HumanTech Spine

VENUS® mini 2.0 Fracture

Extension kit for minimally invasive fracture treatment

Content

Made in Germany

Description

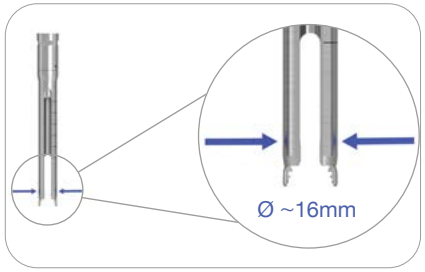
VENUS®mini 2.0

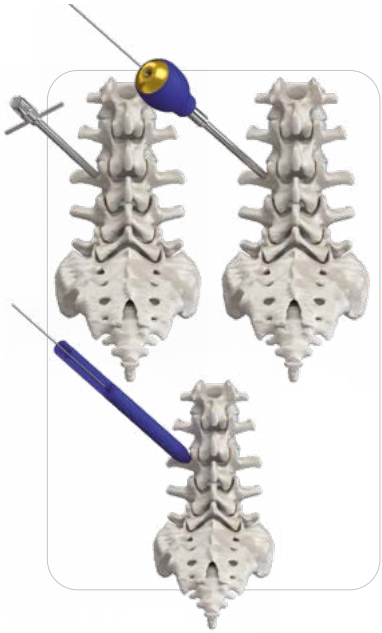
VENUS®mini 2.0 Fracture

The VENUS®mini 2.0 Fracture system is an extension kit for the existing minimally invasive fixation system VENUS®mini 2.0 and is used for the minimally invasive treatment of fractures. For this purpose, the extension kit contains monoaxial VENUS screws in cannulated and fenestrated form.

The following benefits of the VENUS®mini 2.0 Fracture expansion kit system for the patient and the hospital staff

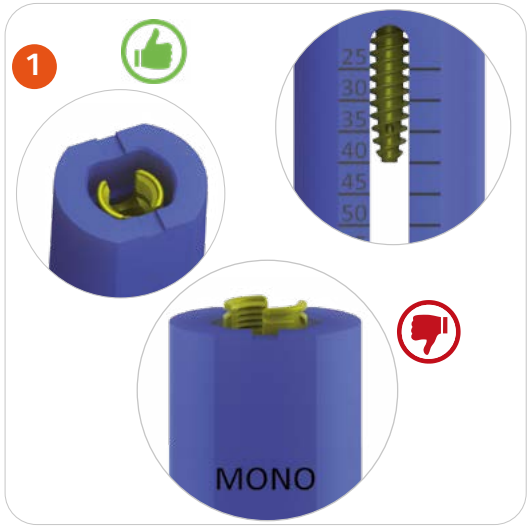
- Towers specially developed for percutaneous fracture treatment that can absorb high forces in the cranial-caudal direction





Preparation of the pedicle and the screw channel

All necessary surgical steps that are or may be required for the preparation of the pedicle or the screw channel (e.g. making the skin incisions, pediculating, placing the guide wire, dilation and thread cutting) are explained in the surgical technique of the VENUSmini 2.0 system.



Attachment of the monoaxial screw / Insertion into the MIS Assembling Tool

The selected monoaxial screw is inserted into the opening of MIS Assembling Tool that is marked with “MONO“. The monoaxial screw must be fully inserted into the deep recess of MIS Assembling Tool (1). If necessary, rotate the screw a little bit until it fully drops into the recess.

Note:
Using the length markings on the MIS Assembling Tool it is possible to determine the length of the screw taken out of the tray.

Attachment of the monoaxial screw / MIS Multitool / MIS Fracture-Tower

The MIS Multitool must be correctly positioned on the MIS Fracture-Tower. The annular spring area must point towards the MIS Fracture-Tower. It must be ensured that the MIS Multitool perceptibly locks into the MIS Interior Clamp of the MIS Fracture-Tower (1). Before attaching the screw, the correct position of the MIS Interior Clamp and MIS Fracture-Tower must be ensured. If the MIS Interior Clamp does not protrude by 5 mm (2), unlock the MIS Interior Clamp by using the MIS Multitool (“unlock” position) and push forward. Then lock the position of the MIS Fracture-Tower and MIS Interior Clamp once again (“lock“ position of MIS Multitool). In the locked position, the MIS Interior Clamp cannot be pushed axially within the MIS Fracture-Tower. The correct position can be checked by simply applying axial pressure to the MIS Interior Clamp. This should not be movable when it is in locked position. The MIS Fracture-Tower is now inserted vertically into the MIS Assembling Tool (3) and locked on the head of the monoaxial screw by pushing downwards, resulting in a noticeable click (4).

Note:
While mounting the MIS Fracture-Tower, it must be ensured that the locking mechanism is placed in the “lock” position (max. position reached by turning MIS Multitool clockwise).

Attachment of the monoaxial screw / Locking the screw to the MIS Fracture-Tower

Now place the locking mechanism into the “unlock” position by turning the MIS Multitool counterclockwise (1). The MIS Fracture-Tower can then be pushed downwards (2). The MIS Multitool must be turned to the “lock” position and tightened by hand in order to lock the monoaxial screw to the MIS Fracture-Tower (3).
The MIS Multitool can then be pulled upwards and withdrawn from the MIS Fracture-Tower (4).

Note:
If the MIS Multitool cannot be turned and the pedicle screw cannot be locked, the setup of the MIS Fracture-Tower must be checked and corrected, if required.

Assembly | Securing of the MIS Monoaxial Screw Driver

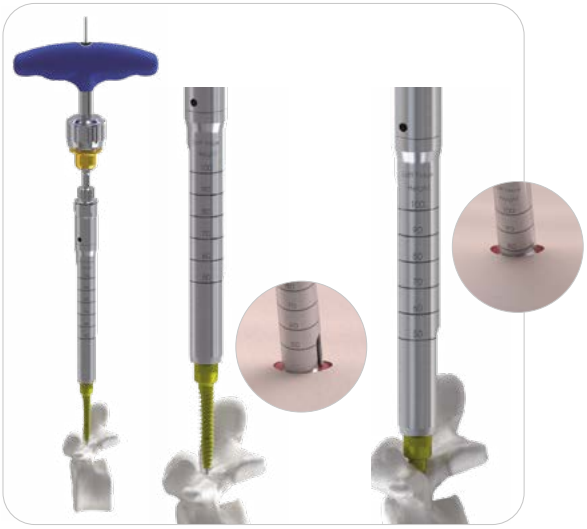
The MIS Monoaxial Screw Driver is inserted into the MIS Fracture-Tower from above (1) and placed into the screw head of the monaxial screw using both gentle pressure and slight rotation (2). Care should be taken that the tip of the MIS Monoaxial Screw Driver is correctly positioned in the rod recess of the screw head of the monoaxial screw. The connecting screw of the MIS Monaxial Screw Driver is now tightened (3).

Assembly of the MIS Monoaxial Screw Driver

The MIS Multitool can be used to tighten the screwdriver. To do so, attach the MIS Multitool to the screwdriver (1) and tighten the connecting screw (2).
Then the desired cannulated handle can be mounted onto the coupling of the MIS Monoaxial Screw Driver.

Note:
The MIS Multitool must be rotated by 180° before mounting. The annular spring away from the MIS Fracture-Tower.

Note:
When the MIS Monoaxial Screw Driver and pedicle screw are correctly assembled, there is a gap of approx. 1 mm between the MIS Fracture-Tower and the connecting screw of the MIS Monoaxial Screw Driver (3).



Implanting the pedicle screw

The pedicle screw is now implanted through the placed K-Wire and under observation via imaging technology.

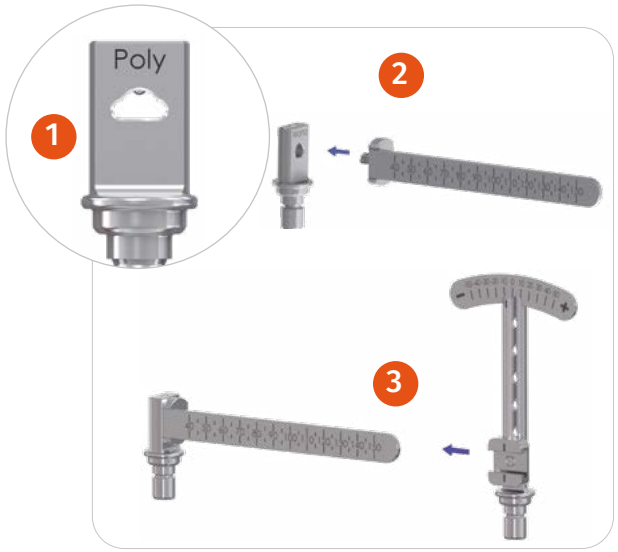
Note:
The length markings located on the outside of the MIS Fracture-Tower can be used as a guide to gauge the screwing depth for the pedicle screw. The thickness of the soft tissue is used as reference value. It is previously determined during setting the pedicle entry point and preparation of the pedicle / dilation. This allows the reduction of X-ray check intensity during the insertion of the pedicle screw.

Caution:
The K-Wire must be held in position to ensure that it is not pushed forwards while the screw is inserted! Lateral imaging is recommended throughout the procedure. Afterwards, the correct implant and the correct screw length must be verified using the image converter.

Note:
Due to the monoaxial screws, the correct orientation of the slots for the insertion of the rods of pedicle screws/ MIS Fracture-Tower must be ensured. These must be facing each other before the MIS Monoaxial Screw Driver is removed.

Loosening the MIS Monoaxial Screw Driver

Following the implantation, the MIS Monoaxial Screw Driver can be loosened and removed by rotating the connecting screw counterclockwise (1).
Where greater force is required to loosen the connecting screw, the MIS Multitool can be mounted (with the annular spring pointing away from the MIS Fracture-Tower). In order to stabilise the MIS Fracture-Tower, the Key Deformity Tower can be inserted into one of the side holes of the MIS Fracture-Tower (2).



Assembly of the MIS Rod Compass for at least one terminal polyaxial screw

To measure the rod length, the MIS Rod Compass Poly (1) must be mounted onto the MIS Rod Compass Ruler (2). Then the MIS Rod Compass Pointer is pushed onto the Ruler (3).

Note:
Once assembled correctly, the MIS Rod Compass Holder Poly cannot be rotated on the MIS Rod Compass Ruler.

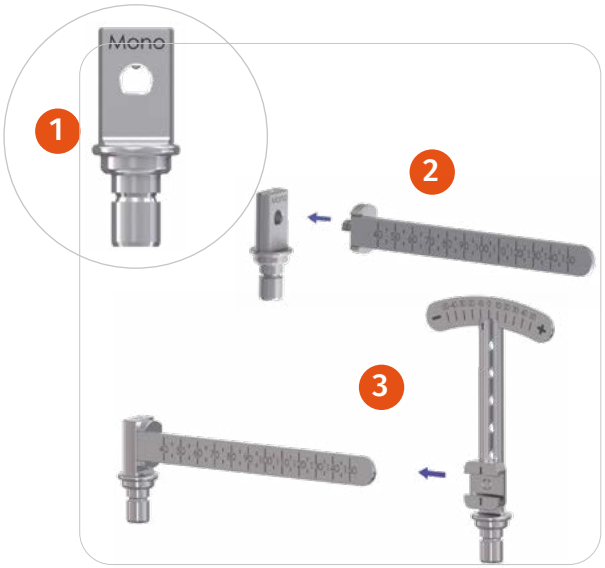
Determining the rod length for at least one terminal polyaxial screw

To determine the rod length, both MIS Rod Compass Holder are inserted into the furthest cranial and the furthest caudal MIS Fracture-Tower. The rod length can now be determined.
To do so, the value on the “Ruler” is read off ((1) or (2)) and either added (3) or subtracted (4) to the value displayed on the subscale.

Caution:
Ensure that the MIS Rod Compass is mounted to the MIS Fracture-Towers until it reaches the stop. Also push down on the MIS Rod Compass, if required.

Example calculation:
Using the representations above:
- Addition: 50 mm (1) + 40 mm (3)
  = rod length 90 mm
- Subtraction: 110 mm (2) - 20 mm (4)
  = rod length 90 mm

Note:
For multi-segmental constructions originating in the sacrum, there may be deviations in the readings during the rod length measurement depending on the curvature of the spine and the number of segments requiring reinforcement. In this case, several individual shorter distances should be measured and the individual lengths added together.



Assembling the MIS Rod Compass for two terminal monoaxial screws

To measure the rod length, the MIS Rod Compass Holder Mono (1) must be mounted onto the MIS Rod Compass Ruler (2). Then the MIS Rod Compass Pointer is slid onto the Ruler (3).

Note:
Once assembled correctly, the MIS Rod Compass Holder Mono can be rotated on the MIS Rod Compass Ruler.

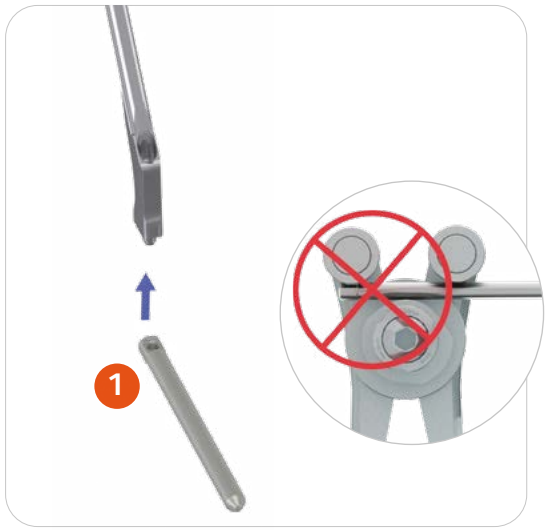
Determining the rod length for two terminal monoaxial screws

To determine the rod length, both MIS Rod Compass Holder are inserted into the furthest cranial and the furthest caudal MIS Fracture-Tower. The rod length can now be determined. To do so, the value is on the “Ruler” is read off ((1) or (2)) and either added (3) or subtracted (4) to the value displayed on the subscale.

Caution:
Ensure that the MIS Rod Compass is mounted onto the MIS Fracture-Tower until it reaches the stop. Also push down the MIS Rod Compass, if required.

Caution:
Due to the necessary angle-variable connection of the Rod Compass Holder to the Ruler, there may be small variations in measurements when determining the rod length. Therefore, 10 mm should be added to the measured result.

Example calculation:
Using the representations above:
- Addition: 50 mm (1) + 40 mm (3) + 10 mm safety
  = rod length 100 mm
- Subtraction: 110 mm (2) – 20 mm (4) +10 mm safety
  = rod length 100 mm



Locking the rod on MIS Rod Holder I

Attach the selected rod to the MIS Rod Holder. In doing so, ensure that the longitudinal marking on the rod points upwards (1).

Note:
Bend the rods with Rod Bender to fit the corresponding radius. The bending radius can also be set on the instrument by adjusting the bending roll. Insert the rod in the screw heads using the MIS Rod Holder, if necessary with manual support.
Do bend a rod at one point only in one direction. Bending the rod at the same point to the other direction afterwards will weaken the rod notably or damage it.

Locking the rod on MIS Rod Holder II

The rod is screwed on the MIS Rod Holder with the aid of the MIS ML2 Locking Screw Driver.

Caution:
The fixation screw must be tightened sufficiently to ensure that the rod is securely positioned on the Rod Holder.

Caution:
It is advised that the fixation screw is secured once again during rod insertion over several segments or for rod insertions requiring a high degree of force. If the connection between the instrument and the implant is loosened, then the fixation screw may break. In this event, the rod must be replaced.

Inserting the rod

To insert the rod, position the MIS Rod Holder vertically next to the MIS Fracture-Tower so that the tip of the rod points downwards. Then insert the rod in a vertical position to below the fascia. By straightening the MIS Rod Holder, the rod can be inserted and then guided through into the MIS Fracture-Tower of the following segment. During this process, the rod must be guided between the muscles, thus avoiding any trauma. The holder element of the MIS Rod Holder must be parallel to the MIS Fracture-Tower once it is in its final position. Check the correct positioning of the rod using the image converter. While doing so, ensure that the rod tip protrudes by at least 3 mm and the rod end by at least 7 mm over the head of the screw.

Fitting the MIS Setscrew

The MIS Set Screw Inserter 2.0 is mounted onto an MIS Setscrew. By screwing the inner threaded rod of the MIS Set Screw Inserter 2.0 into the MIS Setscrew, this becomes secured to the MIS Set Screw Inserter 2.0. Then the desired handle can be mounted onto the MIS Set Screw Inserter 2.0.

Caution:
Only tighten the threaded rod by hand, as otherwise complications can arise when loosening the MIS Setscrew afterwards.

Inserting the MIS Setscrew

The MIS Set Screw Inserter 2.0 is guided into the MIS Fracture-Tower with the fitted MIS Setscrew until it sits on the rod. The MIS Setscrew can then be screwed in.

Caution:
Only tighten the MIS Setscrew gently. For the final torque, use the MIS Set Screw Driver.

Note:
It is recommended to affix the MIS Setscrew on the side of the MIS Rod Holder first.

Marking for the MIS Fracture-Tower

The marking line beneath the label “POSITION SETSCREW START OF THREAD” is for checking the position of the MIS Setscrew in the MIS Fracture-Tower / in the screw head. The marking should make it clear whether the MIS Setscrew has been inserted deep enough in order to be tightened.
If this marking comes to the height of the upper outside edge of the MIS Fracture-Tower or if this is slightly lower in the MIS Fracture-Tower (1), then the position of the MIS Setscrew is correct. The MIS Setscrew can then be tightened without tension (2).

If the marking clearly lies above the MIS Fracture-Tower, the MIS Setscrew cannot be tightened (3) as the rod is situated above the pedicle screw.
The following steps can be taken to allow the MIS Setscrew to be secured:
- Removal of any tissue or foreign material in the screw head or in the MIS Fracture-Tower
- Use the MIS Rod Pusher 2.0 or the MIS Rod Driver to push the rod downwards.

Using the Rod Pusher

If the rod is not yet completely inside the screw head of the pedicle screw, the rod can be pushed downwards with the aid of the MIS Rod Pusher 2.0. To do so, insert the MIS Rod Pusher 2.0 into a MIS Fracture-Tower and push in the anterior direction. In doing so, ensure that the u-shaped recess at the tip of the MIS Rod Pusher 2.0 encloses the rod. This allows the mounted MIS Setscrew to be used in an adjacent MIS Fracture-Tower. The MIS Rod Pusher 2.0 is then removed, and this pedicle screw is also fitted with a MIS Setscrew.

Note:
The optional reposition method using the MIS Rod Driver is described in the surgical technique of the VENUSmini 2.0 system.

Removal of the MIS Set Screw Inserter 2.0

To remove the MIS Set Screw Inserter 2.0, the threaded rod must first be loosened by turning counterclockwise (1). If the connection between the threaded rod and the MIS Setscrew is very tight, the MIS ML2 Locking Screw Driver can be introduced into the MIS Set Screw Inserter 2.0 from the rear (2) and the threaded rod loosened. Then the MIS Set Screw Inserter 2.0 can be removed.

Note:
This procedure is repeated for each individual pedicle screw.

Tightening the MIS Setscrew

The MIS Set Screw Driver is inserted into the Torque Driver - 12. The MIS Counter Handle is pushed onto the MIS Fracture-Tower according to the orientation of the guiding surfaces (1). The pre-mounted Torque Driver - 12 can then be fed through the MIS Counter Handle (2), and the MIS Setscrew can be tightened with torque applied in a clockwise direction. After taking out the Torque Driver - 12, the MIS Counter Handle can be removed again.
The same procedure is carried out for all other MIS Setscrews.

Caution:
The full torque of 12 Nm is reached once you hear a clicking sound in the Torque Driver - 12. In order to achieve maximum stability, the final torque may only be applied with the Torque Driver - 12 once all repositioning and correction maneuvres have been completed. If the tightening of a MIS Setscrew with torque is necessary before this, these MIS Setscrews must be tightened again as described.

Removing the MIS Counter Handle

After removing the Torque Driver - 12 pull the MIS Counter Handle away from the MIS Fracture-Tower.

Removing the MIS Rod Holder

Before the MIS Rod Holder is removed, a final check must be made to ensure the correct positioning of the rods. While doing so, the rod tip should protrude at least 3 mm and the rod end at least 7 mm over the head of the screw. The MIS Rod Holder is loosened from the rod with the help of the MIS ML2 Locking Screw Driver. MIS ML2 Locking Screw Driver must be noticeably locked in the torx of the connecting screw.

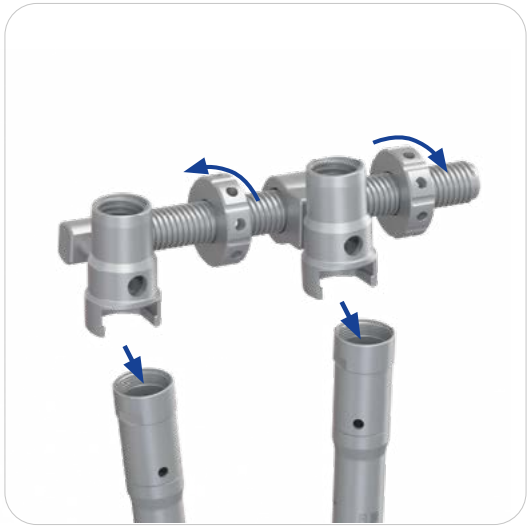
Caution:
In order to remove the MIS Rod Holder, the fixing screw must be completely loosened so that the instrument can be taken off the implant without the use of force. If the instrument is subject to force and the fixing screw is not completely loosened, it is possible that the screw on the MIS Rod Holder may break. In this case, the rod must be replaced.

Removing the MIS Fracture-Tower I

To remove the MIS Fracture-Tower, insert the MIS Multitool into the MIS Fracture-Tower until it is noticeably locked in place and loosen the locking mechanism with a ¼ turn of the MIS Multitool in an counterclockwise direction (1). The exterior sleeve of the MIS Fracture-Tower must then be pulled back to the stop (2).

Removing the MIS Fracture-Tower II

Now tilt the MIS Fracture-Tower slightly in a medial or lateral direction while rotating 90° and pulling it away in a distal direction (1). Then the MIS Fracture-Tower can be removed from the wound.
Then secure the MIS Interior Clamp and MIS Fracture-Tower once again by turning the MIS Multitool a ¼ turn in a clockwise direction (2) and pull the MIS Multitool away in a distal direction (3).
The other MIS Fracture-Tower are then loosened from the pedicle screws in the same way.



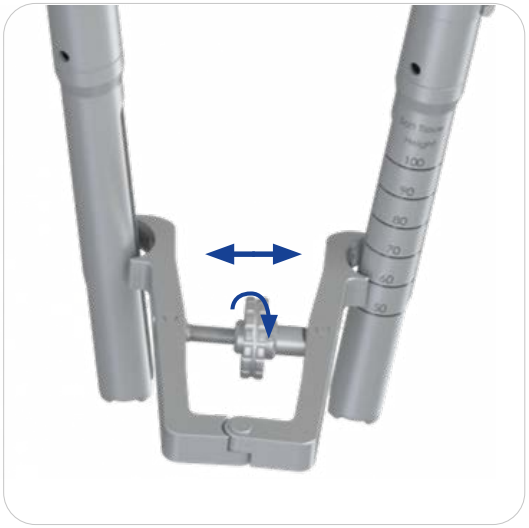
Attaching the MIS Compressor - Distractor 2.0 Extension

Before using the optional MIS Compressor - Distractor 2.0 Extension for fracture correction, the pedicle screws must be implanted with the MIS Fracture-Tower according to the surgical procedure described above.

In order to achieve the desired correction of the fractured vertebral body, MIS Compressor-Distractor 2.0 Extension with a Distance Holder is available.

The MIS Compressor-Distractor 2.0 Extension is mounted onto the MIS Fracture Tower by loosening the Extension Nuts and attaching both Extension Sleeves over the top of each Fracture Tower.

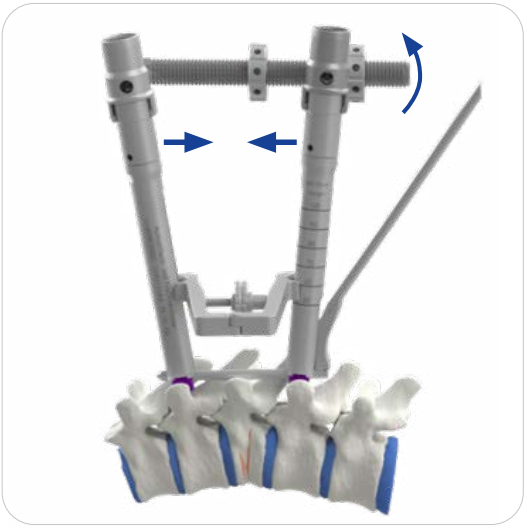
Caution:
Do not apply any forces to the MIS Fracture-Towers while attaching the MIS Compressor-Distractor 2.0. Instead, further readjustment of the Extension Nuts might be necessary.



Attaching the Distance Holder

The Distance Holder is placed between the MIS Fracture-Towers. Depending on the desired distance, the Distance Holder can be expanded as necessary.

Note:
Make sure the Distance Holder is distracted far enough to depict or exceed the desired correction height.



Fracture correction I

By turning the Extension Nut of the MIS Compressor-Distractor 2.0 the posterior ends of the MIS Fracture-Towers can be distracted. The Distance Holder serves as the counter holder of the leverage arm.
Depending on the given anatomy and the fracture of the vertebral body different types of correction are possible.
If a distinctly ventral distraction of the fractured vertebral body is desired, the Distance Holder should be held in a fixed distracted position.
If an additional rotation of the fractured vertebral body is desired, the distraction of the Distance Holder can be reduced slowly in order to approximate the desired height and rotation of the fractured vertebral body.

Note:
The already inserted rod acts as a guide to avoid unwanted rotation during correction. If this prohibits the correction the rod can alternatively be inserted after the correction.

Caution:
Ensure that the Distance Holder is not compressed too far since the instrument is not designed to withstand enough force to re-distract the vertebral bodies.

Fracture correction II

After the desired correction of the fractured vertebral body has been achieved, the rod needs to be inserted if the additional guidance was not required during the correction.

Fitting the MIS Setscrew

The MIS Set Screw Inserter 2.0 is mounted onto an MIS Setscrew. By screwing the inner threaded rod of the MIS Set Screw Inserter 2.0 into the MIS Setscrew, this becomes secured to the MIS Set Screw Inserter 2.0. Then the desired handle can be mounted onto the MIS Set Screw Inserter 2.0.

Caution:
Only tighten the threaded rod by hand, as otherwise complications can arise when loosening the MIS Setscrew afterwards.

Inserting the MIS Setscrew

The MIS Set Screw Inserter 2.0 is guided into the MIS Fracture-Tower with the fitted MIS Setscrew until it sits on the rod. The MIS Setscrew can then be screwed in.

Caution:
Only tighten the MIS Setscrew gently. For the final torque, use the MIS Setscrew Driver.

Note:
It is recommended to affix the MIS Setscrew on the side of the MIS Rod Holder first.

Tightening the MIS Setscrew

The MIS Set Screw Driver is inserted into the Torque Driver - 12. The pre-mounted Torque Driver - 12 can then be fed through the MIS Compressor - Distractor 2.0 Extension, and the MIS Setscrew can be tightened with torque applied in a clockwise direction. The same procedure is carried out for all other MIS Setscrews.
After all MIS Setscrews are fully tightened, the MIS Compressor - Distractor 2.0 Extension can be detached from the Tower.

Caution:
The full torque of 12 Nm is reached once you hear a clicking sound in the Torque Driver - 12. In order to achieve maximum stability, the final torque may only be applied with the Torque Driver - 12 once all repositioning and correction maneuvres have been completed. If the tightening of a MIS Setscrew with torque is necessary before this, these MIS Setscrews must be tightened again as described.

2T Cannulated Monoaxial Screws

Item no.	Article Description	
4000115525	2T Cannulated Monoaxial Screw Ø5.5x25 mm	Ø 5.5
4000115530	2T Cannulated Monoaxial Screw Ø5.5x30 mm	
4000115535	2T Cannulated Monoaxial Screw Ø5.5x35 mm	
4000116525	2T Cannulated Monoaxial Screw Ø6.5x25 mm	Ø 6.5
4000116530	2T Cannulated Monoaxial Screw Ø6.5x30 mm	
4000116535	2T Cannulated Monoaxial Screw Ø6.5x35 mm	

2T Cannulated Monoaxial Screws

STERILE

Item no.	Article Description	
4000115525-S	2T Cannulated Monoaxial Screw Ø5.5x25 mm sterile	Ø 5.5
4000115530-S	2T Cannulated Monoaxial Screw Ø5.5x30 mm sterile	
4000115535-S	2T Cannulated Monoaxial Screw Ø5.5x35 mm sterile	
4000116525-S	2T Cannulated Monoaxial Screw Ø6.5x25 mm sterile	Ø 6.5
4000116530-S	2T Cannulated Monoaxial Screw Ø6.5x30 mm sterile	
4000116535-S	2T Cannulated Monoaxial Screw Ø6.5x35 mm sterile	

2T Fenestrated Monoaxial Screws

Item no.	Article Description	
4000145540	2T Fenestrated Monoaxial Screw Ø5.5x40 mm	Ø 5.5
4000145545	2T Fenestrated Monoaxial Screw Ø5.5x45 mm	
4000145550	2T Fenestrated Monoaxial Screw Ø5.5x50 mm	
4000145555	2T Fenestrated Monoaxial Screw Ø5.5x55 mm	
4000146540	2T Fenestrated Monoaxial Screw Ø6.5x40 mm	Ø 6.5
4000146545	2T Fenestrated Monoaxial Screw Ø6.5x45 mm	
4000146550	2T Fenestrated Monoaxial Screw Ø6.5x50 mm	
4000146555	2T Fenestrated Monoaxial Screw Ø6.5x55 mm	
4000147240	2T Fenestrated Monoaxial Screw Ø7.2x40 mm	Ø 7.2
4000147245	2T Fenestrated Monoaxial Screw Ø7.2x45 mm	
4000147250	2T Fenestrated Monoaxial Screw Ø7.2x50 mm	
4000147255	2T Fenestrated Monoaxial Screw Ø7.2x55 mm	
4000147260	2T Fenestrated Monoaxial Screw Ø7.2x60 mm	

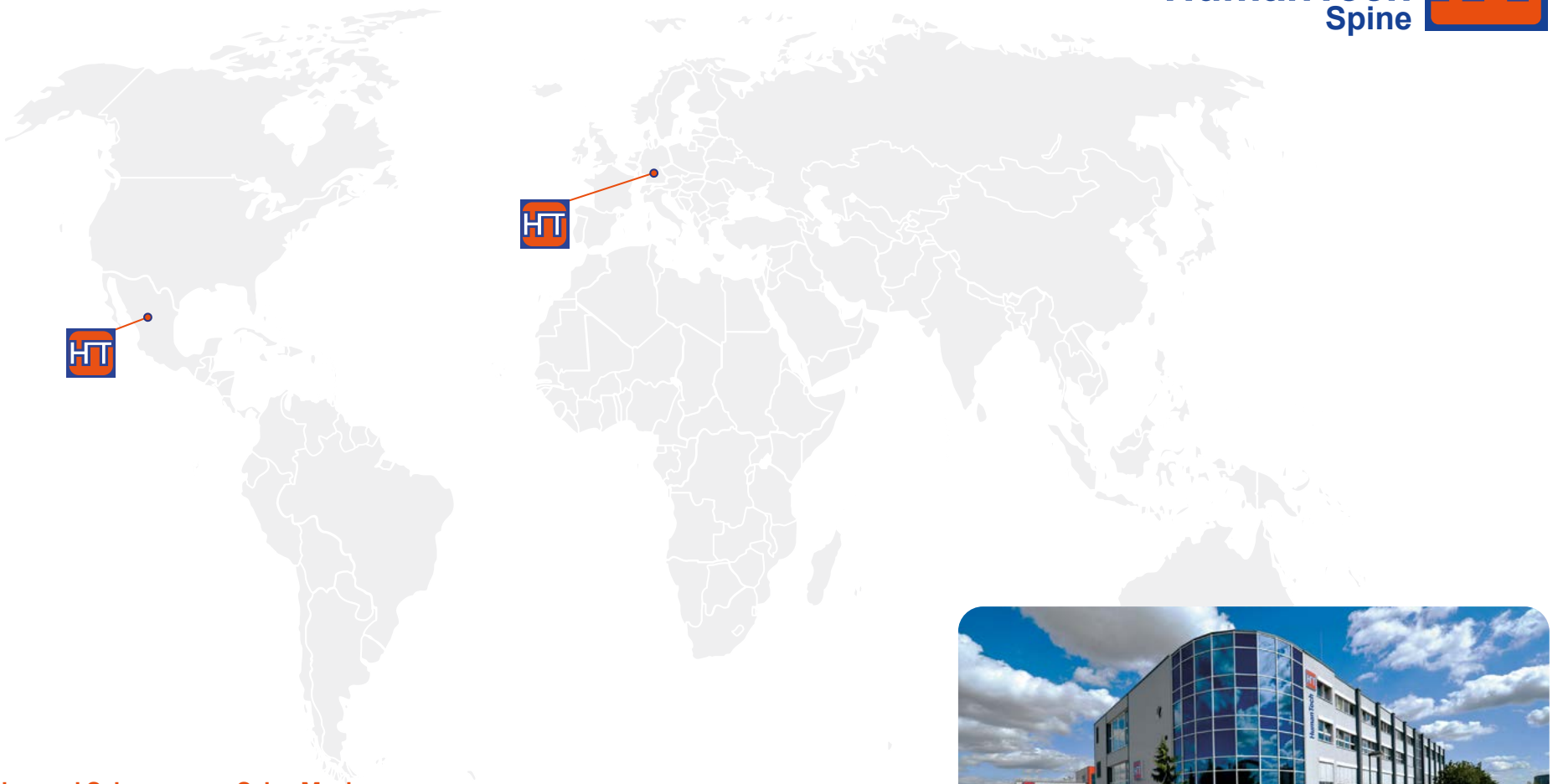
2T Fenestrated Monoaxial Screws

STERILE

Item no.	Article Description	
4000145540-S	2T Fenestrated Monoaxial Screw Ø5.5x40 mm sterile	Ø 5.5
4000145545-S	2T Fenestrated Monoaxial Screw Ø5.5x45 mm sterile	
4000145550-S	2T Fenestrated Monoaxial Screw Ø5.5x50 mm sterile	
4000145555-S	2T Fenestrated Monoaxial Screw Ø5.5x55 mm sterile	
4000146540-S	2T Fenestrated Monoaxial Screw Ø6.5x40 mm sterile	Ø 6.5
4000146545-S	2T Fenestrated Monoaxial Screw Ø6.5x45 mm sterile	
4000146550-S	2T Fenestrated Monoaxial Screw Ø6.5x50 mm sterile	
4000146555-S	2T Fenestrated Monoaxial Screw Ø6.5x55 mm sterile	
4000147240-S	2T Fenestrated Monoaxial Screw Ø7.2x40 mm sterile	Ø 7.2
4000147245-S	2T Fenestrated Monoaxial Screw Ø7.2x45 mm sterile	
4000147250-S	2T Fenestrated Monoaxial Screw Ø7.2x50 mm sterile	
4000147255-S	2T Fenestrated Monoaxial Screw Ø7.2x55 mm sterile	
4000147260-S	2T Fenestrated Monoaxial Screw Ø7.2x60 mm sterile	

Item no.	Name	
4008020003	MIS Monoaxial Screw Driver	
4008020001 and 4008010016	MIS Fracture-Tower MIS Interior Clamp	
4008020006	MIS Rod Compass Holder Mono	
4008010032	MIS Compressor-Distractor 2.0 Extension	

HumanTech Spine



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