



VENUSmini 2.0

Minimally Invasive Fixation System

Content

About us	03
System	04
Preparation	06
How to use the MIS Tower	09
Reposition	15
Subsequent placement of the tower	17
Augmentation	20
Implants - rods, sterile / non-sterile	22
Implants - screws, sterile / non-sterile	24
Instruments	26
Contact	32

About us





HumanTech Spine is a leading manufacturer of human implants and instruments for spinal surgery. Its intelligently designed implant systems are used successfully throughout the world. With in-house production at our site in Steinenbronn, we guarantee added value for our users and clear competitive benefits for our distribution partners. All of our products have the "Made in Germany" seal.

The high level of precision in all manufacturing areas perfectly complements the strict requirements for manufacturing medical devices. Our high-tech machine pool and state-of-the-art testing methods guarantee perfect results and the highest-quality products.

Teamwork, enthusiasm and commitment are ultimately crucial to HumanTech Spine's long-term success. Each of our employees is 100% committed to the wishes and requirements of our users and their patients. This is how we develop and implement new ideas, always with the human body as the focal point.

From research and development to the finished product, HumanTech Spine offers everything from a single source. This means safety, quality and speed in all areas for users and patients. The many different production options and the wide range of technologies for surface treatment in our high-tech machine pool provide unlimited possibilities. All stages of production, from

machining and assembly to functional testing, are carried out in our factory in Steinenbronn, from which we deliver the products around the world.

The most advanced production processes and high quality standards are vital to our ongoing success. Another essential part of our company's philosophy is our commitment to environmentally sustainable practices. All of our production plants are therefore operated in compliance with the latest environmental protection standards. This has been repeatedly confirmed to us over the years through our company's successful ISO 14001 certification.

System

The VENUSmini 2.0 system is the conistent further development the VENUSmini systems. This system has all of the benefits of the VENUSmini in addition to a number of new product features.

This further development offers the following benefits for both patients and hospital staff:

- 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
- Exclusion of inccorect screw assembly on percutaneous sleeves
- Simplified determination of the required rod length
- Lower x-ray intensity thanks to more detailed length markings on specific instruments



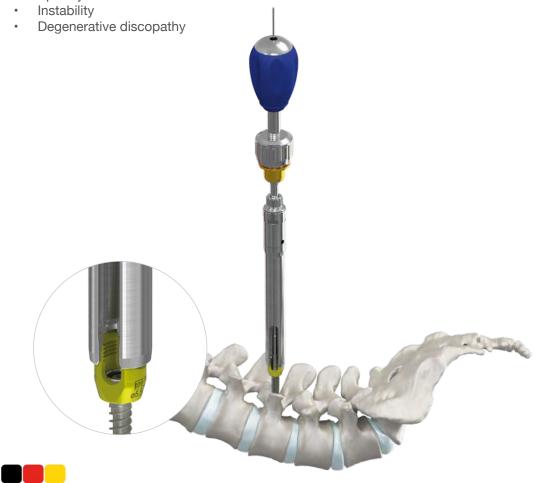


Description of MIS Tower

The percutaneous sleeve (MIS Tower) was designed for use with polyaxial pedicle screws for different indications.

Indications (example):

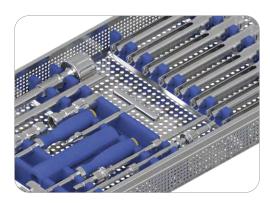
· Spondylolistheses





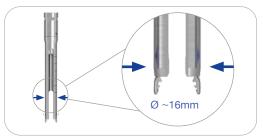












- Reduced soft tissue trauma
- 2 Time-saving
- 3 Reduced exposure to X-ray radiation → Addition of extra length markings on
- → Tower designed with optimal outer diameter
- → Reposition using inlaid Rod Pusher
- → Tower with integrated torque counterholder
- → Simple click 'n' lock screw attachment
 → Simplified determination of the required rod length
- → Reposition instrument with high thread pitch
 - specific instruments for determining the screwing depth









Preparation



Preparing the pedicle using the Cannulated Awl

After the point of incision is determined, a longitudinal incision approx. 2 cm in length is made through the skin and fascia. The Cannulated Awl 30 is inserted into the incision until the tip rests on the bony anatomy of the target segment. The pedicle entry point is established by gentle hammering. In the case of the Cannulated Awl 30, the tip of the awl should be driven in to the stop. In the case of the optionally available Cannulated Awl without stop, the depth of insertion can be varied as desired, but must be monitored by x-ray. Once the selected awl is positioned securely in the pedicle, the trocar wire is then removed by turning the handle anti-clockwise and pulling it off.

Caution:

The trocar wire must be completely screwed in during the insertion of the cannulated awl.

Note:

When the tip of the cannulated awl is resting on the bony structures (1), the thickness of the soft tissue coverage can be determined using the length markings found on the outside of the instrument (2). This serves as a guide to help reduce the intensity of x-ray exposure during the attachment of the screws.



Preparing the pedicle using a Jamshidi needle

After the point of incision is determined, a longitudinal incision approx. 2 cm in length is made through the skin and fascia. The Jamshidi needle is inserted into the incision until the tip rests on the bony anatomy of the target segment. The pedicle entry point is established by gentle hammering. The depth of insertion can be varied as desired, but must be monitored by x-ray. Once the Jamshidi needle is positioned securely in the pedicle, the trocar wire is then removed by opening the handle and pulling.



Preparing the pedicle using the Cannulated Awl compact

After the point of incision is determined, a longitudinal incision approx. 2 cm in length is made through the skin and fascia. The Cannulated Awl compact is inserted into the incision until the tip rests on the bony anatomy of the target segment. The pedicle entry point is established by gentle hammering. The tip of the awl should be driven in to the stop. Once the awl is positioned securely in the pedicle, the trocar wire is then removed by turning the handle anti-clockwise and pulling it off.

Caution:

The trocar wire must be completely screwed in during the insertion of the cannulated awl.

Note:

When the tip of the cannulated awl is resting on the bony structures (1), the thickness of the soft tissue coverage can be determined using the length markings found on the outside of the instrument (2). This serves as a guide to help reduce the intensity of x-ray exposure during the attachment of the screws.

Reposition



Positioning of the K-Wire

The K-Wire is inserted into the Cannulated Awl 30 and advanced through the tip of the awl to ensure adequate fixing in the spongiosa. Once the K-Wire has been positioned at the desired depth, the awl is then carefully removed, during which the K-Wire is held firmly in place.

Note:

As a rule, all K-Wires should be positioned before insertion of the pedicle screws.

There are 2 different types of K-Wires available:

- K-Wire ø 1.3 mm for all ø 4.8 mm screws
- K-Wire ø 1.7 mm for all other screws

The position markings located on the K-Wire should point in the distal direction. This is also the case when using a Jamshidi needle / Cannulated Awl compact.

Caution:

Bent or flexed K-Wires must be disposed of.



Dilating and determining the screw length

In order to gently expand the tissue, the MIS Tissue Dilator is advanced over the K-Wire until its tip touches the pedicle (1). On the dial of the MIS Tissue Dilator, the screw length to be used can be determined by reading the penetration depth marked on the guide wire. The MIS Tissue Dilator is then removed. Meanwhile, the K-Wire must be held firmly in place.

Note

The exact position can be checked on an X-ray image via the integrated metal tip in the MIS Tissue Dilator.

Note:

When the tip of the MIS Tissue Dilator is resting on the bony structures (1), the thickness of the soft tissue coverage can be determined using the length markings found on the outside of the instrument (2). This serves as a guide to help reduce the intensity of x-ray exposure during the attachment of the screws.



Description of the ratchet function

All cannulated handles have a ratchet function. 3 ratchet modes can be set by turning the adjusting screw.

Adjusting screw "L" position (1)

-> anti-clockwise ratchet function / screwing in

Adjusting screw central "." (2)

-> secure handle / screwing and unscrewing **WITHOUT** ratchet function

Adjusting screw "R" position (3)

-> clockwise ratchet function / unscrewing



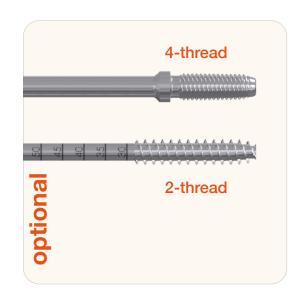
Tapping general

Draw the MIS Protective Sleeve over the K-Wire.

Once the desired screw diameter has been selected, then the Cannulated 6T Tap labeled with the corresponding pedicle screw diameter is attached to the desired cannulated handle. The chosen cannulated tap is screwed into the pedicle over the K-Wire and through the MIS Protective Sleeve. Ensure that the K-Wire is not inadvertently pushed forward by mistake during tapping. Lateral imaging is required to ensure correct alignment. The tap will only be screwed in to the tip of the K-Wire. While removing the tap, ensure that the K-Wire is not removed.

Note:

The correspondig to the desired pedicle screw diameter labeled tap is in its outer an core diameter smaller than the pedicle screw. This ensures an adequate press fit.



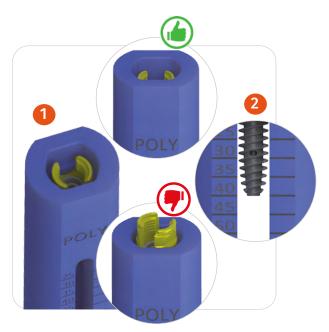
Tapping 6T screws

Two different types of taps are available for the 6T screws. The Cannulated 6T Tap is intended for the two-threaded section of the screw and the Cannulated 6T Tap 4T is intended for the four-threaded section of the screw.

Caution:

When using the Cannulated 6T Tap 4T, the stop must be observed. As soon as this comes into contact with bony structures, the tap must be unscrewed again.





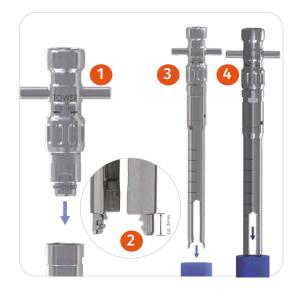
Attachment of the polyaxial screw Inserting the polyaxial screw into the Assembling Aid

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

Note:

The MIS Assembling Aid is only compatible with screws with a diameter of up to \emptyset 7.2 mm.

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



Attachment of the polyaxial screw Applying the MIS Multitool and MIS Tower

The MIS Multitool must be correctly positioned on the MIS Tower. The annular spring area must point in a proximal direction. It must be ensured that the Multitool can be felt locking into the Interior Clamp of the MIS Tower (1).

Before attaching the screw, the correct position of the inner and outer sleeve of the MIS Tower must be ensured. The proximal end of the Interior Clamp should protrude 5 mm out of the exterior sleeve of the MIS Tower (2). Where the Interior 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 Tower and the Interior Clamp once again ("lock" position).

In the locked position, the Interior Clamp cannot be pushed axially into the exterior sleeve of the MIS Tower. The correct position can be checked by simply applying axial pressure to the Interior Clamp.

The MIS Tower is now inserted vertically into the MIS Assembling Aid (3) and locked on the head of the polyaxial screw by pushing downwards, resulting in a noticeable click (4).

Note:

While mounting the MIS Tower, it must be ensured that the locking mechanism is placed in the "lock" position (max. position reached by turning clockwise).



Attachment of the polyaxial screw Securing the screw to the MIS Tower

Now place the locking mechanism into the "unlock" position by turning the Multitool anti-clockwise (1). The exterior sleeve of the MIS 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 polyaxial screw to the MIS 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 Tower must be checked and corrected, if required.



Assembly of the MIS Polyaxial Screwdriver

The MIS Polyaxial Screwdriver is inserted into the MIS Tower from above (1) and mounted onto the hexagonal section of the polyaxial screw using gentle pressure and slight rotation (2). The connecting screw of the MIS Polyaxial Screwdriver is now screwed clockwise into the MIS Tower (3).



Assembly of the MIS Polyaxial 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 Polyaxial Screwdriver.

Note:

The Multitool must be mounted at a rotation of 180° from the position of the previous step. The annular spring points in a proximal direction.

Note:

When the MIS Polyaxial Screwdriver and pedicle screw are correctly assembled, there is a gap of approx. 1 mm between the MIS Tower and the connecting screw of the MIS Polyaxial Screwdriver (3), and the pedicle screw should be connected to the MIS Tower in a fixed-angle position.



Inserting the pedicle screw

The pedicle screw is now implanted using the guide wire in place and under observation using the image converter. Once the final position of the pedicle screw has been reached, the guide wire must be removed.

Note:

The length markings located on the outside of the MIS 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 insertion of the pedicle / dilation is used a reference value. This allows the intensity of x-ray exposure to be reduced during the securing of the pedicle screw.

Caution:

The guide wire must be held in position to ensure that it is not pushed forwards while the screw is secured! Lateral imaging is recommended throughout the procedure. Afterwards, the correct implant and the correct screw length must be verified using the image converter.

Caution:

It is important to check whether the polyaxial action of the screw head is restricted by the depth at which the pedicle screw is secured. To do so, gently move the tower in a circular motion, checking for freedom of mobility.

The other pedicle screws are implanted following the exact same procedure.



Loosening the MIS Polyaxial 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 Key Deformity Tower can be inserted into one of the side holes of the Tower (2).



Assembling the MIS rod compass

To measure the rod length, the MIS Rod Compass Holder 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 <u>cannot</u> be rotated on the MIS Rod Compass Ruler.



Determining the rod length

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:

It must be ensured that the MIS Rod Compass is mounted onto the MIS Tower until it reaches the stop. Also push down on the MIS Rod Compass, if required.

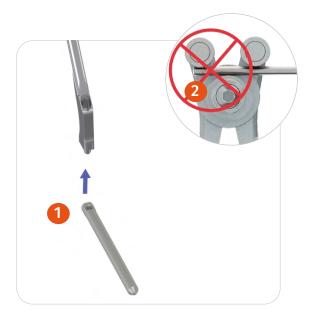
Example calculation:

Using the above representations:

- 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-segment 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.



Locking the rod on 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 rod intake area 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, so that the rod is entirely situated in the heads of the pedicle screw. The rod holder is available in a range of different designs (see Instrument Overview on pages 26-31). 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).



Locking the rod on rod holder II

The rod is screwed into the MIS Rod Holder with the aid of the Torx key (MIS ML2 Locking Screw Driver) (clockwise rotation).

Caution:

The fixing screw must be pulled tight enough to ensure that the rod is securely positioned in the rod inserter.

Caution

It is advised that the fixing screw is secured once again during a lengthy insertion of the rod or for rod insertions requiring a high degree of force. If the connection between the instrument and the implant is loosened, then the fixing 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 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 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 MIS 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.

Note:

It is possible to check whether the rod is correctly inserted by rotating the Tower. It is not possible to freely rotate the Tower once the rod is correctly positioned.

How to use the MIS Tower



Fitting the set screws

The MIS Set Screw Inserter 2.0 is mounted onto an MIS Set Screw. By screwing the internally threaded rod of the MIS Set Screw Inserter 2.0 into the set screw clockwise, this becomes secured to the inserter. 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 head holder with the fitted MIS Set Screw until it sits on the rod. The MIS Set Screw can then be screwed clockwise in.

Caution:

Only tighten the MIS Set Screw slightly. For the final torque, use the MIS Setscrew Driver.

Note

We recommend affixing the MIS Set Screws on the side of the MIS Rod Holder first.



Marking for the MIS 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 material or foreign objects 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 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 by 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.



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 screwdriver 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 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 withdrawing 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, this set screw must be tightened again as described.



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 by at least 3 mm and the rod end by at least 7 mm over the head of the screw. The rod inserter is loosened from the rod with the help of the Torx key. (counterclockwise rotation). You must be able to feel that the MIS Torx key is locked in place in the Torx of the connecting screw.

Caution:

In order to remove the rod inserter, 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, the screw on the rod inserter may break. In this case, the rod must be replaced.

Reposition



Removing the Tower I

To remove the MIS Tower, insert the MIS Multitool into the MIS 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 outer casing must then be pulled back to the stop (2).



Now tilt the whole tower slightly in a medial or lateral direction while rotating it 90° and pulling it away in a distal direction (1). Then the MIS Tower can be removed from the wound.

Next, secure the inner and outer casings 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.



Repositioning preparation

The MIS Counter Handle is pushed onto the Tower according to the orientation of the wrench surfaces (1). The MIS Rod Driver is then inserted into the MIS Counter Handle (2).

Note:

Pay attention to the orientation of the MIS Rod Driver shaft in relation to the geometry of the Counter Handle (3).



Carrying out repositioning

Now the repositioning manoeuvre may be carried out by turning the handle of the MIS Rod Driver in a clockwise direction (1).

Note:

The rod is completely situated in the screw head if there is no gap between the handle piece of the MIS Rod Driver and the Tower (2).



Using the Key Deformity Tower

If the force required for repositioning cannot be applied by using the handle of the MIS Rod Driver, the Key Deformity Tower may also be used.



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.

Caution:

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

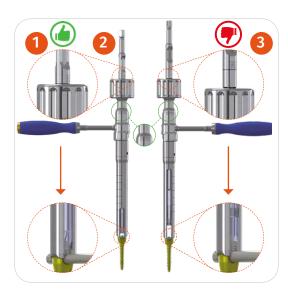


Inserting the set screws

The MIS Set Screw can now be inserted into the pedicle screw through the MIS Rod Driver.

Caution:

Only tighten the MIS Set Screw lightly. For the final torque use the MIS Set Screwdriver.



Marking for the use of the MIS Rod Driver and MIS Counter Handle

Caution:

Before using the MIS Set Screw Inserter 2.0, the MIS Rod Driver must be screwed into a terminal position as the rod is then situated inside the screw head.

The marking line beneath the label "POSITION SETSCREW WITH ROD DRIVER 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 Rod Driver handle piece or if this is slightly lower in the Rod Driver (1), then the position of the set screw is correct. The set screw can be screwed without tension into the screw head (2).

If the marking is clearly above the Rod Driver handle piece, the set screw cannot be screwed in (3) as the set screw is still positioned above the rod, which is situated in the pedicle screw.

In order to screw in the set screw, ensure that any material has been removed from the screw head and/or Tower.

Repositioning / subsequent reattachment of the Tower in situ



Removal of the MIS Set Screw Inserter 2.0

Once the MIS Set Screw is inserted, the handle is removed from the MIS Set Screw Inserter, and the connection between this and the implanted set screw can be loosened by using the MIS ML2 Locking Screw Driver (1). Then the MIS Set Screw Inserter can be pulled out (2).



Final torque tightening

Caution:

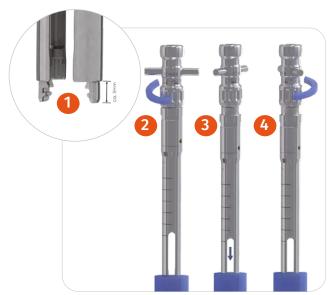
Before the final torque tightening of the set screw, the MIS Rod Driver must be loosened. To do so, unscrew the MIS Rod Driver in an anti-clockwise direction (1).

The Setscrew Driver is inserted into the Torque Driver. The pre-mounted torque screw driver can then be fed through the MIS Rod Driver, and the set screw can be pulled tight with torque applied in a clockwise direction (2). After the final tightening, the torque screw driver, the MIS Rod Driver and the MIS Counter Handle can be removed.

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.

Repositioning / subsequent reattachment of the Tower in situ



Preparation of the MIS Tower / MIS Fracture-Tower

If a subsequent reattachment of the Tower is necessary in the event of revision surgery or if the Tower is accidentally loosed from the head of the pedicle screw during the above-mentioned manoeuvre, it can be subsequently reconnected to the implant using a MIS Tower Reassembler. The correct assembly of the exterior sleeve and the Interior Clamp of the MIS Tower/ MIS Fracture-Tower must be ensured. The proximal end of the Interior Clamp should protrude 5 mm out of the exterior sleeve of the Tower (1). Where the Interior Clamp does not protrude by 5 mm, unlock the Interior Clamp by using the Multitool ("unlock" position) (2) and push forwards (3). Then secure the position of the exterior sleeve of the Tower and Interior Clamps once again ("lock" position) (4). In the locked position, the Interior Clamp cannot be pushed axially into the exterior sleeve of the Tower. The correct assembly, positioning and locking, can be checked by simply applying axial pressure to the Interior Clamp.

Repositioning / subsequent reattachment of the Tower in situ



Attachement of the MIS Tower Reassembler

Guide the proximal end of the MIS Tower Reassembler into the screw head of the previously inserted screw. Here, the noses of the MIS Tower Reassembler must latch into the geometry for the rod attachment of the screw head.

In order to make positioning the MIS Tower Reassembler in the screw head easier, a K-Wire can also be used as an aid. This is positioned in the cannula of the pedicle screw before affixing the MIS Tower Reassembler and is used to help guiding.



Attachement of the MIS Tower / MIS Fracture-Tower

At the start, the MIS Multitool must be correctly aligned on the MIS Tower / MIS Fracture-Tower. The annular spring area must point in a proximal direction. Make sure that the Multitool can be felt locking into the Interior Clamp of the MIS Tower (1).

Then, the MIS Tower/MIS Fracture-Tower is guided with the assembled MIS Multitool via the previously inserted Reassembler in the direction of the screw head of the pedicle screw until you can feel this lock into place on the screw head with a click. When affixing the MIS Tower / MIS Fracture-Tower on the Reassembler, ensure that the slot for the rod on the Tower is correctly aligned with regard to the guide geometry on the Reassembler (2).

The correct positioning of the Reassembler in the screw head must be ensured throughout the entire manoeuvre (where necessary by means of gentle axial pressure on the instrument from above).



Locking the MIS Tower / MIS Fracture-Tower

The locking of the MIS Tower / MIS Fracture Tower takes place in an identical manner to assembly ex-situ.

To achieve this, place the locking mechanism of the MIS Tower / MIS Fracture Tower into the "unlock" position by turning the MIS Multitool anti-clockwise (1). The exterior sleeve of the MIS Tower / 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 pedicle screw to the Tower (3). The Multitool can then be pulled upwards (4).

Pull on the MIS Tower/ MIS Fracture-Tower to check whether this is secured correctly on the screw which has been positioned. The entire MIS Tower/MIS Fracture-Tower and the outer sleeve of the MIS Tower/ MIS Fracture-Tower may not be allowed to move in a distal direction.

After successful assembly of the MIS Tower/MIS Fracture-Tower on the pedicle screw, the Reassembler and the optional K-Wire can be removed upwards from the MIS Tower/MIS Fracture-Tower (5).



Inserting the Cement Adapter I

The Cement Adapter is applied over the guide wire located on the Cement Adapter Inserter and locked into the instrument attachment by applying gentle pressure. The assembled inserter is fed through the Tower in the pedicle screw. Turn the inserter a half rotation to the left and screw the Cement Adapter in fully until it reaches the final position in the pedicle screw head and tighten until you feel resistance.

Note:

To allow exact insertion of the Cement Adapter, it is necessary that the screw head and the screw shaft are aligned in a precise axial orientation when using polyaxial screws. You must be able to screw in the Cement Adapter without using force.

If the polyaxial screw head cannot be easily positioned, this can be made to move freely through the rotating motion of the Tower. Optionally, the screw depth of the pedicle screw may be corrected.

Augmentation



Inserting the Cement Adapter II

Caution:

Never use the Cement Adapter Inserter for alignment because, in this case, the guide wire may bend and the Cement Adapter cannot be positioned correctly! Where a Cement Adapter is attached using polyaxial pedicle screws, any tilting movement of the Tower must be avoided, otherwise deformations can occur in the sealing area of the adapter, which can create a leak at the connection.



Filling the Bone Filler

Mix the bone cement according to the manufacturer's instructions for use and fill the Bone Filler using a syringe.

Recommendation:

Use a moderate- to high-viscose bone cement with a quick curing time. We recommend the use of OSTE-OPAL $^{\circledR}$ Plus bone cement.



Attachement of the Bone Filler

The filled Bone Filler is brought through the Tower and screwed onto the Cement Adapter by hand in a clockwise direction.



Cement injection

When injecting the cement using the Bone Filler, a predefined amount (1.5 ccm) is applied. While doing so, make sure that the injection is carried out evenly and not with too much pressure, to ensure an even distribution of the cement and to prevent it from flowing back. Only one Bone Filler may be used for each Cement Adapter and screw. Premature removal of the Bone Filler or screwing it into the Cement Adapter a second time and/or screwing the Cement Adapter onto the screw a second time may result in unwanted cement discharge in the region of the polyaxial screw head.

Note:

Once the cement has been applied, an x-ray scan is required to monitor the volume of injected cement.



Removing the Cement Adapter

The Bone Filler is then removed and the Cement Adapter is unscrewed using the Cement Adapter Extractor. To do so, insert the Cement Adapter Extractor into the Tower from above and mount it onto the Cement Adapter.

Note:

The Cement Adapter is only intended for single use. To prevent rotation of the polyaxial head during removal of the Cement Adapter, the Tower can be held for support.

Straight rods

Item no.	Name	
VL-RM2-5-40	Rod Mini2 Ø 5.5 mm x 40 mm	
VL-RM2-5-45	Rod Mini2 Ø 5.5 mm x 45 mm	
VL-RM2-5-50	Rod Mini2 Ø 5.5 mm x 50 mm	
VL-RM2-5-60	Rod Mini2 Ø 5.5 mm x 60 mm	
VL-RM2-5-70	Rod Mini2 Ø 5.5 mm x 70 mm	
VL-RM2-5-80	Rod Mini2 Ø 5.5 mm x 80 mm	
VL-RM2-5-90	Rod Mini2 Ø 5.5 mm x 90 mm	
VL-RM2-5-100	Rod Mini2 Ø 5.5 mm x 100 mm	
VL-RM2-5-110	Rod Mini2 Ø 5.5 mm x 110 mm	
VL-RM2-5-130	Rod Mini2 Ø 5.5 mm x 130 mm	
VL-RM2-5-150	Rod Mini2 Ø 5.5 mm x 150 mm	
VL-RM2-5-170	Rod Mini2 Ø 5.5 mm x 170 mm	
VL-RM2-5-190	Rod Mini2 Ø 5.5 mm x 190 mm	
VL-RM2-5-210	Rod Mini2 Ø 5.5 mm x 210 mm	optional
VL-RM2-5-230	Rod Mini2 Ø 5.5 mm x 230 mm	optional
VL-RM2-5-250	Rod Mini2 Ø 5.5 mm x 250 mm	optional
VL-RM2-5-270	Rod Mini2 Ø 5.5 mm x 270 mm	optional
VL-RM2-5-300	Rod Mini2 Ø 5.5 mm x 300 mm	optional

Straight rods STERILE

Item no.	Name
VL-RM2-5-40-S	Rod Mini2 Ø 5.5 mm x 40 mm sterile
VL-RM2-5-45-S	Rod Mini2 Ø 5.5 mm x 45 mm sterile
VL-RM2-5-50-S	Rod Mini2 Ø 5.5 mm x 50 mm sterile
VL-RM2-5-60-S	Rod Mini2 Ø 5.5 mm x 60 mm sterile
VL-RM2-5-70-S	Rod Mini2 Ø 5.5 mm x 70 mm sterile
VL-RM2-5-80-S	Rod Mini2 Ø 5.5 mm x 80 mm sterile
VL-RM2-5-90-S	Rod Mini2 Ø 5.5 mm x 90 mm sterile
VL-RM2-5-100-S	Rod Mini2 Ø 5.5 mm x 100 mm sterile
VL-RM2-5-110-S	Rod Mini2 6 5.5 mm x 1 0 nm sterile
VL-RM2-5-130-S	Bod Mini2 Ø 5.5 mm x 180 mm sterile
VL-RM2-5-150-6	Rod Minix Ø 5.5 mm x 150 mm sterile
VL-RM2-5-170-S	Rod Min 2 5.5 mm x 170 mm sterile
VL-RM2-5-#90-6	Rod Mini2 Ø 5.5 mm x 190 mm sterile
VL-RM2-5-2.0-S	Rod Mini2 Ø 5.5 mm x 210 mm sterile optional
VL-RM2-5-230-S	Rod Mini2 Ø 5.5 mm x 230 mm sterile optional
VL-RM2-5-250-S	Rod Mini2 Ø 5.5 mm x 250 mm sterile optional
VL-RM2-5-270-S	Rod Mini2 Ø 5.5 mm x 270 mm sterile optional
VL-RM2-5-300-S	Rod Mini2 Ø 5.5 mm x 300 mm sterile optional

Implants, sterile / non-sterile

Pre-curved rods

Item no.	Name
VL-RMC2-5-40	Rod Mini Curved 2 Ø 5.5 mm x 40 mm
VL-RMC2-5-45	Rod Mini Curved 2 Ø 5.5 mm x 45 mm
VL-RMC2-5-50	Rod Mini Curved 2 Ø 5.5 mm x 50 mm
VL-RMC2-5-60	Rod Mini Curved 2 Ø 5.5 mm x 60 mm
VL-RMC2-5-70	Rod Mini Curved 2 Ø 5.5 mm x 70 mm
VL-RMC2-5-80	Rod Mini Curved 2 Ø 5.5 mm x 80 mm
VL-RMC2-5-90	Rod Mini Curved 2 Ø 5.5 mm x 90 mm
VL-RMC2-5-100	Rod Mini curved 2 Ø 5.5 mm x 100 mm
VL-RMC2-5-110	Rod Mini curved 2 Ø 5.5 mm x 110 mm



Set Screw

Item no.	Name
VL-PMS-M3	MIS Set Screw



Pre-curved rods STERILE

Name
Rod Mini Curved 2 Ø 5.5 mm x 40 mm sterile
Rod Mini Curved 2 Ø 5.5 mm x 45 mm sterile
Rod Mini Curved 2 Ø 5.5 mm x 50 mm sterile
Rod Mini Curved 2 Ø 5.5 mm x 60 mm sterile
Rod Mini Curved 2 Ø 5.5 mm x 70 mm sterile
Rod Mini Curved 2 Ø 5 5 mm x 80 mm steril
Rod Mini Curved 2 Ø 5.5 mm x 90 mm sterile
Rod Mini Curved 2 0 5.5 mm x 400 mm sterile
Rod Mini Curved 2 0 5.5 mm x 110 mm sterile



Set Screw

STERIL

\	
Item no.	Name
VL-PMS-M3-S	MIS Set Screw, sterile



Implants, sterile / non-sterile

Two-threaded cannulated screws (2T Cannulated Screw)

Item no.	Name	
4000014825	2T Cannulated Screw ø 4.8 x 25mm	
4000014830	2T Cannulated Screw ø 4 8 x 30mm	
4000014835	2T Cannulated Screw ø 4.8 x 35mm	
4000014840	2T Cannulated Screw ø 4.8 x 40mm	
4000014845	2T Cannulated Screw ø 4.8 x 45mm	
4000015525	2T Cannulated Screw ø 5.5 x 25mm	
4000015530	2T Cannulated Screw ø 5.5 x 30mm	
4000015535	2T Cannulated Screw ø 5.5 x 35mm	
4000015540	2T Cannulated Screw ø 5.5 x 40mm	
4000015545	2T Cannulated Screw ø 5.5 x 45mm	
4000015550	2T Cannulated Screw ø 5.5 x 50mm	
4000015555	2T Cannulated Screw ø 5 5 x 55mm	
4000016525	2T Cannulated Screw ø 6.5 x 25mm	
4000016530	2T Cannulated Screw ø 6.5 x 30mm	
4000016535	2T Cannulated Screw ø 6.5 x 35mm	
4000016540	2T Cannulated Screw ø 6,5 x 40mm	
4000016545	2T Cannulated Screw ø 6.5 x 45mm	
4000016550	2T Cannulated Screw ø 6.5 x 50mm	
4000016555	2T Cannulated Screw ø 6.5 x 55mm	
4000017235	2T Cannulated Screw ø 7.2 x 35mm	
4000017240	2T Cannulated Screw ø 7.2 x 40mm	
4000017245	2T Cannulated Screw ø 7.2 x 45mm	
4000017250	2T Cannulated Screw ø 7.2 x 50mm	
4000017255	2T Cannulated Screw ø 7.2 x 55mm	
4000017260	2T Cannulated Screw ø 7.2 x 60mm	

Two-threaded augmentable screws (2T Fenestrated Screw)

Item no.	Name	
4000045530	2T Fenestrated Screw ø 5.5x30mm	
4000045535	2T Fenestrated Screw ø 5.5x35mm	- 10
4000045540	2T Fenestrated Screw ø 5.5x40mm	7.
4000045545	2T Fenestrated Screw ø 5.5x45mm	8
4000045550	2T Fenestrated Screw ø 5.5x50mm	
4000045555	2T Fenestrated Screw ø 5.5x55mm	
4000046530	2T Fenestrated Screw ø 6.5x30mm	
4000046535	2T Fenestrated Screw ø 6.5x35mm	10
4000046540	2T Fenestrated Screw ø 6.5x40mm	6
4000046545	2T Fenestrated Screw ø 6.5x45mm	8
4000046550	2T Fenestrated Screw ø 6.5x50mm	- Or
4000046555	2T Fenestrated Screw ø 6.5x55mm	
4000047240	2T Fenestrated Screw ø 7.2x40mm	
4000047245	2T Fenestrated Screw ø 7.2x45mm	Si
4000047250	2T Fenestrated Screw ø 7.2x50mm	
4000047255	2T Fenestrated Screw ø 7.2x55mm	\Box
4000047260	2T Fenestrated Screw ø 7.2x60mm	

Implants, sterile / non-sterile

Augmentable 6T screws

Item no.	Name		1 E	
1010045540	Fenestrated 6T Screw ø 5.5 x 40mm			
1010045545	Fenestrated 6TScrew ø 5.5 x 45mm	rů.		
1010045550	Fenestrated 6T Screw ø 5.5 x 50mm	10		
1010045555	Fenestrated 6T Screw ø 5.5 x 55mm	Ø	# 3	i E
1010046540	Fenestrated 6T Screw ø 6.5 x 40mm		書	
1010046545	Fenestrated 6T Screw ø 6.5 x 45mm	10		
1010046550	Fenestrated 6T Screw ø 6.5 x 50mm	9		
1010046555	Fenestrated 6T Screw ø 6.5 x 55mm	Ø		1
1010047240	Fenestrated 6TScrew ø 7.2 x 40mm			#
1010047245	Fenestrated 6T Screw ø 7.2 x 45mm			-
1010047250	Fenestrated 6T Screw ø 7.2 x 50mm			
1010047255	Fenestrated 6T Screw ø 7.2 x 55mm			
1010047260	Fenestrated 6T Screw ø 7.2 x 60mm	OX .	響	

Augmentable 6T screws

STERILE

Item no.	Name		3 E
1010045540	Fenestrated 6T Screw ø 5.5 x 40mm		
1010045545	Fenestrated 6TScrew ø 5.5 x 45mm		
1010045550	Fenestrated 6T Screw ø 5.5 x 50mm		
1010045555	Fenestrated 6T Screw ø 5.5 x 55mm		I
1010046540	Fenestrated 6T Screw ø 9:5 x 40mm		- # -
1010046545	Fenestrated of Screw ø 615 x 15mm		
1010046550	Fenestrated 6T Screy ø 6 5 x 50mm		
1010046555	Fenestrated 67 Screw ø 6.5 x 55mm		
1010047240	Ferrestrated 6T8Crew ø 7.2 x 40mm		
1010047245	Fenestrated 6T Screw ø 7.2 x 45mm		
1010047250	Fenestrated 6T Screw ø 7.2 x 50mm		
1010047255	Fenestrated 6T Screw ø 7.2 x 55mm		
1010047260	Fenestrated 6T Screw ø 7.2 x 60mm	O.	#

Revision screws 6T

Item no.	Description	
1006098535	Cannulated Revision Screw 6T Ø 8.5 mm x 35 mm	
1006098540	Cannulated Revision Screw 6T Ø 8.5 mm x 40 mm	
1006098545	Cannulated Revision Screw 6T Ø 8.5 mm x 45 mm	
1006098550	Cannulated Revision Screw 6T Ø 8.5 mm x 50 mm	
1006098555	Cannulated Revision Screw 6T Ø 8.5 mm x 55 mm	
1006098560	Cannulated Revision Screw 6T Ø 8.5 mm x 60 mm	

Revision screws 6T

STERILE

Item no.	Description
1006098535	Cannulated Revision Screw 6T Ø 8.5 mm x 35 mm
1006098540	Cannulated Revision Screw 6T Ø 8.5 mm x 40 mm
1006098545	Cannulated Revision & Crew 6T Ø 8.6 mm x 45 mm
1006098550	Cannulated Revision Sciew 61 00.5 mm x 50 mm
1006098555	Cannutated Revision Screw 6T Ø 8.5 mm x 55 mm
1006098560	Calviulated Revision Screw 6T Ø 8.5 mm x 60 mm



Implants, sterile

Two-threaded cannulated screws (2T Cannulated Screw)

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STERILE		
Item no.	Name	
4000014825-S	2T Cannulated Screw ø 4.8 x 25 mm sterile	
4000014830-S	2T Cannulated Screw ø 4 8 x 30 mm sterile	00
4000014835-S	2T Cannulated Screw ø 4.8 x 35 mm sterile	4
4000014840-S	2T Cannulated Screw ø 4.8 x 40 mm sterile	0
4000014845-S	2T Cannulated Screw ø 4.8 x 45 mm sterile	
4000015525-S	2T Cannulated Screw ø 5.5 x 25 mm sterile	
4000015530-S	2T Cannulated Screw ø 5.5 x 30 mm sterile	
4000015535-S	2T Cannulated Screw ø 5.5 x 35 mm sterile	7
4000015540-S	2T Cannulated Screw ø 5.5 x 40 mm sterile	(C)
4000015545-S	2T Cannulated Screw ø 5.5 x 45 mm sterile	0
4000015550-S	2T Cannulated Serew ø 5.5 x 50 mla eterile	
4000015555-S	2T Cannulated Screw a 5 x 55 mm sterile	
4000016525-S	2 T Cannulated Sprew ø 6.5 x 25 mm sterile	
4000016530-S	21 Cannulated Screw ø 6.5 x 30 mm sterile	
4000016535-6	2T Cannulated Screw ø 6.5 x 35 mm sterile	TO.
4000016540-S	2T Cannulated Screw ø 6.5 x 40 mm sterile	6
4000016545-S	2T Cannulated Screw ø 6.5 x 45 mm sterile	Ø
4000016550-S	2T Cannulated Screw ø 6.5 x 50 mm sterile	
4000016555-S	2T Cannulated Screw ø 6.5 x 55 mm sterile	
4000017235-S	2T Cannulated Screw ø 7.2 x 35 mm sterile	
4000017240-S	2T Cannulated Screw ø 7.2 x 40 mm sterile	
4000017245-S	2T Cannulated Screw ø 7.2 x 45 mm sterile	Si
4000017250-S	2T Cannulated Screw ø 7.2 x 50 mm sterile	2
4000017255-S	2T Cannulated Screw ø 7.2 x 55 mm sterile	Ø
4000017260-S	2T Cannulated Screw ø 7.2 x 60 mm sterile	

Two-threaded augmentable screws (2T Fenestrated Screw)

STERILE

Item no.	Name	
4000045530-S	2T Fenestrated Screw ø 5.5x30 mm sterile	
4000045535-S	2T Fenestrated Screw ø 5.5x35 mm sterile	rÜ
4000045540-S	2T Fenestrated Screw ø 5.5x40 mm sterile	TO.
4000045545-S	2T Fenestrated Screw ø 5.5x45 mm sterile	
4000045550-S	2T Fenestrated Screw ø 5.5x50 mm sterile	_\
4000045555-S	2T Fenestrated Screw ø 5,5x55 mm sterile	(')
4000046530-S	2T Fenestrated Screw ø 6.5x30 mm steril	
4000046535-S	2T Penestrated Strev @ 6.5x35 mm sterile	9
4000046540-S	2T Fenestrated Screw ø 6.5x46 mm sterile	Ø
4000046545-S	PT Fenestrated Serew ø 6.5x45 mm sterile	
4000046550 S	2T Ferrestrated Screw ø 6.5x50 mm sterile	
4000046555-S	2T Fenestrated Screw ø 6.5x55 mm sterile	N
4000047240-S	2T Fenestrated Screw ø 7.2x40 mm sterile	7.
4000047245-S	2T Fenestrated Screw ø 7.2x45 mm sterile	Ø
4000047250-S	2T Fenestrated Screw ø 7.2x50 mm sterile	
4000047255-S	2T Fenestrated Screw ø 7.2x55 mm sterile	
4000047260-S	2T Fenestrated Screw ø 7.2x60 mm sterile	

Instruments

Item no.	Name	
1008010002	MIS Tissue Dilator	
1008010001	MIS Protective Sleeve	
33.2513.400	K-Wire Ø 1,3 x 400 mm round	
33.2517.400	K-Wire Ø 1,7 x 400 mm round	
33.2513.480	K-Wire Ø 1,3 x 480 mm round	optional
33.2517.480	K-Wire Ø 1,7 x 480 mm round	
1006020606	Jamshidi Needle Trokacut	optional



Item no.	Name	
1001010079	Cannulated Awl 30	
1106011101	Cannulated Awl without stop	optional
1008010023	MIS ML2 Locking Screw Driver	
1007010059	Cannulated Awl compact	optional
1007010052	Goniometer Awl	optional



Instruments

Item no.	Name	
1006010600	T-Handle Cannulated	optional
1006010701	Ratchet T-Handle Cannulated T30	optional
1006010711	Ratchet-ST T-Handle Can. T30	
1001012000	Torque Driver-12	-
1006010900	Handle Straight Cannulated	optional
1006010801	Ratchet Handle Straight Cannulated T30	optional
1006010811	Ratchet-ST Handle Straight Can. T30	
1006010501	Ratchet Handle Pear Shaped Cannulated T30	optional
1006010511	Ratchet-ST Handle Pear Shaped Can. T30	



Item no.	Name	
4008010008	MIS Assembling Tool	2 वागामा
4008010003	MIS Polyaxial Screw Driver	
4008010009	MIS Set Screw Inserter 2.0	
1008010014	MIS Set Screw Driver	
4008010005	MIS Counter Handle	
1010030009	Rescue Screw Driver	
1006020600	Cementadapter CPS	
1006020603	Bone Filler	STERILE
1006020601	Cement Adapter Inserter	
1006020602	Cement Adapter Extractor	=
1006020600-S	Cementadapter CPS sterile	STERILE available so

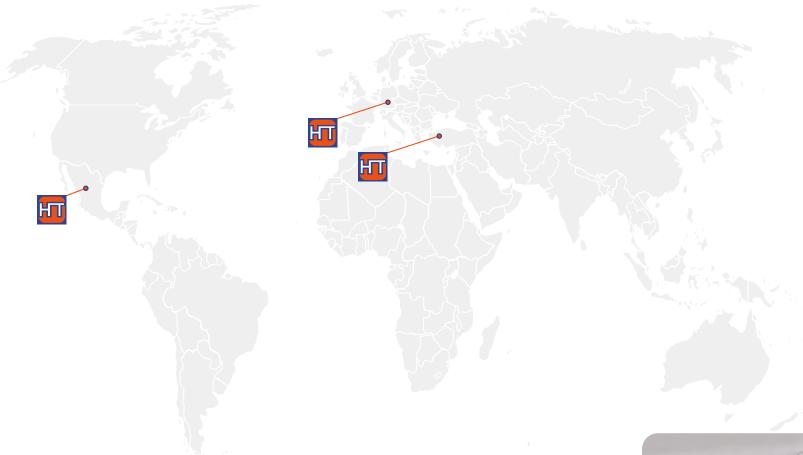


Instruments

Item no.	Name	
4008010001	MIS Tower and	
4008010016	MIS Interior Clamp	
4008010002	MIS Multitool	
4008010004	MIS Rod Driver	
4008010006	MIS Rod Compass comprising:	
4008010006-1	MIS Rod Compass Ruler 4008010006-1	
4008010006-2	MIS Rod Compass Pointer 4008010006-2 MIS Rod Compass Holder Poly 4008010006-11	
4008010006-11	400010000 11	
1016200000	Key Deformity Tower	
1001010052	Rod Inserter	
055069	Rod Bender	



Item no.	Name	
1008010022	MIS Rod Holder short	
1008010024	MIS Rod Holder long	
1008010030	MIS Rod Holder flex	optional
1008010005	MIS Rod Pusher 2.0	25
1010030015 1010030012 1010030013 1010030014	Cannulated 6T Tap 4.8 Cannulated 6T Tap 5.5 Cannulated 6T Tap 6.5 Cannulated 6T Tap 7.2	
1010030016 1010030017 1010030018	Cannulated 6T Tap 5.5 4T Cannulated 6T Tap 6.5 4T Cannulated 6T Tap 7.2 4T	
4008010010	MIS Tower Reassembler	





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