Instructions for Use
USS® Fracture MIS System

This instruction for use is not intended for distribution in the USA.

Not all products are currently available in all markets.

Products available non-sterile and sterile can be differentiated with the suffix "S" added to the article number for sterile products.

Manuals are subject to change;
the most current version of each
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Instructions for Use

USS® Fracture MIS System
The USS Fracture MIS System is a minimally invasive posterior pedicle screw fixation system designed for use in the thoracic, lumbar and sacral region of the spine. This system uses Schanz screws and fracture clamps to reduce vertebral fractures. It is comprised of MIS Schanz screw, MIS fracture clamp, MIS locking cap and rod needed to create spinal constructs.

The implants of the USS Fracture MIS System are available in different types and sizes, allowing the system to be assembled as a spinal construct.

These instructions for use contain information about the following products:

04.627.117	04.627.137S	04.627.616S	04.659.055S	04.659.120
04.627.117S	04.627.138	04.627.617S	04.659.060	04.659.120S
04.627.118	04.627.138S	04.627.618S	04.659.060S	04.659.125
04.627.118S	04.627.147	04.627.619S	04.659.065	04.659.125S
04.627.119	04.627.147S	04.627.623S	04.659.065S	04.659.130
04.627.119S	04.627.148	04.627.624S	04.659.070	04.659.130S
04.627.120	04.627.148S	04.627.625S	04.659.070S	04.659.140
04.627.120S	04.627.149	04.627.626S	04.659.075	04.659.140S
04.627.121	04.627.149S	04.627.627S	04.659.075S	04.659.150
04.627.121S	04.627.150	04.627.628S	04.659.080	04.659.150S
04.627.122	04.627.150S	04.628.101	04.659.080S	04.659.160
04.627.122S	04.627.151	04.628.101S	04.659.085	04.659.160S
04.627.123	04.627.151S	04.628.103	04.659.085S	04.659.170
04.627.123S	04.627.152	04.628.103S	04.659.090	04.659.170S
04.627.132	04.627.152S	04.659.030	04.659.090S	04.659.180
04.627.132S	04.627.153	04.659.030S	04.659.095	04.659.180S
04.627.133	04.627.153S	04.659.035	04.659.095S	04.659.190
04.627.133S	04.627.605S	04.659.035S	04.659.100	04.659.190S
04.627.134	04.627.606S	04.659.040	04.659.100S	04.659.200
04.627.134S	04.627.607S	04.659.040S	04.659.105	04.659.200S
04.627.135	04.627.608S	04.659.045	04.659.105S	04.659.230S
04.627.135S	04.627.609S	04.659.045S	04.659.110	04.659.260S
04.627.136	04.627.610S	04.659.050	04.659.110S	04.659.290S
04.627.136S	04.627.614S	04.659.050S	04.659.115	04.659.320S
04.627.137	04.627.615S	04.659.055	04.659.115S	04.659.350S

Important note for medical professionals and operating room staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.
For accompanying information, such as Surgical Techniques, please visit www.jnjmedtech.com/en-EMEA/product/accompanying-information or contact local customer support.

Materials
Titanium Alloy: TAN (Titanium – 6% Aluminium – 7% Niobium) according to ISO 5832-11
Titanium: TiCP (Commercially pure Titanium) according to ISO 5832-2

Intended Use
The USS Fracture MIS System is intended for posterior segmental stabilization of the thoracic, lumbar and sacral spine (T1-S1) in skeletally mature patients.
Surgery can be performed with either a minimally invasive or open approach.

Indications
– Fracture or Trauma

For USS Fracture MIS Perforated Screws: Diminished bone quality when used concurrently with VERTECEM™ V+ cement.

Contraindications
– In fractures with severe vertebral body disruption, an additional anterior support or vertebral body reconstruction is required
– Poor bone quality in which significant purchase cannot be established

For USS Fracture MIS Perforated Screws: Diminished bone quality when used without VERTECEM V+ cement.

For additional contraindications and potential risks related to VERTECEM V+, please refer to the corresponding instructions for use for the VERTECEM V+ system.

Patient Target Group
The USS Fracture MIS System is intended for use in skeletally mature patients. These products are to be used with respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.

Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures.

This device is intended to be used by qualified health care professionals who are experienced in spinal surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.

All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical procedure.

Expected Clinical Benefits
When the USS Fracture MIS System is used as intended and according to the instructions for use and labeling, the device provides segmental stabilization of the spine, which is expected to provide relief of back pain and/or disability caused by fracture or trauma.

A summary of safety and clinical performance can be found at the following link (upon activation): https://ec.europa.eu/tools/eudamed

Performance Characteristics of the Device
The USS Fracture MIS System is a posterior fixation device, designed to provide stability at the motion segment(s).

Potential Adverse Events, Undesirable Side Effects and Residual Risks
As with all major surgical procedures, there is a risk of adverse events. Possible adverse events may include: problems resulting from anesthesia and patient positioning; thrombosis; embolism; infection; excessive bleeding; neural and vascular injury; death, stroke; swelling, abnormal wound healing or scar formation; heterotopic ossification; functional impairment of the musculoskeletal system; paralysis (temporary or permanent); complex regional pain syndrome (CRPS); allergy/hypersensitivity reactions; symptoms associated with implant or hardware prominence, implant breakage, loosening or migration; malunion, non-union or delayed union; decrease in bone density due to stress shielding; adjacent segment degeneration; ongoing pain or neurological symptoms; damage to adjacent bones, discs, organs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; device or graft material displacement; vertebral angulation.

Sterile Device

STERILE R Sterilized using irradiation

Store sterile devices in their original protective packaging, and do not remove them from the packaging until immediately before use.

Do not use when packaging is damaged

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use if the package is damaged or date of expiration has passed.

Do not resterilize

Resterilization of the device can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single Use Device

 Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, re-use or reprocessing of single use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Warnings and Precautions
- It is strongly advised that the USS Fracture MIS System is implanted only by operating surgeons who have acquired the appropriate qualifications, are experienced in spinal surgery, are aware of general risks of spinal surgery, and are familiar with the product-specific surgical procedures. The operating surgeon must have knowledge of the device limitations, which are detailed in the contraindications as well as warnings and precautions listed below.
- Implantation is to take place as per the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.
- Warning: Special considerations should be taken with patients with known allergies or hypersensitivities to implant materials.

Kirschner wire handling
- 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.

Prepare pedicle and insert Kirschner wire (with multiple-use instruments)
- Use radiographic imaging to confirm orientation and depth while inserting the pedicle awl.
- The distance between the instrument and the cannulated awl should be equal to the insertion depth of the Kirschner wire.
- 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.
- While removing the pedicle awl, secure the Kirschner wire at all times.

Prepare pedicle and insert Kirschner wire (with single use instruments)
- Use radiographic imaging to confirm orientation and depth while inserting the bone access needle.
- While removing the bone access needle, secure the Kirschner wire at all times.

Screw insertion
Dilate incision and determine screw length
- Use radiographic imaging to confirm orientation and depth of the Kirschner wire while inserting the dilators.
- While removing the dilators, secure the Kirschner wire at all times.

Prepare and insert pedicle screws
For 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 bicortically, the anterior cortical wall may be penetrated and cement leakage might occur.
- 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.
- 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.
- 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.
- 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.

Prepare the site of the MIS fracture clamp
- Do not use the reamer through the dilator.
- When reaming the most superior and inferior levels, take care to protect the facet joints.

Rod insertion
Verify rod placement
- Ensure the coupling and the tip of the rod protrude outside the MIS fracture clamps.

Setting the rod
Rod fixation and removal of rod holder
- Ensure the coupling and the tip of the rod protrude outside the MIS fracture clamps.

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

Augmentation of perforated Schanz screws
Cement handling
- The perforated Schanz screws are combined with VERTECEM V+. Handling knowledge of VERTECEM V+ is required prior to augmentation of perforated screws. Please refer to the associated instructions for use for details on its use, precautions, warnings and side effects.

Injection procedure
- Ensure that no cement leakage occurs outside the intended area. Immediately stop the injection if leakage occurs.
- 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).
- 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.
- 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. Please refer to the associated instructions for use for details on its use, precautions, warnings and side effects.
- 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 procedure 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 patient’s neurological situation. In case of compromised neurological functions an emergency CT (Computed Tomography) 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.
- In order to minimize the risk of extravasation, it is strongly recommended to follow the surgical procedure, 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 anteroposterior (AP) projection is recommended.
- 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.

Fracture clamp insertion
– 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.

Tap pedicle
– 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.

Reduction of spondylolisthesis
– Ensure the coupling and the tip of the rod protrude outside the MIS fracture clamps.

Distraction with rack distractor
– Ensure the coupling and the tip of the rod protrude outside the MIS fracture clamps.

Implant removal
Untighten the nut of the MIS fracture clamp
– Once the Schanz screw is cut, use solely the instrument (Untightening instrument for nut) to untighten the nut of the fracture clamp.
– Only make two to three 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.

Untighten the locking cap of the MIS fracture clamp
– Misalignment and/or excessive force while removing locking cap might lead to slippage of the instrument.

For more information, please refer to the Synthes brochure "Important Information".

Combination of Medical Devices
The USS Fracture MIS System consists of MIS Schanz screw with cannulated and perforated options (∅ 5.0, 6.0, 7.0 mm) MIS fracture clamp, MIS locking cap and rod ∅ 6.0 mm.
The USS Fracture MIS perforated screws are combined with VERTECEM V+. For information related to VERTECEM V+, please refer to the corresponding instructions for use for the VERTECEM V+ system.

The USS Fracture MIS System is applied using associated USS Fracture MIS Instruments.

391.771	Bolt Cutting Head ∅ 5.0 mm, long
02.606.003	Kirschner Wire ∅ 1.6 mm w/o trocar tip, L 480 mm
02.648.001S	Cleaning Stylet f/perforated Pedicle Screws
03.606.020	Trocar ∅ 1.6 mm
03.606.021	Trocar Holder, f/No. 03.606.020
03.610.001	Dilator ∅ 1.8/10.0 mm, f/Guide Wire ∅ 1.6 mm
03.616.070	Handle f/Kirschner Wire ∅ 1.6 mm
03.620.205	Tap, cannulated, f/Pedicle Screws ∅ 5.0 mm
03.620.206	Tap, cannulated, f/Pedicle Screws ∅ 6.0 mm
03.620.207	Tap, cannulated, f/Pedicle Screws ∅ 7.0 mm
03.620.225	Protection Sleeve 7.2/5.3, f/No. 03.620.205
03.620.226	Protection Sleeve 8.2/6.3, f/No. 03.620.206
03.620.227	Protection Sleeve 9.2/7.3, f/No. 03.620.207
03.620.230	Pedicle Probe ∅ 3.5 mm, f/Screws ∅ 5.0–7.0 mm
03.627.008	Distraction Instrument f/MIS
03.627.012	T-Handle f/Reduct. Instrument, f/Spondylolisthesis
03.627.015	Handle, 13 mm, f/Bolt Cutter
03.627.016	Handle, 24 mm, f/Bolt Cutter
03.627.017	Torque-limiting Ratchet Handle, 7 Nm
03.627.024	Spline Drive Screwdriver, f/Schanz Screws
03.627.029	Instrument Holder, radiolucent
03.627.077	Distraction Forceps f/MIS
03.628.101	Dilator ∅ 13 mm, eccentric, f/No. 03.628.103
03.628.102	Loading Unit f/Clamp
03.628.103	Dilator ∅ 10.0/13.0 mm, f/No. 03.610.001
03.628.104	Reduction Tool f/Spondylolisthesis
03.628.105	Clamp Holder
03.628.106	Reamer, cannulated
03.628.107	Rod Length Indicator
03.628.108	Guide f/Locking Cap
03.628.109	Persuader
03.628.110	Counter Torque
03.628.111	Release Key
03.628.112	Screwdriver f/Locking Cap, T25
03.628.113	Socket Wrench Shaft w/3-Lobe-Drive
03.628.114	Handle w/Hexagonal Coupling 7.0mm
03.628.115	Adapter f/Hexagonal Coupling 7.0mm
03.628.116	Removal Instrument f/Clamp
03.628.117	Removal Instrument f/Rod
03.628.119	Removal Instrument f/Screw
03.628.120	Spline Drive Screwdriver, f/Schanz Screws
03.628.121	Removal Instrument f/Locking Cap
03.628.122	Removal Sleeve
03.628.123	Untightening Instrument f/Nut
03.628.124	Rod Indicator
03.628.125	USS Fracture MIS Compression/Distraction Adapter
03.628.126	Toothed Rack, long
03.628.127	Connecting Bar, long
03.628.128	Position Retainer
03.628.129	Push Button f/Position Retainer
03.631.521	Screw Length Indicator
03.631.528	Slider w/Wing Nut
03.631.537	Handle f/Rod Holder
03.631.538	Rod Holder, straight
03.632.017	Rod Bender w/Silicone Handle
03.702.215S	Vertecem V+ Syringe Kit
03.702.627S	Augmentation Kit w/Luer-Lock
07.702.016S	Vertecem V+ Cement Kit
68.628.323	Module f/Fracture Clamp and Schanz Screws

Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance Environment
MR Conditional:
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the USS Fracture MIS system are MR conditional. These articles can be scanned safely under the following conditions:
– Static magnetic field of 1.5 Tesla and 3.0 Tesla.
– Spatial gradient field of 300 mT/cm (3000 Gauss/cm).
– Maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 15 minutes of scanning.

Based on non-clinical testing, the USS Fracture MIS implant will produce a temperature rise not greater than 5.3 °C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5 Tesla and 3.0 Tesla MR scanner.

MR Imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the USS Fracture MIS device.

Treatment before Device is Used
Sterile Device:
The devices are provided sterile. Remove products from the package in an aseptic manner.
Store sterile devices in their original protective packaging.
Do not remove them from the packaging until immediately before use.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging by visual inspection:
– Inspect the entire area of sterile barrier package including the sealing for completeness and uniformity.
– Inspect the integrity of the sterile packaging to ensure there are no holes, channels or voids.
Do not use if the package is damaged or expired.

Non-Sterile Device:
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes brochure "Important Information".

Implant Removal
Any decision to remove the device must be made by the surgeon and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

If an implant has to be removed the following technique is recommended:
– 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
– Insert the untightening instrument for nut over the trimmed Schanz screw and fully introduce it into the 3-lobe drive of the nut of the MIS fracture clamp. Turn two to three revolutions counterclockwise to untighten the nut.
– Repeat the operation for all the screws belonging to the ipsilateral construct.

Untighten the locking cap of the MIS fracture clamp
– With the removal sleeve stopped in the upper position, fully insert the removal instrument for locking cap into the recess of the locking cap.
– Push down the removal sleeve and maintain it down over the MIS fracture clamp. Turn counterclockwise to untighten the locking cap until the locking cap is captured by the sleeve. 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.
– Repeat the operation for all the locking caps belonging to the ipsilateral construct.

Rod removal
– Insert the removal instrument for rod into one incision and firmly grab the rod with the instrument. Maintain a firm grip and slide the rod out of the incision.

Fracture clamp removal
– 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. Pull back the clamp over the trimmed Schanz screw.
– 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 (two to three revolutions) or use the alternative technique for MIS fracture clamp and Schanz screw removal listed below.

Schanz screw removal
– 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. From then on, only hold the handle and keep on turning counterclockwise until the screw is completely removed.
– 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.

Alternative technique for MIS fracture clamp and Schanz screw removal
– 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.
– 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.
– Repeat the operation for all the screws belonging to the ipsilateral construct.

Please note that precautions/warnings related to implant removal are listed in section "Warnings and Precautions".

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Special Operating Instructions

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.

General recommendations on Kirschner wire handling
– 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.

Kirschner wire insertion
– Each Kirschner wire is placed through an individual incision. Kirschner wire insertion can be performed either using multiple or single use instruments (see step "Pedicle Preparation" in Special Operating Instructions).
– Bi-planar fluoroscopy with two C-arms might be helpful and should be considered for radiographic assessment during the surgical procedure.

Pedicle preparation
Prepare pedicle and insert Kirschner wire with multiple-use instruments
– 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. Fully tighten the assembly into the pedicle awl. Adjust the radiolucent sleeve to a length of 10 mm.
– 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.
– 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.
– 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.
– Unscrew the trocar holder and the trocar from the pedicle awl, ensuring the awl remains in its position.
– Insert a Kirschner wire into the awl and guide it through the pedicle. 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.
– Gently tap on the impaction surface of the Kirschner wire handle to advance the Kirschner wire. Observe the position under fluoroscopic control. 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.
– All USS Fracture MIS Schanz screws are self-tapping; however, if tapping is preferred, use the appropriate tap and tap handle.

Prepare pedicle and insert Kirschner wire with single-use instruments
– 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.
– Open the cortex of the pedicle. Observe the position under fluoroscopic control.
– 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. Advance the wire under fluoroscopic control to the dedicated depth where the screw is to be positioned.
– Use the handle for Kirschner wire to advance the wire (see step "Pedicle preparation" in Special Operating Instructions).
– 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

Dilate incision and determine screw length

– Insert the Ø 1.8/10.0 mm dilator over the Kirschner wire. Continue dilation placing the Ø 10.0/13.0 mm dilator over the Ø 1.8/10.0 mm dilator. Subsequently place the 13.0 mm eccentric dilator over the Ø 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.
– 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 step "Pedicle preparation" in Special Operating Instructions).
– Optional: 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 and the Kirschner wire. Read off the screw length between the double lines of the Kirschner wire.
– Remove the dilator Ø 1.8/10.0 mm while carefully holding the Kirschner wire in place to ensure the pedicle entry point for screw placement is maintained.
– Leave dilator Ø 10.0/13.0 mm and the 13.0 mm eccentric dilator in place to protect the surrounding tissue while inserting the pedicle screw.

Prepare and insert pedicle screws

– Select the appropriate screw length. Choose screws with the maximum possible diameter and length to achieve desired stability.
– Mount the Schanz screw into the self-holding spline drive screwdriver.
– 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.
– 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.
– 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.

Prepare the site of the MIS fracture clamp (optional)

– 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. Repeat for each Schanz screw.

Fracture clamp insertion

Load MIS fracture clamp

– Properly position the MIS fracture clamp into the loading station. 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.
– Press down firmly to capture the MIS fracture clamp. Ensure that the MIS fracture clamp is firmly attached to the instrument.
– Repeat this step for all clamps needed.
– 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.
– 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.

Insert fracture clamp

– 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; the reamer can be used according to the optional technique in step "Prepare and insert pedicle screws" in Special Operating Instructions.
– Ensure that the MIS fracture clamp can angulate freely.

Rod insertion

Determine rod length

– Introduce the rod length indicator through the holes of the clamp holders. Keep the clamp holders parallel during introduction and slide the rod length indicator until the instrument is fully inserted.
– Read the corresponding rod length on the scale.
– 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.

Prepare the implant holder

– Mount the handle of the rod holder and lock it.
– 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.
– 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. Ensure that the rod is firmly connected.

Insertion of rod

– 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.

Verify rod placement

– Verify the placement of the rod by introducing the rod indicator through the clamp holder.
– Use the rod indicator to verify the presence of the rod in the implant.
– The visible black marking on the rod indicator indicates the presence of the rod in the clamp holder or MIS fracture clamp. If the black marking disappears into the clamp holder, no rod is in place.
– 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.

Setting the rod

Load locking cap

– Properly position the MIS locking cap into the loading unit. Properly orient and position the guide for locking cap over the locking cap on the loading unit.
– 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.
– The locking cap will snap into the distal tip of the guide for locking cap.

Insert locking cap

– Insert the guide for locking cap into the clamp holder. 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 and squeeze the handle until the stop.
– 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.

Rod fixation and removal of rod holder

– 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.

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, press the push button and slide up the locking sleeve on the rod holder. For the removal of the rod holder, squeeze the handle and simultaneously pull up the rod holder.
– 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 used.
– 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.

Fracture reduction

Kyphosis correction with the MIS fracture clamps fixed on the rod

– Ensure that all the MIS fracture clamps are positioned as deep as possible (see step "Fracture Clamp Insertion" in Special Operating Instructions).
– 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. Tilt both posteriorly projecting caudal screws cranially to lordose the spine.

– 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.
– Locate the handles with hexagonal coupling on the socket wrench shafts on both cranial Schanz screws and lordose the spine. Tilt both posteriorly projecting cranial screws caudally to complete the lordosing operation and secure in the desired position.
– 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. A wrong position of the clamp on the screw is identifiable when the screw is visible in the window. In this case, check the screw insertion depth according to step "Dilate incision and determine screw length" in Special Operating Instructions (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 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.
– Ensure that all the MIS fracture clamps are positioned as deep as possible (see step "Fracture Clamp Insertion" in Special Operating Instructions).
– To keep position of the fracture clamp during fracture reduction, adjust height of the push button for position retainer by pressing the button and pushing down.
– Perform fracture reduction according to step "Fracture Reduction" in Special Operating Instructions.

Distraction (optional):
– Ensure that all the nuts of the MIS fracture clamps are provisionally tightened and positioned as deep as possible (see step "Fracture Clamp Insertion" in Special Operating Instructions)
– 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. 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.
– 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.
– 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.
– 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.

Final tightening
Tightening of nut and locking cap
– Seat the counter torque in the proximal socket of the guide for locking cap and adjust the orientation of the handle as desired.
– 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.
– 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.
– 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.

Removal of instruments
Removal of guide for locking cap / clamp holder assemblies
– Insert the release key into the dedicated slot of the guide for locking cap. Forcefully push down the release key until it stops. If necessary, use the persuader to push down the release key.
– Pull out the instrument assembly by holding the clamp holder underneath the instrument's shoulders.
– Repeat this procedure for all guide for locking cap/clamp holder assemblies.

Trim Schanz screws
Trim Schanz screws using the 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.
– 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.

Optional technique
Augmentation of perforated Schanz screws
Preparation
– Ensure that the perforated Schanz screws have been inserted according to the surgical technique for implant introduction in Special Operating Instructions.
– Use the cleaning stylet to clear the cannula for proper cement injection. Visualize the stylet position under image intensifier control.

Cement handling
Prepare cement
– For handling VERTECEM V+ Cement, please refer to the VERTECEM V+ Instructions for Use.

Injection preparation
– 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.

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.
   – The first 1.5 cc 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.

Fracture clamp insertion
– Continue with step "Fracture clamp insertion" in Special Operating Instructions and the following surgical steps.

Optional technique
Tap pedicle
– 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.
– To lock the protection sleeve onto the cannulated tap shaft, align the arrows and push the tap and the sleeve together. 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.

Optional technique
Reduction of spondylolisthesis
– Follow the surgical technique for implant introduction (see Special Operating Instructions).
– 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.
– Turn the T-handles clockwise on both sides simultaneously until the desired reduction is achieved.
– Secure the Schanz screws in the desired position by tightening the nut using the handle with hexagonal coupling on the socket wrench shaft.
– Secure the rod by tightening the MIS locking cap using the handle with hexagonal coupling on the corresponding screwdriver.
– Remove the reduction tool and continue with the final tightening (see step "Final tightening" in Special Operating Instructions).
– 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. A wrong position of the clamp on the screw is identifiable when the screw is visible in the window. In this case, check the screw insertion depth according to step "Screw insertion" in Special Operating Instructions, 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.

Optional technique
Distraction with rack distractor
– Follow the surgical technique for implant introduction (see Special Operating Instructions).
– Ensure that all the nuts of the MIS fracture clamps are provisionally tightened and positioned as deep as possible (see step "Fracture Clamp Insertion" in Special Operating Instructions).
– 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 on the toothed rack, and snap the USS Fracture MIS compression/distraction adapters onto the dedicated mounting features.
– 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. 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.
– 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.
– 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, 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 instead.
– Check final rod placement with lateral radiographic imaging.

Disposal
Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

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