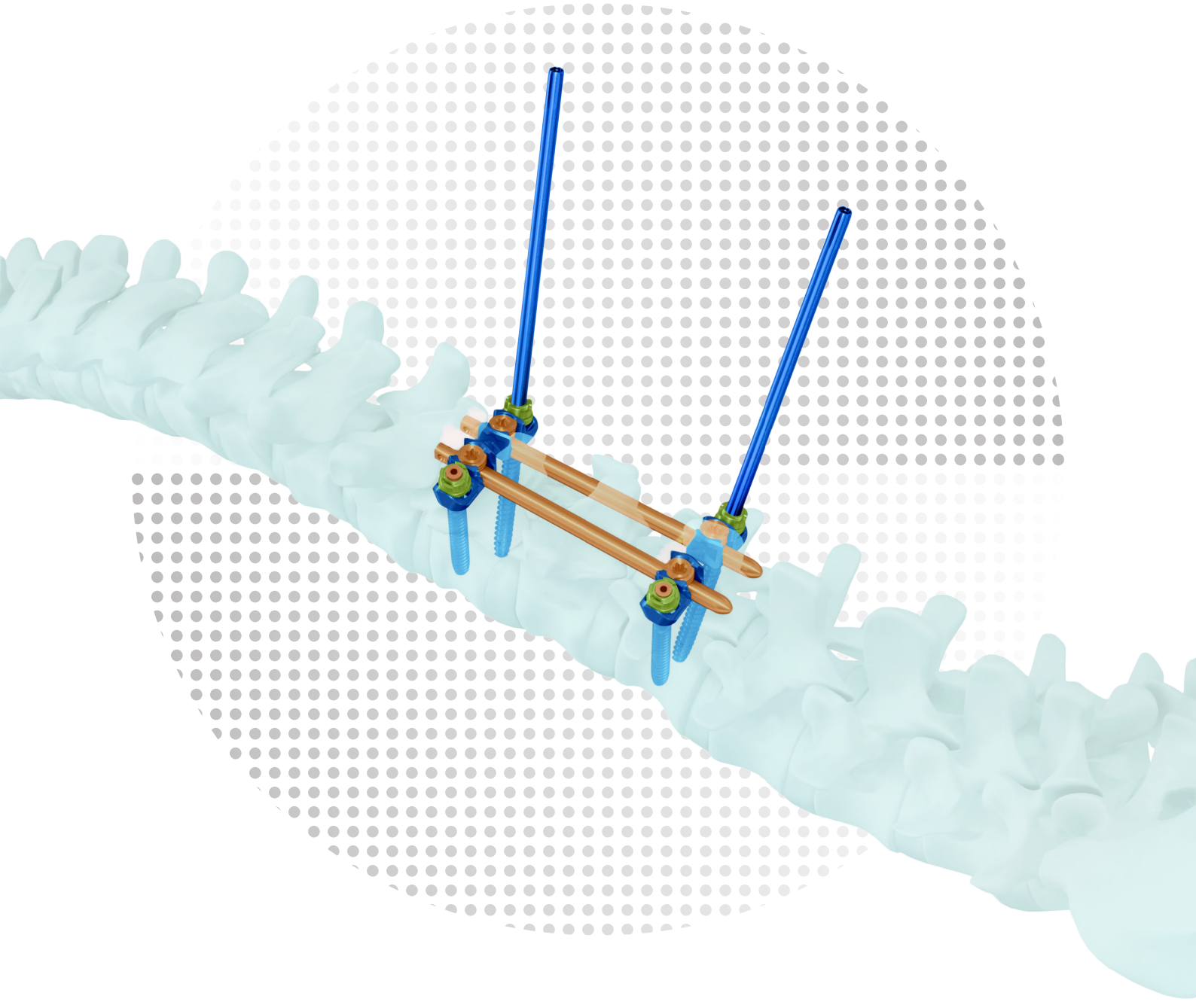
# USS® Fracture MIS System

## Surgical Technique

Fracture Fixation for Spine



DePuy Synthes

THE ORTHOPAEDICS COMPANY OF Johnson&Johnson

 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 guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-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

# Table of Contents



Image Intensifier Control

▲ Warnings/Precautions

For Product Catalogue contact your local DePuy Synthes representative.

# Introduction

## USS Fracture MIS. The minimally invasive Schanz Screw system for complete spinal fracture reduction

**❶ Schanz screws**

- Designed to facilitate correction of the sagittal alignment
- Dual core / double thread lead design

**❷ Fracture Clamps**

- Top loading fracture clamp

**❸ Perforated Schanz Screws**

- Six radial openings for cement distribution
- Augmentation can be performed after final screw positioning

**❹ Percutaneous implantation**

**❺ Adjustable rod holder**

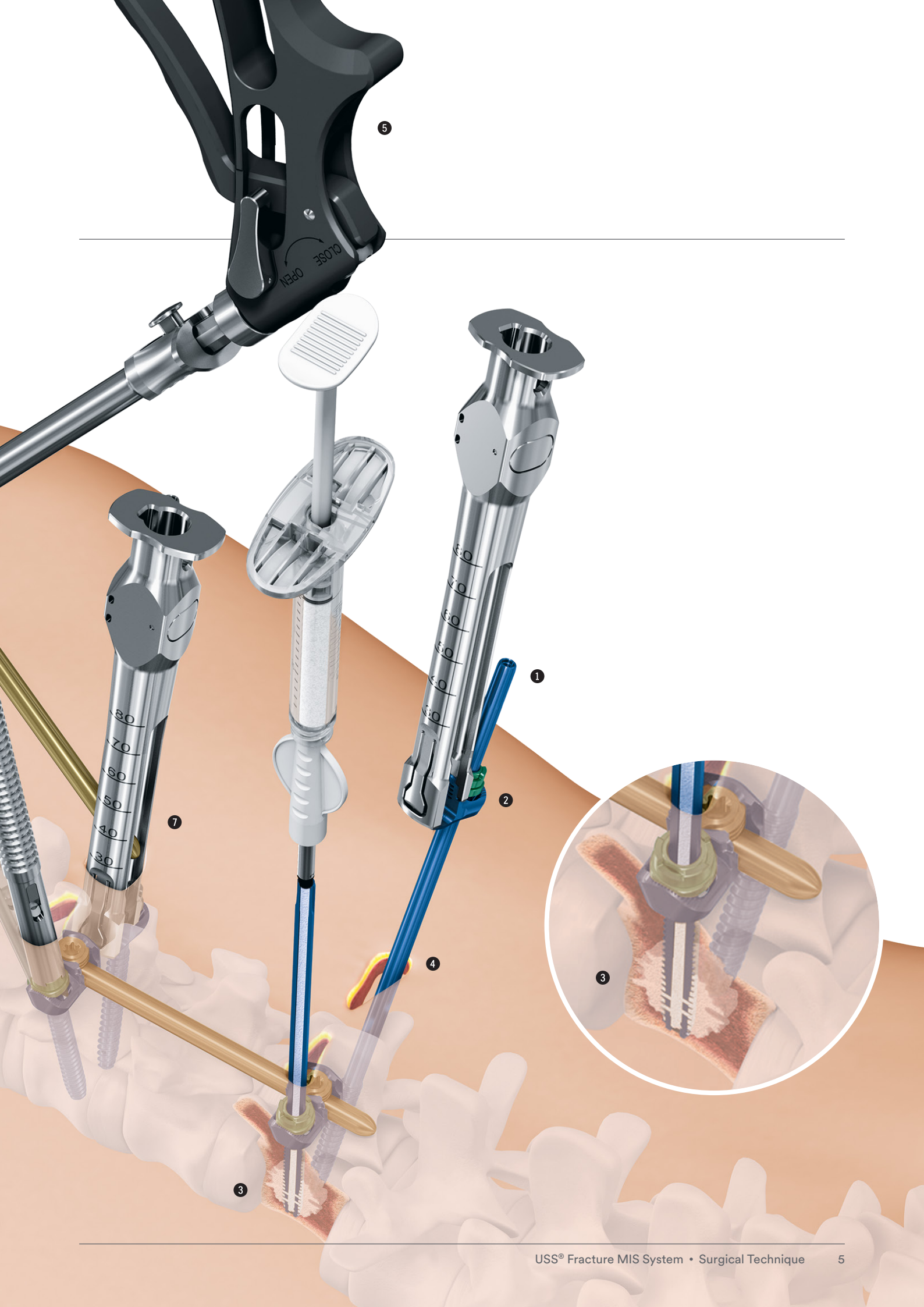
- Allows for adjustable rod angulation during insertion

**❻ Percutaneous distraction and compression**

- Parallel distraction performed above the skin
- Compression/distraction is designed to be independent of any sagittal correction performed

**❼ Percutaneous removal**

- Implants can be removed percutaneously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# AO Spine Principles

The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability, Alignment, Biology, Function.[1,2]

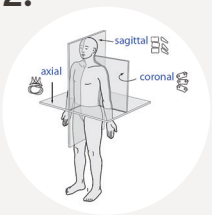
## AO Principles[1,2]

**1.**

**Stability**

Stabilization to achieve a specific therapeutic outcome.

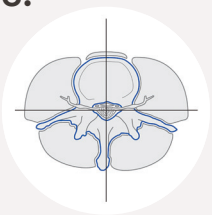
**2.**




**Alignment**

Balancing the spine in three dimensions.

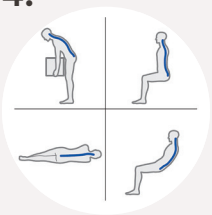
**3.**



**Biology**

Etiology, pathogenesis, neural protection, and tissue healing.

**4.**



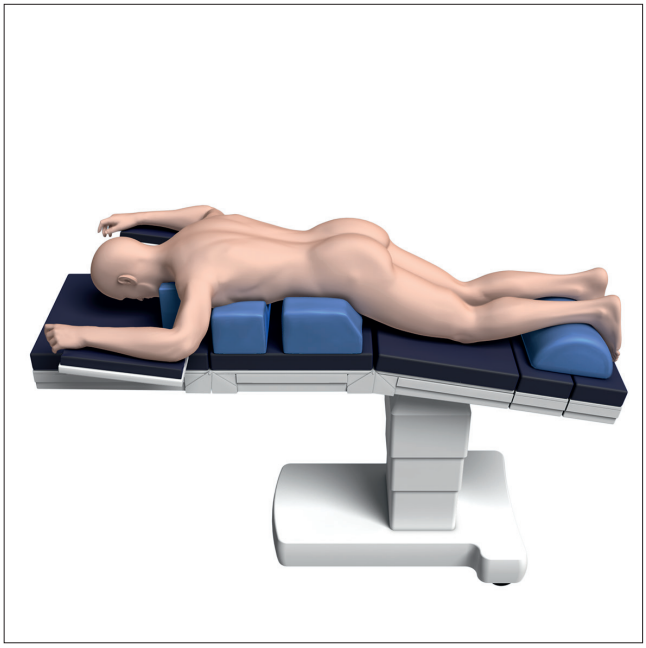
**Function**

Preservations and restoration of function to prevent disability.

# Preparation

## 1. Patient positioning

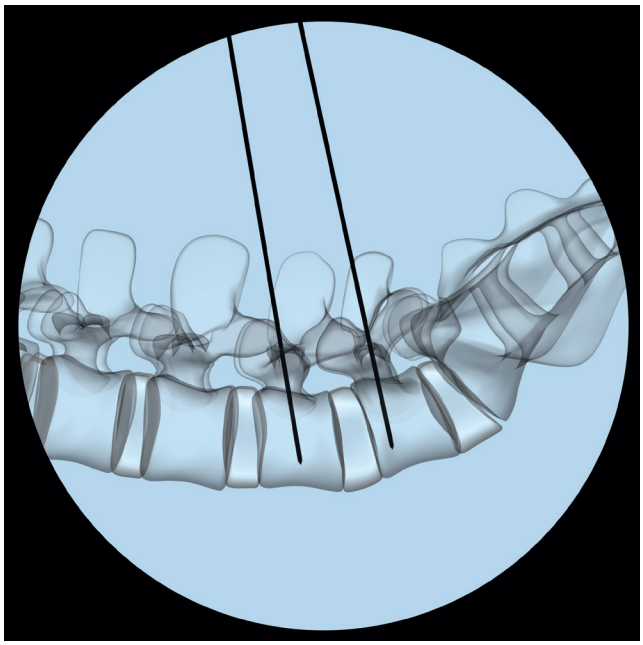
Position the patient on a radiolucent OR table in the prone position. To obtain optimal visualization of the spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for AP, oblique and lateral views. Accurate visualization of the anatomic landmarks and fluoroscopic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



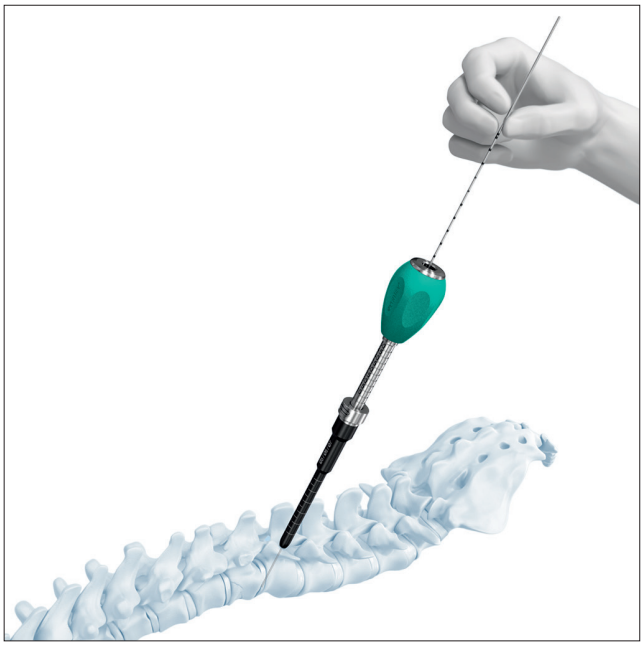
## 2. General recommendations on Kirschner Wire handling

**▲ Warning:**

- Ensure that the Kirschner Wires remain securely in position throughout the entire duration of the procedure.
- Monitor the tip of the Kirschner Wire under fluoroscopy to ensure it does not penetrate the anterior wall of the vertebral body.



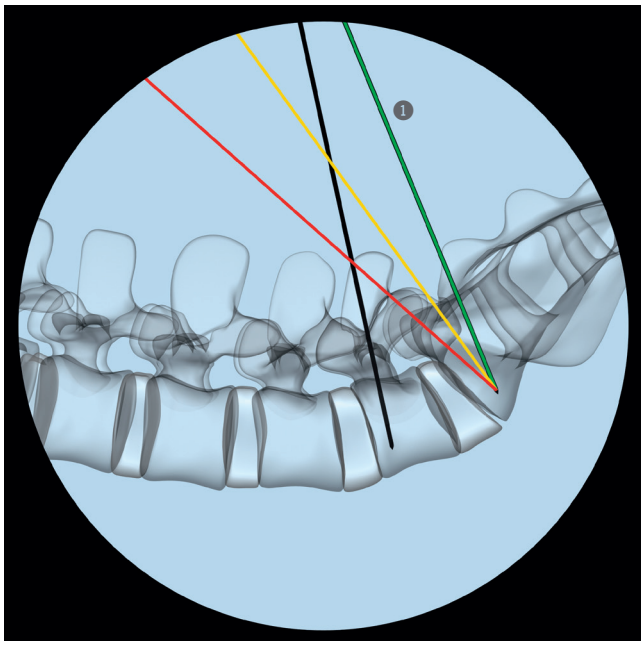
Ensure that the Kirschner Wires do not slip out before the screws are inserted. The Kirschner Wires are long enough to be held in place by hand during pedicle preparation and soft tissue dilation.



## Recommendation for positioning the Kirschner Wire

When inserting the Kirschner Wires at the L5-S1 level, be mindful to position them as parallel as possible to each other along the line of the L5 cranial endplate.

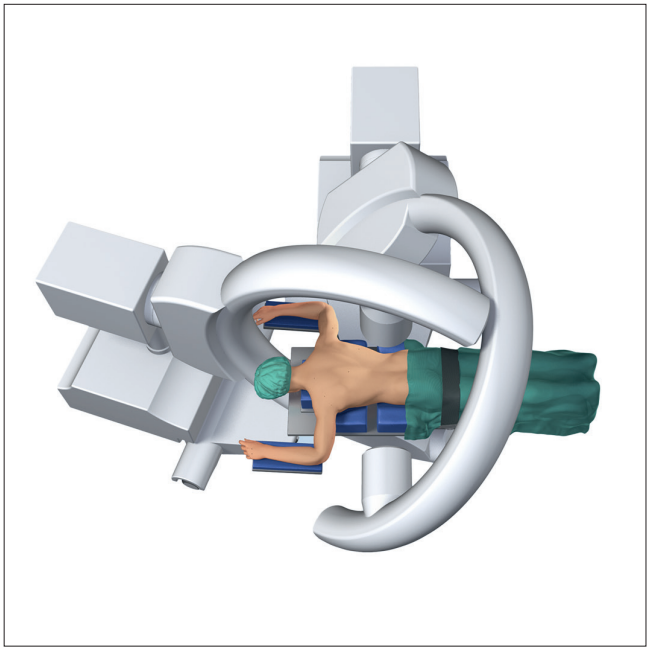
When operating on L5-S1, position the Kirschner Wires according to the green-colored Kirschner Wire (see image ❶).



## 3. Kirschner Wire insertion

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

Bi-planar fluoroscopy with two C-arms might be helpful and should be considered for 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 Ø 1.6 mm without trocar tip, length 480 mm, Stainless Steel |
| 03.606.020 | Trocar Ø 1.6 mm |
| 03.606.021 | Trocar Holder, for No. 03.606.020 |
| 03.620.230 | Pedicle Probe Ø 3.5 mm, cannulated, radiolucent, length 253 mm, for Screws Ø 5.0 to 7.0 mm |

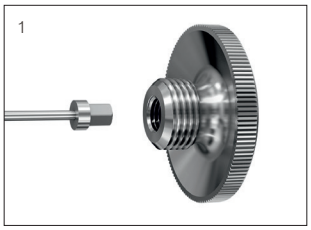
| Optional instruments | |
|---|---|
| 03.616.070 | Handle for Kirschner Wire Ø 1.6 mm |
| 03.627.029 | Instrument Holder, radiolucent |

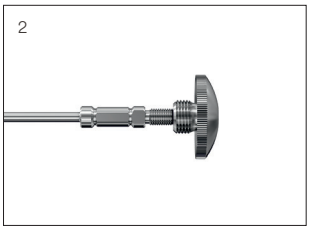
Use radiographic imaging to locate pedicles and the site of skin incision. With a scalpel, create an incision of approximately 25 mm in length and bluntly dissect the subcutaneous tissue down to the pedicle.

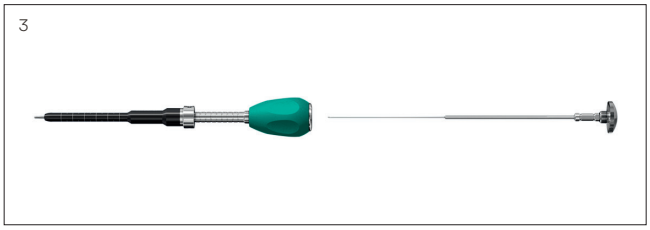
Use the pedicle awl to perforate the cortex and prepare the screw channel.

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.




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).

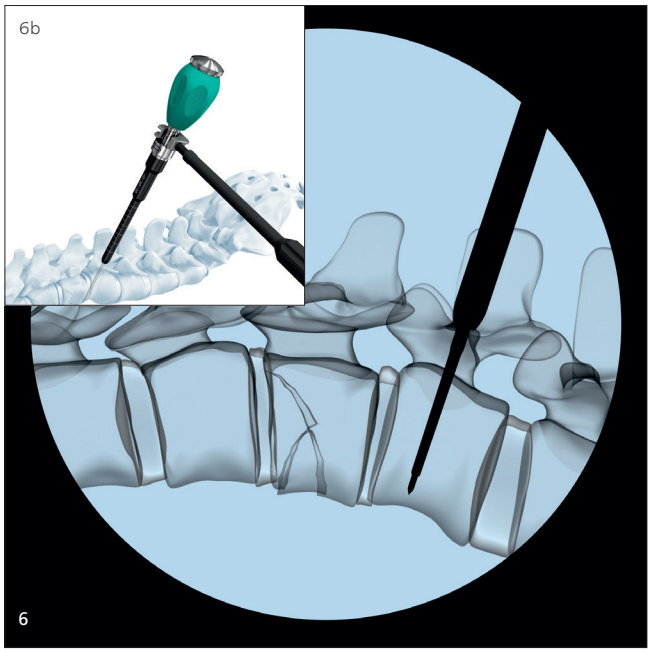
**▲ Warning:**

- **Use radiographic imaging to confirm orientation and depth while inserting the pedicle awl.**

The sleeve prevents the awl from advancing further than the prescribed screw length due to a stop on the pedicle probe. 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.**

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

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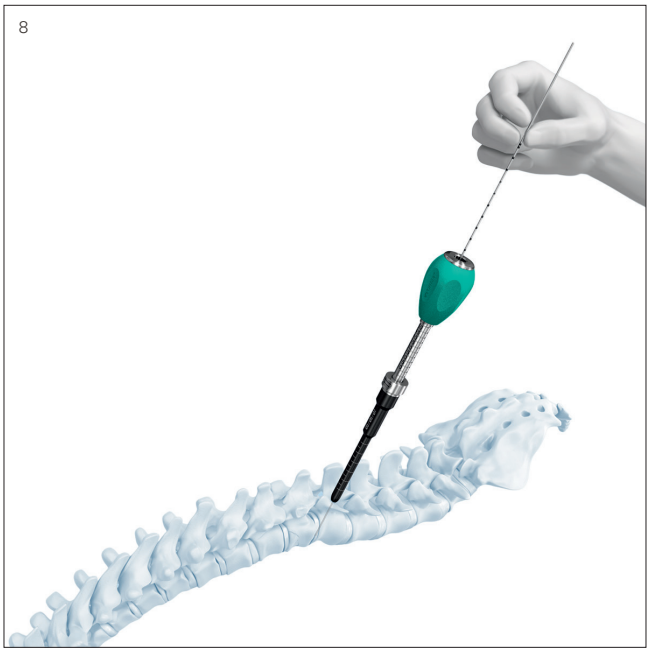

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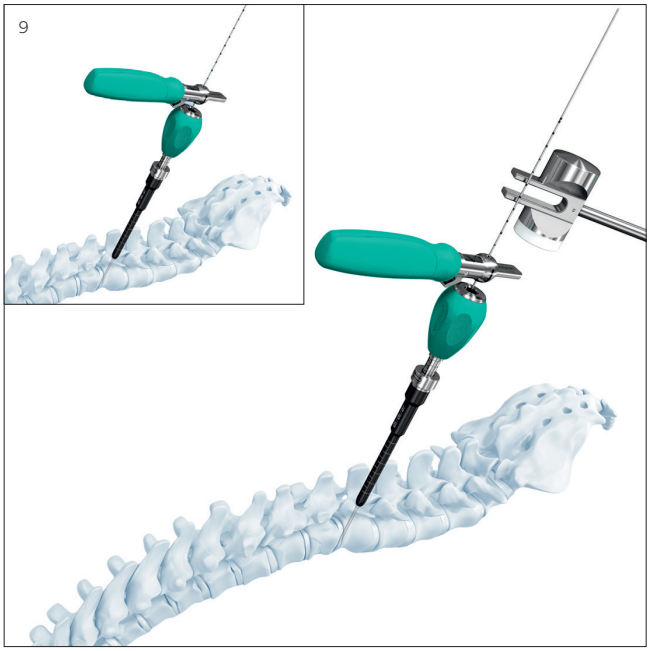


## 1b. Prepare pedicle and insert Kirschner Wire with single-use instruments

| Instrument | |
|---|---|
| 02.606.003 | Kirschner Wire Ø 1.6 mm without trocar tip, length 480 mm, Stainless Steel |

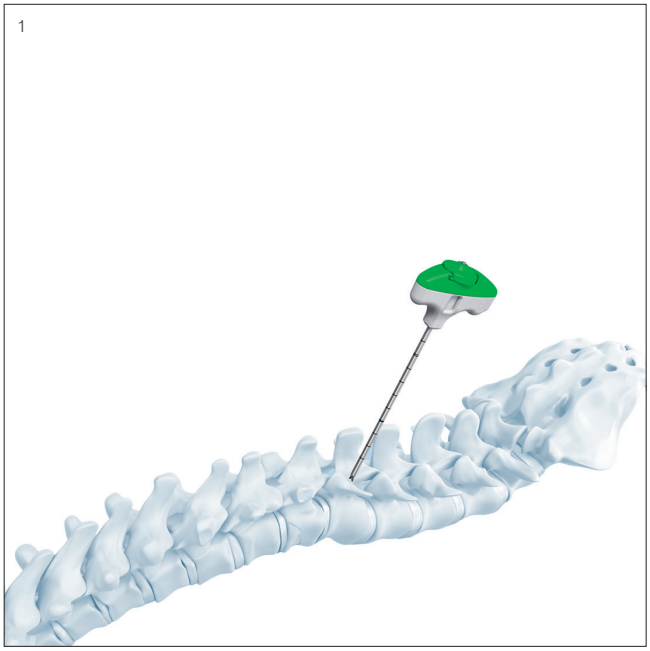
| Optional instruments | |
|---|---|
| 03.616.070 | Handle for Kirschner Wire Ø 1.6 mm |
| 03.627.029 | Instrument Holder, radiolucent |

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.

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

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

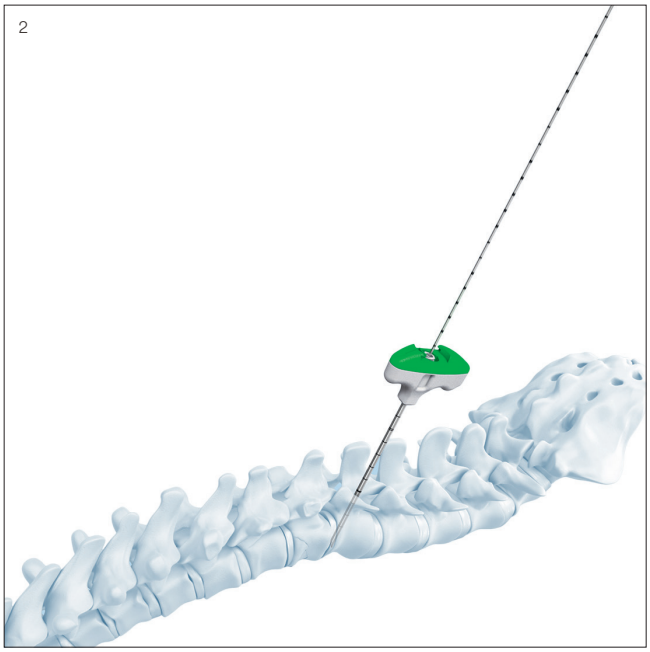

1

Unscrew the trocar from the bone access needle ensuring the needle remains in place.

Insert a Kirschner Wire into the bone access 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.

**▲ Warning:**

- **Use radiographic imaging to confirm orientation and depth while inserting the bone access needle.**



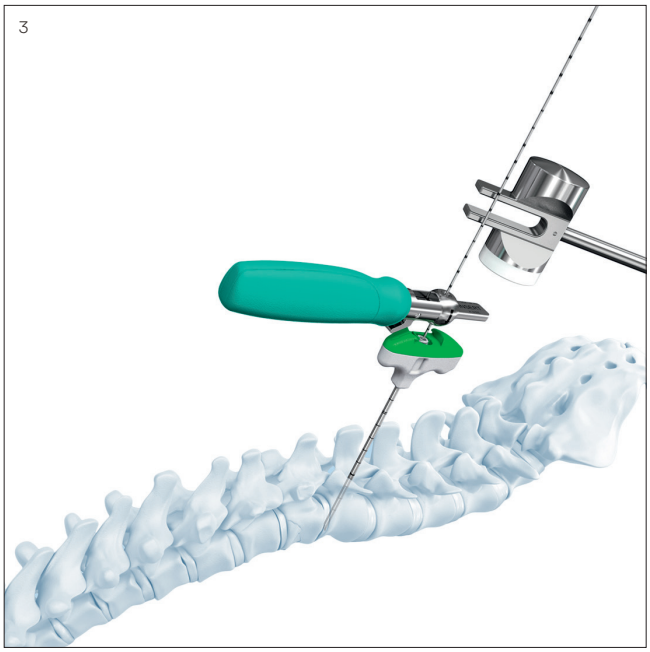

Use the handle for Kirschner Wire to advance the wire (3; see Pedicle preparation, 1a for handling).

**▲ Warning:**

- **While removing the bone access needle, secure the Kirschner Wire at all times.**

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.

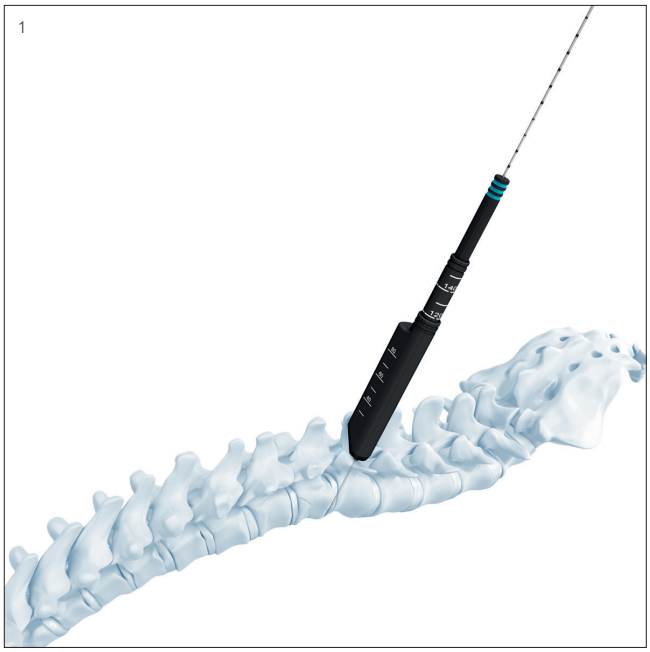


# Screw Insertion

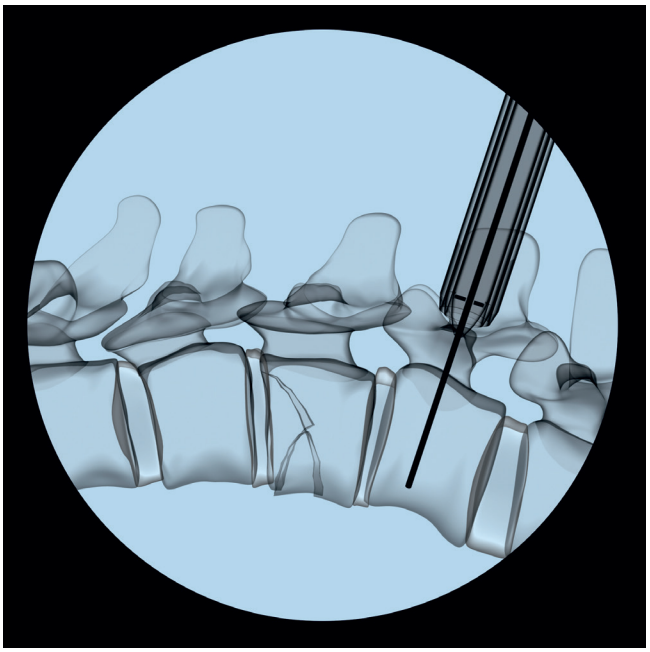
## 1. Dilate incision and determine screw length

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

| Optional instrument | |
|---|---|
| 03.631.521 | Screw Length Indicator |




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).



▲ **Warning:**

- 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 due to the 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.**

- **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.


**▲ Warning:**

- **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 Ø 13 mm, eccentric, for No. 03.628.103 |
| 03.628.103 | Dilator Ø 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 |

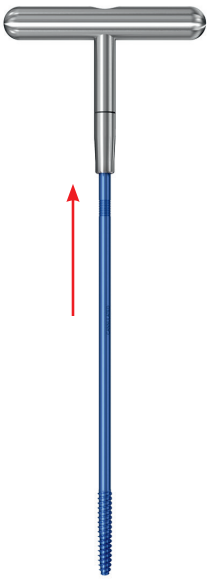
Select the appropriate screw length. Choose screws with the maximum possible diameter and length to achieve desired stability.

**▲ Warnings 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 B 10.0/13.0 mm until the tip of the screw reaches the pedicle entry point (2).

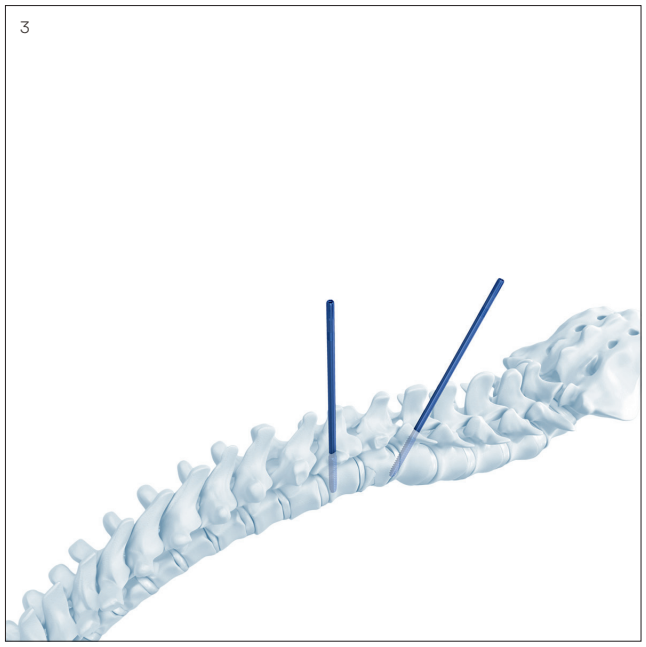
- **Visualize the insertion depth of the Schanz screw by inserting the screw until the etched line on the spline drive screwdriver is flush with the edge of the dilator (2).**

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).

**Precautions on the optional use of perforated Schanz screws:**

**▲ Precautions:**

- If perforated Schanz screws are used, assess the cortical shell for perforations.
- The perforated Schanz screw must enter in approximately 80% of the vertebral body (4).

**▲ Warning:**

- 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.
- 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.

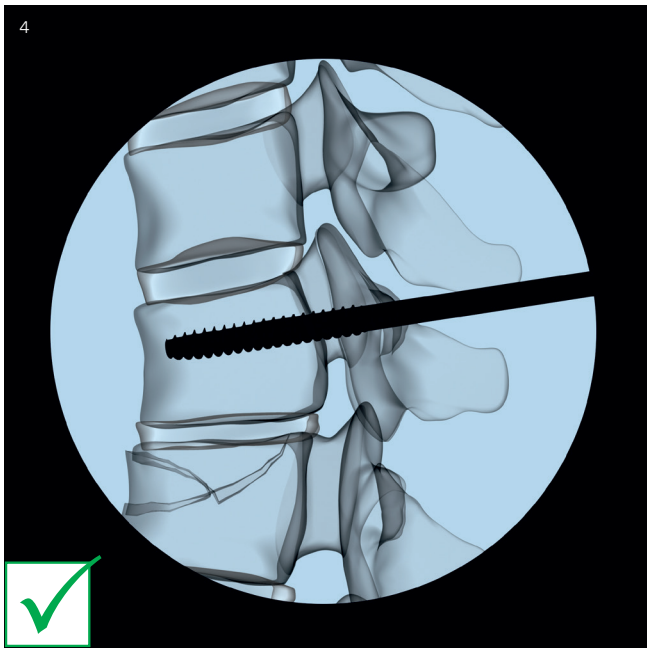
**▲ Precaution**

- 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.

**▲ 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.
- If tapping is optionally done before screw insertion, use the corresponding protection sleeve to protect soft tissue.

4



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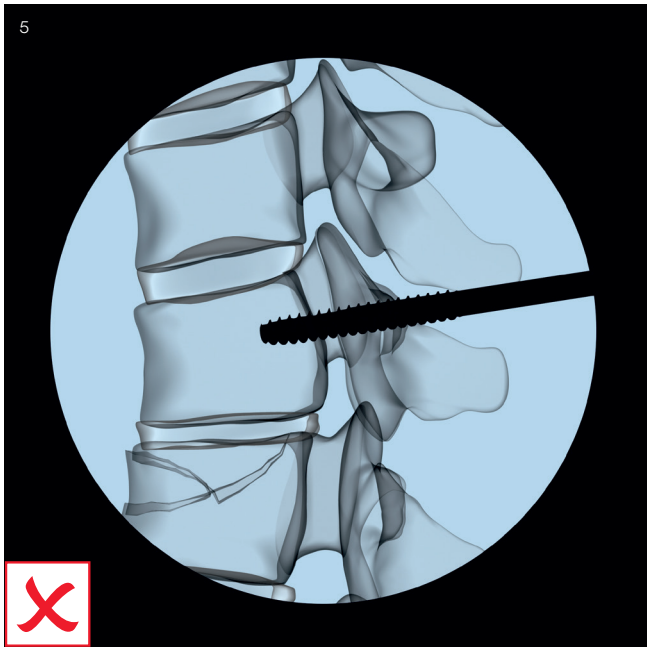


### Optional technique

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.

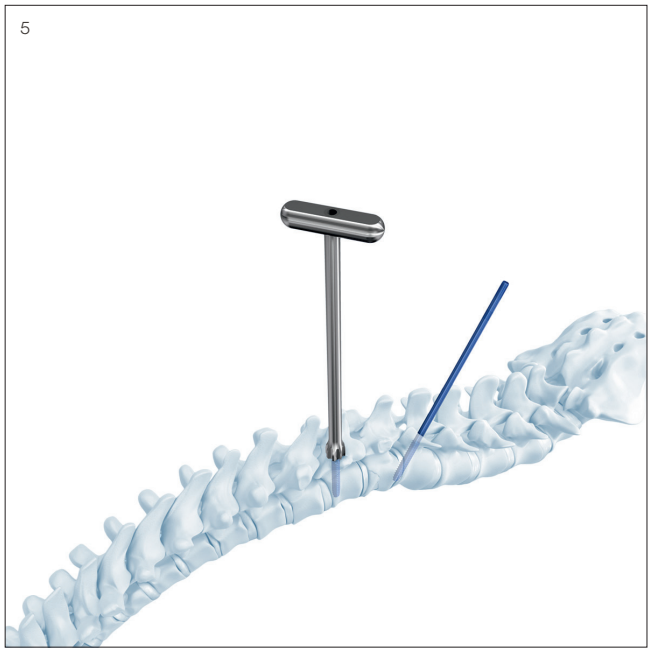
**▲ Precaution:**

- Do not use the reamer through the dilator.

**▲ Precaution:**

- When reaming the most superior and inferior levels take 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 |

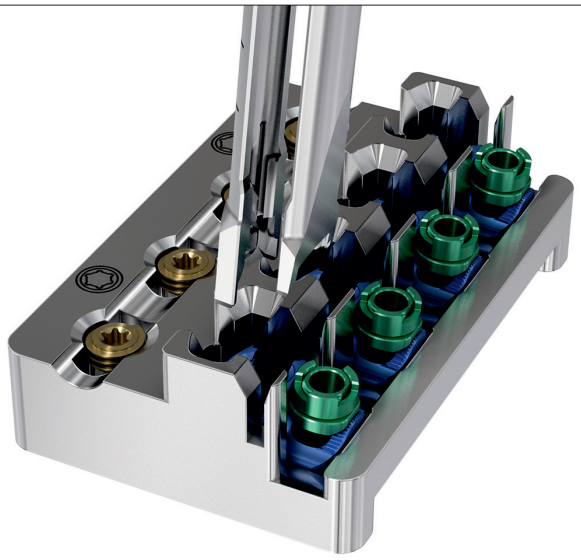
Properly position the MIS fracture clamp into the loading station (1). Ensure that the MIS fracture clamp can angulate freely by untightening the nut of the MIS fracture clamp with the socket wrench shaft by two revolutions.

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.

1



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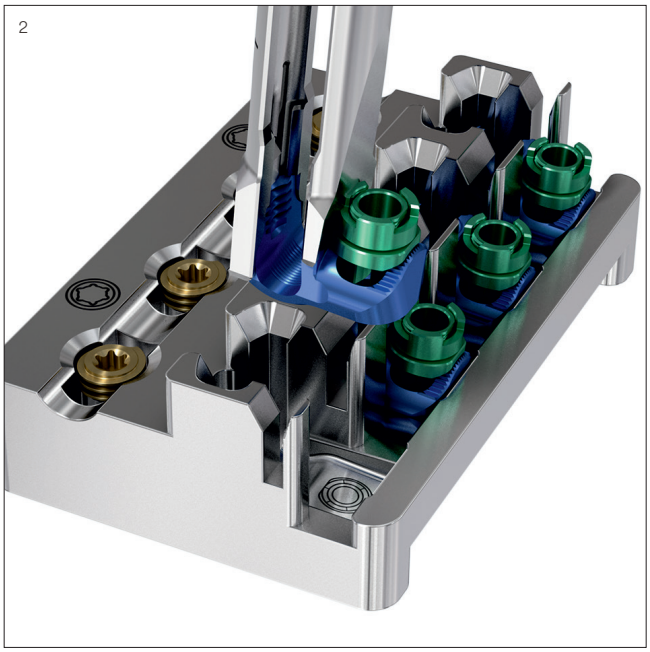
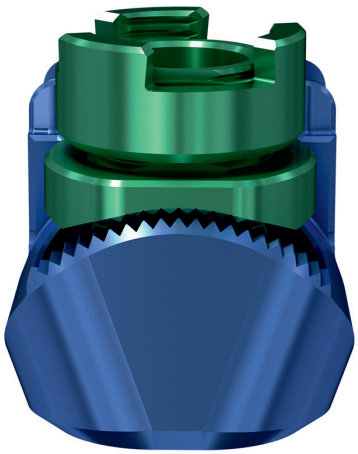


- If the MIS fracture clamp does not snap into the clamp holder, gently pinch the blades of the clamp holder while pressing on the implant until it snaps.
- In case of MIS fracture clamp disassembling, ensure the correct reassembling of the implant, with the orientation of the washer and of the nut according 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

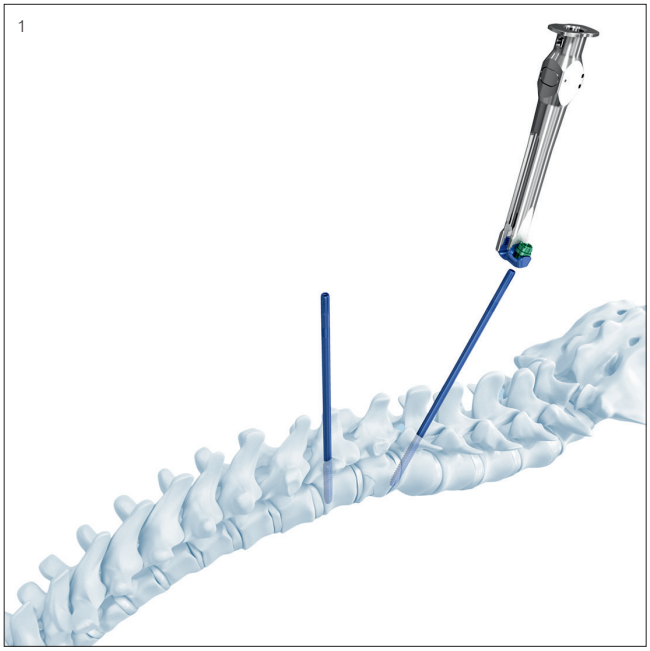
Insert the assembly (MIS fracture clamp attached to the clamp holder) over Schanz screw and through the skin incision.

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

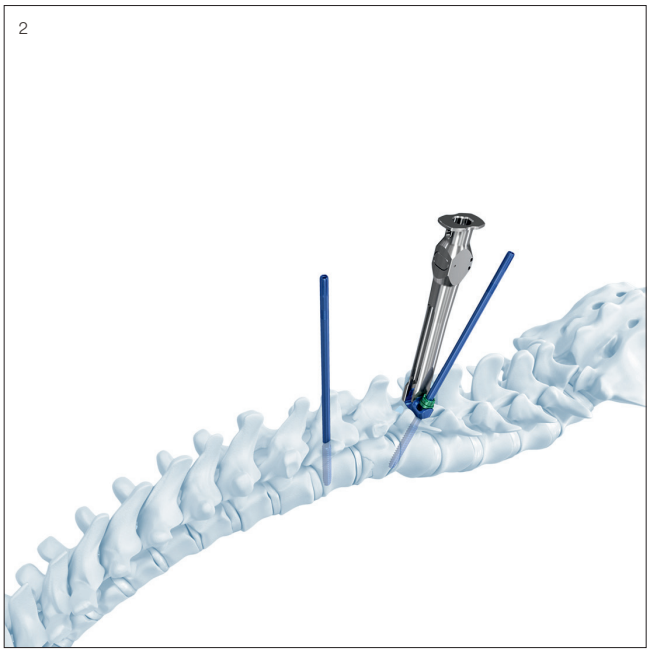
Repeat this step for all Schanz screws.

- **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



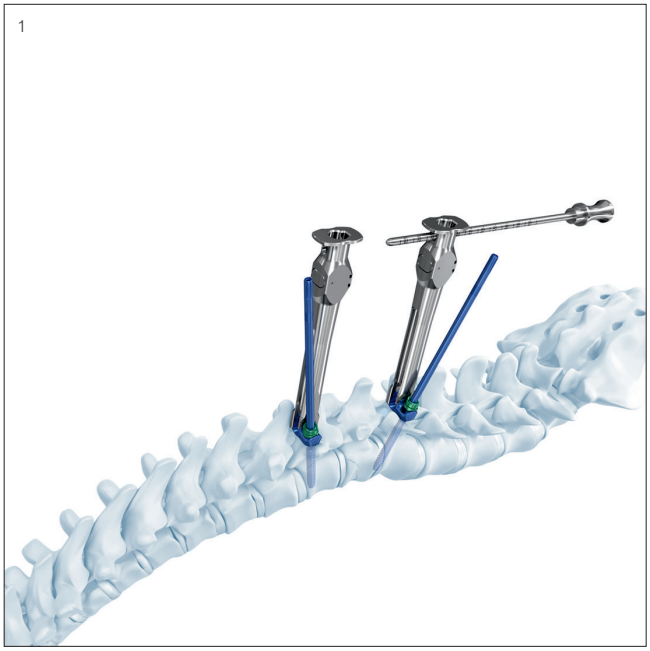
# Rod Insertion

## 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).

1



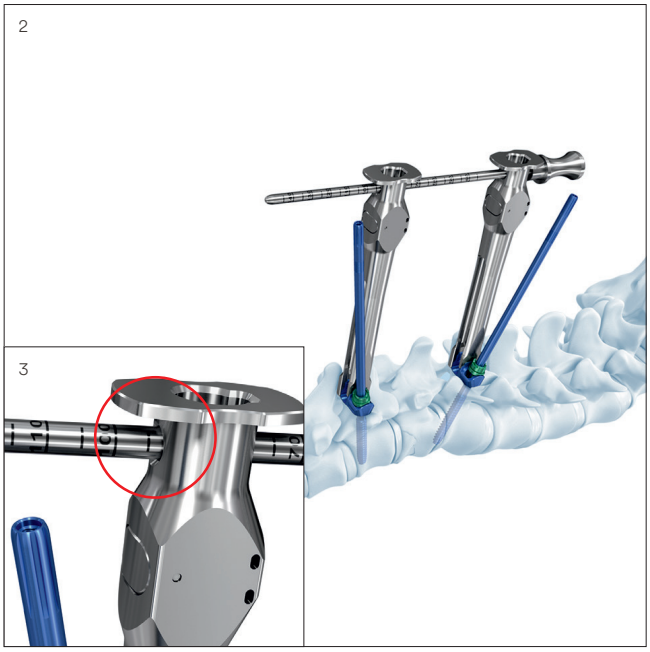
Read the corresponding rod length on the scale (3).

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

- 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

3



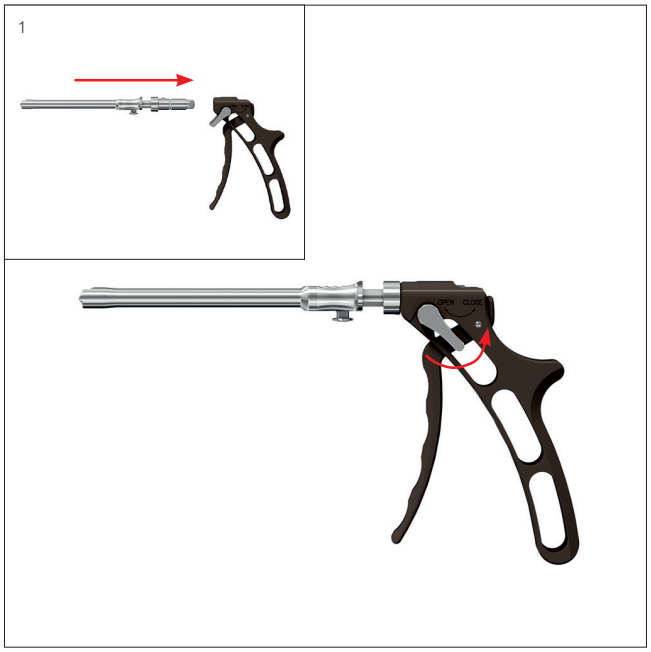
## 2. Prepare the implant holder

| 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).

- **Do not squeeze the trigger of the handle while mounting the handle.**

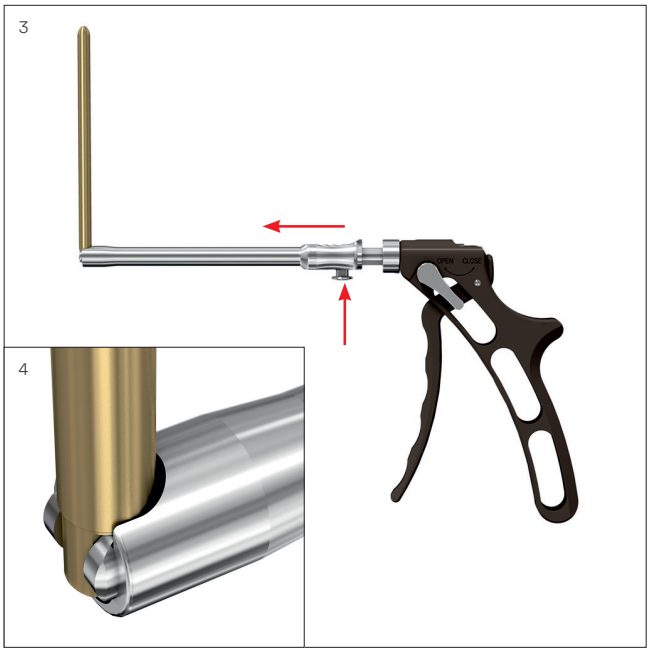
Ensure to pull back the locking sleeve and that the distal end of the rod holder shaft is visible.




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

- **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

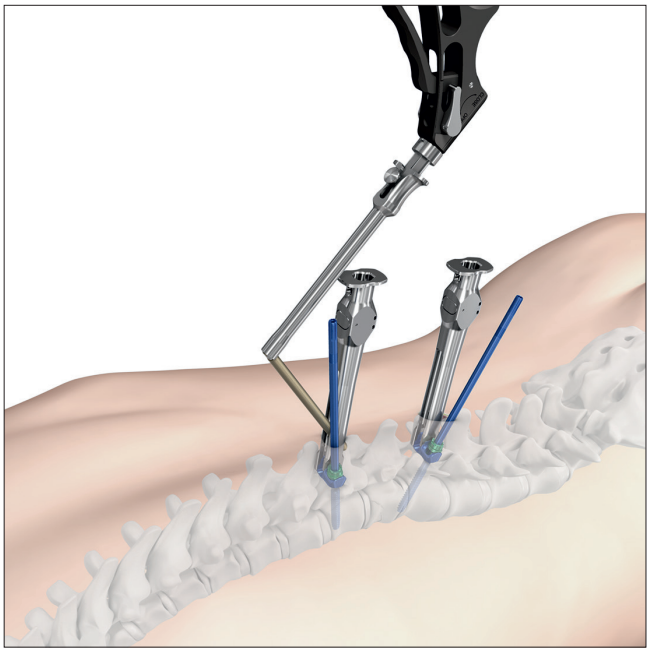
| Instruments | |
|---|---|
| 03.631.537 | Handle for Rod Holder |
| 03.631.538 | Rod Holder, straight |

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.

- **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).

Use the rod indicator to verify the presence of the rod in the implant.

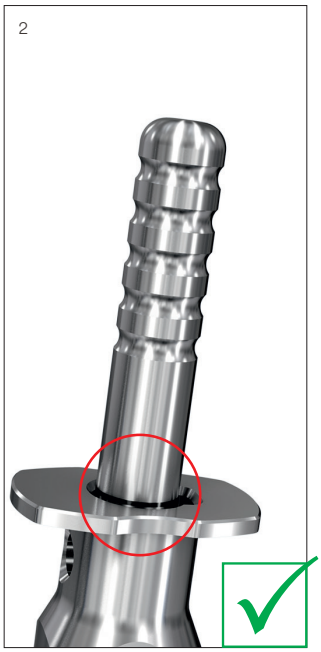
The visible black marking indicates the presence of the rod in the clamp holder or MIS fracture clamp (2). If the black marking disappears into the clamp holder, no rod is in place (3).

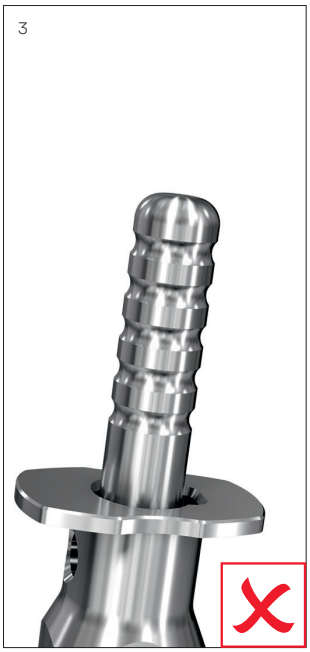
Alternatively, verify rod placement through the adjacent clamp holder by attempting to rotate the clamp holders or under visual control.

Check final rod placement with lateral radiographic imaging.

**▲ Warning:**

- **Ensure 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<br>Screws, with Loading Station, with Lid,<br>without Contents<br>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).

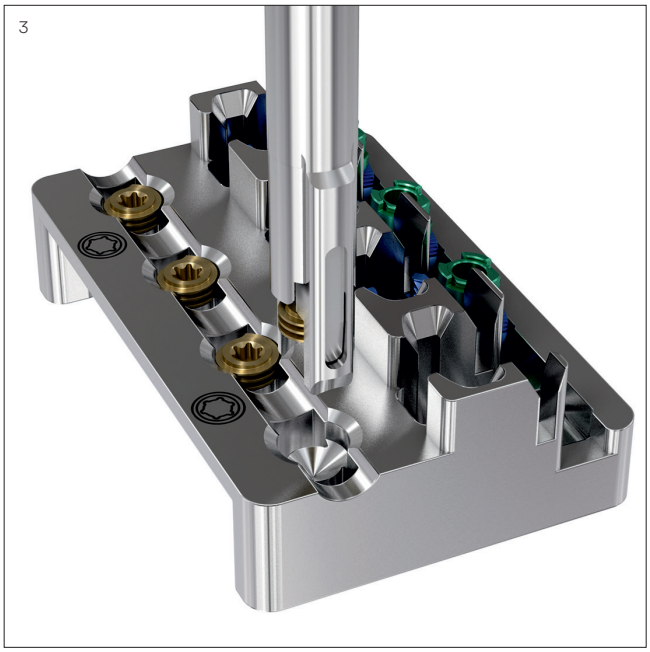
- **Ensure the correct positioning of the MIS locking cap according to the etchings on the loading unit.**

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

1

2

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



## 2. Insert locking cap

| Instruments | |
|---|---|
| 03.628.108 | Guide for Locking Cap |
| 03.628.109 | Persuader |

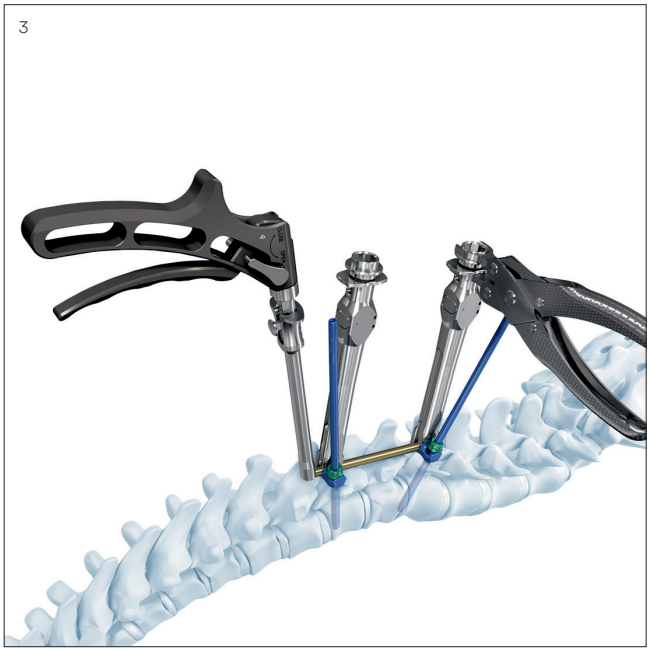
Insert the guide for locking cap into the clamp holder (1). Push down the guide for locking cap to press down the rod in the designated notch of the MIS fracture clamp. The last 20 mm of the insertion are supported by a ratchet mechanism and avoid the sliding back of the guide for locking cap.

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).

- **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.

Check final rod placement with lateral radiographic imaging.

**▲ Warning:**

- **Ensure the coupling and the tip of the rod protrude outside the MIS fracture clamps.**

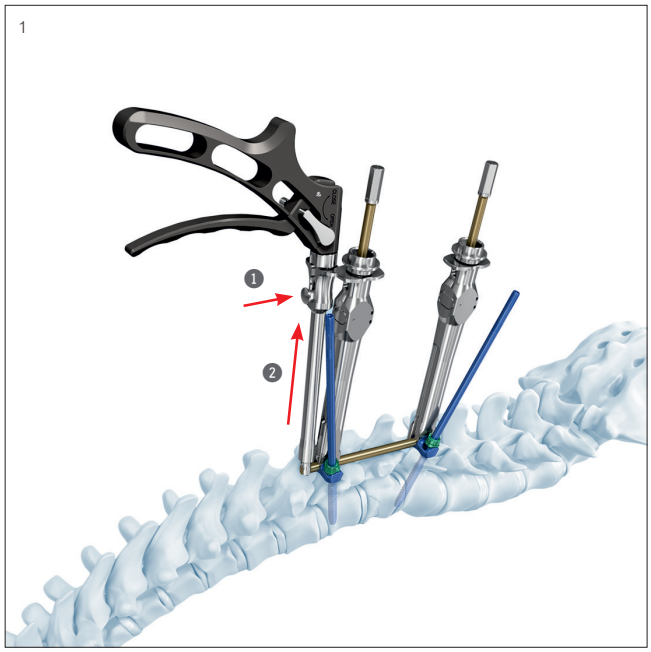
**Removal of rod holder**

- 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.

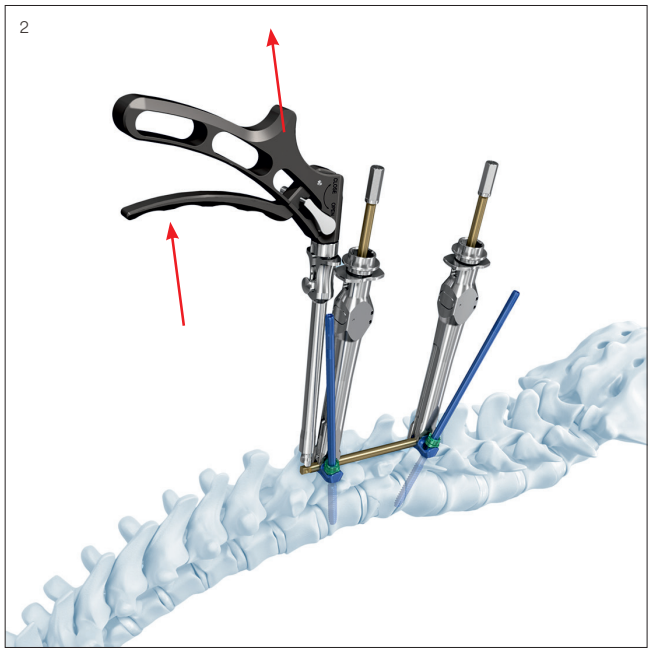
To remove the rod holder (1), press the push button ❶ and slide up the locking sleeve ❷. For the removal of the rod holder, squeeze the handle and simultaneously pull up the rod holder (2).

- 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 03.628.128 |

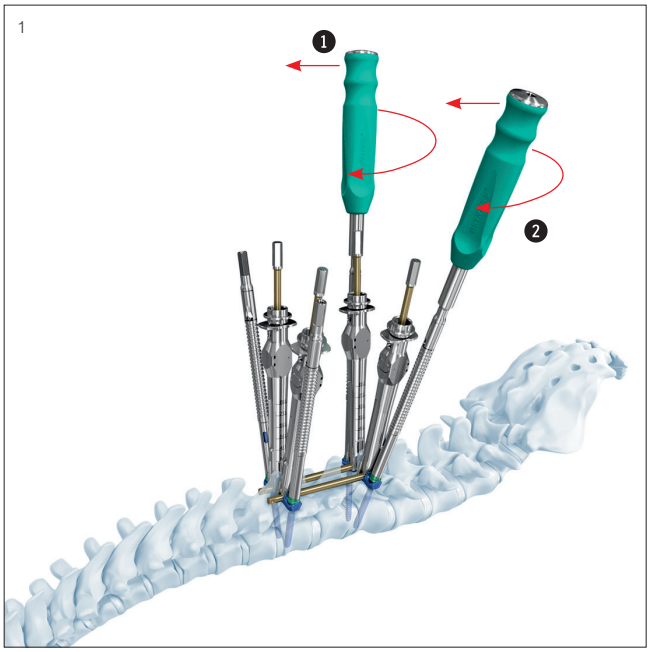
Ensure that all the MIS fracture clamps are positioned as deep as possible (see “Fracture Clamp Insertion”, Step 2 on page 24).

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.

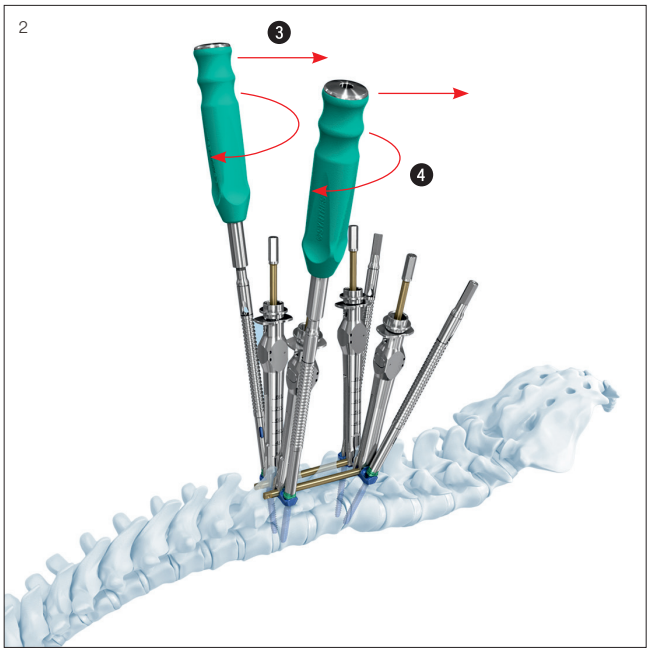
Secure the MIS fracture clamps / Schanz screws in the desired position by mounting the handle with hexagonal coupling on the socket wrench shaft to tighten the nut ❷.

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



- 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.



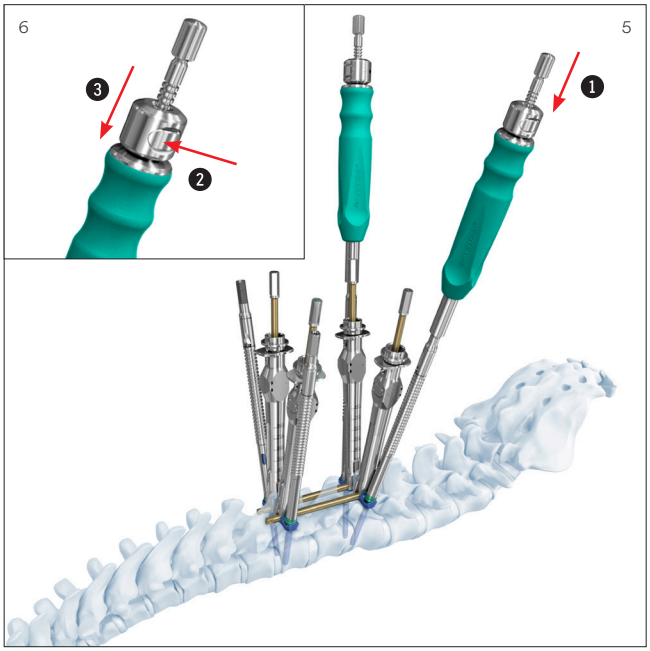
### Optional technique

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.



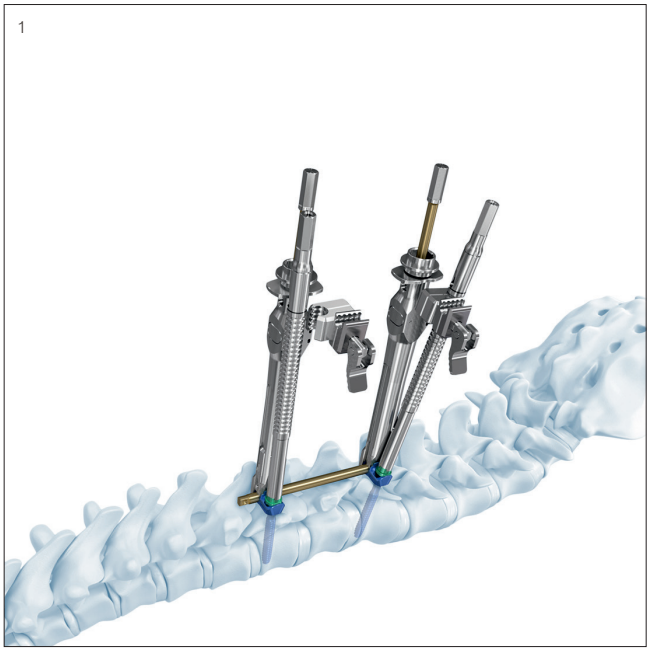
## 2. Distraction (optional)

| 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 |

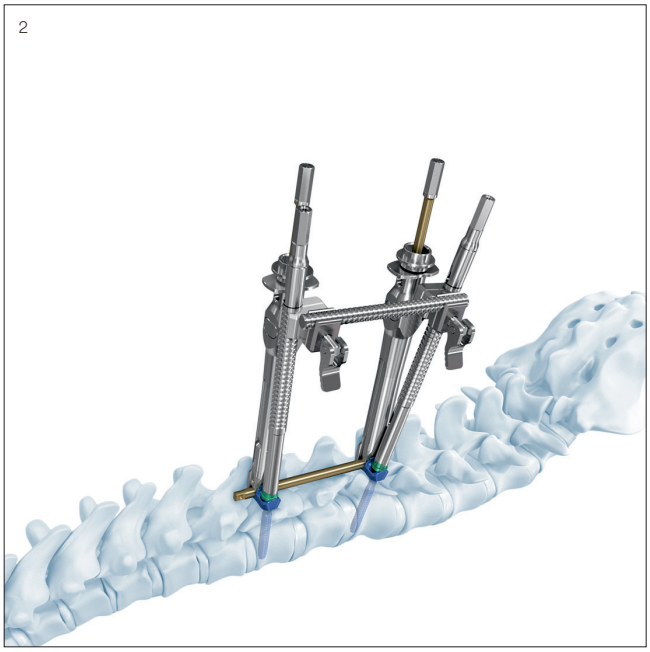
Ensure that all the nuts of the MIS fracture clamps are provisionally tightened and positioned as deep as possible (see “Fracture Clamp Insertion”, Step 2 on page 24)

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

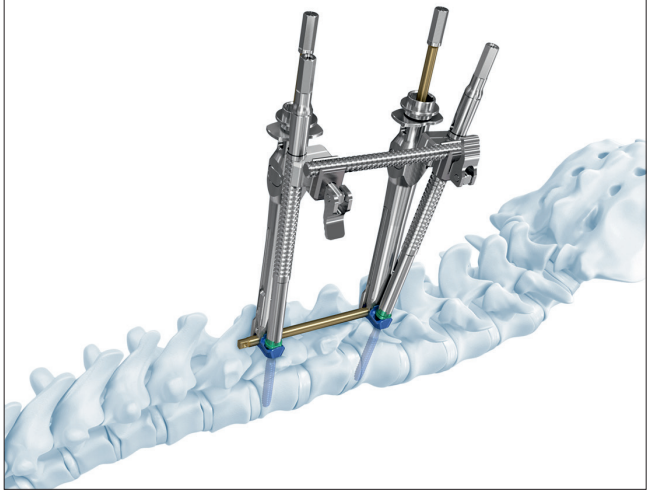


2

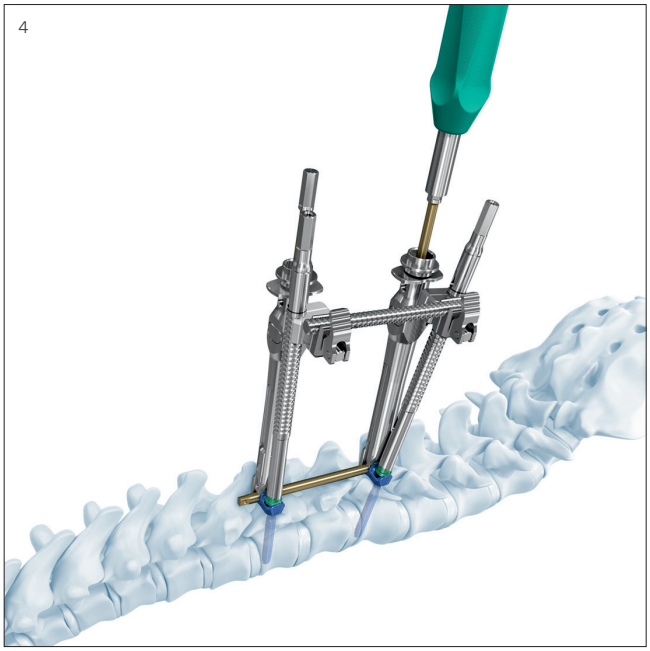


Place the handle with hexagonal coupling on the screwdriver and loosen the locking cap of the MIS fracture clamp on the side of the rod with bullet nose (4).

3



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).

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

- **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.

- **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.

**▲ Warning:**

- **Ensure the coupling and the tip of the rod protrude outside the MIS fracture clamps**

5

# 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).

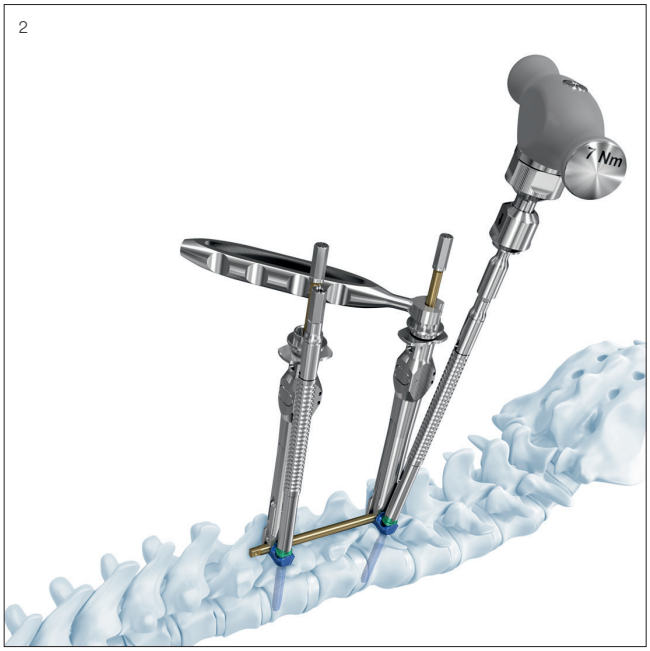
Place the torque-limiting ratchet handle with the adapter for hexagonal coupling on the adjacent socket wrench shaft (tightening of the same fracture clamp), and final tighten the nut of the MIS fracture clamp to the audible click (2).

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

- **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 |

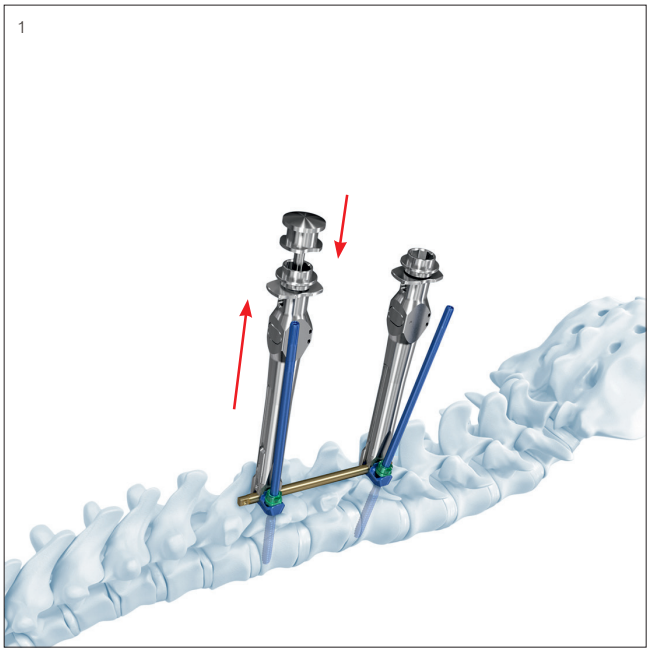
| Optional instrument | |
|---|---|
| 03.628.109 | Persuader |

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



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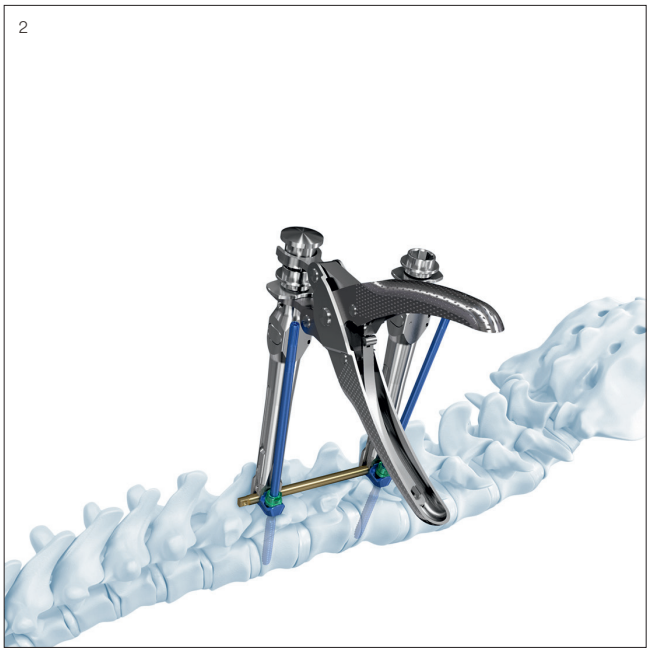


# Trim Schanz Screws

**Trim Schanz screws using the bolt cutter**

| Instruments | |
|---|---|
| 391.771 | Bolt Cutting Head Ø 5.0 mm, long, cutting height 2 mm, for Nos. 391.780 and 391.790 |
| 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).

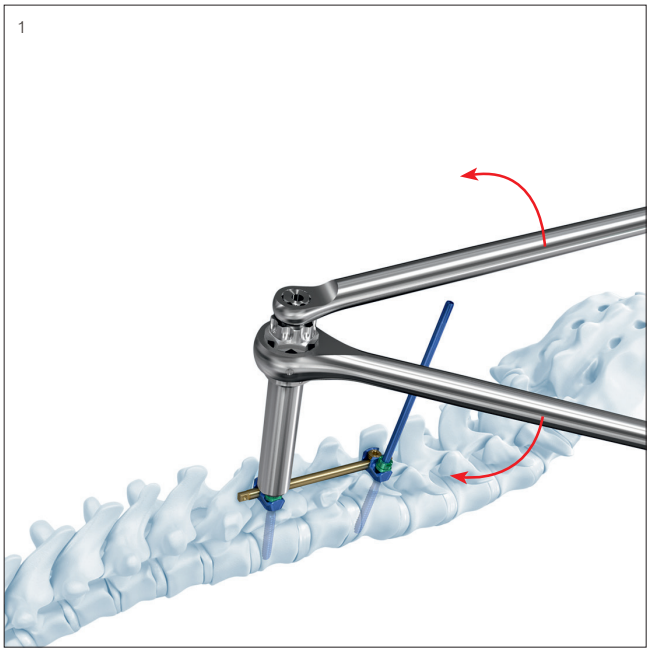
- **With the assembled bolt cutter in the neutral position, it is possible to see through the 5 mm hole.**
- **Ensure that the nut of the bolt cutting head is firmly tightened.**

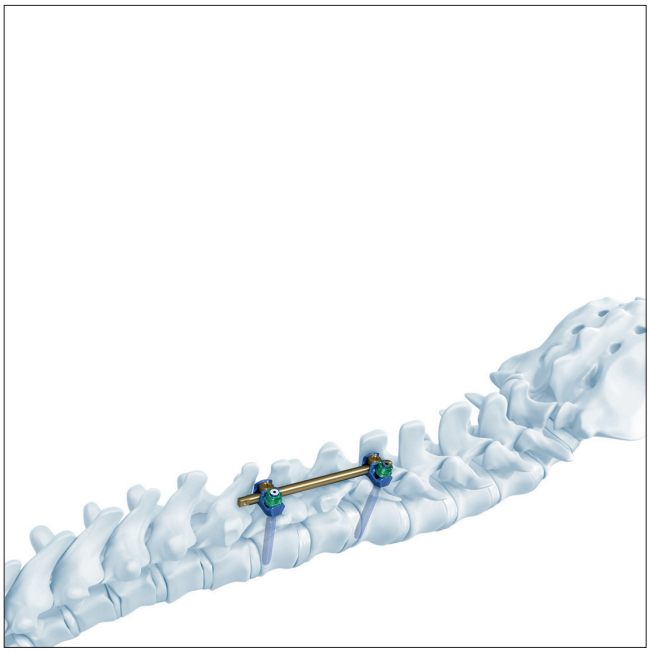
Pull the handles apart until the Schanz screw audibly breaks and is cut.

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.

- **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





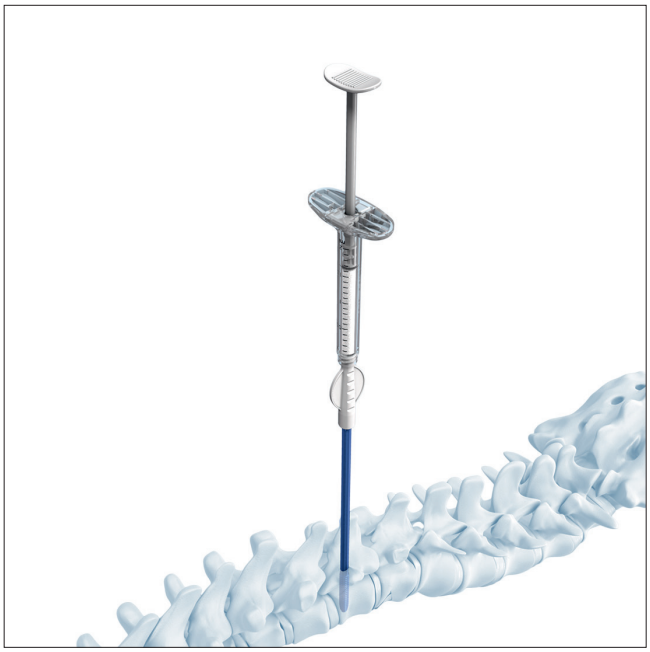
# Optional Techniques
# Augmentation of Perforated Schanz Screws

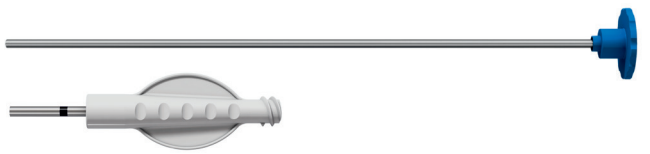
## 1. Preparation

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

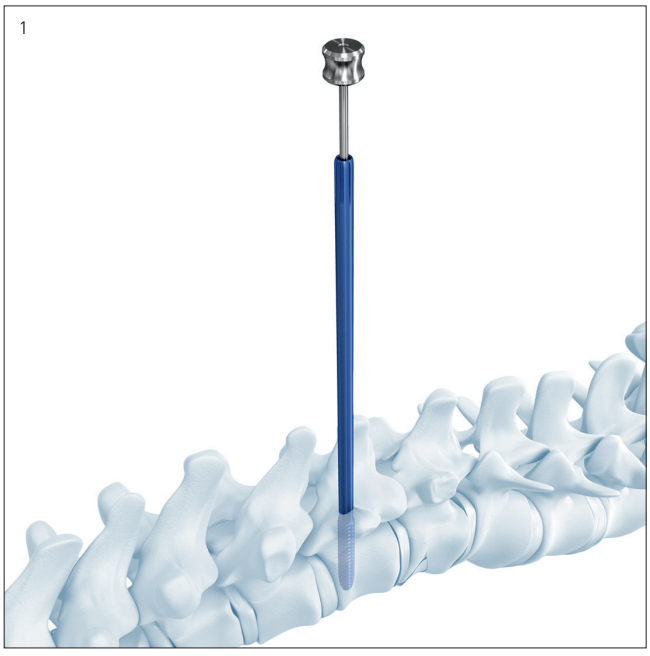
| Instruments | |
|---|---|
| 03.702.627S | Augmentation Kit for perforated Schanz Screws, with Luer-Lock, sterile |
| 07.702.016S | VERTECEM™ V+ Cement Kit, sterile |
| 03.702.215S | VERTECEM™ V+ Syringe Kit |
| 02.648.001S | Cleaning Stylet for perforated Pedicle Screws, sterile |

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





Augmentation Kit for perforated Schanz Screws, with Luer-Lock



## 2. Cement handling

### 2a. Prepare cement

| Implant | |
|---|---|
| 07.702.016S | VERTECEM V+ Cement Kit, sterile |

| Instrument | |
|---|---|
| 03.702.215S | VERTECEM V+ Syringe Kit |

For handling VERTECEM V+ Cement, please refer to the VERTECEM V+ Surgical Technique.

## 2b. Injection preparation

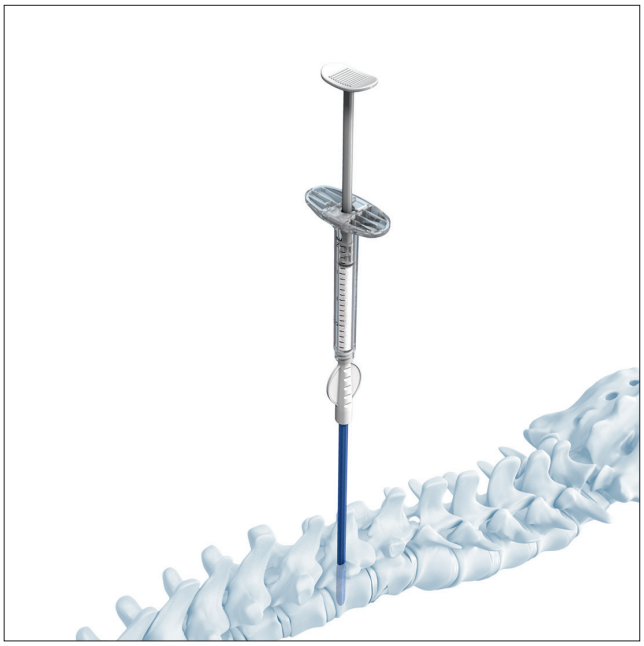
**Instrument**

| | |
|---|---|
| 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.

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



## 2c. Injection procedure

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

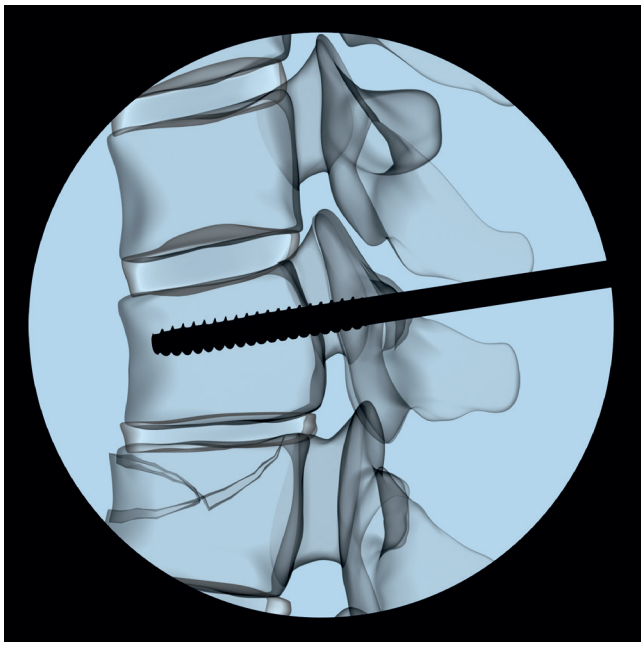
Additional image intensifier control in the AP projection is recommended.

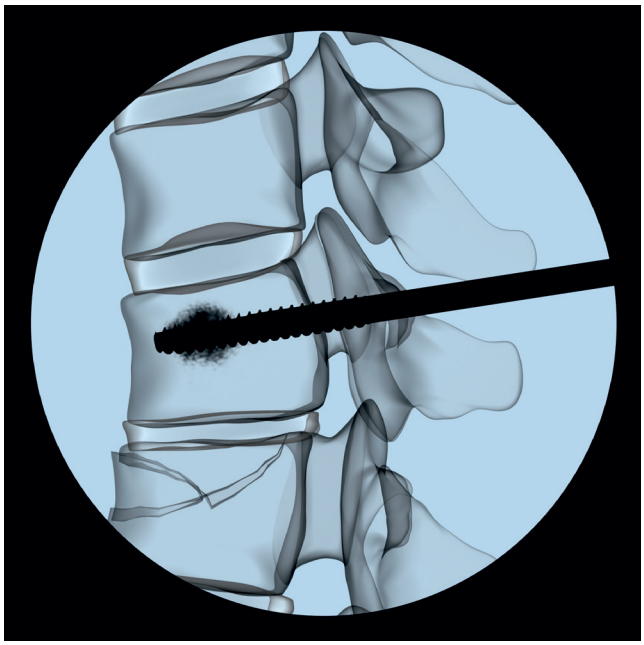
1. Make sure that the syringes with the adapters are firmly connected with the Schanz screws to be augmented prior to cement application. Make sure that the adapter is fully introduced into screw recess.
2. Inject as much cement as required until it slowly starts to extrude from the perforations of the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

**▲ Warning:**

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

The first 1.5cc of cement injected will only fill the adapter and the cannulation of the Schanz screw. Only if more cement is injected will cement start to fill the vertebra.



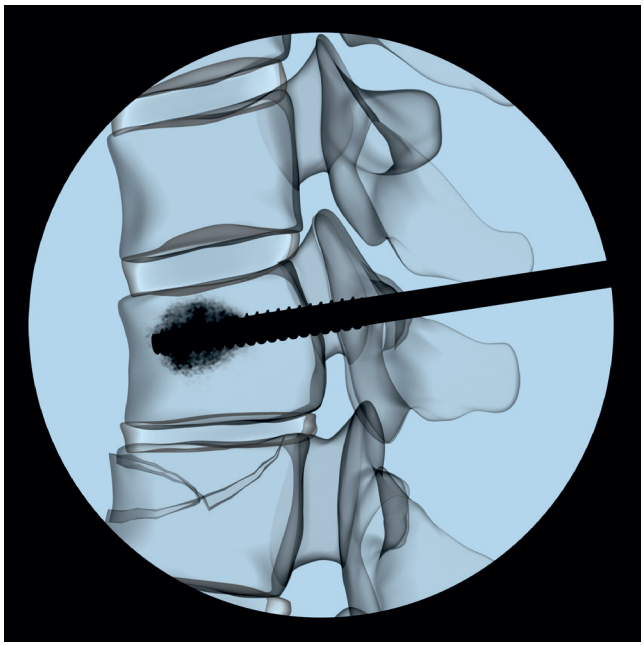


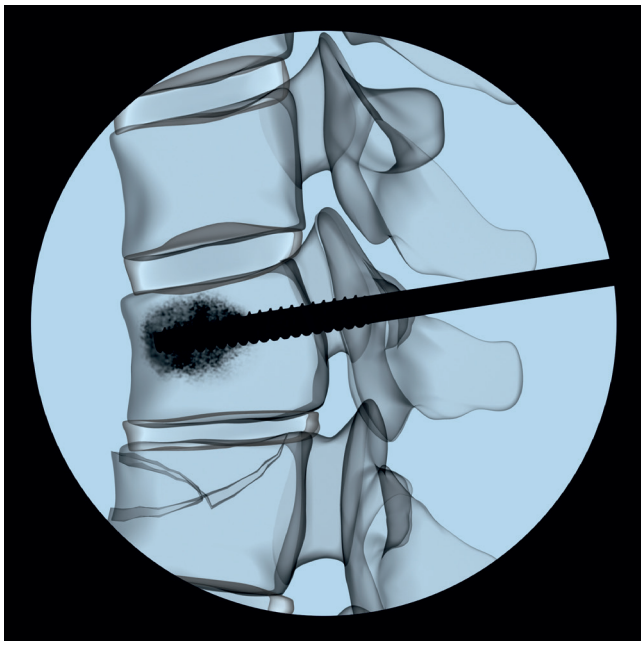
3. Continue to add cement to each screw using continuous image intensifier control. A growing cloud pattern should form. If a spider web-like pattern forms, wait approximately 30 to 45 seconds or proceed with another screw and return to the present screw later.

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.

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.





**▲ Warnings:**

- **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).**

**▲ Warnings:**

- 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.
- 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.

**▲ Warning:**

- Correction maneuvers might lead to loosening of the augmented screws resulting in construct failure.
- Prior to performing correction maneuvers, ensure that the cement is fully hardened.

# Warnings

**Cement Leakage**

Handling knowledge of VERTECEM V+ is required prior to the augmentation of any screws, with particular emphasis being paid to “fill patterns” and “cement flow” within the vertebral body.

Ensure you are familiar with the IFU, including the side effects, precautions and warnings associated with VERTECEM V+.

Avoid uncontrolled or excessive bone cement injection, as this may cause cement leakage with severe consequences such as tissue damage, paraplegia or fatal cardiac failure.

A major risk from performing screw augmentation is cement leakage.  Therefore all steps of the surgical technique should be followed to minimize complications.

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 pedicle screw placement
- Use a high-quality C-arm in lateral position

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.

**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.

# 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 | Ø 5.0 mm |
| 03.620.206 | Ø 6.0 mm |
| 03.620.207 | Ø 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 Schanz screws with the cannulated taps by penetrating the pedicle prior to screw insertion. Protection sleeves cover the proximal tip of the tap, to reduce trauma to surrounding soft tissues (1).

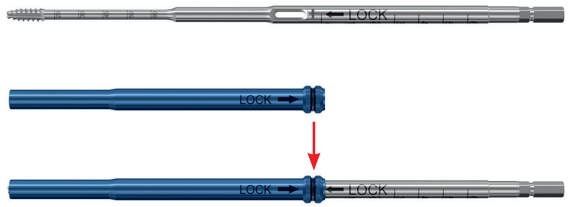
1

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.

**▲ Warning:**

- **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.

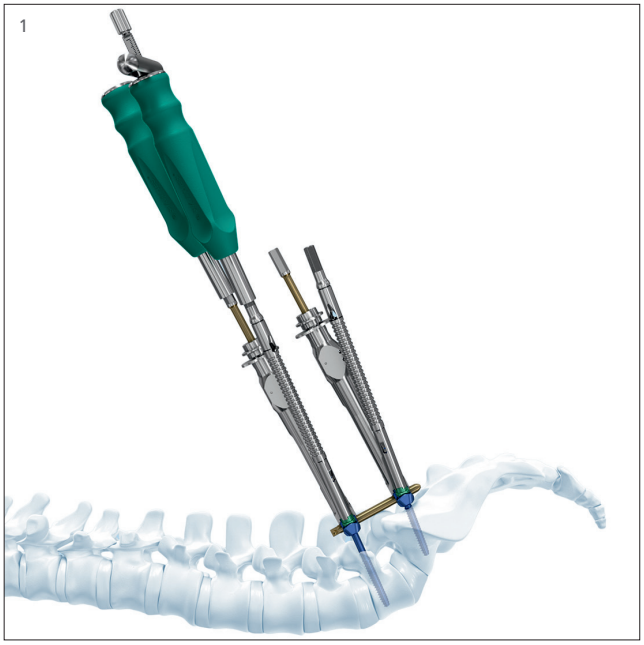
Insert the reduction tool for spondylolisthesis together with the T-handle into the handle with hexagonal coupling located on the displaced vertebra. Screw the threaded tip of the reduction tool into the end of the Schanz screw to fix them together (1).

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



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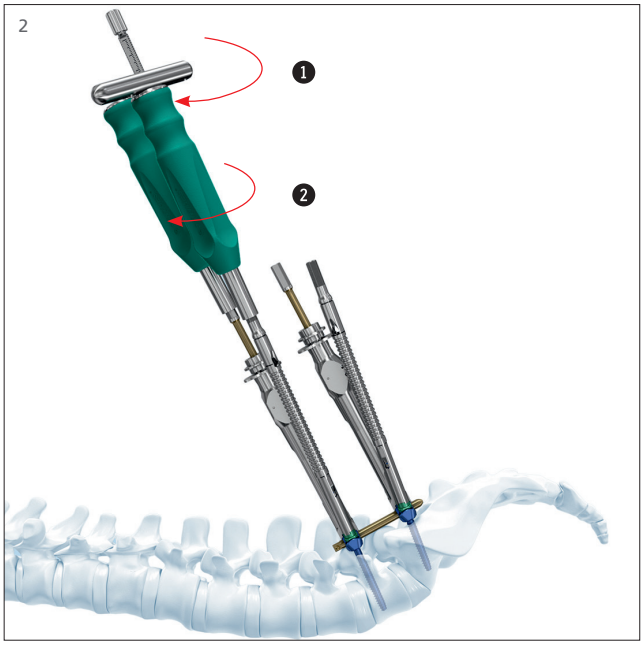
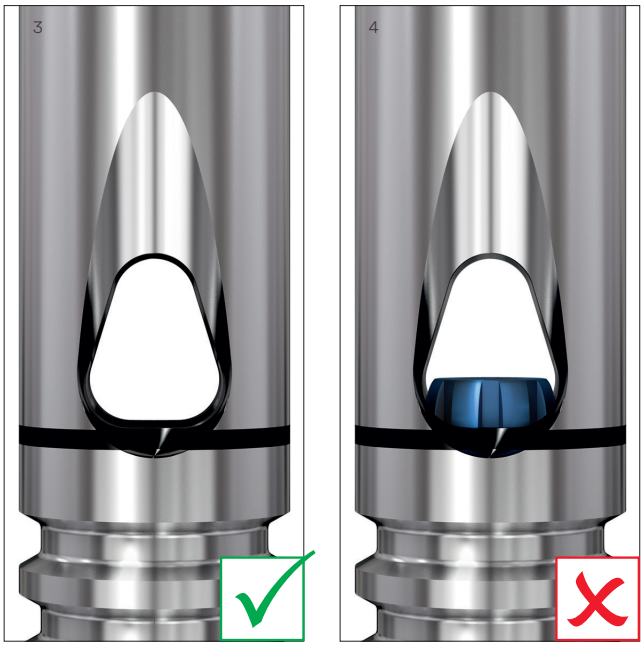


Remove the reduction tool and continue with the final tightening on page 41.

- 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.

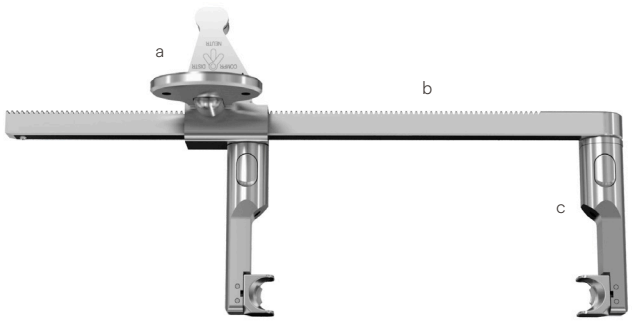
**▲ Warning:**

- 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 | Compression/Distraction Adapter USS Fracture MIS |
| 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 |



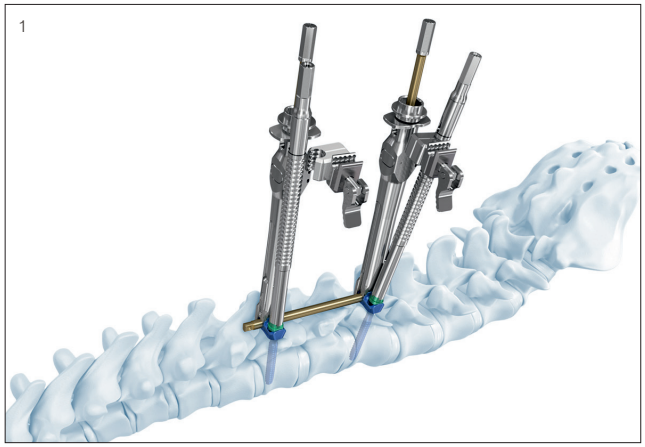

Follow the surgical technique for implant introduction on pages 6–35.

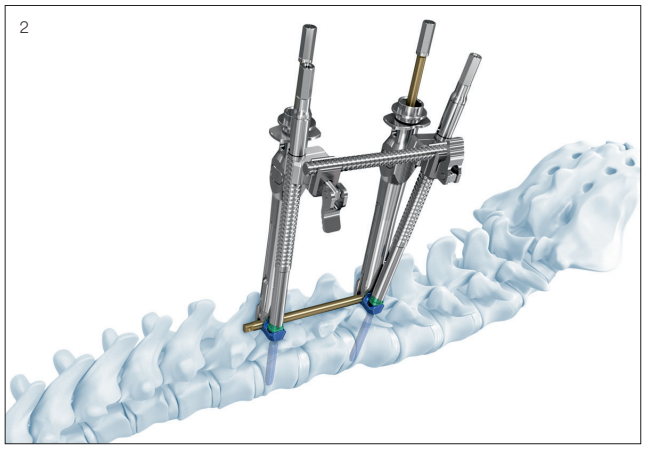
Ensure that all the nuts of the MIS fracture clamps are provisionally tightened and positioned as deep as possible (see “Fracture Clamp Insertion”, Step 2 on page 24).

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.

- **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.

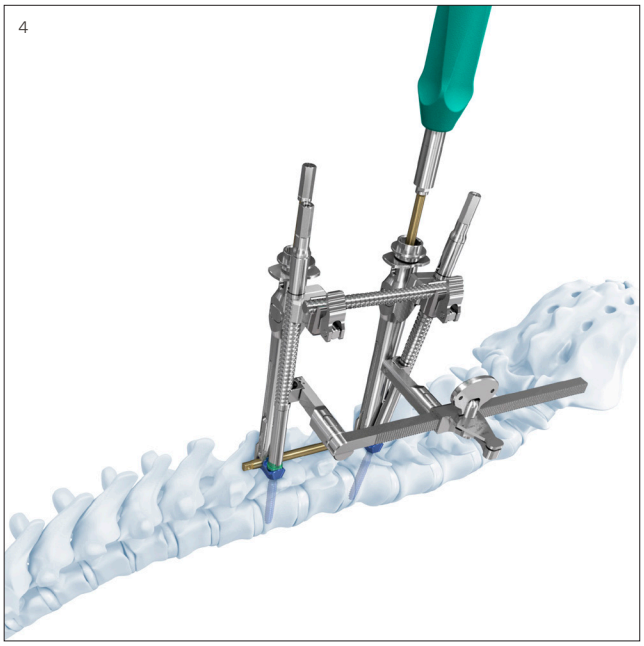
- **Place the distraction instrument as high as possible on the ridges of the socket wrench shafts.**
- **For compression, follow the same steps and switch the rack distractor to compression [→ ←, Compr.] instead (5).**

Check final rod placement with lateral radiographic imaging.

**▲ Warning:**

- **Ensure that the coupling and the tip of the rod protrude outside the MIS fracture clamps.**

4



5

# Implant 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 |

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.

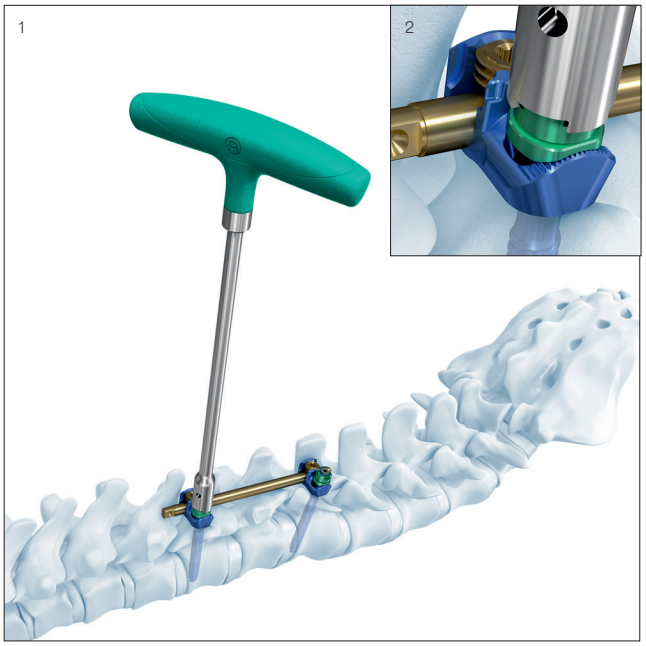
Free the locking cap recess and nut of the fracture clamp from ingrown scars and bone tissue using appropriate instruments. Check the condition and the geometry of the recess of locking cap and the nut of the fracture clamp exposed.

### 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.




**▲ Precautions:**

- 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.
- 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).

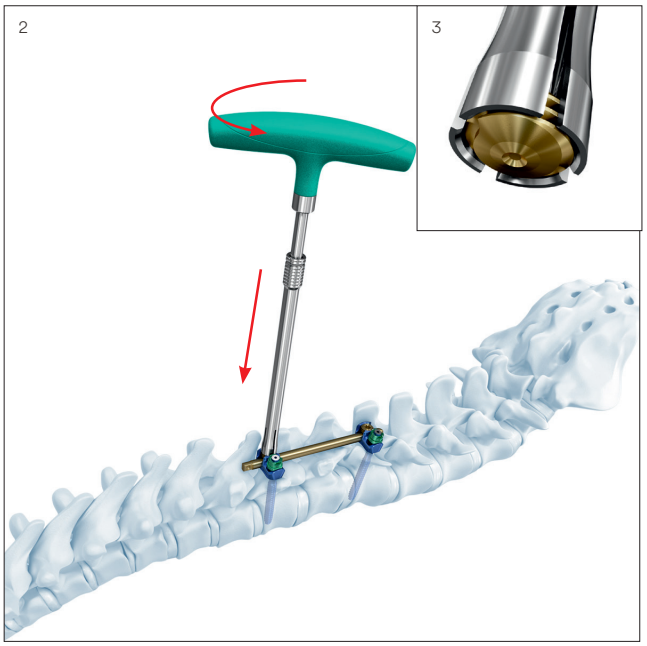
Push down the removal sleeve and maintain it down over the MIS fracture clamp (2). Turn counterclockwise to untighten the locking cap until the locking cap is captured by the sleeve (3). Take out the implant by holding the T-handle only.

- **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.**

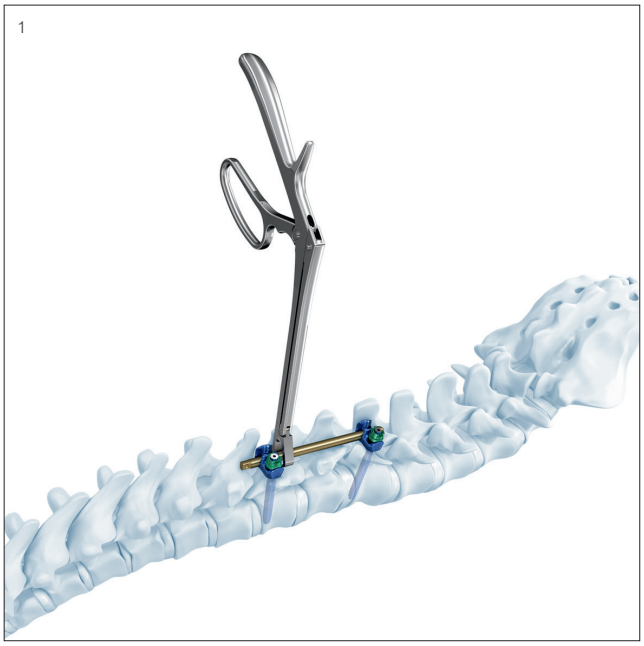



## Rod removal

| 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



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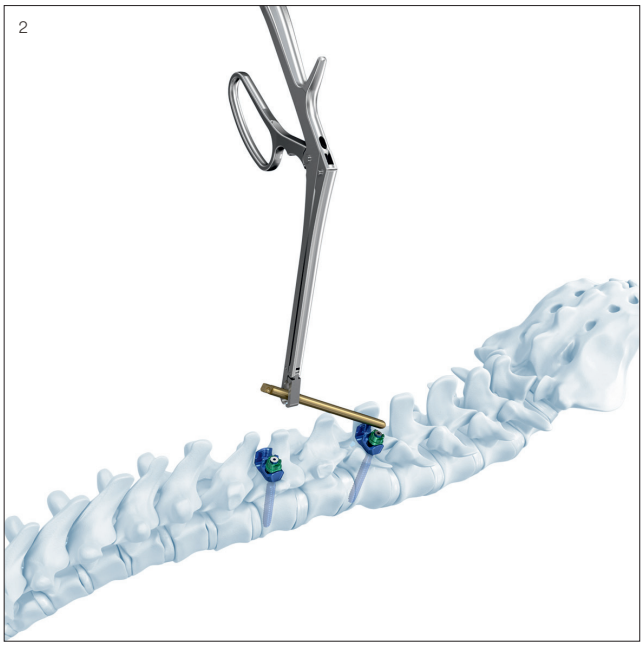


## Fracture clamp removal

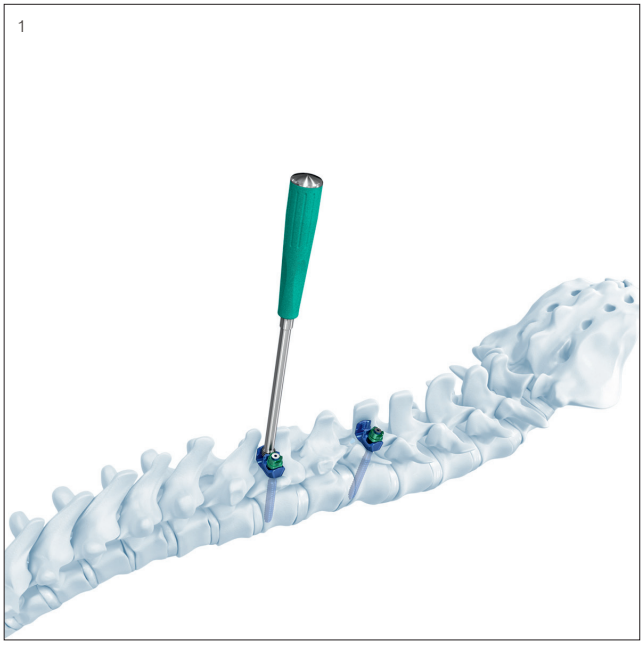
| Instrument | |
|---|---|
| 03.628.116 | Removal Instrument for Clamp |

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.

- **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



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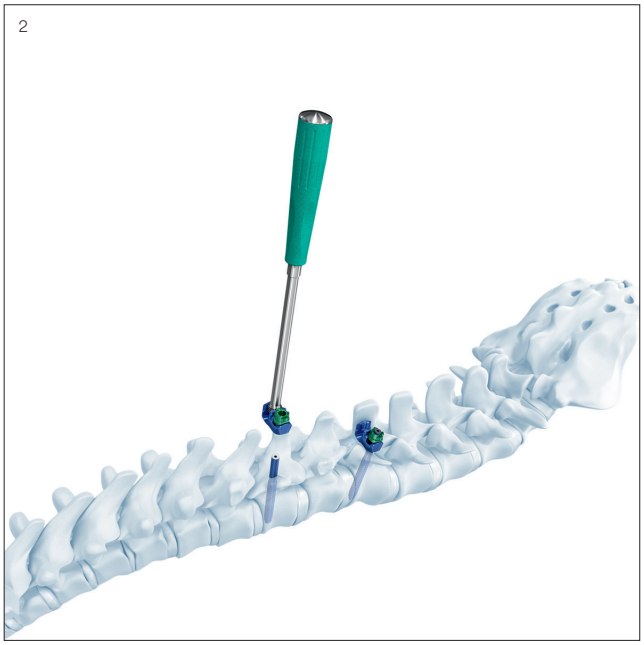


## Schanz screw removal

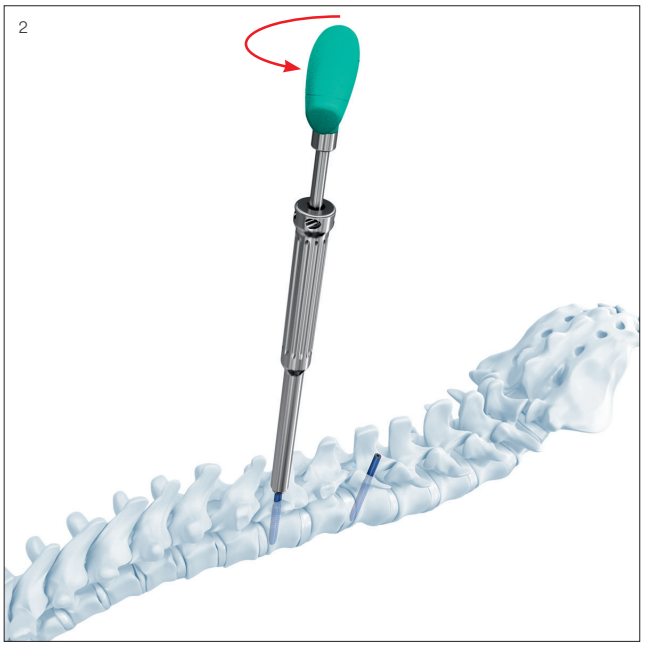
| Instrument | |
|---|---|
| 03.628.119 | Removal Instrument for Screw |

| 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.

- 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).

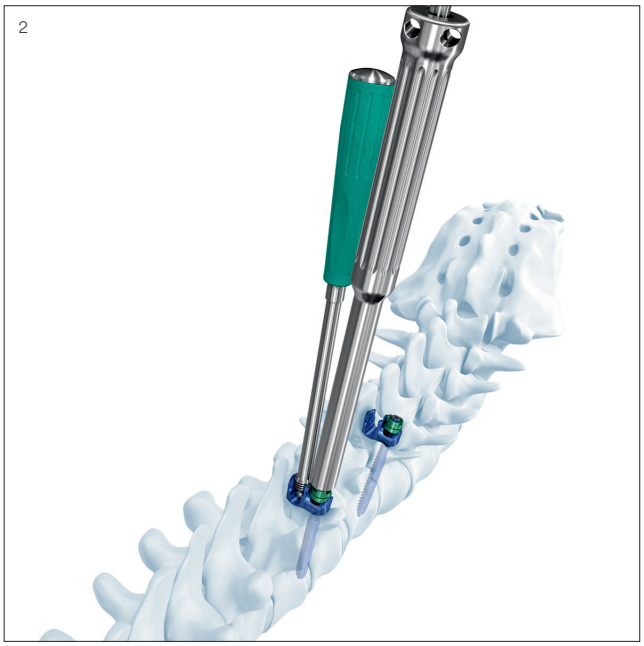
Insert the removal instrument for clamp into the thread of the clamp on the locking cap side and turn clockwise to attach the MIS fracture clamp to the instrument.

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.

1

2



# Bibliography

1. Aebi M, Thalgott JS, Webb JK (1998) AO/ASIF Principles in Spine Surgery. Springer-Verlag, Germany.
2. Aebi M, Arlet V, Webb JK (2007): AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.

# Indications and Contraindications

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks.

Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu

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