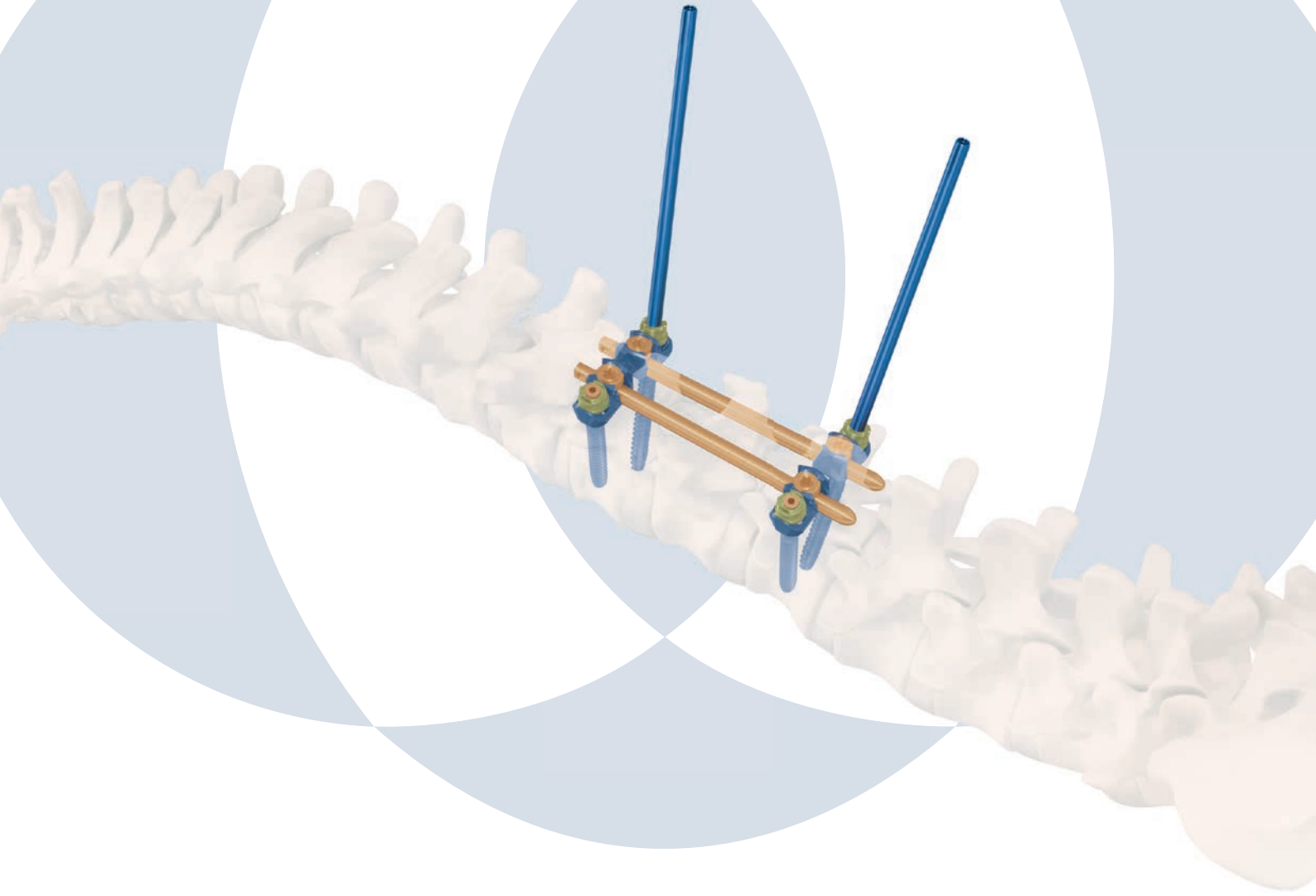
DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

USS FRACTURE MIS

The minimally invasive Schanz Screw system for complete spinal fracture reduction



Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

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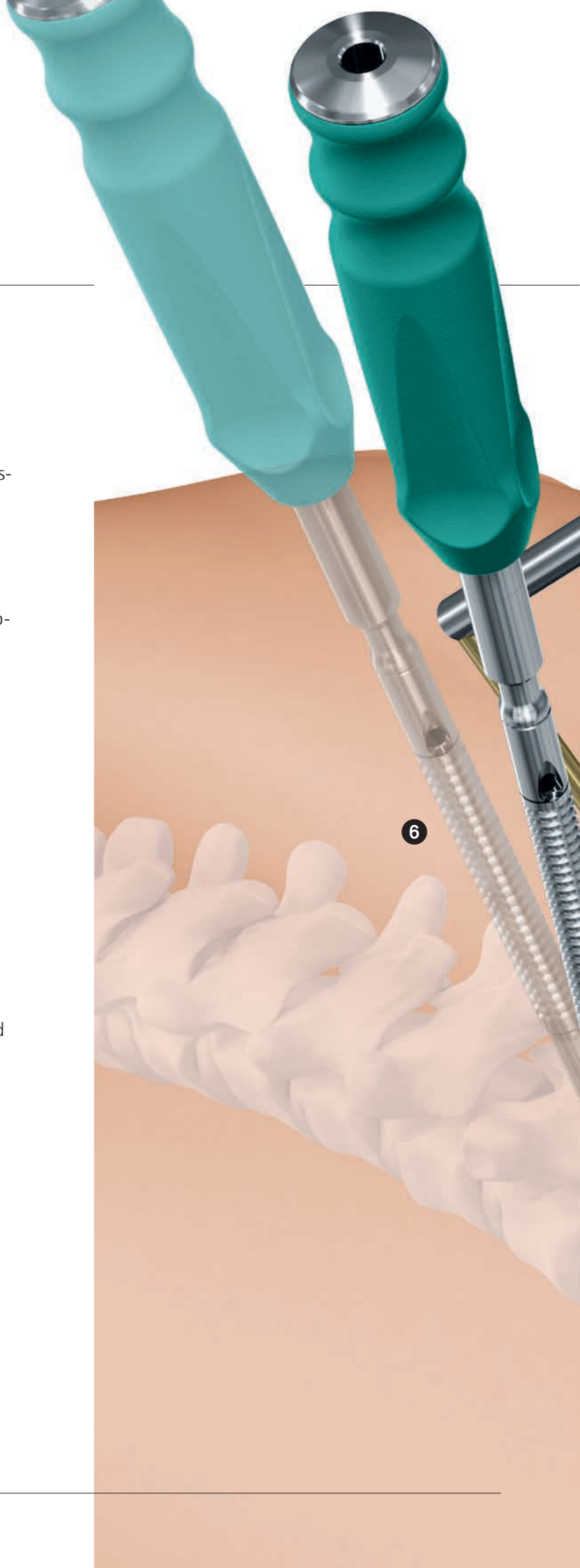


1 Schanz screws
- Enable active correction of the sagittal balance
- Provide immediate tactile feedback
- Dual Core design for screw adjustments without clinical relevant loss of bone purchase

2 Fracture clamps
- Allow for independent kyphosis correction and distraction as per the AO technique
- Top loading fracture clamp allows for easy rod introduction

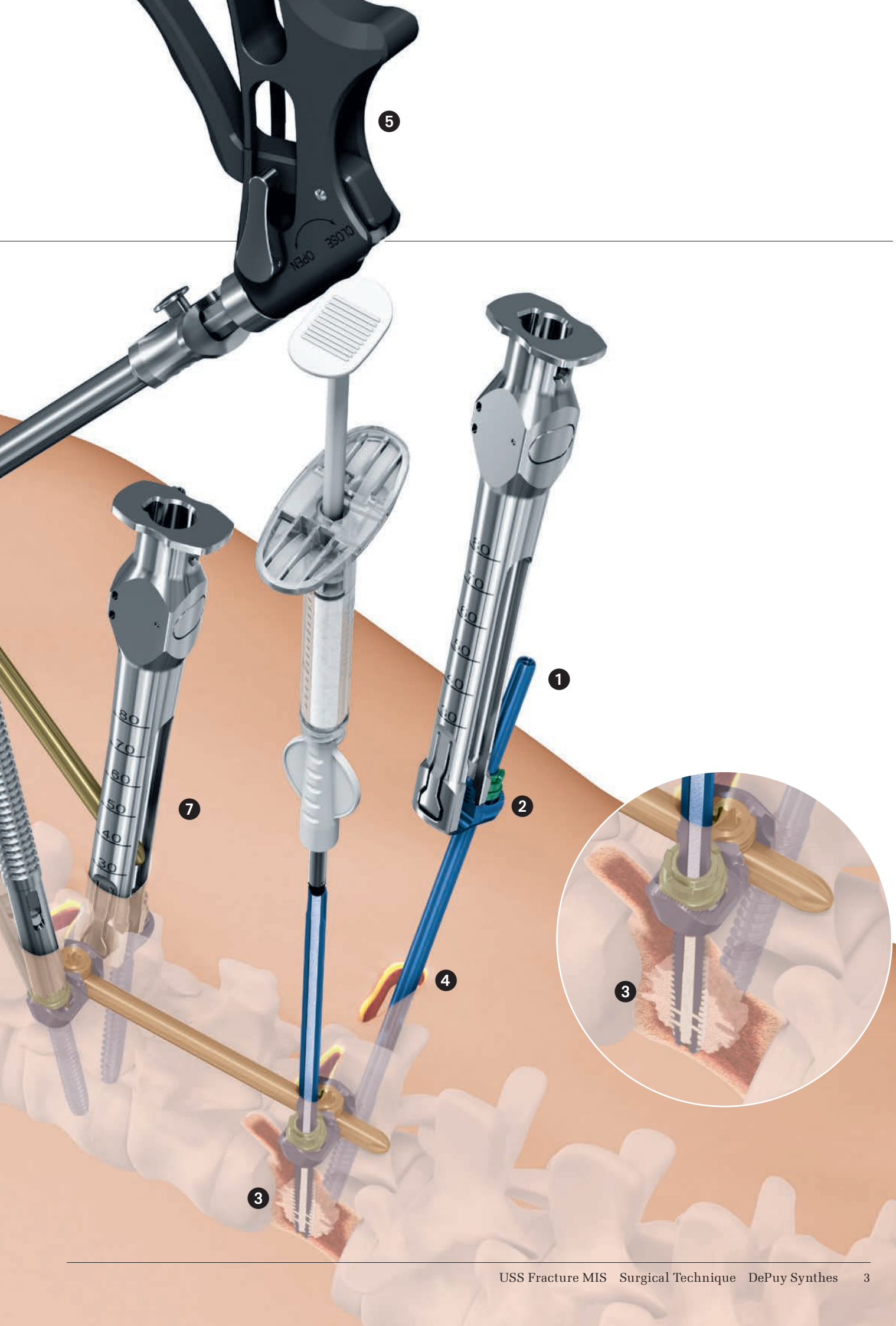
3 Perforated Schanz screws for osteoporotic bone
- Improved screw anchoring and vertebral body support due to cement cloud
- Six radial openings for 360° cement distribution
- Augmentation after final screw positioning

4 Percutaneous implantation
- Less trauma and blood loss
- Fast recovery

5 Adjustable rod holder
- Allows for individual rod angulation during insertion
- 6.0 mm diameter rods available in TAN

6 Percutaneous distraction and compression
- Parallel distraction performed with bridge above the skin
- Adjustability independent of previously performed sagittal correction

7 Percutaneous removal possible
- Allows for restauration of motion segments after fracture healing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AO PRINCIPLES

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.[1,2]
They are:
- Anatomic reduction
- Stable internal fixation
- Preservation of blood supply
- Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.[2]

AO Principles as Applied to the Spine [3]

Anatomic alignment
Restoration of normal spinal alignment to improve the biomechanics of the spine.

Stable internal fixation
Stabilization of the spinal segment to promote bony fusion.

Preservation of blood supply
Creation of an optimal environment for fusion.

Early, active mobilization
Minimization of damage to the spinal vasculature, dura, and neural elements, which may contribute to pain reduction and improved function for the patient.

[1] Müller ME, Allgöwer M, Schneider R, Willenegger H (1995) Manual of Internal Fixation. 3rd, expanded and completely revised ed. 1991. Berlin, Heidelberg, New York: Springer
[2] Ibid.
[3] Aebi M, Arlet V, Webb JK (2007). AOSPINE Manual (2 vols.), Stuttgart, New York: Thieme

INDICATIONS AND CONTRAINDICATIONS

The USS Fracture MIS system is a posterior thoracolumbar pedicle screw fixation system (T1 – S2) intended to provide precise and segmental stabilization of the spine in skeletally mature patients. Surgery can be performed with either a minimally invasive or open approach.

Indications
- Fractures: unstable fractures of the thoracic, lumbar and lumbosacral spine and fractures associated with unacceptable deformities (Discoligamentous disruptions or previous laminectomies do not constitute contraindications)
- Tumors
- Infections
- Posttraumatic deformities
- Spondylolisthesis
- Degenerative Disc Disease
- Osteoporosis when used concurrently with Vertecem V+

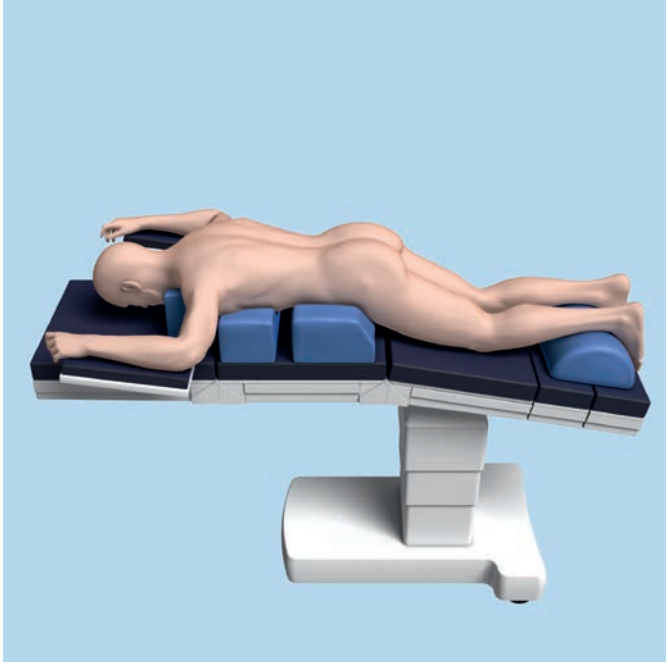
Contraindications
- In fractures and tumors with severe anterior body disruption, an additional anterior support or column reconstruction is required
- Osteoporosis when used without augmentation
- Severe Osteoporosis

Contraindications related to Vertecem V+
Please refer to the corresponding technique guide for the Vertecem V+ system.

PREPARATION

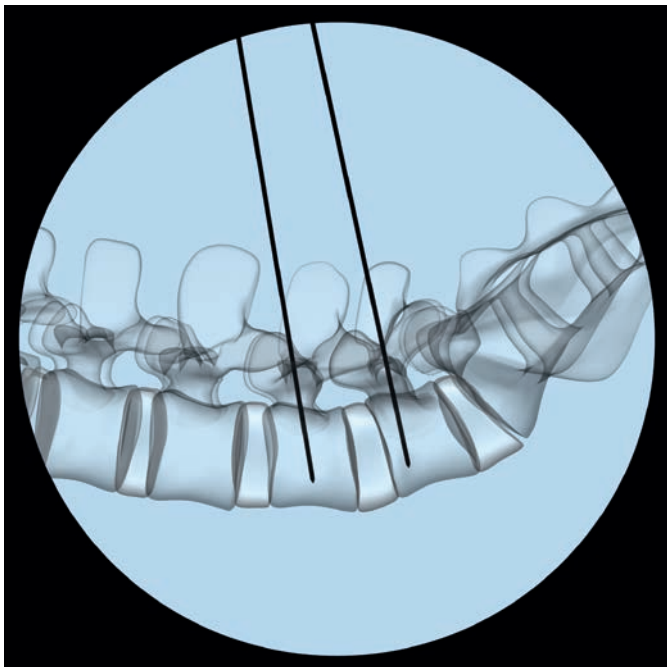
1
Patient positioning

Position the patient on a radiolucent OR table in the prone position. To obtain optimal visualization of the spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for AP, oblique and lateral views. Accurate visualization of the anatomic landmarks and fluoroscopic visualization of the pedicles are imperative for using the USS Fracture MIS System.



2
General recommendations on Kirschner wire handling

Ensure that the Kirschner wires remain securely in position throughout the entire duration of the procedure. Although the tips of the Kirschner wires are blunt, the Kirschner wires should be monitored under fluoroscopy to ensure they do not penetrate the anterior wall of the vertebral body and damage the vessels situated in front.

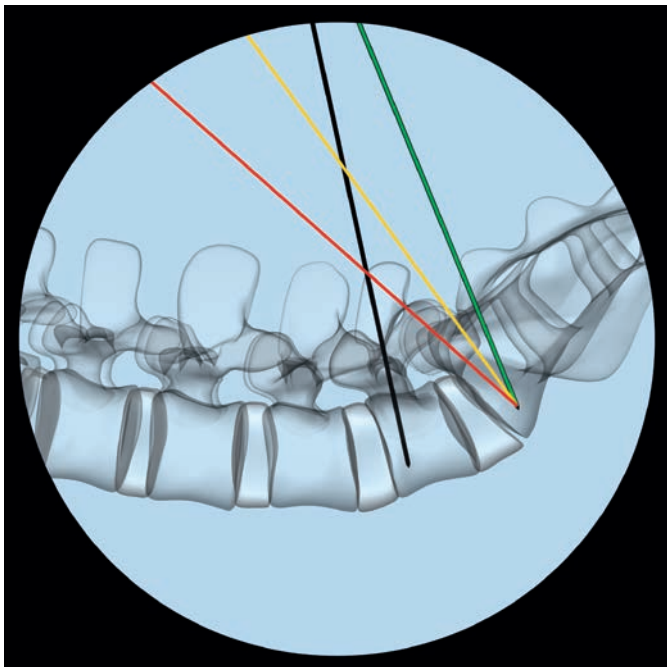


Ensure that the Kirschner wires do not slip out before the screws are inserted. The Kirschner wires are long enough to be held in place by hand during pedicle preparation and soft tissue dilation.

Recommendation for positioning the Kirschner wire

When inserting the Kirschner wires, be mindful to position them as parallel as possible to each other and to the cranial endplates of the vertebrae.

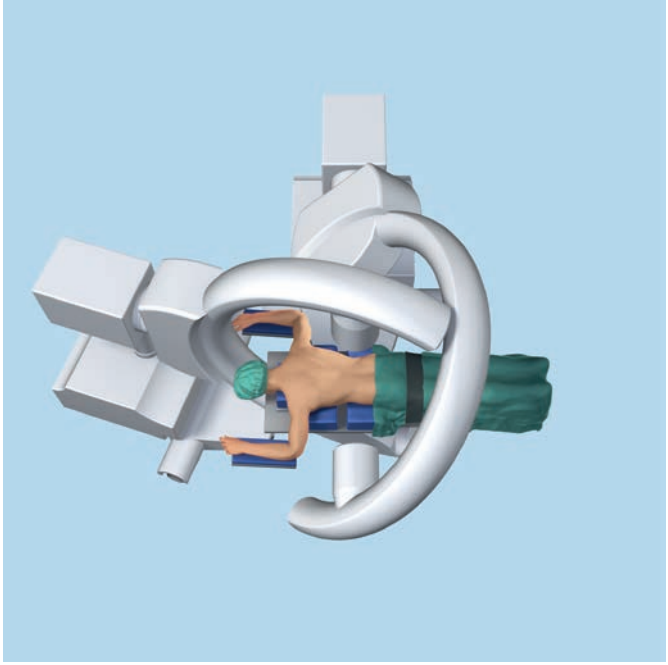
Note: **When operating on L5/S1, position the Kirschner wires according to the green-colored Kirschner wire (see image).**



3
Kirschner wire insertion

Each Kirschner wire is placed through an individual incision. Kirschner wire insertion can be realized either using multiple (see "Pedicle Preparation", step 1a) or single (see "Pedicle Preparation", step 1b) use instruments.

Technique tip: **Bi-planar fluoroscopy with two C-arms facilitates a safer, easier and quicker radiographic assessment during the surgical procedure.**



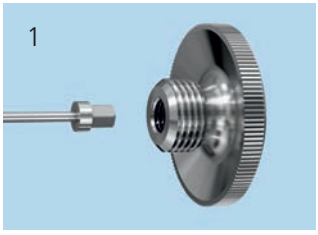
PEDICLE PREPARATION

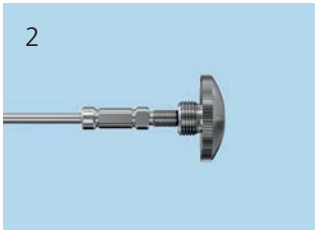
1a

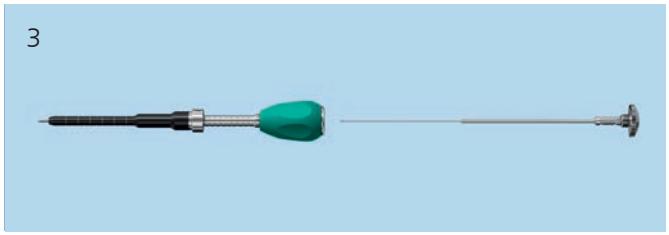
Prepare pedicle and insert Kirschner wire with multiple-use instruments

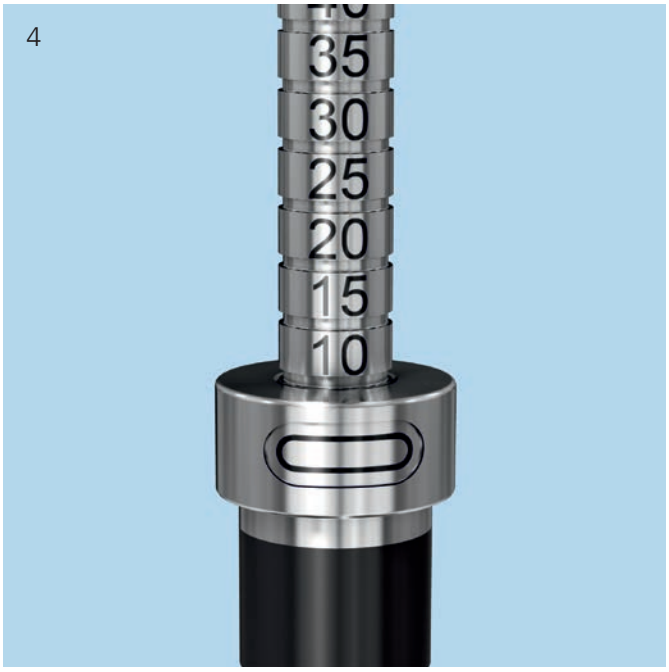
Instruments	
02.606.003	Kirschner Wire ∅ 1.6 mm without trocar tip, length 480 mm, Stainless Steel
03.606.020	Trocar ∅ 1.6 mm
03.606.021	Trocar Holder, for No. 03.606.020
03.620.230	Pedicle Probe ∅ 3.5 mm, cannulated, radiolucent, length 253 mm, for Screws ∅ 5.0 to 7.0 mm

Optional instruments	
03.616.070	Handle for Kirschner Wire ∅ 1.6 mm
03.627.029	Instrument Holder, radiolucent









Use radiographic imaging to locate pedicles and the site of skin incision. With a scalpel, create an incision of approximately 25 mm in length and bluntly dissect the subcutaneous tissue down to the pedicle.

Use the pedicle awl to perforate the cortex and prepare the screw channel.

Screw the trocar into the trocar holder (1,2). Fully tighten the assembly into the pedicle awl (3). Adjust the radiolucent sleeve to a length of 10 mm (4).

Position the awl on the pedicle and open the cortex. Before the pedicle awl is advanced into the pedicle, the dedicated screw length can be determined using the radiolucent sleeve.

Note: The tip of the advanced pedicle awl indicates the tip of the screw.

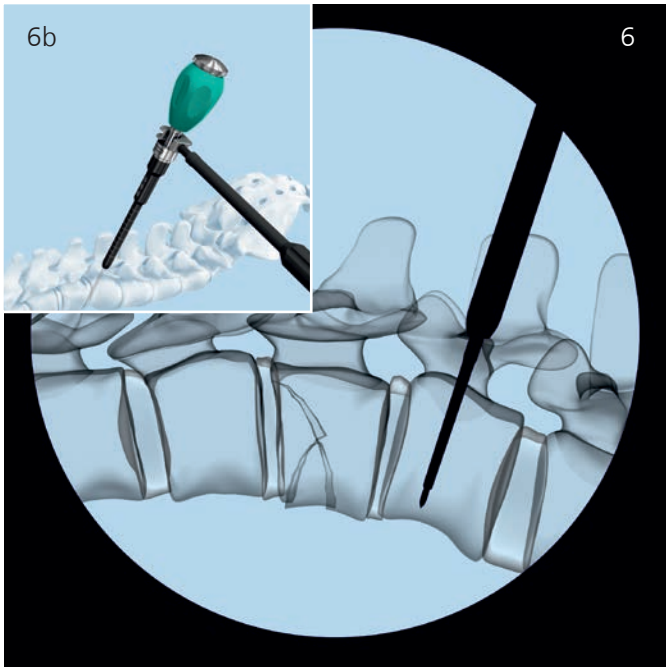
Adjust the sleeve to match the dedicated screw length and advance the pedicle awl (5).

Precaution: Use radiographic imaging to confirm orientation and depth while inserting the pedicle awl.

Notes:

- The sleeve prevents the awl from advancing further than the prescribed screw length thanks to a stop on the pedicle. For verification purposes, the sleeve tip is indicated with an x-ray marker (6).
- Rotate the pedicle awl continuously while advancing it into the vertebra.

Optional: Use the radiolucent instrument holder to hold the pedicle awl during radiographic imaging (6b).



Unscrew the trocar holder and the trocar from the pedicle awl, ensuring the awl remains in its position (7).

7

Insert a Kirschner wire into the awl and guide it through the pedicle (8). Advance the wire under fluoroscopic control to the dedicated depth where the screw is to be positioned.

Optional: **Use the handle for Kirschner wire to advance the wire. The handle for Kirschner wire is used either to advance or remove Kirschner wires during the procedure. The arrow on the instrument indicates the direction of Kirschner wire advancement or removal. Press the locking trigger and slip the instrument over the Kirschner wire. Release the trigger to lock the instrument at a position above the end of the cannulated awl.**

Warning: **The distance between the instrument and the cannulated awl should be equal to the insertion depth of the Kirschner wire.**

Gently tap on the impaction surface of the Kirschner wire handle to advance the Kirschner wire. Observe the position under fluoroscopic control (9). Stop impacting when the instrument reaches the top of the cannulated awl.

Remove the pedicle awl while maintaining the position of the Kirschner wire within the pedicle.

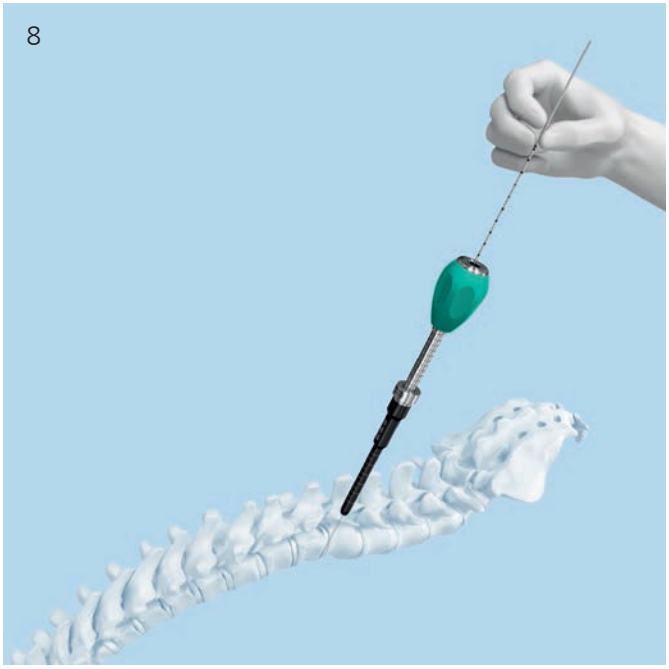
Warnings:

- **To prevent inadvertent advancement of the Kirschner wire, align the trajectory of the probe with the Kirschner wire and monitor the Kirschner wire position using fluoroscopy.**
- **Proceed with small steps for the insertion of the Kirschner wire with the Kirschner wire handle. The distance between the Kirschner wire handle and the cannulated awl should be equal to the additional insertion depth of the Kirschner wire to avoid inadvertent advancement.**

Precaution: **While removing the pedicle awl, secure the Kirschner wire at all times.**

Note: **All USS Fracture MIS Schanz screws are self-tapping; however, if tapping is preferred, use the appropriate tap and tap handle.**

8



9

1b

Prepare pedicle and insert Kirschner wire with single-use instruments

Instrument	
02.606.003	Kirschner Wire ∅ 1.6 mm without trocar tip, length 480 mm, Stainless Steel

Optional instruments	
03.616.070	Handle for Kirschner Wire ∅ 1.6 mm
03.627.029	Instrument Holder, radiolucent

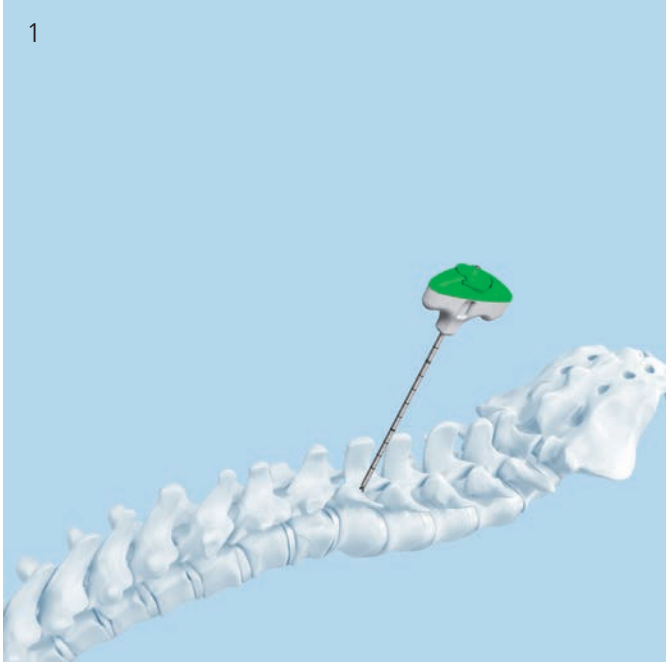
Note: **Use radiographic imaging to locate pedicles and the site of skin incision.**

With a scalpel, create an incision of approximately 25 mm in length and bluntly dissect the subcutaneous tissue down to the pedicle.

Insert a Jamshidi needle in the skin incision. Locate the entry point of the pedicle and align the Jamshidi needle with the pedicle trajectory. If necessary, reinsert and re-align the needle (1).

Open the cortex of the pedicle. Observe the position under fluoroscopic control.

1



Unscrew the trocar from the Jamshidi needle ensuring the needle remains in place.

Insert a Kirschner wire into the Jamshidi needle and guide it through the pedicle (2). Advance the wire under fluoroscopic control to the dedicated depth where the screw is to be positioned.

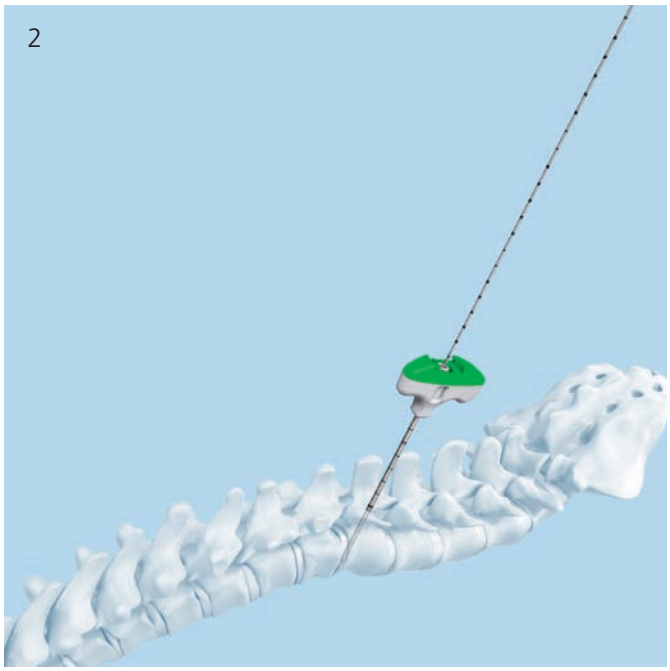
Note: **Use radiographic imaging to confirm orientation and depth while inserting the Jamshidi needle.**

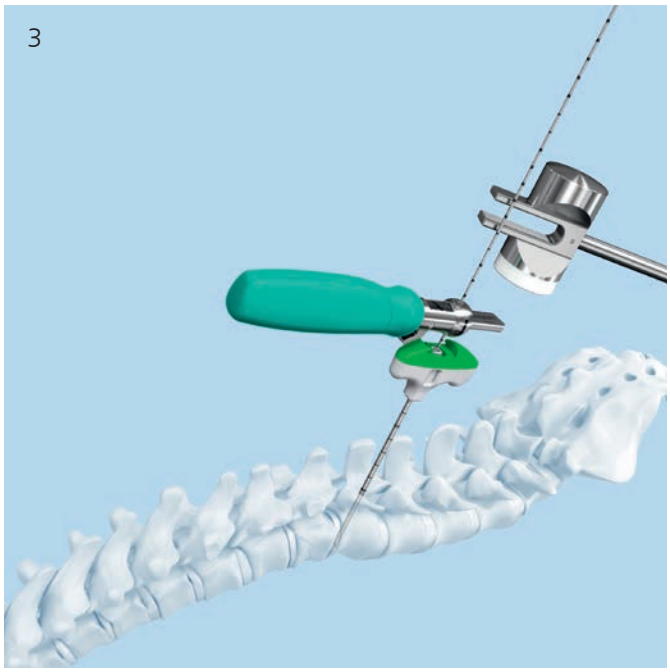
Technique tip: **Use the handle for Kirschner wire to advance the wire (3; see Pedicle preparation, 1a for handling).**

Precaution: **While removing the Jamshidi needle, secure the Kirschner wire at all times.**

Notes:

- **Enlarge screw channel with probe or tap prior to screw insertion.**
- **All USS Fracture MIS Schanz screws are self-tapping; however, if tapping is preferred, use the appropriate tap and tap handle.**





SCREW INSERTION

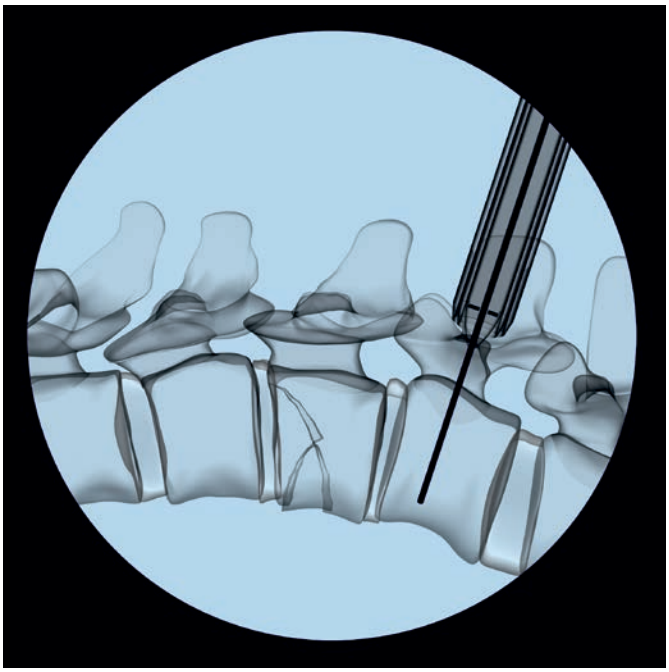
1
Dilate incision and determine screw length

Instruments	
03.610.001	Dilator ∅ 1.8/10.0 mm, cannulated, for Guide Wire ∅ 1.6 mm
03.628.101	Dilator ∅ 13 mm, eccentric, for No. 03.628.103
03.628.103	Dilator ∅ 10.0/13.0 mm, for No. 03.610.001
02.606.003	Kirschner Wire ∅ 1.6 mm without trocar tip, length 480 mm, Stainless Steel

Optional instrument	
03.631.521	Screw Length Indicator


1

Insert the 1.8/10.0 mm dilator over the Kirschner wire. Continue dilation placing the 10.0/13.0 mm dilator over the 1.8/10.0 mm dilator. Subsequently place the 13.0 mm eccentric dilator over the 10.0/13.0 mm dilator, and orient the oblong part of the instrument on the side where the rod is going to be placed (1).



Notes:

- **Use radiographic imaging to confirm orientation and depth of the Kirschner wire while inserting the dilators. Also use radiographic imaging to confirm that the dilators are placed as deep as possible, on the pedicle entry point. The eccentric dilator can be monitored thanks to a radiographic marker.**
- **The handle for Kirschner wire may be used for Kirschner wire impaction (see "Pedicle Preparation", step 1a).**

Option: **Use the MIS screw length indicator for determining the screw length.**

Note: **The screw length indicator shows the depth of the Kirschner wire tip starting at the pedicle entry point. The screw length is indicated by the thread length.**

Determine the screw length using the MIS screw length indicator on the top of the dilator (03.610.001) and the Kirschner wire. Read off the screw length between the double lines of the Kirschner wire (2).

Remove the dilator 1.8/10.0 mm while carefully holding the Kirschner wire in place to ensure the pedicle entry point for screw placement is maintained (3).

Leave dilator 10.0/13.0 mm and the 13.0 mm eccentric dilator in place to protect the surrounding tissue while inserting the pedicle screw.

Precaution: **While removing the dilators, secure the Kirschner wire at all times.**

2
Prepare and insert pedicle screws

Instruments	
03.628.120	Spline Drive Screwdriver, for Schanz Screws, with T-Handle
03.628.101	Dilator ∅ 13 mm, eccentric, for No. 03.628.103
03.628.103	Dilator ∅ 10.0/13.0 mm, for No. 03.610.001

Optional instruments	
03.627.024	Spline Drive Screwdriver, for Schanz Screws, cannulated, with Hexagonal Quick Coupling 6.0 mm
03.627.017	Torque-limiting Ratchet Handle, 7 Nm
03.628.106	Reamer, cannulated

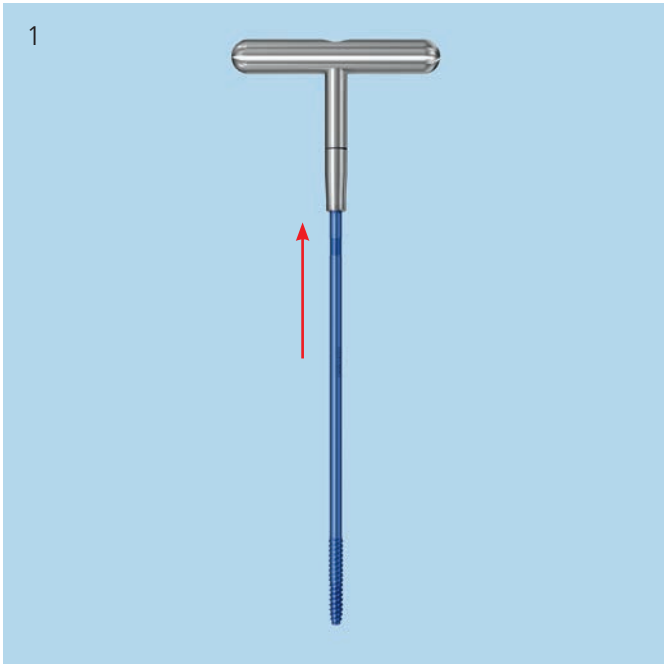
Select the appropriate screw length. Choose screws with the maximum possible diameter and length to achieve maximum stability.

Notes on the optional use of perforated Schanz screws:

- **If the screws are too short, the bone cement might be injected too close to the pedicle. It is required that the screw perforations are located in the vertebral body, close to the anterior cortical wall. For this reason, 35 mm screws should be placed in the sacrum only.**
- **If the screws are too long, or placed bi-cortically, the anterior cortical wall may be penetrated and cement leakage might occur.**

Mount the Schanz screw into the self-holding spline drive screwdriver (1).

1



Match the screw axis to the Kirschner wire axis by passing the Schanz screw/spline drive screwdriver assembly over the Kirschner wire through the dilator ∅ 10.0/13.0 mm until the tip of the screw reaches the pedicle entry point (2).

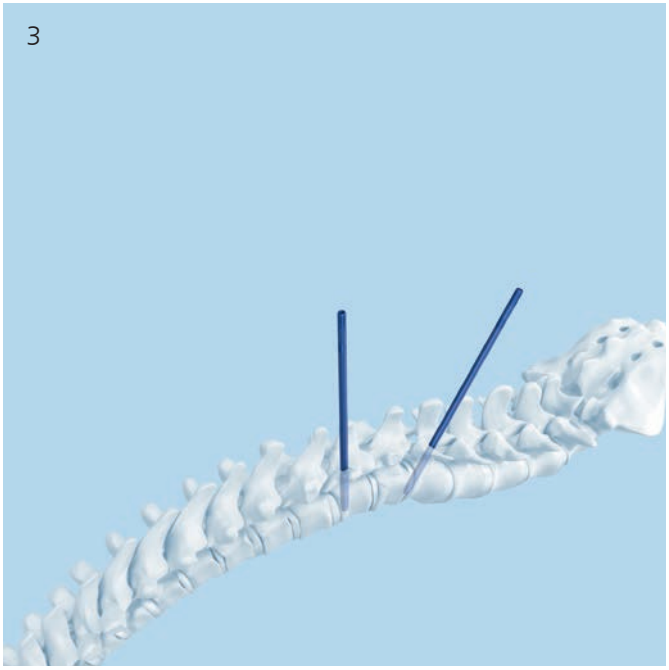
Note: Visualize the insertion depth of the Schanz screw by inserting the screw until the etched line on the spline drive screwdriver is flush with the edge of the dilator (2).

Carefully advance the screw in the pedicle until the screw tip passes through the pedicle.

Control the Kirschner wire exiting the proximal end of the spline drive screwdriver.

Remove the Kirschner wire once the tip of the screw enters the vertebral body.

Detach the spline drive screwdriver from the Schanz screw and remove the dilators (3).

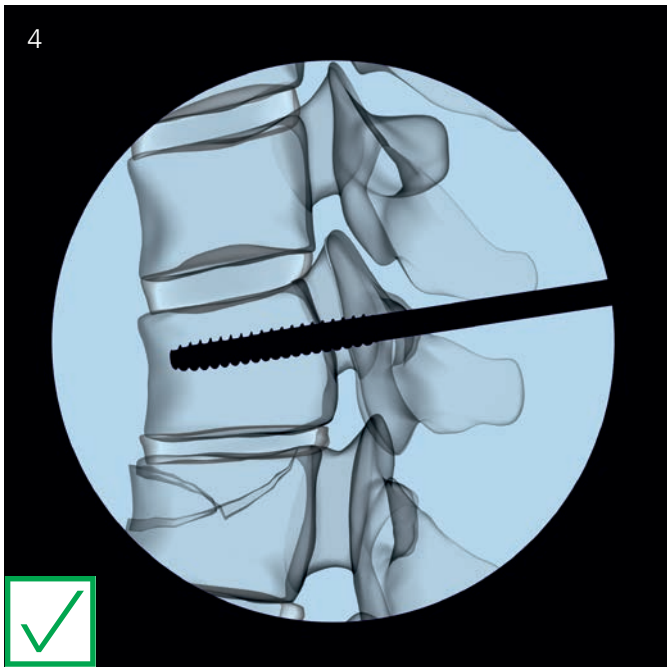


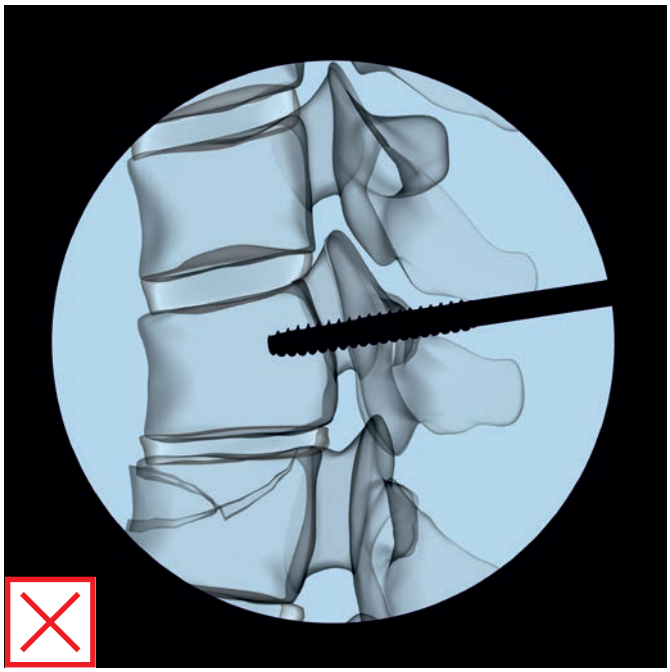
Notes on the optional use of perforated Schanz screws:

- If perforated Schanz screws are used, assess the cortical shell for perforations.
- In case of any perforation, special caution is required when bone cement is applied. Cement leakage and its related risks may compromise the physical condition of the patient.
- The perforated Schanz screw must enter in approximately 80% of the vertebral body (4).

Notes and Warnings:

- Monitor the tip of the Kirschner wire under image intensifier control to ensure that it does not penetrate the anterior wall of the vertebral body.
- To prevent inadvertent advancement of the Kirschner wire, align the trajectory of the implant with the Kirschner wire and monitor the Kirschner wire position under image intensifier control.
- During screw insertion, use the image intensifier to confirm screw trajectory and depth. The tip of the Schanz screw must not penetrate the anterior wall of the vertebral body. The end of the thread of the Schanz screw must be flush with the pedicle entry point.
- Pay attention when using cannulated instruments in combination with Kirschner wires (e.g. screwdrivers, awls etc.). Ensure that the exit point for the Kirschner wire in the instrument is not covered, to avoid pinching of the glove.
- Guided screw placement is required to avoid misplacement of screws.
- If tapping is optionally done before screw insertion, use the corresponding protection sleeve to protect soft tissue.





Optional technique
To prepare the site of the MIS fracture clamp, insert the reamer over the implanted Schanz screw. Rotate the reamer to remove all interfering bone (5). Repeat for each Schanz screw.

Note: **Do not use the reamer through the dilator.**

Warning: **Anatomical structures might be damaged when using the reamer; use the image intensifier and take special care to protect the facet joints.**

5

FRACTURE CLAMP INSERTION

1
Load MIS fracture clamp

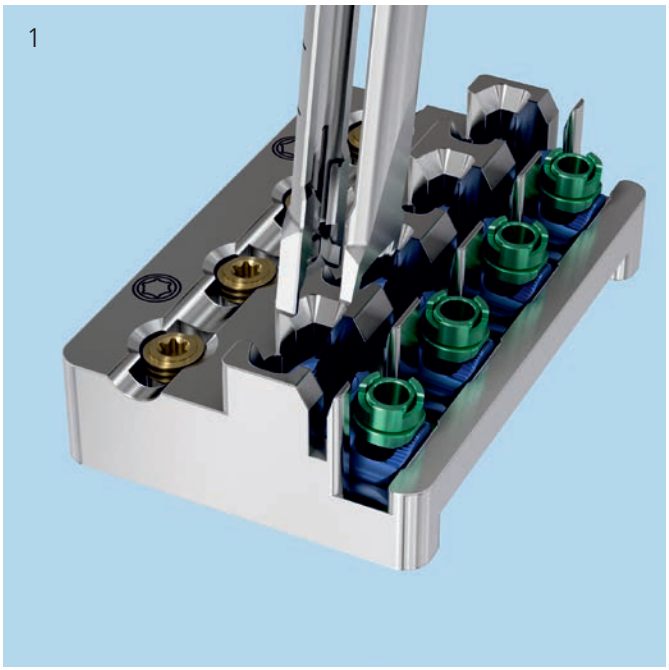
Instruments	
03.628.105	Clamp Holder
03.628.113	Socket Wrench Shaft with 3-Lobe-Drive
68.628.323	Module for Fracture Clamp and Schanz Screws, with Loading Station, with Lid, without Contents
or	
03.628.102	Loading Unit for Clamp

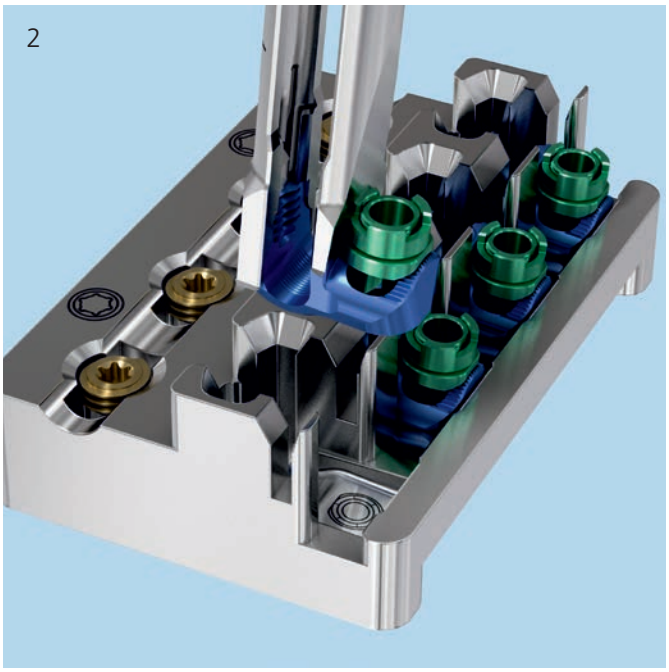
Properly position the MIS fracture clamp into the loading station (1). Ensure that the MIS fracture clamp can angulate freely by untightening the nut of the MIS fracture clamp with the socket wrench shaft by two revolutions.

Align the blades of the clamp holder with the MIS fracture clamp and slide down into the loading station to snap a MIS fracture clamp with the clamp holder (1).

Press down firmly to capture the MIS fracture clamp. Ensure that the MIS fracture clamp is firmly attached to the instrument (2).

Repeat this step for all clamps needed.

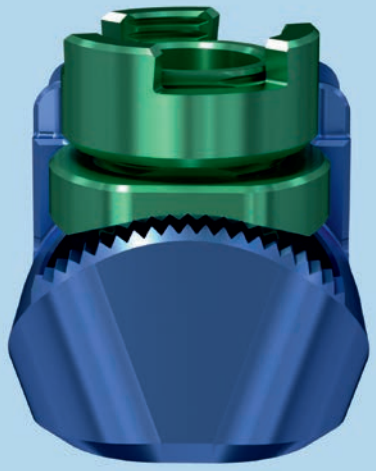




Notes:

- If the MIS fracture clamp does not snap into the clamp holder, gently pinch the blades of the clamp holder while pressing on the implant until it snaps.
- In case of MIS fracture clamp disassembling, ensure the correct reassembling of the implant, with the orientation of the washer and of the nut according to the picture (3).
- Check by pulling the clamp holder/MIS fracture clamp assembly construct to ensure a secure attachment.
- Remove all implants from the loading station for cleaning and sterilization purposes. Implants must be stored in the corresponding pockets of the module.

3



2
Insert fracture clamp

Instrument	
03.628.105	Clamp Holder

Insert the assembly (MIS fracture clamp attached to the clamp holder) over Schanz screw and through the skin incision.

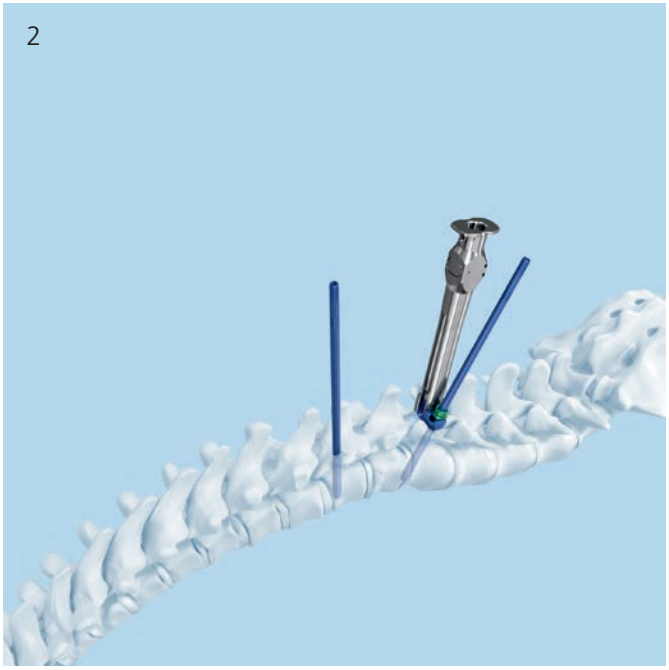
Position the clamp holder to receive the rod according to the planned position of the rod.

Repeat this step for all Schanz screws.

Notes:
- **Ensure that the MIS fracture clamp is seated as deep as possible, close to the pedicle entry (2); the reamer can be used according to the optional technique on page 21.**
- **Ensure that the MIS fracture clamp can angulate freely.**

1

2

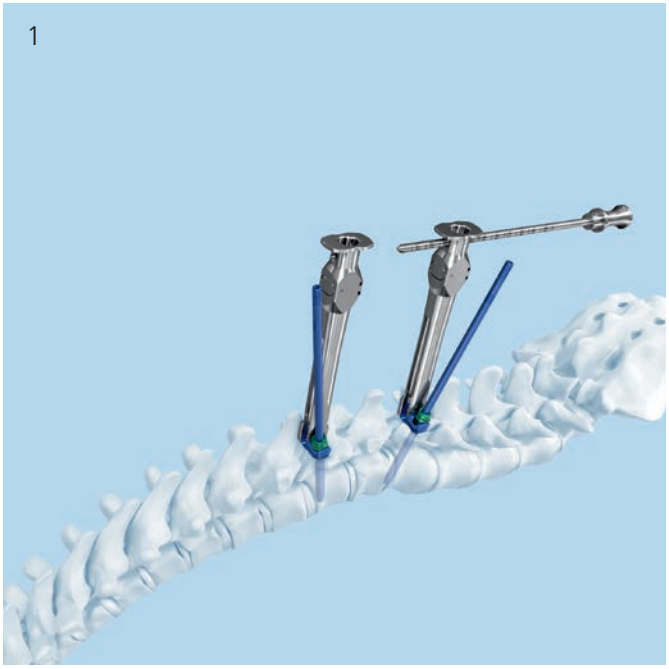


ROD INSERTION

1
Determine rod length

Instruments	
03.628.105	Clamp Holder
03.628.107	Rod Length Indicator

Introduce the rod length indicator through the holes of the clamp holders. Keep the clamp holders parallel during introduction (1) and slide the rod length indicator until the instrument is fully inserted (2).



Read the corresponding rod length on the scale (3).

The rod length indicator is removed by pushing back the instrument while keeping the clamp holders parallel.

Notes:
- **To determine the rod length most precisely, align the clamp holders as parallel as possible.**
- **To determine the length of the rod in case of distraction, add the desired distraction's length to the length determined with the instrument.**

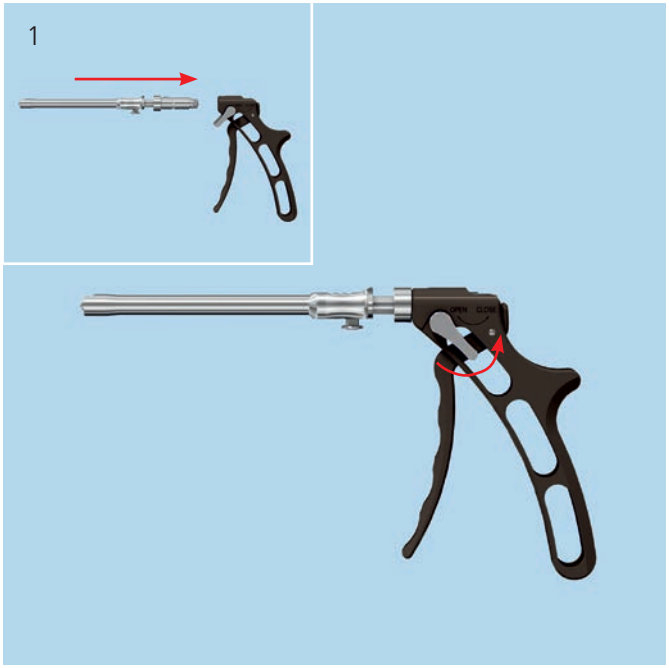
2
Prepare the implant holder

Instruments	
03.631.537	Handle for Rod Holder
03.631.538	Rod Holder, straight

Mount the handle of the rod holder and lock it (1).

Note: Do not squeeze the trigger of the handle while mounting the handle.

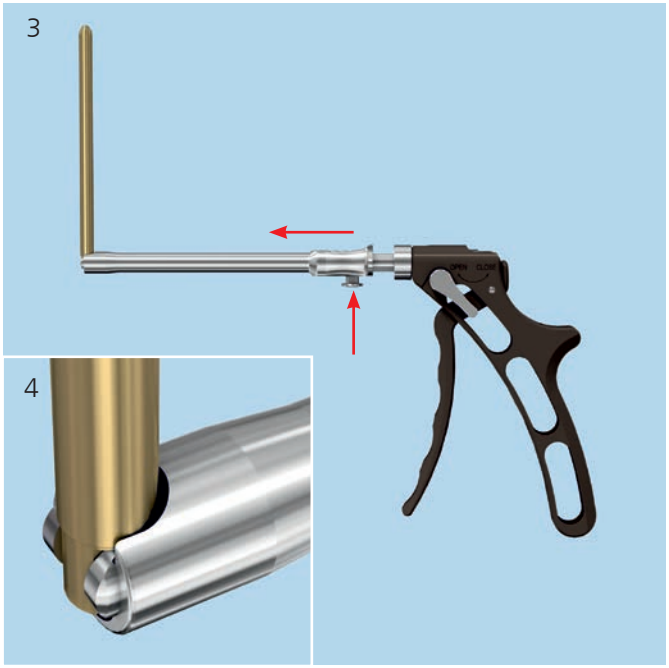
Ensure to pull back the locking sleeve and that the distal end of the rod holder shaft is visible.



Snap the rod into the corresponding interface at the distal part of the rod holder (2).

Precaution: When loading the rod, do not press the trigger of the handle.

Press the push button of the rod holder and simultaneously press down the locking sleeve (3). Ensure that the rod is firmly connected (4).



3
Insertion of rod

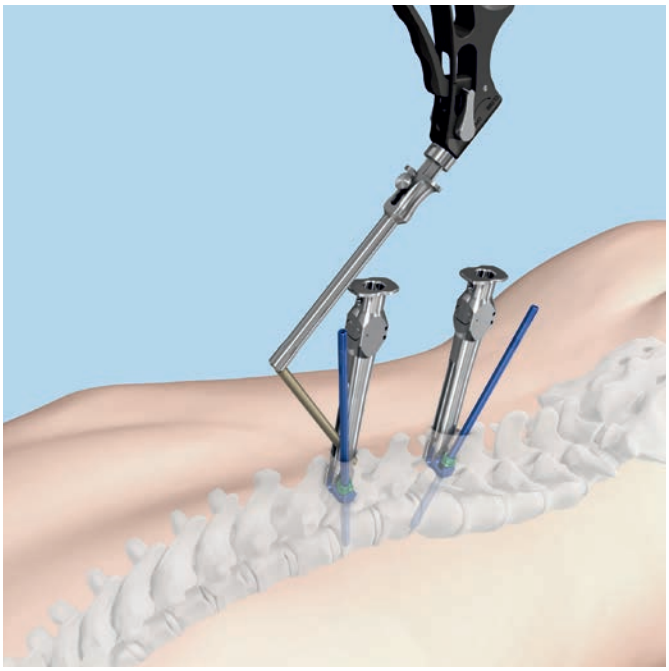
Instruments	
03.631.537	Handle for Rod Holder
03.631.538	Rod Holder, straight

Align the slots of the clamp holders prior to rod insertion.

Introduce the rod with a steep angle through slot of the most cranial or caudal clamp holder. The fixation of the rod angulation is achieved by squeezing the handle of the rod holder. Navigate the rod through the neighboring implants.

If increased resistance is felt, verify under image intensifier control whether the rod has passed through or is placed below the fascia.

Note: **Check the depth of the tip of the rod with lateral imaging.**



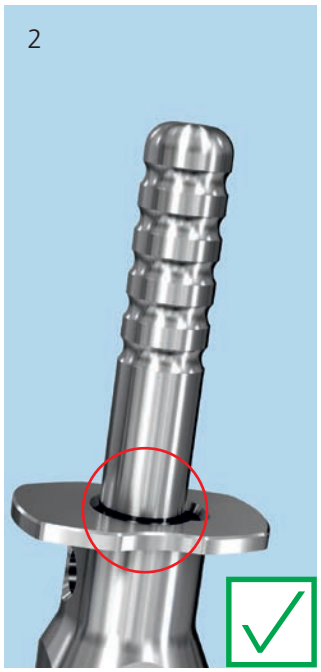
4
Verify rod placement

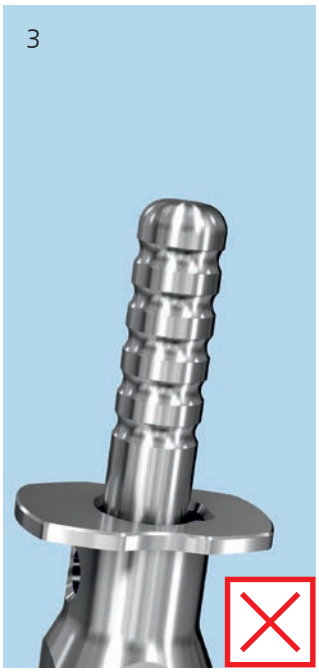
Instrument	
03.628.124	Rod Indicator

Verify the placement of the rod by introducing the rod indicator through the clamp holder (1).

Notes:

- **Use the rod indicator to verify the presence of the rod in the implant. The visible black marking indicates the presence of the rod in the clamp holder or MIS fracture clamp (2). If the black marking disappears into the clamp holder, no rod is in place (3). Alternatively, verify rod placement through the adjacent clamp holder by attempting to rotate the clamp holders or under visual control.**
- **Check final rod placement with lateral radiographic imaging. Ensure that the coupling and the tip of the rod protrude outside the MIS fracture clamps.**





SETTING THE ROD

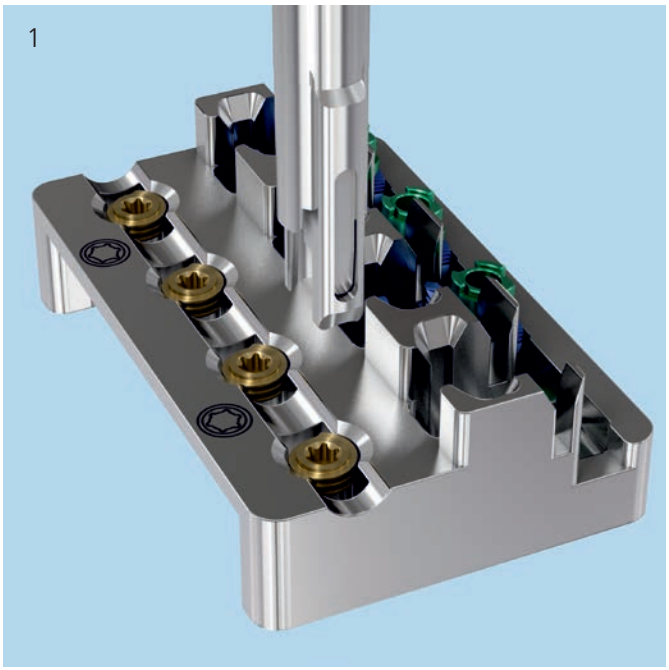
1
Load locking cap

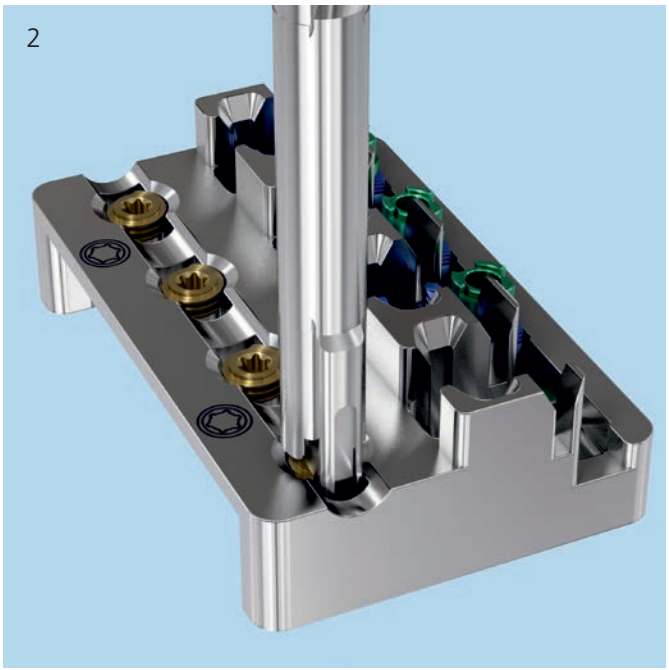
Instruments	
03.628.108	Guide for Locking Cap
68.628.323	Module for Fracture Clamp and Schanz Screws, with Loading Station, with Lid, without Contents
or	
03.628.102	Loading Unit for Clamp

Properly position the MIS locking cap into the loading unit (1). Properly orient and position the guide for locking cap over the locking cap on the loading unit (2).

Note: **Ensure the correct positioning of the MIS locking cap according to the etchings on the loading unit.**

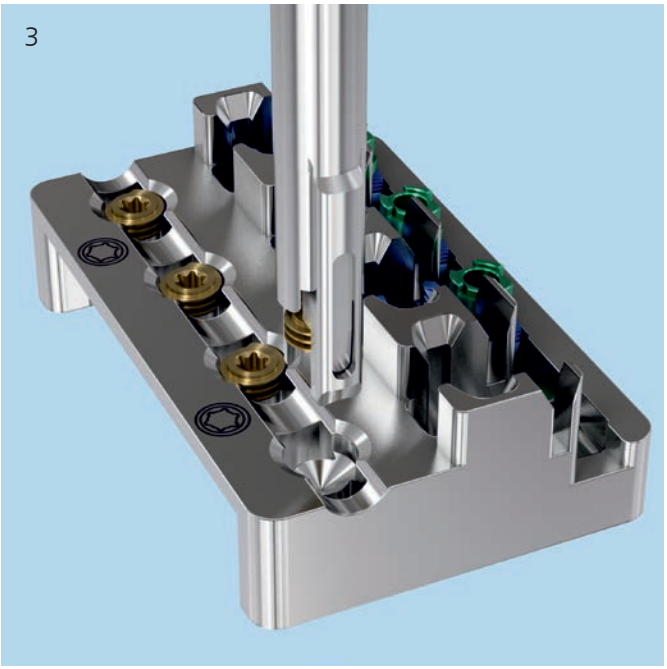
Press down firmly to capture the locking cap (2).





The locking cap will snap into the distal tip of the guide for locking cap (3).

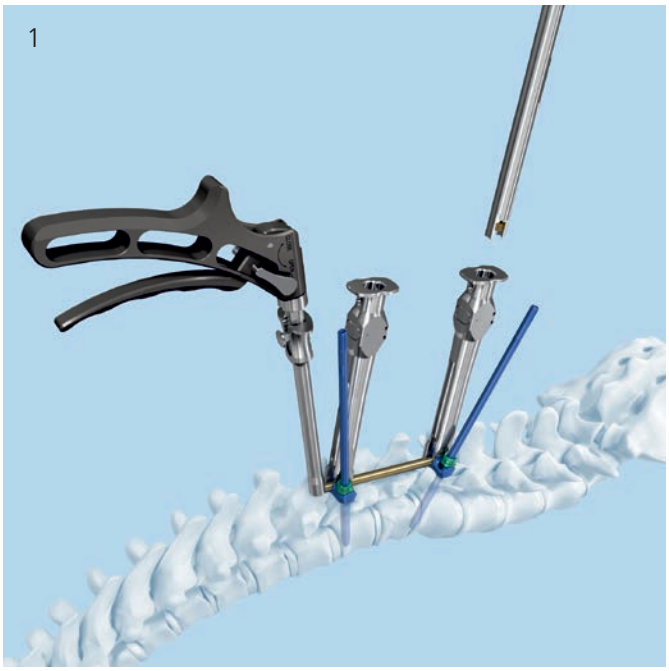
3



2
Insert locking cap

Instruments	
03.628.108	Guide for Locking Cap
03.628.109	Persuader

Insert the guide for locking cap into the clamp holder (1). Push down the guide for locking cap to press down the rod in the designated notch of the MIS fracture clamp. The last 20 mm of the insertion are supported by a ratchet mechanism and avoid the sliding back of the guide for locking cap.



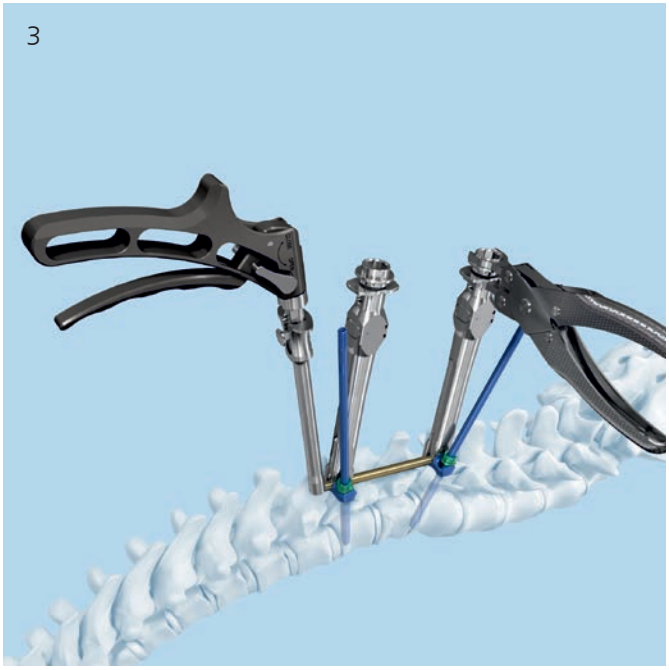
Position the persuader on the shoulders of the guide for locking cap and underneath the shoulder of the clamp holder (2) and squeeze the handle until the stop (3).

Notes:

- **Ensure that the MIS fracture clamp is seated as deep as possible, close to the pedicle entry.**
- **To remove the guide for locking cap, press the push button on the clamp holder.**

2

3



3
Rod fixation and removal of rod holder

Instruments	
03.628.112	Screwdriver for Locking Cap, T25
03.628.114	Handle with Hexagonal Coupling 7.0 mm
03.631.537	Handle for Rod Holder
03.631.538	Rod Holder, straight

Optional instrument	
03.628.110	Counter Torque

Insert the screwdriver for locking cap through the guide for locking cap. Hand-tighten the MIS locking cap with the handle positioned on the screwdriver. Leave the screwdriver in place until final tightening is accomplished.

Repeat this procedure for all locking caps.

Note: Check rod placement under lateral radiographic imaging. Ensure that the coupling and the tip of the rod protrude outside the MIS fracture clamps. Also ensure that the length of the rod inserted allows for potential distraction.

Removal of rod holder

Before removing the rod holder, ensure that the rod is securely fixed in the MIS fracture clamp adjacent to the clamp holder; use the handle with hexagonal coupling to hand-tighten the MIS locking cap and fix the rod.

To remove the rod holder (1), press the push button ❶ and slide up the locking sleeve ❷. For the removal of the rod holder, squeeze the handle and simultaneously pull up the rod holder (2).

Notes:

- **Do not remove the rod holder and keep the rod attached to the rod holder as long as control over the position of the rod is required. Optionally, a second rod holder can be made available for the system.**
- **If the rod holder has been removed, do not untighten the locking cap that was adjacent to the rod holder at any time during surgery.**
- **The handle of the rod holder can be dismantled by tilting the lever on the side of the handle downward to the open position.**
- **Do not try to reattach the rod to the rod holder in situ.**

1

2

FRACTURE REDUCTION

1
Kyphosis correction with the MIS fracture clamps fixed on the rod

Instruments	
03.628.113	Socket Wrench Shaft with 3-Lobe-Drive
03.628.112	Screwdriver for Locking Cap, T25
03.628.114	Handle with Hexagonal Coupling 7.0 mm

Optional instruments	
03.628.128	Position Retainer
03.628.129	Push Button for Position Retainer

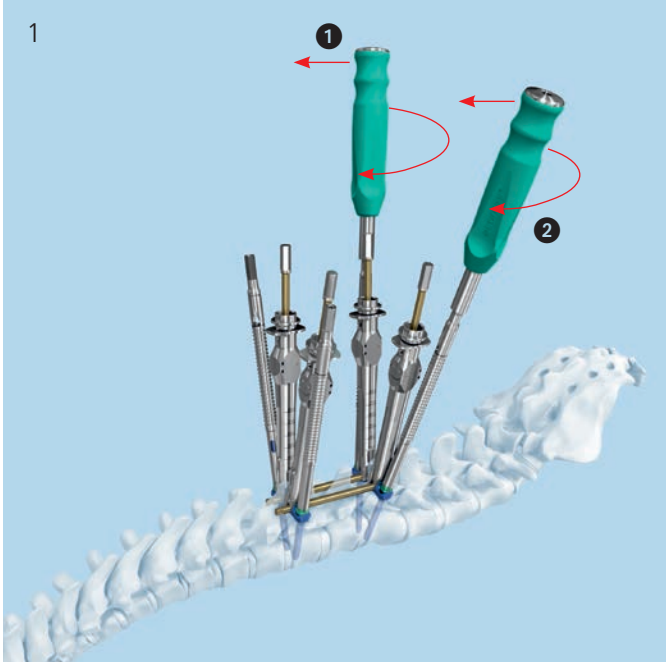
Ensure that all the MIS fracture clamps are positioned as deep as possible (see "Fracture Clamp Insertion", Step 2 on page 24).

Ensure that all MIS locking caps are hand-tightened to secure the distance between the MIS fracture clamps on the rod. Place the socket wrench shafts on the four Schanz screws. First connect the handles with hexagonal coupling to the socket wrench shafts on both caudal Schanz screws and lordose the spine (1). Tilt both posteriorly projecting caudal screws cranially to lordose the spine ❶.

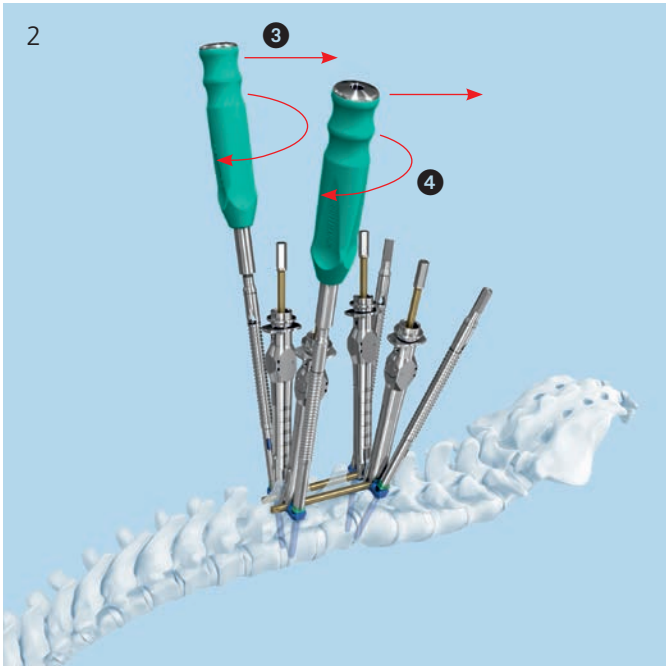
Secure the MIS fracture clamps/Schanz screws in the desired position by mounting the handle with hexagonal coupling on the socket wrench shaft to tighten the nut ❷.

Locate the handles with hexagonal coupling on the socket wrench shafts on both cranial Schanz screws and lordose the spine (2). Tilt both posteriorly projecting cranial screws caudally to complete the lordosing operation ❸ and secure in the desired position ❹.

1

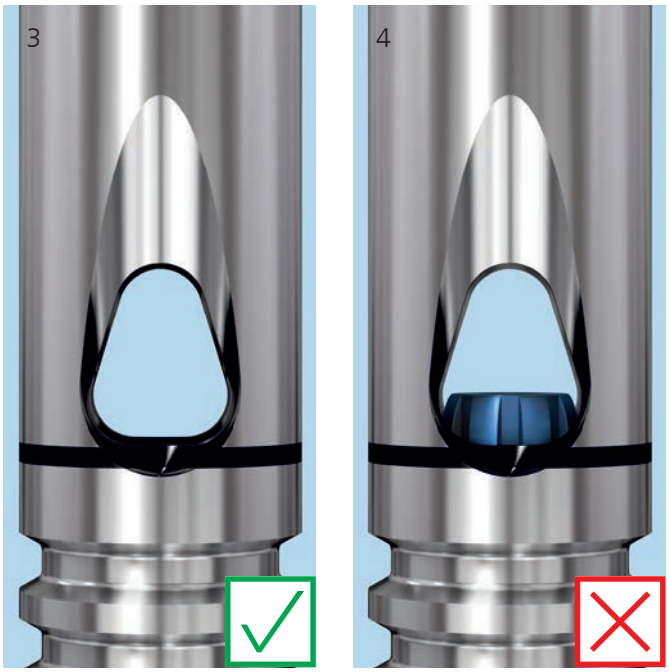


2



Notes:

- **For further manipulations, leave the socket wrench shafts in place until final tightening has been accomplished. To control the desired instrument (socket wrench shaft or screwdriver), only exchange the handles with hexagonal coupling.**
- **Ensure that the MIS fracture clamp is positioned correctly on the shaft of the Schanz screw by controlling the height with the window within the socket wrenches. The range limit is when the top of the screw is flush with the window (3). A wrong position of the clamp on the screw is identifiable when the screw is visible in the window (4). In this case, check the screw insertion depth according to p.18 –19 (except for MIS Schanz screw perforated) or / and correct the height of the MIS fracture clamp with the clamp holder.**



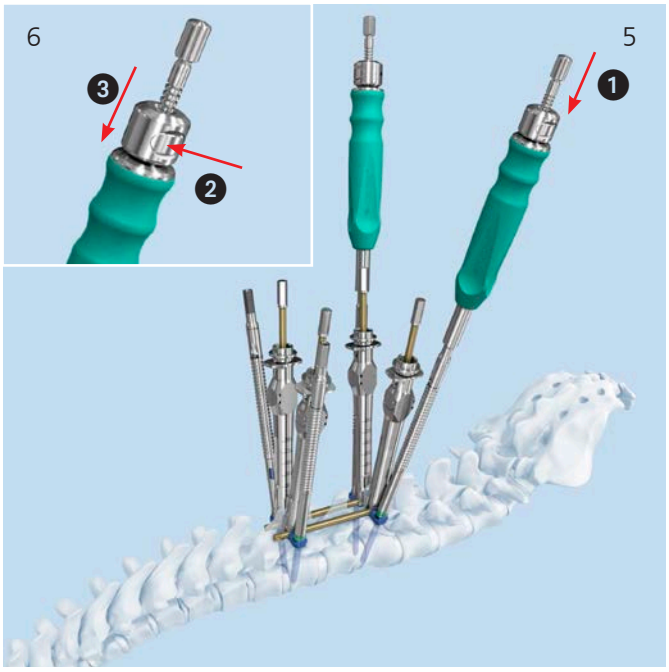
Optional technique

Before performing fracture reduction, insert the Position Retainer together with the Push Button for Position Retainer ❶ into the corresponding handle with hexagonal coupling. Screw the threaded tip of the Position Retainer into the end of the Schanz Screw to fix them together (5).

Ensure that all the MIS fracture clamps are positioned as deep as possible (see "Fracture Clamp Insertion", Step 2 on page 24).

To keep position of the Fracture Clamp during fracture reduction, adjust height of the Push Button for Position Retainer by pressing the button ❷ and pushing down ❸ (6).

Perform fracture reduction according to instructions on page 36.



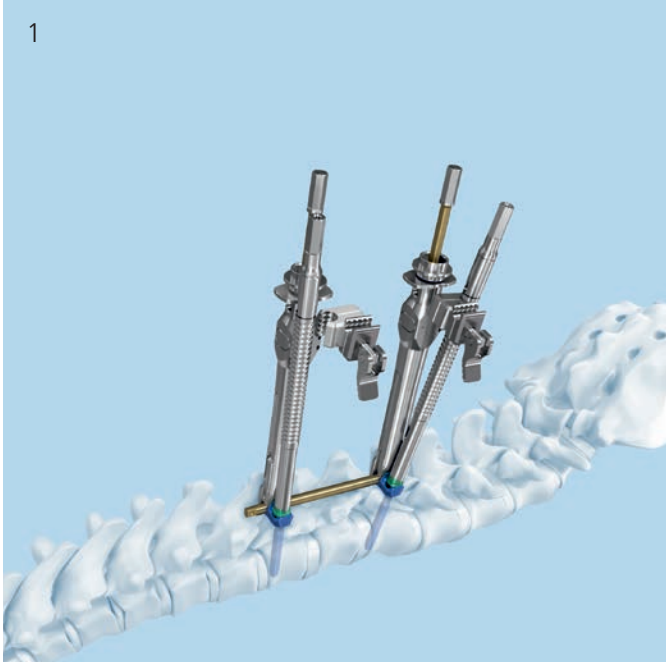
2
Distraction (optional)

Instruments	
03.627.008	Distraction Instrument for MIS
03.627.077	Distraction Forceps for MIS
03.628.113	Socket Wrench Shaft with 3-Lobe-Drive
03.628.114	Handle with Hexagonal Coupling 7.0 mm

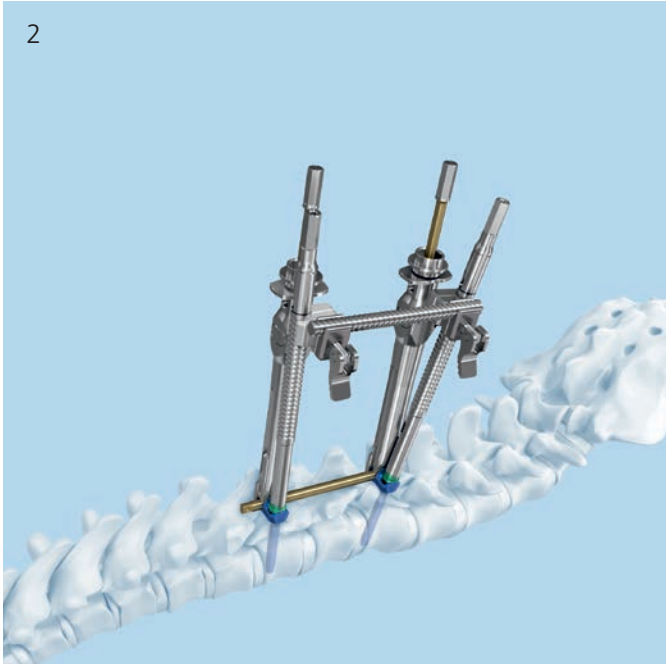
Ensure that all the nuts of the MIS fracture clamps are provisionally tightened and positioned as deep as possible (see "Fracture Clamp Insertion", Step 2 on page 24)

Assemble the distraction instrument onto the upper part of the ridged section of both socket wrench shafts and ensure a firm connection of the instrument to the socket wrench shaft (1–3). The clamps of the distraction instrument need to be positioned as high as possible on the ridged section of the socket wrenches. Verify that the connecting bar clicks audibly into the clamps. Fix the connecting bar in the clamps by closing the lever (1–3).

1



2



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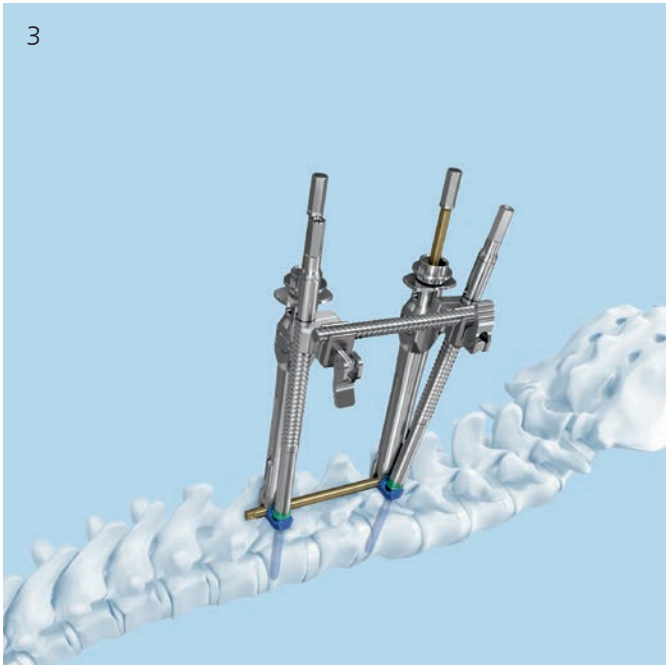


Place the handle with hexagonal coupling on the screwdriver and loosen the locking cap of the MIS fracture clamp on the side of the rod with bullet nose (4).

4

Place the distraction forceps between the caudal and ipsilateral cranial socket wrench shafts. Position the forceps on the ridged section underneath the distraction instrument, as close as possible to the skin level (5).


5

Perform careful distraction to complete the anatomical reduction and restore the original level of the fractured vertebral body.

Note: **Use lateral radiographic imaging during distraction to control adequate manipulation of the spine.**

Fix the forceps using the ratchet. Leave the forceps in place and hand-tighten the MIS locking cap.

Remove the forceps and the distraction instrument.

Notes:

- **Place the distraction instrument as high as possible on the ridged section of the socket wrench shafts.**
- **Check final rod placement with lateral radiographic imaging. Ensure that the coupling and the tip of the rod protrude outside the MIS fracture clamps.**

FINAL TIGHTENING

Tightening of nut and locking cap

Instruments	
03.627.017	Torque-limiting Ratchet Handle, 7 Nm
03.628.110	Counter Torque
03.628.112	Screwdriver for Locking Cap, T25
03.628.113	Socket Wrench Shaft with 3-Lobe-Drive
03.628.115	Adapter for Hexagonal Coupling 7.0 mm

Seat the counter torque in the proximal socket of the guide for locking cap and adjust the orientation of the handle as desired (1).

Place the torque-limiting ratchet handle with the adapter for hexagonal coupling on the screwdriver. Turn the torque-limiting ratchet handle clockwise while holding the counter torque and tighten the locking cap to the audible click, which indicates that 7 Nm of torque have been applied (1).

Place the torque-limiting ratchet handle with the adapter for hexagonal coupling on the adjacent socket wrench shaft (tightening of the same fracture clamp), and final tighten the nut of the MIS fracture clamp to the audible click (2).

Repeat this procedure for all clamps. Remove all screwdrivers and socket wrench shafts.

Notes:

- **Ensure that the required torque of 7 Nm is applied to screwdriver for locking cap by using the torque limiting handle.**
- **Use the counter torque for final tightening to avoid transmitting tightening torque to the construct.**

1

2

REMOVAL OF INSTRUMENTS

Removal of guide for locking cap / clamp holder assemblies

Instrument	
03.628.111	Release Key

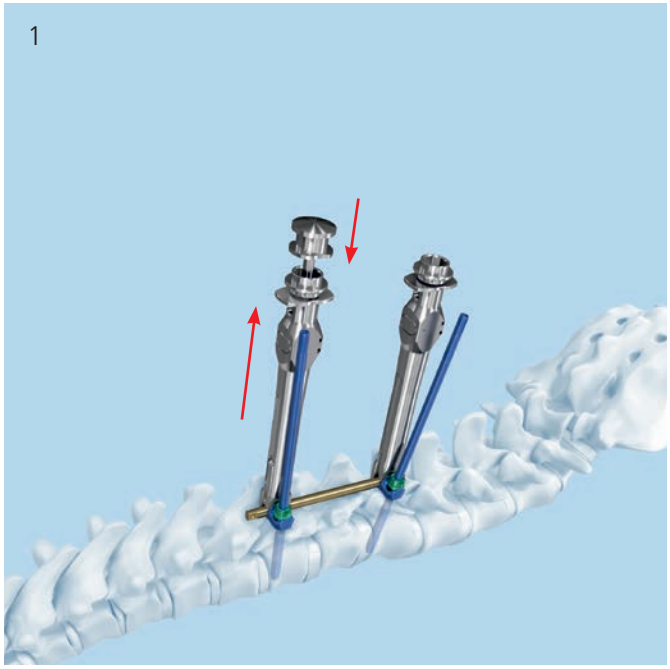
Optional instrument	
03.628.109	Persuader

Insert the release key into the dedicated slot of the guide for locking cap. Forcefully push down the release key until it stops (1). If necessary, use the persuader to push down the release key (2).

Pull out the instrument assembly by holding the clamp holder underneath the instrument's shoulders (1).

Repeat this procedure for all guide for locking cap/clamp holder assemblies.

1



2

TRIM SCHANZ SCREWS

Trim Schanz screws using the bolt cutter

Instruments	
391.771	Bolt Cutting Head ∅ 5.0 mm, long
03.627.015	Handle, 13 mm, for Bolt Cutter
03.627.016	Handle, 24 mm, for Bolt Cutter

When reduction is complete and the assembly has been secured, trim the Schanz screws to the required length using the bolt cutter.

Assemble the bolt cutter and place it in the neutral position. Position the handles, one on top of the other, on the bolt cutting head like the hands of a clock. Slide down the bolt cutting head over the Schanz screw so that it seats directly on the MIS fracture clamp (1).

Notes:
- **With the assembled bolt cutter in the neutral position, it is possible to see through the 5 mm hole.**
- **Ensure that the nut of the bolt cutting head is firmly tightened.**

Pull the handles apart until the Schanz screw audibly breaks and is cut.

Return the handles to the original position and move the bolt cutting head to the next Schanz screw. The previously cut screw shaft will fall out during this operation.

Notes:
- **If the cut screw shaft does not fall out of its own accord, it can be pushed out using the shaft of another Schanz screw. If it is not possible, the bolt cutting head will have to be disassembled and the screw shaft pushed out of the inner bolt.**
- **Always dismantle the bolt cutting head for cleaning purposes.**

1

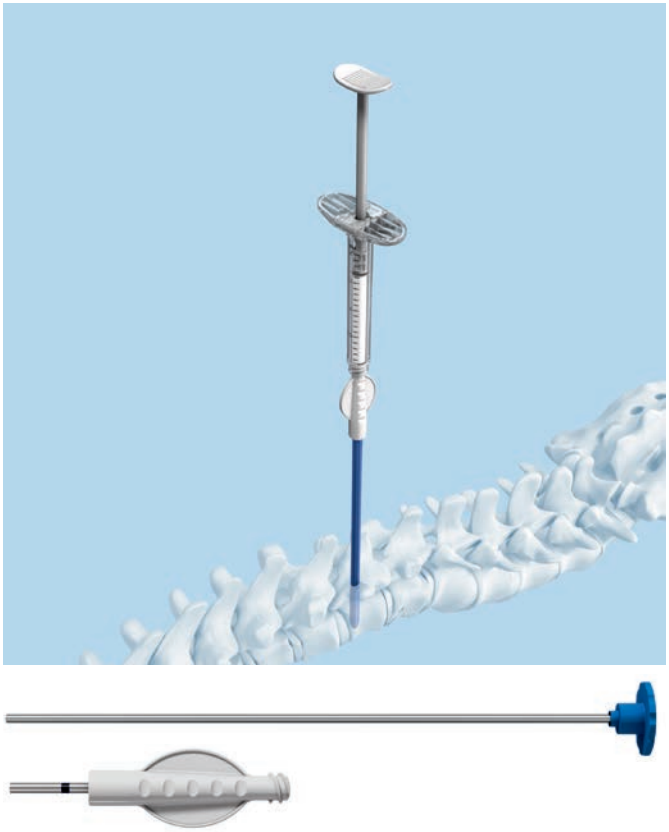
2

AUGMENTATION OF PERFORATED SCHANZ SCREWS

1
Preparation

Ensure that the perforated Schanz screws have been inserted according to the surgical technique for implant introduction on pages 10 – 21.

Instruments	
03.702.627S	Augmentation Kit for perforated Schanz Screws, with Luer-Lock, sterile
07.702.016S	Vertecem V+ Cement Kit
03.702.215S	Vertecem V+ Syringe Kit
02.648.001S	Cleaning Stylet for perforated Pedicle Screws, sterile



Augmentation Kit for perforated Schanz Screws, with Luer-Lock

Use the cleaning stylet to clear the cannula for proper cement injection. Visualize the stylet position under image intensifier control (1).

2
Cement handling

2a
Prepare cement

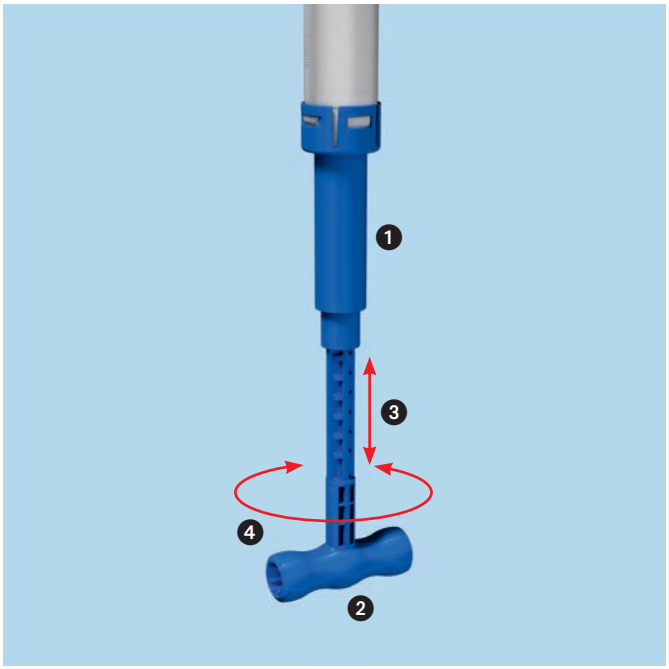
Implant	
07.702.016S	Vertecem V+ Cement Kit

Hold the Vertecem V+ Cement Kit upright (1) and gently tap with the finger tip at the top of the mixing device in order to ensure no cement powder sticks to the cartridge and transportation lid.

Note: **During preparation, mixing and injection make sure to always handle the mixing device by gripping the blue part located directly below the transparent cartridge. If the transparent part is used as gripping surface, the body heat provided by the users hand might result in a shorter working time than intended.**

Open the glass ampoule by breaking off its neck with the plastic cap ❶. Place the opened ampoule in the ampoule holder in the Vertecem V+ Cement Kit inner blister or on a flat, sterile surface. Hold the mixing device upright and make sure the blue handle is in its outmost position. Tap gently on its lid with your finger to ensure that no powder sticks to transportation lid or mixer walls. Remove the transportation lid from the mixing device and dispose of it. Pour the full content of the ampoule ❷ into the mixer and close it tightly with the separate mixing and transfer lid ❸. Make sure that both mixing lid and the small sealing plug on top of it are securely tightened.

Grip the mixer by the blue part ❶. Start mixing the Vertecem V+ cement by pushing and pulling the handle ❷ from endpoint to endpoint ❸ for 20 seconds (1– 2 strokes per second). Perform the first few mixing strokes slowly with an oscillating-rotating movement (❸ and ❹ combined). Once properly mixed, the blue handle ❷ must be left in its outmost position.



2b
Fill injection syringes

Instrument	
03.702.215S	Vertecem V+ Syringe Kit

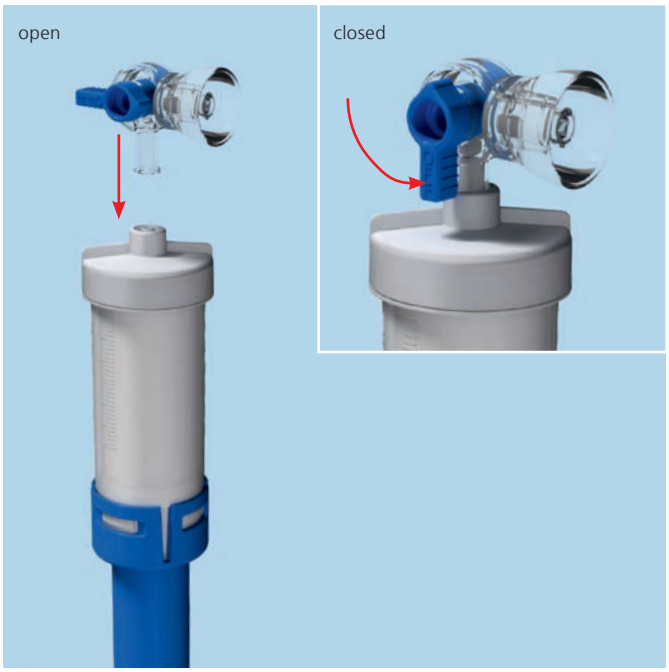
Once cement has been mixed, remove the sealing plug and connect the stop cock. Use the side without the funnel when connecting the stop-cock to the mixer.

The handle in the initial position is turned 90° away from the mixer and the “off” sign is on the opposite side from the funnel. Ensure a tight fit between the stop-cock and mixing device, but avoid breakage of the stop-cock due to the application of excessive torque.

First, the air has to be removed from the system. Hold the cement mixer in a vertical position and gently turn its handle clockwise.

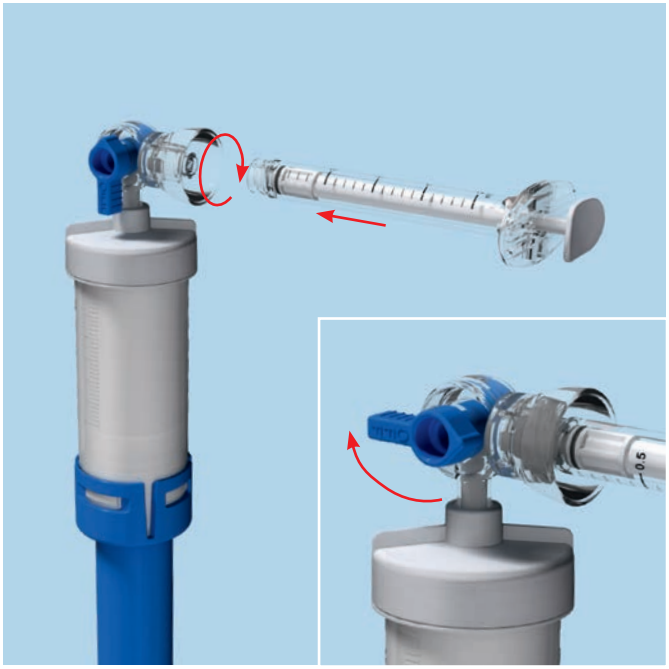
Turn the handle clockwise to extrude cement from the mixer, do not push.

The piston of the mixer will then advance in the translucent cartridge and a steady flow of cement move into the stop-cock. As soon as the cement is visible at the funnel end of the stop-cock, close the stop-cock by turning the handle (“off”) toward the mixer (90°).



Attach a syringe to the stop-cock (funnel side). We recommend using the 2 mL syringes first.

Open the stop-cock by turning the handle (90° turn), back to its original position.



Use slow, controlled turning movements on the mixer handle to fill the syringe. As soon as the syringe is filled, turn the valve of the stop-cock again (90°) towards the mixer. The “off” sign is directed toward the mixer, stopping the cement flow.

To transfer cement, simply rotate the handle. Do not push.

Disconnect the full syringe and attach the next one. Continue until all syringes are filled. Always fill all syringes directly after mixing.

2c
Injection preparation

Instrument	
03.702.627S	Augmentation Kit for perforated Schanz Screws, with Luer-Lock, sterile

Connect the adapter of the Augmentation Kit for perforated Schanz Screws to the screws and press down firmly.

Turning clockwise, attach the prefilled syringe onto the Luer-Lock.

Note: **Ensure that the needle adapter is firmly seated into the screw recess.**

2d

Injection procedure

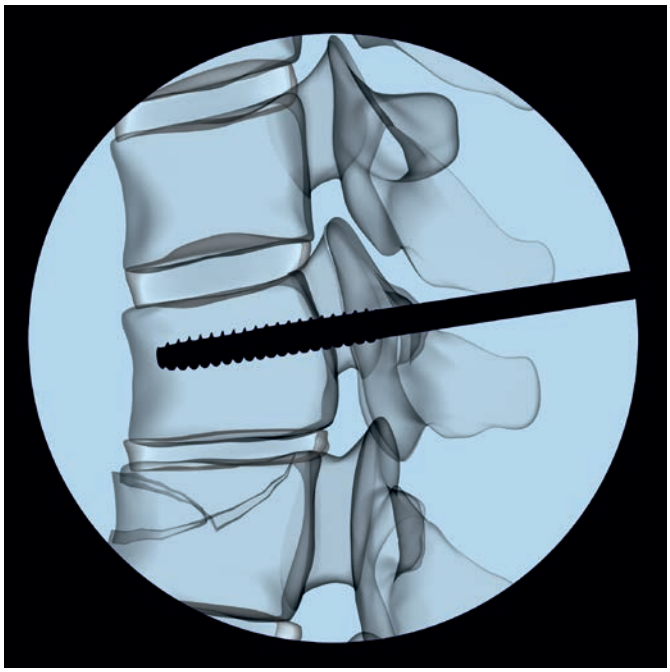
Place the C-Arm in a lateral position to monitor the extrusion of the cement into the vertebral body.

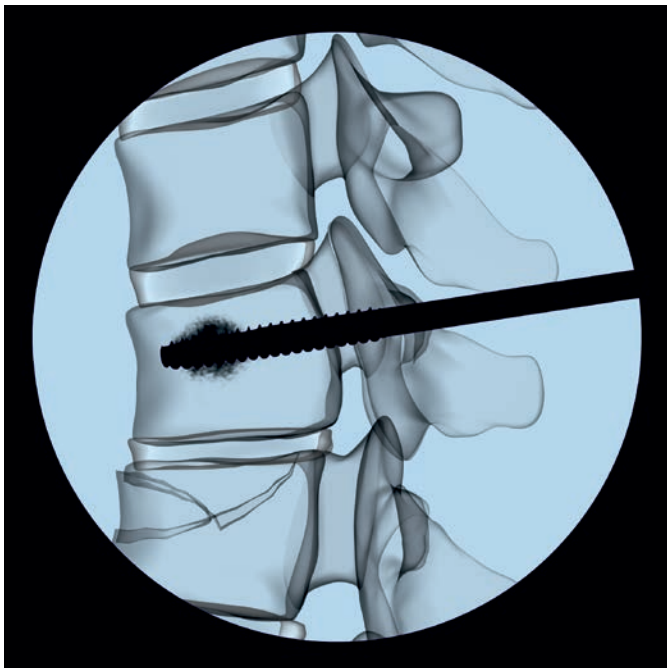
Additional image intensifier control in the AP projection is recommended.

1. Make sure that the syringes with the adapters are firmly connected with the Schanz screws to be augmented prior to cement application. Make sure that the adapter is fully introduced into screw recess.
2. Inject as much cement as required until it slowly starts to extrude from the perforations of the screw.

Ensure that no cement leakage occurs outside the intended area. Immediately stop the injection if leakage occurs.

The first 1.5 cc of cement injected do fill only the Schanz screw and the adapter. Only if more than 1.5 cc of cement are injected with the syringe, cement will start to fill the vertebra.





3. Continue to add cement to each screw using continuous image intensifier control. A growing cloud pattern should form. If a spider web-like pattern forms, wait approximately 30 to 45 seconds or proceed with another screw and return to the present screw later.

4. If more cement is needed or the injection pressure is too high, switch to the 1 cc syringes. Start again with the first screw. Augmentation is complete when each screw has been augmented with a total cloud volume of approximately 2 to 3 cc.

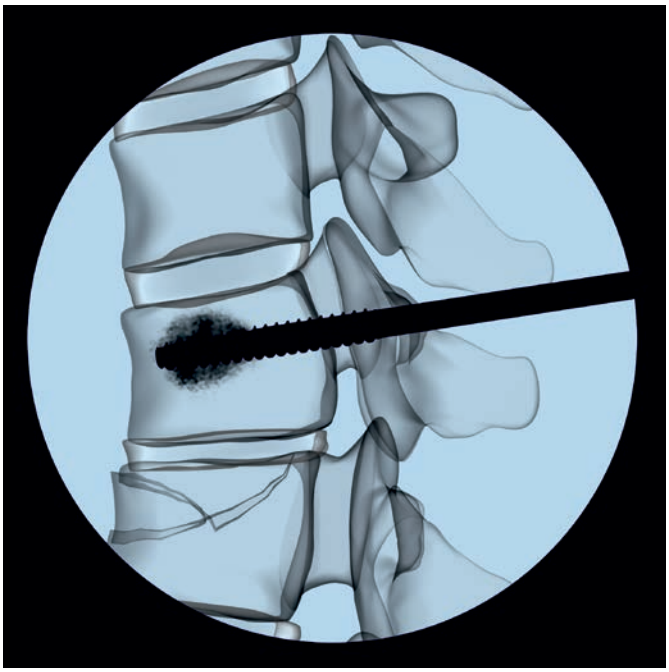
Ensure that the adapter remains fully inserted in the screw recess when replacing of syringes is necessary, as cement can be left in the inner thread of the screw.

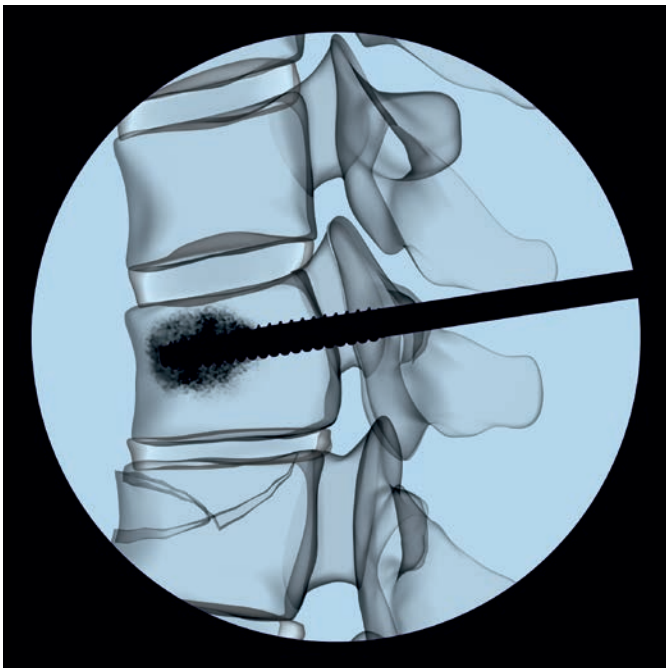
5. After injection is made, the cement in the shaft of the screw and in the adapter (approximately 1.5 cc) can be utilized using the plunger. Leave the adapter in place and insert the plunger.

The plunger has to be removed from the adapter while the cement is still soft (or has not hardened yet).

Do not remove nor replace syringes immediately after injection. The longer the syringe remains connected to the screw, the lower the risk of undesired cement flow.

Wait until the cement has cured before removing adapters and continuing with the instrumentation (about 15 minutes after last injection).





Precaution: **The cement flow follows the path of least resistance. Therefore it is mandatory, during the whole injection procedure, to maintain real-time image intensifier control in the lateral projection. In case of unexpected cloud forming patterns or if the cement is not clearly visible, the injection must be stopped.**

Note: **Any cement remaining in the inner thread at the end of the screw shaft must be removed with the cleaning stylet while it is still soft (or has not hardened yet). This will ensure that future spondylolisthesis reduction remains possible with the respective instruments.**

3
Fracture clamp insertion

Continue with the surgical technique on page 22 for fracture clamp insertion and the following surgical steps.

Note: **Prior to performing correction maneuvers, ensure that the cement is fully hardened.**

Warning: **Correction maneuvers might lead to loosening of the augmented screws, resulting in construct failure.**

Notes and Warnings

Cement leakage
A major risk performing screw augmentation is cement leakage. By respecting the steps of the surgical technique the complication rate is minimized.

Cement injection might cause fat embolism due to bone marrow being pushed into the blood circulation. Therefore the amount of cement that is injected during surgery should be limited to approximately 25 ml and less if the patient shows severe compromised cardiovascular function. Furthermore, systemic reactions during cement injection can occur as a consequence of cement monomer release.

If significant leakage occurs, the procedure has to be stopped. Return the patient to the ward and assess the patients' neurological situation. In case of compromised neurological functions an emergency CT scan should be performed to assess the amount and location of the extravasation.
If applicable, an open surgical decompression and cement removal may be performed as an emergency procedure.

Extravasation
In order to minimize the risk of extravasation, it is strongly recommended to follow the described surgical technique, i.e.:
- use a Kirschner wire for the placement of Schanz screws
- use a high-quality C-arm in lateral position
- use Synthes' Vertecem V+, a highly viscous and radiopaque cement

Additionally, image intensifier control in the AP projection is recommended.

Leakage outside the vertebra
If leaking outside the vertebra is recognized, the injection has to be stopped immediately. Wait for 45 seconds. Slowly continue with the injection. Due to faster curing in the vertebral body, the cement occludes the small vessels and the filling can be accomplished. Amounts of cement of approximately 0.2 cc are recognizable. If filling cannot be performed as described, stop the procedure.

Leakage into the spinal canal
Stop the injection. If the cement amount is very small, you may proceed as described in chapter Cement Handling.

Fracture
The risk of a fracture at adjacent levels appears to be increased after cement reinforcement. Patients and their doctors should therefore be made aware that if new pain occurs, a new fracture may have occurred. Radiological control should be performed and, if necessary, further reinforcement should be considered – in such cases also including the adjacent vertebrae. All patients with osteoporotic fractures should be evaluated and treated by an osteologist or their family doctor and, if applicable, receive systemic treatment with vitamin D and bisphosphonates.

Pregnancy
There is no safety data regarding the use of Vertecem V+ in children, during pregnancy or during lactation. There is inadequate information to determine whether this material might affect fertility in humans or produce teratogenic or other adverse effects on the fetus.

Screw size
Preoperative planning and selection of the appropriate screw length and diameter is important. In the average lumbar spine ∅ 6.0 mm screws are recommended, as scientific papers report a higher rate of pedicle perforation using ∅ 7.0 mm screws.

Placement of pedicle screw
MIS Schanz screws perforated should be placed in approximately 80% of the vertebral body.

TAP PEDICLE

Instruments	
03.627.017	Torque-limiting Ratchet Handle, 7 Nm

Tap, cannulated, for Pedicle Screws with dual core, length 230/15 mm	
03.620.205	∅ 5.0 mm
03.620.206	∅ 6.0 mm
03.620.207	∅ 7.0 mm

Protection Sleeve	
03.620.225	7.2/5.3, for No. 03.620.205, violet
03.620.226	8.2/6.3, for No. 03.620.206, blue
03.620.227	9.2/7.3, for No. 03.620.207, green

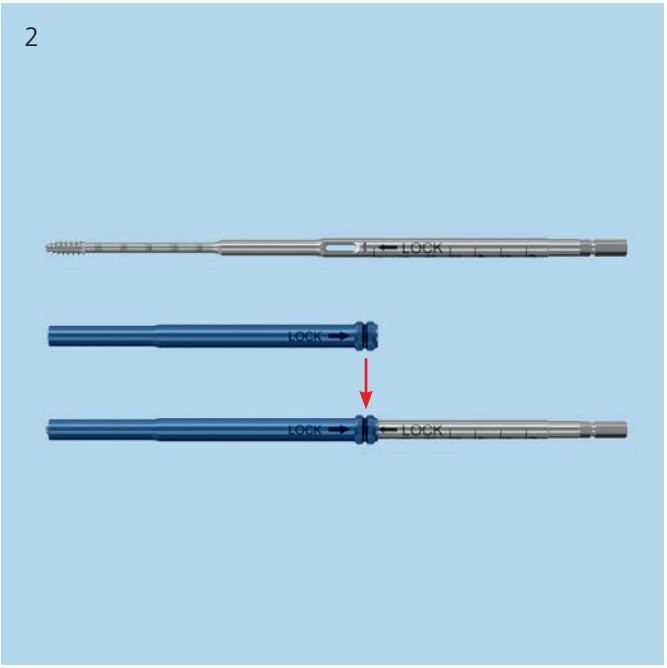
Prepare a pathway for the dual core screws with the cannulated taps by penetrating the pedicle prior to screw insertion. Protection sleeves cover the proximal tip of the tap, to minimize trauma to surrounding soft tissues (1).

1

To lock the protection sleeve onto the cannulated tap shaft, align the arrows and push the tap and the sleeve together (2). To unlock the protection sleeve, hold the knurled portion of the protection sleeve and turn the tap clockwise and advance. Depth graduations are provided at both ends of the tap to estimate depth for proper implant sizing.

Note: **To prevent inadvertent advancement of the Kirschner wire, align the trajectory of the tap with the Kirschner wire and monitor the Kirschner wire position using fluoroscopy.**

2



REDUCTION OF SPONDYLOLISTHESIS

Instruments

03.627.012	T-Handle for Reduction Instrument, for Spondylolisthesis
03.628.104	Reduction Tool for Spondylolisthesis
03.628.114	Handle with Hexagonal Coupling 7.0 mm

Follow the surgical technique for implant introduction on pages 6 – 35.

Place the socket wrench shafts on the four Schanz screws and ensure that the MIS locking cap and the nut of the MIS fracture clamp on the side to be reduced are untightened.

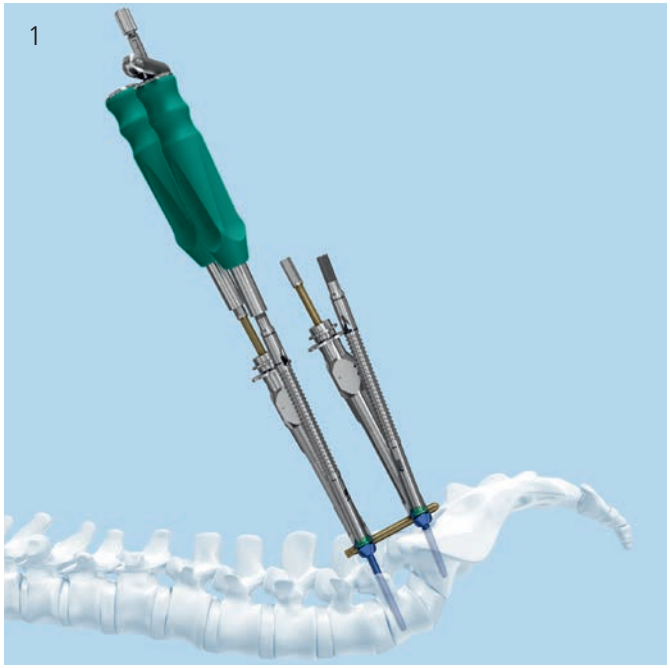
Insert the reduction tool for spondylolisthesis together with the T-handle into the handle with hexagonal coupling located on the displaced vertebra. Screw the threaded tip of the reduction tool into the end of the Schanz screw to fix them together (1).

Turn the T-handles clockwise on both sides simultaneously until the desired reduction is achieved ❶.

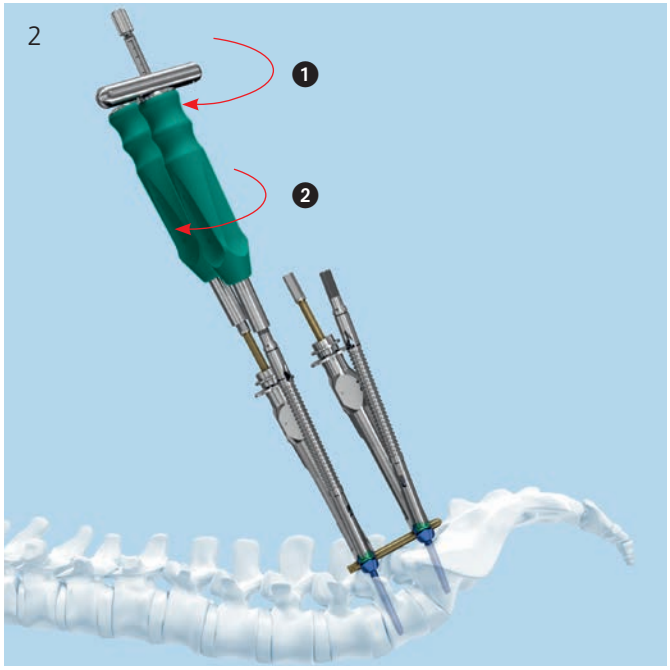
Secure the Schanz screws in the desired position by tightening the nut using the handle with hexagonal coupling on the socket wrench shaft ❷.

Secure the rod by tightening the MIS locking cap using the handle with hexagonal coupling on the corresponding screwdriver.

1



2



Remove the reduction tool and continue with the final tightening on page 41.

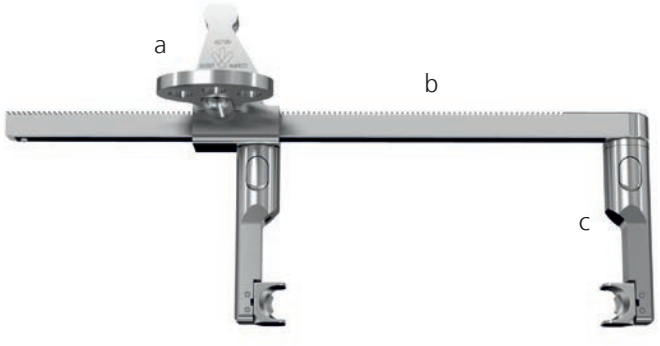
Notes:

- Use lateral radiographic imaging to monitor the reduction of the spondylolisthesis.
- Ensure that the reduction tool is fully inserted into the Schanz screw by tightening the instrument until the stop.
- Hold the handle with hexagonal coupling while spinning the T-handle for reduction instrument during reduction of spondylolisthesis.
- Ensure that the MIS fracture clamp is positioned correctly on the shaft of the Schanz screw by controlling the height with the window of the socket wrenches. The maximum reduction is achieved when the top of the screw is flush with the window (3). A wrong position of the clamp on the screw is identifiable when the screw is visible in the window (4). In this case, check the screw insertion depth according to pages 18 – 20, except for MIS Schanz screw perforated – or/and correct the height of the MIS fracture clamp with the clamp holder and the reduction tool.
- Check final rod placement with lateral radiographic imaging. Ensure the coupling and the tip of the rod protrude outside the MIS fracture clamps.

DISTRACTION WITH RACK DISTRACTOR

Instruments

03.627.008	Distraction Instrument for MIS
03.628.125	USS Fracture MIS Compression/ Distraction Adapter
03.628.126	Toothed Rack, long
03.628.127	Connecting Bar, long
03.631.528	Slider with Wing Nut
03.628.113	Socket Wrench Shaft with 3-Lobe-Drive
03.628.114	Handle with Hexagonal Coupling 7.0 mm



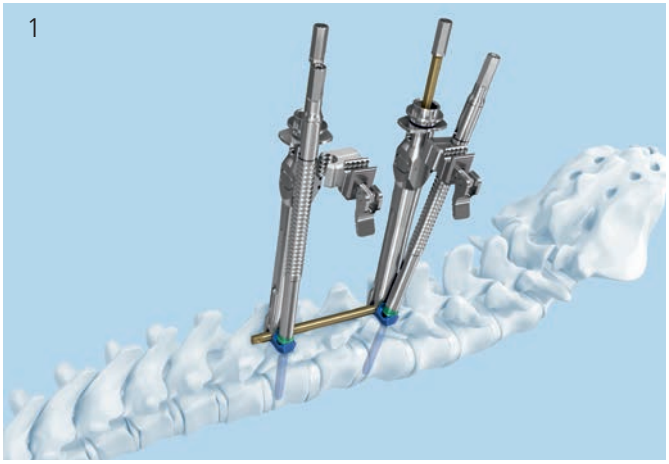
Follow the surgical technique for implant introduction on pages 6–35.

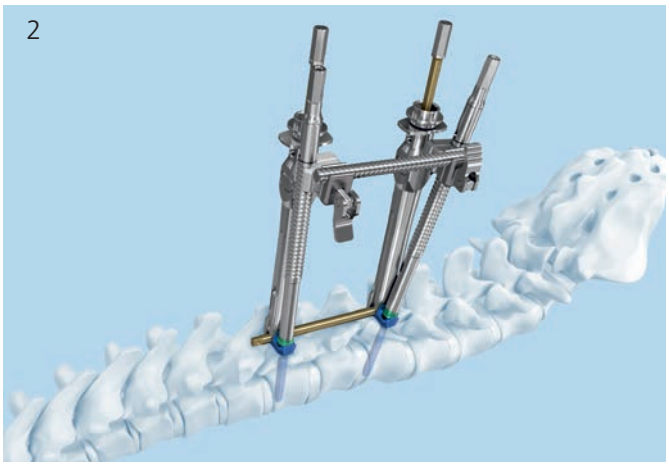
Ensure that all the nuts of the MIS fracture clamps are provisionally tightened and positioned as deep as possible (see “Fracture Clamp Insertion”, Step 2 on page 24).

Perform careful compression or distraction if this is necessary to complete the anatomical reduction and restore the original level of the fractured vertebral body.

Mount the slider with wing nut (a) on the toothed rack (b), and snap the USS Fracture MIS compression/distraction adapters onto the dedicated mounting features (c).

Assemble the distraction instrument onto the upper part of the ridges of both socket wrench shaft and ensure a firm connection of the instrument to the tips (1–2). The clamps of the distraction instrument need to be positioned as high as possible on the ridged section of the socket wrenches. Verify that the connecting bar (long) clicks audibly into the clamps. Fix the connecting bar (long) in the clamps by closing the lever (1–2).





Place the handle with hexagonal coupling on the screwdriver and loosen the locking cap of the MIS fracture clamp on the side of the rod with bullet nose (4).

Position the adapter to the distraction position [◀— —▶]. Guide the rack distractor between the caudal and ipsilateral cranial socket wrench shafts. Place the rack distractor on the ridges underneath the distraction clip, as close as possible to the skin level (4), and rotate the wing nut clockwise until the desired distraction is achieved.

Note: **Use lateral radiographic imaging during distraction to control adequate manipulation of the spine.**

Use the handle to hand-tighten the MIS locking cap. Remove the rack distractor and the distraction instrument.

Notes:

- **Place the distraction instrument as high as possible on the ridges of the socket wrench shafts.**
- **For compression, follow the same steps and switch the rack distractor to compression [—▶ ◀—, Compr.] instead (5).**
- **Check final rod placement with lateral radiographic imaging. Ensure that the coupling and the tip of the rod protrude outside the MIS fracture clamps.**

4

5

IMPLANT REMOVAL

For many patients, implant removal often represents the true completion of fracture treatment. While giving due concern to the patient's own wishes, the expense, utility, and risks of removal of the implants must be weighed up. The implications of leaving the implant in place should always be explained to the patient.

As a matter of principle, implants can be removed once the fracture has healed and the load capacity has been re-established. In the case of implant removal, complications may arise for a variety of reasons and it is important that the surgeon should be prepared for this.

Instruments	
03.628.116	Removal Instrument for Clamp
03.628.117	Removal Instrument for Rod
03.628.119	Removal Instrument for Screw
03.628.121	Removal Instrument for Locking Cap
03.628.122	Removal Sleeve
03.628.123	Untightening Instrument for Nut

Make the access to the implants to be removed by creating stab incisions to the screw/clamp to be removed (preferably along the incision that was used to bring in the implants).

Optionally, use a soft tissue spreader to provide a visual access.

Free the locking cap recess and nut of the fracture clamp from ingrown scars and bone tissue using appropriate instruments. Check the condition and the geometry of the recess of locking cap and the nut of the fracture clamp exposed.

Recommended literature

Rüedi T.P. et al (2001): Implant removal – general comments. AO Principles of Fracture Management, pgs 729 –731

Müller-Färber J (2003): Die Metallentfernung nach Osteosynthesen. In: Der Orthopäde, Book 11, pgs 653 – 670

Georgiadia G (2004): Removal of the Less Invasive Stabilization System. In: Journal of Orthopaedic Trauma, Volume 18, pgs 562 – 564

Untighten the nut of the MIS fracture clamp

Instrument	
03.628.123	Untightening Instrument for Nut

Insert the untightening instrument for nut over the trimmed Schanz screw (1) and fully introduce it into the 3-lobe drive of the nut of the MIS fracture clamp (2). Turn 2 to 3 revolutions counterclockwise to untighten the nut.

Notes:

- **Once the Schanz screw is cut, use solely the instrument 03.628.123 to untighten the nut of the fracture clamp.**
- **Only make 2 to 3 revolutions to ensure that the loosened nut is not lost in the soft tissues, as the nut is not self-holding.**
- **Properly align the instrument with the axis of the screw to avoid stripping of the nut while untightening.**

Precaution: **Misalignment and/or excessive force while untightening the nut might lead to slippage of the instrument.**

Repeat the operation for all the screws belonging to the ipsilateral construct.

Untighten the locking cap of the MIS fracture clamp

Instruments	
03.628.121	Removal Instrument for Locking Cap
03.628.122	Removal Sleeve

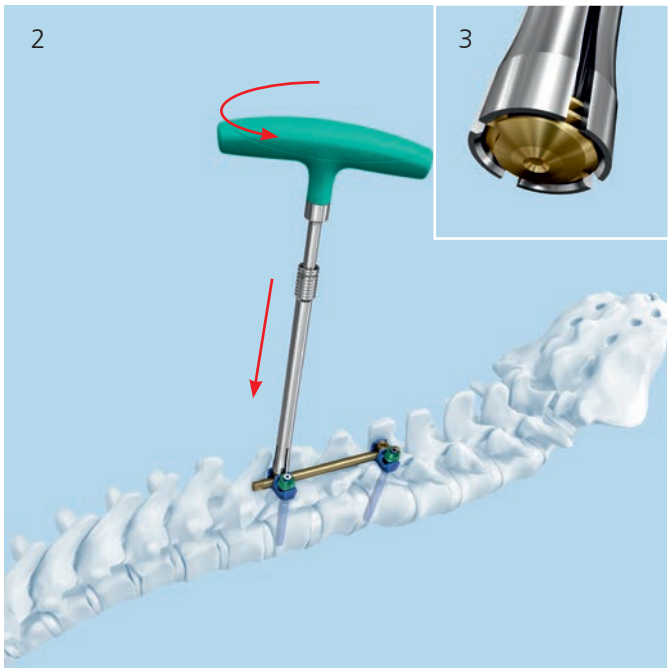
With the removal sleeve stopped in the upper position, fully insert the removal instrument for locking cap into the recess of the locking cap (1).

Push down the removal sleeve and maintain it down over the MIS fracture clamp (2). Turn counterclockwise to untighten the locking cap until the locking cap is captured by the sleeve (3). Take out the implant by holding the T-handle only.

Note: **Ensure that the removal sleeve is pushed down to accommodate the locking cap while turning the removal instrument for locking cap (2).**

Repeat the operation for all the locking caps belonging to the ipsilateral construct.

Precaution: **Misalignment and/or excessive force while removing locking cap might lead to slippage of the instrument.**



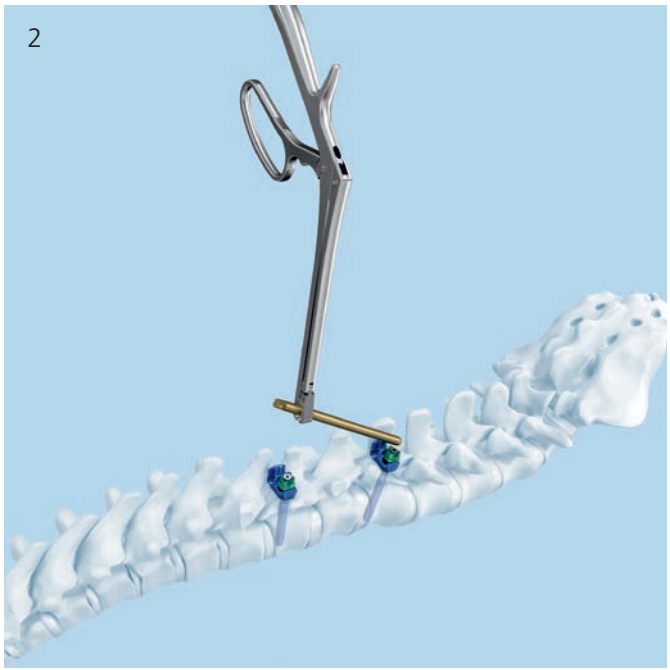
Rod removal

Instrument	
03.628.117	Removal Instrument for Rod

Insert the removal instrument for rod into one incision and firmly grab the rod with the instrument (1). Maintain a firm grip and slide the rod out of the incision (2).

1

2



Fracture clamp removal

Instrument	
03.628.116	Removal Instrument for Clamp

Fully insert the removal instrument for clamp into the thread of the clamp on the locking cap side and turn clockwise to attach the MIS fracture clamp to the instrument (1). Pull back the clamp over the trimmed Schanz screw (2).

Repeat the operation for all the MIS fracture clamps belonging to the ipsilateral construct.

Note: **If the clamp cannot be removed, ensure that the nut of the MIS fracture clamp is untightened (2 to 3 revolutions) or use the alternative technique for MIS fracture clamp and Schanz screw removal (see page 69).**

1

2

Schanz screw removal

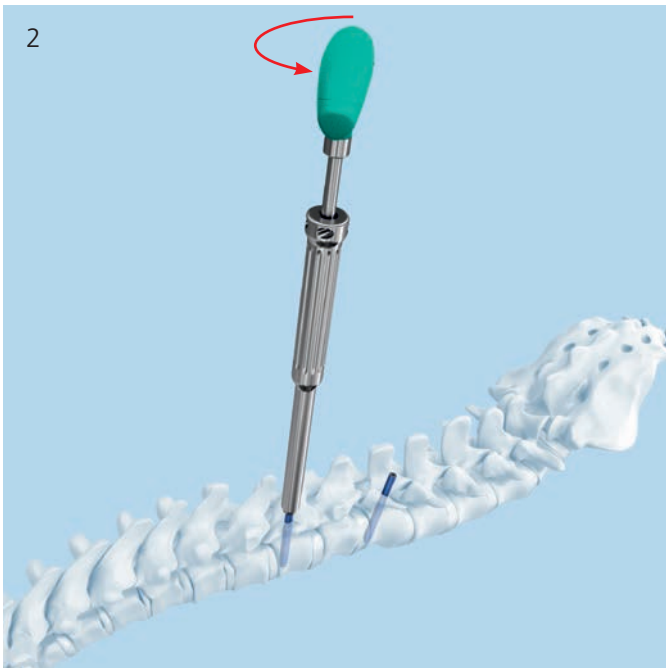
Instrument	
03.628.119	Removal Instrument for Screw

Optional Instrument	
03.628.121	Removal Instrument for Locking Cap

Ensure that the removal instrument for screw is open.

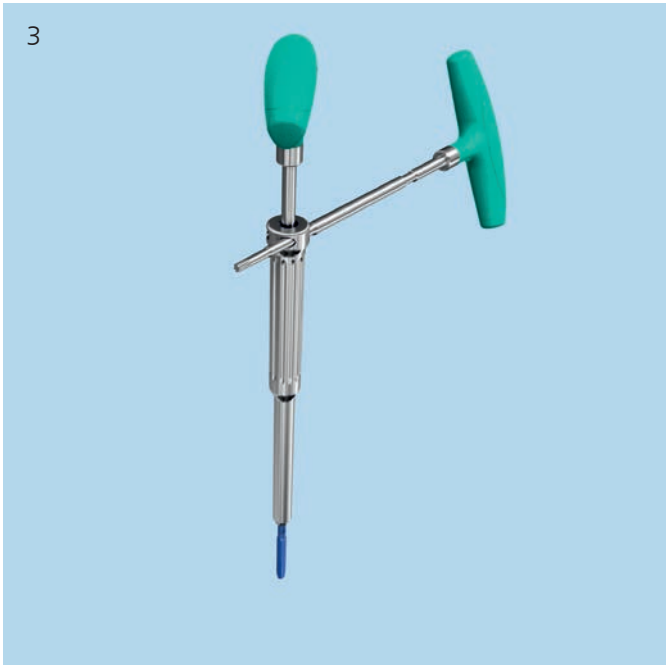
Insert the removal instrument for screw over the trimmed Schanz screw. Turn the handle counterclockwise while holding firmly the sleeve with the other hand. Continue turning until the sleeve starts to turn with the handle (1). From then on, only hold the handle and keep on turning counterclockwise until the screw is completely removed (2).

Repeat the operation for all the screws belonging to the ipsilateral construct.



Note: To open the removal instrument for screws, the removal instrument for locking cap can be used optionally as a counter torque. Insert the removal instrument for locking cap into the hole at the top of the sleeve of the removal instrument for screw. Turn the handle of the removal instrument for screw while holding the removal instrument for locking cap (3).

3



Alternative technique for MIS fracture clamp and Schanz screw removal

Instruments	
03.628.119	Removal Instrument for Screw
03.628.116	Removal Instrument for Clamp

Insert the removal instrument for screw over the trimmed Schanz screw. Turn the handle counterclockwise while holding firmly the sleeve with the other hand. Continue turning until the sleeve starts to turn with the handle (1).

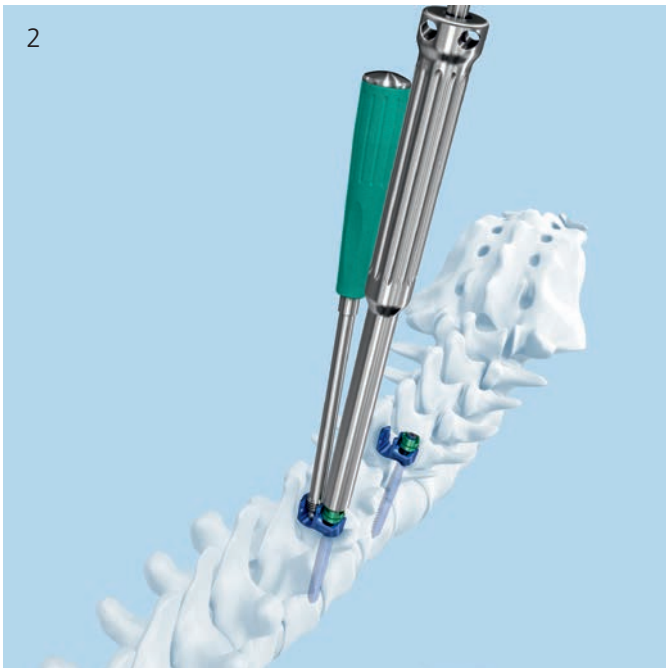
Insert the removal instrument for clamp into the thread of the clamp on the locking cap side and turn clockwise to attach the MIS fracture clamp to the instrument .

1

From then on, turn the handle of the removal instrument for screw counterclockwise, and simultaneously hold the clamp with the respective instrument to prevent the clamp from spinning out of the wound (2).

Repeat the operation for all the screws belonging to the ipsilateral construct.

2



IMPLANTS

04.628.101*	MIS Fracture Clamp

04.628.103*	MIS Locking Cap, one-step

MIS Schanz Screws ∅ 5.0 mm, cannulated, with dual core, Titanium Alloy (TAN)	
	thread length (mm)
04.627.117*	30
04.627.118*	35
04.627.119*	40
04.627.120*	45
04.627.121*	50
04.627.122*	55
04.627.123*	60

* Implants/products are available nonsterile or sterile packed.
Add suffix "S" to article number to order sterile product.

MIS Schanz Screws ∅ 6.0 mm, cannulated, with dual core, Titanium Alloy (TAN)

	thread length (mm)
04.627.132*	30
04.627.133*	35
04.627.134*	40
04.627.135*	45
04.627.136*	50
04.627.137*	55
04.627.138*	60

MIS Schanz Screws ∅ 7.0 mm, cannulated, with dual core, Titanium Alloy (TAN)

	thread length (mm)
04.627.147*	30
04.627.148*	35
04.627.149*	40
04.627.150*	45
04.627.151*	50
04.627.152*	55
04.627.153*	60

* Implants/products are available nonsterile or sterile packed.
Add suffix "S" to article number to order sterile product.

MIS Schanz Screws ∅ 5.0 mm, perforated, with dual core, sterile

	thread length (mm)
04.627.605S	35
04.627.606S	40
04.627.607S	45
04.627.608S	50
04.627.609S	55
04.627.610S	60

MIS Schanz Screws ∅ 6.0 mm, perforated, with dual core, sterile

	thread length (mm)
04.627.614S	35
04.627.615S	40
04.627.616S	45
04.627.617S	50
04.627.618S	55
04.627.619S	60

MIS Schanz Screws ∅ 7.0 mm, perforated, with dual core, sterile

	thread length (mm)
04.627.623S	35
04.627.624S	40
04.627.625S	45
04.627.626S	50
04.627.627S	55
04.627.628S	60

Rod ∅ 6.0 mm, straight, with MIS Coupling, Pure Titanium

	thread length (mm)
04.659.030*	30
04.659.035*	35
04.659.040*	40
04.659.045*	45
04.659.050*	50
04.659.055*	55
04.659.060*	60
04.659.065*	65
04.659.070*	70
04.659.075*	75
04.659.080*	80
04.659.085*	85
04.659.090*	90
04.659.095*	95
04.659.100*	100
04.659.105*	105
04.659.110*	110
04.659.115*	115
04.659.120*	120
04.659.125*	125
04.659.130*	130
04.659.140*	140
04.628.150*	150
04.659.160*	160
04.659.170*	170
04.659.180*	180
04.659.190*	190
04.659.200*	200
04.659.230S	230
04.659.260S	260
04.659.290S	290
04.659.320S	320
04.659.350S	350

* Implants/products are available nonsterile or sterile packed. Add suffix "S" to article number to order sterile product.

INSTRUMENTS

Basic instruments

03.627.015	Handle, 13 mm, for Bolt Cutter	
03.627.016	Handle, 24 mm, for Bolt Cutter	
391.771	Bolt Cutting Head ∅ 5.0 mm, long, cutting height 2 mm	
03.628.112	Screwdriver for Locking Cap, T25	
03.628.113	Socket Wrench Shaft with 3-Lobe-Drive	
03.628.114	Handle with Hexagonal Coupling 7.0 mm	

03.628.115	Adapter for Hexagonal Coupling 7.0 mm	
03.627.017	Torque-limiting Ratchet Handle, 7 Nm	
03.628.110	Counter Torque	

MIS pedicle preparation

02.606.003*	Kirschner Wire ∅ 1.6 mm without trocar tip, length 480 mm, Stainless Steel	
03.616.070	Handle for Kirschner Wire ∅ 1.6 mm	
03.610.001	Dilator ∅ 1.8/10.0 mm, cannulated, for Guide Wire ∅ 1.6 mm	
03.628.101	Dilator ∅ 13 mm, eccentric, for No. 03.628.103	
03.628.103	Dilator ∅ 10.0/13.0 mm, for No. 03.610.001	
03.631.521	Screw Length Indicator	
03.628.106	Reamer, cannulated	

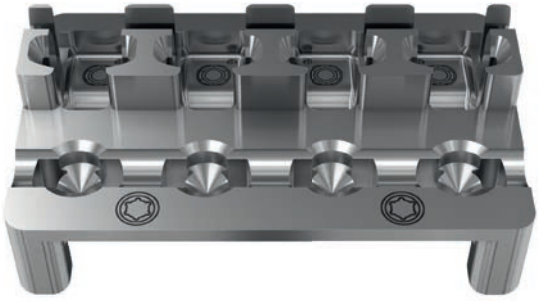
* Implants/products are available nonsterile or sterile packed.
Add suffix "S" to article number to order sterile product.

03.627.024	Spline Drive Screwdriver, for Schanz Screws, cannulated, with Hexagonal Quick Coupling 6.0 mm	
03.620.205	Tap, cannulated, for Pedicle Screws ∅ 5.0 mm	
03.620.206	Tap, cannulated, for Pedicle Screws ∅ 6.0 mm	
03.620.207	Tap, cannulated, for Pedicle Screws ∅ 7.0 mm	
03.620.225	Protection Sleeve 7.2/5.3, for No. 03.620.205	
03.620.226	Protection Sleeve 8.2/6.3, for No.03.620.206	
03.620.227	Protection Sleeve 9.2/7.3, for No.03.620.207	
03.620.230	Pedicle Probe ∅ 3.5 mm, cannulated, radiolucent, length 253 mm, for Screws ∅ 5.0 to 7.0 mm	
03.606.020	Trocar ∅ 1.6 mm	
03.606.021	Trocar Holder, for No. 03.606.020	
03.627.029	Instrument Holder, radiolucent	
03.628.120	Spline Drive Screwdriver, for Schanz Screws, with T-Handle	

MIS additional instruments

03.627.008	Distraction Instrument for MIS	
03.627.077	Distraction Forceps for MIS	
03.632.017	Rod Bender with Silicone Handle	
03.627.012	T-Handle for Reduction Instrument, for Spondylolisthesis	
03.628.104	Reduction Tool for Spondylolisthesis	
03.628.114	Handle with Hexagonal Coupling 7.0 mm	

MIS instruments 1

03.628.105	Clamp Holder	
03.628.108	Guide for Locking Cap	
03.628.111	Release Key	
03.628.124	Rod Indicator	
03.628.107	Rod Length Indicator	
03.628.102	Loading Unit for Clamp	

MIS instruments 2A, straight rod holder (for modular tray 68.628.306)

03.628.109	Persuader	
03.631.537	Handle for Rod Holder	
03.631.538	Rod Holder, straight	

Removal instruments

03.628.116	Removal Instrument for Clamp	
03.628.117	Removal Instrument for Rod	
03.628.119	Removal Instrument for Screw	
03.628.121	Removal Instrument for Locking Cap	
03.628.122	Removal Sleeve	
03.628.123	Untightening Instrument for Nut	

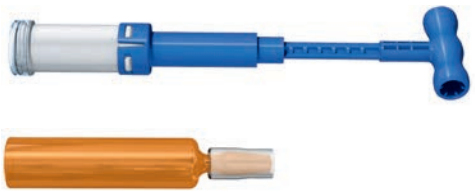
Rack distractor

03.628.125	USS Fracture MIS Compression/ Distraction Adapter	
03.628.126	Toothed Rack, long	
03.628.127	Connecting Bar, long	
03.631.528	Slider with Wing Nut	

Position Retainer

03.628.128	Position Retainer	
03.628.129	Push Button for Position Retainer 03.628.128	

Additional material for cement augmentation

03.702.627S	Augmentation Kit for perforated Schanz Screws, with Luer-Lock, sterile	
07.702.016S	Vertecem V+ Cement Kit Content: 1× Vertecem V+ Mixer prefilled with cement powder 1× Monomer glass ampoule	
03.702.215S	Vertecem V+ Syringe Kit Content: 8× blue 1 cc syringes 5× white 2 cc syringes 1× one-way stop-cock	
02.648.001S	Cleaning Stylet for perforated Pedicle Screws, sterile	

Modules and Cases

68.628.300	Modular Tray, for Basic Instrument Set, without Lid, without Contents
68.628.301	Modular Tray, for MIS Approach for Pedicle Preparation, without Lid, without Contents
68.628.303	Modular Tray, for MIS Additional Instruments, without Lid, without Contents
68.628.305	Modular Tray, for MIS Instruments 1, without Lid, without Contents
68.628.306	Modular Tray, for MIS Instruments 2A, with Rod Holder straight, without Lid, without Contents
68.628.308	Modular Tray, for Removal Instruments 1, without Lid, without Contents
68.628.321	Module for MIS Rods ∅ 6.0 mm, straight, length 30 –200 mm, with Lid, without Contents
68.628.322	Module for Schanz Screws, with Lid, without Contents
68.628.323	Module for Fracture Clamp and Schanz Screws, with Loading Station, with Lid, without Contents
68.631.516	Module for Rack Distractor/Compressor and Adapters, with Lid, without Contents
684.060	Lid for Modular Tray, size 1/2

68.000.101	Lid for Modular Tray, size 1/1
689.507	Lid (Stainless Steel), size 1/1, for Vario Case
689.508	Vario Case, Framing, size 1/1, height 45 mm
689.509	Vario Case, Framing, size 1/1, height 67 mm
689.510	Vario Case, Framing, size 1/1, height 88 mm
689.511	Vario Case, Framing, size 1/1, height 126 mm
689.513	Vario Case, Framing, size 1/2, height 45 mm
689.514	Vario Case, Framing, size 1/2, height 67 mm
689.515	Vario Case, Framing, size 1/2, height 88 mm
689.516	Vario Case, Framing, size 1/2, height 126 mm
689.537	Lid (Stainless Steel), size 1/2, for Vario Case

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People inspired™

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuysynthes.com

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