Instructions for Use
USS™ Universal Spine 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.
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Instructions for Use

USS™ Universal Spine System
Universal Spine System family consists of pedicle screw systems designed for use with either ∅ 5.0 mm (i.e., USS II, USS II Polyaxial, USS II Polyaxial Perforated and USS II Ilio-Sacral) or ∅ 6.0 mm rods (i.e., USS, USS II, USS Low Profile, USS II Polyaxial, USS II Polyaxial Perforated and USS II Ilio-Sacral). These are used with the compatible posterior rods, connectors and connecting rods to build a Universal Spine System construct.

Pedicle screw designs may vary between systems, they include monoaxial and polyaxial screw heads, single and dual side opening for rod attachment, single and dual lead thread forms, and solid, cannulated, and perforated screws. The different rods provide multiple options for implantation depending on the patient anatomy.

The USS Small Stature/Paediatric Spine devices are designed for spinal fixation and the correction of deformity in adults of small stature and paediatric patients. The system is based upon dual side opening pedicle screws and ∅ 5.0 mm rods.

Alternative fixation is also available including dual side opening or front opening pedicle hooks, lamina hooks, and angled lamina hooks.

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 Universal Spine System is intended for posterior fixation of the thoracolumbar and sacral spine (T1-S2) as an adjunct to fusion in skeletally mature patients.
Additionally, vertebral body screws and washers can be used anteriorly in the thoracolumbar spine for deformity correction.

USS II Ilio-Sacral is intended to provide fixation of posterior rod constructs in the ilium and in S2, both in combination with an S1 fixation.

The USS Small Stature/Paediatric Spine System is intended for posterior fixation of the thoracolumbar and sacral spine (T1-S2) as an adjunct to fusion in adults of small stature and paediatric patients.
Additionally, vertebral body screws and washers can be used anteriorly in the thoracolumbar spine.

Indications
- Degenerative spine disease
- Deformities
- Tumors
- Infections
- Fractures

USS II Polyaxial Perforated Screws: Diminished bone quality when used concurrently with VERTECEM™ V+ cement.

USS Small Stature/Paediatric Spine System: Spinal column deformities

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

For USS II Polyaxial 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.

USS II Ilio-Sacral should not be used where no fixation in S1 is possible.

USS Small Stature/Paediatric Spine System: Poor bone quality in which significant purchase cannot be established.

Patient Target Group
The Universal Spine 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.

The USS Small Stature/Paediatric Spine System is intended for use in adults of small stature and paediatric patients in spinal fusion applications. 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 Universal Spine System is used as intended and according to the instructions for use and labeling, the device provides segmental stabilization as an adjunct to fusion, which is expected to provide relief of back and/or leg pain caused by indicated conditions, and correction of spinal deformity.

When the USS Small Stature/Paediatric Spine System is used as intended and according to the instructions for use and labeling, the device provides segmental stabilization as an adjunct to fusion, which is expected to correct spinal deformity and associated improvement in quality of life/self-image.

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 Universal Spine System is a posterior fixation device, designed to provide stability at the motion segment(s) prior to fusion.

The USS Small Stature/Paediatric Spine System is a posterior fixation device, designed to provide stability at the motion segment(s) prior to fusion.

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

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 Universal Spine 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.

USS

Pedicle hook positioning
Prepare the pedicle using the pedicle feeler
- Make sure to place it in the articular space and not into the bone of the inferior facet.
- Do not push medially.

Drill hole for ∅ 3.2 mm screw
- Do not start the power drill if the drill does not hit bone after passing through the drill sleeve.

Lamina hook positioning
Prepare the seat for the lamina hook using the lamina feeler
- Make sure the foot of the lamina hook does not lie too deep or presses upon the spinal cord.

Rod contouring
- Do not bend titanium rods backwards and do not bend rods more than 45°.

Introducing rods into side-opening implants
Using USS rod introduction pliers (i.e. the persuader)
- Do not completely close the persuader, as this is a very powerful instrument.
- Do not apply too much force on the anchorage or it will tear out of the bone.

USS Low Profile Spine System

Handling implants with the stick
- If the stick is required for subsequent manipulations, make sure that the stick is firmly tightened to the implant. To do this, use the small hexagonal screwdriver to tighten the stick-implant-thread connection.

Insert pedicle screws
Open pedicle
- If the probe resists advancement, use image intensifier control to check the position and orientation.

Pedicle hook positioning
Prepare the pedicle using the USS pedicle feeler
- Carefully check that the instrument is placed in the articular joint space and not in the bone of the inferior facet.
- Do not push medially.

Drill hole for screw ∅ 3.2 mm
- Do not start the power drill if the bit does not hit bone after passing through the drill sleeve.

Angled lamina hook positioning at the transverse process
- Aim for a hook position as medially as possible in order to limit stress on transverse process.

Rod contouring
- Once bent, titanium rods should not be bent back again. Do not bend titanium rods more than 45°.

Tightening of construct
Pick up and place sleeve with the universal handle
- Be sure to use USS Low Profile sleeves and nuts only. Do not use sleeves and nuts from other USS systems.

Firmly tighten the nut
- At the end of the surgery, it is necessary to check with the socket wrench with L-handle if every single implant is firmly tightened to the rod. The counter torque instrument is used simultaneously.
- Also check that the rods overlap the screws at the respective ends (min. 5 mm).

Introduction of rods into side openings
Using rod introduction pliers (i.e. the persuader)
- Carefully apply force to the anchorage to prevent pull-out from the bone.

USS II Spine System

Pedicle hook positioning
Prepare the pedicle with the USS pedicle feeler
- Ensure that the feeler is placed in the articular space and not in the bone of the inferior facet.
- Do not push medially.

Drill hole for screw ∅ 3.2 mm
- Do not start the power drill if the bit does not hit bone after passing through the drill sleeve.

Lamina hook positioning
Prepare the seat for the lamina hook using the lamina feeler
- Ensure that the lamina hook does not lie too deep or press upon the spinal cord.

Rod contouring
- Once bent, titanium rods should not be bent back again. Do not bend titanium rods more than 45°.

Locking implants to rods
Using rod introduction pliers (i.e. the persuader)
- Do not close the persuader completely since it can transmit very high forces. If necessary, the locking clamp can be tilted up so that the persuader does not remain in the closed position.
- Do not apply too much force on the anchorage of the implant or it will tear out of the bone.

Connecting rod and implant using rod connector
- The rod connectors supplied in the set can only be used with the 6 mm rod.

USS II Polyaxial Spine System

Insert screws into pedicles
– For patients with suboptimal bone quality, the use of cancellous bone screws is recommended.

Insert 3-D heads
– If more than one level has to be fused, it is recommended to check the required curvature of the rod before inserting the 3-D heads. Do so by aligning the rod template with the screws.
– Once the polyaxial head is secured, if it is removed a new polyaxial head must be used.

Select and insert rods
– Do not bend titanium rods more than 45°. Do not bend back and forth.
– Never use the rod introduction pliers without guidance provided by the screw holder.

Tighten the nuts
– Make sure to firmly tighten all nuts.

Remobilization and/or removal
– Always apply the screw holder as a guide.
– Once the polyaxial head is secured, if it is removed a new polyaxial head must be used.

USS II Polyaxial Perforated

Preoperative planning
– USS II Polyaxial Perforated screws are combined with VERTECEM V+ cement. 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.
– Image intensifier control is mandatory while injecting cement.

Approach
Assess proper screw placement
– 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.
– The USS II Poly Perforated screw must enter in approximately 80% of the vertebral body.
– 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.

Injection sequence
– Make sure the adapter is fully introduced into the screw recess. Apply cement. The adapters should be left in place until the cement is hardened.
– Care should be taken when exchanging the syringes, as cement might be left in the stardrive head of the screw. Use only syringes with the largest reasonable volume to avoid disconnecting and reconnecting the syringe to the screw recess.
– Make sure the adapter is fully introduced into screw recess. Screw syringe onto the Luer-lock and apply the cement. The adapters should be left in place until the cement is hardened.
– Ensure that no cement leakage occurs outside the intended area. Immediately stop the injection if leakage occurs.
– Do not remove or replace syringes immediately after injection. This avoids cementing the screw drive and the patients' soft tissue. The longer the syringe remains connected to the screw, the lower the risk of undesired cement flow.
– 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 immediately.
– Any cement remaining in the screw drive must be removed with the cleaning stylet while it is still soft (or has not hardened yet). This will ensure that future revision surgeries remain possible.
– Wait until the cement has cured before removing adapters and continuing with the instrumentation (about 15 minutes after last injection).
– 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.
– 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 ml are recognizable. If filling cannot be performed as described, stop the procedure.

Attach construct
– Distraction/compression might lead to loosening of the augmented screws resulting in construct failure.
– Prior to performing correction maneuvers ensure that the cement is fully hardened.

Kirschner wire screw placement
– Ensure that the guide wire is in position for all manipulations; especially the tip of the guide wire should be radiologically monitored to ensure that it does not penetrate the anterior wall of the vertebral body and damage the vessels in front of it.

USS II Ilio-Sacral Spine System

Iliac fixation with iliac connector
Attach clamp
– To prevent possible tissue irritation, remove enough bone on the ilium so that the iliac connector will be seated below the original iliac crest.

Click on the collet
– Make sure that no tissue is stuck between the screw head and the collet.

Lock iliac connector
– In some cases, the iliac connector may not be properly seated on the rod, and the nut cannot be tightened. In this case, use the procedure described below.
– With the socket wrench with L-handle in place, attach the clip for persuader at the distal end of the clamp holder. Press the spreader forceps. This will pull up the clamp. At the same time, turn the socket wrench until the nut engages.

S2 fixation with S2 connector
Click on the collet
– Make sure that no tissue is stuck between the screw head and the collet.

USS Small Stature/Paediatric Spine System

Pedicle hook positioning
Prepare the pedicle with the USS pedicle feeler
– Ensure that the feeler is placed in the articular space and not in the bone of the inferior facet.
– Do not push medially.

Drill hole for screw ∅ 3.2 mm
– Do not start the power drill if the bit does not hit bone after passing through the drill sleeve.

Lamina hook positioning
Prepare the seat for the lamina hook using the lamina feeler
– Ensure that the lamina hook does not lie too deep or press upon the bone marrow.

Rod contouring
– Once bent, the titanium rods should not be bent back again. Do not bend titanium rods more than 45°.

Introducing rods into dual-opening implants
Using the USS small stature/paediatric rod introduction pliers (i.e. the persuader)
– Carefully close the persuader since this instrument can exert considerable force. If necessary, the catch can be flipped up so that the persuader does not remain in the closed position.
– Do not apply too much force on the anchorage of the implant or it will tear out of the bone.

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

Combination of Medical Devices
The implants within the Universal Spine System family can be used interchangeably across Universal Spine System systems of the same size. Each of these systems within the Universal Spine System family is comprised of a combination of pedicle screws, hooks, set screws, rods, connectors and locking nuts. Screws are designed to accommodate rods in either ∅ 5.0 mm or ∅ 6.0 mm diameters as well as a variety of connectors.
Hooks are provided as part of the USS, USS Low Profile and USS II systems. The hooks offer surgeons a different option for posterior fixation.
There are a range of connectors utilized within systems and also as part of connecting Universal Spine System Systems to other Universal Spine System or other compatible Synthes posterior fixation systems with the same or different rod diameters. Please ensure that the matching diameter is used with the corresponding implants.

USS

The USS System consists of a set of implants including
– Rod ∅ 6.0 mm
– Side opening pedicle screw (∅ 4.0, 5.0, 6.0, 7.0 mm) with sleeve and nut
– Pedicle hook
– Screw for pedicle hook (∅ 3.2 mm)
– Lamina hook
– Angled lamina hook
– Rod connector
– Connectors for rod
– Parallel connector and extension connector
– Cross-link clamp for rod
– Rod ∅ 3.5 mm for cross-link
– Washer for side-opening pedicle screw
– Fixation ring

USS Low Profile Spine System

The Low Profile Spine System consists of a set of implants including
– Rod ∅ 6.0 mm
– Single side opening pedicle screw (∅ 4.2, 5.0, 6.0, 7.0 mm),
– Sleeve and nut
– Pedicle hook
– Screw for pedicle hook (∅ 3.2 mm)
– Lamina hook
– Angled lamina hook
– Transverse connector
– Connectors for rod
– Parallel connector and extension connector
– Fixation ring
– Cross-link clamp for rod
– Rod ∅ 3.5 mm for cross-link

USS II Spine System

The USS II System consists of a set of implants including
– Rod (∅ 5.0 mm and 6.0 mm)
– Pedicle screw with dual opening and dual-core diameter (∅ 4.2, 5.2, 6.2, 7.0, 8.0 and 9.0 mm)
– Sleeve and nut
– Pedicle hook
– Screw for pedicle hook (∅ 3.2 mm)
– Lamina hook
– Angled lamina hook
– Rod connectors for rod
– Connectors for rods
– Extension connector and parallel connector
– Transverse connector
– Cross-link clamps for rod
– Rod ∅ 3.5 mm for cross-link
– Fixation ring
– Anterior vertebral body screw (∅ 6.2, 8.0 mm)
– Washer for vertebral body screw
– Anterior connecting clamp

USS II Polyaxial Spine System

USS II Polyaxial Spine System combined with USS II Ilio-Sacral Spine System is designed for fixation of the thoracolumbar spine and the pelvis. This system consists of rod (∅ 5.0 mm and 6.0 mm), dual-core pedicle screw (∅ 4.2, 5.2, 6.2, 7.0, 8.0 mm), cancellous bone screw (∅ 6.2, 7.0, 8.0 mm), polyaxial 3-D head, sleeve and nut.

USS II Polyaxial Perforated

This system consists of rod (∅ 5.0 mm and 6.0 mm), USS II Polyaxial Perforated pedicle screw (∅ 5.2, 6.2, 7.0 mm), Polyaxial 3-D heads, sleeve and nut.
USS II Polyaxial Perforated screws are combined with VERTECEM V+ cement. Please refer to the associated instructions for use for details on its use, precautions, warnings and side effects.

USS II Ilio-Sacral Spine System

The USS II Ilio-Sacral Spine System is used to provide additional rod fixation in the ilium and in S2. There are different connectors available for the linkage to the ilium and to the S2 pedicle. All connectors are combined with the USS II Polyaxial bone screws.
This system is an add-on to USS II Polyaxial System and uses the same bone screws. This system consists of pelvic rod, dual-core cancellous bone screws (∅ 6.2, 7.0, 8.0 mm), fixed length iliac connector, telescopic iliac connector, clamp for fixed length/telescopic iliac connector, collet, S2 connector, pelvic connector and nut.

USS Small Stature/Paediatric Spine System

The USS Small Stature/Paediatric Spine System consists of a set of implants including
– Rods (∅ 5.0 mm)
– Pedicle screws (∅ 4.2, 5.0, 6.0, 7.0 mm) with dual side-openings
– Sleeve and nut
– Pedicle hooks
– Screw for pedicle hooks (∅ 3.2 mm)
– Lamina hooks
– Angled lamina hooks
– Transverse connectors
– Rod connectors and toothed sleeve
– Extension connector
– Parallel connector
– Cross-link connectors (consists of cross-link clamp, cross-link rod)
– Washers for pedicle screws
– Fixation ring for rods.

The Universal Spine System implants are applied using associated USS 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 Universal Spine 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 Universal Spine System 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 Universal Spine System devices.

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 one of the Universal Spine System must be removed, the following techniques are recommended:

USS

– Remove the cross-link clamps and closed rod connectors if they are part of the construct. The set screws on the cross-link clamps can be removed with the small, hexagonal screwdriver (2.5 mm) and the holding sleeve with catches. The set screws on the closed rod connectors that attach to the longitudinal rods can be removed with the small, hexagonal screwdriver (2.5 mm) and the holding sleeve.
– The nuts can be removed with the socket wrench 11.0 mm with L-handle. The socket wrench 6.0 mm can be used for counter-torque as necessary.
– The pedicle screws can be removed with the USS hook and screw holder attached to USS handle.
– The screw that anchors the pedicle hook can be removed with the small, hexagonal screwdriver (2.5 mm) and holding sleeve.

USS Low Profile Spine System

– Remove the rod connectors if they are part of the construct. The set screws on the rod connectors that attach to the longitudinal rods can be removed with the small, hexagonal screwdriver (2.5 mm).
– The nuts can be removed with the socket wrench 11.0 mm with L-handle. The socket wrench 6.0 mm can be used for counter-torque as necessary. Alternatively, the USS Low Profile (LP) counter-torque instrument with L-handle can be used to provide counter-torque.
– The pedicle screws can be removed with the Low Profile (LP) USS hook and screw holder attached to the USS universal handle.
– The screw that anchors the pedicle hook can be removed with the small, hexagonal screwdriver (2.5 mm).

USS II Spine System

– Remove the cross-link connectors, cross-link clamps, transverse connectors, and/or open rod connectors if they are part of the construct. The set screws on the cross-link connectors and transverse connectors that attach to the longitudinal rods can be removed with the 4.0 mm screwdriver with T-handle. The additional set screws for the transverse connector and the set screws on the open rod connectors can be removed with the small, hexagonal screwdriver (2.5 mm). The set screw on the cross-link clamp can be removed with the small, hexagonal screwdriver.
– The nuts can be removed with the socket wrench for 12-point nut with L-handle. The socket wrench 5.0 mm with T-handle can be used for counter-torque as necessary.
– The pedicle screws can be removed with the USS hook and screw holder with hexagonal socket 4.0 mm attached to the handle for USS hook and screw holder.
– The screw that anchors the pedicle hook can be removed with the small, hexagonal screwdriver (2.5 mm).

USS II Polyaxial Spine System

In the following situations, the USS II Polyaxial heads can be remobilized with the remobilizing instrument:

Head with rod introduced
– Loosen the nut with the socket wrench as far as possible. Then slide the remobilizing instrument over the screw head (make sure the red mark on the shaft with the T-handle is visible) and push the outer sleeve down. Turn the T-handle until it stops. The head is now mobile again.

Head without rod
– Apply the stop sleeve over the polyaxial head. Then apply the remobilizing instrument as described before.

Notes:
– If the head has to be removed, remove nut and sleeve using the socket wrench. Remove the rods. Apply the remobilizing instrument as described above without inserting the stop sleeve. This is how the locking ring will be completely removed. Then remove the polyaxial head with the screw holder.
– If the use of the remobilizing instrument is hindered by bone touching the polyaxial screw head, use the hollow reamer, guided by the screw holder, to remove excessive bone first.

USS II Polyaxial Perforated

In the following situations, the USS II Polyaxial Perforated heads can be remobilized with the remobilizing instrument:

Head with rod introduced
– Loosen the nut with the socket wrench as far as possible. Then slide the remobilizing instrument over the screw head (make sure the red mark on the shaft with the T-handle is visible) and push the outer sleeve down. Turn the T-handle until it stops. The head is now mobile again.

Head without rod
– Apply the stop sleeve over the polyaxial head. Then apply the remobilizing instrument as described before.

Notes:
– If the head has to be removed, remove nut and sleeve using the socket wrench. Remove the rods. Apply the remobilizing instrument as described above without inserting the stop sleeve. This is how the locking ring will be completely removed. Then remove the polyaxial head with the screw holder.
– If the use of the remobilizing instrument is hindered by bone touching the polyaxial screw head, use the hollow reamer, guided by the screw holder, to remove excessive bone first.

USS II Ilio-Sacral Spine System

Remobilization of the polyaxial connection for implant removal
– After removing the nuts, move the collet back and forth using the screw holder. The collet will come loose.
– The nuts can be removed with the socket wrench for 12-point nut with L-handle. The socket wrench 5.0 mm with T-handle can be used for counter-torque as necessary.
– The pedicle screws can be removed with the bi-hexagonal 3.0 mm screwdriver with T-handle and USS II Polyaxial holding sleeve.

USS Small Stature/Paediatric Spine System

If a USS Small Stature/Paediatric Spine System must be removed the following technique is recommended:
– Remove the cross-link connectors and open rod connectors if necessary.
– The set screws on the cross-link connectors that attach to the longitudinal rods can be removed with the 4.0 mm screwdriver with T-handle.
– The additional set screws for the cross-link rod and the set screws on the open rod connectors can be removed with the small, hexagonal screwdriver (2.5 mm).
– The nuts can be removed with the socket wrench for 12-point nut with L-handle.
– The socket wrench 5.0 mm with T-handle can be used for counter-torque as necessary.
– The pedicle screws can be removed with the 4.0 mm hexagonal screwdriver.
– The screw that anchors the pedicle hook can be removed with the small, hexagonal screwdriver (2.5 mm).

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:
www.e-ifu.com