Instructions for Use
USS® Fracture 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 System
The USS Fracture System is a posterior pedicle screw fixation system designed for use in the thoracolumbar and sacral region of the spine. This system uses Schanz screws and fracture clamps to reduce vertebral fractures. It is comprised of Schanz screw, fracture clamp, rod, cross-link clamp, cross-link rod, fixation ring for rod needed to create spinal constructs.

The implants of the USS Fracture 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:

496.711	496.724S	496.795	498.102S
496.711S	496.725	496.795S	498.103
496.712	496.725S	496.796	498.103S
496.712S	496.776	496.796S	498.104
496.713	496.776S	496.797	498.104S
496.713S	496.777	496.797S	498.105
496.714	496.777S	496.798	498.105S
496.714S	496.778	496.798S	498.106
496.715	496.778S	496.930	498.106S
496.715S	496.791	496.930S	498.120
496.721	496.791S	496.950	498.120S
496.721S	496.792	496.950S	498.813
496.722	496.792S	496.970	498.813S
496.722S	496.793	496.970S	498.831
496.723	496.793S	496.980	498.831S
496.723S	496.794	496.980S	498.833
496.724	496.794S	498.102	498.833S

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 System is intended for posterior segmental stabilization of the thoracic, lumbar and sacral spine (T6-S1) in skeletally mature patients.

Indications
– Fracture or Trauma

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.

Patient Target Group
The USS Fracture 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 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 System is a posterior fixation device, designed to provide stability at the vertebral 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

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.

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 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.

Locate and open the pedicles
- Do not penetrate the anterior wall of the vertebral body.

Insert Schanz screws
- The tips of the Schanz screws must not penetrate the anterior cortex.

Fractures with intact posterior wall
- It is absolutely essential that the blue-marked socket wrench ∅ 11 mm is used for the low-profile fracture clamps.

Fractures with fractured posterior wall and rupture of posterior longitudinal ligament
- Since any reduction produced by pressing the Schanz screw ends together may produce undesirable compression on the damaged posterior wall of the vertebral body, there may be an associated risk of fragment dislocation into the spinal canal. Therefore, every clamp on the rod must be secured by a fixation ring for rods ∅ 6.0 mm. This shifts the centre of rotation to the level of the rod. Similarly, pushing the screw ends away from each other may cause undesirable distraction in the situation where the posterior longitudinal ligament is ruptured or damaged.

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

Combination of Medical Devices
The USS Fracture System consists of transpedicular Schanz screw (∅ 5.0, 6.2, 7.0 mm), fracture clamp, rod ∅ 6.0 mm, cross-link clamp, cross-link rod ∅ 3.5 mm, fixation ring for rod.

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

314.070	Screwdriver, hexagonal, small, 2.5 mm, w/Groove
388.140	Socket Wrench 6.0mm, w/straight Handle
388.363	Holding Sleeve w/Catches, f/No. 314.070
388.410	Spreader Forceps f/Pedicle Screws, L 330 mm
388.422	Compression Forceps, L 335 mm, f/Pedicle Screws
388.450	Holding Forceps f/USS Rods ∅ 3.5/4.5 mm, L 295 mm
388.540	Pedicle Probe ∅ 3.8 mm, L 230 mm
388.550	Pedicle Awl ∅ 4.0 mm, L 230 mm
388.750	USS Rod Cutting and Bending Device
388.931	USS Reduction Sleeve, f/Nos. 296.750 and 496.750
388.932	USS Nut, knurled, f/No. 388.931
391.771	Bolt Cutting Head ∅ 5.0 mm, long
391.780	Handle ∅ 13.0 mm f/Bolt Cutting Head, L 455 mm
391.790	Handle ∅ 24.0 mm f/Bolt Cutting Head, L 455 mm
393.100	Universal Chuck w/T-Handle
394.570	Cancellous Bone Impactor, straight
394.701	Socket Wrench ∅ 11.0 mm, cannulated, L 300 mm
395.380	T-Handle f/Steinmann Pins+Schanz Screws
319.011	Length Indicator f/Pedicle Screw
388.545	Feeler f/Screw Channel, straight
388.546	Feeler f/Screw Channel, curved

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 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 150 mT/cm (1500 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 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 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:
- The clamps are loosened using the socket wrench ∅ 11 mm, while the set screws are loosened with the socket wrench 6.0 mm. The rod and clamps can then be removed from the Schanz screws.
- Next, grasp the ends of the Schanz screws with the screw forceps or the T-handle and turn counterclockwise to remove the screw.

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
Locate and open the pedicles
- Locate and open the pedicles using the pedicle awl ∅ 4.0 mm to a depth of 10 mm and the pedicle probe ∅ 3.8 mm. The pedicle probe has markings at 30, 40 and 50 mm for checking the depth of the pedicle / vertebral body penetration.

Verify trajectory
- Using the hook of a depth gauge or a ball tipped feeler, probe the drilled channel to check that the channel is fully intact and that the spinal canal has not been opened.

Insert Schanz screws
- Insert the Schanz screws using the T-handle or universal chuck.
- The Schanz screws should be inserted under lateral image intensifier control.

Assemble USS fracture clamps and rod
– Select the appropriate rod length. Take any necessary distraction into account when determining the length of the rod.
– Place the clamps on the Schanz screws, push the rod through both clamps and push the entire construction toward the spine.
– A slight resection of the spinal process will cause the assembly to lie close to the lamina.
– The rod comes to rest medially.

Assembly with USS fracture clamp for the cranial end (optional)
– The fracture clamp for rods can also be used for the cranial end. Since this clamp is firmly fixed to the rod, only one clamp can be used on each side. This clamp prevents the rod from jutting out at the cranial end, thereby protecting adjacent mobile segments. The cranial fracture clamp is fixed to the vertical rod using the socket wrench 6.0 mm.

Fractures with intact posterior wall

Principle of kyphosis correction with intact posterior wall
Pressing the Schanz screws together dorsally lordoses the adjacent vertebrae around the pivot point of their facing posterior edges. The clamps on the rod move toward the centre. The fracture clamps must be able to slide freely along the rod, otherwise kyphosis correction will not be achieved.
Principle of kyphosis correction with the cranial clamp with an intact posterior wall (optional). The use of the cranial fracture clamp allows correction of 10° in each case by moving the caudal clamp 10 mm (guide distance).

Locate socket wrench on both caudal Schanz screws and lordose the spine
– Tilt both posteriorly projecting caudal screws cranially to lordose the spine. Secure the clamps/Schanz screws in the desired position using the socket wrench ∅ 11 mm.
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Locate socket wrench on both cranial Schanz screws and lordose the spine
– Repeat the above procedure for the cranial Schanz screws: Tilt in the caudal direction to complete the lordosing operation and secure in the desired position.

Fractures with fractured posterior wall and rupture of posterior longitudinal ligament

5 mm gaps between the fixation rings and the clamps allow kyphosis correction of 10 degree in each case (guide value).
Principle of kyphosis correction with the cranial clamp with fractured posterior wall (optional). The use of the cranial fracture clamp allows correction of 10° in each case by moving the caudal clamp 10 mm (guide distance). A fixation ring must be used as a stop.

Mount fixation rings according to the degree of lordosing
– Pick up fixation rings using the screwdriver, hexagonal and the holding sleeve with catches, locating theholding sleeve on the head of the set screw. Secure the fixation rings between the fracture clamps accordingto the desired degree of lordosing.

Locate Socket Wrench and lordose the spine
– Locate the socket wrench ∅ 11 mm and create the corresponding lordosis by tilting the Schanz screws as described in steps in "Fractures with Intact Posterior Wall" in Special Operating Instructions.

Fix the clamps on the rods
– Using the socket wrench 6.0 mm, tighten the set screws to fix the fracture clamps on the vertical rods.
– If the cranial clamp is used, the caudal fracture clamps are fixed to the vertical rods by tightening the set screws with the socket wrench 6.0 mm.

If required: Distraction with the spreader forceps under image intensifier control
– Using the socket wrench 6.0 mm, loosen the set screws on the fracture clamps for the relevant vertebra and perform careful distraction if this is necessary to complete the anatomical reduction and restore the original level of the fractured vertebral body.
  – If the cranial clamp is used, distraction can only be performed with the caudal clamp.

Remove fixation rings
– When reduction is complete, tighten the set screws and remove the fixation rings.

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 and bolt cutting head.

Using the bolt cutter
– Assemble the bolt cutter and place in the neutral position (you should be able to see through the 5 mm hole). Position the handles, one on top of the other, on the bolt cutting head like the hands of a clock. Slide the bolt cutting head over the Schanz screw.
– Pull the handles apart to an angle of approximately 45° until the Schanz screw audibly breaks.
– 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 cancellous bone Impactor, straight or the shaft of another Schanz screw.
  – If this is not possible, the bolt cutting head will have to be dismantled and the screw shaft pushed out of the inner bolt.

Assembling the cross-link system

Cross-links are transverse stabilizers that link the two vertical rods, thereby increasing the stiffness of the construct. They are recommended for unstable fractures and multisegmental constructs.

Pick up first cross-link clamp
– Assemble the small screwdriver, hexagonal and the holding sleeve with catches. To pick up the preassembled crosslink clamp for rods ∅ 6.0 mm, insert the hexagonal screwdriver into the set screw on the clamp, push down the holding sleeve and clip the catches onto the sleeve of the preassembled clamp.

Mount first cross-link clamp
– Pull the holding sleeve back slightly, place the clamp onto the rod and release the holding sleeve.

Insert cross-link rod
– The special design of the cross-link sleeve with its two recesses on the top allows the cross-link rod to be angled up to±20° to suit the anatomical situation.
– Determine the appropriate length of the ∅ 3.5 mm cross-link rod. If necessary, cut the rod to length using the USS rod cutting and bending device.
– Hold the clamp with the small hexagonal screwdriver and introduce the Ø 3.5 mm cross-link rod through the hole in the cross-link clamp. If necessary, use the holding forceps for USS rods ∅ 3.5/4.5 mm to introduce the cross-link rod. Tighten the set screw of the Cross-Link Clamp with the small hexagonal screwdriver.

Mount second cross-link clamp
– Repeat the procedure described in step "Pick up first cross-link clamp" in Special Operating Instructions for the second clamp on the opposite rod. Introduce the ∅ 3.5 mm cross-link rod through the second clamp so that it protrudes by 5 mm beyond the clamp. Tighten the set screw with the small hexagonal screwdriver.

Distract cross-link assembly (optional)
– Loosen one of the set screws. Place the holding forceps for USS rods ∅ 3.5/4.5 mm next to the clamp and use the spreader forceps for pedicle screws to exert distraction. Retighten the set screw with the small hexagonal screwdriver.

Check all set screws on the system
– When the system is fully assembled, check that all screws are securely tightened.

Techniques depending on fracture type

Fracture of the posterior elements of the spine or disruption with distraction
– Reduce the fracture as described in steps in "Fractures with Intact Posterior Wall" in Special Operating Instructions, then perform appropriate compression using the fixation rings and the compression forceps.

Complete disruption of the anterior and posterior elements of the spine with rotation
– If necessary, perform compression using the fixation rings and the compression forceps.
– The additional use of one or two cross-link stabilizers to produce a frame construction is recommended.

Reduction of spondylolisthesis

Insert transpedicular Schanz screws
– Insert the transpedicular Schanz screws with dual core and double thread into the displaced vertebra (cranial) as described in steps "locate and open the pedicles", "verify trajectory" and "insert Schanz screws" in Special Operating Instructions. Normal Schanz screws are inserted into the caudal vertebra. Assemble USS fracture clamps and rods as described in step "Assemble USS fracture clamps and rod" in Special Operating Instructions. Secure caudal fracture clamps to the rod.

Perform reduction
– Slide the USS reduction sleeve and USS nut, knurled over the Schanz screws with double thread. Turn the nuts on both sides until the desired reduction is achieved.

Tighten fracture clamps
– Remove the USS Nuts, knurled and tighten the fracture clamps using the Socket Wrench ∅ 11 mm.

Fix fracture clamps on the rods and trim Schanz screws
– Remove the USS reduction sleeves. Fix the USS fracture clamps using the Socket Wrench 6.0 mm as described in step "fix the clamps on the rods" in Special Operating Instructions. Trim the Schanz screws with the bolt cutter as described in step "trim Schanz screws using the bolt cutter" in Special Operating Instructions.

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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Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
www.jnjmedtech.com

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www.e-ifu.com