Instructions for Use
USS™ – Universal Spine System

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

DePuy Synthes
SPINE
COMPANIES OF Johnson&Johnson

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Instructions for Use

USS™ – Universal Spine System
Please read these instructions for use, the Synthes brochure "Important Information" and the corresponding surgical techniques carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Material

Material:	Standard:
TAN	ISO 5832-11
CPTI	ISO 5832-2
Stainless Steel	ISO 5832-1
TAV	ISO 5832-3

Intended use
The USS System is a posterior pedicle screw and hook fixation system (T1–S2) designed to provide precise and segmental stabilization of the spine in skeletally mature patients.
Additionally, vertebral body screws can be used anteriorly in the thoracolumbar spine.
The USS II Polyaxial Perforated screws are an addition to the USS II Polyaxial System, a posterior pedicle screw fixation system (T1–S2) suitable for the treatment of degenerative diseases as well as for correcting deformities. USS II Polyaxial Perforated pedicle screws may be inserted traditionally as solid USS II Polyaxial screws and with K-wire guidance. USS II Polyaxial Perforated screws direct Vertecem V+ bone cement through lateral perforations to augment the pedicle screw in the vertebral body. Augmentation of pedicle screw with cement increases pedicle screw anchoring in vertebral bone, especially in cases of diminished bone quality.

USS Small Stature/Pediatric was developed specially for children and adults of small stature.

USS II Ilio-Sacral is indicated for fixation of long posterior rod constructs in the ilium and in S2, both in combination with an S1 fixation.

Indications
USS:
– Degenerative diseases
– Thoracolumbar and lumbar scoliosis
– Tumors, infections
– Fractures with anterior support
– Multisegmental fractures with segmental fixation

USS II:
– Spinal deformities (congenital, idiopathic, neuromuscular)
– Degenerative diseases
– Tumors
– Fractures

USS II Polyaxial:
– Degenerative diseases
– Deformities in combination with USS II or USS Low Profile pedicle screws
– Fractures and tumors with sufficient anterior support when using USS II Polyaxial as a stand-alone device for posterior fixation

USS II Polyaxial Perforated
– Degenerative disc diseases
– Deformities in combination with USS II or USS Low Profile pedicle screws
– Fractures and tumors with sufficient anterior support when using USS II Polyaxial as a stand-alone device for posterior fixation
– Osteoporosis when used concurrently with Vertecem V+ bone cement

USS II Ilio-Sacral:
S1 fixation combined with iliac fixation:
– Severe scoliosis (e.g. neuromuscular)
S1 fixation combined with S2 fixation:
– Degenerative diseases (e.g. spondylolisthesis)

USS Small Stature/Pediatric:
Indications (in children and adults of small stature)
– Spinal column deformities (congenital, idiopathic, neuromuscular)
– Tumors
– Fractures
Note: In comparison to the USS with 6 mm diameter rods, the mechanical strength of the USS Small Stature/Pediatric System with 5.0 mm diameter rods is 50% less.

USS Low Profile:
– Thoracolumbar scoliosis and other deformities
– Tumors
– Degenerative diseases
– Fractures with anterior support and multisegmental fractures with segmental fixation
– Infections

USS VAS:
– Degenerative diseases
– Instabilities after decompression

Contraindications
USS:
– Should not be used above T6
– Fractures: a controlled reduction cannot be performed with pedicle screws
– Fractures: pedicle screws should only be used to supplement anterior column reconstruction with bone graft or cage

USS II:
– Additional anterior support or reconstruction of the spine is required in the case of fracture and tumors with poor ventral support.
– Osteoporosis

USS II Polyaxial:
– Fractures and tumors with insufficient anterior support
Precautions: For patients with osteoporosis, the use of cancellous bone screws is recommended.

USS II Polyaxial Perforated:
– In fractures and tumors with severe anterior body disruption, an additional anterior support or column reconstruction is required
– Osteoporosis when used without augmentation
– Severe Osteoporosis
Contraindications related to Vertecem V+ bone cement: Please refer to the corresponding technique guide, for Vertecem V+

USS Ilio-Sacral:
– Fractures and tumors with insufficient anterior support
– USS II Ilio-Sacral should not be used where no fixation in S1 is possible.

USS Low Profile:
Contraindications as stand-alone procedures are:
– Spondylolisthesis Grades IV & V
– Fractures with loss of anterior column support
– Tumors with loss of anterior column support

USS VAS:
– Fractures and tumors with loss of anterior support, with the VAS Variable Axis Screw as a stand-alone implant

Side effects
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common may include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, side effects associated with implant or hardware prominence, malunion, non-union, ongoing pain; damage to adjacent bones, discs, or soft tissue, dural tear or spinal fluid leak; spinal cord compression and/or contusion, partial displacement of the graft, vertebral angulation.

Sterile device

STERILE R Sterilized using irradiation

Store implants 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. Do not use, if the package is damaged.

Do not resterilize

Single-use device

Do not re-use

Products intended for single-use must not be re-used.
Re-use or 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, reuse 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.

Precautions
The general risks associated with surgery are not described in these instructions for use. For more information, please refer to the Synthes brochure "Important Information".

Warnings
It is strongly advised that the Universal Spine System is implanted only by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical techniques. 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.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
USS II Polyaxial Perforated screws are combined with Vertecem V+. Please refer to the associated product information for details on its use, precautions, warnings and side effects.

Magnetic Resonance environment
MR Conditional:

USS II Polyaxial, USS II Polyaxial Perforated, USS Low Profile, USS VAS
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the USS (Titanium based) systems 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 (Titanium based) implants will produce a temperature rise not greater than 5.7°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 (Titanium based) devices.

USS, USS Small Stature / Pediatric, USSII, USSII Iliosacral
Non-clinical testing of the worst-case scenario has demonstrated that the implants of the USS (Stainless Steel based) systems 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 (Stainless Steel based) implants will produce a temperature rise not greater than 5.7°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 (Stainless Steel based) devices.

Treatment before device is used
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".

Processing/reprocessing of the device
Detailed instructions for processing implants and reprocessing reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling Multipart Instruments" can be downloaded from: http://www.synthes.com/reprocessing

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