HumanTech
Smart German Solutions

TRISTAN®

CERVICAL INTERBODY FUSION SYSTEM

TRISTAN® is an intelligent interbody device system made highly efficient by its instrumentation, representing a universally acknowledged product line for cervical indications. It opens up scope for the surgeon to achieve extreme precision combined with fast, safe implantation.

TRISTAN® is deployed following anterior access and cervical discectomy and offers following outstanding product-specific benefits:

Anatomical Design

• Form is analogous to the anatomical in cross-section as well as in the sagittal profile.
• Large contact area designed to reduce the risk of migration.

Stability

• Antegrade toothing for solid adherence (not all variants)
• Convex-Cranial formed contact areas to insure an integrated, continuous and durable fitting.

Integrity

• Large graft area to facilitate filling material for a more rapid fusion (not all variants).
• The circular groove inside the graft area contains the filling material and increases the filling capacity.

Modularity

Due to three free-to-choose material options:

• **Titanium**
It has been found out, that titanium is highly biocompatible and yet modifiable. Numerous studies have proved, that human cells are not influenced negatively by the few nanometer thin surface oxide of titanium materials, instead, its growth is activated through an appropriate surface structure.

• **PEEK**
Our PEEK-material is tested under ISO 10993, classified under US P-VI, there are available corresponding FDA Device und Drug Master Files. Due to its characteristics and approvals, PEEK is predestined for the use as implant material.

• **PEEK-Ti-coated**
The titanium coat offers an optimum basis due to its balanced ratio between pore depth, porosity and roughness, at the same time it has proved to be the ideal material as it stimulates bone cells in attaching to the implant. The osseointegrative characteristics of titanium facilitate the direct adhesion between bone and implant.

TRISTAN®

Interbody Device System

Product-Specific Advantages

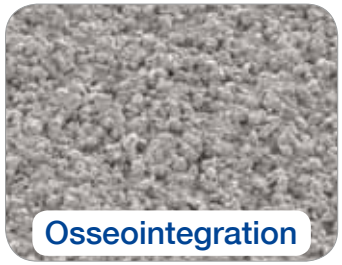
Modularity

Integrity

Stability

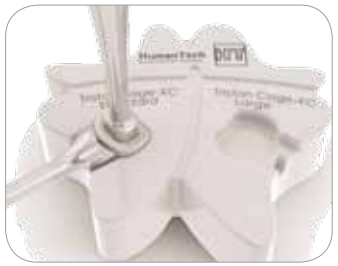
Anatomy

Osseointegration



Osseointegration

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



Osseointegration

TRISTAN® Classic

TRISTAN® Classic is a solid titanium implant designed for cervical interbody fusion, to be applied in degenerative disc diseases and instabilities in the C3 to C7 area. In combination with the safe and easy-to-use TRISTAN® instrumentary, TRISTAN® Classic is the perfect solution for cervical interbody fusion.
State-of-the-art scientific findings are used when implementing the titanium material with customized surface properties in our implants. We exclusively use Titanium Ti 6Al-4V ELI (DIN Ti3.7165)

TITANIUM

TRISTAN®Avantgarde

TRISTAN® Avantgarde is a biocompatible PEEK-Optima® Implant for cervical interbody fusion, to be applied in degenerative disc diseases and instabilities in the C3 to C7 area.

The X-ray transparency of this material facilitates a fast and easy appreciation of the bone structure and the fusion process. Titan markers are built in for position verification. The mechanical stability of 3,6 GPa allows an optimum load transmission between implant material and bone. Due to this the bone healing process is stimulated.

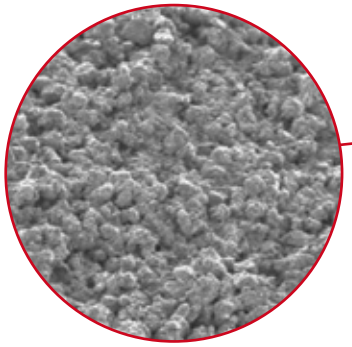
Our PEEK material is tested under ISO 10993 and classified under US P-VI, there are available corresponding FDA Device und Drug Master Files. Due to its characteristics and approvals, PEEK is predestined for the use as implant material.

PEEK

Tristan® Exclusive

TRISTAN® Exclusive sets new standards in cervical interbody fusion.

Due to the TRISTAN® Exclusive-Cages titanium coating the benefits of both materials are combined in one implant. The implant base is a solid PEEK core. This core is coated with titanium, for maximum contact between implant and vertebral body surface by surface enlargement.



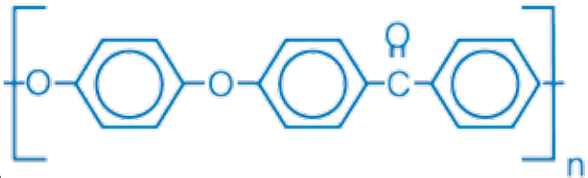
PEEK Ti-coated

The titanium coat offers an optimum base due to its balanced ratio between pore depth, porosity and roughness, at the same time it has proved to be the ideal material as it stimulates bone cells in attaching to the implant. The osseointegrative characteristics of titanium facilitate the direct adhesion between bone and implant

Characteristics of PEEK and PEEK Ti-coated

- PEEK is X-Ray transparent and artifactfree
- Position verification through titanium markers
- Anatomical design and toothed or Ti-coated surface
- The semicircular shape allows a maximum contact area
- Bone or bone-substitute filling is possible in order to improve the bone growth through the implant in pure PEEK-Cages
- Fast interconnection with introduction instrument due to clamp mechanism

PEEK-OPTIMA®
is a polyaromatic, semicrystalline thermoplast, based on the formula:
(-C6H4-O-C6H4-O-C6H4-CO-)
and generally known as Polyetheretherketon.



Classic

	Art.No.	Description	Heigth	Diameter	Depth	Angle
	1501040304 1501050304	Tristan Ti 12x14x4 Tristan Ti 14x16x4	4 mm	12 14	14 16	12° 11°
	1501040305 1501050305	Tristan Ti 12x14x5 Tristan Ti 14x16x5	5 mm	12 14	14 16	12° 11°
	1501040306 1501050306	Tristan Ti 12x14x6 Tristan Ti 14x16x6	6 mm	12 14	14 16	12° 11°
	1501040307 1501050307	Tristan Ti 12x14x7 Tristan Ti 14x16x7	7 mm	12 14	14 16	12° 11°
	1501040308 1501050308	Tristan Ti 12x14x8 Tristan Ti 14x16x8	8 mm	12 14	14 16	12° 11°

Avantgarde

	Art.No.	Description	Heigth	Diameter	Depth	Angle
	1501040404 1501050404	Tristan Peek 12x14x4 Tristan Peek 14x16x4	4 mm	12 14	14 16	12° 11°
	1501040405 1501050405	Tristan Peek 12x14x5 Tristan Peek 14x16x5	5 mm	12 14	14 16	12° 11°
	1501040406 1501050406	Tristan Peek 12x14x6 Tristan Peek 14x16x6	6 mm	12 14	14 16	12° 11°
	1501040407 1501050407	Tristan Peek 12x14x7 Tristan Peek 14x16x7	7 mm	12 14	14 16	12° 11°
	1501040408 1501050408	Tristan Peek 12x14x8 Tristan Peek 14x16x8	8 mm	12 14	14 16	12° 11°

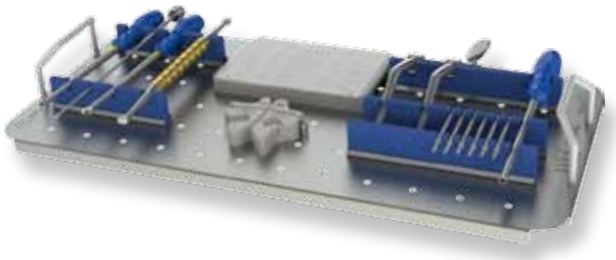
Exclusive

12 mm x 14 mm 14 mm x 16 mm

	Art.No.	Description	Heigth	∅	Depth	Angle
	1501040504 1501050504	Tristan Peek-Ti Coated 12x14x4 Tristan Peek-Ti Coated 14x16x4	4 mm	12 14	14 16	12° 11°
	1501040505 1501050505	Tristan Peek-Ti Coated 12x14x5 Tristan Peek-Ti Coated 14x16x5	5 mm	12 14	14 16	12° 11°
	1501040506 1501050506	Tristan Peek-Ti Coated 12x14x6 Tristan Peek-Ti Coated 14x16x6	6 mm	12 14	14 16	12° 11°
	1501040507 1501050507	Tristan Peek-Ti Coated 12x14x7 Tristan Peek-Ti Coated 14x16x7	7 mm	12 14	14 16	12° 11°
	1501040508 1501050508	Tristan Peek-Ti Coated 12x14x8 Tristan Peek-Ti Coated 14x16x8	8 mm	12 14	14 16	12° 11°

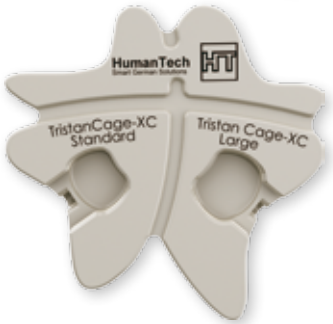
Retrival Body Retractor

Distraction Pins



Tray 1

Tray 2



Filling Block Base

Implant Rack

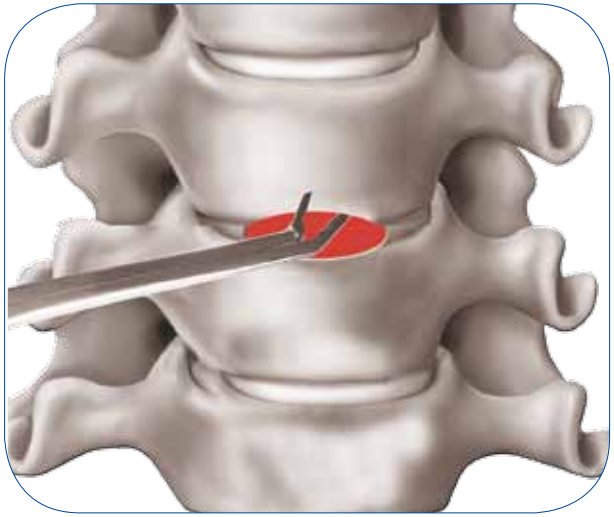


Fig. 1

Illustration of the intervertebral space

Access the interverbral area through an incision in the anterior ligament and perform the excision of the annulus fibrosus. Resection of the anterior osteophytes utilizing a punch and rongeur. Widening of the breach with the aid of a high speed milling cutter if necessary. (Fig. 1)

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

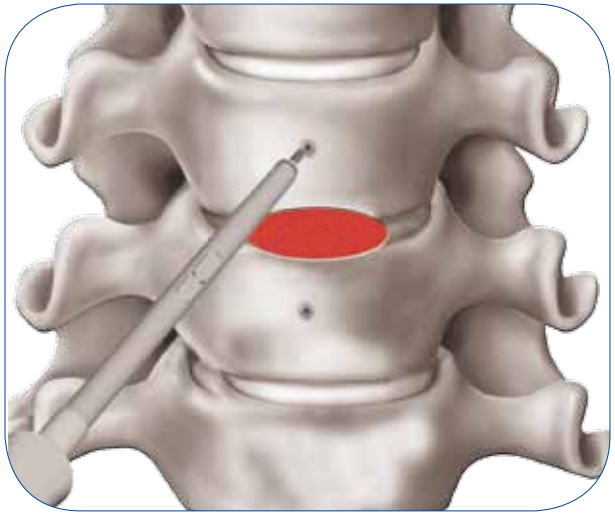


Fig. 1.1

Utilization of the vertebral body retractor

Placement of the retraction pins respectively into the caudal and cranial areas of the vertebrae.
An optimal positioning within the centre of the vertebral bodies is preferred. In the case of osteoporosis, the retraction screws may also be placed near the endplate in order to achieve an improved grip and span capability. (Fig. 1.1)

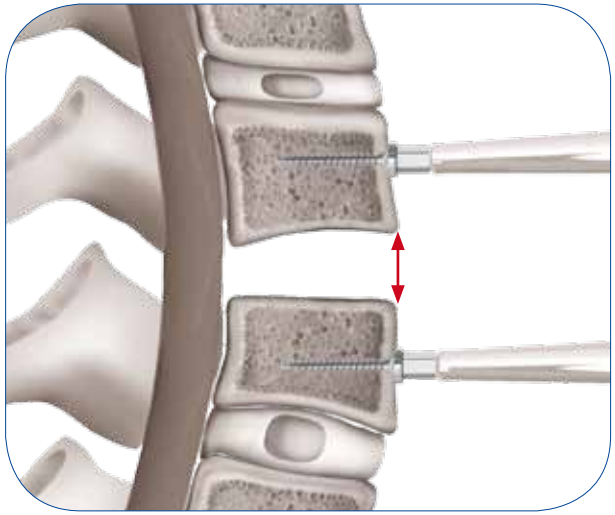


Fig. 1.2

Expansion of the intervertebral area

Careful separation of the vertebral bodies using the retractor, with the same view to the posterior edge. Resection of the posterior osteophytes if necessary and complete mobilisation of the intervertebral area through an opening in the posterior ligament.
(Fig. 1.2)

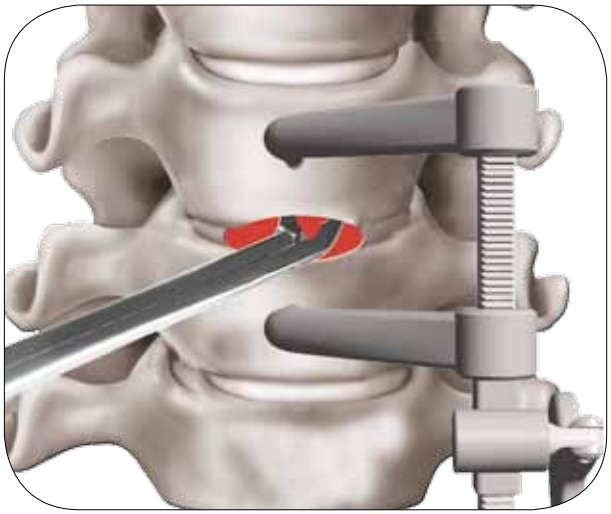


Fig. 2

Preparation of the intervertebral area

Complete disc dissection in the interverbral area with a rongeur and preparation of the endplates. Dissection of the intervertebral disc and careful debridement of the endplates with a curette and if necessary with a high speed milling cutter as well. (Fig. 2)

Notice: The endplates may not be chisseled out or perforated.

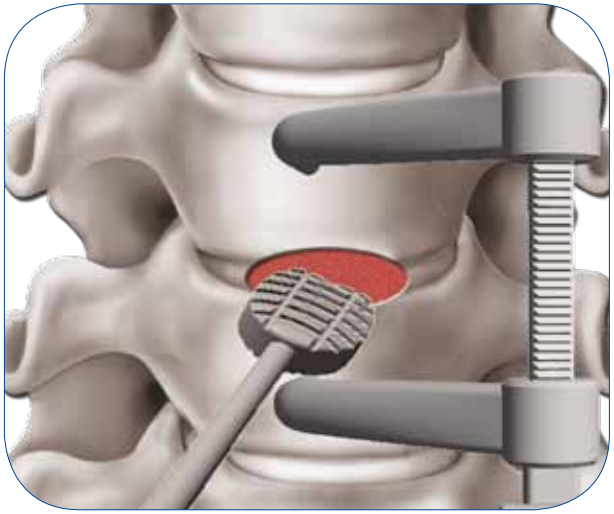


Fig. 3

Preparation of the implant bed

Preparation of the implant bed by means of an endplate shaped rasp. Rasp carefully in an anterior-posterior direction. (Fig.3)

Notice: In order to guarantee a stable implant base, insure that the vertebrae endplates are in no way damaged.

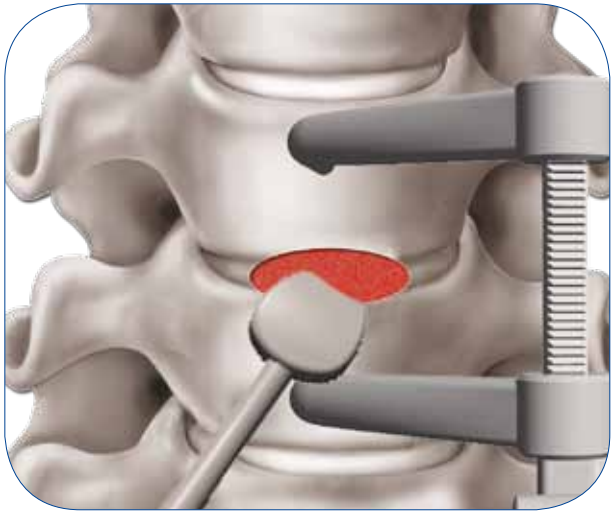


Fig. 4

Determining implant size

Evaluate the size of the implant using a sample implant guided with a fluoroscope.
The shape of the implant specimen should have a form preferably to fit the shape of the prepared intervertebral disc and should fit closely behind the anterior edge. If necessary, continued preparation of the implant bed until a proper fit is achieved.
(Fig. 4)

Notice: Over extension should be avoided.
Use a fluoroscope in order to check the lateral profiles and the state of separation within the segment.

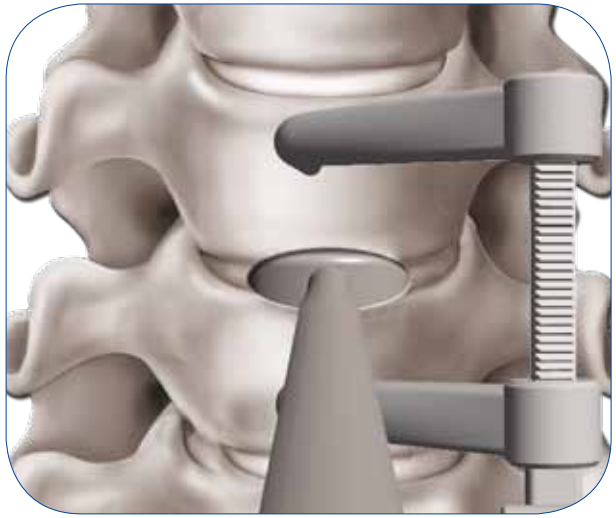


Fig. 5

Final fitting of the trial implant

Final assessment of the implant size, if necessary with aid of a fluoroscope. The correct position of the test implant is only possible when the anterior edge of the cage is aprox. 1-2 mm behind the anterior edge of the vertrabral body and the length of the cage takes up aprox. 4/5 of anterior posterioren expansion of the intervertebral area and ends in front of the posterior edge. (Fig. 5)

Fig. 6

Filling implant graft area

The cage can be filled with autologous bone, allogeneic or other bone substitute material for a more solid and rapid fusion. Place the cage in the filling block and fill it with the chosen bone or bone substitute material. Seal and compress the material with a darner. (Fig. 6)

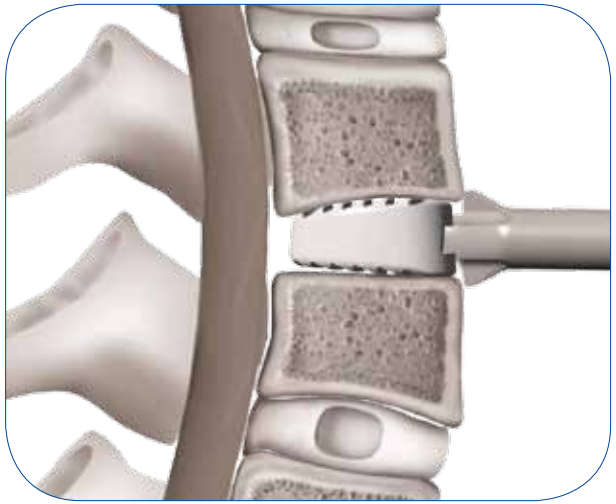


Fig. 7

Insertion of the implant

Placement of the cages with the inserter. There are two types of cage inserters available, one with and one without impact stop. The cage inserter without stop can also be used for re-striking in order to attain the optimal fitting of the cage within the intervertebral area. Final testing of the proper fit with use of a fluoroscope. (Fig. 7)

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 8) 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.

TRISTAN® 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 TRISTAN® Exclusive HenniaPore-Surface (Fig. 9) leads to a better bone adherence. HenniaPore has been developed in order to optimize the implant surface in a way, fast and postoperative adherence of young bones is encouraged (Fig. 10).
A review of clinical- and animal studies of Shalabi et alvi affirms this statement.

Actually the vacuum-plasma-injection-procedure used for TRISTAN® 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.

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, TRISTAN® 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.

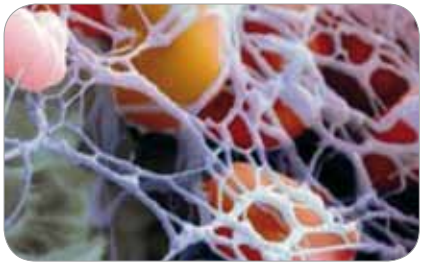


Fig. 8

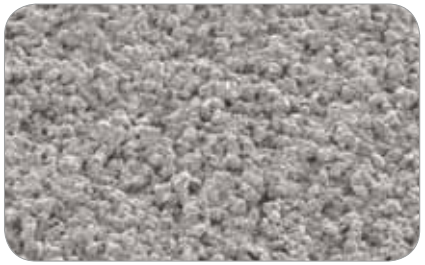
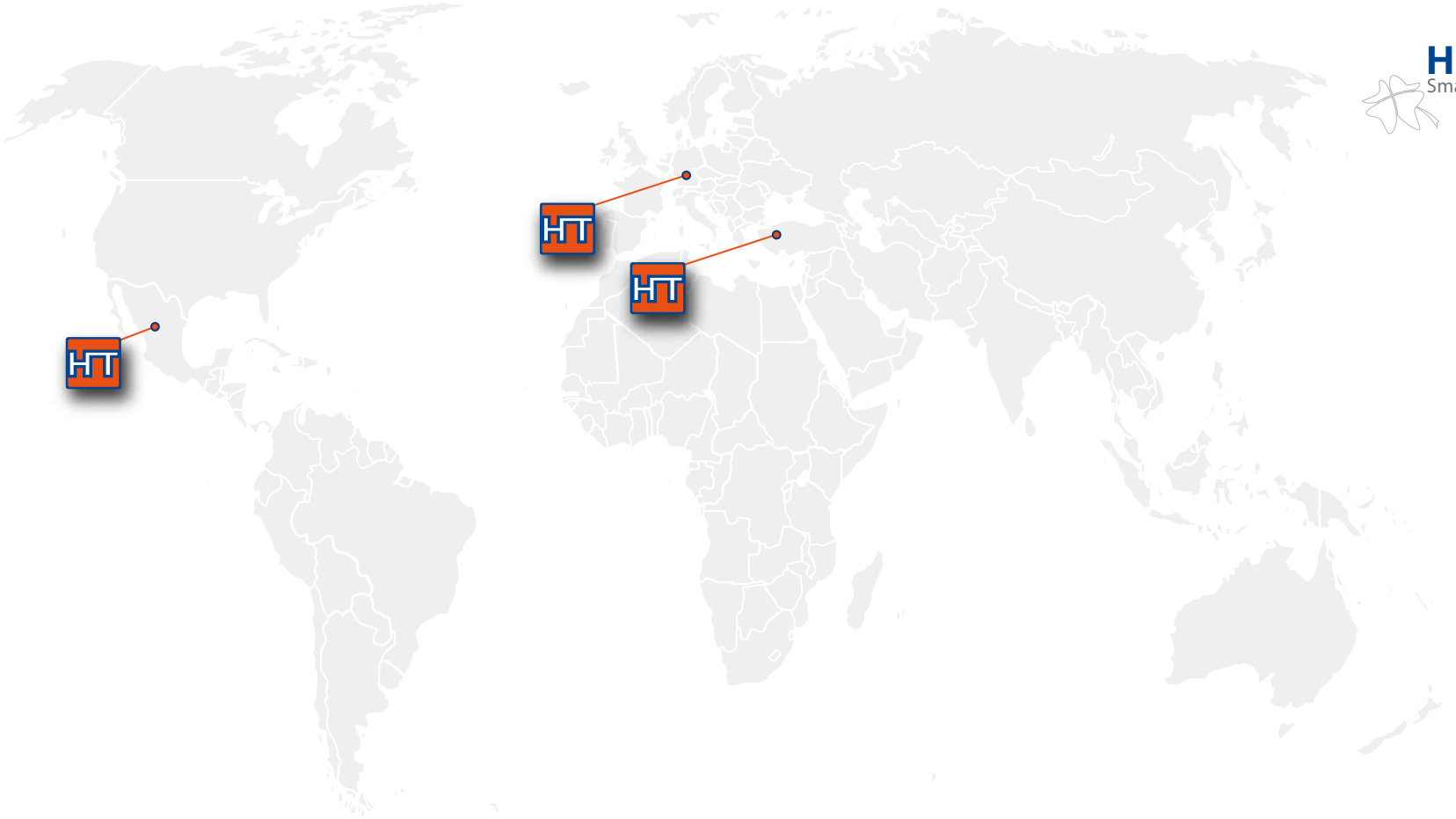


Fig. 9


Fig. 10

Roughness: Rz>70
Coating Thickness: 50-150µm
Porosity: 20%
Adhesive Strength: > 22 MPa
Shear Strength: > 20 MPa



HumanTech
Smart German Solutions

Manufacturer and Sales Europe

HumanTech Germany GmbH

Gewerbestr. 5
D-71144 Steinenbronn

Germany

Phone: +49 (0) 7157/5246-71
Fax: +49 (0) 7157/5246-33
info@humantech-solutions.de
www.humantech-solutions.de

Sales Middle East

HumanTech Med. Sag. Tic. Ltd.

İkitelli OSB Tümsan 2. Kısım
C-Blok No: 47
TR-34306 Başakşehir İstanbul

Turkey

Phone: +90 (0) 212/485 6675
Fax: +90 (0) 212/485 6674
info@humantech.com.tr
www.humantech-solutions.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-solutions.de

Other Countries

HumanTech Germany GmbH

Gewerbestr. 5
D-71144 Steinenbronn

Germany

Phone: +49 (0) 7157/5246-71
Fax: +49 (0) 7157/5246-33
info@humantech-solutions.de
www.humantech-solutions.de

CE 0297

Made in Germany

Document 1501030100 - subject to change