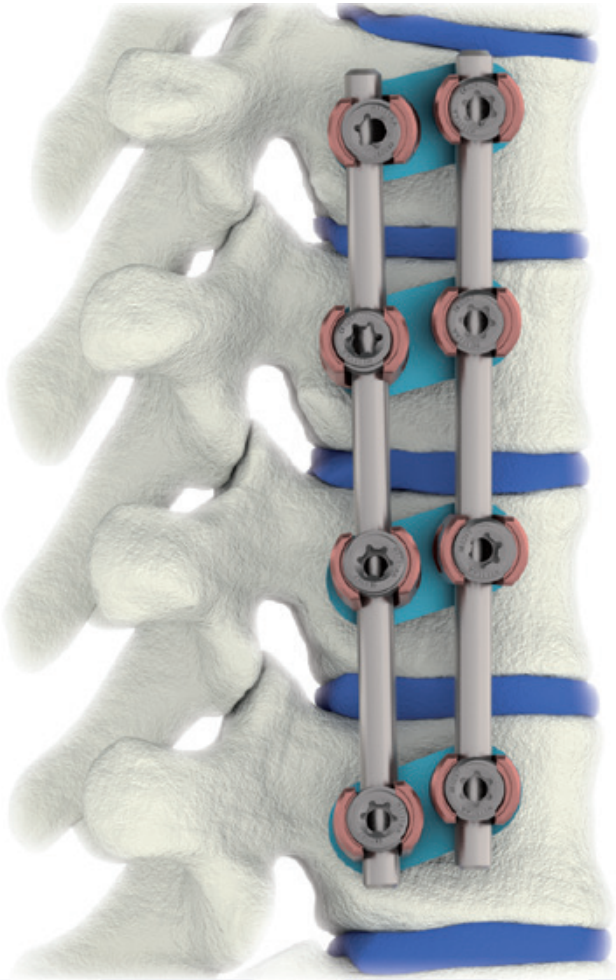


HumanTech Spine

VENUS nano VDS

Ventral derotataion spondylodesis

The VENUSnano VDS was developed for use in the area of the thoracic spine in children and adults. Its main areas of application are deformities in the area of the thoracic spine. It may be used mono-segmentally as well as multi-segmentally. This system stands out due its high degree of mechanical stability and user-friendliness; the instruments, which have been developed with specialists, enable minimally-invasive access to the anterior region by means of its optimum angulation, even in the case of long-segment treatments.

Implants for primary fusion and revision surgery

The VENUSnano VDS is extremely well suited for the treatment of scoliosis and helps to prevent the crankshaft phenomenon in young patients by means of this intervention. It is suitable for both single-rod and double-rod treatments. The special instruments take into consideration the anatomical situation so the surgeon can work in an uncomplicated and minimally-invasive manner.

We develop and produce all our implants and instruments in Germany, and will continue to do so. To us, Made in Germany is a special quality label, one which we are proud of.
Our HumanTech expert team operates all over the world. Solid market analysis and active, renowned surgeons provide us with the know-how for our development and production processes.

The perfectly crafted VENUSnano VDS implant and instrument system meets every requirement when it comes to style, stability, handling, aesthetics and quality, and conforms to the highest international standards. With the specially developed thread design, the screws can be introduced incredibly gently and are capable of withstanding maximum loading.
All components are of outstanding quality. The instruments are highly ergonomic, winning users over with their ease of use.

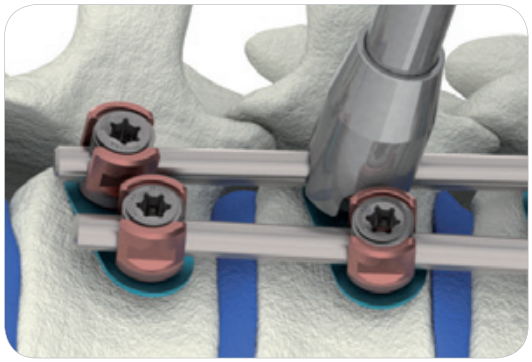
Product-specific advantages

- Versatile in use
- Design perfectly adapted to the anatomy
- Optimum osseointegration of the implant due to special surface structure
- Square thread for optimum fit in the pedicle
- Special thread profile for minimal bone trauma
- Gentle correction
- Maximum mechanical durability
- Development and production from a single source

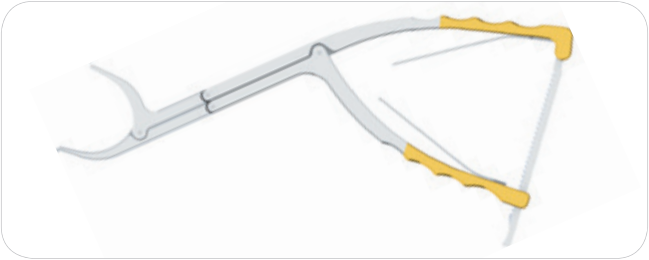
Made in Germany

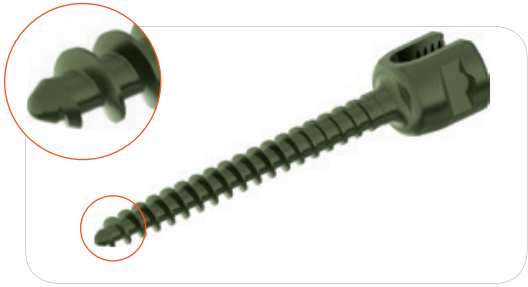
Ventral derotation spondylodesis

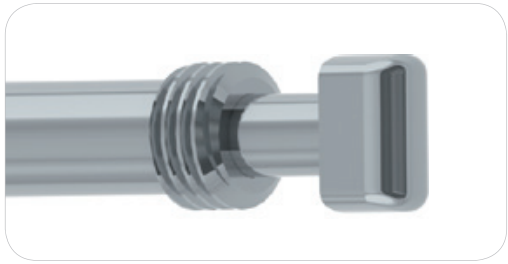
VENUS nano VDS



- transparent
- stable
- flexible

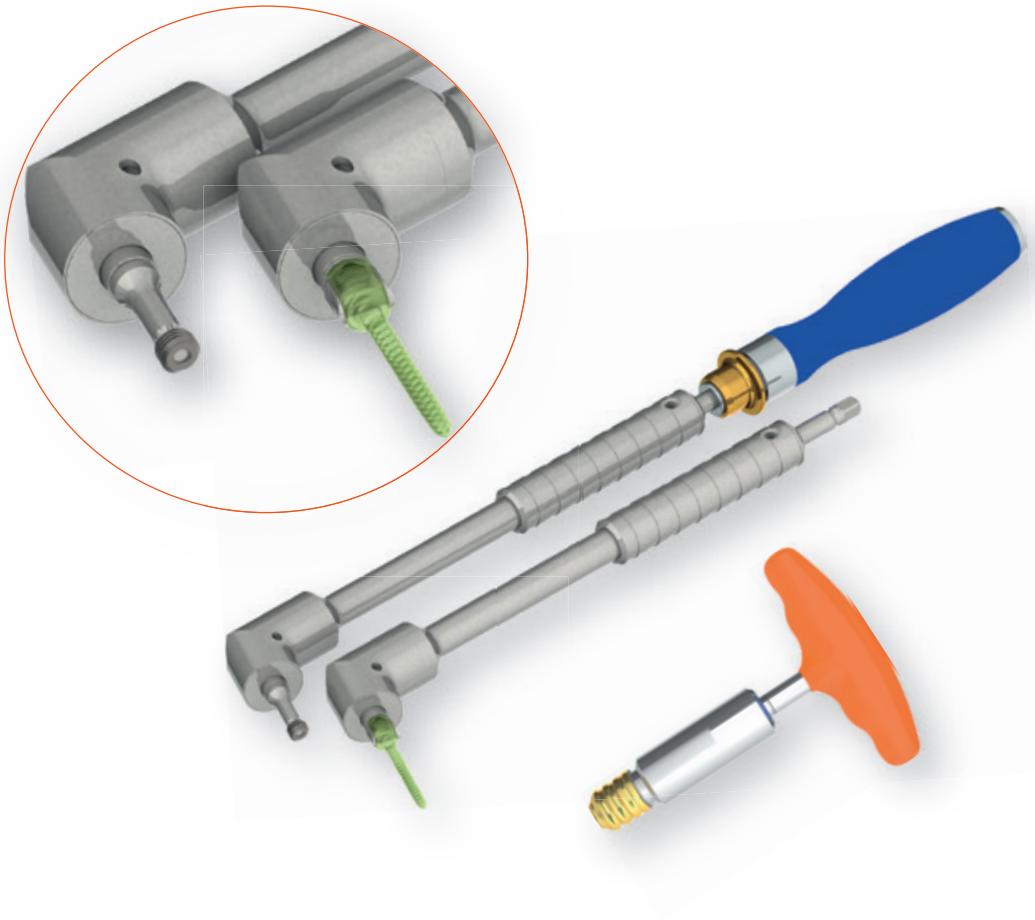






Special tools

The specially-angled LP mono-axial screwdrivers allow the pedicle screws to be screwed in reliably, even in cases where there is very little space.
With the unique power transmission mechanism, it is now also possible to insert the set screws using the correct torque by using the torque key.

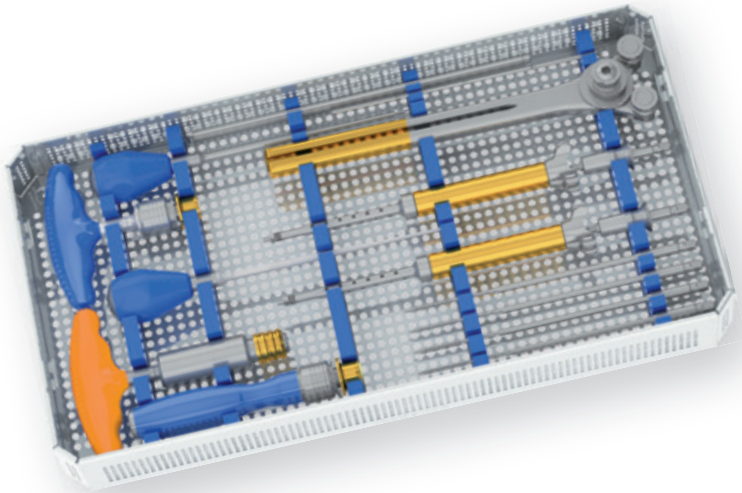


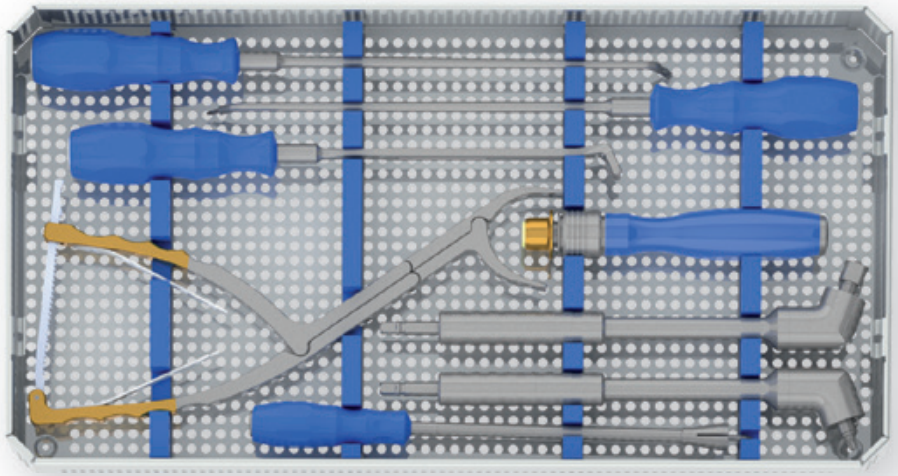
Screws

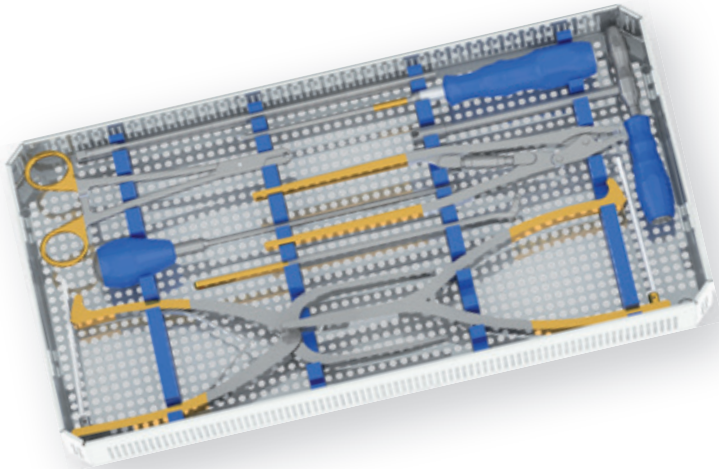
The screws in the VENUSnano VDS system have low-profile threads to preserve soft tissue and generate minimal trauma in the bone, too.
Despite this, the screw still manages to engage the bone immediately while being screwed in. The rounded screw tip is also suitable for anterior fixation due to its profile. The gradient of the screw thread enables the screw to be screwed into the bone quickly and precisely, yet safely. The four different angles in the thread profile guarantee an optimum fit in the bone and thus a secure primary fixation. The surface structure then enables optimum osseointegration of the implant.

Rods

The 4.5mm rods in varying lengths reduce the effort involved in cutting the rods to length during the OP to a minimum. Nitinol phantom
rods and special alignment markers on the rods enable the rod to undergo optimum preparation before being penetrated into the structure.
Rods with hexagonal-shaped ends allow the rod to be rotated before the final fixation, thus making it possible to perform simple corrections of deformities. The rods are available in CoCr alloy for increased stability.



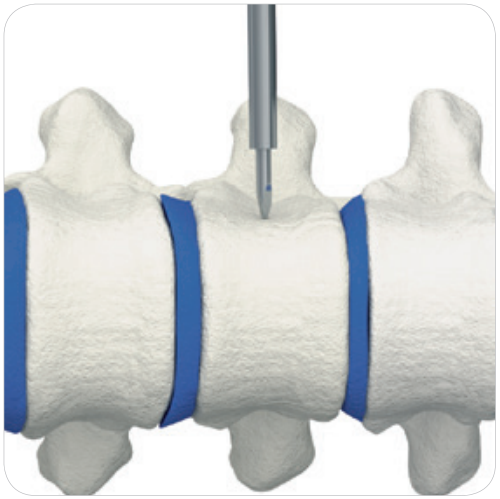




Instruments

The VENUSnano VDS instrument set is among the most outstanding surgical instrument systems. The system is the exclusive product of “Made in Germany” engineering skill in line with ISO and EC specifications. The perfection of the instrument set can also be attributed to its simplicity, which ensures optimum sterilisation as well as safe and easy use.

Highly-qualified quality management, accurate testing methods and complete traceability ensure the highest production standard, something that our customers can always rely on. Quality and precision are our incentive for developing new, ground-breaking and more effective ways of improving the VENUSnano VDS instrumentation system. Close contact with users is critical for our developments in this process.

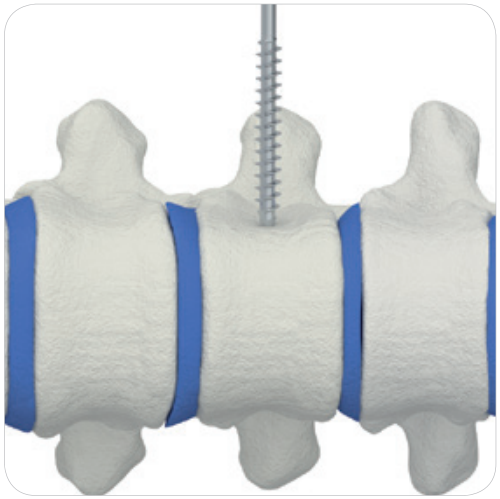


Preparation

In the case of an operation using the anterior approach, operating takes place ventrally along the ribs. Here a rib is removed and then, after being milled to form an autologous graft, inserted into the intervertebral spaces to bridge gaps. After opening up the thoracic cavity and/or the abdominal cavity, the spine is exposed in such a way that the surgeon obtains free access to the vertebral bodies and the intervertebral discs. For the purposes of correction, the intervertebral discs are removed in the selected area and the mono-axial screws ventrally inserted into the relevant vertebral bodies. First, the screw insertion point is defined and the vertebra is opened up using an awl (LP Awl).

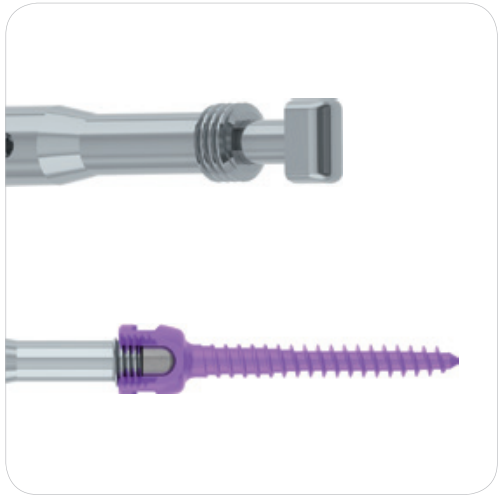
Awling and probing

The screw channel is awled. Using light pressure, the awl is advanced (Pedicle Probe 2.5) into the vertebral body carefully in half rotations.



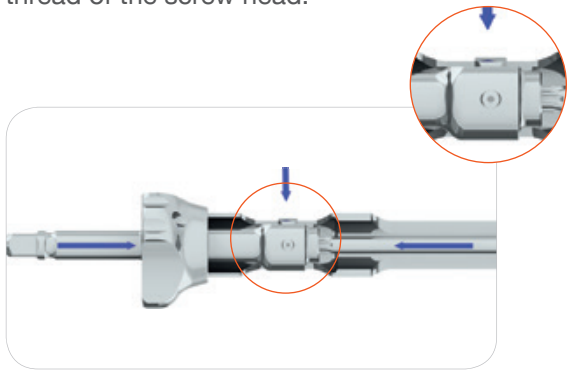
Tapping

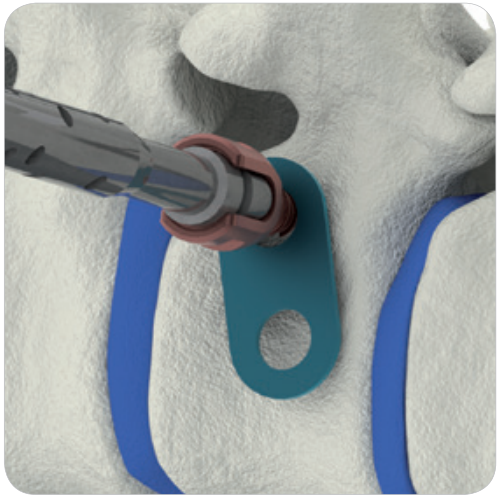
All implant screws are self-tapping. In cases where there is a very rigid bone structure, making the use of a tap necessary, taps are available to suit screw diameters.



Fitting the screws

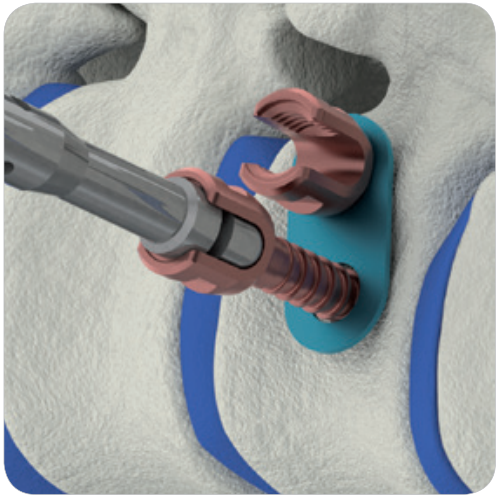
Insert the inner screwdriver shaft into the LP mono-/poly-axial screw driver guide and secure with the locking adapter (see below). Now insert the tip of the screwdriver into the screw head and connect the outer guide to the screw head by screwing it into the inner thread of the screw head.





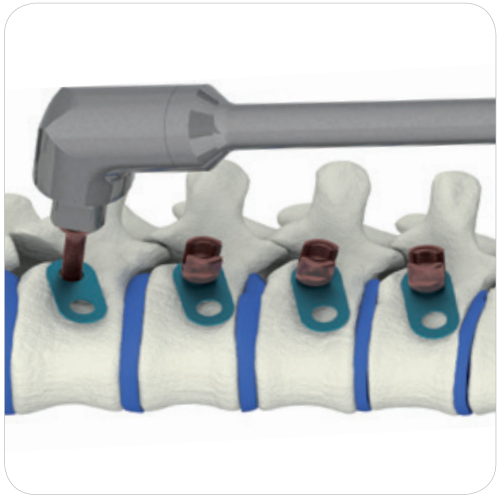
Inserting the mono-axial screw using the dual washer

Position and hold the LP dual washer using forceps or the LP rod holder. Screw the screw into the screw channel using the LP mono-/poly-axial screwdriver. After screwing it into the final position, release the screwdriver. In order to do so, grip the handle and turn the outer nut counter-clockwise (see below).



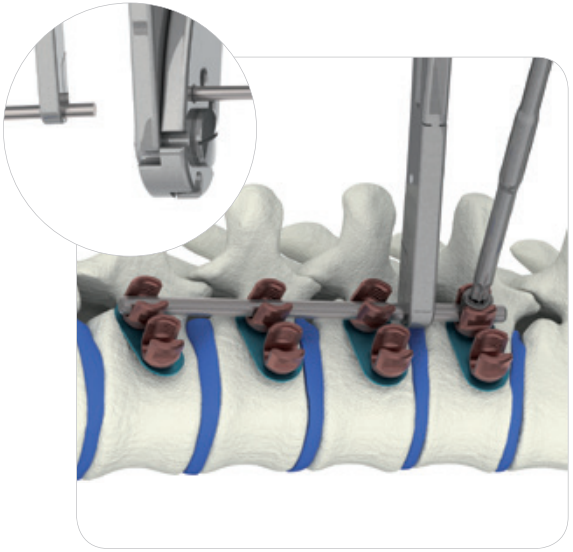
Inserting the second mono-axial screw using the dual washer

After the dual washer has been positioned, the screw channel is prepared as described before. The second screw is screwed into the screw channel. After screwing it into the final position, release the screwdriver.



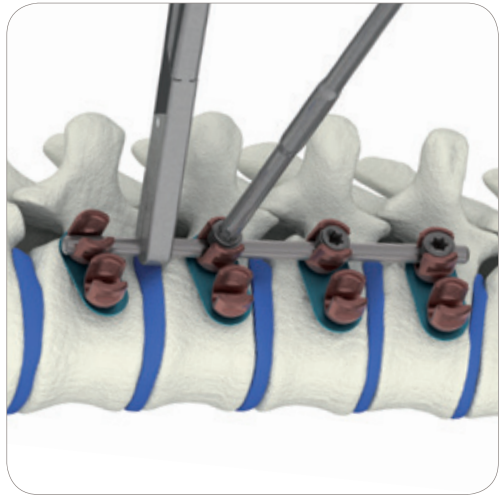
Inserting all screws

In the same way, inserting all other washers and screws at the planned positions. For this purpose place the screws into the screw channel using LP Mono / polyaxial screwdriver. In limited conditions the LP Angled Monoaxially Screw Driver can be used alternatively.



Inserting the rod

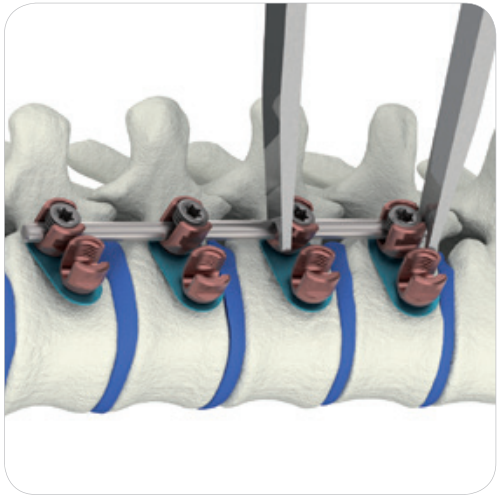
Set the rod length. A phantom rod is contained in the instruments to make it easier to set the rod length. Insert the rod into the screw heads using the LP rod inserter and, if need be, with the help of your fingertips. The rod profile undergoes fine tuning and the rod is bent to the corresponding radius. If necessary, place the rod using an LP rod pusher or an LP rocker to ensure the correct positioning in the screw head.



Fixing the rod

Fix the rod in the screw head with the set screw using the LP setscrew inserter. To prevent cross-threading while screwing in the set screw, first screw in a counter-clockwise direction until you clearly feel the thread “click into” the screw head. Then continue to screw in the set screw.

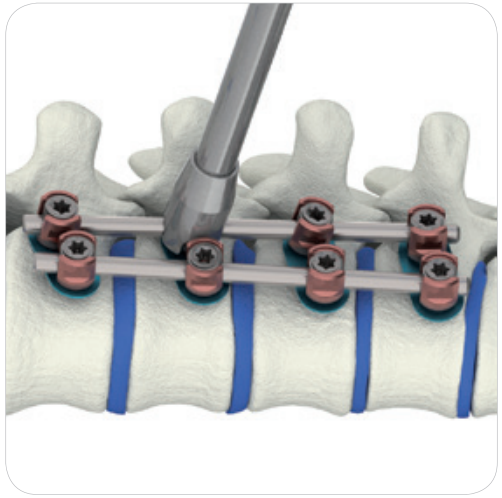
Caution!
Be sure to only screw in the set screw loosely; the final torque is applied using the LP set screw driver.



Compression / Distraction

Position the LP compressor or LP distractor on the screw heads and carry out the compression or distraction procedure until the desired position has been achieved. Insert the set screws using the LP setscrew inserter to
ensure the compression or distraction result. Tighten using the setscrew driver.

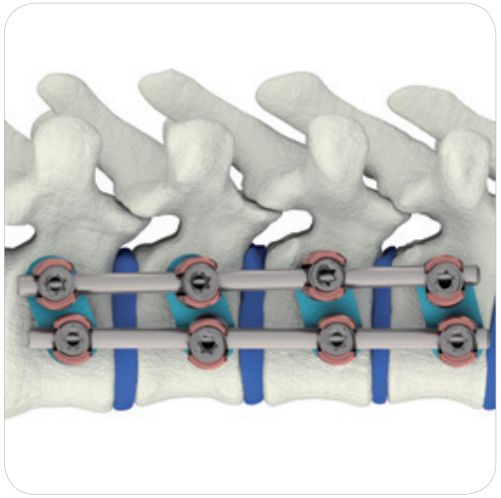
Note:
The set screws must not be fully tightened during this manoeuvre. If need be, loosen the set screws carefully using the LP setscrew driver.



Subsequent tightening

Slot the LP setscrew driver and the LP torque driver into one another, and then insert both components into the LP counter holder. Attach the combined instrument to the screw head. It is also possible to attach the two instruments separately.
Tighten the set screw. Same approach for all other set screws.

Note:
The full torque of 10Nm is reached when an audible signal is heard.



Final Structure

Final check on the structure with X-ray control images taken in two planes. Cleanse the surgical area and wound closure.

Monoaxial Screws

Art.No.	Description
	Monoaxial Screws Ø5 mm
2200065025	Monoaxial Screw LP Ø5x25mm
2200065030	Monoaxial Screw LP Ø5x30mm
2200065035	Monoaxial Screw LP Ø5x35mm
2200065040	Monoaxial Screw LP Ø5x40mm
2200065045	Monoaxial Screw LP Ø5x45mm
2200065050	Monoaxial Screw LP Ø5x50mm
	Monoaxial Screws Ø5.5 mm
2200065525	Monoaxial Screw LP Ø5.5x25mm
2200065530	Monoaxial Screw LP Ø5.5x30mm
2200065535	Monoaxial Screw LP Ø5.5x35mm
2200065540	Monoaxial Screw LP Ø5.5x40mm
2200065545	Monoaxial Screw LP Ø5.5x45mm
2200065550	Monoaxial Screw LP Ø5.5x50mm

Art.No.	Description
	Monoaxial Screws Ø6 mm
2200066025	Monoaxial Screw LP Ø6x25mm
2200066030	Monoaxial Screw LP Ø6x30mm
2200066035	Monoaxial Screw LP Ø6x35mm
2200066040	Monoaxial Screw LP Ø6x40mm
2200066045	Monoaxial Screw LP Ø6x45mm
2200066050	Monoaxial Screw LP Ø6x50mm

Rods and Setscrews

Art.No.	Description
LP-PMS	LP Set Screw
2200160010	LP Dual Washer SP
2200160020	LP Dual Washer

Art.No.	Description
2200084503	Rod straight LP CoCr Ø4.5x30mm
2200084505	Rod straight LP CoCr Ø4.5x50mm
2200084507	Rod straight LP CoCr Ø4.5x70mm
2200084510H	Rod straight LP CoCr Ø4.5x100mm Hex
2200084515H	Rod straight LP CoCr Ø4.5x150mm Hex
2200084520H	Rod straight LP CoCr Ø4.5x200mm Hex
2200084548H	Rod straight LP CoCr Ø4.5x480mm Hex

Art.No.	Description
2200094503	Rod straight LP Ø4.5x30mm
2200094505	Rod straight LP Ø4.5x50mm
2200094507	Rod straight LP Ø4.5x70mm
2200094510H	Rod straight LP Ø4.5x100mm Hex
2200094515H	Rod straight LP Ø4.5x150mm Hex
2200094520H	Rod straight LP Ø4.5x200mm Hex
2200094548H	Rod straight LP Ø4.5x480mm Hex

Art.No.	Description	
2200010000	LP Awl	
2200010002	Pedicle Probe 2.5mm	
2200010003 2200010004 2200010005 2200010006	LP Tap Ø4 LP Tap Ø5 LP Tap Ø5.5 LP Tap Ø6	
2200010007	LP Counter Holder	
2200010008	LP Set Screw Driver	
2200010009	LP Set Screw Inserter	
2200010011	LP Rocker	

Art.No.	Description	
2200010012	LP Long Head Sleeve	
2200010013	LP Reduction Crown Breaker	
2200010014	LP Shaft Monoaxial Screw Driver	
2200010015	LP Shaft Polyaxial Screw Driver	
2200010016	LP Mono/Polyaxial Screw Driver	
2200010054	Torque Driver-10	

Art.No.	Description	
2200010017	LP Rod Inserter	
2200010018	LP Rod Bender	
2200010019	LP Rod Pusher	
2200010020	LP Compressor	
2200010021	LP Distractor	
055084	Rod Cutter	
055072	Rod Holder	

Art.No.	Description	
2200010047	LP Awl angled	
2200010042	LP Set Screw Driver angled	
2200010035	LP Rocker with Handle	
2200010026	LP Compressor angled 4.5	
2200010028	LP Washer Inserter	
2200010027	LP Angled Monoaxial Screw Driver	
2200010052	LP Angled Setscrew Driver	

The VENUSnano Spinal System is intended for use as a posterior and anterior implant system for fixation in spinal surgery for children and adults of small stature. It consists of rods, pedicle screws, fasteners, flat washers and a variety of hooks.
The VENUSnano VDS instrument kit contains mono-axial screws, washers, rods and set screws for a ventral insertion using a double-rod treatment. A bicortical screw with a minimum diameter of 5 mm should be used for a ventral treatment. These implants are available in different shapes and sizes, which means that adjustments can be made according to the individual pathology of each patient.

Material

The VENUSnano Spinal System is made from Ti6Al4V, a titanium alloy certified in accordance with ISO 5832-3. It also contains rods made from cobalt-chrome (CoCr) certified in accordance with ISO 5832-12.

Indications for use

The VENUSnano Spinal System is designed for the surgical treatment of diseases and injuries of the thoracic, lumbar, and sacral spine, in particular for indications such as instability, degenerative disc disease, deformities such as scoliosis and kyphosis, spondylolisthesis, tumours, and revision surgery.
As a guideline, the implants are designed for patients aged from 5 to 11 years and for patients weighing less than 45 kg.

Area of application

The area of application is the thoracic, lumbar and sacral spine.

General conditions for use

- The implants must only be inserted by surgeons who have completed the requisite training in spinal surgery. The insertion of implants must be carried out in line with the surgical and medical indications, the potential dangers, and with the restrictions associated with this type of surgery. It should also be performed with an awareness of the contraindications, side effects, defined precautionary measures, and with regard for the structure and the metallic, metallurgical and biological characteristics of the implant.
- This leaflet provides essential information, but this is not sufficient to enable you to use the system. This information is not a substitute for the following: the professional judgement and/or clinical skills and experience of the physician with regard to careful patient selection; preoperative planning and implant selection; knowledge of the anatomy and biomechanics of the spine; an understanding of the material and the mechanical properties of the used implants; training and skills in spinal surgery and the use of the instruments required for inserting the implants; the surgeon's ability to gain the patient's consent, adhere to a clearly defined post-operative treatment regimen, and to conduct scheduled follow-up examinations.
- Use of the VENUSnano Spinal System in conjunction with components of other fusion systems from other suppliers or manufacturers, or which are made from a material other than Ti6Al4V and cobalt-chrome (CoCr), is not recommended. HumanTech Germany GmbH shall accept no liability in such cases.
- The implants must not be used more than once under any circumstances. Although the implant may appear intact after revision surgery, changes to the interior of the implant, or small defects caused by loads and stresses, can cause the implant to break.

Contraindications

Contraindications may be either relative or absolute. The selection of a particular implant must be weighed carefully against the overall assessment of the patient. The following conditions can have an adverse impact on the chances of successful surgery.
Contraindications include, but are not limited to, the following:

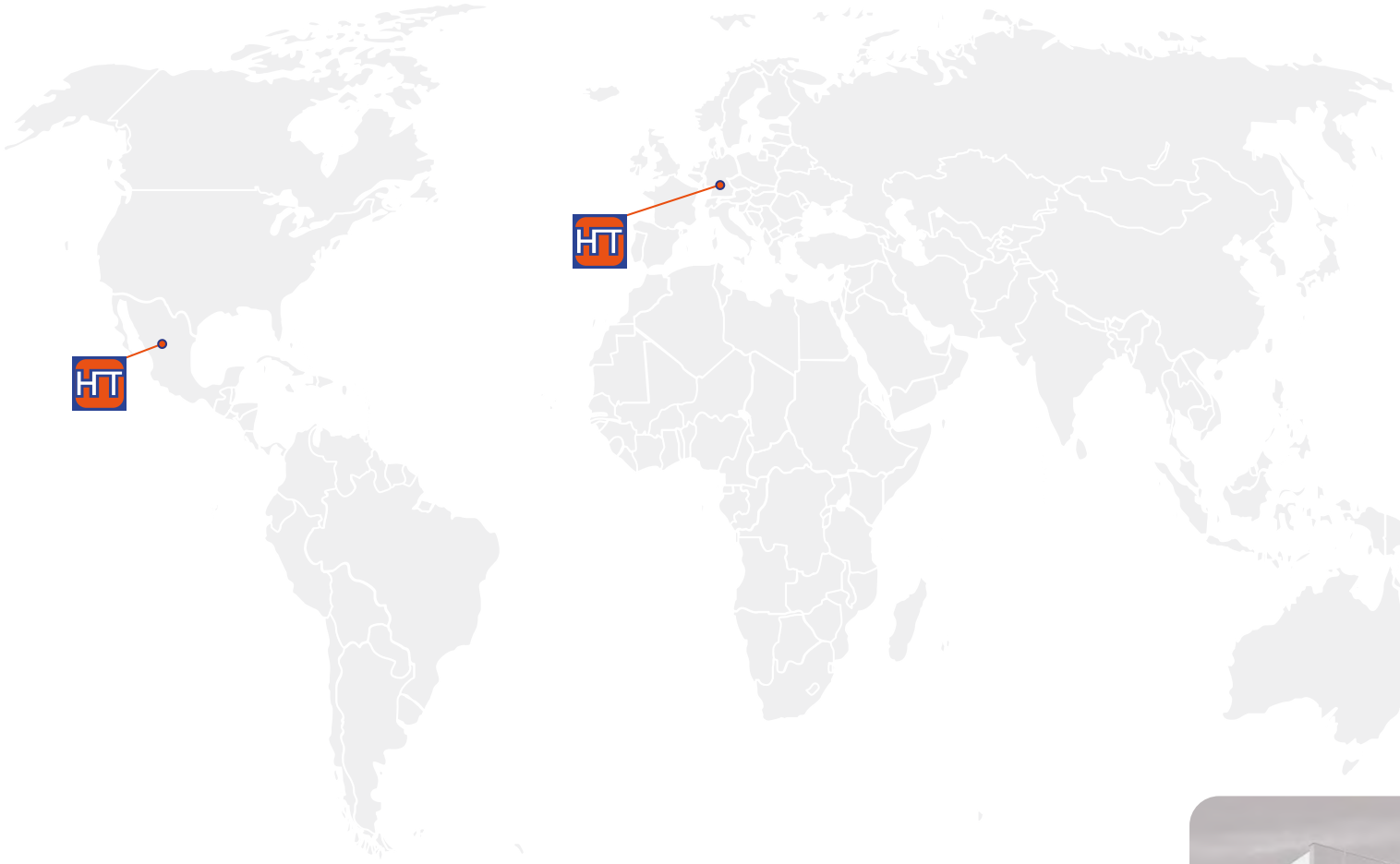
1. Acute infections or significant risk of infection (weakened immune system).
2. Signs of local inflammation.
3. Open wounds.
4. Fever or leukocytosis.
5. Morbid obesity.
6. Pregnancy.
7. Psychological illness.

8. If the anatomy is too deformed due to congenital abnormalities.
9. Any other medical or surgical condition which prevents possible improvement through the use of implant systems, such as the presence of congenital abnormalities, increased white blood cell count (WBC) or a marked shift to the left in the WBC differential blood count.
10. Joint diseases, bone shrinkage, osteopenia, osteomalacia and/or osteoporosis.
11. Any neuromuscular disease that would place excess strain on the implant during the healing period.
12. Suspicion of a metal allergy or intolerance, and documented metal allergy or intolerance. Appropriate tests should be carried out.
13. All cases in which fusion is not required.
14. All cases in which the selected implant components are too large or too small to achieve a satisfactory result.
15. All cases which require the use of components other than the metals or alloys used in this system.
16. Any patient with inadequate tissue structure on the operational side, or an inadequate osseous bed or bone quality.
17. Any patient who is not willing to follow post-operative instructions.
18. All cases which are not described in the indications.

Complications / side effects

Complications and side effects include, but are not limited to, the following:

- Delayed bone growth or no visible fusion and pseudarthrosis.
- Neurological complications, paralysis, soft-tissue lesions and/or migration of the implant.
- Breakage, loosening or deformation of the implant.
- Partial loss of the level of correction achieved during the operation.
- Superficial or deep infection and inflammation.
- Allergic reaction to the implant material.
- Reduction of bone density .
- Neurological or spinal lesion in the dura mater caused by surgical trauma.
- Genitourinary disorders, gastrointestinal disorders, vascular disorders including thrombus, respiratory tract disorders including embolism, bursitis, secondary bleeding, myocardial infarction, or death.
- Disorder of anatomical structures.
- Restricted physiological function.
- Fracture of a vertebra, the pedicle, and/or the sacrum.
- Occurrence of microparticles in the area of the implant (metallosis).
- Modified growth of the fused spine.
- Stopped growth of the chest wall and lungs, with associated consequences.
- Change in the curvature and stiffness of the spine.
- Pain, discomfort or abnormal sensations due to the presence of the implant.
- Pressure on the skin caused by components located in positions with insufficient tissue coverage over the implant, with potential penetration of the skin.



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