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.

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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.

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; swelling, abnormal wound healing or scar formation; functional impairment of the musculoskeletal system; 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, organs, discs, or other soft tissues; dural tear or spinal fluid leak; spinal cord compression and/or contusion; displacement of the graft material; vertebral angulation.

Sterile Device

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.
- Implantation is to take place with 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.

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 bi-cortically, 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 patients’ 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 Instrumentation.

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, and 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, and the sealing, for completeness and uniformity.
– Inspect for the absence of holes, channels or voids of the sterile barrier package and the sealing.
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.

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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Instructions for Use:
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