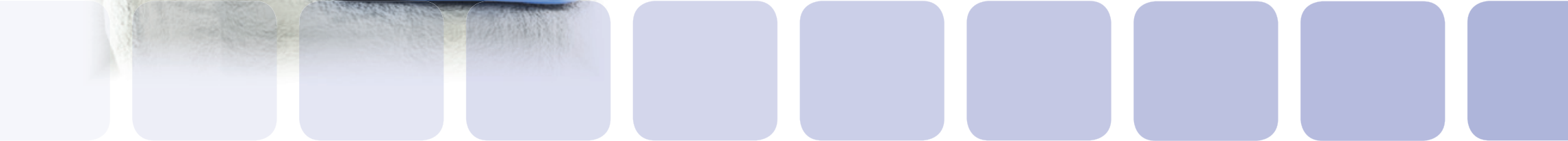




TRISTAN[®]flex

Cervical Interbody Fusion



TRISTAN®flex is an intelligent and, due to its associated instruments, highly rational cervical interbody device system.

TRISTAN®flex is an extension of the existing Tristan system. Thanks to its expansion mechanism, the TRISTAN®flex allows the surgeon greater precision in the restoration of the natural lordosis of the spine, for which the angulation can be set individually in situ for each patient.

The TRISTAN®flex system is inserted via anterior access and cervical discectomy and offers the following exceptional 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 – reduced risk of migration
- Adjustable angulation (5 ° -10 °) for direct reconstruction of the sagittal profile in situ

stable

- Antegrade toothings for stable anchorage with additional spikes for optimum primary fixation (stand-alone)
- Latch mechanism to secure the selected angulation
- Fixed connection to the inserter by a clamping mechanism

reliable

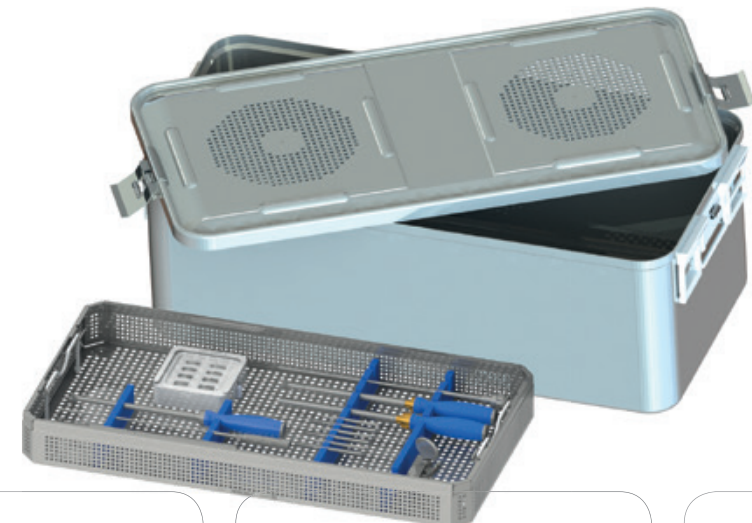
- Filling aperture for rapid fusion

biocompatible

- The basic body of the TRISTAN®flex is made of our PEEK material, which has been tested according to ISO 10993 and classified to USP-VI. PEEK has a mechanical stability of 3.6 GPa, allowing for optimal load transmission between the implant material and the natural bone. The titanium components of the TRISTAN®flex are extremely biocompatible. The osseointegrative properties of titanium (Ti 6Al-4V to ISO 5832-3) are well documented and facilitate direct bone growth.

safe

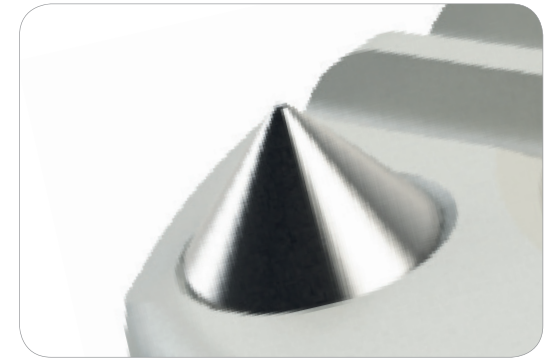
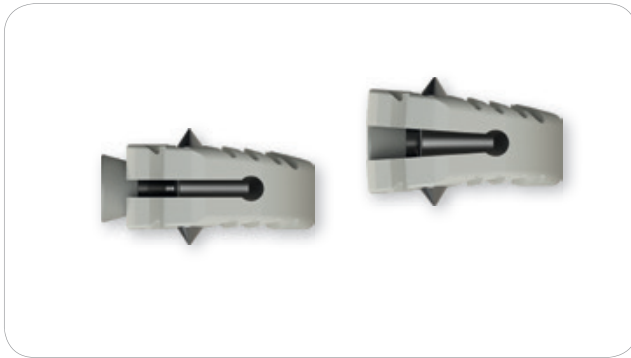
- Radiopaque markers at the trailing edge for identification under X-ray control



TRISTAN[®] flex

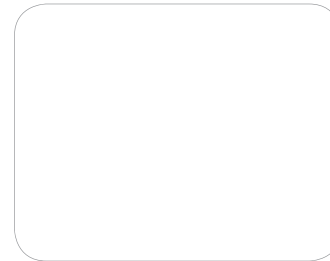
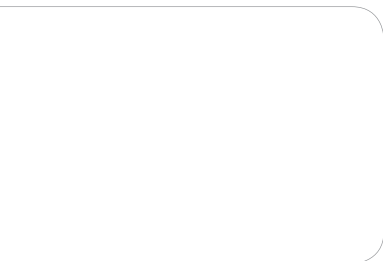
Interbody Device System

product specific advantages



Four outstanding product characteristics

- 1 insitu adjustment to anatomical conditions
- 2 avoiding interbody stress peaks at the endplates
- 3 gentle reconstruction of sagittal profile by lordosis of the mobile segment (5 ° -10 °)
- 4 stand-alone with titanium spikes and antegrade toothing



TRISTAN®flex

TRISTAN®flex is an flex implant made from biocompatible PEEK-Optima® for the cervical interbody fusion used to treat degenerative disc diseases and instabilities in discs C3-C7. Thanks to its expansion mechanism, the TRISTAN®flex gives the surgeon greater precision in the restoration of the natural lordosis of the spine. This mechanism makes it extremely easy to individually adjust the angulation in situ to each patient during surgery and integral titanium spikes enable additional primary fixation.

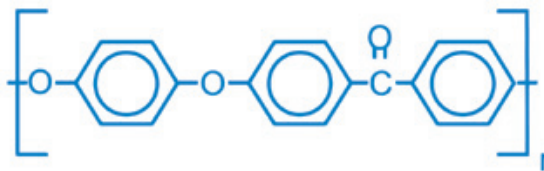
PEEK properties

- PEEK is radiolucent and does not generate artifacts
- Extremely strong, durable and highly resistant to fatigue
- Bone-like modulus helps to minimize tension peaks and to stimulate bone healing
- PEEK-OPTIMA® is successfully used in spinal interbody fusion supply for 15 years

Titanium properties

The titanium spikes and expansion mechanism used are made of tried and tested Ti 6Al- 4V to ISO 5832-3, which has been proven to be exceptionally biocompatible and correspondingly modifiable.

PEEK-OPTIMA® is a polyaromatic, semi-crystalline thermoplastic, which is based on the basic formula $(-C_6H_4-O-C_6H_4-O-C_6H_4-CO-)_n$ and which is generally known as polyetheretherketone.



Retracted

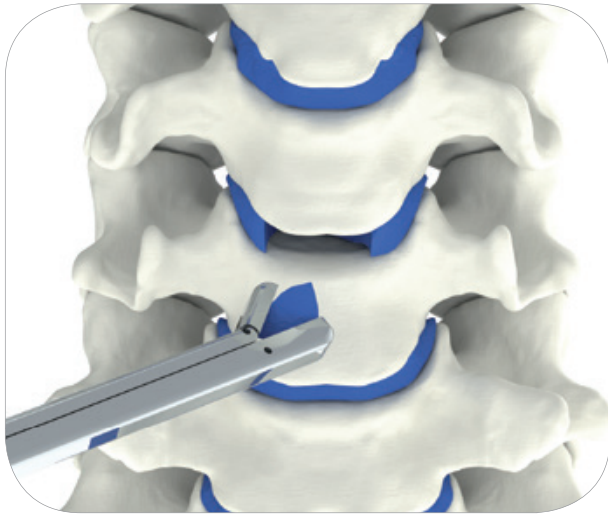


Expanded

TRISTAN[®] flex

Interbody Device System



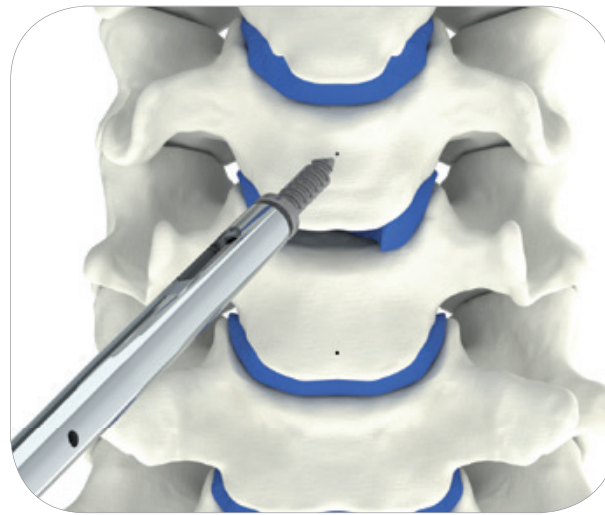


Exposure of the intervertebral space

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.

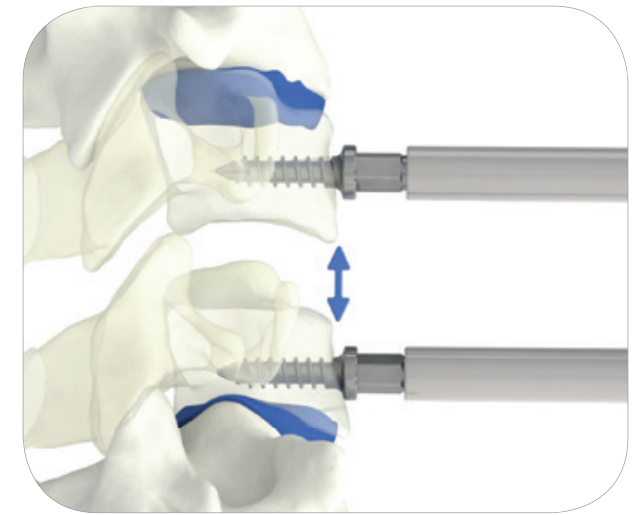
Note:

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



Inserting the intervertebral spreader

Placing the distraction pins in the respective caudal and cranial spine. Position as centrally as possible in the vertebral body. In osteoporotic bony conditions, the distraction pins can also be inserted close to the endplates in order to achieve better and more secure anchoring and spread stability .

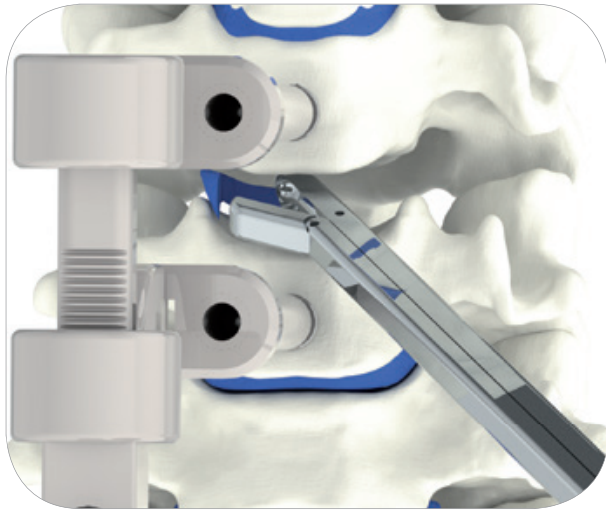


Spreading the intervertebral space

Careful spreading of the intervertebral space using the Retrieval Body Retractor and exposure of the intervertebral space as far as the rear edge, and if necessary, resection of the osteophytes on the vertebral body rear edge and full mobilisation of the intervertebral space by opening up the rear longitudinal ligament.

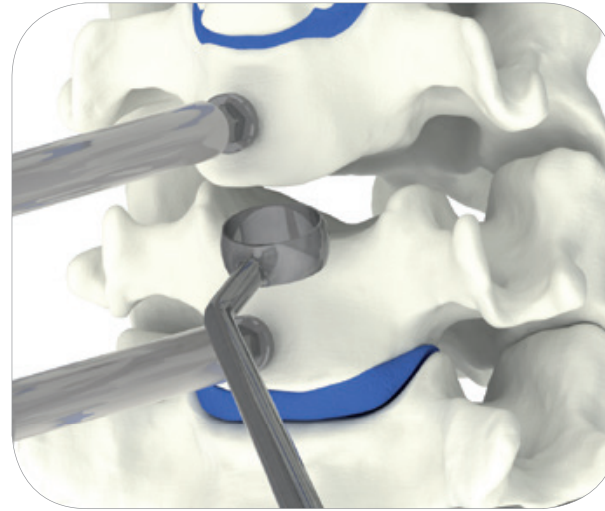
Note:

The distraction pins are designed for single use only!



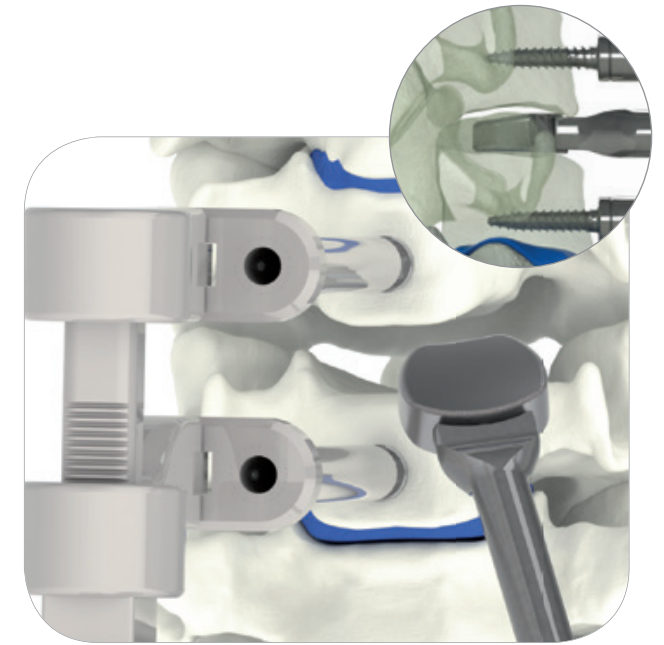
Preparing the intervertebral space

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



Preparation of the implant bed

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



Determining the implant size

The trial implant should fit maximally into the prepared intervertebral space. The trial implant is sitting correctly, if the front edge is placed 1-2mm behind the front edge of the vertebral body and occupies the length of about 4/5 of the anterior-posterior extent of the intervertebral space and ends in front of the rear edge of the vertebral bodies.

Note:

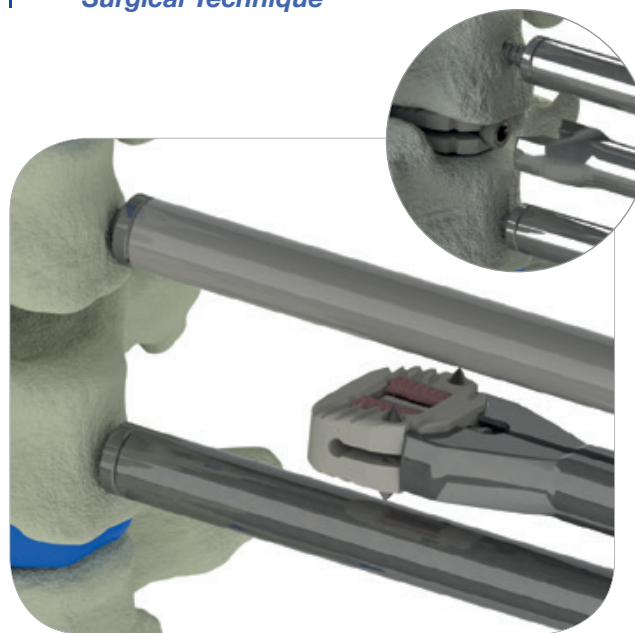
The trial implant provides information about height of the base body in the retracted state without spikes. In order to minimize violations of the cover plates by the titanium spikes, a further distraction (1-2mm) is provided. Here, an overdistract is to prevent. Fluoroscopic control to assess the lateral profile and the stage of distraction.



Filling the implant

Remove the selected TRISTAN®flex from the sterile outer packaging and separate from the sterile coloured packaging aid. Put the implant on the front of the Tristan F Inserter flat and fix it by turning the handle. After assembly on the inserter, for faster and more secure fusion, the cage can be filled with autologous bone material or with allogenic or other bone replacement material.

Surgical Technique



Insertion of the cage

Implantation of the cage using the associated insertion instrument. When doing so, pay attention to the direction of insertion of the implant. The arrow on the implant must point in the cranial direction. As soon as the implant is correctly positioned in the intervertebral space, the insertion instrument must be loosened. The Tristan F Driver can be used to distract the implant through the cannulated inserter. For this purpose, the distraction screw is screwed into the implant. The implant has three levels which prevent screw migration.



Expansion of the cage

The Tristan F Driver can be used to distract the implant through the cannulated inserter. For this purpose, the distraction screw is screwed into the implant. The implant has three levels which prevent screw migration. In the initial position, the implant has an angulation of 5°, in the interim position, 7.5°, and with complete distraction, 10°. For 7.5°, the screwdriver (Tristan F Driver) should be turned approximately 2 turns to the right (see picture). When distraction is complete, the distraction screw is turned up to the stop and must not be turned over.

Final review of the implant fit using image converter checks.



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 four 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.

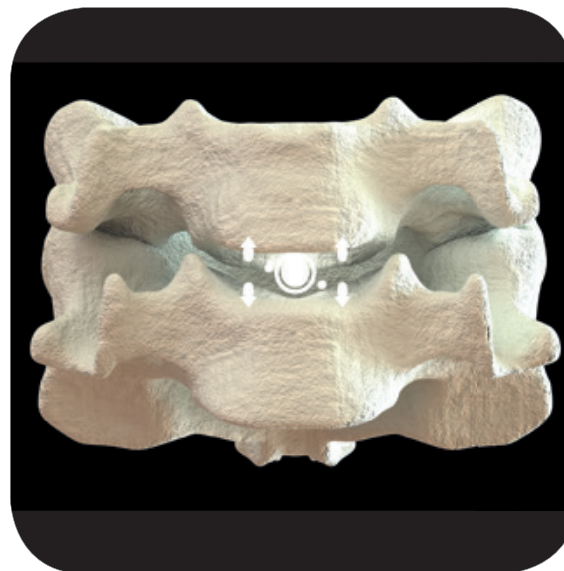
The TRISTAN@flex has two tantalum beads in the medial area of the implant posterior edge and four titanium spikes in the lateral area of the anterior implant edge. The four anterior markers are used to indicate the maximum width of the cage. The implant depth can be estimated in combination with the two posterior markers. With TRISTAN@flex implants, the two posterior and four anterior markers are visible on the X-ray for an implant placed centrally within the disc space. The expansion screw and the interior shell of the implant are also clearly visible.



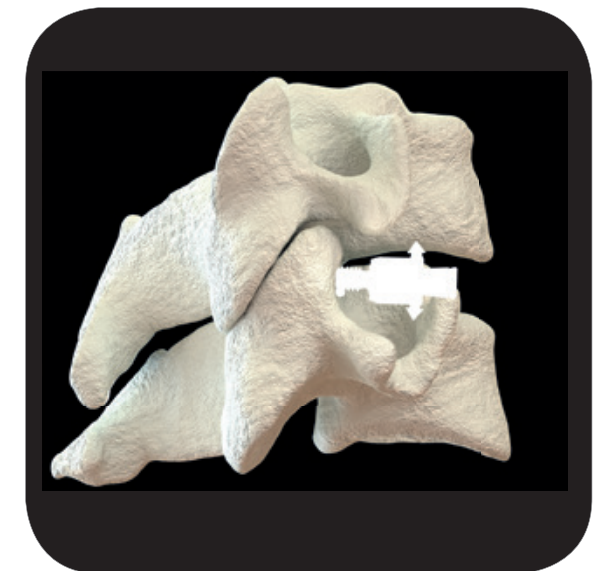
Anteroposterior view
of a centrally positioned TRISTAN@flex cage



Sagittal view
of a centrally positioned TRISTAN@flex cage



Anteroposterior X-ray view
of a centrally positioned TRISTAN@flex cage

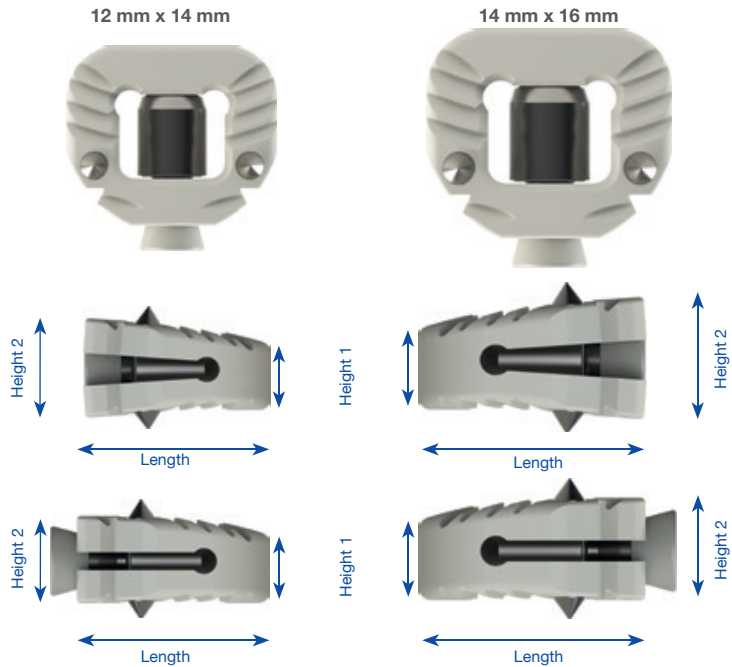
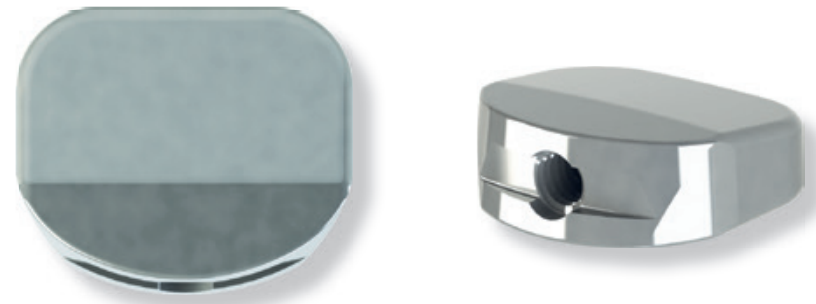


Sagittal X-ray view
of a centrally positioned TRISTAN@flex cage









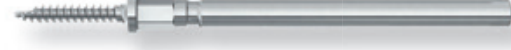
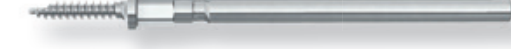

Item no.	Name	Length	Width	Height 1	∠ 5° Height 2	∠ 7.5° Height 2	∠ 10° Height 2
1503121405	Tristan Flex 12x14x05	12	14	4.2	5.4	5.9	6.4
1503121406	Tristan Flex 12x14x06	12	14	5.2	6.4	6.9	7.4
1503121407	Tristan Flex 12x14x07	12	14	6.2	7.4	7.9	8.4
1503121408	Tristan Flex 12x14x08	12	14	7.2	8.4	8.9	9.4
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

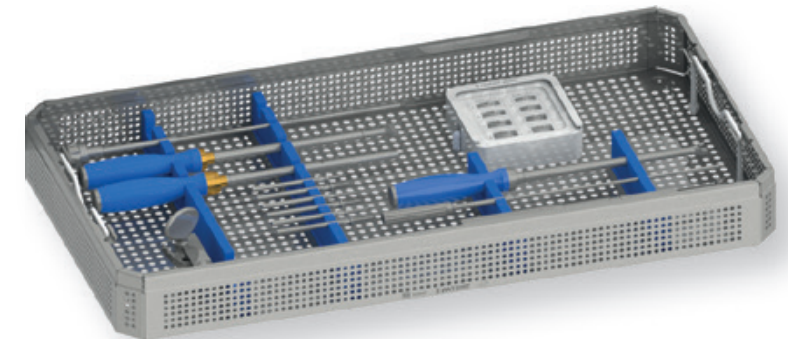
Item no.	Name
1503012145	TF Trial 12x14x05 5°
1503012146	TF Trial 12x14x06 5°
1503012147	TF Trial 12x14x07 5°
1503012148	TF Trial 12x14x08 5°
1503014165	TF Trial 14x16x05 5°
1503014166	TF Trial 14x16x06 5°
1503014167	TF Trial 14x16x07 5°
1503014168	TF Trial 14x16x08 5°

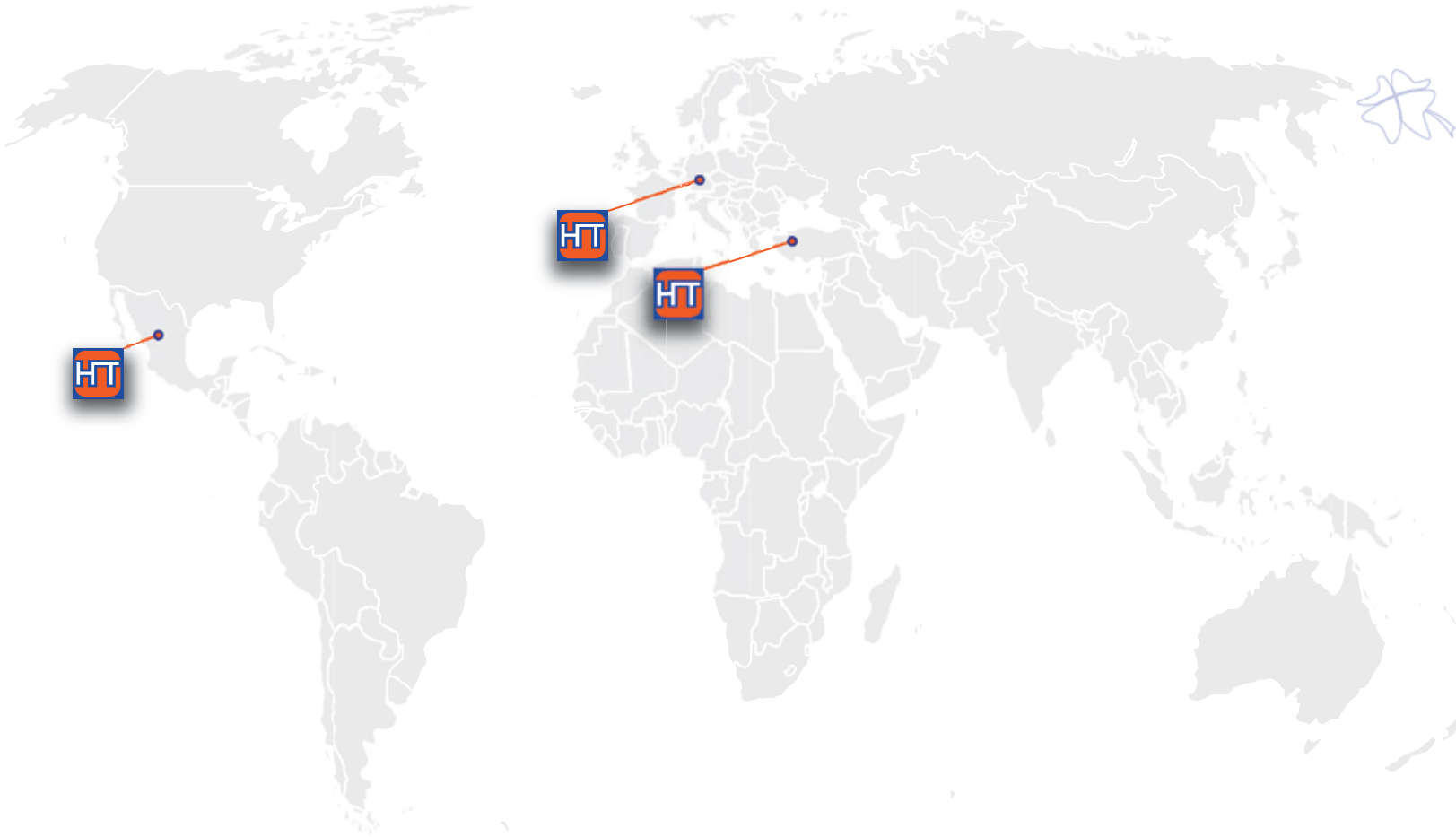
5°



10°
5°

Item no.	Description	
1501010001	Cage inserter	
1501010001	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	Retrieval body retractor	





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