502101505	Tristan PEEK - S 14x16x5 0°	14	16	5	5	0°
1502101506	Tristan PEEK - S 14x16x6 0°	14	16	6	6	0°
1502101507	Tristan PEEK - S 14x16x7 0°	14	16	7	7	0°
1502101508	Tristan PEEK - S 14x16x8 0°	14	16	8	8	0°

12 mm x 14 mm



14 mm x 16 mm



TRISTAN® R-PEEK Ti (Peek with titanium coating) sterile

Item no.	Name	Length	Width	Height 1	Height 2	Angle
1502131204	Tristan R-PEEK-Ti Coated 12x14x4 10°	12	14	6	4	10°
1502131205	Tristan R-PEEK-Ti Coated 12x14x5 10°	12	14	7	5	10°
1502131206	Tristan R-PEEK-Ti Coated 12x14x6 10°	12	14	8	6	10°
1502131207	Tristan R-PEEK-Ti Coated 12x14x7 10°	12	14	9	7	10°
1502131208	Tristan R-PEEK-Ti Coated 12x14x8 10°	12	14	10	8	10°
1502131404	Tristan R-PEEK-Ti Coated 14x16x4 10°	14	16	6	4	10°
1502131405	Tristan R-PEEK-Ti Coated 14x16x5 10°	14	16	7	5	10°
1502131406	Tristan R-PEEK-Ti Coated 14x16x6 10°	14	16	8	6	10°
1502131407	Tristan R-PEEK-Ti Coated 14x16x7 10°	14	16	9	7	10°
1502131408	Tristan R-PEEK-Ti Coated 14x16x8 10°	14	16	10	8	10°
1502151204	Tristan R-PEEK-Ti Coated 12x14x4 5°	12	14	5	4	5°
1502151205	Tristan R-PEEK-Ti Coated 12x14x5 5°	12	14	6	5	5°
1502151206	Tristan R-PEEK-Ti Coated 12x14x6 5°	12	14	7	6	5°
1502151207	Tristan R-PEEK-Ti Coated 12x14x7 5°	12	14	8	7	5°
1502151208	Tristan R-PEEK-Ti Coated 12x14x8 5°	12	14	9	8	5°
1502151404	Tristan R-PEEK-Ti Coated 14x16x4 5°	14	16	5	4	5°
1502151405	Tristan R-PEEK-Ti Coated 14x16x5 5°	14	16	6	5	5°
1502151406	Tristan R-PEEK-Ti Coated 14x16x6 5°	14	16	7	6	5°
1502151407	Tristan R-PEEK-Ti Coated 14x16x7 5°	14	16	8	7	5°
1502151408	Tristan R-PEEK-Ti Coated 14x16x8 5°	14	16	9	8	5°

Implants

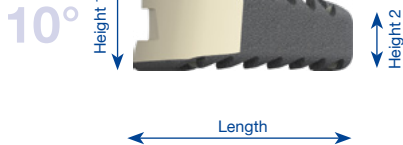
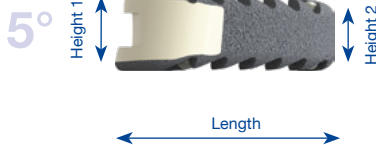
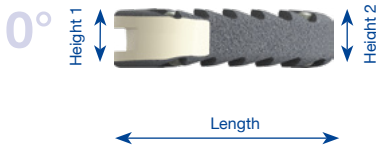


Item no.	Name	Length	Width	Height 1	Height 2	Angle
1502141204	Tristan R-PEEK-Ti Coated 12x14x4 0°	12	14	4	4	0°
1502141205	Tristan R-PEEK-Ti Coated 12x14x5 0°	12	14	5	5	0°
1502141206	Tristan R-PEEK-Ti Coated 12x14x6 0°	12	14	6	6	0°
1502141207	Tristan R-PEEK-Ti Coated 12x14x7 0°	12	14	7	7	0°
1502141208	Tristan R-PEEK-Ti Coated 12x14x8 0°	12	14	8	8	0°
1502141404	Tristan R-PEEK-Ti Coated 14x16x4 0°	14	16	4	4	0°
1502141405	Tristan R-PEEK-Ti Coated 14x16x5 0°	14	16	5	5	0°
1502141406	Tristan R-PEEK-Ti Coated 14x16x6 0°	14	16	6	6	0°
1502141407	Tristan R-PEEK-Ti Coated 14x16x7 0°	14	16	7	7	0°
1502141408	Tristan R-PEEK-Ti Coated 14x16x8 0°	14	16	8	8	0°

12 mm x 14 mm



14 mm x 16 mm





Item no.	Name
1502010038	TRISTAN Trial 12x14x4 10°
1502010039	TRISTAN Trial 12x14x5 10°
1502010040	TRISTAN Trial 12x14x6 10°
1502010041	TRISTAN Trial 12x14x7 10°
1502010042	TRISTAN Trial 12x14x8 10°
1502010043	TRISTAN Trial 14x16x4 10°
1502010044	TRISTAN Trial 14x16x5 10°
1502010045	TRISTAN Trial 14x16x6 10°
1502010046	TRISTAN Trial 14x16x7 10°
1502010047	TRISTAN Trial 14x16x8 10°

10°

1502010017	TRISTAN Trial 12x14x4 5°
1502010018	TRISTAN Trial 12x14x5 5°
1502010019	TRISTAN Trial 12x14x6 5°
1502010020	TRISTAN Trial 12x14x7 5°
1502010021	TRISTAN Trial 12x14x8 5°
1502010027	TRISTAN Trial 14x16x4 5°
1502010028	TRISTAN Trial 14x16x5 5°
1502010029	TRISTAN Trial 14x16x6 5°
1502010030	TRISTAN Trial 14x16x7 5°
1502010031	TRISTAN Trial 14x16x8 5°

5°











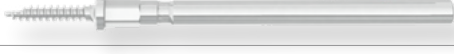
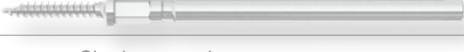



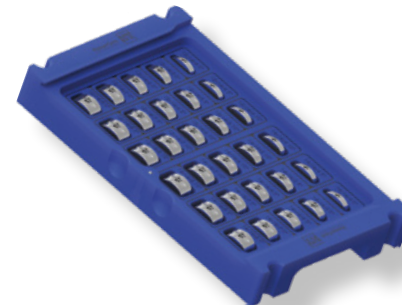
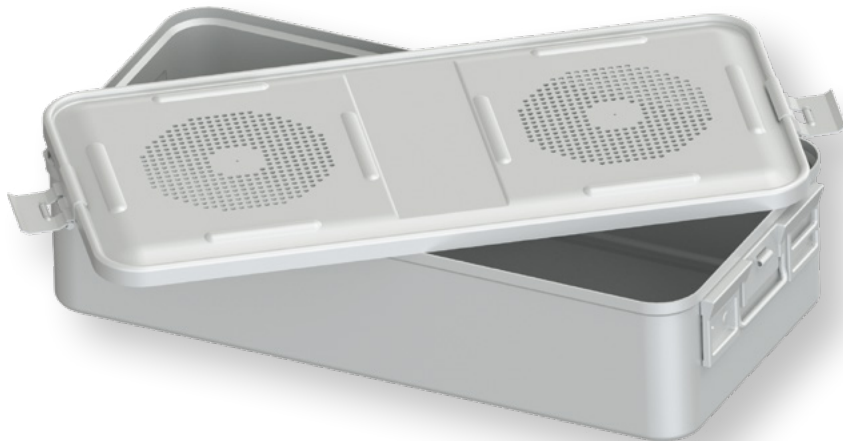
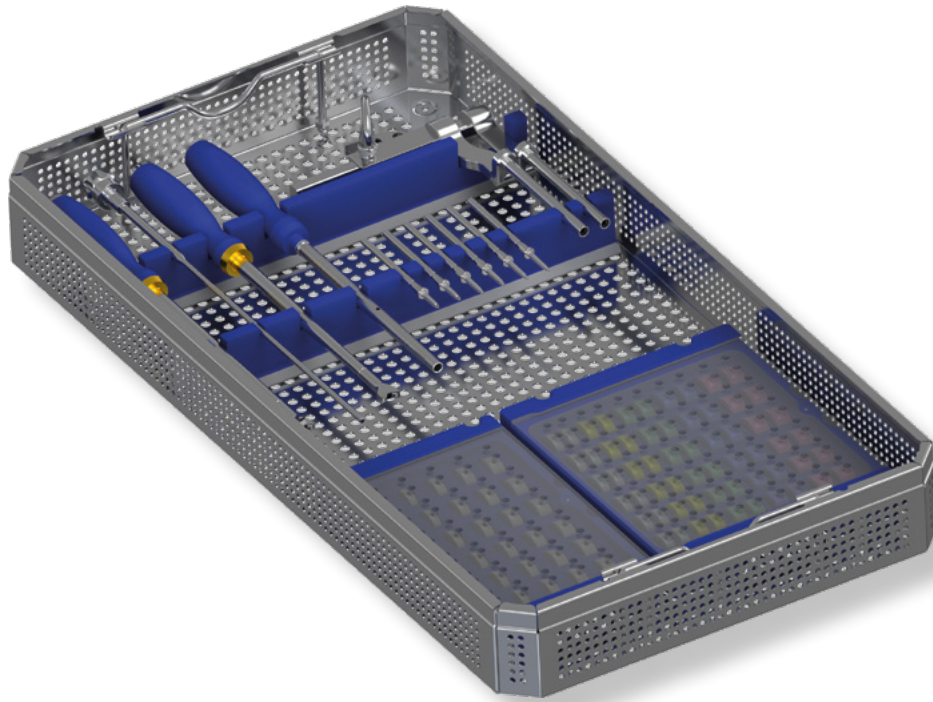
Item no.	Name
1502010022	TRISTAN Trial 12x14x4 0°
1502010023	TRISTAN Trial 12x14x5 0°
1502010024	TRISTAN Trial 12x14x6 0°
1502010025	TRISTAN Trial 12x14x7 0°
1502010026	TRISTAN Trial 12x14x8 0°
1502010032	TRISTAN Trial 14x16x4 0°
1502010033	TRISTAN Trial 14x16x5 0°
1502010034	TRISTAN Trial 14x16x6 0°
1502010035	TRISTAN Trial 14x16x7 0°
1502010036	TRISTAN Trial 14x16x8 0°

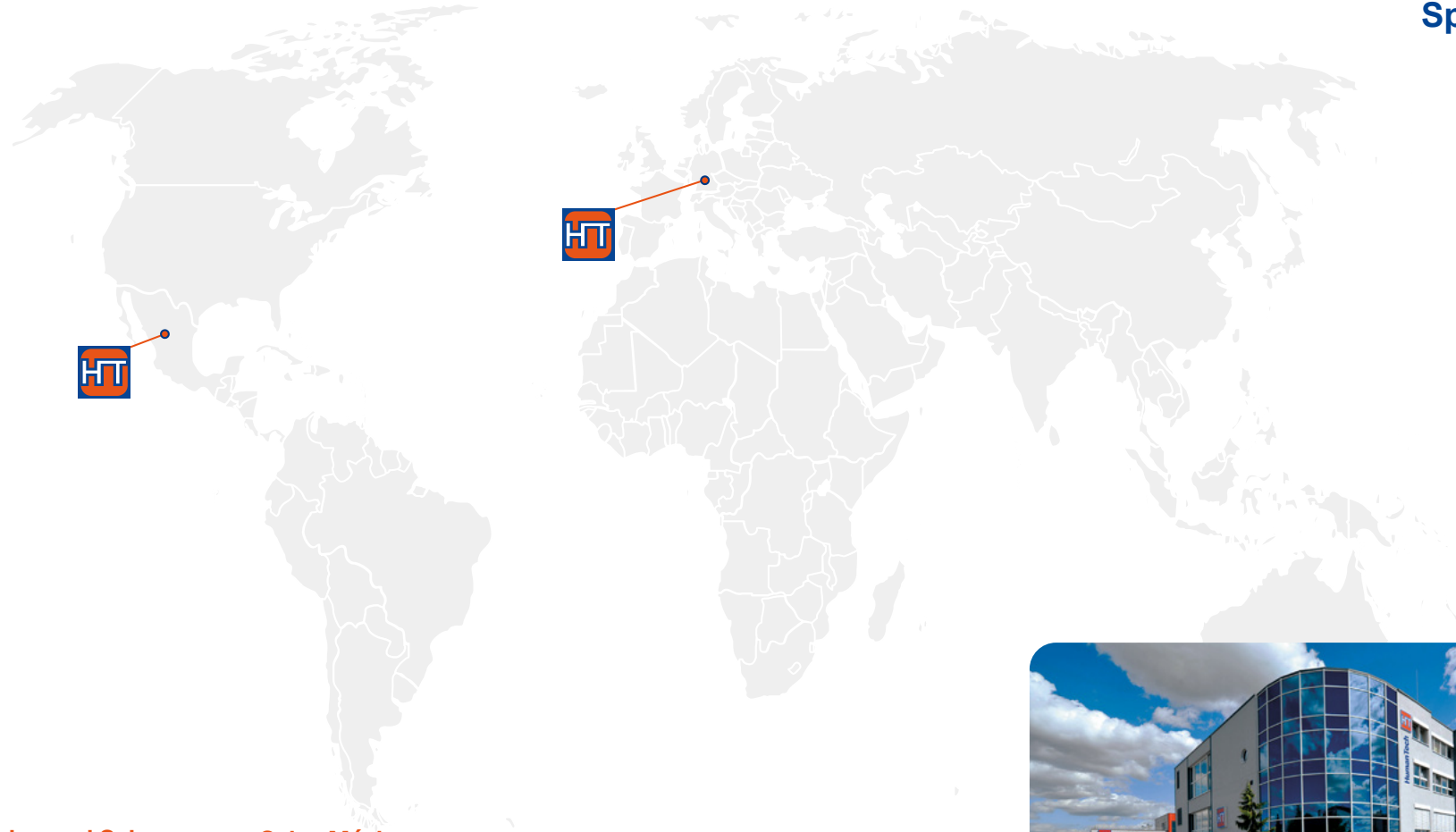
0°



Instruments

Item no.	Description	Illustration
1501010001	Cage Inserter	
1501010002	Cage Inserter with stop	
1501010001B	Tristan Inserter B	
1501010011	Pindriver	
1501010022	Distraction Pin14mm	-Single use only- 
1501010023	Distraction Pin16mm	-Single use only- 
1501010024	Distraction Pin18mm	-Single use only- 
1501010010	Retrieval body retractor	
1501010022-S	Distraction Pin14mm sterile	STERILE -Single use only- 
1501010023-S	Distraction Pin16mm sterile	STERILE -Single use only- 
1501010024-S	Distraction Pin18mm sterile	STERILE -Single use only- 





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