HumanTech Spine

VENUSmini 2.0 FRACTURE

Extension kit for minimally invasive fracture treatment

Content

Made in Germany

For a better life

The German family business HumanTech Spine with headquarter in Baden-Württemberg develops and manufactures all products inhouse and sells high-quality innovative spinal implant systems worldwide.

Our traditional company group, founded in 1948, is a reliable employer for around 500 employees and has a manufacturing area of approx. 15.000 m^2, in which our complete range of products is produced. Our high-tech manufacturing facilities as well as state-of-the-art, sustainable production and logistics processes guarantee high-quality and in-time-production and delivery processes.

The independent medical business segment with a focus on spine and dental was founded in 2010 and is now well-known and well represented in the national and international market. Together with renowned spinal surgeons, our development team breaks new ground every day to ensure that every patient receives uncompromisingly high-quality care.

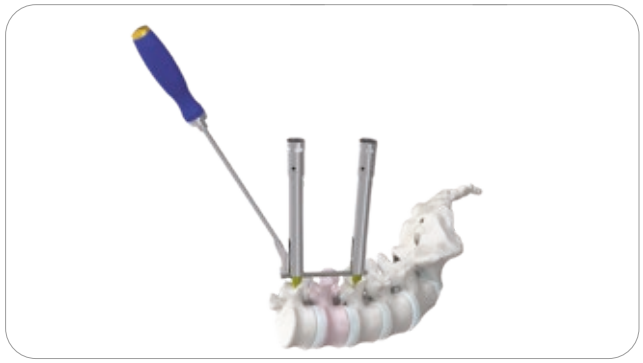
The design of our systems follows the aim of maximum user-friendlyness, safety and completeness. That‘s why HumanTech Spine counts as a reliable partner in the field of spine - in the area of research, development, production and marketing as well as in continuing education and training through our HumanTech Academy. Everything from a single source. This is how we ensure our quality promise 100% Made in Germany.

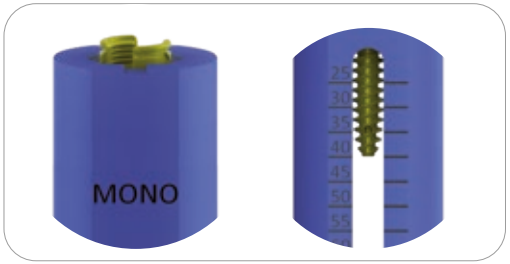
The VENUSmini 2.0 Fracture system is an extension kit for the existing minimally invasive fixation system VENUSmini 2.0 and is used for the minimally invasive treatment of fractures. For this purpose, the extension kit contains monoaxial VENUS screws in cannulated and fenestrated form.

The following benefits of the VENUSmini 2.0 system for the patient and the hospital staff could also be realized in the VENUSmini 2.0 Fracture expansion kit:

- Reduction in the size of the incision required due to the decreased outer diameter of the percutaneous sleeves
- Shorter instruments allow an easier rotation of the C-arm
- Possibility of reposition using an inlaid Rod Pusher
- Percutaneous sleeves with integrated counter holder
- Shorter operation times thanks to simplified attachment of the pedicle screws to the percutaneous sleeves
- Shorter operation times as a result of fewer screw connections
- Impossible to use incorrect screws for the percutaneous sleeves
- Easier to determine the required length
- Lower x-ray intensity thanks to more detailed length markings on specific instruments

Venusmini 2.0 FRACTURE





The following additional benefits for the patient and the clinic staff could be realized by adding the VENUSmini 2.0 Fracture expansion kit to the VENUSmini 2.0:

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

→ Complete compatibility of the instruments and implants of the extension kit VENUSmini 2.0 Fracture with the instruments of the VENUSmini 2.0 system

→ Combined use of polyaxial and monoaxial pedicle screws possible

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 Assembling Aid

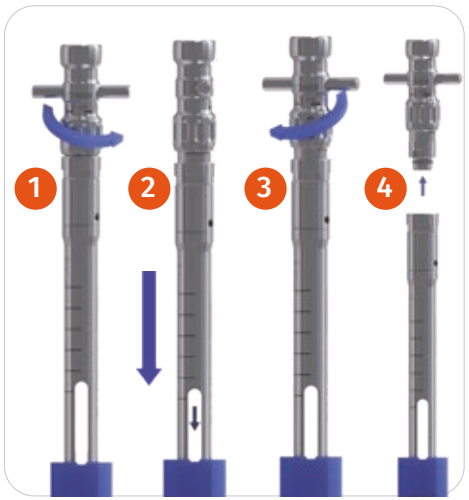
The selected monoaxial screw is inserted into the side of the MIS Assembling Aid marked “MONO”. The monoaxial screw must be inserted into its specific deep recess (1). To help the screw enter the recess, twist the screw a little, if necessary.

Note:
Using the length markings provided, it is possible to determine the length of the screw taken out of the tray (2).

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

The MIS Multitool must be correctly positioned on the MIS Fracture-Tower. The annular spring area must point in a distal direction. It must be ensured that the Multitool can be felt locking into the Interior Clamp of the MIS Fracture-Tower (1). Before attaching the screw, the correct position of the inner and outer sleeve of the MIS Fracture-Tower must be ensured. The proximal end of the Interior Clamp should protrude approx. 5 mm out of the exterior sleeve of the MIS Fracture-Tower (2). Where the Interior Clamp does not protrude by 5 mm, unlock the Interior Clamp by using the Multitool (“unlock” position) and push forwards. Then secure the position of the exterior sleeve of the MIS Fracture-Tower and Interior Clamps once again (“lock” position). In the locked position, the Interior Clamp cannot be pushed axially into the exterior sleeve of the MIS Fracture-Tower. The correct position can be checked by simply applying axial pressure to the Interior Clamp. This should not be movable when in a locked position. The MIS Fracture-Tower is now inserted vertically into the MIS Assembling Aid (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 clockwise).



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

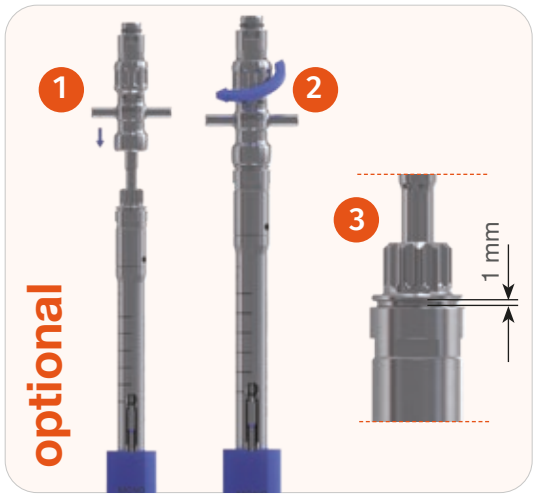
Now place the locking mechanism into the “unlock” position by turning the Multitool anti-clockwise (1). The exterior sleeve of the MIS Fracture-Tower can then be pushed downwards (2). The MIS Multitool must be turned to the “lock” position and pulled tight by hand in order to secure the monoaxial screw to the MIS Fracture-Tower (3). The Multitool can then be pulled upwards (4).

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

Assembly

Securing the screw to the MIS Fracture-Tower

The MIS Monoaxial Screwdriver 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 Screwdriver is correctly positioned in the rod recess of the screw head of the monoaxial screw. The connecting screw of the MIS Monaxial Screwdriver is now screwed clockwise into the MIS Fracture-Tower (3).



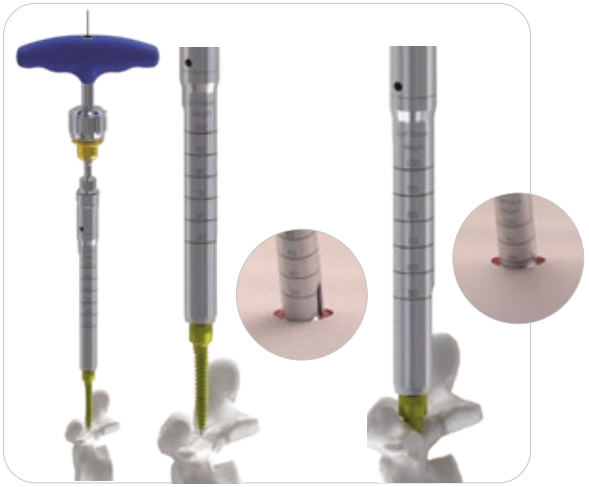
Assembly

of the MIS Monoaxial Screwdriver

The Multitool can be used to tighten up the screwdriver. To do so, attach the 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 Monaxial Screwdriver.

Note:
The Multitool must be mounted rotated 180° to the position of the previous step. The annular spring points in a proximal direction.

Note:
When the MIS Monoaxial Screwdriver 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 Screwdriver (3).



Inserting the pedicle screw

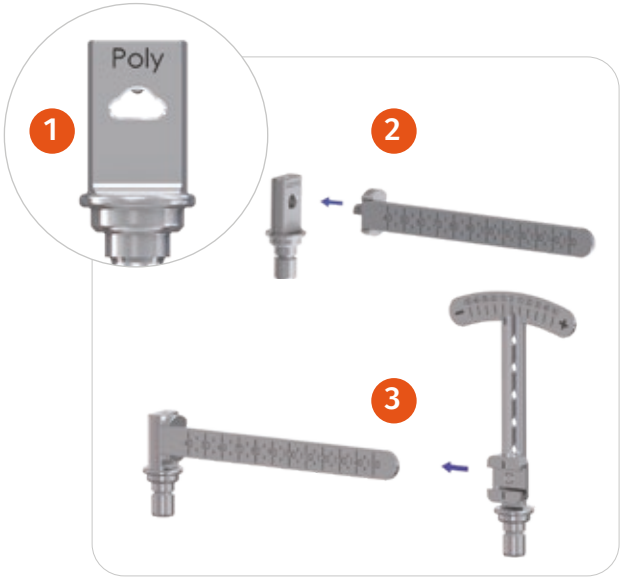
The pedicle screw is now implanted using the K-Wire in place and under observation using imaging technology.

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 as previously determined during setting the pedicle entry point and preparation of the pedicle / dilation is used as reference value. This allows the intensity of x-ray exposure to be reduced 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 Screwdriver

Following the implantation, the Screwdriver can be loosened and removed by rotating the connecting screw anti-clockwise (1).
Where greater force is required to loosen the connecting screw, the Multitool can be mounted (with the annular spring pointing in a proximal direction). In order to stabilise the Tower, the Deformity Key can be inserted into one of the side holes of the 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).

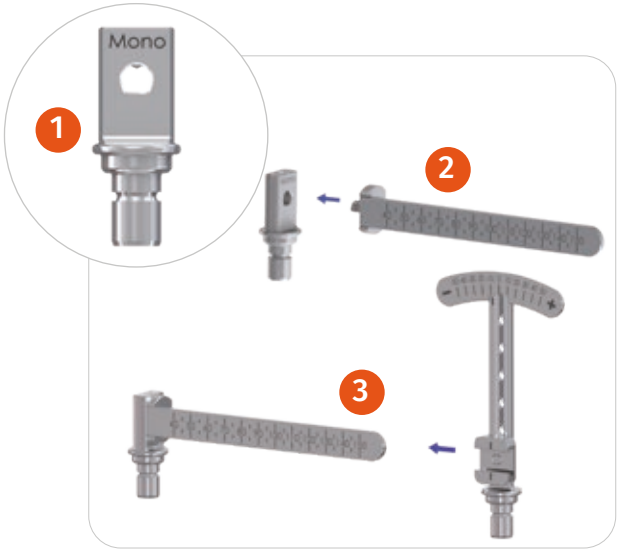
Note:
Once assembled correctly, the MIS Rod Compass Holder Poly cannot be rotated on the MIS Rod Compass Ruler.

Determining the rod length

for at least one terminal polyaxial screw

To determine the rod length, both pins of the Rod Compass Holder are inserted into the furthest cranial and the furthest caudal 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 onto the 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 spinal column 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 pushed 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

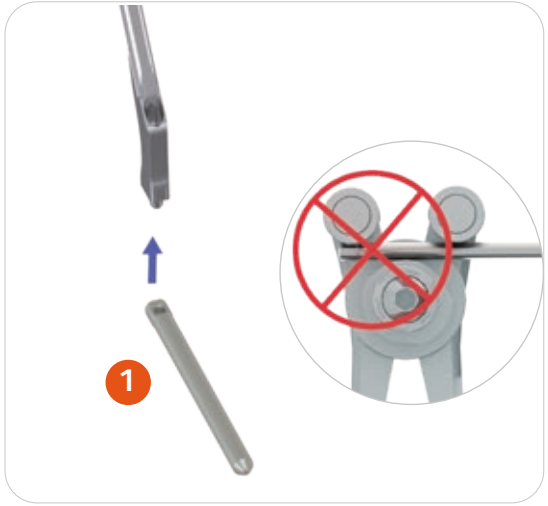
for two terminal monoaxial screws

To determine the rod length, both pins of the Rod Compass Holder are inserted into the furthest cranial and the furthest caudal 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 Towers until it reaches the stop. Also push down on 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 is pointing upwards (1).

Note:
The rod can also be bent according to the desired operation outcome by using the Rod Bender, where necessary. Multiple attempts to bend the rod should be avoided. Care should be taken to ensure that the area of the instrument connection is not bent (2). To ensure a secure fit, the contour of the rod must be selected so that it can be assembled without producing any tension and that the rod is entirely situated in the heads of the pedicle screw.
The Rod Holder is available in a range of different variants (see Instrument overview of the standard VENUSmini 2.0 system). These differ in the length of the anterior holder element (MIS Rod Holder Long and MIS Rod Holder Short). In another available variant, the angulation of the handle is adjustable (MIS Rod Holder Flex).

Loosening
on MIS Rod Holder II

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

Caution:
The fixation screw must be pulled tight enough 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 insertions of the rod over more 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 is pointing 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 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 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 set screws

The MIS Set Screw Inserter 2.0 is mounted onto an MIS Set Screw. By screwing the inner threaded rod of the MIS Set Screw Inserter 2.0 into the set screw, 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.

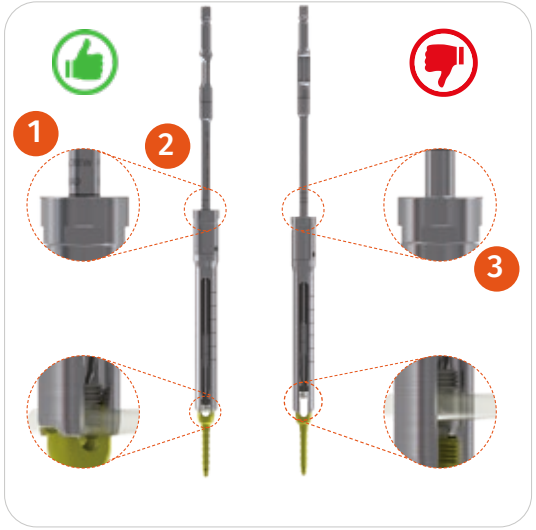
Caution:
Only tighten the threaded rod by hand, as otherwise complications can arise when loosening the MIS Set Screw afterwards.

Inserting the MIS Set Screw

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

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

Note:
It is recommended to affix the MIS Set Screws 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 set screw in the Tower / in the screw head. The marking should make it clear whether the set screw has been inserted deep enough in order to be screwed into the thread of the screw head.
If this marking comes to the height of the upper outside edge of the Tower or if this is slightly lower in the Tower (1), then the position of the set screw is correct. The set screw can then be screwed without tension into the screw head (2).
If the marking clearly lies above the Tower, the set screw cannot be screwed in (3) as the rod is situated above the pedicle screw.
The following steps can be taken to allow the screw to be secured:
- Removal of any tissue or foreign material in the screw head or in the Tower
- Use the MIS Rod Pusher 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 an 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 set screw to be used in an adjacent Tower. The MIS Rod Pusher 2.0 is then removed, and this pedicle screw is also fitted with a set screw.
Note:
It is best not to use the MIS Rod Pusher 2.0 in the nearest adjacent Tower, but instead in the segment after that. By pushing the Rod Holder downwards, the rod can be pushed into the Rod Holder on the next available Tower without using the MIS Rod Pusher 2.0.
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 anti-clockwise (1). If the connection between the threaded rod and the MIS Set Screw 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.

Securing the instrumentation

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

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

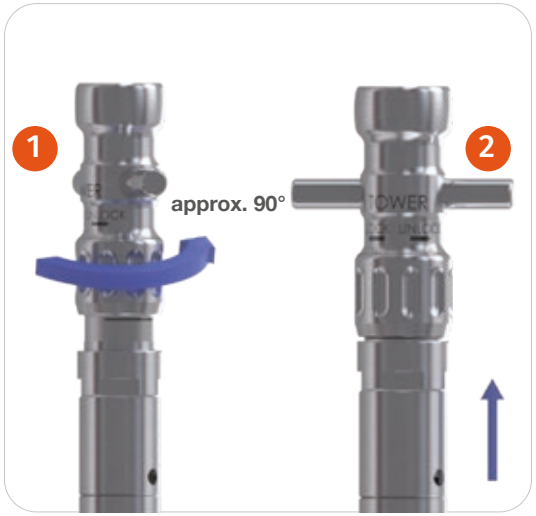
Removing the MIS Counter Handle

After removing the Torque Driver, 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. You must be able to feel that the MIS ML2 Locking Screw Driver is locked in place 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. Where the instrument is subject to force and the fixing screw is not completely loosened, it is possible that the screw on the rod inserter may break. In this case, the rod must be replaced.



Removing the Fracture-Tower I

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

Removing the Fracture-Tower II

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

2T Cannulated Monoaxial Screws

Item no.	Name	
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	

STERILE

2T Cannulated Monoaxial Screws

Item no.	Name	
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	

available soon

2T Fenestrated Monoaxial Screws

Item no.	Name	
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	

STERILE

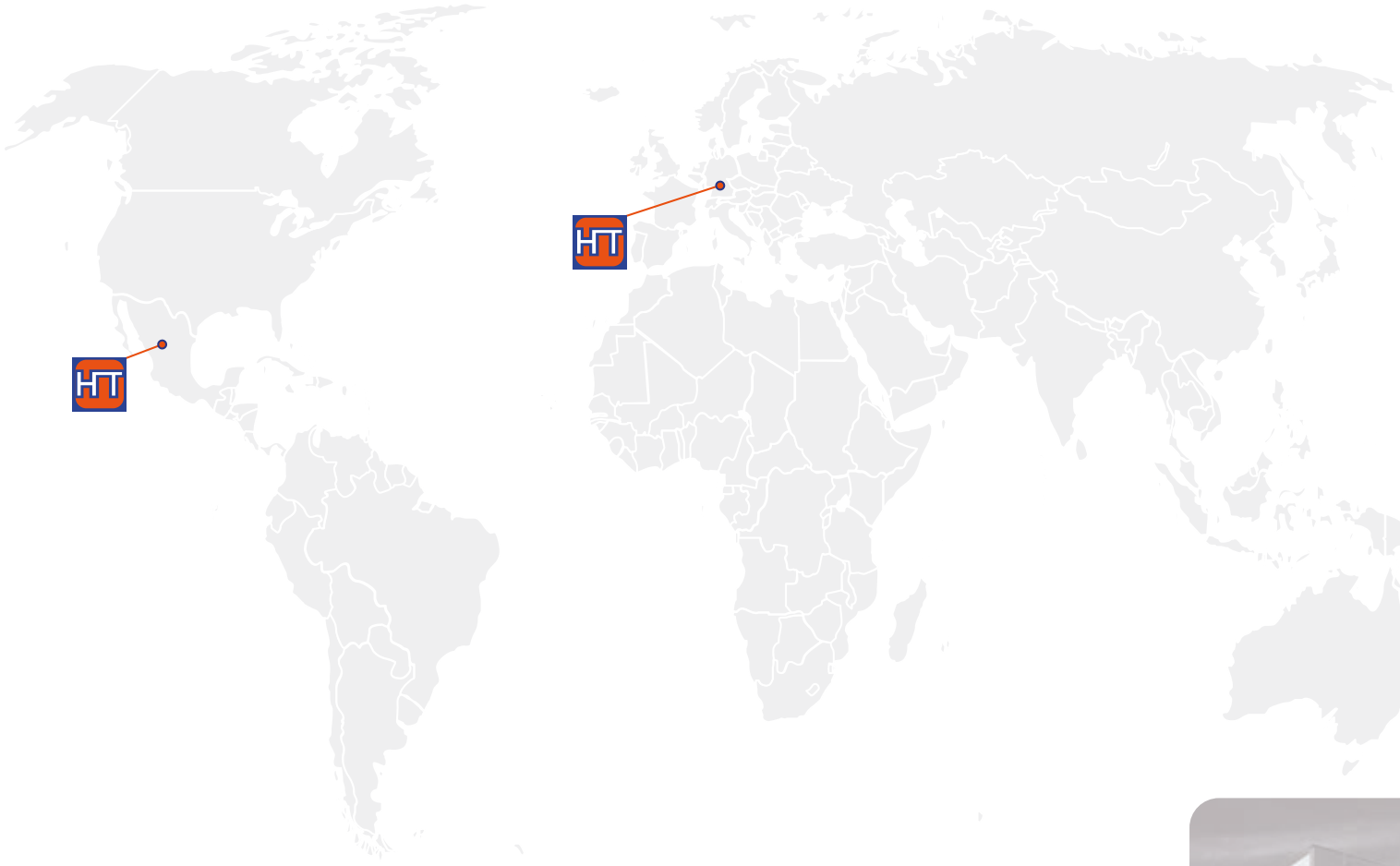
2T Fenestrated Monoaxial Screws

Item no.	Name	
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	

available soon

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

HumanTech Spine



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