# 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 manual is always available online.
Printed on: Mär 08, 2022

DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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 SE_528805 AE 11/2021

# 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 | 496.725 | 496.796 | 498.104 |
| 496.711S | 496.725S | 496.796S | 498.104S |
| 496.712 | 496.776 | 496.797 | 498.105 |
| 496.712S | 496.776S | 496.797S | 498.105S |
| 496.713 | 496.777 | 496.798 | 498.106 |
| 496.713S | 496.777S | 496.798S | 498.106S |
| 496.714 | 496.778 | 496.930 | 498.120 |
| 496.714S | 496.778S | 496.930S | 498.120S |
| 496.715 | 496.791 | 496.950 | 498.813 |
| 496.715S | 496.791S | 496.950S | 498.813S |
| 496.721 | 496.792 | 496.970 | 498.831 |
| 496.721S | 496.792S | 496.970S | 498.831S |
| 496.722 | 496.793 | 496.980 | 498.833 |
| 496.722S | 496.793S | 496.980S | 498.833S |
| 496.723 | 496.794 | 498.102 | 498.911 |
| 496.723S | 496.794S | 498.102S | 498.911S |
| 496.724 | 496.795 | 498.103 | |
| 496.724S | 496.795S | 498.103S | |

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 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; 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.

**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.
- 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.

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 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 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, 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:
- 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.

**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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